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CICLO XXVI

ASSESSMENT AND MANAGEMENT OF PAEDIATRIC HEAD INJURIES IN THE EMERGENCY DEPARTMENT

APPROCCIO DIAGNOSTICO E GESTIONE DEL TRAUMA CRANICO PEDIATRICO IN PRONTO SOCCORSO

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ABSTRACT

Background: Head injuries (HI) are one of the most common causes of morbidity and mortality in the paediatric population in developed countries. Their management places a considerable burden on emergency services, being one of the most common reasons to visit the Emergency Department (ED). The care delivered in the ED covers multiple key aspects to ensure a timely successful recovery and prevent re-injury. Despite evidence supporting the care of paediatric HIs has substantially increased in recent years, many aspects of care still benefit from further research for an optimal management of these patients.

Objectives: To investigate different elements of the journey of paediatric patients with HI in the ED, including: **1.** Diagnosis of possible intracranial injuries; **2.** Management of concussion; **3.** HI prevention.

Methods: This is a collection of eight observational studies with both prospective and retrospective designs, conducted at the paediatric EDs of either Padova Hospital, in Italy, or at the Royal Children's Hospital Melbourne, in Australia. All the studies included patients presenting to the ED following a head trauma with some project focusing on specific populations (i.e. minor HIs, concussions, and recreational vehicles-related HIs). Data were collected between November 2009 and June 2014, with study periods for each project ranging between nine months and approximately three years.

Results: Key findings are presented for the three research topics listed in the objectives section.

1. Diagnosis of possible intracranial injuries, including the following aspects:

a) Clinical decision rules validation and implementation

We externally validated in 2439 children the Pediatric Emergency Care Applied Research Network (PECARN) rule for computed tomography (CT) scan decision-making in children with minor HI. We found a diagnostic accuracy comparable to the derivation and internal validation cohorts (overall sensitivity 100%, 95% confidence interval (CI) 83.2%-100%; specificity 55%, 95% CI 52.5%-56.6%, and negative predictive value 100%, 95% CI 99.6%-100%).

The PECARN rule was successfully implemented in the paediatric ED of Padova, Italy, showing high adherence (93.5%), unchanged CT rate compared to previous practice (8.4%, 95% CI 6.0%-11.8% vs. 7.3%, 95% CI 4.8%-10.9%), high safety and efficacy (100%,

95% CI 36.8%-100% and 92.3%, 95% CI 89%-95% respectively) and increased medical staff satisfaction compared with the previous minor HI guideline (96% vs. 51%, p<0.0001).

When the PECARN rule was used in clinical practice neither single nor multiple intermediate-risk predictors were significantly associated with ordering a CT scan. Only age younger than three months was found to be significantly associated to the decision to perform a CT (OR 18.1, 95% CI 4.91-66.61).

b) Risks associated with CT – sedation use, practice and adverse events

In our study, sedation for cranial CT scan in children with HI was needed in only 6.3% (95% CI 4.2%-9%), with a higher rate in children < 5 years (OR 22.8 95% CI 6.7-119.1). A Glasgow Coma Scale < 12 was not associated with a lower sedation rate (OR 0.34, 95% CI 0.1-2.2). The most commonly used sedative agent was chloral hydrate in 64.3% of cases. No adverse effects were recorded.

c) Role of an Infrared device as screening tool to reduce CT scan use

We demonstrated the feasibility of use in children (completion of test in 94% of patients after a mean of 4.4±2.9 minutes) of a near-infrared handheld device (Infrascanner) able to detect traumatic intracranial haematomas. Our exploratory analysis showed a specificity of 93% (95% CI 86.5%-96.6%) and a negative predictive value of 100% (95% CI, 81.6%-100%). The use of Infrascanner would have reduced the CT scan rate by 58.8%.

2. Management of concussion.

a) *Sport –related concussions*. When exploring compliance with and awareness of on-field management and return to play guidelines we found that 42% of children who sustain a sport-related concussion are not managed according to recommended guidelines on the field. Almost all parents (93%) and patients (96%) were unaware of concussion or return to play guidelines from their organization. Overall, 72% were compliant with return to play guidelines provided in the ED before discharge.

b) Post-concussive symptoms. The majority of patients recovered within 2 weeks post-injury. The prevalence of patients with clinically significant post-concussive symptoms was 30% (95% CI, 21%-46%) at 2 and 15% (95% CI 5%-32%) at 3 months post-injury. The health-related quality of life (HRQOL) score at 1 month was significantly worse in patients with clinically significant post-concussive symptoms at 2 weeks compared with asymptomatic or improving subjects (median 68, interquartile range (IQR) 55-89 vs 96,

IQR 90-100, p=0.000 for the child report and 71, IQR 55-82 vs 89, IQR 79-95, p=0.002 for the parent report). HRQOL was still worse at 3-months post-injury as per child report (83, IQR 69-92 vs 97, IQR 81-100, p=0.020), but significantly improving compared to the 1-month time point (p=0.031).

3. *Prevention of recreational vehicle (RV)-related HIs.*

RV-related HIs accounted for 7.5% of all HIs presenting to the ED. The RVs most commonly involved were bicycles (36.3%), push scooters (18.5%) and motorcycles (18.4%). Motorized vehicles were responsible for the most severe HIs. Helmet use was documented in 85.3%, with a positive use in 66.7%.The highest rates of helmet use were recorded for motorcycle riders (83.2%), horse riders (82.9%) and cyclists (65.1%). The CT scan and neurosurgery rate was higher in non-helmeted children compared with children wearing a helmet (37.0% vs. 20.1%, p<0.001 and 5.4% vs. 0.8%, p<0.001 respectively).

Conclusions: 1. The work presented in this thesis provides evidence for the wide implementation of the PECARN rule in clinical practice and supports further research to investigate which rule predictors mostly influence clinicians' decision-making on CT scan in children at intermediate risk of clinically significant intracranial injury. The use of an infrared device to screen for intracranial haemorrhages and refine the CT scan decision-making seemed promising and should be investigated further. The need of sedation in children undergoing a CT scan for HI was overall quite low and mainly associated to patients' age. The data provided may help with resource allocation in the ED.

2. Compliance with on-field management and information provided for sport-related concussions in organised sport were not optimal. Education based on return to play guidelines should be routinely provided in the ED for these patients.

The majority of children recovered within two weeks following their concussion. The prevalence of children with clinically significant post-concussive symptoms halved from 2 weeks to 3 months post-injury. Symptomatic children showed a worse HRQOL at 1 and 3 months post-injury.

3. Helmet use and documentation varied by RV with highest usage rates amongst children riding a motorcycle or a horse. Motorized RVs accounted for a small proportion of cases overall, but the majority of intracranial injuries. Helmet use was associated with

less severe RV-related HIs and should be encouraged through legislative, social marketing strategies and education in the ED.

RIASSUNTO

Introduzione: Il trauma cranico (TC) è una delle maggiori cause di morbilità e mortalità nella popolazione pediatrica nei paesi sviluppati. La sua gestione costituisce un notevole onere per i servizi di emergenza, essendo una delle ragioni più comuni di accesso al Pronto Soccorso (PS). Le cure erogate in PS coprono molteplici aspetti chiave per garantire una rapida guarigione e prevenire possibili re-infortuni. Benché le evidenze scientifiche a supporto della cura del TC pediatrico siano aumentate considerevolmente negli ultimi anni, molti aspetti necessitano ancora di ulteriori ricerche al fine ultimo di ottenere un'ottima gestione dei pazienti interessati.

Obiettivi: Analizzare i diversi elementi che caratterizzano la cura dei pazienti pediatrici con trauma cranico in PS, compresi: 1. la diagnosi di possibili lesioni intracraniche; 2. la gestione dei pazienti con commozione cerebrale; 3. la prevenzione del trauma cranico.

Metodi: Questa tesi è una raccolta di otto studi osservazionali, sia prospettici che retrospettivi, condotti nei PS dell'Ospedale di Padova e del Royal Childrens Hospital di Melbourne, Australia. Tutti gli studi includono pazienti presentatisi al PS in seguito a trauma cranico e alcuni di essi si focalizzano su popolazioni specifiche, quali traumi cranici minori, commozioni cerebrali, e traumi cranici relativi all'utilizzo di veicoli ricreativi. I dati sono stati raccolti tra novembre 2009 e giugno 2014 e la durata di ciascun progetto varia da un minimo di nove mesi fino ad un massimo di tre anni.

Risultati: I risultati principali della tesi sono presentati secondo gli obiettivi elencati precedentemente.

1. Diagnosi di possibili lesioni intracraniche, compresi i seguenti argomenti.

a) Validazione ed implementazione di strumenti di supporto decisionale

La nostra ricerca ha condotto alla validazione esterna dello strumento decisionale PECARN, (Pediatric Emergency Care Applied Research Network) sviluppato per supportare la decisione in merito all'esecuzione della tomografia computerizzata (TAC) cerebrale nei bambini con trauma cranico minore in 2439 pazienti. L'accuratezza diagnostica è paragonabile a quella riscontrata nelle coorti di derivazione e validazione interna del protocollo (sensitività complessiva del 100%, con intervallo di confidenza al 95% – IC – di 83.2%-100%, specificità del 55% con IC 52.5%-56.6% e valore predittivo negativo del 100%, IC 99.6%-100%).

Lo strumento decisionale PECARN è stato implementato con successo nel PS pediatrico di Padova, dimostrando alta aderenza (93.5%), un tasso invariato di TAC in confronto alla pratica clinica precedente (8.4%, IC 6.0%-11.8%, contro 7.3%, IC 4.8%-10.9%), elevata sicurezza ed efficacia (rispettivamente 100%, IC 36.8%-100%, e 92.3%, IC 89%-95%) ed un'aumentata soddisfazione del personale medico in confronto alle precedenti linee guida sul trauma cranico minore (96% contro 51%, $p<0.0001$).

Il monitoraggio dell'utilizzo dello strumento decisionale PECARN nella pratica clinica ha dimostrato che per i pazienti a rischio intermedio di lesione intracranica nessuno dei predittori di rischio per se o in associazione sembra aver influenzato la richiesta di TAC cerebrale. Solo un'eta' inferiore ai 3 mesi e' risultata significativamente associata all'esecuzione di TAC cerebrale (OR 18.1, IC 4.91-66.61).

b) Rischi associati alla TAC cerebrale – sedazione, pratica ed eventi avversi

In questo studio, la TAC in sedazione per bambini con trauma cranico è risultata necessaria solo nel 6.3% dei casi (IC 4.2%-9%), con un tasso più elevato nei bambini di età inferiore a 5 anni (OR 22.8, IC 6.7-119.1). Un punteggio < 12 nella scala del coma di Glasgow non è stato associato a un ridotto tasso di sedazione (OR 0.34, IC 0.1-2.2). Il sedativo più usato è stato il cloralio, nel 64.3% dei casi. Non è stato registrato nessun evento avverso.

c) Ruolo di un dispositivo ad infrarossi per ridurre l'esecuzione di TAC cerebrale.

In questo studio si è dimostrata la fattibilità dell'uso nella popolazione pediatrica di un dispositivo palmare ad infrarossi (infrascanner) in grado di rilevare ematomi intracranici conseguenti a traumi. Il test è stato completato nel 94% dei bambini in un tempo medio di 4.4±2.2 minuti. L'analisi esplorativa ha evidenziato una specificità del 93% (IC 86.5%-96.6%) e un valore predittivo negativo del 100% (IC 81.6%-100%), dimostrando che l'uso dell'infrascanner avrebbe potuto ridurre l'esecuzione di TAC del 58.8% nella popolazione oggetto di studio.

2. Gestione della commozione cerebrale

a) Commozioni cerebrali legate ad attività sportive.

In questo studio si è valutata la compliance e la consapevolezza delle linee guida sulla gestione della commozione cerebrale sul campo sportivo e sul successivo rientro in campo dei giocatori, scoprendo che il 42% dei bambini che subiscono una commozione cerebrale connessa ad attività sportive non sono gestiti in conformità alle linee guida consigliate. Quasi tutti i genitori (93%) e i pazienti (96%) non erano a conoscenza delle

suddette linee guide raccomandate dalle organizzazioni competenti. Complessivamente, solo il 72% dei pazienti ha rispettato le raccomandazioni riguardanti il ritorno alla piena attivita' sportiva fornite dal personale del PS prima della dimissione.

b) Sintomi post-commozione cerebrale

La prevalenza di sintomi clinicamente significativi a seguito di commozione cerebrale nella popolazione in studio e' risultata pari a 30% (95% CI, 21%-46%) a distanza di 2 settimane dal trauma, e di 15% (95% CI 5%-32%) a distanza di 3 mesi. I soggetti sintomatici a 2 settimane hanno dimostrato un indice peggiore di qualita' di vita ad un mese di distanza dal trauma, rispetto ai soggetti asintomatici o con notevole miglioramento clinico a 2 settimane (mediana 68, range interquartile (RIQ) 55-89 contro 96, RIQ 90-100, p=0.000 secondo la valutazione del paziente e 71, RIQ 55-82 contro 89, RIQ 79-95, p=0.002 secondo la valutazione del genitore). La qualita' di vita globale si e' mantenuta inferiore a distanza di 3 mesi dal trauma (83, RIQ 69-92 contro 97, RIQ 81-100, p=0.020), ma ha dimostrato un miglioramento rispetto al valore riportato ad 1 mese (p=0.031).

3. *Prevenzione del trauma cranico connesso all'uso di veicoli ricreativi (VR)*

I traumi cranici connessi all'utilizzo di veicoli ricreativi hanno rappresentato il 7.5% di tutti gli accessi al PS per TC. I VR più comunemente coinvolti sono stati biciclette (36.3%), monopattini (18.5%) e motocicli (18.4%). I veicoli a motore si sono dimostrati responsabili dei traumi cranici più severi. L'utilizzo del casco e' stato documentato nell' 85.3% dei casi, con utilizzo effettivo riscontrato nel 66.7%. I tassi più elevati di utilizzo sono stati riscontrati nei motociclisti (83.2%), nei cavallerizzi (82.9%) e nei ciclisti (65.1%). Le percentuali di TAC ed interventi neurochirurgici sono risultate più elevate nei bambini che non indossavano il casco in confronto a quelli che lo indossavano (rispettivamente 37% contro 20.1% e 5.4% contro 0.8%, $p < 0.001$).

Conclusioni: 1. I risultati di questa tesi supportano l'implementazione a larga scala dello strumento decisionale PECARN nella pratica clinica e suggeriscono la necessità di proseguire nella ricerca per indagare quali siano i predittori che influenzano maggiormente la decisione dei medici di ordinare la TAC nei bambini a rischio intermedio di lesione intracranica. L'utilizzo di un dispositivo palmare ad infrarossi in grado di rilevare emorragie intracraniche e raffinare il processo decisionale sulla necessità o meno della TAC ha dato risultati promettenti e merita ulteriori studi. La necessità di sedare i bambini sottoposti a TAC cerebrale in seguito a trauma cranico si

è rivelata relativamente bassa e perlopiù associata all'età dei pazienti. I dati forniti in questa tesi potrebbero essere utili per un'ottimale allocazione delle risorse in PS.

2. La compliance alle linee guida per la gestione sul campo sportivo delle commozioni cerebrali connesse ad attività sportive organizzate e le relative informazioni fornite ai pazienti coinvolti sono risultate non ottimali. Questi pazienti dovrebbero ricevere regolarmente in PS istruzioni chiare, basate sulle linee guida, per il rientro alla piena attivita' sportiva.

La maggioranza dei bambini che hanno subito una commozione cerebrale si è ristabilita entro due settimane dall'infortunio. La prevalenza di sintomi clinicamente significativi che conseguono a commozione cerebrale si e' dimezzata tra 2 settimane e 3 mesi di distanza dal trauma. I pazienti sintomatici hanno dimostrato un indice peggiore della qualita' di vita globale ad 1 e 3 mesi di distanza dal trauma.

3. L'utilizzo del casco e la relativa documentazione nelle note cliniche sono risultati variabili a seconda del veicolo ricreativo usato, con maggiori percentuali di utilizzo tra i bambini che usano la moto o che praticano equitazione. L'uso di VR a motore ha rappresentato una piccola frazione dei casi totali, ma e' stato responsabile della maggioranza delle lesioni intracraniche. L'uso del casco è stato associato a casi meno severi di TC connessi all'uso di VR e dovrebbe quindi essere fortemente incoraggiato tramite provvedimenti legislativi, strategie di marketing sociale e campagne informative in PS.

LIST OF ACRONYMS AND ABBREVIATIONS

APHIRST = Australasian Paediatric Head Injury Rules Study

ATP = Adenosine TriPhosphate

BESS = Balance Error Scoring System

CATCH = Canadian Assessment of Tomography for Childhood Head injury

CHALICE = Children's Head injury ALgorithm for the prediction of Important Clinical Events

CDR = Clinical Decision Rule

ciTBI = clinically important Traumatic Brain Injury

CI = Confidence Interval

CT = Computed Tomography

CTE= Chronic Traumatic Encephalopathy

DSM-5 = Diagnostic and Statistical Manual of Mental Disorders 5th edition

ED = Emergency Department

GCS = Glasgow Coma Scale

GFAP = Glial Fibrillary Acidic Protein

HI = Head Injuries

HRQOL = Health Related Quality Of Life

ICD = International Classification of Diseases

IQR = Interquartile Range

MCRI = Murdoch Children's Research Institute

MRI = Magnetic Resonance Imaging

NIRS = Near Infra-Red Spectroscopy

NSE = Neuron Specific Enolase

PECARN = Pediatric Emergency Care Applied Research Network

PCS = Post-Concussive Syndrome

PREDICT = Paediatric Research in Emergency Departments International Collaborative

RCH = Royal Children's Hospital

RTP = Return-To-Play

S-100B = S-100 calcium binding protein B

SAC = Standardized Assessment of Concussion

SCAT3 = Sport Concussion Assessment Tool, 3rd edition

SD = Standard Deviation

TBI = Traumatic Brain Injury

UK = United Kingdom

US = United States

1. MOTIVATIONS

Head injuries (HI) are one of the most common presentations to the Emergency Department (ED) worldwide, and one of the most common causes of morbidity and mortality in the paediatric population in developed countries.

Paediatric HI differ from adult for their mechanism, patterns of injury (as a consequence of differences in their anatomy), assessment challenges associated to different developmental stages, and long term implications (insult to a developing brain, higher susceptibility to CT-associated radiation with higher risk of malignancy later in life, larger window of opportunity for re-injury).

The main goal of the ED assessment and management of paediatric HI is to prevent secondary injury by avoiding hypoxia and hypotension in the most severe cases, and promptly identify those patients with an intracranial injury who will benefit from a timely neurosurgical intervention. Fortunately the HI spectrum in paediatrics is largely skewed towards the mild end, where the risk for an intracranial injury is quite low. In these patients the long-term risks associated to radiation exposure from CT scan, necessary to identify an intracranial injury, should be carefully balanced against the very small possibility of a missed injury. However, if such an injury goes unrecognized and is not treated in a timely manner, the patient's outcome can be seriously compromised. For uncooperative patients, the possible risks related to the need for sedation need also to be taken into account.

Within the mild HI spectrum a large number of patients sustain an acute functional disturbance of the brain, which manifests with signs and symptoms such as loss of consciousness, headache, dizziness, nausea and vomiting, amnesia, etc. in the absence of an intracranial injury identified on imaging. This presentation is defined as concussion. Patients who sustain a

concussion may experience a delayed recovery, and suffer from prolonged symptoms significantly affecting their daily lives (i.e. headache, memory and concentration problems, fatigue, sleep disturbance, emotional lability, depression and anxiety). Premature return to learning will further delay recovery, while premature return to sport bears the additional risk of a second HI, if reaction time, balance and coordination have not returned to normal. Clinicians involved in the acute care of these patients should provide them and their families with adequate information and advice about return to school and return to sport, as well as ensuring appropriate follow-up for the patients who may be at risk of delayed recovery.

Finally, targeted education on HI prevention should be provided or reinforced according to the injury mechanism, before the patient leaves the ED.

The care delivered to paediatric HI patients in the ED covers multiple key aspects to ensure a timely successful recovery and prevent re-injury. Evidence based guidance and decision support tools are essential to help the emergency physicians deliver optimal care to children who sustain a HI.

2. THESIS OUTLINE

The work presented in this thesis aimed to investigate different elements of the journey of paediatric patients with HI through the ED, focusing on key aspects of care, including diagnosis of possible intracranial injury, management of concussion and injury prevention.

The collection of papers included in the thesis (partly already published and partly under consideration for publication) are the results of multiple research projects conducted both at my home institution, the Paediatric ED of Padova, Italy, and at the Paediatric ED of the Royal Children's Hospital (RCH) and Murdoch Children's Research Institute (MCRI) in Melbourne, Australia.

These institutions share a mutual interest in research on the broad topic of HI in paediatrics. The studies presented reflect the different clinical and research expertise, patient populations and setting characteristics of the two institutions.

In addition, some of the studies are the result of the collaboration with other international institutions: the University of Alberta, Canada (Professor Emeritus Ivan Steiner, Faculty of Medicine, University of Alberta, Edmonton) and Boston Children's Hospital, USA (Dr Lise Nigrovic, Assistant Professor, Harvard Medical School).

The rationale and research question for each project will be presented in dedicated subchapters in the introduction section.

The aim of each project will be summarized in the objectives section of the thesis.

The methods section will include an overview of the different study designs, while specific methodology details for each study will be provided either in dedicated chapters or in the each paper or manuscript included in full text in the results section. The main findings of each project will be

summarized at the beginning of the results section, before the papers collection. Similarly, the discussion will focus on the key findings of each project and their relevance for clinical practice, while more detailed discussion can be found in the corresponding papers or manuscripts.

Finally a summary of the conclusions that can be drawn from each project will be provided.

3. INTRODUCTION

3.1 Head Injuries in paediatrics

3.1.1. Definitions

The terminology used in the HI literature is varied with the intent to describe specific subgroups of injuries with common clinical implications. However, the use of different terms may at times lead to confusion. For the purpose of this thesis the following definitions will be used:

Head injury (HI): broad term used to define an injury to the head secondary to an external mechanical force that results in clinical symptoms (functional disturbance) or physical signs of trauma to the head. Neuroimaging, when performed, can be normal or positive for traumatic injuries.

Traumatic brain injury (TBI): is a type of HI that includes a broad severity spectrum of functional disturbance of the brain (from a brief change in mental status or consciousness to an extended period of unconsciousness or amnesia after the injury).[1] Neuroimaging, when performed, can be normal or positive for traumatic injuries. This term is to be considered a subgroup of HIs.

Concussion: is a type of TBI, characterized by a milder spectrum of symptoms, with no structural abnormality identified on neuroimaging when performed. A more detailed definition is provided in section 5.3.2.

3.1.2 Epidemiology

In developed countries, injury is the leading cause of death and neurological disability among children,[2] with HI being the most common injury type.[3] Minor HI is responsible for approximately 400,000 paediatric outpatient visits (office-based practices and hospital-based outpatient clinics) per year in the Unites States (US).[4] Between 600,000 and 700,000

children are evaluated annually in the ED for blunt head trauma,[4,5] with increasing trends in ED-diagnosed traumatic brain injuries (TBI).[6] HI is therefore a very common reason in children for presenting to the ED, although the vast majority are mild in severity.[6-8]

In the paediatric ED of Padova in Italy, approximately 900 children present with minor HI every year,[9] with children younger than 2 years, accounting for 45% of the total population.

At the RCH ED, in Melbourne, the presentations for HI of any severity more than doubled in the last decade, increasing from approximately 1000 to nearly 3000 per year.[10,11] The proportion of children younger than 2 years almost halved from 40% to 20%. In this age group the most common mechanisms of injury are falls, in order of frequency from bed, couch, pram, change table, stairs, high chair and shopping trolley.[10,12] In older children sport is the most common mechanisms of HI,[10] with Australian Rules football followed by cricket and horse riding.[13]

In addition, trauma associated with the use of recreational vehicles (i.e. bicycle, motorcycle, scooter, skateboard, quads or horse) also represents a growing cause of head injuries and a growing public health concern,[14-16] highlighting the importance of preventive strategies.[2]

The neuroimaging rate for paediatric HI widely varies worldwide with average computed tomography (CT) rates between 35% and 50% in North America,[3,17-19] between 10% and 20% in Australia (with higher rates in selected populations),[11,20] and less than 10% in Italy,[9,21] and in the United Kingdom (UK).[22]

The risks and implications of CT scan utilization for HI in children are discussed in the following sections.

3.2 Diagnosis of intracranial injury

3.2.1 Clinical decision rules for computed tomography

Children with clinically significant intracranial injuries require urgent identification to prevent further damage to the brain. Cranial CT scans provide rapid and definitive identification of the presence or absence of intracranial injuries, and help guide subsequent management where intracranial injuries are identified. Negative results are reassuring and may allow accelerated discharge and reduce unnecessary admissions.

In children with a Glasgow Coma Scale (GCS) score of 13 to 15 the risk of a clinically significant intracranial injury is less than 5%, with less than 1% requiring neurosurgical intervention.[3,17,22]

In the decision-making process on whether or not to perform a head CT scan emergency physicians have to balance the potential consequence of missing an intracranial injury, with the increased incidence of malignancy related to CT scan radiation exposure, as well as the sedation-associated risks for uncooperative patients.

Children are more vulnerable to radiation-associated cell damage.[23] Radiation from cranial CT scans can cause lethal malignancies, with a reported cancer related mortality rate between 1:1000 and 1:10000 paediatric CTs, with higher risk in younger age groups. [23-27]

Children may also require sedation to allow imaging and avoid motion artefacts, with consequent sedation-associated. [28,29]

In addition, resource implications and costs for the ED and the health system as a whole[30,31] need to be taken into account in the CT scan decision making process, and balanced against the patient's risk of intracranial injury. Recent decision analyses suggest that for most children who are at low risk of intracranial injury, the risks of radiation outweigh the risks of traumatic

brain injury and CT is not warranted.[32] Despite this, the number of cranial CT scans performed for head injuries in children has increased in a number of countries,[17,18,33-35] in part due to concern amongst physicians of being unable to reliably identify intracranial injury based solely on a child's clinical condition.

Clinical decision rules (CDRs) are designed to help physicians with diagnostic and therapeutic decisions at the bedside, and can be defined as decision-making tools that are derived from original research (as opposed to a consensus-based clinical practice guideline) which incorporate three or more variables from the history, physical examination, or simple tests. These tools help clinicians cope with the uncertainty of medical decision-making and improve their efficiency.[36] Several recent systematic reviews of existing paediatric head injury CDRs have been published.[8,37,38] The three CDRs of highest quality and accuracy are the Children's Head Injury Algorithm for the Prediction of Important Clinical Events from the UK (CHALICE),[22] the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) from Canada,[17] and the prediction rule for identification of children at very low risk of clinically important traumatic brain injury developed by the Pediatric Emergency Care Applied Research Network (PECARN) from the US.[3] All three rules were derived with high methodological standards and are based on large multicentre data sets. However, they differ in key areas, including study population, predictor variables based on mechanism of injury, clinical history, and clinical examination (Table 1), inclusion and exclusion criteria (Table 2), as well as outcomes and the terminology and definitions used (Table 3).

Table 1. Comparison of predictor variables[3,8,17,22]

CATCH	CHALICE	PECARN <2 years	PECARN ≥2 years
Mechanism of injury			
Dangerous mechanism of injury (e.g. MVC, fall from elevation ≥3 ft [≥0.91 cm] or 5 stairs, fall from bicycle with no helmet).	High speed RTA as pedestrian, cyclist, occupant (>64 km/h). Fall of > 3 m in height. High speed injury from projectile or object.	Severe mechanism of injury.	Severe mechanism of injury.
History			
	Witnessed LOC > 5 min.	LOC ≥5 seconds.	Any/suspected LOC.
	Amnesia (antegrade or retrograde) >5 min.		
Irritability on examination.	Abnormal drowsiness (in excess of that expected by examining doctor).	Altered mental status.	Altered mental status.
		Not acting normally per parent.	
	≥3 vomits after head injury (discrete episodes).		History of vomiting.
	Suspicion of NAI.		
	Seizure in patient with no history of epilepsy.		
History of worsening headache.			Severe headache.
Examination			
GCS <15, 2 hr after injury.	GCS <14, or <15 if <1 yr.	GCS<15	GCS<15
Suspected open or depressed skull fracture.	Suspicion of penetrating or depressed skull injury, or tense fontanel.		
Any sign of basal skull fracture (e.g. hemotympanum, "raccoon" eyes, otorrhoea/rhinorrhoea of CSF, Battle's sign).	Signs of basal skull fracture.	Palpable or unclear skull fracture.	Clinical signs of basilar skull fracture.
	Positive focal neurology.		
Large boggy hematoma of the scalp.	Presence of bruise, swelling or laceration > 5cm if < 1 yr old.	Occipital, parietal or temporal scalp haematoma.	

MVC: Motor vehicle crash, RTA: Road traffic accident, LOC: Loss of consciousness, NAI: Non-accidental injury, GCS: Glasgow Coma Score, CSF: Cerebrospinal fluid.
In each of the three CDRs, the absence of all of the above predictor variables indicates that cranial CT scan is unnecessary.
Note: while the predictor variables are reproduced verbatim, the order in which the variables from each CDR are presented has been altered to facilitate comparison

Table 2. Comparison of subject selections, inclusion and exclusion criteria[3,8,17,22]

	Setting	Demographic	Inclusion criteria	Exclusion criteria
CATCH	10 tertiary paediatric teaching institution EDs in Canada	0-16 yr	*All of the following:* • blunt trauma to head resulting in witnessed LOC/disorientation, definite amnesia, persistent vomiting (>1 episode), persistent irritability (in children <2 yr) • initial GCS in ED ≥13 as determined by treating physician • injury within the past 24 hours.	*Any of:* • Obvious penetrating skull injury • Obvious depressed fracture • Acute focal neurologic deficit • Chronic generalized developmental delay • HI secondary to suspected child abuse • Returning for reassessment of previously treated HI • Patients who were pregnant
CHALICE	10 EDs in NW England: 3 children's hospitals, 3 teaching hospitals, 4 district general hospitals	0-<16 yr	Any history or signs of injury to the head.	Refusal to consent
PECARN	25 EDs in different hospital types, part of a paediatric research network in the US	0-<18 yr	Present within 24 hours of HI.	*Any of:* • Trivial HI (defined by ground level fall, walking/running into stationary object, no signs or symptoms of head trauma except scalp abrasions and lacerations). • Penetrating trauma • Known brain tumour • Pre-existing neurological disorder complicating assessment • Neuro-imaging at another hospital before transfer • Patient with ventricular shunt* • Patient with bleeding disorder* • GCS<14*

GCS: Glasgow Coma Score, LOC: Loss of consciousness

*enrolled but being analysed separately, not used in CDR derivation

Table 3. Comparison of outcomes[3,8,17,22]

	Primary outcome	Secondary outcome
CATCH	Need for neurologic intervention[1]	Brain injury on CT[2].
CHALICE	Clinically significant intracranial injury[3]	Presence of skull fracture. Admission to hospital.
PECARN	Clinically important traumatic brain injury (ciTBI)[4]	None

1 Death within seven days secondary to the head injury or need for any of the following within 7 days: craniotomy, elevation of skull fracture, monitoring of intracranial pressure, insertion of endotracheal for the treatment of head injury

2 Any acute intracranial finding revealed on CT attributable to acute injury, including closed depressed skull fracture (depressed past the inner table) and pneumocephalus but excluding nondepressed skull fractures and basilar skull fractures

3 Death as a result of head injury, requirement for neurosurgical intervention, marked abnormality on CT (any new, acute, traumatic intracranial pathology as reported by consultant radiologist, including intracranial haematomas of any size, cerebral contusion, diffuse cerebral oedema and depressed skull fractures)

4 Death from TBI, neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, haematoma evacuation, lobectomy, tissue debridement, dura repair, other), intubation of more than 24 hours for TBI, hospital admission of 2 nights or more for the TBI (admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe headache, or ongoing seizure management) in association with TBI on CT (intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull).

Most importantly the focus is different in each CDR. CHALICE was derived for children with head injuries of all severities, presenting at any point after the injury. CATCH was derived to manage children with minor head injuries presenting within 24 hours, with specific inclusion criteria to be fulfilled before employing the CDR. Both aim to identify those children likely to have significant intracranial injury who therefore warrant a cranial CT scan. PECARN focuses on children with minor head injuries presenting within a 24 hour period and aims to identify those patients not likely to have a clinically important traumatic brain injury who can therefore be safely discharged without CT scan. In addition PECARN has derived different rules for children less than and greater than 2 years of age. The comparative performance accuracy (as assessed by sensitivity, specificity, negative predictive value and positive predictive value) for each CDR is reported in Table 4a and 4b.[8]

Table 4a. Performance of the three CDRs in their derivation sets[3,8,17,22]

	Sensitivity	Specificity	Negative predictive value	Positive predictive value
Need for neurosurgery				
CATCH†	24/24, 100% (86.2-100%)	2698/3842, 70.2% (68.8-71.6%)	2698/2698, 100%**	24/1168, 2.1%**
CHALICE	134/137, 97.8% (93.7-99.6%)	19559/22635, 86.4% (86.0-86.9%)	19559/19562, 99.9%**	134/3210, 4.4%**
PECARN <2 yr	14/14, 100%**	4529/8488, 53.4%**	4529/4529, 100%**	14/3973, 3.5%**
PECARN ≥2 yr	30/30, 100%**	14663/25253, 58.1%**	14663/14663, 100%**	30/10620, 2.8%**
CT visible brain injury				
CATCH††	156/159, 98.1% (94.6-99.4%)	1856/3707, 50.1% (48.5-51.7%)	1856/1859, 99.8%**	156/2007, 7.8%**
CHALICE	277/281, 98.6% (96.4-99.6%)	Not possible to calculate as reported by composite outcome, not by cranial CT		
PECARN <2 yr	Not possible to calculate as derivation group reported with ciTBI only, not cranial CT data. See PECARN validation table for details.			
PECARN ≥2 yr				
Clinically important traumatic brain injury				
PECARN <2 yr	72/73, 98.6% (92.6-99.97)	4528/8429, 53.7% (52.6-54.8%)	4528/4529, 99.9% (99.88-99.999)	72/3973, 1.8% (1.4-2.3)
PECARN ≥2 yr	208/215, 96.7% (93.4-98.7)	14656/25068, 58.5% (57.9-59.1)	14656/14663, 99.95% (99.9-99.98)	208/10620, 2.0% (1.7-2.2)
Clinically significant intracranial injury				
CHALICE	277/281, 98.6% (96.4-99.6%)	19558/22491, 86.9% (86.5-87.4%)	19558/19562, 99.9% (99.9-100)	277/3210, 8.63% (7.68-9.65)
Clinically significant intracranial injury in patients with GCS 13-15				
CHALICE	164/168, 97.6% (94.0-99.4)	19558/22411, 87.3% (86.8-87.7)	19558/19562, 99.9% (99.9-100)	164/3017, 5.4% (4.7-6.3)

Reported sensitivity and specificity are used where reported in papers, and calculated where not reported. For PECARN sensitivity and specificity, only the derivation population characteristics are used. Values in parentheses are 95% confidence intervals.

†when reporting sensitivity and specificity of the primary outcome "need for neurologic intervention", only the four high risk predictor variables are used.

††reported using all seven predictor variables

**these have been calculated

Table 4b. Performance of PECARN CDR in the validation group[3]

	Sensitivity	Specificity	Negative predictive value	Positive predictive value
Need for neurosurgery				
PECARN <2 yr	5/5, 100%**	1176/2211, 53.2%**	1176/1176, 100%**	5/1040, 0.5%**
PECARN ≥2 yr	11/11, 100%**	3800/6400, 59.4%**	3800/3800, 100%**	11/2611, 0.4%**
CT visible brain injury				
PECARN <2 yr	68/68, 100% (94.7-100)	1176/2148, 54.7%**	1176/1176, 100% (97.8-100)	68/1040, 6.5%**
PECARN ≥2 yr	109/116, 94% (88.0-97.5%)	3793/6295, 60.3%**	3793/3800, 99.8% (96.8-99.4)	109/2611, 4.2%**
Clinically important traumatic brain injury				
PECARN <2 yr	25/25, 100.0% (86.3-100)	1176/2191, 53.7% (51.6-55.8)	1176/1176, 100.0% (99.7-100)	25/1040, 2.4% (1.6-3.5)
PECARN ≥2 yr	61/63, 96.8% (89.0-99.6)	3798/6348, 59.8% (58.6-61.0)	3798/3800, 99.95% (99.81-99.99)	61/2611, 2.3% (1.8-3.0)

**these have been calculated using data in the original reports.
Values in parentheses are 95% confidence intervals.

CATCH and CHALICE CDRs suggest a dichotomous course of action (cranial CT scan/no cranial CT scan). While CATCH provides 4 high risk (need for neurologic intervention) and 3 medium risk (brain injury on CT scan) predictor variables, the rules state that CT of the head is required if their inclusion criteria are met and any of these variables are present.

Before being widely incorporated into practice, CDRs require internal and external validation.[38] Without validation, results may represent unique aspects of the studied patient population, clinicians using the rule, or over-fitting of the model. According to a recent systematic review and economic evaluation validation of CDRs for children is one of the main research priorities for the management of HI.[39]

PECARN is the only CDR that has been internally validated, as part of the original study.[3] A CATCH validation study has been performed in the derivation setting and is only available in abstract form at present.[40] Recently

the three rules have been prospectively validated in the same cohort of 1009 children presenting to an urban medical centre with a designated paediatric ED in the US. The results of this study showed that baseline physician ordering practice and PECARN outperformed the other CDRs. However the study population did not reflect the exact population for which each rule was originally developed and the study was underpowered to determine appropriately narrow confidence intervals for rare but critically important events.[41]

None of the rule has been so far implemented in paediatric EDs in Australia and New Zealand. The results of a recent survey circulated among paediatric ED physicians in this setting showed marked variation in the management of paediatric HI, both between ED physicians in Australia and New Zealand, and in comparison to published CDRs from the UK and North America.[42] Eight different clinical practice guidelines for management of paediatric HI were found to be used at the 13 sites included in the survey, each with different indications for cranial CT scan and none based on the published CDRs. However all sites indicated that they were considering implementation of one of the three major HI CDRs (CATCH, PECARN, CHALICE). All the 13 sites are part of the Paediatric Research in Emergency International Collaborative (PREDICT) network,[43] which involves all major paediatric hospitals in Australia and New Zealand. In order to support an evidence based decision to implement one of the 3 CDRs nationwide, the PREDICT network set out a prospective multicentre observational study to concurrently externally validate and compare the diagnostic accuracy of the 3 rules against current practice in Australia and New Zealand. The study aims to recruit 20.000 patients and our research team will be able to present the results of this study in 2015.

Differently from the multicentre Australasian-wide project led by my host institution, the research conducted on this topic in my home institution

mainly focused on the PECARN rule. A panel of local experts on head injury deemed the PECARN rule the highest quality rule based on high methodological standards and internal validation data, and more suitable for our setting and clinical needs.

The results of the research projects on the PECARN rule conducted at the paediatric ED of Padova, Italy, will be presented in this thesis. Our research addressed the following key aspects:

i) external validation
ii) implementation
iii) actual use of the rule in clinical practice

i) External validation of a rule should be conducted independent of rule derivation, in a multicentre setting, and possibly in different countries in order to increase generalizability. The mutual interest in the research on this topic led to the collaboration between the paediatric ED of Padova and Boston's Children Hospital. Compared with the internal validation, the external validation will allow for collection of composite predictors (altered mental status and severe injury mechanism) as composite variables, rather than individual components, thus testing the performance of the rule in the actual format that will be used in clinical practice.

ii) The PECARN rule was chosen to replace the internal guideline on minor head injury management in use at the paediatric ED of Padova. The local guideline was very complex and not suitable to support quick bedside decision-making. In contrast to the North American setting, where the PECARN rule was developed to reduce the high CT scan rate (of approximately 35%), the local CT scan rate was already below 10%. The implementation of the PECARN rule in a low-CT-scan setting, such as the paediatric ED of Padova, needs close monitoring of its effects with respect

to adherence to the rule, CT scan rate, safety and efficacy, as well as medical staff satisfaction with its use.

iii) Based on the original study data, PECARN researchers also developed algorithms to risk-stratify patients with minor HI and support decision-making according to the patient's risk for clinically important TBI (ciTBI). For children at high risk for ciTBI, a CT scan is recommended, while for the patients at intermediate risk, it is up to the clinician to decide whether to observe the patient or perform a CT scan (Table 5), taking into account the following factors: presence of multiple versus isolated findings, worsening symptoms or signs after ED observation, age < 3 months, clinician experience, and parental preference.[3]

Table 5. PECARN minor head injury age-based clinical prediction rules: high, intermediate and very low risk groups for clinically important TBI.

Risk group	Age < 2 years of age	Age ≥ 2 years of age	Risk of ciTBI
High	Altered mental status[a]	Altered mental status[a]	4.4%
	Palpable skull fracture	Signs of basilar skull fracture	
Intermediate	Severe injury mechanism[b]	Severe injury mechanism[b]	0.9%
	Loss of consciousness >5s	Any loss of consciousness	
	Non-frontal hematoma	Vomiting	
	Not acting right as per parents	Severe headache	
Very low	None	None	<0.05%

[a]GCS 14, agitation, sleepiness, slow response or repetitive questioning

[b] Motor vehicle crash with patient ejection, death of another passenger or rollover, pedestrian or bicyclist without helmet struck by motorized vehicle, falls (of >3 feet for children < 2 years of age or > 5 feet for children ≥ 2 years) or head struck by high impact object

ciTBI*: death from traumatic brain injury, neurosurgery, intubation for more than 24 h for traumatic brain injury, or hospital admission of 2 nights or more associated with traumatic brain injury on CT (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull)*

Proposed evidence based management tools that include different possible options for a certain category of risk are assistive rather than directive and rely on a more thorough clinical judgment for decision-making. In the PECARN study, approximately one third of the patients fit in the intermediate risk group, with only 0.9% having a ciTBI. Variability in clinical approach, CT scan versus observation, is expected in this group of patients. This translates in a wide variation in the CT scan rate. This potential variability makes it challenging to predict what will be the consequences of using these tools in clinical practice, in terms of both imaging use and accurate identification of ciTBI. Evaluation of the actual use of such decision-making tools provides valuable information in estimating long-term effects in clinical practice with regards to patient outcome and resource utilization; helps to refine risk-benefits balance for the patients and the health care system, and to plan education, or targeted interventions for improving the selection of patients who need a CT scan within the intermediate risk group.

Research questions

i) In children presenting to the paediatric ED following a minor HI, is the diagnostic accuracy of the PECARN rule maintained when applied to an external population presenting to different settings (the paediatric ED of Padova and Boston Children's Hospital)? Can the PECARN rule be externally validated?

ii) In children who present to the paediatric ED of Padova, what are the effects of the implementation of the PECARN rule for the management of minor head injury, with respect to adherence to the rule, CT scan rate, safety and efficacy, as well as medical staff satisfaction with its use, compared to previous practice?

iii) In children with PECARN rule intermediate risk for ciTBI, what are the predictors associated with the physician's decision to perform a cranial CT scan?

3.2.2 Sedation use and practice for computed tomography

In the era of high-speed helical CT usage there seems to be a decreasing requirement for pharmacological sedation for CT.[44-46] However, despite the newer high-speed helical CT scanners completing a cranial CT in less than a minute, some children may still require pharmacological sedation to prevent movement and ensure optimal imaging quality. A paucity of data exists on the actual use of sedation, sedation practice and patients' characteristics of head injured patients sedated in the ED for cranial CT scanning. Many agents are available for sedating children undergoing CT, and all have risks associated with their use. These include acute complications such as apnoea, hypoxia, hypotension, vomiting, and aspiration.[47-53]

The recent paper by Hoyle et al [54] investigated the frequency, type of sedation and complications in children undergoing a CT scan for a minor HI (GCS ≥14). This multicentre study conducted in the US, with a CT scan rate of 35%, found that sedation is infrequently needed (3% of their population, corresponding to 527 patients). A single agent was used in 93% of the times, with the most common medications being pentobarbital and chloral hydrate. Complications of sedation were uncommon, and were most often found with the use of chloral hydrate. Sedation initially failed in 6% of children. Other complications included hypotension (4%), vomiting (1%), hypoxia and laryngospasm (0.2% each) with no effect on the final outcome of the patient. Documentation of vital signs during sedation was found to be sub-optimal. The authors also reported a high variability in sedation frequency and sedation medications administered across the different centres that highlights the need for evidence-based guidelines and physicians education. No data from the Australian setting are currently available.

Research question

iv) In children undergoing CT scan for HI in the ED, what are the rate of sedation, the sedation practice, the characteristics of patients needing sedation and the sedation-related complications at RCH? Is there any difference in sedation rate before and after the introduction of the high speed helical CT scan?

3.2.3 Radiation-free bedside devices to reduce computed tomography rate.

Despite recent availability of high-quality clinical decision rules to assist decision-making on CT scan in paediatric minor HI,[3,17,22] the rate of unnecessary neuroimaging is far from being optimal.[8]

In the paediatric EDs of Padova and Treviso hospitals, in the Veneto region in Italy, the PECARN rule was implemented in clinical practice.[9] For children at intermediate and high risk of clinically important TBI the rate of CT scan is still considerable with a rate of unnecessary CT of approximately 20 % in our setting[9], and more than double in the United States.[3]

In the effort of further optimizing the use of head CT scan in children with minor HI new management strategies should be investigated, such as the additional use of radiation-free painless and portable tools for the identification of patients with potentially clinically important intracranial haemorrhages.

Near-infrared spectroscopy (NIRS) technology devices have been shown to have good accuracy for the detection of traumatic intracranial haemorrhages in adults with a sensitivity ranging from approximately 70 to 100 % and a specificity equal or greater than 80%.[55-60]

Promising results have also recently been reported in children.[61,62] However, data are still limited and no studies have specifically assessed the feasibility and usefulness of NIRS technology devices in detecting intracranial haemorrhages in the challenging group of children with minor HI in the ED setting.

Research question

v) In children presenting to the paediatric ED following a minor HI, is the use of a NIRS-technology device feasible and could it be helpful in detecting intracranial haemorrhages?

3.3 Concussion in children

In addition to the diagnostic challenge of promptly identifying possible intracranial injuries, emergency physicians play an important role in the management of children who sustain a concussion, with respect to acute management, planning of follow-up and education.

Given the high frequency of concussion presentations to the ED their management places a considerable burden on emergency services. However emergency medicine providers may not have adequate training or infrastructure to systematically diagnose and manage paediatric concussion.[63] Specific education, evidence based assessment and decision support tools and information for the family, school and coaches should be provided to enhance and standardize concussion diagnosis and management.

Community understanding of concussion and its recovery is limited, but has recently been the focus of wide media coverage. Previously, concussions were viewed as minor mishaps to be shaken off and thought not to interfere with daily activities or cause long term sequelae. However, recent research describing chronic and degenerative brain changes following concussion, has been amazingly influential, despite a number of methodological flaws and lack of corroborating direct evidence.[64] Parents and coaches have come to view concussion as a serious threat to child health and well-being. Heightened community concern has also translated into policy changes, and legal requirements in many US states, which specify details of child concussion management.[65,66]

More recently the president of the US held a summit on the dangers of concussions on May the 29th 2014, that received worldwide media attention.[67]

3.3.1 Epidemiology

Concussion, especially sports-related, have almost reached epidemic proportions in the modern era, with nearly 4,000,000 sports-related concussions reported each year in the US.[68] The "concussion epidemic" has been most evident in the paediatric population, where a 4-fold increase in the incidence of diagnosed concussions sustained by high school athletes has been shown in a 10-year period.[69] The actual numbers could be even higher as some studies suggest that a substantial proportion of athletes have suffered previously undiagnosed concussions.[70,71] However, although concussions dominate the sport literature, 50% of the concussions in the 11- to 15-year-old group are not sports-related.[72]

According to a large Canadian nationally representative health survey the annual prevalence of concussion is approximately 200 per 100,000 population of children younger than 14 years.[73]

In the US ED visits for concussion have doubled for the age group 8-13 years, and nearly tripled for those 14-19 years of age.[74] Nearly 150000 children present each year to US EDs with concussion,[75,76] while millions are treated by athletic trainers, primary care providers, or outpatient specialists.[77] Between one fourth and one third of all the paediatric concussions seen in the ED occur during sport participation.[75,78,79]

The dramatic rise in the number of concussion diagnoses in recent years may be due, in part, to increased awareness regarding the potential for complications of concussion and long-term sequelae of multiple concussions, as opposed to an actual increase in the incidence of concussion alone.[65,78]

In Australia, contact sport participation is common and mainly consists of Australian Rules football and rugby. These sports have amongst the highest rates of head injury of any team sport in the world.[80] Data from Victoria show a 60% increase in hospitalization for sport-related concussion

in a decade in people ≥ 15 years.[81] At the Children's Hospital at Westmead, in Sydney, the number of presentations for concussion has increased from approximately 150 to 230 per year in children of all ages.[20,79] At the RCH Melbourne the recent publication by Lyttle et al.[11] estimated approximately 500 visits per year of children presenting with concussive symptoms, as per CATCH rule inclusion criteria.

In Europe, where contact sport participation is not as common as in the US, Canada and Australia, data on concussion are scarce. While a few data exist on paediatric minor head injury epidemiology in the UK[22] and Italy,[9,21] no specific epidemiological data on paediatric concussion have been published so far.

3.3.2 Definition

The word concussion comes from the Latin verb *concutere* ("to shake violently"). Concussion is a traumatically, or biomechanically, induced alteration of brain function.

Current guidelines on concussion by the American Medical Society for Sports Medicine,[82] The American Academy of Neurology,[83] and the Zurich Consensus working group,[84] place "emphasis on the pathophysiological process, or functional disruption, as opposed to anatomic, structural or tissue injury".[85] However some debate remains about the distinction between "mild TBI" and "concussion", with many authors using these terms interchangeably, while others consider mild TBI to reflect a more serious injury than concussion.[85-87]

Two recent surveys, conducted in a paediatric hospital[88] and among the general public[89] respectively, found that clinicians may use the concussion label as less alarming to parents than the term mild TBI, with the intent of implying that the injury is transient with no significant long-term

health consequences, while public knowledge about concussion and different terminology associated with this injury type is substantially inaccurate.

The most commonly used definition of concussion in research and clinical practice is the one provided by the 2012 Zurich Consensus Statement, by a working group of experts on concussion, who have met four times since 2001 to address key issues in the understanding and management of concussion in sport,[84] (Box 1).

Box 1. Definition of concussion as per Zurich Consensus Statement of Concussion in Sport [84]

Concussion is a brain injury and is defined as a complex pathophysiological process affecting the brain, induced by biomechanical forces.

Several common features that incorporate clinical, pathologic and biomechanical injury constructs that may be utilised in defining the nature of a concussive head injury include:

1. Concussion may be caused either by a direct blow to the head, face, neck or elsewhere on the body with an ‘‘impulsive’ force transmitted to the head.
2. Concussion typically results in the rapid onset of short-lived impairment of neurological function that resolves spontaneously. However, in some cases, symptoms and signs may evolve over a number of minutes to hours.
3. Concussion may result in neuropathological changes, but the acute clinical symptoms largely reflect a functional disturbance rather than a structural injury and, as such, no abnormality is seen on standard structural neuroimaging studies.
4. Concussion results in a graded set of clinical symptoms that may or may not involve loss of consciousness. Resolution of the clinical and cognitive symptoms typically follows a sequential course. However, it is important to note that in some cases symptoms may be prolonged.”

3.3.3 Pathophysiology

Our knowledge on concussion pathophysiology is mainly derived from animal models.[90] Multiple factors are thought to contribute to the neurometabolic mismatch and the neurotransmission dysfunction, that are responsible for the functional disturbance of the brain and the symptoms experienced following a concussion. The shear forces sustained by the cells and the axons at the time of injury lead to cellular membrane disruption, ionic fluxes, unorganized depolarization of neurons causing a spreading depression-like phenomenon, with the indiscriminate release of excitatory neurotransmitters.[65,91]

Large amounts of adenosine triphosphate (ATP) are required for the ATPase-dependent ion membrane proteins to restore the ionic gradients and the cell homeostasis. However, a decrease in the cerebral blood flow has been shown following the injury,[92] thus impairing the delivery of glucose to the damaged neurons. The reduced supply of energy substrate for ATP production and the impaired mitocondrial function secondary to the neurometabolic and inflammatory cascade following the primary insult, both contribute to a decreased ATP availability at the moment of increased metabolic demand for neurons recovery, leading to a cellular energy crisis.[90,93,94]

This metabolic mismatch between the increased demand for ATP and decreased supply of ATP is thought to result in prolonged concussion symptoms. During the early phase of brain healing there remains reduced energy for the typical daily physical and cognitive demands.

The pathophysiological changes underlying concussion clinical manifestations provide the foundation to institute cognitive rest, in order to conserve the limited ATP supplies for injury recovery, as opposed to using ATP for intellectual tasks.[90]

3.3.4 Diagnosis

The diagnosis of concussion remains a clinical diagnosis. After excluding an intracranial injury based on imaging or on clinical presentation, the diagnosis of concussion is made when symptoms and signs such as those reported in Table 6 are present immediately after or up to hours following a direct trauma to the head or a collision (where forces can be transmitted to the brain). Clinical symptoms and signs can change rapidly and may evolve over time.

Making a diagnosis of concussion may be challenging as many of the symptoms are not specific to concussion and no reliable test or marker is currently available for an objective diagnosis.

One of the recommendations from the Zurich consensus statement was to improve recognition and reporting of concussion.[84]

Table 6. Typical signs and symptoms of concussion (adapted from Marshall S, Can Fam Physicians 2012)[95]

Physical	Cognitive	Emotional/Behavioural
Headache	Feeling "slowed down"	Irritability
Nausea	Feeling "in a fog"	Anxiety
Vomiting	Difficulty concentrating	Sadness
Blurred or double vision	Difficulty remembering	Depression
Balance problems	Amnesia	
Dizziness		
Sensitivity to light or noise		
Fatigue		
Sleep disturbance		
Drowsiness		
Loss of consciousness		
Balance disturbance		

The use of a graded symptom checklist is often helpful in the diagnosis of concussion,[96] as it provides a measure of symptom severity and

it can be used to monitor recovery. The latest Zurich consensus statement includes a comprehensive Sport Concussion Assessment Tool, 3rd edition (SCAT3) for children older than 13 years of age, to facilitate assessment of athletes who sustained a head injury.[84,97] This tool, primarily designed for side-line assessment in the sport field is also very useful to monitor recovery. Key components of the SCAT3 are the Glasgow Coma Scale (GCS), the Post-Concussive Symptom Scale[98] as well as a cognitive test (the standardized assessment of concussion-SAC), the balance (balance error scoring system-BESS), and coordination tests.[97]

A modified version of the SCAT3, the child-SCAT3 has been developed for children aged 5 to 12 years,[84] to take into account the different language, reading, cognitive and physical development of younger children. The symptom checklist in the child-SCAT3 is the Health Behavioural Inventory and includes a parent and child scale.[98,99] Other commonly used symptom scales are the Post-Concussive Symptom Inventory[100] and the Rivermead Post-Concussion Symptoms Questionnaire.[101] Many symptoms scales are available, however their psychometric properties are not fully defined, especially in the younger age group.[98,102] Common limitation to the use of any symptom scale is that accuracy of reported symptoms may be less reliable in certain subgroups of the population. Athletes, for example, may have had an incentive to report symptom resolution to expedite return-to-play, while other children may report symptoms that are no longer present to avoid schoolwork. Finally some children may have difficulty understanding the questions.

Unfortunately the lack of national or international guidelines on which post-concussion symptom scale is recommended has prevented comparisons across studies. In addition, there is no preferred method of ideal symptom reporting (child self-report, parent self-report, by interview, or a combination).[103] Future studies should incorporate the common data

elements selection of measures chosen by expert opinion by the Paediatric Traumatic Brain Injury Demographics and Clinical Assessment Working Group through the National Institutes of Health, in order to facilitate comparison of results and high- quality meta-analysis.[103,104]

In the modern era it is also worth mentioning the growing use of smart-phones and tablets apps to help healthcare professionals and the lay public in the recognition and diagnosis of concussion. Many apps are currently available and a review of their quality and purpose has been recently undertaken by Lee et al.[105] Our research team in conjunction with the MCRI health technology team has recently developed an app (HeadCheck^{TM}) for concussion recognition and initial management advice based on the Zurich consensus statement recommendations. The app has also been endorsed by RCH, the University of Melbourne and the Australian football league concussion working group and can be downloaded for free from the App store.

Multiple serum biomarkers have been described and investigated as diagnostic and prognostic adjuncts for TBI. Numerous studies have provided evidence that biomarkers of brain damage can be used in the diagnosis and risk stratification of TBI in adults, while research in children is more limited.[106-108] The most studied biomarkers in children are Neuron specific enolase (NSE), S-100 calcium binding protein B (S-100 B), glial fibrillary acidic protein (GFAP).[107,109,110] The need for age-corrected normative values, possible difficulties in obtaining blood samples, especially in younger children, and the small sample sizes of the available studies are important limitations to the paediatric research in this field.

However, despite the increasing interest in the research in this area there is currently a lack of reliable serum biomarkers for routine use in the diagnostic workup of children with concussion.

Although traditional CT and magnetic resonance imaging (MRI) scans after concussion are typically normal, recent research using advanced MRI techniques, including functional MRI, has found more subtle abnormalities in brain structure and brain function that seem to correlate with physical and cognitive symptoms (i.e. attention, working memory) following concussion.[111-114] However, studies in paediatrics are still very limited and, despite advanced imaging provides additional insight into the pathophysiological mechanisms of concussion and holds promise as a potential biomarker and contributor to the diagnosis of concussion, there is currently no role for it in routine clinical practice.

3.3.5 Clinical implications of concussion

As for adults, children may experience short term and long term sequelae following a concussion. However, their developing brain and their younger age at the time of the cerebral insult have different implications compared to adults.[102] Duration of post-concussive symptoms may last longer than in adults; the malignant cerebral oedema that seems related to a second impact close to a previous concussion has only been reported in children and young adults; in addition they have a larger "window of opportunity" for repeat concussion, compared with persons who do not sustain their first concussion until their twenties, and have increased susceptibility to the long-term effects of cumulative damage.[102]

a) Post-Concussive Syndrome

Recent research has highlighted that a substantial minority of children with concussion suffer from a constellation of long term physical, cognitive, emotional and behavioural symptoms, known as post-concussive syndrome

(PCS).[103,111,115] These symptoms include headaches,[116] dizziness, visual disturbance, memory/concentration deficits, mental slowness, confusion, fatigability, irritability, light/noise sensitivity, sleep disturbances, depression and anxiety,[117] Table 6.

A whole body of literature has shown that post-concussive symptoms are more common in children with concussion than those who sustain extra-cranial injuries, and should be regarded as a unique and valid diagnosis apart from other forms of recovery from trauma.[111,115,118-121]

There are 2 definitions of PCS that differ mainly in the definition of concussion, the timing of post-concussive symptoms onset and duration. The International Classification of Diseases, 10th revision (ICD-10) refers to head trauma with loss of consciousness and post-concussive symptoms that should appear within 4 weeks, with no mention of their duration[122] (Box 2). According to the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5) symptoms should occur shortly after the trauma and last at least 3 months, while loss of consciousness is not an absolute requirement for the definition of concussion[123] (Box 3).

The lack of consensus on how a case of PCS is defined is a limitation of the current literature and research on this topic, contributing to study heterogeneity, and preventing between-studies comparisons.

The process of recovery varies from person to person and injury to injury. In adults symptoms generally resolve in 7-10 days.[124-127] Some studies suggest that high-school athletes take longer to recover than collegiate athletes, consistent with delayed recovery after serious child head injury.[102,111,115,128] However recent research showed that adolescents present longer duration of symptoms compared to younger children, [129,130] while another study found that the mean difference in symptom duration did not

differ significantly between school age, junior high/high school age or adult athletes.[91]

Box 2. ICD-10 diagnostic criteria for post-concussive syndrome[122]

A. History of head trauma with loss of consciousness preceding symptom onset by a maximum of 4 wk.

B. Symptoms in 3 or more of the following symptom categories:

- headache, dizziness, malaise, fatigue, noise intolerance;
- irritability, depression, anxiety, emotional lability;
- subjective concentration, memory, or intellectual difficulties without neuropsychological evidence of marked impairment;
- insomnia;
- reduced alcohol tolerance; and
- preoccupation with above symptoms and fear of brain damage with hypochondriacal concern and adoption of sick role.

Box 3. Diagnostic and Statistical Manual of Mental Disorders, 5th edition, 8 diagnostic criteria for post-concussional disorder [123]

A. A history of head trauma that has caused considerable cerebral concussion.*

B. Evidence from neuropsychological testing or quantified cognitive assessment of difficulty in attention (concentrating, shifting focus of attention, performing simultaneous cognitive tasks) or memory (learning or recall of information).

C. Three (or more) of the following occur shortly after the trauma and last at least 3 months:

- becoming fatigued easily;
- disordered sleep;
- headache;
- vertigo or dizziness;
- irritability or aggression on little or no provocation;
- anxiety, depression, or affective instability;
- changes in personality (e.g., social or sexual inappropriateness); or
- apathy or lack of spontaneity.

D. The symptoms in criteria B and C have their onset following head trauma or else represent a substantial worsening of pre-existing symptoms.

E. The disturbance causes considerable impairment in social or occupational functioning and represents a considerable decline from a previous level of functioning. In school-aged children, the impairment might manifest as a substantial worsening in school or academic performance dating from the trauma.

F. The symptoms do not meet criteria for dementia due to head trauma and are not better accounted for by another mental disorder (e.g., amnestic disorder due to head trauma, personality change due to head trauma).

**The manifestations of concussion include loss of consciousness, posttraumatic amnesia, and, less commonly, posttraumatic onset of seizures. The specific method of defining this criterion needs to be established by further research.*

It is uncertain what role age plays in the recovery from concussion and whether possible differences between younger children and adolescents reflects differing neurobiology between the two groups or more severe mechanisms, as games between older children involve more contact and higher-force impacts.

Estimates as to duration of post-concussive symptoms in children range widely.[119] Paediatric studies have reported an incidence of PCS varying between 6% and 59% following a concussion.[103,115,131,132] In the majority of children symptoms will resolve within 2 weeks.[119] However, approximately one fourth to one third of children will still be symptomatic at 1 month, a smaller proportion will have symptoms at 3 months, and less than 5% will be still symptomatic at 1 year.[115,119]

A recent study on duration of individual post-concussive symptoms showed that although the majority of children initially present to care with symptoms of headache, dizziness and fatigue, new symptoms often develop during the course of recovery, particularly those that have a substantial emotional component.[119] It is not clear whether this is the result of the underlying physiopathology of concussion or the consequence of the restrictions placed in children during their recovery.

The same study reported that physical symptoms of concussion generally present early and resolve early after the injury, emotional symptoms develop later than the other domains, and cognitive symptoms are present both immediately following the concussion and long into the recovery period.[119]

Children who experience delayed recovery can develop significant disability with longer-lasting symptoms and cognitive impairment, which may interfere with children's school and social participation. Inability to lead their normal lives may contribute to the development of more persistent

symptoms, including concentration and memory problems, reduced quality of life, mental health problems[133] and family distress.[134]

Given the large number of children who are assessed in the ED following a concussion, emergency physicians may play a key role in the management of this injury. After a possible traumatic intracranial injury is ruled out, emergency physicians should provide initial advice on return to school and return to sport and identify those children at high risk of developing PCS, in order to arrange a closer follow-up in a dedicated concussion clinic.

Quite a few studies have investigated risk factors or predictors for developing PCS in children, leading to different results. A recent systematic review[103] on prognosticators of persistent symptoms following paediatric concussion has included 15 relevant studies. However pooling and interpreting of data was precluded by the excessive heterogeneity in the populations studied, outcomes measured, definitions of cases, and follow-up intervals. The few most recently published studies, not included in the above mentioned systematic review,[129,135-139] suffer from the same limitations and do not provide clinicians with definite answers as to which are the best predictors to identify those children at risk of delayed recovery.

A more recent paediatric study found that a history of previous concussion, particularly recent (within the previous year) or multiple concussions, is predictive of a longer time to symptom resolution after concussion.[130] These results support previous research in animal models that showed temporal vulnerability and a dose-response effect of previous injuries.[130]

Other recent studies suggest that post-concussive symptoms are the result of an interaction between biological changes induced by concussion and psychosocial factors.[111,140] Risk factors such as maladaptive coping strategies, injury perception, high-risk psychological traits and pre-injury

psychiatric conditions, as well as a dysfunctional family modulate this interaction contributing to the development of post-concussive symptoms.[102,111]

Finally it has been shown that, similar to adults, a subset of children who has persistent post-concussive symptoms may be exaggerating or feigning symptoms,[141] suggesting that future research on post-concussive symptoms should include validity tests to the assessment batteries in use. This will help avoid errors in etiologic statements, which may have important repercussion for appropriate patient's care.

There are currently no biomarkers to predict recovery from concussion.[142]

Serum biomarkers have also been investigated as possible prognosticators of PCS in children. While an S-100 B does not seem to predict PCS[109,143] a recent preliminary report showed that GFAP may offer an objective measure of injury and recovery after paediatric concussion. However the research in this field is in its infancy and far from providing results that could be incorporated into clinical practice.

Advanced MRI techniques showed structural-metabolic alterations as well as functional alterations that seem to correlate with persistence of post-concussive symptoms. However advanced imaging currently does not have a role in routine clinical practice for prediction or monitoring of PCS, but its use should continue to be encouraged in the research setting.[111-114,144,145]

From the emergency physicians perspective availability of accurate clinical prediction rules based on pre-injury and injury-related data will be highly beneficial to optimize the follow-up and to better target interventions to children at risk of poor outcomes. For the clinicians who follow up these children beyond the ED, predictive tools that include early post-injury data may help to better tailor the follow-up timing and the type of advice and care delivered to patients at risk of persistent post-concussive symptoms.

Unfortunately clinical prediction tools are not yet available for the early identification of children at high risk of PCS.[146]

b) Second Impact Syndrome

Second impact syndrome is a controversial condition where repeated head injury in sport, over a period of days to few weeks, will lead to non-survivable massive cerebral oedema. There is little epidemiological data about second impact syndrome, with most of the information coming from case reports or case series lacking sufficient clinical detail to make definitive statements [147,148] A recent registry-based study on sudden death in young athletes younger than 21 years of age, reported a trauma-related death rate of 14% over a 30-year period. Of these, approximately 90% were from trauma to the head and/or neck. Of the 138 football players who died as a result of head/neck[149] blows, 17 (12%) had a positive history of concussion within the prior 4 weeks, which was followed by persistent symptoms. These athletes were 14 to 18 years of age.[150]

Prior concussion is a risk factor for recurrent concussion. Two studies reported that the window of greatest risk of repeat concussion is within the first 7–10 days, with 80–92% of repeat injuries occurring during that time.[151,152] According to some animal studies this time interval would correspond to the time of greatest brain vulnerability, while cerebral haemostasis is being restored following the injury-induced neurometabolic dysfunction.[153]

However there is no clear scientific evidence that an initial concussion predisposes these individuals to a devastating cerebral oedema after a second or less significant repeat head injury.[154,155] In fact, a single blow to the head may be severe enough to cause a severe traumatic intracranial injury, where reactive oedema might be a contributing factor to the fatal

outcome. All the 17 head injury-related deaths following a previous recent concussion, reported by Thomas et al.[150] had also a documented subdural haematoma. In addition diffuse cerebral oedema following a single head injury has been reported to be a condition more common in children than in adults, and usually has a poor outcome.[154,156] However the rarity of diffuse cerebral swelling following a head injury suggests that it might more likely be due to an underlying genetic susceptibility, than a response to the impact alone. [154]

Despite the controversy surrounding the supposed increased susceptibility to catastrophic cerebral oedema when still suffering from concussive symptoms, return-to-play (RTP) guidelines have been driven by the fear of this condition and a cautious approach is recommended.

c) Chronic traumatic encephalopathy

Of particular importance to paediatric athletes are the potential cumulative effects of repetitive concussions.[157] Although almost all patients recover from a single concussion, not everyone recovers from recurrent concussions with important implications for the individual, as well as for society given the high incidence of concussion. There is growing evidence that exposure to multiple concussions is associated with neurocognitive impairments, neuropsychiatric and behavioural symptoms and specific neurodegenerative brain changes later in life. This condition has been defined as chronic traumatic encephalopathy (CTE). It was originally described in 1928 in professional boxers, but has increasingly been diagnosed in other collision or contact sport in more recent times.[64,86,158]

At present the diagnosis of CTE remains limited to autoptic findings, characterized by the detection of specific amounts and patterns of abnormal

tau protein deposition in the brain. Neuroimaging does not currently play any role in its diagnosis.[159,160]

So far CTE has been recognized in hockey, football, wrestling and rugby players. At present no clinical epidemiological, cross-sectional or prospective studies on CTE are available and data are insufficient to confirm a causal link.[159]

However, studies on animal models of repetitive concussion performed in mice showed that recurrent TBI correlates with greater neuropathological brain changes and that repeated frequent concussive injuries are associated with persistent long-term behavioural and neurocognitive impairment. [161-164] New and emerging animal models of sport-related concussion will have the potential to increase our understanding of how repetitive concussion, starting in adolescence, influence the neurocognitive and hystopathological outcomes later in life.[165]

Many other unanswered questions still remain such as how big a problem this is, whether it is a real unique clinical syndrome,[166] what is the percentage of concussed athletes that will develop CTE, what other factors contribute to its development and whether age at time of concussions has an impact on the time of onset and severity of impairment.

Not all individuals exposed to repetitive concussions develop CTE. This suggests that other factors play a role, such as genetic predisposition, differing comorbidities, or drug or alcohol abuse.[64,86,157,158] However the contribution of additional risk factors is still largely unknown.[159]

The majority of clinical data for youth concussions come from college and high- school players, so there is a paucity of data for younger ages. Some researchers have hypothesized that immature brains are more plastic and thus better able to recover from concussion, while others have argued that a developing brain is more susceptible to injury.[157,158]

Whether or not age at time of concussion affects the risk of development of CTE is an open question and an area of active research. If a cumulative risk does exist, it is reasonable to think that those children beginning sports at very young ages would have greater odds of developing long-term impairment, and that some caution is warranted until more definitive data are available.

3.3.6 Management

The lack of prognostic ability on concussion recovery, to accurately predict from the beginning what each patient's recovery trajectory will be, has led to wide variation in recommendations for activity cessation and specialized follow-up. However current guidelines from the American Academy of Pediatrics,[167] the American Medical society for Sport Medicine,[82] the American Academy of Neurology [83] and the Zurich consensus statement [84] agree that the cornerstone of concussion management is early recognition, removal from play, rest until cerebral recovery and then graduated return to cognitive and physical activity.

These recommendations are based on expert consensus, as the supporting evidence is sparse and more research in the area is needed. Current consensus is that premature return to school or high cognitive activity can lead to prolonged symptoms, and early return-to-play (RTP) with ongoing symptoms and slowed protective reactions put the athlete at risk of further injury and exacerbation of concussive symptoms.[87] Whether "second impact" before complete recovery from the first concussion causes more severe cumulative injury is still controversial, but fear of this condition has certainly contributed to recommending a cautious approach.[80,168]

a) Return to learn

The prospective study by Brown et al.[91] has recently added to the previously scant evidence on the effect of cognitive rest on concussion recovery.[169-171] Their study in more than 300 patients aged 8 to 23 years showed that patients engaged in the highest level of cognitive activity had the longest times to symptom resolution. These results support the current consensus opinion that limiting extensive cognitive activity reduces duration of concussive symptoms.

In children return to learn should precede RTP, however there are no clear guidelines to guide the return to school.[66,84,102,172] Clinicians caring for children following a concussion are faced with the challenge of balancing the cognitive exertion and cognitive rest in an individualized recovery plan. The aim is to expedite recovery from disruptive concussion symptoms by carefully choosing the appropriate cognitive protective strategy while avoiding the stress and anxiety of excessive restrictions.

Cognitive symptoms of concussion include decreased attention, decreased learning and memory, slowed processing speed and decreased reaction time[102]. These can negatively impact the student's participation and performance at school and may lead to frustration and anxiety. Although difficult to quantify, cognitive rest entails limiting activities that require attention and concentration, such as video/electronic game playing, text messaging, reading, computer work and doing school work.[66,72,102,172] The goal is to keep cognitive activity below the level that triggers symptoms and parents should be instructed that activities that make symptoms worse should be stopped in order to take a cognitive break. Parents will ultimately make the decision when the child should return to school, which is advised when symptoms are absent or can be comfortably tolerated for more than 30 minutes during cognitive activity.[72]

The transition back to school should be gradual. Total resolution of symptoms is not necessary prior to resuming school attendance, however a gradual return to school initially for only half a day or for certain classes is recommended following a temporary absence.

Because most children look physically normal after a concussion, school personnel may fail to recognize the need for special adjustments for these patients. Good communication between the family, the school officials and healthcare professionals is vital to facilitate return to school without exacerbating symptoms during recovery. Specific adjustments or accommodations to the academic schedule may be required in this process, such as frequent breaks in a quiet place in between classes, additional time for assignments, additional help and tutoring as needed, untimed testing, etc.[66,102] An example of a graduated return to learn plan, by Master CL and colleagues[172] is provided in Table 7.

Table 7. Graduated return to learn plan (adapted from Master et al. 2012[172])

Rehabilitation stage	Activity	Objective of each stage
1. No activity	Complete cognitive rest – no school, no homework, no reading, no texting, no videogames, no computer work	Recovery
2. Gradual reintroduction of cognitive activity	Relax previous restrictions on activities and add back for short periods of time (5-15 min at a time)	Gradual controlled increase in sub-symptom threshold cognitive activities
3. Homework at home before school work at school	Homework in longer increments (20-30 min at a time)	Increase cognitive endurance by repetition of short periods of self-paced cognitive activity
4. School re-entry	Part day of school after tolerating 1-2 cumulative hours of homework at home	Re-entry into school with accommodations to permit controlled subsymptom threshold increase in cognitive load
5. Gradual reintegration into school	Increase of full day school	Accommodations decrease as cognitive endurance improves
6. Resumption of full cognitive workload	Introduce testing, catch up with essential work	Full return to school; may commence RTP protocol

In the United States 49 of the 50 states (a bill is pending in the 50th state) have introduced legislation on concussion management, with most mandating that athletes with suspect concussion are removed from play.[65,159] The Americans with Disabilities Act temporarily covers students who sustain a concussion, and reasonable adjustments and accommodations need to be made for their disability. Schools often have a policy in place that accommodates students recovering from a concussion (e.g. reduced school hours, frequent breaks during the day, excuse non-essential work, etc.). At the same time they often prohibit students from driving to school in order to limit the organization's liability and to reduce attempts to game the system by people faking symptoms of concussion to avoid certain academic requirements.[173]

b) Return to play

RTP in children should be preceded by a successful return to school without worsening of symptoms. The physical rest recommended before return-to play includes not only restrictions of sport participation, but also of physical education classes and leisure activities such as bike riding, skateboarding, roller blading, etc. Full RTP may be considered when athletes are symptom-free at rest, they have achieved their baseline levels of cognitive functioning and postural stability and are symptom free on a supervised graduated exertion protocol (Table 8).[65,84] RTP should be cautious and individualized to the athlete. No child who has sustained a concussion should be allowed to return to play the same day.

Table 8. Graduated return to play protocol. Source: Concussion Statement on Concussion in Sport 4th International Conference on Concussion in Sport held in Zurich, November 2012[84]

Rehabilitation stage	Functional exercise at each stage	Objective of each stage
1. No activity	Symptom limited physical and cognitive rest	Recovery
2. Light aerobic exercise	Walking, swimming or stationary cycling keeping intensity <70% maximum permitted heart rate	Increase heart rate
	No resistance training	
3. Sport-specific exercise	Skating drills in ice hockey, running drills in soccer. No head impact activities	Add movement
4. Non-contact training drills	Progression to more complex training drills, e.g., passing drills in football and ice hockey	Exercise, coordination and cognitive load
	May start progressive resistance training	
5. Full-contact practice	Following medical clearance participate in normal training activities	Restore confidence and assess functional skills by coaching staff
6. Return to play	Normal game play	

Sport-specific RTP guidelines have recently been provided by May et al.[174] for football, gymnastics, cheerleading, wrestling, soccer, basketball, lacrosse, baseball, softball, and ice hockey.

Neurocognitive testing is a tool to assess the cognitive impairments in the different cognitive domains (e.g. attention, memory, concentration, processing speed, reaction time) that are often associated with concussion and a useful additional component in return to sport decision-making. Cognitive recovery often reflects symptom recovery. However it has been shown that it may occasionally precede or most commonly follow symptom resolution, as documented by the use of symptom scales. Neurocognitive testing is not required for all athletes. When used it is typically performed when the athletes is clinically asymptomatic, to detect persistent sub-clinical cognitive impairment that may affect the patient ability to adequately tolerate and cope with protracted high-pace contact-sport activity.[84,145,175]

Nowadays computerized tests are more commonly used than formal neuropsychological "paper and pencil" testing. Both methods have limitations and advantages,[176] but due to the prohibitive cost and availability of trained neuropsychologists to administer formal neurocognitive tests to increasing numbers of athletes, the repeat assessments performed to monitor recovery and the need to control for "practice effect" in this circumstance, the use of computerized neurocognitive tests is increasing. This modality may also provide a more accurate measurement of reaction time and speed of information processing.[175] The most commonly used computerized neurocognitive test batteries are the Immediate Post-Concussion Assessment and Cognitive Testing [ImPACT (ImPACT Application, Inc., Pittsburgh, Pennsylvania, USA], CogSport/Axon (CogState Ltd, Victoria, Australia), Concussion Resolution Index (Headminder, Inc., New York, New York, USA) and Automated Neurocognitive Assessment Metrics (US Department of Defence, Washington, DC).

Baseline testing is helpful to the overall interpretation of the test in order to understand whether performance on a post injury test represents diminished cognitive functioning as a consequence of concussion or the athlete's usual capability (as the athletes serve as their own control).[65] Tests results may be misinterpreted when compared to normative data, if the baseline performance is not known. However limitations of baseline testing have also been reported, as some athletes may perform sub-optimally on baseline tests hoping to show unchanged performance on repeat test following a possible concussion and expedite the return to sport.[175] Currently there is insufficient evidence to recommend the widespread use of baseline neuropsychological testing.[84]

Tests results must always be considered within the broader clinical context and should ideally be performed by a trained neuropsychologist.[84] However a recent study conducted in the US found that 40% of US high

schools used computerized neurocognitive tests for sport-related concussion and that the tests are most often interpreted by athletic trainers or physicians as opposed to neuropsychologists. In addition athletes assessed with computerized neurocognitive tests are less likely to be returned to play within 10 days of injury than athletes with concussion managed without such testing.[177]

Although conclusive evidence is lacking, strengthening the cervical musculature, teaching the skills for collision anticipation and changing the rules of sport may help reduce the risk of sport related concussion. Helmets, such as those worn in football and hockey decrease the rates of intracranial injuries and skull fractures, but do not seem to be effective at preventing concussions.

Education of patients and their families on the typical recovery process following concussion seems effective in reducing post-concussive symptoms.[178] The Centers for Disease Control and Prevention in the US has promoted awareness in both the public and the health care professionals with the "Heads up" program. This initiative covers a broad spectrum of professionals who may care for children with concussion at different levels, including physicians (with some material specifically targeted at emergency physicians), school administrators and personnel, and athletic trainers and coaches.[87]

In settings with legislation on concussion management it is unclear if general or sports specific guidelines for concussion management translate into changed on field practice and it remains unclear how much players and parents know about the management of concussion and return to play instructions. There have been few studies assessing on-field management sport-related concussions in children and youth, or coach awareness and understanding of recommended guidelines. A recent survey of community Australian Football League (AFL) and National Rugby League (NRL) coaches

and sports trainers identified knowledge gaps in key aspects of on-field management and the importance of a graduated return-to-play.[179] International studies have recognised similar gaps in both coach and player knowledge.[180,181]

Involvement in sport is highly encouraged for children to improve health, fitness, confidence and teamwork skills. However it is crucial that sport is also safe for children who are rapidly developing both cognitively and physically.

c) Treatment of prolonged symptoms

Non-pharmacological treatment

Patients who experience prolonged symptoms, after 3-4 weeks following concussion will benefit from "active rehabilitation" rather than strict rest.[111,145,182] The most common prolonged symptoms and specific rehabilitation strategies are reported in Table 9. At present, however, limited data exist on the effectiveness of these techniques in the management of prolonged symptoms following concussion.

Table 9. Rehabilitation strategies specific to the most common prolonged post-concussive symptoms

Symptoms	Rehabilitation strategy	Objective of strategy
Vestibular system deficits (dizziness, balance problems)	Oculomotor, balance and cervical spine exercises to restore the vestibulo-ocular and vestibule spinal reflexes	Re-establish physiological integration of postural control by the vestibular, visual and somatosensory system
Cervicogenic headache	Manual physical therapy	Treat myofascial pain or neck trigger points contributing to headache
Exercise intolerance/ dysautonomia	"Subthreshold exercise" (progressive, low impact aerobic exercise program)	To facilitate neurogenesis and physical reconditioning
Persistent cognitive symptoms	Memory tasks, coping skills, compensatory strategies for memory, language, executive functioning and other cognitive-communication skills	Re-establish learning and academic performance, social interaction, activities of daily living
Psychological symptoms (anxiety, depression)	Meditation, biofeedback or psychological therapy	Re-establish behavioural self-regulation
Sleep disturbances and fatigue	Sleep hygiene strategies Treatment of possible underlying psychological symptoms	Re-establish normal sleeping pattern

Pharmacological treatment

Pharmacological therapies may mainly be required for persistent somatic symptoms (mostly headache), sleep disturbances, cognitive symptoms (memory deficits and difficulty in concentration) and emotional symptoms (anxiety and depression). However, as evidence supporting medication use for post-concussive symptoms is scant, no standard approach exists.[183]

The pharmacological options to treat prolonged post-concussive headache are similar to those used to treat primary headaches. The treatment should be tailored to the patient, taking into consideration the other post-concussive symptoms, co-morbidities, learning disabilities or attention deficit hyperactivity disorder. Amitryptiline, a tricyclic

antidepressant, has been used to treat post-concussive headaches and may help with insomnia.[111,183]

Melatonin can improve the sleep pattern and play a role in the overall recovery. Benzodiazepines are generally avoided for their negative effects on arousal and cognition.[111,183]

Amantadine and methylphenidate may be given to improve cognitive functioning, but evidence is limited.[111,183]

Sertraline and other serotonin reuptake inhibitors should be considered in patients with depression not-responsive to coping strategies and psychological support.[183]

The results of a recent US survey on medication use for treating post-concussive symptoms in children showed that the majority of paediatrician managed symptoms with medications, most commonly acetaminophen (62%) and nonsteroidal anti-inflammatory medications (54%) followed by tricyclic antidepressants (23%), amantadine (10%) and methylphenidate (8%).[184]

Potential risks and benefits as well as expertise of the treating clinician in caring for patients with post-concussive symptoms should always be taken into account when prescribing a pharmacologic treatment.

Current consensus advocates that patients with prolonged post-concussion symptoms are managed in a multidisciplinary concussion clinic with access to expertise in a wide range of areas.

Our research in the field of concussion has focused on two key aspects of management:

- on field management and RTP
- early identification of children at risk of developing PCS

The research questions that our group has endeavoured to address are reported below.

Research questions

vi) What is the current compliance with on-field management guidelines, parent and player awareness and compliance with return-to-play guidelines in children presenting to the ED for a sport-related concussion?

vii) How can we best develop a clinical decision rule for the early identification of children at high risk of prolonged clinically significant post-concussive symptoms?

3.4 Primary and secondary head injury prevention

Data collected from ED visits of injury-related presentations provide useful information for both primary and secondary prevention. The goal of *primary prevention* is to protect healthy people from experiencing an injury in the first place and research findings in this field are useful to support public health policies, legislative changes and to develop targeted public awareness programs.

The aim of *secondary prevention* is to limit long-term disability associated to an injury, but also to prevent re-injury. Education on strategies to prevent re-injury should be provided at the time of ED assessment for every child who sustains an injury as a result of not using recommended protective equipment or excessive risk-taking behaviour.

With regards to HI prevention we particularly focused on recreational-vehicle (RV) –related HIs, for which helmet use has been shown to reduce morbidity and mortality associated with HI.

3.4.1 Recreational vehicles-related head injuries

Trauma associated with the use of recreational vehicles (RV), defined for the purpose of our project as a bicycle, motorcycle, scooter, skateboard, quad bike or horse, represents a growing cause of head injuries and therefore a public health concern.[185].[16,186,187] Of all the RV-related injuries, HI in both adults and children, is associated with the highest rates of admission, long-term disability and death.[14,15,185,186,188-191]

Helmet use reduces the risk of death and severe head trauma in both non-motorized (e.g. bicycles,[188,192-194] and horses[195,196]) and motorized (e.g. motorcycles[197] and "all-terrain vehicles[187,198-200] RV-related incidents. As such, RV-related helmet use in Australia is mandated across a spectrum of

activities and settings and in a variety of ways. In the absence of comprehensive legislation, helmet use in children riding bicycles, push scooters or skateboards was found to be less than 50% from direct observation of children riding RV in the community.[16,201] Introduction of mandatory helmet laws has proved effective in increasing helmet use in bicycle riders.[202,203,204]

The state of Victoria in Australia was the first state in the world to introduce a mandatory motorcycle helmet law for road users in 1961.[205] This state law was later superseded by the Australian Road Rules, a nationally standardised set of road use regulations that are regularly revised and enacted into legislation across all states and territories in Australia.[206] In 1990 the Helmet law became mandatory also for cyclists and their passengers.[207] For the purpose of the Australian Road Rules, a person in or on a wheeled recreational device or wheeled toy (i.e. skateboard and scooters) is a pedestrian, and the use of helmet is not compulsory.[208] Helmet and other personal protective equipment use are also mandated in many competition settings, particularly motorcycle and horse-related events. For horse riders younger than 18 years of age helmet use is compulsory but rarely enforced.[209] Data on paediatric RV-related HI presentations to the ED and associated helmet use are scarce, both in settings with and without mandatory helmet laws. Most of the studies include data on a mixed paediatric and adult population,[13,198,210,187,201] focus on broader paediatric HI populations,[10,13] on specific RVs,[15,187,196,198,211] or examine helmet use alone.[16,201,212]

Research questions

e) What are the epidemiology, helmet use and the clinical characteristics of children presenting to the ED for RV-related HIs?

4. OBJECTIVES

i) To externally independently validate the PECARN TBI age-based clinical prediction rules in two tertiary care academic paediatric ED in the US and Italy.

ii) To describe the implementation of an adapted version of the PECARN rule in a tertiary care academic paediatric ED in Italy and to evaluate implementation success, in terms of medical staff adherence and satisfaction, as well as its effects on clinical practice.

iii) To assess the actual use of PECARN rule in clinical practice by determining the predictors associated with the decision to perform a CT scan, in children at intermediate risk for clinically important TBI.

iv) To examine procedural sedation use and patient characteristics in children undergoing a cranial CT in the ED following a HI.

v) To assess the feasibility of use and usefulness of a radiation-free, painless NIRS technology device to detect intracranial haemorrhages in children with minor HI at PECARN rule intermediate and high risk.

vi) To investigate on-field management practice, parent and patient awareness of return-to-play guidelines and compliance with return-to-play in sports-related concussion in children.

vii) To assess the feasibility of study procedures and describe the preliminary results of a pilot study on the development of a clinical prediction rule for prolonged clinically significant post-concussive symptoms following a concussion.

viii) To describe the epidemiology, helmet use and characteristics of children with a recreational vehicle-related HI presenting to the ED.

5. METHODS

5.1 Overview of study designs

The collection of projects included in this thesis comprises a variety of study designs within the observational studies category:

- retrospective
- before-after
- cross-sectional
- prospective longitudinal

A detailed description of study design, setting, study period, population characteristics and outcome measures for each project are reported in Table 1.

Of the eight studies included in this thesis, four were carried out at the paediatric ED of Padova, Italy (two of the projects were the results of collaboration with the Boston Children's Hospital in the US and the Paediatric Unit of Treviso Hospital in Italy respectively). These projects focused on the external validation, implementation and actual use of the PECARN rule in clinical practice, as well as the investigation of an infrared portable device as a refinement tool to be incorporated in the PECARN algorithm to reduce CT scan rate.

The four projects conducted at the paediatric ED of the RCH Melbourne described the sedation practice for CT scan in the ED, addressed key aspects of concussion management (on-field management, return to play and identification of patients at higher risk of developing post-concussive syndrome) and analysed ED RV-related head strikes presentations from and injury prevention perspective.

Two of the projects conducted at the RCH Melbourne, (the study describing sedation practice for cranial CT and the RV-related HIs study) were embedded in the APHIRST research platform. A detailed description of

APHIRST methods is provided in the protocol paper included at the end of this Methods section (subchapter 5.9).

The prospective longitudinal study on persistence of clinically significant post-concussive symptoms is still on-going at the RCH and MCRI and results of the preliminary analysis will be presented. This is a pilot study part of the Take CARe (Concussion Assessment and Recovery Research) project.

For all the other projects a more detailed description of the methodology can be found in the correspondent paper or manuscript included in the Results section.

5.2 Settings

The projects were mainly carried out at the paediatric ED of Padova Hospital in Italy and the RCH Melbourne. The Boston children's hospital, United States, and the Paediatric Unit of Treviso Hospital in Italy, were also involved in one project each.

Padova Children's Hospital is an academic hospital providing primary and secondary care for a metropolitan area of 350,000 people (45,000 younger than 15 years) and tertiary care for a regional and extra-regional population, with approximately 25,000 PED visits per year of children up to 15 years of age. Its four-bed short-stay observation unit allows for management of patients whose expected length of stay is 4 to 24 hours. Consultants, registrars and residents in paediatrics provide patient care in the paediatric ED. The training program in paediatrics at the University of Padova is a 5-year program. Residents and registrars on duty in the paediatric ED primarily see approximately 95% of the children and discuss their diagnostic and therapeutic management with the consultant in charge, according to their level of training.

The RCH Melbourne is the sole paediatric trauma service for the five million people living in the state of Victoria, Australia. Up to 90% of the state's major traumas aged up to 16 years are admitted to RCH.[213] The annual census of RCH ED is 82,000 paediatric patients up to 18 years of age. Consultants, and trainees (fellows, registrars and residents) in paediatrics and general emergency medicine provide patient care in the paediatric ED. Junior medical staff rotate every 3-12 months in the ED as part of the Victorian training hospitals network.

The Boston Children's Hospital, which was involved in one of the projects part of this thesis, is a tertiary care academic hospital with a level 1 trauma centre designation and an annual ED census of approximately 65000 paediatric ED visits per year of patients up to 21 years of age.

The paediatric ED of Treviso Hospital has a yearly census of approximately 15,000 visits of children younger than 15 years. This hospital is part of the Veneto region training hospitals network for paediatric trainees from the University of Padova. The Paediatric Department of Padova and the Paediatric Unit in Treviso share clinical guidelines and collaborate in common research projects.

5.3 Study periods

Overall the data collection time span, including both retrospective and prospective projects, went from November 2009 to June 2014, with data collection periods for each study ranging from 9 months to approximately 3 years (Table 1).

5.4 Study populations

Children presenting to the ED following a head injury between the age of 0 and 18 years were included in the studies.

All projects carried out at the paediatric ED of Padova included children with minor HI defined as GCS ≥ 14.

The studies conducted and still ongoing at the RCH Melbourne, include HI of different severities, with some projects specifically focusing on concussion. Specific populations' characteristics for each project are reported in Table 1.

5.5 Study outcomes

The study outcomes were different and specific to each project's objectives. The main study outcomes are reported in Table 1 for each project.

5.6 Statistical analysis

We reported and analysed the data using appropriate measures of central tendency and statistical testing for the distribution of the continuous variables.

Continuous variables with parametric distribution were expressed as mean and standard deviation (SD) and were compared using the t-test.
Continuous variables with non-parametric distribution were expressed as medians and interquartile range (IQR) and compared using Mann-Whitney test. Wilcoxon pairwise comparisons using a Bonferroni adjustment to compensate for the multiplicity were used to compare groups with repeated continuous non-parametric variables over time.

We reported categorical variables, with counts, percentages, and 95% confidence intervals (CIs) for key findings. Comparison of categorical variables was performed by means of chi-square test.

We used odds ratios with 95% CIs to assess the association between variables in retrospective studies. Comparisons displaying $p \leq 0.05$ were considered statistically significant.

The diagnostic accuracy of the CDRs was assessed by calculating the sensitivity, specificity, negative and positive predictive values and their 95% CIs.

Multiple logistic regression analysis was used to identify variables independently associated with an outcome of interest, and results were expressed by means of OR and their CI.

The following statistical computer prgrams were used for data analysis in the different projects:

- MedCalc (version 11.1, MedCalc Software, Mariakerke, Belgium)
- Open Epi software[214]
- SPSS (Statistical Program for the Social Sciences for all analyses) (PASW Statistics 21. 21.0 ed. Chicago. 2012)
- STATA (version 13.0, StataCorp, College Station, Tex, USA).

5.7 Ethics approval and funding

All the projects were approved either by the Ethics Committee of Padova Hospital or the Human Ethics Research Committee of the Royal Children's Hospital Melbourne.

The studies embedded within the APHIRST research structure were supported by a National Health and Medical Research Council Centre of Research Excellence Grant for Paediatric Emergency Medicine (GNT1058560), Canberra, ACT, Australia and the Victorian Government's Infrastructure Support Program, Melbourne, Australia.

5.8 Reporting guidelines used

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting observational studies were followed for the design and reporting of all the studies.[215]

The STARD (Standards for Reporting of Diagnostic Accuracy) guidelines were used for the studies assessing the diagnostic accuracy of CDRs and the NIRS device.[216]

Recommended strategies for data abstraction were used for retrospective studies.[217]

Table 1. Summary of methodological aspects of studies included in the thesis

Study	Design	Setting	Period	Population	Intervention*	Comparison*	Outcome measures
i) PECARN rule external validation	Cross-sectional	Padova, Italy Boston, US	June 2010-May 2011 Apr 2011-July 2013	n=782, < 15 y n=1657, < 18 y MHI < 24h	Assessment of PECARN rule accuracy in excluding ciTBI in an external population	Patients with ciTBI	- Presence of ciTBI
ii) PECARN rule implementation	Before-after	Padova, Italy	Nov 2009-Nov 2010	n=644, < 15 y MHI < 24h	Assessment of changes in management and staff satisfaction with PECARN rule	Practice before rule implementation	- Adherence to rule - CT scan rate - ciTBI rate - Safety & efficacy of rule - Medical staff satisfaction
iii) PECARN rule use for intermediate risk patients	Cross-sectional	Padova, Italy	June 2010-May 2011	n=308, < 15 y MHI < 24h Intermediate-risk per PECARN	Assessment of predictors associated to CT performance	Patients who did not have CT scan	- Performance of CT scan
iv) Sedation practice for cranial CT	Retrospective	RCHM, Australia	Apr 2011-Apr 2013	n=442, < 18 y HI any severity	Assessment of sedation use & practice for cranial CT for HI	/	- Rate of sedation use - Characteristics of patients - Type of sedation - Adverse effects
v) NIRS portable device (Infrascanner) to detect intracranial haematomas	Prospective	Padova, Italy Treviso, Italy	June 2012-Feb 2013 Sep 2012-Mar 2013	n=110, < 15 y MHI < 12 h PECARN intermediate & high-risk	Assessment of feasibility of use and accuracy of Infrascanner to detect intracranial haematomas	Patients with no intracranial haematomas	- Successful completion of test - Time to completion - Intracranial haematoma on CT - Presence of ciTBI
vi) Sport concussion on-field management and RTP	Prospective	RCHM, Australia	May 2013-Nov 2013	n=93, 5-18 y Sport concussion	Assessment of compliance with on-field and RTP management guidelines	/	- Proportion of patients managed according to current on- field management guidelines - Proportion of patients and parents aware of guidelines

					Assessment of parents & patient awareness of guidelines		- Proportion of patients compliant with provided RTP guidelines
vii) 'Take CARe' project-pilot study to develop a CDR for PCS	Prospective Longitudinal	RCHM, Australia	Oct 2013-June 2014 (ongoing)	n=82, 5-18 y Concussion <48 h	Assessment of study procedures completion and recovery trajectories	Incomplete procedures Patients with no PCS	- Recruitment rate - Dropout rate - Dropout reasons - Patients characteristics - Presence of PCS
viii) Epidemiology, helmet use and characteristics of RV-related HIs	Retrospective	RCHM, Australia	Apr 2011 Jan 2014	n=647, < 18 y RV-related HI any severity	Assessment of ED presentations for RV-related HI, helmet use and characteristics	Various types of RV No documentation of helmet use No use of helmet	- Numbers of RV –related HI by type of RV - Helmet documentation and use - Clinical characteristics

* Adapted for observational studies

CDR = clinical decision rules; ciTBI = clinically important Traumatic Brain Injury; CT = computed tomography; ED= Emergency Department; HI = head injury; MHI= minor head injury; NIRS = near infrared spectroscopy; PECARN = Pediatric Emergency Care Applied Research Network; PCS = Post-Concussive symptoms; RCHM = Royal Children's Hospital Melbourne; RTP = Return-to-play; RV = Recreational Vehicles; Take CARe = Concussion Assessment and Recovery Research; US = United States

5.9 Australasian Prospective Head Injury Study (APHIRST) protocol paper

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BMC Pediatrics

STUDY PROTOCOL Open Access

A prospective observational study to assess the diagnostic accuracy of clinical decision rules for children presenting to emergency departments after head injuries (protocol): the Australasian Paediatric Head Injury Rules Study (APHIRST)

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On behalf of the PREDICT research network

Abstract

Background: Head injuries in children are responsible for a large number of emergency department visits. Failure to identify a clinically significant intracranial injury in a timely fashion may result in long term neurodisability and death. Whilst cranial computed tomography (CT) provides rapid and definitive identification of intracranial injuries, it is resource intensive and associated with radiation induced cancer. Evidence based head injury clinical decision rules have been derived to aid physicians in identifying patients at risk of having a clinically significant intracranial injury. Three rules have been identified as being of high quality and accuracy: the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) from Canada, the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE) from the UK, and the prediction rule for the identification of children at very low risk of clinically important traumatic brain injury developed by the Pediatric Emergency Care Applied Research Network (PECARN) from the USA. This study aims to prospectively validate and compare the performance accuracy of these three clinical decision rules when applied outside the derivation setting.

Methods/design: This study is a prospective observational study of children aged 0 to less than 18 years presenting to 10 emergency departments within the Paediatric Research in Emergency Departments International Collaborative (PREDICT) research network in Australia and New Zealand after head injuries of any severity. Predictor variables identified in CATCH, CHALICE and PECARN clinical decision rules will be collected. Patients will be managed as per the treating clinicians at the participating hospitals. All patients not undergoing cranial CT will receive a follow up call 14 to 90 days after the injury. Outcome data collected will include results of cranial CTs (if performed) and details of admission, intubation, neurosurgery and death. The performance accuracy of each of the rules will be assessed using rule specific outcomes and inclusion and exclusion criteria.
(Continued on next page)

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(Continued from previous page)

Discussion: This study will allow the simultaneous comparative application and validation of three major paediatric head injury clinical decision rules outside their derivation setting.

Trial registration: The study is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR)- ACTRN12614000463673 (registered 2 May 2014).

Keywords: Head injury, Clinical decision rule, Computed tomography, Validation

Background

Children with clinically significant intracranial injuries require urgent identification to prevent further damage to the brain. Cranial computed tomography (CT) scans provide rapid and definitive identification of the presence or absence of intracranial injuries, and help guide subsequent management. Positive results allow early intervention and optimise outcomes whilst negative results are reassuring and may allow accelerated discharge and reduce unnecessary admissions.

However, cranial CT scans also have negative effects, particularly in children, who are more vulnerable to radiation-associated cell damage [1]. Radiation from cranial CT scans can cause lethal malignancies with higher risk in younger age groups [1-4]. Children may require sedation to allow imaging with consequent sedation-associated risks [5,6]. They also have resource implications for Emergency Departments (EDs) and the health system as a whole [7]. Despite this, the number of cranial CT scans performed for head injuries in children has increased in a number of countries [8-11]. This increase is likely due to a combination of easier access to CT scanners and more efficient technology and concern amongst physicians of being unable to reliably identify intracranial injury based solely on a child's clinical condition. One way of increasing clinical sensitivity and specificity (i.e. minimising both missed clinically significant intracranial injuries and unnecessary investigations) is to develop and use clinical decision rules (CDRs).

CDRs help physicians with diagnostic and therapeutic decisions, and can be defined as decision making tools derived from original research (as opposed to a consensus-based clinical practice guideline) which incorporate three or more variables from the history, physical examination, or simple tests. These tools help clinicians cope with the uncertainty of medical decision making and improve their efficiency [12]. Several recent systematic reviews of existing paediatric head injury CDRs have been published [13-15]. The three CDRs of highest quality and accuracy [15] are the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) from Canada [11], the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE) from the UK [16] and the prediction rule for the identification of children at very low risk of clinically important traumatic brain injury developed by the Pediatric Emergency Care Applied Research Network (PECARN) from the USA [17]. All three CDRs were derived with high methodological standards using large multicentre data sets. However, they differ in key areas, including study population, predictor variables (based on mechanism of injury, clinical history, and clinical examination) (Table 1), inclusion and exclusion criteria (Table 2) and outcomes (including the terminology and definitions used) (Table 3). Most importantly the focus is different in each CDR. CATCH was derived to manage children with minor head injuries presenting within 24 hours, with specific inclusion criteria to be fulfilled before employing the CDR. CHALICE was derived for children with head injuries of all severities, presenting at any point after the injury. Both aim to identify children likely to have significant intracranial injury who warrant a cranial CT scan. PECARN's CDR focuses on children with minor head injuries presenting within a 24 hour period and aims to identify patients unlikely to have a clinically important traumatic brain injury who can be safely discharged without a CT scan. In addition PECARN has derived different CDRs for children aged less than two years and children aged two years and older. The comparative performance accuracy (as assessed by sensitivity, specificity, negative predictive value and positive predictive value) for each CDR has been presented elsewhere [15]. CATCH and CHALICE CDRs suggest a dichotomous course of action (cranial CT scan/no cranial CT scan) although CATCH stratifies this risk into high and medium categories. The PECARN CDR defines a low risk population in whom cranial CT scans can routinely be obviated.

PECARN's is the only CDR which has been internally [17] and externally [18] validated. A CATCH validation study has been performed in the derivation setting though results are only available in abstract form at present [19]. Recently the three CDRs have been prospectively validated in the same cohort of 1,009 children presenting to an urban medical center with a designated paediatric ED in the United States. This study showed that baseline physician ordering practice and PECARN outperformed the other CDRs. However, the study population did not reflect the exact population for which each rule was originally developed and the study was underpowered to determine narrow confidence intervals for rare but critically important events [20].

Table 1 Comparison of predictor variables [11,15-17]

CATCH	CHALICE	PECARN <2 years	PECARN ≥2 years
Mechanism of injury			
Dangerous mechanism of injury (eg MVC, fall from elevation ≥3 ft [≥0.91 m] or 5 stairs, fall from bicycle with no helmet).	High speed RTA as pedestrian, cyclist, occupant (>40 miles/h or >64 km/h). Fall of > 3 m in height. High speed injury from projectile or object.	Severe mechanism of injury (MVC with patient ejection, death of another passenger or rollover; pedestrian/bicyclist without helmet struck by motorized vehicle; falls >0.9 m; head struck by high impact object).	Severe mechanism of injury (MVC with patient ejection, death of another passenger or rollover; pedestrian/bicyclist without helmet struck by motorized vehicle; falls >1.5 m; head struck by high impact object).
History			
	Witnessed LOC > 5 min.	LOC ≥5 seconds.	Any/suspected LOC.
	Amnesia (antegrade or retrograde) >5 min.		
		Altered mental status.	Altered mental status.
		Not acting normally per parent.	
	≥3 vomits after head injury (discrete episodes).		History of vomiting.
	Suspicion of NAI.		
	Seizure in patient with no history of epilepsy.		
History of worsening headache.			Severe headache.
Examination			
GCS <15, 2 hr after injury.	GCS <14, or <15 if <1 yr.	GCS < 15	GCS < 15
Irritability on examination.	Abnormal drowsiness (in excess of that expected by examining doctor).	Other signs of altered mental status (agitation, somnolence, repetitive questioning, slow response to verbal communication)	Other signs of altered mental status (agitation, somnolence, repetitive questioning, slow response to verbal communication)
Suspected open or depressed skull fracture.	Suspicion of penetrating or depressed skull injury, or tense fontanelle.		
Any sign of basal skull fracture (eg haemotympanum, "raccoon" eyes, otorrhoea/rhinorrhoea of CSF, Battle's sign).	Signs of basal skull fracture.	Palpable or unclear skull fracture.	Clinical signs of basilar skull fracture.
	Positive focal neurology.		
Large boggy haematoma of the scalp.	Presence of bruise, swelling or laceration > 5 cm if < 1 yr old.	Occipital, parietal or temporal scalp haematoma.	

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In each of the three clinical decision rules (CDRs) the absence of all of the above predictor variables indicates that cranial computed tomography is unnecessary.
Note: while the predictor variables are reproduced verbatim, the order in which the variables from each CDR are presented has been altered to facilitate comparison.
CATCH Canadian Assessment of Tomography for Childhood Head Injury.
CHALICE Children's Head Injury Algorithm for the Prediction of Important Clinical Events.
PECARN Pediatric Emergency Care Applied Research Network.
MVC Motor vehicle crash.
RTA Road traffic accident.
LOC Loss of consciousness.
NAI Non-accidental injury.
GCS Glasgow Coma Score.
CSF Cerebrospinal fluid.

We propose to validate and compare the accuracy of the CATCH, CHALICE and PECARN CDRs using prospectively collected data from 20,000 patients in a multicentre setting in Australia and New Zealand, i.e. outside the countries where these CDRs were derived, and compare their performance against that of our current practice. Triggers for cranial CT use by clinicians in paediatric EDs in Australia and New Zealand are different from the triggers developed in CATCH, CHALICE and PECARN [21]. This study will also help determine which CDR is best suited for use in the Australian and New Zealand setting before incorporating them into local practice.

Table 2 Comparison of inclusion and exclusion criteria [11,15-17]

	Inclusion criteria	Exclusion criteria
CATCH	*All of the following:*	*Any of:*
	• Blunt trauma to head resulting in witnessed LOC/disorientation, definite amnesia, persistent vomiting (>1 episode), persistent irritability (in children <2 yrs)	• Obvious penetrating skull injury
		• Obvious depressed fracture
		• Acute focal neurologic deficit
		• Chronic generalized developmental delay
		• Head injury secondary to suspected child abuse
	• Initial GCS in ED ≥13 as determined by treating physician	• Returning for reassessment of previously treated head injury
	• Injury within the past 24 hours.	• Patients who were pregnant
CHALICE	Any history or signs of injury to the head.	Refusal to consent
PECARN	Present within 24 hours of head injury.	*Any of:*
		• Trivial head injury (defined by ground level fall, walking/running into stationary object, no signs or symptoms of head trauma except scalp abrasions and lacerations).
		• Penetrating trauma
		• Known brain tumour
		• Pre-existing neurological disorder complicating assessment
		• Neuro-imaging at another hospital before transfer
		• Patient with ventricular shunt*
		• Patient with bleeding disorder*
		• GCS < 14*

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CATCH Canadian Assessment of Tomography for Childhood Head Injury.
CHALICE Children's Head Injury Algorithm for the Prediction of Important Clinical Events
PECARN Pediatric Emergency Care Applied Research Network.
GCS Glasgow Coma Score.
LOC Loss of consciousness.
ED emergency department.
*enrolled but being analysed separately, not used in clinical decision rule derivation.

Methods/design

Aims

The primary aim of this study is to determine the performance accuracy of the three major international paediatric head injury CDRs (CATCH, CHALICE and PECARN) when applied to a prospective multicentre population of consecutive children presenting with head injury to 10 EDs in Australia and New Zealand. This will allow the comparative external validation of the CDRs outside their derivation settings (Figure 1).

Design

This is a multi-centre prospective observational study of consecutive children presenting with head injuries to paediatric EDs. All data points necessary for analysis including predictor variables and outcome data for the three clinical rules under investigation (Tables 1, 2 and 3) will be collected for all patients but treating clinicians will manage patients as per their usual practice. The study has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000463673). The study follows the STAndards for the Reporting of Diagnostic accuracy studies (STARD) guidelines [22].

Setting

The study is taking place at 9 tertiary paediatric EDs, and 1 large combined adult and paediatric ED in Australia and New Zealand. These centres are members of the Paediatric Research in Emergency Departments International Collaborative (PREDICT) [23]: in New Zealand Kidz First Children's Hospital, Auckland, and Starship Children's Hospital, Auckland; in Australia Monash Medical Centre, Clayton, VIC, Children's Hospital at Westmead, Sydney, NSW, Royal Children's Hospital, Melbourne, VIC, Royal Children's Hospital, Brisbane, QLD, Mater Children's Hospital, Brisbane, QLD, Princess Margaret Hospital for Children, Perth, WA, Women's & Children's Hospital, Adelaide, SA, and Townsville Hospital, Townsville, QLD. The annual paediatric census of the 10 participating EDs is >400,000. The central site for the study is the Murdoch Children's Research Institute, which is affiliated with the Royal Children's Hospital Melbourne.

Table 3 Comparison of outcomes [11,15-17]

	Primary outcome	*Secondary outcomes*
CATCH	Need for neurological intervention, defined as death within 7 days secondary to the head injury or need for any of the following within 7 days: craniotomy, elevation of skull fracture, monitoring of intracranial pressure, insertion of endotracheal tube for the management of head injury	Brain injury on CT, defined as any acute intracranial finding revealed on CT attributable to acute injury, including closed depressed skull fracture (depressed past the inner table) and pneumocephalus but excluding non-depressed skull fractures and basilar skull fractures
CHALICE	Clinically significant intracranial injury (CSII), defined as death as a result of head injury, requirement for neurosurgical intervention, marked abnormality on CT (any new, acute, traumatic intracranial pathology as reported by consultant radiologist, including intracranial haematomas of any size, cerebral contusion, diffuse cerebral oedema and depressed skull fractures)	Presence of skull fracture Admission to hospital
PECARN	Clinically important traumatic brain injury (ciTBI), defined as death from TBI, neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, haematoma evacuation, lobectomy, tissue debridement, dura repair, other), intubation of more than 24 h for TBI or hospital admission of 2 nights or more for TBI* in association with TBI on CT**	None

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*Admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe headache or ongoing seizure management.
**Intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull.
CATCH Canadian Assessment of Tomography for Childhood Head Injury.
CHALICE Children's Head Injury Algorithm for the Prediction of Important Clinical Events.
PECARN Pediatric Emergency Care Applied Research Network.
CT computed tomography.

Inclusion criteria

Patients less than 18 years of age with head injuries of all severities irrespective of length of time from injury to presentation will be included. The definition of head injury does not include patients who have sustained a trivial facial injury (ground level fall or walking or running into an object with no signs or symptoms of injury other than facial abrasions or lacerations below the eyebrows).

Exclusion criteria

We will exclude patients and families who refuse to participate, are being referred directly from ED triage to a general practitioner or other external provider (i.e. not seen in the ED), or who do not wait to be seen. We will exclude from analysis patients with neuroimaging prior to transfer (Figure 1). Individual exclusion criteria (relevant to each CDR (Table 2)) will be applied during analysis.

Primary outcome measure

Primary outcome will be the performance accuracy (sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV)) of each CDR in identifying rule specific outcomes (Table 3) when applied to those patients who meet the individual inclusion and exclusion criteria (Table 2).

Secondary outcome measures

1. Rate of clinically important traumatic brain injury (ciTBI) [17] and clinically significant intracranial injury (CSII) [16] in the study population.
2. Rate of neurosurgical intervention in the study population.
3. Rate of cranial CT use in the study population.
4. Number of missed ciTBI and CSII in the study population.
5. Characteristics of missed significant intracranial injuries that would have been identified by the application of each CDR to the study population.
6. Number of extra cranial CT scans that would be performed by applying each CDR.
7. Sensitivity, specificity, NPV and PPV of PECARN in identifying traumatic brain injury on cranial CT.
8. Diagnostic accuracy of each of the CDRs when applied to those patients attending with head injury who do not meet the specific individual inclusion and exclusion criteria.
9. Rule performance in patients with bleeding diathesis, ventriculoperitoneal shunt, non-accidental injuries and pre-existing neurological conditions.
10. Economic evaluation of financial savings or burden of implementing each CDR.
11. Rate of prolonged symptoms following a non-severe head injury.

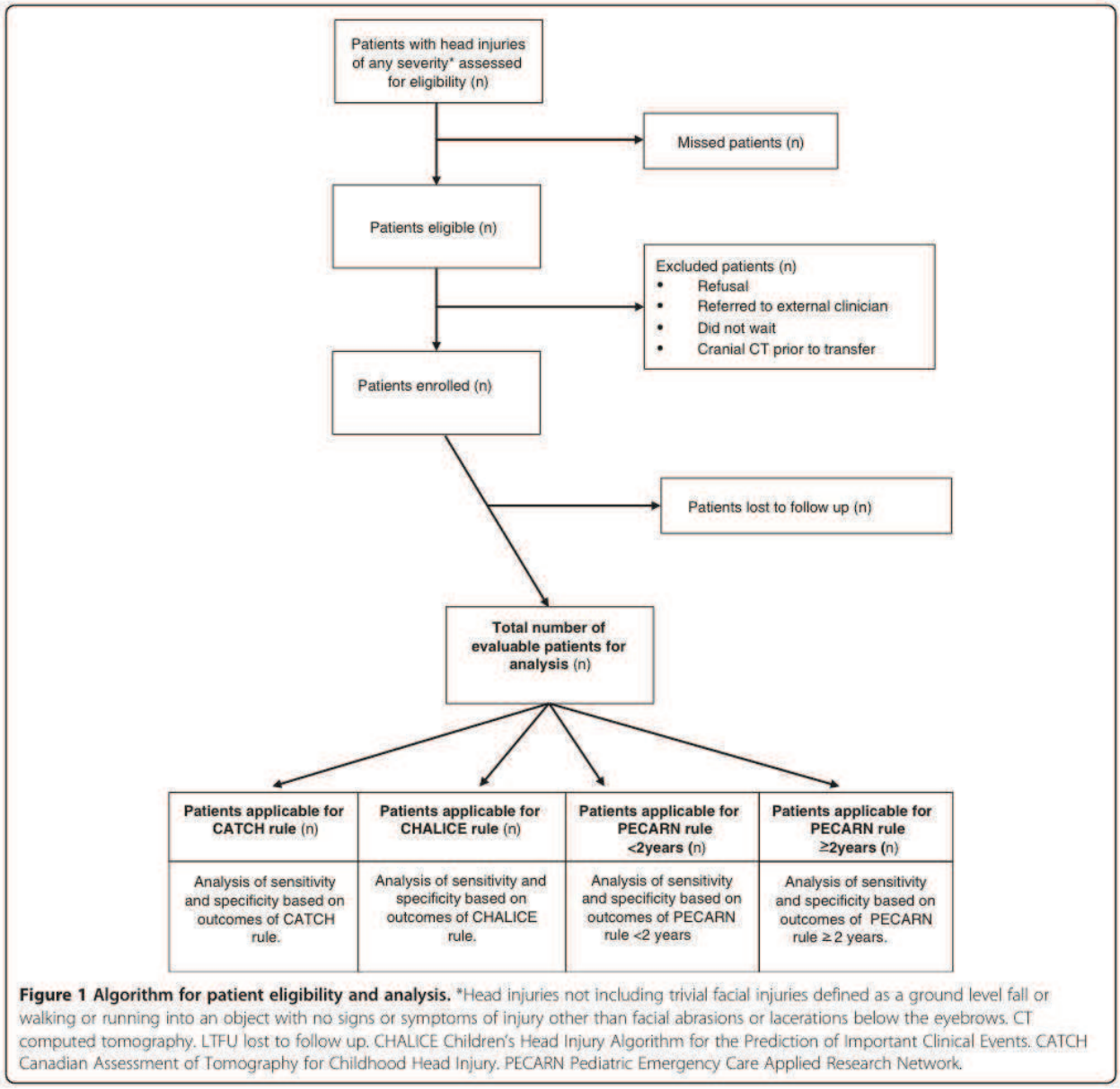

Figure 1 Algorithm for patient eligibility and analysis. *Head injuries not including trivial facial injuries defined as a ground level fall or walking or running into an object with no signs or symptoms of injury other than facial abrasions or lacerations below the eyebrows. CT computed tomography. LTFU lost to follow up. CHALICE Children's Head Injury Algorithm for the Prediction of Important Clinical Events. CATCH Canadian Assessment of Tomography for Childhood Head Injury. PECARN Pediatric Emergency Care Applied Research Network.

Patient recruitment, study procedure and data collection

Patients with head injuries will be identified at the ED triage desk using electronic alerts and visual reminders for patients who receive a head injury type injury code. Triage nurses will attach a clinician study clinical report form (CRF) to the patient record. Patients will be enrolled in the study by the treating clinician. Verbal consent for participation will be sought and documented by the treating clinician; consent for participation will include permission to telephone families 14–90 days after the ED visit for follow-up. Consent will be sought at the time of the initial ED visit. Should the parent or guardian of the child not be available at that time, we will seek consent for involvement in the study either during the in-patient stay (where admitted) or at the time of telephone follow up (where discharged from ED). Identification of missed eligible patients will be undertaken by the research assistant in each participating centre through a review of the daily ED attendance record.

Data collected by the ED treating clinicians will include the predictor variables from the three CDRs (CATCH [11], PECARN [17], CHALICE [16]). The initial ED assessment data will be documented prior to management decisions.

A separate CRF will be completed by the site research assistant during the hospital stay (in admitted patients)

or after ED discharge (in those patients discharged direct from ED) once outcome data are available. It will collect the following parameters: detailed demographics, time lines (times of triage, clinician evaluation, ED and hospital discharge), ED observation and duration of observation, admission status and duration of admission, intensive care admission, intubation and ventilation and duration of ventilation, imaging and results, neurosurgical interventions and mortality.

The telephone follow-up to screen for possible initially missed intracranial injuries will be completed by the research assistant or the site physician investigators 14–90 days after the injury if no cranial CT is performed. Data on ongoing signs and symptoms, neuroimaging, admission and neurosurgery will be elicited. Six contact attempts will be made. If more than 90 days have elapsed from the time of injury, or if there have been six failed contact attempts, the patient follow up will be regarded as unsuccessful and the patient deemed lost to follow up.

All study materials have been piloted at a single site (Royal Children's Hospital Melbourne) [23]; modification of the materials to comply with local patient flow and administrative requirements have been assessed and approved by the study steering committee.

CRFs will be de-identified after all data points have been completed and any data queries have been addressed. Data collation and analysis will take place at the central study site (Murdoch Childrens Research Institute, Melbourne).

All participating clinicians (physicians and nurse practitioners) at all sites receive formal training in the completion of the clinician CRF prior to the commencement of the study. Research assistants collecting data on the accompanying CRFs undergo formal training at the central site prior to the commencement of the study. Standardised teaching materials have been created and provided to participating sites. The study coordinator will ensure that all staff have received appropriate orientation and training and will ensure compliance with study protocol through site visits. Investigators and research assistants are not blinded to the results of the collected outcome data.

Determination of outcome

Patient outcome will be determined by:

1. Consultant radiologist reports of CTs.
2. Operative reports for those who required neurosurgical intervention.
3. Review of medical record for the duration of admission and secondary outcomes.
4. Structured telephone follow up at 14–90 days post injury for patients discharged without neuroimaging.
5. Patients for whom final outcome data are not available will be excluded from data analysis.

This process will permit the identification of the presence and extent of injury allowing classification as per the definitions of each head injury CDR.

Definitions

CDR specific definitions of inclusion and exclusion criteria, predictor variables and outcomes are set out in Tables 1, 2 and 3.

Further definitions used:

ED observation: Ongoing clinical assessment and observation of the patient in ED for less than 6 hours post initial clinical assessment.

Admission: Transfer from ED to a hospital inpatient unit (including short stay, observation, or intensive care unit) for longer than 6 hours.

Neurosurgical interventions will be categorised based on operative reports into the following categories: Dura repair of cerebrospinal fluid leaks, skull fracture elevation, haematoma drainage, intracranial pressure (ICP) monitoring, lobectomy, tissue debridement, ventriculostomy, other.

Head imaging (CT and magnetic resonance imaging) will be categorised as follows based on reports by consultant radiologists: Cerebellar haemorrhage, cerebral contusion, cerebral oedema, cerebral haemorrhage, intracerebral haematoma, diastasis of the skull, extradural/epidural haematoma, extra-axial haematoma, intraventricular haemorrhage, midline shift/shift of brain structures, pneumocephalus, skull fracture (and depth of depression), subarachnoid haemorrhage, subdural haematoma, traumatic infarction.

Statistical methods

When applying each CDR, items will be scored as present, absent or unknown. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) of each of the CDRs will be calculated using the definitions and parameters set out in the derivation studies as published [11,16,17]. In addition, the two CDRs limited to minor head injuries (CATCH and PECARN) will also be applied to patients of all head injury severities to assess their performance in this extended patient group. Likewise, the CHALICE CDR, though derived for all severities of head injury, will undergo separate analysis in minor head injury to allow comparison of performance accuracy of the three CDRs in that population. Performance accuracy will also be calculated in patient subgroups including but not restricted to patients with bleeding diathesis and ventriculoperitoneal shunts. Rates of secondary outcomes such as cranial

CT, neurosurgical intervention, ciTBI and CSII and missed ciTBI and CSII will be calculated. Key percentages will be presented with 95% confidence intervals. Data will be entered using Epidata (The Epidata Association, Odense, Denmark) and analysed using Stata 12 (Statacorp, College Station, Texas, USA).

Sample size and power calculation

In deriving a sample size for patient subgroups we extrapolated from the PECARN data as it is the only CDR which differentiates between children aged less than two years and children aged two years and older [17].

Based on PECARN's ciTBI rate of 1%, and the ability to determine the sensitivity and specificity of the CDRs to a precision level of between 94% and 100%, we determined that we would require 10,000 patients to be enrolled in our study in order to maintain the precision for the two subgroups in the PECARN CDR, children aged less than two years and children aged two years and older (i.e. 5,000 children in each age sub-group). Previous retrospective research of children diagnosed with a head injury, conducted at Royal Children's Hospital Melbourne, had identified a 1:1 ratio between children aged less than two years and those aged two years or greater [24]. After an analysis of the first 1,000 patients enrolled in the APHIRST study [23] this premise was found to be incorrect and in the prospectively enrolled patients the true ratio of children less than 2 years presenting with a head injury to children 2 years of age or older presenting with a head injury was 1:4. Therefore, to preserve the precision of the study in the younger age group of children for the PECARN CDR the sample size was recalculated to 20,000 children. Table 4 illustrates the precision that would be achieved (using 95% confidence intervals) based on these assumptions for several different plausible values for sensitivity for the outcomes (i) ciTBI (ii) need for neurosurgery and (iii) brain injury on CT (as based on PECARN data [17]).

Ethical issues and consent

In this observational non-interventional study parental verbal consent and participant verbal assent (for patients deemed capable to understand and appropriately answer questions) will be obtained for all patients; it will include permission to conduct a follow-up telephone call to determine outcome. Delayed consent at the time of the phone call if necessary has been approved for patients not enrolled during the initial ED visit. Ethics approval has been granted at all 10 study sites.

Patients who refuse consent or withdraw will continue to be managed as per the treating clinician.

As this is an observational study we are not anticipating adverse events.

Limitations

Ideally, all patients with head injuries would receive a cranial CT to determine the presence or absence of significant intracranial injuries. However, this would expose a large number of patients to unnecessary CTs and the associated cancer related risks; therefore, similar to the methodology used in the derivation and validation studies for CATCH [11] and PECARN [17] this study relies on patient follow up by telephone. In doing so we will establish whether a relevant outcome has occurred or not.

CT rates in Australia and New Zealand may be lower [23,25] than in North America and as reported for the CATCH and PECARN studies [8,10,11,17] and higher than the baseline rates reported from the United Kingdom in the CHALICE study [16]. This highlights one of the potential key strengths of this study as it tests the CDRs in a setting different to that in which each one was derived. Finally, while we were provided with copies of the telephone follow up questionnaires used by the CATCH and PECARN investigators (personal communication, Dr Martin Osmond and Dr Nathan Kuppermann) we reconstructed the predictor variables for the three CDRs

Table 4 Projected sensitivity for outcomes of clinically important traumatic brain injury (ciTBI), need for neurosurgery and brain injury on computed tomography (CT) based on PECARN data [17]

Outcome	Number of patients predicted	Projected performance of CDR in predicting outcome (sensitivity)	Sensitivity%	95% confidence interval
ciTBI	50	50/50	100	93-100
	50	49/50	98	89-100
	50	48/50	96	86-99.5
	50	47/50	94	83-99
Need for neurosurgery	30	30/30	100	88-100
	30	29/30	96.5	83-100
Brain injury on CT	300	300/300	100	98.8-100
	300	290/300	97	94-98

CDR clinical decision rule.

solely from the published papers [11,16,17]. This may have introduced an element of interpretation in terms of the most precise wording to be used in a clinical emergency setting.

Discussion

This study will allow the simultaneous comparative application and validation of three major paediatric head injury clinical decision rules outside their derivation setting. In addition to a high recruitment rate, the study will depend on high follow up rates to ensure that our results accurately represent the whole population of children presenting with head injuries.

Time plan

We have so far recruited more than 10,000 of the planned 20,000 patients. We will complete recruitment by the end of 2014.

Abbreviations

CHALICE: Children's head injury algorithm for the prediction of important clinical events; CATCH: Canadian assessment of tomography for childhood head injury; PECARN: Pediatric emergency care applied research network; CT: Computed tomography; CSII: Clinically significant intracranial injury; ciTBI: Clinically important traumatic brain injury; CDR: Clinical decision rule; ED: Emergency Department; NPV: Negative predictive value; PPV: Positive predictive value.

Competing interests

None of the authors have any competing interests arising from this research.

Authors' contributions

FEB was responsible for identifying the research question and the design of the study. FEB, MDL and EO were responsible for refining the design and developing the research protocol. All authors have contributed to the development of the protocol, the implementation of the study at participating sites and the enrolment of patients. FEB was responsible for the drafting of this paper. All authors provided comments on the drafts and have read and approved the final version. FEB takes responsibility for the manuscript as a whole.

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6. RESULTS

6.1 Overview of study results

A brief summary of the results of each project is presented below. A detailed description is reported in a dedicated subchapter for each study.

i) External validation of the PECARN clinical decision rule

This cross-sectional study conducted in the paediatric EDs of Padova, Itay, and the Boston Children's hospital, US, included 2439 children with minor head injury (91% of eligible patients), of which 959 (39%) were <2 years of age and 1439 (59%) were male. Of the study patients, 373 (15%) had a CT performed, 69 (3%) had traumatic findings on their computed tomography (CT) and 19 (0.8%) had a clinically important traumatic brain injury (ciTBI). None of the children with a ciTBI were classified as very low risk by the PECARN TBI prediction rules (overall sensitivity 100%; 95% confidence interval (CI) 83.2%-100%, specificity 55%, 95% CI 52.5%-56.6%, and negative predictive value 100%, 95% CI 99.6%-100%), comparable to the diagnostic accuracy of the derivation and internal validation cohorts.

ii) Implementation of the PECARN clinical decision rule

This before-after study conducted in the paediatric ED of Padova, Italy, included a total of 288 and 356 patients with minor head injury respectively in the 6 months prior and 6 months following the implementation of an adapted PECARN rule. The adherence to the adapted PECARN rule was overall 93.5%. The percentage of medical staff satisfied with it, in terms of usefulness and ease of use for rapid decision-making, was significantly higher (96% vs. 51%, p <0.0001) compared with the previous, more complex, internal guideline. The CT scan rate was unchanged compared to previous practice (8.4%, 95% CI 6%-11.8% after the implementation

period vs 7.3%, 95% CI 4.8%-10.9% before implementation). A ciTBI occurred in 0.8%, 95% CI 0.3%-2.5% and 0.7%, 95% CI 0.2%-2.5% respectively in the two 6-month periods. No difference in the return visits was recorded in the post implementation period compared to the 6 months prior to implementation (1.4% versus 2.4%, p = 0.506). The safety of use of the adapted PECARN rule in clinical practice was 100% (95% CI 36.8%-100%); three of three patients with ciTBI who received CT scan at first evaluation), while efficacy was 92.3% (95% CI 89%-95%; 326 of 353 patients without ciTBI who did not receive a CT scan).

iii) Use of the PECARN rule for intermediate risk patients in practice

This 1-year cross-sectional study conducted in the paediatric ED of Padova, Italy, included 308 children with minor head injury at PECARN intermediate risk for ciTBI. Of these 47% were younger than 2 years, 13% received a CT scan and 1.3% had a ciTBI. Neither single nor multiple PECARN intermediate-risk predictors were found to be associated with ordering a CT scan in both the younger and older than 2 year age group. Age younger than 3 months was the only clinical variable associated to the decision to perform a CT (OR 18.1, 95% CI 4.91-66.61). There was 1 initially missed ciTBI that had a CT scan performed on representation and did not require neurosurgery.

iv) Sedation use and practice for head CT following a head injury

In this retrospective study carried out at the Royal Children's Hospital, Melbourne, Australia, a total of 477 children underwent a head CT scan for a head injury. Of these, 33 were intubated for medical management of severe head injury and 2 received midazolam for seizure management. Of the remaining 442, 67.4% were male and mean age was 8.3 years. Abnormal CT findings were reported in 30.8% of children and 2.0% required neurosurgery. A total of 28 patients (6.3%,

95% CI 4.2 – 9.0%) were sedated for CT including 10 who initially failed CT without sedation. Two patients were intubated for CT. The sedation rate was 18.4% in patients <5 years versus 1.0% in children >5 years of age (OR 22.8 95% CI 6.7 – 119.1; p<0.001). The sedation rate was 3.7% in patients with initial GCS <12 versus 10.2% in children with GCS >12 (OR 0.34 , 95% CI 0.1 - 2.2, p = 0.27).

The most commonly used sedative agent was chloral hydrate, in 64% of patients. No adverse events or complications were recorded in any of the sedations. No difference in sedation use was observed before and after the introduction of the faster 128-slice CT scanner (OR 1.1, 95% CI 0.5 – 3.1).

v) Use of an infrared device to reduce head CT rate following a head injury

The results of this prospective observational pilot study conducted in the paediatric ED of Padova, Italy, showed that the use of a portable infrared device (Infrascanner) is feasible in children with a minor head injury. Completion of the Infrascanner measurement was successfully achieved in 103 (94 %) of 110 patients enrolled, after a mean of 4.4±2.9 min. Six of the 7 patients with incomplete measurements were less than 2 years old, leading to a success rate of 88.5 % in children younger than 2 years of age. The completion time was longer in this age group compared with older children (5.5±3.1 min and 3.5±2.2 min, respectively, p =0.018).

A CT scan was performed in 18 (17.5 %) children. Only one had an intracranial haemorrhage that was correctly identified by the Infrascanner. The exploratory analysis showed a specificity of 93 % (95 % CI 86.5– 96.6) and a negative predictive value of 100 % (95 % CI 81.6–100) for ciTBI. The use of Infrascanner would have led to ten fewer CT scans, reducing the CT scan rate by 58.8% in the study population.

vi) Management of sport-related concussion

A total of 93 children with sport-related concussion were included in this prospective observational study conducted at the peadiatric ED of the Royal Children's Hospital, Melbourne, Australia. Their mean age was 12.7 (±0.27) years, and 83% of them were males. Sports played included Australian Football (47%), soccer (12%), rugby (9%) basketball (8%), other (25%). Overall 82% participated in organised sports. Concussive signs or symptoms included loss of consciousness (41%), disorientation (36%), vomiting (23%), amnesia (30%), and headache (60%). For concussive injury in organised sports (n=76), 42%of patients were not managed according to recommended guidelines: 19% were not immediately removed from play, 29% were allowed to return to play on the same day and 27% were not assessed by qualified personnel. A total of 93% of parents and 96% of patients were unaware of concussion or return to play guidelines from their organisations. Overall, 72% were compliant with provided return to play guidelines.

vii) Concussive recovery trajectories

The preliminary analysis of this ongoing prospective longitudinal pilot study conducted at the Royal Children's Hospital, Melbourne, Australia included 81 patients who presented to the ED following an acute concussion. The recruitment rate was 49% (CI 95% 41%-57%) and the completion of study follow-up visits was 30% (95% CI 23%-38%).

The majority of patients recovered within 2 weeks post-injury. The prevalence of patients with clinically significant post-concussive symptoms was 30% (95% CI, 21%-46%) at 2 and 15% (95% CI 5%-32%) at 3 months post-injury. The scores of the standardised assessment of concussion tool, that identifies acute cognitive deficits, significantly improved at 2 weeks post-injury in the overall population ($p<0.005$ for both children younger than 13 years of age and older ones). The health-related quality of life (HRQOL) score at 1 month was significantly worse in

patients with clinically significant post-concussive symptoms at 2 weeks compared with asymptomatic or improving subjects (median 68, interquartile range (IQR) 55-89 vs 96, IQR 90-100, p=0.000 for the child report and 71, IQR 55-82 vs 89, IQR 79-95, p=0.002 for the parent report). HRQOL was still worse at 3-months post-injury as per child report (83, IQR 69-92 vs 97, IQR 81-100, p=0.020), but significantly improving compared to the 1-month time point (p=0.031).

viii) Recreational vehicle-related head injuries and helmet use

This was a retrospective study conducted at the ED of the Royal Children's Hospital, Melbourne, Australia. During the study period there were 8,469 ED visits of children with a head injury of any cause, and 647 (7.6%) were RV-related. Bicycles were the most commonly involved (36.3%), followed by push-scooters (18.5%), motorcycles (18.4%), horses (11.7%), skateboards (11.6%), all-terrain vehicles (2.8%) and go-karts (0.6%). Motorized vehicles were associated with a higher need for neurosurgery (5.7% vs. 1.2%, p=0.001). Helmet use was documented in 85.3%, with a positive use in 66.7%. The highest rates of documentation and use were recorded for motorcycles (97.5% and 83.2%), horses (92.1% and 82.9%) and bicycles (94.5% and 65.1%). Computed tomography and neurosurgery rates were higher in non-helmeted children (37.0% vs. 20.1%, p<0.001, and 5.4% vs. 0.8%, p<0.001, respectively).

6.2. Papers and manuscripts collection

6.2.1 External validation of a clinical decision rule

Published in Archives of Disease in Childhood

Schonfeld D, Bressan S, Da Dalt L, Henien MN, Winnett JA, Nigrovic LE. Pediatric Emergency Care Applied Research Network head injury clinical prediction rules are reliable in practice. *Arch Dis Child.* 2014; **99**(5):427-31. doi: 10.1136/archdischild-2013-305004.

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Pediatric Emergency Care Applied Research Network head injury clinical prediction rules are reliable in practice

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ABSTRACT

Objective The Pediatric Emergency Care Applied Research Network (PECARN) traumatic brain injury (TBI) age-based clinical prediction rules identify children at very low risk of a significant head injury who can safely avoid CT. Our goal was to independently validate these prediction rules.

Design Cross-sectional study.

Setting Two paediatric emergency departments located in USA and in Italy.

Patients All children presenting within 24 h of a head injury with a Glasgow Coma Score of ≥14.

Intervention Assessment of PECARN TBI clinical predictors.

Main outcome measure Clinically important TBI defined as head injury resulting in death, intubation for >24 h, neurosurgery or two or more nights of hospitalisation for the management of head trauma.

Results During the study period, we included 2439 children (91% of eligible patients), of which 959 (39%) were <2 years of age and 1439 (59%) were male. Of the study patients, 373 (15%) had a CT performed, 69 (3%) had traumatic findings on their CT and 19 (0.8%) had a clinically important TBI. None of the children with a clinically important TBI were classified as very low risk by the PECARN TBI prediction rules (overall sensitivity 100%; 95% CI 83.2% to 100%, specificity 55%, 95% CI 52.5% to 56.6%, and negative predictive value 100%, 95% CI 99.6% to 100%).

Conclusions In our external validation, the age-based PECARN TBI prediction rules accurately identified children at very low risk for a clinically significant TBI and can be used to assist CT decision making for children with minor blunt head trauma.

What is already known on this topic

- The Pediatric Emergency Care Applied Research Network (PECARN) traumatic brain injury (TBI) age-based clinical prediction rules identify children at very low risk of a clinically significant head injury.
- These rules were derived and then validated in a large concurrent population, but have not been externally validated to date.

What this study adds

- The PECARN TBI clinical prediction rules performed well in our two-centre patient population.
- Our findings in combination with the concurrent validation study, suggest that the PECARN TBI rules are ready for prospective implementation.

INTRODUCTION

The number of annual paediatric emergency department (ED) visits due to head injury has dramatically increased over the last decade.[1 2] Increasing concerns about radiation exposure from cranial CT scans has made the evaluation of children with minor head trauma particularly challenging. Emergency physicians must balance the possibility of missing a clinically significant traumatic brain injury (TBI) with the future risk of malignancy associated with ionizing radiation.[3] Clinicians often rely on clinical prediction rules to assist decision making by estimating the risk of a given outcome.[4] Only clinical prediction rules that have been derived according to rigorous clinical standards and validated in a wide variety of clinical settings, should be implemented in routine clinical practice.[5 6]

Using a large prospective cohort study of children with minor blunt head trauma, the Pediatric Emergency Care Applied Research Network (PECARN) derived two aged-based TBI clinical prediction rules to identify children who are at very low risk of having a clinically significant injury who may safely avoid cranial CT.[7] These rules were validated in a concurrent patient population enrolled at the same study centres after derivation population. To date, the PECARN TBI rules have not been externally validated and, therefore, the broader generalisability has not been adequately examined.

We performed a two-centre cross-sectional study of children presenting to the ED with minor blunt head trauma. Our goal was to evaluate the performance of the PECARN TBI age-based clinical prediction rules in an external patient population.

METHODS

Study design and setting

We conducted a cross-sectional study of children with minor blunt head trauma presenting to the ED for evaluation at one of two paediatric EDs located in Boston, Massachusetts (USA) and Padova (Italy). Padova Children's Hospital is a tertiary care academic hospital with approximately 25 000 paediatric ED

visits per year. Boston Children's Hospital is a tertiary care academic hospital with a level 1 trauma centre designation and an annual ED census of approximately 65 000 paediatric ED visits per year.

The study protocol differed by participating centre. The PECARN TBI rules were published in October 2009. In Boston, we performed a prospective cross-sectional cohort study (April 2011–July 2013). Clinicians in Boston had an available head trauma guideline based on the PECARN TBI rules (institutional guideline released in August 2011). The PECARN TBI rules were introduced into clinical practice in May 2010 in Padova. In the Italian ED we performed a prospective (June 2010–November 2010)[8] cross-sectional study, immediately followed by retrospective (December 2010–May 2011) data collection. The institutional review board of each participating centre approved the study protocol.

Patient participants

We included all children with blunt head trauma and an initial Glasgow Coma Score ≥14, who presented to the ED within 24 h of injury. In Boston we included children <18 years of age and in Padova children <15 years of age (reflecting current patient triage practices at this site). We excluded children with a trivial injury mechanism (eg, ground-level falls or running into stationary objects with no signs of TBI other than scalp abrasions and lacerations), as well as those with any of the following: neurological comorbidities, bleeding disorders or suspected child abuse. Patients with neuroimaging performed prior to ED physician evaluation were excluded. For the prospective cohorts, we also excluded children who had any neuroimaging performed prior to study form completion.

Data collection

Paediatric emergency medicine or general paediatrics attendings (Boston and Padova), paediatric emergency medicine fellows (Boston) or senior residents (Padova) completed all study forms for the two prospective cohorts. For the retrospective cohort, a trained researcher (SB) performed a standardised medical record review and chart abstraction but was not blinded to the patient's clinical outcome. Study forms were completed for all patients to capture the presence or absence of each of the six PECARN age-based TBI predictors including the composite predictors (table 1). Children who arrived in the ED with an initially normal mental status which declined within 1 h of ED arrival were classified as having an abnormal mental status.

For the retrospective and prospective Padova cohort, children who were discharged from the ED without a CT scan were contacted by telephone for clinical follow-up approximately 2 weeks after initial evaluation. For the Boston prospective cohort, clinical follow-up was limited to complete hospital medical record review for the 2 weeks from the initial ED evaluation to determine whether or not the study patient had any neuroimaging performed or any clinical interventions for the management of their head injury. For the purposes of this study, children who had either cranial MRI or CT performed were included in the CT group.

Outcome measures

Our primary outcome was the presence of a clinically important TBI (ie, gold standard for the clinical prediction rule) defined as death, intubation >24 h, neurosurgery or two or more nights in the hospital for management of the head injury.[7] Our secondary outcome measure was a positive CT defined as any of the following traumatic findings: intracranial haemorrhage or contusion, traumatic infarction, sigmoid sinus thrombosis, diffuse axonal injury, pneumocephalus, midline shift or signs of brain herniation, diastasis of the skull, and/or skull fracture.[7]

Table 1 PECARN TBI age-based clinical prediction rules (high, intermediate and very low TBI risk groups) for children with minor blunt head trauma and initial GCS ≥14

Inclusion criteria	
Age <18 years of age	
Non-trivial* head trauma within 24 h	
Exclusion criteria	
Neurological comorbidities	
Bleeding disorders	
Suspected child abuse	
Previous neuroimaging	
Outcome measure=clinically important TBI	
Death, intubation >24 h, neurosurgery, or two or more nights in the hospital for management of the head injury	
PECARN TBI risk groups	
Age <2 years	**Age ≤2 years**
High risk	
Altered mental status†	Altered mental status†
Palpable skull fracture	Signs of basilar skull fracture‡
Intermediate risk	
Severe injury mechanism§	Severe injury mechanism¶
Loss of consciousness >5 s	Any loss of consciousness
Non-frontal haematoma	Vomiting
Not acting right as per parents	Severe headache
Very low risk	
No predictors	No predictors

*Ground-level falls or running into stationary objects with no signs of TBI other than scalp abrasions and lacerations.
†GCS 14, agitation, sleepiness, slow response or repetitive questioning.
§Retroauricular bruising (battle sign), periorbital bruising (raccoon eyes), cerebrospinal fluid otorrhoea or haemotympanum.
¶Motor vehicle crash with patient ejection, death of another passenger or rollover, pedestrian or bicyclist without helmet struck by motorised vehicle, falls (of >3 feet for children <2 years of age or >5 feet for children ≥2 years) or head struck by high impact object.
GCS, Glasgow Coma Score; PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury.

Statistical analysis

We described the data with population proportions with 95% CIs. The age-based PECARN TBI prediction rules were applied to the study population to stratify children into three risk groups (very low, intermediate and high) based on published classifications (table 1). Children with no TBI predictors were classified as very low risk. Children with one or more high-risk TBI predictors were classified as high risk and those with no high risk but one or more intermediate-risk predictors were classified at intermediate risk. Children who were missing one or more predictors with no high-risk predictors could not be classified. We calculated the performance of the two age-based PECARN TBI rules in our study population for the primary (clinically important TBI) and the secondary (positive CTs) outcome measures. We report the sensitivity, specificity, negative predictive values (NPV) and positive predictive values for the age-based rules independently and combined together.

We used the Statistical Program for the Social Sciences for all analyses.[9]

RESULTS

During the study period, 2750 eligible children presented to two participating EDs of which 2439 (91%) were enrolled in our study

(figure 1). The vast majority of patients were missed during overnight hours when research co-ordinators were not available to assist with enrolment. Missed eligible patients had a similar age distribution and CT rate as those children included in the study (data not shown).

Of 2439 included patients, 959 (39%) were <2 years of age and 1439 (59%) were male. Overall, 371 (15% of study population) had a CT performed and 2 (0.1%) patients underwent MRI, for an overall neuroimaging rate of 15%. Of the 373 children that had neuroimaging, 69 (18%) had a positive CT. Overall, 19 patients (0.8% of entire study cohort) had a clinically important TBI. Of those with a clinically important TBI, two children required neurosurgery and all 19 children were hospitalised for two or more nights for management of their head injuries. We completed clinical follow-up for 578 patients (81% of children in the Padova cohorts who did not have an initial neuroimaging) and none had a clinically important TBI.

CT rates differed between participating centres (304/1657 (18%) Boston vs 69/782 (9%) Padova, p<0.001), although positive CT (59/304 (19%) Boston vs 10/69 (15%) Padova, p=0.34) and clinically important TBI (11/1651 (0.7%) Boston vs 8/782 (1%) Padova, p=0.35) rates were similar.

We successfully applied the PECARN age-based TBI clinical prediction rules to 2428 children (99.5% of study patients). The CT rate varied by the PECARN TBI risk strata: 139/197 (70%) of high-risk patients, 199/918 (22%) of intermediate-risk patients and 34/1313 (3%) of very low-risk patients had a CT performed (p<0.001).

We assessed the performance of the PECARN TBI prediction rules for the primary outcome (table 2) and secondary outcome measure (table 3) overall and for children <2 years of age and ≥2 years. None of the children with a clinically important TBI were classified as very low risk (table 4). In the 372 children to whom we could apply the PECARN TBI rules and who had a CT performed, we measured the ability of these rules to identify children with a positive CT: sensitivity 97.1% (95% CI 90.0% to 99.2%), specificity 10.5% (95% CI 7.6% to 14.5%) and NPV 94.1% (95% CI 80.9% to 98.4%). Two children with a positive CT were classified as very low risk. Both of these children had an isolated skull fracture without intracranial injury and were hospitalised overnight without requiring other interventions.

DISCUSSION

We report the first published external validation of the PECARN TBI clinical prediction rules in a cohort of 2439 children with minor blunt head trauma who presented to one of two EDs located in the USA or Italy. In our study cohort, the two age-based rules had excellent sensitivity and NPV for clinically important TBI as well as positive cranial CT. Children in the PECARN TBI very low risk group can safely avoid a CT scan, as the risk of significant head injury is quite low.

Our results were similar to the previously published concurrent validation study.[7] In that study of 8627 children, only two of the 88 children with a clinically important TBI were classified as very low risk. These children were ≥2 years of age and required two or more nights of hospitalisation for management of their head trauma. Our external validation study adds to these results in two ways. First, our study was conducted independently from the rule derivation at two paediatric EDs located in different countries, increasing generalisability. Second, the PECARN TBI rules include two composite predictors (altered mental status, severe injury mechanism). Our validation study was the first to collect the PECARN TBI predictors as composite variables rather than individual components.

In this study the PECARN TBI rules classified two children with a positive CT as very low risk. Both children had an

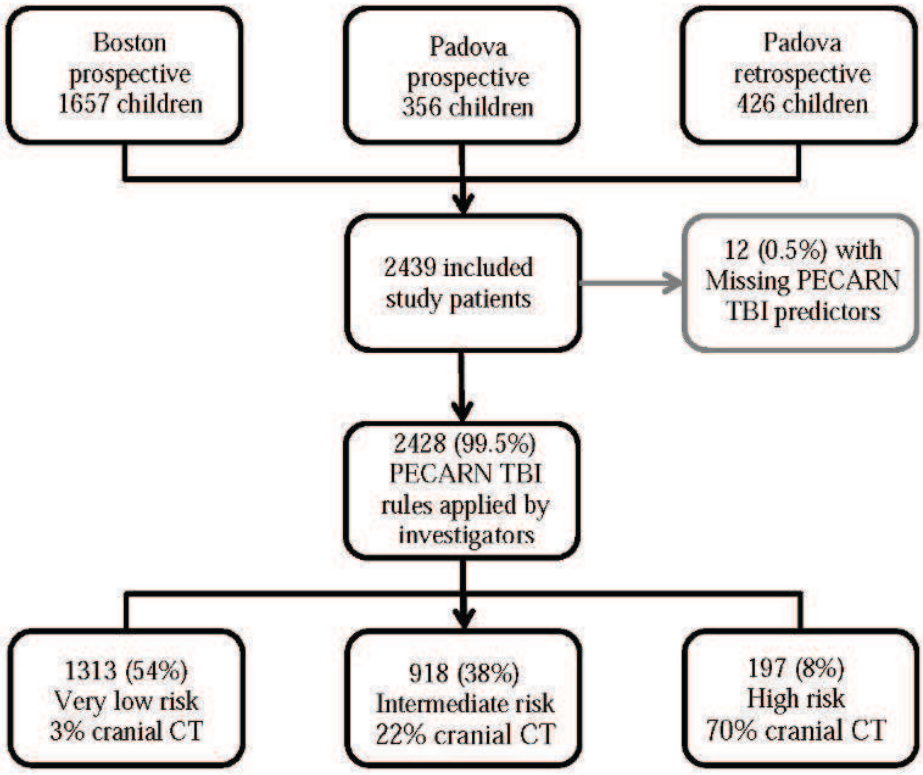

Figure 1 Study population. PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury.

Table 2 PECARN TBI risk groups and the distribution of clinically important TBIs for children <2 years and ≥2 years of age

PECARN TBI risk group <	Children in TBI risk group N	Clinically important TBI* n (% within risk group; 95% CI)
Children <2 years of age	956	6 (0.6; 0.3 to 1.4)
Very low risk	546	0 (0; 0 to 0.7)
Not very low risk	410	6 (1.5; 0.6 to 3.2)
Intermediate risk	381	4 (1.1; 0.4 to 2.7)
High risk	29	2 (6.9; 1.9 to 22.0)
Children ≥2 years of age	1472	13 (0.9; 0.5 to 1.5)
Very low risk	767	0 (0; 0 to 0.5)
Not very low risk	705	13 (1.8; 1.1 to 3.2)
Intermediate risk	537	2 (0.4; 0.1 to 1.4)
High risk	168	11 (6.6; 3.7 to 11.4)
Overall (both age groups)	2428	19 (0.8; 0.5 to 1.2)
Very low risk	1313	0 (0; 0 to 0.3)
Not very low risk	1115	19 (1.7; 1.1 to 2.7)

*Clinically important TBI defined as death, intubation >24 h, neurosurgery or two or more nights in the hospital for management of the head injury.
PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury.

isolated skull fracture and were hospitalised overnight but required no acute neurosurgical or social work interventions. In particular, most children with non-depressed skull fractures without intracranial injury (ie, an isolated linear skull fracture), do not require hospitalisation as the risk of requiring neurosurgical intervention is quite low. Despite this fact, current admission rates for children with isolated skull fractures remain high (approximately 80%).[10] Although CT scans may not be necessary for some types of TBI, clinicians must maintain a high level of suspicion for non-accidental trauma, especially in the youngest children.[11 12]

PECARN TBI rules can assist clinical decision making by providing an accurate assessment of the risk of a significant head injury. Children at very low risk for TBI may not need a cranial CT as ionizing radiation from CT has been associated with an increased lifetime risk for radiation-associated malignancies.[13–16] For children who are not at very low risk, observation can also be an important management strategy, allowing selective CT use for those children whose symptoms progress or fail to improve during the period of observation. Observation has been associated with a significant reduction in cranial CT rate with no change in rate of clinically important TBI.[17 18] Importantly, children with significant head injuries very rarely have delayed presentations (more than 4–6 h after injury),[19] mitigating the risk of missing a significant TBI when clinicians choose to observe a child prior to CT decision making.

Table 3 PECARN TBI risk groups and the distribution of positive CT scans for children <2 years and ≥2 years of age who had a CT performed*

PECARN TBI risk group <	Children in TBI risk group N	Positive CT† n (% within risk group who had CT performed; 95% CI)
Children <2 years of age	121	38 (17.2; 13.0 to 22.7)
Very low risk	17	2 (12.5; 3.5 to 36.0)
Not very low risk	104	36 (34.6; 26.2 to 44.2)
Intermediate risk	85	32 (37.2; 6.0 to 11.7)
High risk	19	4 (21.1; 8.5 to 43.3)
Children ≥2 years of age	251	30 (12.0; 8.5 to 16.6)
Very low risk	17	0 (0; 0 to 12.5)
Not very low risk	234	30 (12.8; 9.1 to 17.8)
Intermediate risk	114	8 (7.0; 3.6 to 13.2)
High risk	120	22 (18.3; 12.4 to 26.2)
Overall (both age groups)	372	68 (18.3; 14.7 to 22.5)
Very low risk	34	2 (5.9; 1.6 to 19.1)
Not very low risk	338	66 (19.5; 15.6 to 24.1)

*Either a cranial CT or MRI was included.
†Positive CT defined as intracranial haemorrhage or contusion, traumatic infarction, sigmoid sinus thrombosis, diffuse axonal injury, pneumocephalus, midline shift or signs of brain herniation, diastasis of the skull, or skull fracture.
PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury.

Patient and parental preference should play a significant role in CT decision making for children with minor blunt head trauma. In a recent survey of parents of children with head trauma, the majority preferred observation to immediate CT after a standardised education about the risks of ionizing radiation.[20] In a second survey of parents of ED patients, approximately half were aware of the risks of ionizing radiation from diagnostic CT scans.[21] Additionally, most parents preferred disclosure of risk before proceeding with imaging. Further study is needed to better understand the optimal methods of risk communication as well as parental preferences for the ED management of minor head trauma for their children.

Our study has the following limitations. First, our study was conducted in two academic paediatric EDs, raising the possibility that our findings may not be generalisable to other settings, particularly general EDs that care for children. Although additional impact studies are needed, the implementation of the PECARN TBI might may have a greater impact on CT utilisation in general than paediatric EDs since current CT rates for children with blunt head trauma are higher at general than at paediatric EDs.[22] Second, the data was abstracted from the medical record for some study patients. However, the Padova retrospective cohort followed the prospective implementation study and treating clinicians were previously trained to collect and record the age-based PECARN TBI predictors. Third, of the five children who developed altered mental status within 1 h of initial assessment, two had a clinically important TBI. These injuries might have been missed injury if clinical decision making occurred immediately on arrival to the ED. We considered these patients to be high risk by the PECARN TBI rules, further highlighting the utility of clinical observation prior to CT decision making to minimise the risk of missing a significant head injury. Fourth, not all patients had a CT scan performed. As children with a positive CT may not require specific interventions (eg, children with an isolated skull fracture[10]), we likely underestimated the rate of our secondary outcome measure (positive CT). Fifth, we did not perform clinical follow-up for all patients discharged from the ED without a CT scan although we did review all medical records after the initial ED visit for repeat visits within 2 weeks of initial injury. In the previous PECARN TBI derivation study where clinical follow up was performed, only 1 out of the more than 40 000 children studied had a clinically important TBI diagnosed after initial ED discharge,[7] suggesting that risk of missing our primary outcome measure was quite low even if the patient presented again to another ED. Sixth, although we were unable to apply the PECARN TBI rules to those children missing clinical predictors, we only excluded 11 children (0.5% of study patients) for missing data, minimising the potential impact or bias on our study findings. Last, few children had a clinically significant TBI which limited our ability to assess rule sensitivity. Future multicentre validation studies

Table 4 Performance of the two PECARN TBI age-based rules independently and combined

Age group	Sensitivity n/N (%; 95% CI)	Specificity n/N (%; 95% CI)	Negative predictive value n/N (%; 95% CI)	Positive predictive value n/N (%; 95% CI)
<2 years	6/6 (100; 64.3 to 100)	410/950 (43.2; 40.0 to 46.3)	546/546 (100; 99.4 to 100)	6/410 (1.7; 0.6 to 3.2)
≥2 years	13/13 (100;79.4 to 100)	705/1459 (48.3; 45.8 to 50.9)	1313/1313 (100; 99.8 to 100)	13/705 (2.0; 1.1 to 3.2)
Overall	19/19 (100;83.2 to 100)	131/2409 (55; 52.5 to 56.6)	1313/1313 (100; 99.6 to 100)	19/1115 (1.8; 1.1 to 2.7)

PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury.

are needed to further demonstrate the accuracy and generalisability of the PECARN TBI prediction rule across different domains, such as general EDs.

CONCLUSIONS

In our external validation study, the PECARN TBI age-based clinical predication rules performed well by accurately identifying children who are at very low risk for a clinically important TBI who can safely avoid a CT scan. These can be used to assist with clinical decision making for children with minor head trauma. Prospective implementation of the PECARN TBI rules must be carefully studied to determine the impact on CT rates as well as missed injuries.

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Contributors DS and LEN were responsible for the conception and design of the study and drafted the manuscript. DS, SB, MNH and JAW acquired the data. DS, SB, LDD and LEN were responsible for the analysis and interpretation of data. All collaborators critically revised the manuscript and granted final approval of the submitted manuscript.

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6.2.2. Implementation of a clinical decision rule

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ORIGINAL RESEARCH CONTRIBUTION

Implementation of Adapted PECARN Decision Rule for Children With Minor Head Injury in the Pediatric Emergency Department

Silvia Bressan, MD, Sabrina Romanato, MD, Teresa Mion, MD, Stefania Zanconato, MD, and Liviana Da Dalt, MD

Abstract

Objectives: Of the currently published clinical decision rules for the management of minor head injury (MHI) in children, the Pediatric Emergency Care Applied Research Network (PECARN) rule, derived and validated in a large multicenter prospective study cohort, with high methodologic standards, appears to be the best clinical decision rule to accurately identify children at very low risk of clinically important traumatic brain injuries (ciTBI) in the pediatric emergency department (PED). This study describes the implementation of an adapted version of the PECARN rule in a tertiary care academic PED in Italy and evaluates implementation success, in terms of medical staff adherence and satisfaction, as well as its effects on clinical practice.

Methods: The adapted PECARN decision rule algorithms for children (one for those younger than 2 years and one for those older than 2 years) were actively implemented in the PED of Padova, Italy, for a 6-month testing period. Adherence and satisfaction of medical staff to the new rule were calculated. Data from 356 visits for MHI during PECARN rule implementation and those of 288 patients attending the PED for MHI in the previous 6 months were compared for changes in computed tomography (CT) scan rate, ciTBI rate (defined as death, neurosurgery, intubation for longer than 24 hours, or hospital admission at least for two nights associated with TBI) and return visits for symptoms or signs potentially related to MHI. The safety and efficacy of the adapted PECARN rule in clinical practice were also calculated.

Results: Adherence to the adapted PECARN rule was 93.5%. The percentage of medical staff satisfied with the new rule, in terms of usefulness and ease of use for rapid decision-making, was significantly higher (96% vs. 51%, $p < 0.0001$) compared to the previous, more complex, internal guideline. CT scan was performed in 30 patients (8.4%, 95% confidence interval [CI] = 6% to 11.8%) in the implementation period versus 21 patients (7.3%, 95% CI = 4.8% to 10.9%) before implementation. A ciTBI occurred in three children (0.8%, 95% CI = 0.3 to 2.5) during the implementation period and in two children (0.7%, 95% CI = 0.2 to 2.5) in the prior 6 months. There were five return visits (1.4%) postimplementation and seven (2.4%) before implementation ($p = 0.506$). The safety of use of the adapted PECARN rule in clinical practice was 100% (95% CI = 36.8 to 100; three of three patients with ciTBI who received CT scan at first evaluation), while efficacy was 92.3% (95% CI = 89 to 95; 326 of 353 patients without ciTBI who did not receive a CT scan).

Conclusions: The adapted PECARN rule was successfully implemented in an Italian tertiary care academic PED, achieving high adherence and satisfaction of medical staff. Its use determined a low CT scan rate that was unchanged compared to previous clinical practice and showed an optimal safety and high efficacy profile. Strict monitoring is mandatory to evaluate the long-lasting benefit in patient care and/or resource utilization.

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Minor head injuries (MHIs) continue to be a major problem in pediatrics, representing one of the most common reasons for visits in the pediatric emergency department (PED). The management of these children has long presented a common dilemma for emergency physicians due to the challenging task of balancing the need of head computed tomography (CT) scan for intracranial injury (ICI) identification on one hand, and of limiting the radiation- and sedation-associated risks,[1–3] as well as resource utilization, on the other. To optimize this balance, availability of effective and validated clinical decision rules in the ED is pivotal. Of the published decision rules for minor head injuries in children,[4,5] the recent Pediatric Emergency Care Applied Research Network (PECARN) rule,[6] derived and validated in the largest multicenter prospective study cohort with high methodologic standards, appears to be the best to accurately identify children at very low risk of clinically important traumatic brain injuries (ciTBIs) in the PED,[5,7] providing differentiated algorithms for children younger and older than 2 years of age.

These features, along with their simple and easy-to-remember structure, offer the potential for broad use in the ED. The implementation of evidence-based tools for clinical decision-making in the acute care setting has shown to improve quality of care as well as patients' outcomes.[8–10] Physician adherence to new decision rules and protocols, and their satisfaction with the innovation, are key points to achieve a significant change in clinical practice, which results in a long-lasting benefit in patient care and resource utilization.

The aims of this study were to describe the implementation of an adapted version of the PECARN rules for the management of children with MHI in a tertiary care academic PED in Italy and to evaluate implementation success, in terms of medical staff adherence and satisfaction, as well as the effects on clinical practice.

METHODS

Study Design

This was an observational before–after study. The study was approved by the hospital ethics committee with waiver of written consent, and verbal consent was given for telephone follow-up in the postimplementation period.

Study Setting and Population

The study was carried out in the PED of Padova Children's Hospital, an academic hospital providing primary and secondary care for a metropolitan area of 350,000 people (45,000 younger than 15 years) and tertiary care for a regional and extraregional population, with approximately 25,000 PED visits per year. Its four-bed short-stay observation unit allows for management of patients whose expected length of stay is 4 to 24 hours. Both attending physicians and residents in pediatrics provide patient care in the PED. The residency program in pediatrics at the University of Padova is a 5-year training program. Residents on duty in the PED primarily see approximately 95% of the children and discuss their diagnostic and therapeutic management with the attending physician, according to their level of training. First- and second-year residents are fully supervised. Decisions on CT scan ordering have always to be taken in accordance with the PED consultant, independently of the level of training of the residents.

The adapted PECARN rule was applied to children presenting to the PED within 24 hours of blunt head trauma and Glasgow Coma Scale (GCS) ≥ 14, between June and November 2010. Children with trivial injury mechanisms defined by ground-level falls or running into stationary objects, and no signs or symptoms of head trauma other than scalp abrasions and lacerations, were excluded. Children with penetrating trauma, preexisting neurologic disorders, known bleeding disorders, or neuroimaging at an outside hospital before transfer were also excluded.

Data were compared with those of children evaluated in the PED for MHI 6 months prior to the implementation of the adapted PECARN rule, between November 2009 and April 2010.

Study Protocol

Local Adaptation and Dissemination. In our PED, patients with head trauma had been managed according to an internal protocol in use since 2003, based on the prediction rule published by Da Dalt et al. in 2006[11] (a summary of the protocol is reported in Appendix 1).

The use of this protocol allowed for a low cranial CT rate (between 5 and 10%) with no missed ICI requiring neurosurgery since its introduction, but its complex structure made it impractical for rapid consultation and decision-making in the ED. Furthermore, the protocol did not provide a separate rule for younger children. Therefore, after discussion with local experts on MHI, implementation of the adapted PECARN rules for a 6-month testing period was decided upon, and some minor modifications were made to the original algorithms. The PECARN rule categories "CT recommended," "Observation versus CT on the basis of other clinical factors," and "CT not recommended" were named, respectively, "high risk," "moderate risk," and "low risk" for ease of use.

Local adaptations to the PECARN rules, related to the moderate-risk group, were the following:

- For children younger than 2 years of age:
  - Amnesia was introduced alongside the other original predictors.[11–13]
  - In the presence of isolated vomiting, CT was highly suggested if there was repetitive vomiting (more than 5 episodes) or persistent vomiting for more than 6 hours after head trauma and a negative personal history for recurrent vomiting or motion sickness.[14]
- For all children:
  - The recommended duration of observation in the PED for children who did not undergo a CT scan was set to be of at least 6 hours for trauma and at least 12 hours for infants <6 months.

Dissemination of the adapted PECARN rules to physicians working in the PED was carried out in May 2010 and included: 1) dedicated teaching sessions; 2) e-mailing of teaching material, as well as the adapted

PECARN rules; 3) posters explaining the algorithms in the PED; 4) availability of the new protocol for the management of MHI, for online consultation in the intranet website; and 5) ample supply of pocket cards, including the pediatric GCS to the physicians working in the PED. Periodic reminders to on-call physicians were also performed by the study investigators during the implementation period.

Data Sources

During implementation of the adapted PECARN rule, examining physicians were required to report clinical data in a standardized manner before any decision-making on the most appropriate management option. Prospective data collection was monitored weekly by study investigators.

Patients assessed for MHI during the preimplementation period were identified through the electronic PED database. Medical charts were then reviewed for inclusion/exclusion criteria and data abstraction.

Patient data included demographic features, data on out-of-hospital care when appropriate, time of injury, detailed mechanism of injury, site of trauma, features and onset of posttraumatic symptoms, at arrival, physical examination findings (including other sites of trauma), CT scan results when performed, duration of symptoms and observation in the PED, need for neurosurgery, and final disposition.

Data abstractors received formal training in medical records review using a standardized data collection form tested on a set of 20 charts of patients evaluated for MHI in May 2010 (dissemination period). Clear variable definitions (as reported in Kuppermann et al.[6]) and abstraction guidelines were also provided prior to the start of data collection. Data abstractors were not blinded to the study outcomes. Periodic meetings with the senior study coordinator were held to discuss conflicting, ambiguous, or missing data, as well as review of inclusion and exclusion criteria. CT scans were independently interpreted by site faculty radiologists unaware of this study.

Return visits within 2 weeks from discharge were monitored for each patient in both study periods, to identify possible cases of missed TBI. Telephone follow-up was also carried out for the same purpose, between 10 and 90 days from PED discharge for patients in the postimplementation period.

Outcomes

The primary outcome of this study was evaluation of medical staff adherence to adapted PECARN rules, defined as the proportion of children managed according to the new rules, in relation to risk group stratification.

Satisfaction of medical staff with the implementation of the adapted PECARN rules was also assessed comparing the results of a survey asking to grade (from 1 to 4) the usefulness and ease of use for rapid decision-making of the protocol in use for MHI, prior to dissemination of adapted PECARN rules, and 6 months after their implementation. The questionnaire used was developed based on consensus by local experts on MHI.

The clinical and patient outcomes were: 1) CT scan rate in the pre- and postimplementation periods; 2) ciTBI rates in the pre- and postimplementation periods (ciTBI was a priori defined, according to Kuppermann et al.,[6] as death from TBI, neurosurgery, intubation for more than 24 hours due to TBI or hospital admission of two nights or more associated with brain injury on CT); 3) return visits for symptoms and/or signs potentially related to MHI; 4) the safety of adapted PECARN rules application to clinical practice, defined according to Reilly and Evans[15] as the proportion of all patients experiencing a ciTBI who received head CT scan; and 5) the efficacy of adapted PECARN rules application to clinical practice, defined according to Reilly and Evans[15] as the proportion of all patients not experiencing a ciTBI who did not receive head CT scan.

Data Analysis

Continuous variables were expressed as median and interquartile range (IQR), because of nonnormal distribution. Categorical variables were expressed as percentages and 95% confidence intervals (CIs) were reported for main results. Comparison of categorical variables was performed by means of chi-square tests. Parameters displaying $p \leq 0.05$ were considered statistically significant, with no adjustment for multiple comparisons. Statistical analyses were conducted using the statistical program MedCalc 11.1 (MedCalc Software, Mariakerke, Belgium).

RESULTS

A total of 902 patients were evaluated for MHI in the two study periods. Of these, 644 met the inclusion criteria (356 after and 288 before implementation of adapted PECARN rule) and were ultimately included in the study (Figure 1).

Overall, 292 patients (45.3%) were younger than 2 years, and the median age was 2.4 years (IQR = 0.9 to 5.2 years). A total of 332 patients (51.6%) were male, 591 (91.8%) were brought to the PED within 6 hours of trauma, and 258 (40.1%) had a frontal site of impact. Injury mechanisms were: fall from height (n = 397, 61.6%), fall from ground level or ran into stationary object (n = 91, 14.1%), bicycle collision or fall (n = 33, 5.1%), fall down the stairs (n = 32, 5%), head struck by

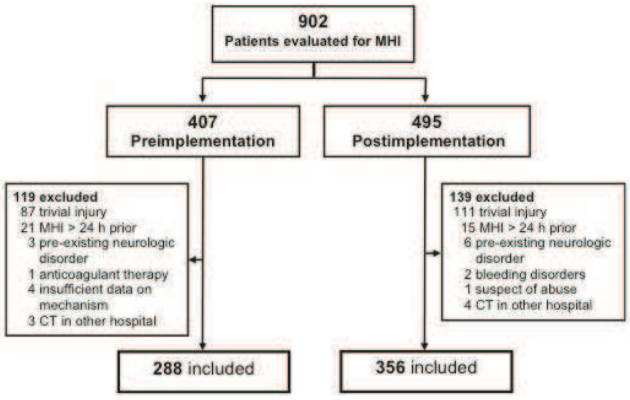

Figure 1. Flow chart of patient selection. MHI = minor head injury.

an object (n = 29, 4.5%), occupant in motor vehicle crash (n = 16, 2.5%), sports-related (n = 15, 2.3%), bicyclist struck by a motorized vehicle (n = 6, 0.9%), assault (n = 3, 0.5%), pedestrian struck by vehicle (n = 2, 0.3%), and other (n = 20, 3.1%).

Isolated head trauma occurred in 92% of patients and 637 (99%) had GCS scores of 15. Patient characteristics and outcomes were similar between the two periods (Table 1).

Adherence to and Satisfaction With Adapted PECARN Rules

Adherence to the adapted PECARN rule was observed for 330 of 353 patients (93.5%). Three patients were excluded from calculation because they left the PED earlier than recommended, due to parents' decisions. All of them were classified as moderate risk, they did not receive CT scans, and they did well at home as ascertained by telephone follow-up. Details on medical staff adherence to the new rule, according to risk and age group, are reported in Table 2.

As for satisfaction of medical staff working in the PED (11 either full-time or part-time attending physicians and 46 residents during the study period) with the implementation of the new rules, the answer rates to the pre- and postimplementation surveys were 90 and 84%, respectively. The usefulness and ease of use for rapid decision-making at the bedside was scored ≥3 in 51% of cases for previous protocol and 96% for adapted PECARN rules ($p < 0.0001$).

Clinical and Patient Outcomes

CT Scan Rate. The CT scan rate observed after adapted PECARN rule implementation was 8.4% (95% CI = 6% to 11.8%), not significantly different from that of the preimplementation period at 7.3% (95% CI = 4.8% to 10.9%). When the CT scan rate was analyzed by age group and study period, there were no

Table 1
Distribution of Patient Characteristics and Outcomes According to Age Group and Study Period

	Preimplementation (N = 288)		Postimplementation (N = 356)	
Characteristic	Age < 2 years (n = 130)	Age > 2 years (n = 158)	Age < 2 years (n = 162)	Age > 2 years (n = 194)
Sex (M/F)	62/68	83/75	79/83	108/86
Site of impact				
Frontal only	55 (42.3)	64 (40.5)	71 (43.8)	68 (35)
Other than frontal only	56 (43.1)	91 (57.6)	70 (43.2)	118 (60.8)
Unknown*	19 (14.6)	3 (1.9)	21 (13)	8 (4.2)
Severe mechanism of injury	19 (14.6)	28 (17.7)	20 (12.3)	35 (18)
History of LOC (known or suspected)	3 (2.3)	8 (5)	5 (3)	12 (6.2)
LOC duration				
<5 seconds	1 (0.8)	2 (1.2)	2 (1.2)	7 (3.6)
>5 seconds	2 (1.5)	6 (3.8)	3 (1.8)	5 (2.5)
Amnesia		5 (3.2)		10 (5.2)
Headache		51 (32.3)		54 (27.8)
Severity of headache				
Mild		8 (5)		17 (8.7)
Moderate		24 (15.2)		24 (12.3)
Severe		10 (6.3)		8 (4.1)
Not reported		9 (5.7)		5 (2.5)
History of vomiting	11 (8.5)	38 (24)	14 (8.6)	58 (29.8)
Number of vomiting episodes				
<5 episodes	8 (6.2)	38 (24)	13 (8)	53 (27.3)
>5 episodes	3 (2.3)	0 (0)	1 (0.6)	5 (2.5)
Acting abnormally according to parent	6 (4.6)	14 (8.9)	9 (5.5)	21 (10.8)
GCS score (14/15)	1/129	2/156	0/162	4/190
Altered mental status	0 (0)	0 (0)	1 (0.6)	5 (2.5)
Signs of basilar skull fracture	0 (0)	0 (0)	0 (0)	1 (0.5)
Palpable skull fracture (or unclear exam)	3 (2.3)	1 (0.6)	0 (0)	7 (3.6)
Scalp hematoma	58 (44.6)	80 (50.6)	72 (44.4)	85 (43.8)
Location of scalp hematoma				
Frontal	30 (23.1)	38 (24.1)	45 (27.8)	39 (20.1)
Nonfrontal	28 (21.5)	42 (26.6)	27 (16.7)	46 (23.7)
CT scan rate	10 (7.7)	11 (7)	6 (3.7)	24 (12.4)
Patient outcomes				
ICI on CT	2 (1.5)	0 (0)	1 (0.6)	4 (2.1)
ciTBI				
Death	0 (0)	0 (0)	0 (0)	0 (0)
Neurosurgery	0 (0)	0 (0)	0 (0)	0 (0)
Intubation >24 hours	0 (0)	0 (0)	0 (0)	0 (0)
Hospital admission >2 nights	2 (1.5)	0 (0)	1 (0.6)	2 (1)

Values are reported as n (%) unless otherwise noted.
ciTBI = clinically important traumatic brain injury; GCS = Glasgow Coma Scale; ICI = intracranial injury; LOC = loss of consciousness.
*Not directly witnessed fall with no evident signs of head trauma on physical examination.

Table 2
Medical Staff Adherence to Adapted PECARN Rules According to Age and Risk Group

	Age < 2 years (Total *N* = 162)			Age > 2 years (Total *N* = 194)		
Group	*n* (%)	CT Performed	Adherence	*n* (%)	CT Performed	Adherence
High-risk group (*n* = 13)	0	0	0/0	13 (6.7)	12 (92.3)	12/13 (92.3%)
Moderate-risk group (*n* = 139)*	52 (32)	5 (9.6)	45/50 (90)†	87 (44.8)	11 (12.3)	71/86 (82.5%)†
Low-risk group (*n* = 204)	110 (68)	1 (0.9)‡	109/110 (99)	94 (48.5)	1 (1.1)‡	93/94 (99%)

PECARN = Pediatric Emergency Care Applied Research Network; PED = pediatric ED.
*Three patients (two younger than 2 years and one older than 2 years) were excluded from adherence calculation because of the parents' decision to leave the PED earlier than recommended.
†Five patients younger than 2 years were observed in the PED for less than 6 hours from trauma: four had isolated risk factors (two mechanisms of trauma interpreted as severe, both falls, one initially not acting normally according to parents, one with an isolated episode of vomiting), while one presented an isolated episode of vomiting after a fall from borderline height. Fifteen patients older than 2 years were observed in the PED for less than 6 hours from trauma: 73% of these patients presented as isolated risk factors a history of vomiting of three or fewer episodes.
‡The patient younger than 2 years underwent CT because of a scheduled flight back home with his family the same day; the patient older than 2 years underwent CT because of borderline features: 26 months of age, fall from approximately 120 cm, and enlarging occipital hematoma during observation. Both CT scans results were normal.

differences between the pre- and postimplementation periods for children younger than 2 years (7.7% vs. 3.7%, p = 0.219) or for children older than 2 years (7% vs. 12.4%, p = 0.132).

Intracranial injuries were detected by CT in 1.4% (95% CI = 0.4% to 2.8%) of children or 16.7% of performed CTs in the postimplementation period, compared to 0.7% (95% CI = 0.2% to 2.5%) or 9.5% of performed CTs in the preimplementation period. The ICIs identified on CT scan in the postimplementation period were one epidural hematoma, one subarachnoid bleed, one cerebral contusion, and two subdural hematomas (all cases but one subdural hematoma associated with skull fracture). In the preimplementation period, a case of subdural hematoma and one subdural hematoma and cerebral contusion with associated skull fracture were detected on CT. An isolated skull fracture was found in four patients (three in the post- and one in the preimplementation period).

Clinically Important Traumatic Brain Injury Rate. Three patients (0.8%, 95% CI = 0.3 to 2.5) in the postimplementation period and two children (0.7%, 95% CI = 0.2% to 2.5%) in the preimplementation period met the definition of ciTBI, all of them because of hospital admission of two nights or more due to TBI. No patient died, needed neurosurgery, or was intubated for longer than 24 hours. Initially missed ciTBIs were also excluded by telephone follow-up, which was accomplished for 78% of patients presenting to the PED after adapted PECARN rule implementation.

Return Visits. Return visits for symptoms potentially related to head trauma occurred in five (1.4%) and seven (2.4%) patients in the post- and preimplementation periods, respectively (p = 0.506). None of these patients subsequently satisfied the definition of ciTBI.

Safety and Efficacy of Adapted PECARN Rules. The safety of the adapted PECARN rules in our PED clinical practice was 100% (95% CI = 36.8% to 100%; three of three patients with ciTBI who received CT scan at first evaluation), while efficacy was 92.3% (95% CI = 89% to 95%) (326 of 353 patients without ciTBI who did not receive a CT scan).

DISCUSSION

Many clinical decision rules have been derived to identify the best diagnostic management of children with MHI, but only a few have been validated,[5,16] and no data are currently available on the effects of implementing any of these rules in daily clinical practice. Availability of high-quality evidence-based tools for clinical decision-making is especially useful in the acute care setting to optimize the approach to common presentations for which only a small minority of patients are at risk of a bad outcome. Our results showed that the new rules were successfully implemented, achieving high adherence and satisfaction of medical staff working in the PED. These findings are likely related to the easy structure of the rules, their flexibility, being assistive rather than directive for the moderate risk group, and the availability of risk estimates for ciTBI for each risk group. Nonadherence was mostly registered for the moderate-risk group in children older than 2 years, in terms of earlier discharge than recommended, especially for patients who presented with isolated vomiting (≤ 3 episodes) as the only risk factor and who were classified as low risk in the previous protocol. Compared to the United States, our clinical setting is characterized by a lower overall CT scan rate for MHI (~8% vs. 35%),[6] which may be attributed to differences in the population, the local management of MHI, the availability of observation beds in the PED, and different legal implications.

Patients included in our study satisfied the same inclusion and exclusion criteria as the PECARN rule, except for the upper age limit of 15 years for our population, compared to 18 years in the American study. This difference likely explains the higher percentage of children younger than 2 years found in our study (45% vs. 25% in the PECARN study) and the larger proportion of falls as trauma mechanism (80% vs. 51%), which

is more common in younger children and is generally responsible for less severe trauma. The lower percentages of children with GCS = 14 (1% vs. 3%), signs of altered mental status (1% vs. 12%), and signs of basilar or skull fractures (2% vs. 3.5%), all high-risk predictors for ciTBI, reflect the overall lower severity of trauma in our PED compared to the North American setting. Street accidents, generally responsible for the most severe trauma mechanisms, were four times more frequent in the United States, compared to our population (15% vs. ~ 4%). Even though ciTBI occurred in a similar proportion of patients (0.9% vs. 0.8%) in the two studies, none of our patients underwent neurosurgery or intubation for longer than 24 hours because of TBI, compared to 68 patients (0.16%) who needed either intervention in the PECARN study, while no cases of death from TBI were registered in either study. Nevertheless, the limited sample size of our study may also account for this finding.

Despite the differences in population and local context with the original setting, adapted PECARN rule implementation in our PED maintained unchanged the previous low CT scan rate, showing an optimal safety and high-efficacy profile. These results are noticeable because the PECARN rule was developed to reduce unnecessary head CT scans in a setting with a four-times-higher CT rate compared to ours, so that implementation of the rule in our setting might have brought an increase in the CT scan rate. The flexibility in decision-making provided by the rule for moderate-risk patients might have contributed to this potential effect, despite the recommended discretion for scanning this group, citing observation as the alternative course of action. The weight of other clinical factors influencing the decision-making process for moderate-risk patients, such as physician's experience and parental preference, is a priori unpredictable.

The unchanged CT scan rate in the postimplementation period may be explained by several factors: 1) the traditional conservative watchful waiting approach in the diagnostic management of head trauma in our center, 2) the availability of a short-stay observation unit within the PED that favors this approach,[17] and/or 3) the flexibility of the rule itself, which allowed physicians to prefer a conservative approach, choosing observation instead of CT scan for the great majority of moderate-risk patients.

Strict monitoring of the adapted PECARN rules use in our PED following the 6-month active implementation period is mandatory to evaluate the long-lasting benefit in patient care and/or resource utilization. Larger well-designed studies and rigorous impact analysis, as well as cost-effectiveness analysis, are advocated to provide evidence-based data to support the use of PECARN rules in daily clinical practice.

LIMITATIONS

Several limitations of our study should be noted. First are the limitations inherent to the study design. Without a randomized controlled trial, it is difficult to assess the possible influence of clinical advances or other system changes on the effects observed in this study. However, a single-site randomized controlled trial would have been difficult to carry out because of the high risk for contaminating the intervention and control groups, while a multi-institutional randomized study, the preferred trial design, implies relevant logistic and economic challenges that are difficult to overcome, especially without previous evidence of impact.

As far as data collection is concerned, all medical charts were reviewed by chart abstractors who were not blinded to the study hypothesis. This is the most common limitation in medical record review studies in emergency medicine and could have introduced bias to the study results. CT scan evaluation, however, was performed in a blinded manner by consultant radiologists unaware of this study. Furthermore, recommended strategies for medical chart data abstraction[18] (i.e., standard chart abstraction form with clear a priori variable definitions and abstraction form guidelines) were provided to study investigators. Collection of prospective data by on-call residents during the postimplementation period might have affected quality of clinical data. However, specific instructions provided to the medical staff working in the PED during the teaching sessions, as well as supervision by attending physicians and monitoring by the study investigators, limited the possibility of incorrect data gathering and reporting.

With regard to medical staff satisfaction, the use of a nonvalidated assessment tool might have influenced our results. Nevertheless, the large difference in medical staff satisfaction between the previous protocol and the adapted PECARN rules, along with the high adherence to the new rules, make a false-positive result very unlikely.

The limited sample size of our study should also be considered. In our PED, implementation of the adapted PECARN rules for an initial 6-month testing period was decided upon due to the need to closely monitor the effects of its use in a different setting from the one of original derivation and validation, taking into account that the flexibility of the rule itself did not allow for accurate estimation of its actual effect in clinical practice. In addition, this time frame best suited the need for a reliable evaluation of medical staff satisfaction in a setting where residents rotate on a yearly basis.

Finally, telephone follow-up in the postimplementation period was not possible for 22% of patients. However, the monitoring of all patients records for any return visit in our PED and the written instructions given to parents on the need to reassess the child in our center for symptoms or signs potentially related to head trauma limit the possibility of unrecognized ciTBIs. Our hospital is a referral center for a large metropolitan area, being a tertiary care pediatric facility provided with both pediatric neurosurgery and a pediatric intensive care unit. Nevertheless, the small possibility that discharged children, for whom telephone follow-up was not possible, were subsequently examined at other hospitals cannot be completely excluded.

CONCLUSIONS

An adapted version of the Pediatric Emergency Care Applied Research Network minor head injury rules was

successfully implemented in an Italian tertiary-care academic pediatric ED, achieving high adherence and satisfaction of medical staff. Its use resulted in a low CT scan rate that was unchanged compared to previous clinical practice, and showed excellent safety and efficacy profiles. Strict monitoring is mandatory to evaluate the long-lasting benefit in patient care and resource utilization.

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APPENDIX 1

Summary of Previous Protocol for Management of Children With MHI in Our PED

Patients who sustained a blunt head trauma were classified into three groups:

1. A high-risk group of children for whom CT was recommended. Patients were defined as high-risk if they met at least one of the following criteria: GCS score ≤ 12 or drop of 2 points since arrival, focal neurologic signs, loss of consciousness > 5 minutes, signs of basal or complicated skull fracture.
2. A moderate-risk group of children, who did not present any of the above reported features, and whose risk of ICI and subsequent management (CT, skull x-rays, or observation alone) was differentiated according to a three-subgroup classification, based on the presence of specific clinical predictors or the combination given by the severity of trauma mechanism with the presence and site of large scalp hematoma (the last feature considered only for children < 2 years).
3. A low-risk group of children for whom no diagnostic imaging was recommended. Patients were defined as low-risk in the absence of any of the features of the high- and moderate-risk groups and the possible presence of up to four episodes of vomiting immediately after trauma, mild headache confined to site of trauma, or loss of consciousness of only a few seconds.

6.2.3. Use of a clinical decision rule in clinical practice

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The Pediatric Emergency Care Applied Research Network rule intermediate-risk predictors were not associated with scanning decisions for minor head injuries

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Abstract

Aim: This study determined the predictors associated with the decision to perform a computed tomography (CT) scan in children with a minor head injury (MHI), at intermediate risk of clinically important traumatic brain injury (ciTBI) according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rule.

Methods: A one-year, cross-sectional study was performed in an Italian paediatric emergency department, focusing on children presenting within 24 hours of an MHI and meeting the PECARN intermediate risk criteria.

Results: We included 308 children and 47% were younger than two-years-old. CT scans were carried out on 13%, 1.3% had a ciTBI and one was initially missed but did not need neurosurgery following diagnosis. Single and multiple PECARN intermediate risk predictors were not associated with whether a CT scan was carried out. The only clinical variable associated with the decision to perform a CT scan was if the child was under three-months-of-age (OR 18.1, 95% CI, 4.91-66.61).

Conclusion: The PECARN intermediate risk predictors did not play a major role in the decision to perform a CT scan. The only factor significantly associated with the decision to perform a CT scan was when the patient was younger than three-months-of-age.

Key words: Children, computed tomography scan, minor head injury, Pediatric Emergency Care Applied ResearchNetwork, clinically important traumatic brain injury

Key notes

- It is unknown how clinicians use the Pediatric Emergency Care Applied Research Network (PECARN) rule for decision making on computed tomography (CT) in children with minor head injury (MHI)
- A one-year, hospital-based study was carried out, focusing on 308 children with an MHI at PECARN rule intermediate risk.
- This found that the PECARN intermediate risk predictors did not play a major role in the decision to perform a CT scan.

INTRODUCTION

Head injuries continue to be one of the most common reasons why children are taken to the emergency department [21,78,218]. More than 90% will have sustained a minor head injury (MHI), but a small number will have a clinically important traumatic brain injury (ciTBI) [3,17,22]. A non-contrast computed tomography (CT) is the initial investigation of choice to detect a possible intracranial injury. However, increasing concerns about radiation exposure from cranial CT scans [23,25-27], as well as possible risks related to sedation in uncooperative patients, has made evaluating children with an MHI particularly challenging.

Clinicians often rely on clinical prediction rules to assist clinical decision-making, by estimating the risk of a given outcome [36]. A number of rules have been published to help clinicians predict MHI in children. The Paediatric Emergency Care Applied Research Network (PECARN) rule [3] was developed following the largest multicentre prospective cohort. It used high methodological standards to develop

different algorithms for children younger and older than two-years-of-age. The rule was developed to identify patients at very low risk of ciTBI, who could safely avoid a CT scan and internal (4) and external (12,13) validation have confirmed that it provides high diagnostic accuracy. Based on the original study data, PECARN researchers also developed algorithms to risk-stratify patients with MHI and support decision-making according to the patient's risk of ciTBI. A CT scan is recommended for children at high risk of ciTBI, while the advice for patients at intermediate risk is that it is up to the clinician to decide whether to observe the patient or perform a CT scan (Table 1). Clinicians are advised to take into account the following factors: presence of multiple versus isolated findings, worsening symptoms or signs after emergency department observation, age of less than three months, the clinician's experience and the parents' preference.

Proposed evidence-based management tools that include different management options for a certain category of risk are designed to assist rather than direct and rely on more thorough clinical judgment for decision-making. In the PECARN study, approximately one-third of the patients fell into the intermediate risk group, with only 0.9% being diagnosed with a ciTBI (4). Variability in the clinical approach and the use of CT scans versus observation is to be expected in this group of patients. This means that there is a wide variation in the CT scan rate that could, theoretically, lead to healthcare professionals performing a CT scan on all patients in the intermediate risk group. This would expose approximately one-third of this overall population to radiation, when less than 1% of them have ciTBI. This potential variability makes it challenging to predict what the consequences would be of using these tools in clinical practice, in terms of both imaging use and accurate identification of ciTBI. Evaluating the actual use of such decision-making tools provides valuable information that helps clinicians to: 1) estimate the long-term effects of patient outcome and resource utilisation in clinical practice, 2) refine the balance between risks and benefits for the patients and the healthcare system and 3) plan education or targeted interventions to

optimise the selection of patients who need a CT scan within the intermediate risk group.

Table 1. PECARN minor head injury age-based clinical prediction rules: high, intermediate and very low risk groups for clinically important traumatic brain injury (ciTBI)

ciTBI predictors	**Age < 2 years of age**	**Age ≥ 2 years of age**
High-risk	Altered mental status[a]	Altered mental status[a]
	Palpable skull fracture	Signs of basilar skull fracture
Intermediate-risk	Severe injury mechanism[b]	Severe injury mechanism[b]
	Loss of consciousness >5 seconds	Any loss of consciousness
	Non-frontal haematoma	Vomiting
	Unusual behaviour reported by parents	Severe headache
Very low risk	None	None

[a]GCS 14, agitation, sleepiness, slow response or repetitive questioning

[b]Motor vehicle crash with patient ejection, death of another passenger or rollover, pedestrian or bicyclist without helmet struck by motorised vehicle, falls (of >3 feet for children < 2 years of age or > 5 feet for children ≥ 2 years) or head struck by high impact object

ciTBI*: death from traumatic brain injury, neurosurgery, intubation for more than 24 hours for traumatic brain injury, or hospital admission of two nights or more for persistent symptoms associated with traumatic brain injury on CT (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull)*

When an adapted PECARN rule was implemented at our institution in 2010, it achieved high adherence and high satisfaction rates among the medical staff. In addition, the low CT scan rate remained unchanged from previous clinical practice [9].

The aim of this study was to determine the predictors associated with the decision to perform a CT scan in children who satisfied the PECARN rule for intermediate risk of ciTBI.

METHODS

Study design and setting

This cross-sectional study included children with MHI who attended the Paediatric Emergency Department at Padova Childen's Hospital in Italy between June and November 2010. The Hospital, which forms part of the University of Padova, provides primary and secondary care for a metropolitan area with a population of 350,000 people, including approximately 45,000 children under the age of 15. It also provides tertiary care for children in the surrounding area and wider regional population. The Paediatric Emergency Department receives 25,000 visits per year and it has a four-bed short-stay observation unit for patients who are expected to stay for four to 24 hours. Both attending physicians and residents in paediatrics provide patient care in the department, but final decisions about whether to perform a CT scan are only made the attending physicians.

The use of an adapted PECARN rule was added to the department's clinical practice in May 2010. Following this, we performed a prospective cross-sectional study from June to November 2010 [9], followed by retrospective data collection from December 2010 to May 2011 [219].

The study was approved by the institutional review board of Padova Children's Hospital.

Study population

We included children under the age of 15 with blunt MHI who presented to the emergency department within 24 hours of injury and satisfied the PECARN rule for intermediate risk of ciTBI (Figure 1). Children who sustained trivial injuries

caused by ground-level falls or running into stationary objects, and with no signs or symptoms of head trauma other than scalp abrasions and lacerations, were excluded. We also excluded children with pre-existing neurologic disorders, known bleeding disorders or who had undergone neuroimaging at a referring hospital before their transfer.

Data collection

During the prospective study period, the treating physicians reported, in a standardised manner, the clinical data that led to their decisions on the most appropriate management options for MHI cases. Following this period, the treating physicians were trained to report the presence of PECARN predictors in medical records. The patients' charts were then reviewed fortnightly and the treating physicians were asked for clarification as necessary. For the retrospective cohort, a trained researcher (SB) performed a standardised medical record review and chart abstraction, but was not blinded to the patient's clinical outcome. Ambiguous data were discussed with a senior investigator (LDD) and consensus was sought. For example, children who initially presented to the emergency department with a normal mental status, which then declined within one hour of arrival, were classified as having abnormal mental status.

In order to identify possible cases of ciTBI that had initially been missed, we monitored all children who were discharged without a CT scan for any return visits within two weeks of the initial evaluation. The parents of children who did not return to the paediatric emergency department within two weeks were contacted by telephone for clinical follow-up. We did this for both the prospective and retrospective cohort.

Outcome measure

The primary outcome measure was performing head CT scans in children who satisfied the PECARN rule for intermediate risk of ciTBI. Our secondary

outcome measure was the presence of a ciTBI, defined as: death, intubation for more than 24 hours, neurosurgery or two or more nights in the hospital for persistent symptoms associated with a traumatic brain injury identified using CT [3].

Statistical analysis

Children without high-risk PECARN rule predictors, but with one or more intermediate risk predictors, were classified as being at intermediate risk. Children without high-risk predictors, who were missing one or more predictors, were excluded from the analysis because their data were incomplete and they could not be classified. We described the data using proportions of the population with 95% Confidence Intervals (CI). Comparison of categorical variables was performed using the chi-square test. Continuous variables were expressed as medians and interquartile ranges (IQR) and were compared using the Mann-Whitney test. Comparisons displaying $p \leq 0.05$ were considered statistically significant. Odds ratios (OR) with 95% CI were used to analyse the association between predictors that led to a CT scan being performed and different age groups. Logistic regression analysis was used to test the possible associations between the study outcome measures and both intermediate-risk predictors and the duration of the observation in the emergency department. Statistical analyses were conducted using Open Epi software [220].

RESULTS

A total of 1,072 patients were evaluated for MHI during the study period and 283 patients met the exclusion criteria. We also included 426 patients in the retrospective cohort, as seven were excluded for incomplete data on predictors. Complete data on the use of the PECARN rules were available for 782 patients. Of these, 24 (3.1%) patients faced a high risk of ciTBI and 450 (57.5%) faced a very low risk, leaving 308 (39.4%) patients at intermediate risk (Figure 1). Of these, 168

(54.5%) were male and 145 (47%) were younger than two-years-old. Detailed demographic and clinical characteristics of these patients are reported in Table 2. The overall CT scan rate for the intermediate group on initial presentation was 39 (12.7%) out of 308 patients. CT rates were similar in children under the age of two (10.3%) and older than two (14.7%) (p =0.330). We identified five (1.6%) patients with ciTBI and none of them needed neurosurgery. The most commonly reported predictors were severe injury mechanism, which was present in 60% of children under two-years-of-age, and vomiting, which was seen in 57.7% of older children.

The association between each predictor and the decision to carry out a CT scan is reported, as well as single versus multiple predictors (Table 3). A logistic regression analysis could not be performed, as there was no predictor that showed a positive association with the study outcome.

Even the analysis of the vomiting predictor in children older than two, based on the number of episodes – less than three or three or more - did not result in a significant association with having a CT scan (OR 0.59, 95% CI, 0.16-2.13). Similarly the presence of multiple PECARN predictors did not seem to influence the decision to carry out a CT scan in both age groups, for children under two-years-of-age (OR 2.59, 95% CI, 0.74 – 9.12) and for older children (OR 1.26, 95% CI, 0.39-4.10).
When the 13 children younger than three-months-of-age were analysed, they were significantly more likely to receive a CT scan (OR 18.1, 95% CI, 4.91-66.61).

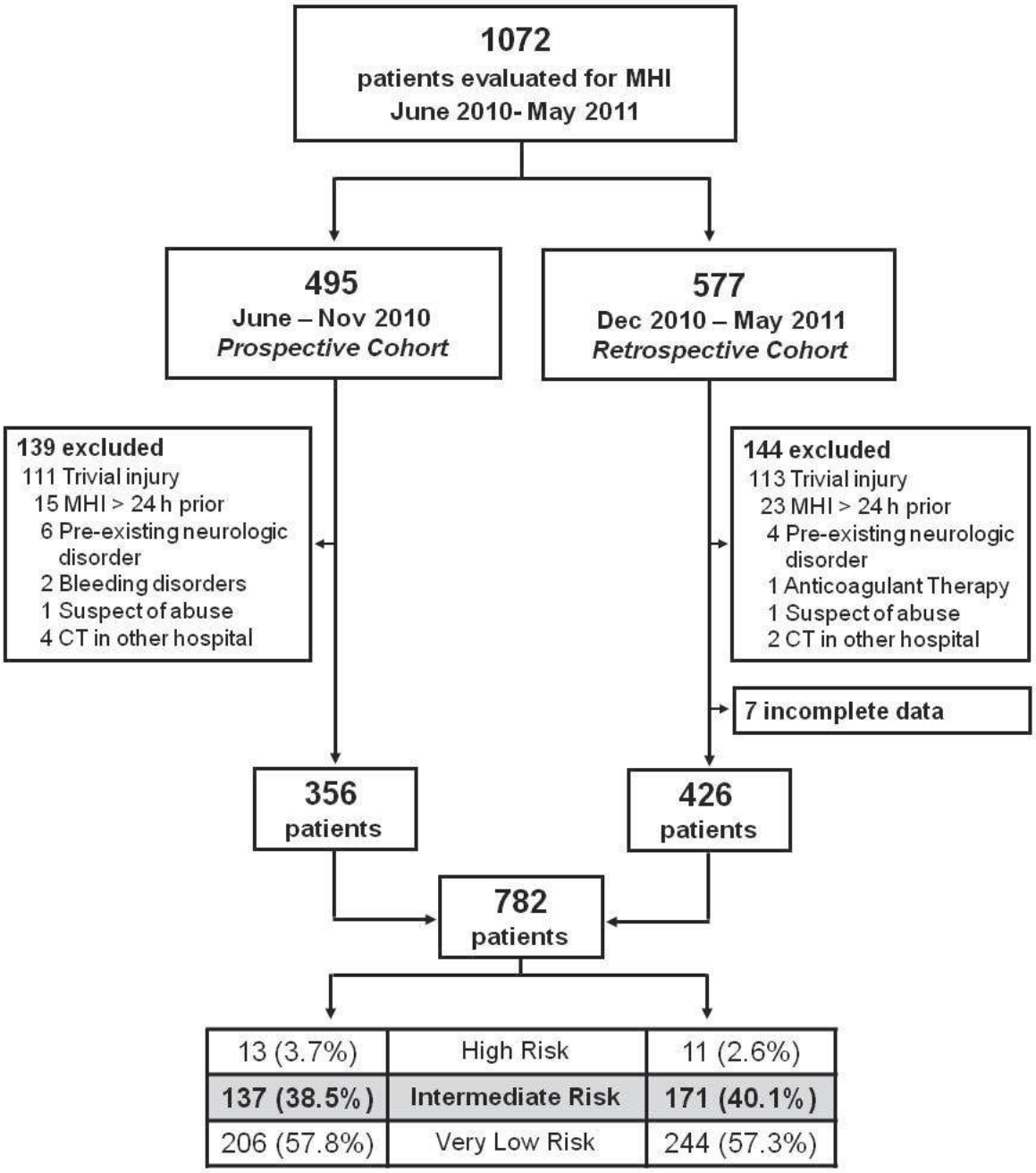

Figure 1. Flow chart of patient selection. Final study population is highlighted in grey colour. MHI= minor head injury

Table 2. Distribution of Patient Characteristics and Outcome According to Age Group

Characteristic	**Age < 2 years** (n=145)	**Age ≥ 2 years** (n=163)	**p**
Gender (M/F)	67/78	101/62	0.008
Hours from trauma to ED presentation (median, IQR)	1.5 (1-3)	2 (2-3)	0.001
Intermediate Risk Predictors (n, %)			
Severe injury mechanism	87 (60%)	57 (35%)	0.0000
Loss of consciousness*	7 (4.8%)	19 (11.6%)	0.039
Non –frontal hematoma	45 (31%)	NA	NA
Non acting right as per parents	27 (18.6%)	NA	NA
Vomiting	NA	94 (57.7%)	NA
Severe headache	NA	18 (11%)	NA
Presence of >1 predictor (n, %)	20 (13.7%)	23 (14.1%)	0.89
CT scan (n, %)	15 (10.3%)	24 (14.7%)	0.330
Positive CT scan (n, %)	3 (2%)	2 (1.2%)	0.895
ciTBI (n, %)	3 (2%)	2 (1.2%)	0.895
Initially missed ciTBI (n, %)	0 (0%)	1 (0.6%)	0.953

*Age-group defined: > 5 s for children < 2 years and any loss of consciousness for children ≥ 2 years.

NA = Not Applicable; ciTBI= clinically important Traumatic Brain Injury; IQR = inter quartile range

Table 3. Association of Predictors to CT scan performance per age-group

Predictor - Age < 2 years	**CT performed** (n=15)	**CT not performed** (n=130)	**OR (95% CI)**
Severe injury mechanism (n=87)	8	79	0.74 (0.25-2.16)
Loss of consciousness > 5 s (n=7)	1	6	1.47 (0.17-13.2)
Non –frontal hematoma (n=45)	7	38	2.11 (0.72-6.25)
Non acting right as per parents (n=27)	3	24	1.10 (0.29-4.22)
More than 1 predictor (n=20)	4	16	2.59 (0.74 - 9.12)
Predictor - Age ≥ 2 years	**CT performed** (n=24)	**CT not performed** (n=139)	**OR (95% CI)**
Severe injury mechanism (n=57)	12	45	2.08 (0.85-5.08)
Loss of consciousness (any) (n=19)	4	15	1.65 (0.50-5.49)
Vomiting (n= 94)	9	85	0.38 (0.16-0.93)
Severe headache (n=18)	4	14	1.78 (0.53-5.97)
More than 1 predictor (n=23)	4	19	1.26 (0.39-4.10)

A longer duration of emergency department observation, measured as the time from a physician assessment to the CT request or the child being discharged from the emergency department without a CT scan, was associated with a lower CT rate after adjusting for time from injury (OR 0.62, 95% CI, 0.42-0.91). A CT scan was performed on 20% of the children who had an emergency department stay of less than two hours, on 14% of those who were observed for between two and six hours, and on 8% of those observed for a longer period of time.

We also followed up those patients who had did not receive a CT scan. We did this by reviewing return visits two weeks after the initial presentation with an MHI and speaking to the parents of the 80% who did not pay a subsequent visit within two weeks by telephone. This showed that just one ciTBI (0.3%) was initially missed. This was a four-year-old-boy who presented 16 hours after sustaining an occipital head injury after falling less than five feet from playground equipment. He initially presented to the emergency department following three episodes of vomiting and mild headache on the site, with his parents reporting that he was behaving strangely. In the emergency department he had a Glasgow Coma Scale of 15 and a normal neurologic examination. He was sent home with head injury advice after a three-hour period of uneventful observation in the department, but returned the following day as he had balance problems while trying to kick a ball, followed by headaches. A CT scan showed an extradural haematoma of the right posterior fossa, with a maximum diameter of 1.6cm. The child was admitted for more than two nights because of on-going symptoms, but he did not need surgical management.

DISCUSSION

The role of the PECARN algorithms for MHI patients with an intermediate risk of ciTBI are that they assist, rather than direct, medical decisions. They empower clinicians and parents to assess traumatic brain injury risk data so that they can

make informed decisions about whether to carry out a CT scan or observe the patient [3]. Multiple factors play a role in the decision-making process, but it is unclear whether some predictors play a more important role than others in this process.

Our study focused on children with MHI presenting to a single tertiary care paediatric emergency department, where PECARN MHI algorithms were used to support decision-making in clinical practice. The results showed no association between any PECARN intermediate-risk predictors and the decision about whether to perform a CT scan. In addition, children with age-appropriate multiple PECARN intermediate-risk predictors were no more likely to undergo a CT scan than children with an isolated predictor. However, children who were younger than three-months-old were significantly more likely to have a CT scan.

As this is the first study to assess the actual use of PECARN algorithms in clinical practice by investigating the association between PECARN intermediate-risk predictors and performing a CT scan, no other data are available for comparison. It is very likely that the lack of association between the intermediate-risk predictors and the decision to perform a CT scan performance reflects the complex and multifactorial nature of decision-making for this group of patients. Clinicians have to manage a wide spectrum of possible symptom combinations and severity and different patient and family-related factors. Most importantly, they need to ensure that the risk of ciTBI does not clearly outweigh the related radiation risk from a CT scan or resource utilisation and costs. In addition, the alternative management strategy of observation is a safe and risk-free option for patients who do not have an obvious time-critical injury on initial assessment. In our centre, we have traditionally favoured observation over CT scans for the management of MHI and our study showed an association between longer observation times and lower CT rates. As well as explaining our low CT scan rate, this may account for our results showing a lack of association between single or multiple predictors and the number of scans performed CT in this group of patients.

A recent publication from the Boston Children's Hospital [221], showed that emergency department observation time for children with MHI was associated with a time-dependent reduction in cranial CT rate, with no delay in the diagnosis of a ciTBI.

In our study we missed one ciTBI during the initial assessment. The child promptly represented to our emergency department when new symptoms were noted, following the advice given to the family on discharge, and did not need neurosurgery.

Since this study was performed in our centre, a new sub-analysis from the original PECARN study has been published (17-19). In particular, the study has provided data on the risk of ciTBI for some of the isolated intermediate-risk predictors. In children with isolated severe mechanism of injury, the risk of ciTBI for children younger than two-years-old was 0.3% (95% CI, 0.1%-0.8%) and it was 0.6% (95% CI, 0.3%-1.1%) for older children [222]. A ciTBI occurred in 0.2% (95% CI, 0%-0.9%) of children with isolated vomiting, with no significant independent associations found with either the timing of onset or the time since the last episode of vomiting [223]. In children younger than two-years-old with isolated scalp haematoma, a ciTBI was diagnosed in 0.4% of cases (95% CI, 0.2%-0.7%), with no child needing neurosurgery, while 8.8% (95% CI, 6.6%-11.4%) of the 570 patients who had a CT scan, representing 19% of the study population, had a traumatic brain injury when scanned [224].

Being younger than three-months-old is not a PECARN predictor, but it is mentioned in the additional clinical information that should be taken into account in the decision-making process. In addition, the PECARN authors suggest that CT scans should be strongly considered for this group of patients. Being younger than three months was the only clinical variable in our study that showed a significant association with whether a CT scan was performed. A CT scan was ordered for 54% of infants younger than three months, three (27%) had a ciTBI and none of them needed neurosurgery. The unique anatomy of young infants, and the fact that they

have soft bones that allow energy to transfer directly to the brain, putting them a higher potential risk of ciTBI, seems to play an important role in the decision-making process.

Our study had limitations. It included both prospective and retrospective data collection. However, the retrospective cohort followed the prospective implementation study and treating clinicians were previously trained to collect and report age-based PECARN traumatic brain injury predictors.

This study did not collect data on factors such as parental preferences or how experienced the clinician making the CT decision was. These may play a role in the decision-making process, independently of the PECARN predictors. In addition, the small sample size and the low CT rate in our sample may account for our non-significant results.

Decision-making in clinical practice is a complex and multifaceted process. Larger prospective studies should ask clinicians direct questions about the contribution that each clinical predictor, as well as other factors, play in their decision on whether to order a CT scan. The development of a hand-held infrared device that provides clinicians with further help to decide which children at intermediate-risk should receive a CT scan seems promising and could be used as a refinement tool in this context [225]. Further studies will help to improve our understanding of how clinicians use rules and decision-support tools in practice and which ones influence their management decisions the most. In the future, as new technology allows CT scans to be carried out even faster, and possibly with a lower dose of radiation, the usefulness of MHI rules and the way that they are used to guide clinical decisions may change significantly. However, balancing resource utilisation and healthcare costs will remain a valuable consideration when it comes to choosing observation or CT scans.

CONCLUSION

None of the PECARN intermediate risk predictors seemed to play a major role in the decision to perform a CT scan when a child presented with an MHI, either in isolation or when combined. Being younger than three-months-old was the only variable that was significantly associated with whether a CT scan was performed. Clear advice to families on when to return to the emergency department after the initial assessment is vital if we are to identify injuries that may have been missed the first time, because of benign observations in the emergency department.

Abbreviations list

CI	Confidence Interval
ciTBI	clinically important Traumatic Brain Injury
CT	Computed Tomography
ED	Emergency Department
IQR	Inter Quartile Range
MHI	Minor Head Injury
OR	Odds Ratio
PECARN	Pediatric Emergency Care Applied Research Network

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6.2.4 Sedation use for head computed tomography

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Use of Sedation in Children receiving Computed Tomography after Head Injuries

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Abstract

Objective: To determine the use of procedural sedation for head trauma related computed tomography (CTB) in children and its association with age and Glasgow Coma Scale (GCS).

Methods: Retrospective review of charts of children undergoing a CTB for head injury at a tertiary paediatric emergency department (ED) with an annual census of 82,000 over a 2 year period. Patients were identified through the database of an ongoing prospective study involving children with head injuries of all severity. We extracted demographics, Glasgow Coma Scale (GCS) scores, characteristics of sedation used for CTBs and adverse events.

Results: 477 patients underwent CTB after head injury. 33 were intubated for medical management of severe head injury and 2 received midazolam for seizure management. Of the remaining 442, 67.4% were male and mean age was 8.3 years. 30.8% had abnormal CTBs and 2.0% required neurosurgery. 28 (6.3% 95% CI 4.2 – 9.0%) were sedated for CTB including 10 who initially failed CTB without sedation. Two patients were intubated for CTB. The sedation rate was 18.4% in patients <5 years versus 1.0% in children $\geq$5 years of age (OR 22.8 95% CI 6.7 – 119.1; p<0.001). The sedation rate was 3.7% in patients with initial GCS $\leq$12 versus 10.2% in children with GCS >12 (OR 0.34 , 95% CI 0.1 - 2.2, p = 0.27).

Conclusions: Children with head injury who require CTB are infrequently sedated. Younger children are more likely to receive sedation. These data will be useful in assessing CTB associated risks.

Keywords: Imaging/CT, sedation, child, head injury

INTRODUCTION

Children commonly present to the emergency department (ED) with head injuries. A non-contrast computed tomography of the brain (CTB) scan is the initial investigation of choice for accidental and non-accidental head injuries[1]. Numerous clinical decision rules have been developed to help clinicians identify which children with head injuries require further investigation with neuroimaging. The three clinical decision rules of highest quality and accuracy[2,3,4,5] had projected CTB rates of 14% - 52% within the target populations with CT findings of intracranial trauma and neurosurgical intervention of 0.9% - 4.1% and 0.1% - 0.6% respectively.

Neuroimaging with CTB does not come without risks and costs. In addition to resource requirements of staffing, expertise and equipment, radiation from CTBs is associated with an increased risk of brain tumours and other malignancies [6,7,8]. Even though CTBs are more rapidly obtained than in the past, some children are unable – due to young age, anxiety, or injury associated encephalopathy - to lie still for the length of time to perform a CTB and require procedural sedation, or general anaesthesia, to obtain images without motion artefact. Procedural sedation in children in general and for imaging in particular is associated with variably described rates of adverse events [9-13]; in children with acute head injuries procedural sedation is often conducted urgently and in unfasten patients. In addition, procedural sedation in a patient with a neurological injury may interfere with the accurate monitoring of a patient's neurological progress. An Italian study[14] evaluating the neurological assessment of patients with head injuries found that a portion of patients were mistakenly categorized as having a more severe head injury due to the sedatives used in their management.

The need for sedation is one of the factors used in deciding which children should undergo a CTB or where alternative strategies may be employed such as observation. In addition to sedation related adverse events, it would be important to know the proportion of head injured children requiring sedation to obtain CTB. Only one study has focused solely on head injured patients sedated in ED for CTB[15]. The United States based study only investigated children with Glasgow Coma Scale (GCS) 14 or 15.

The goal of this retrospective study was to describe the characteristics of children undergoing a CTB post head injury of any severity with and without sedation, and determine the procedural sedation rate in this population.

METHODS

Study design

We conducted a retrospective study of patients receiving sedation for CTB post head injury. The study was approved by the hospital ethics committee at Royal Children's Hospital (RCH)(HREC 33080). Consent was waived. This study was embedded within an existing prospective head injury study, the Australasian Paediatric Head Injury Study (APHIRST) [16], which identifies children with head injury of all severities, and seeks to validate three high quality head injury clinical decision rules for CTB use in children in an Australian population. Management of head injuries was based on published hospital guidelines[16].

Study setting and population

We included all children aged 0 to less than 18 years who underwent a CTB in the ED after presenting with a head injury of any severity to a tertiary ED from April 2011 to April 2013. The annual census of RCH ED is 82,000 paediatric patients. From these patients were extracted those who had received either procedural sedation or were intubated at the time of the CT scan. Sedated and non-sedated

patients were identified by examining their written medical notes and medication charts.

We excluded children who had neuroimaging carried out prior to transfer or while on the wards or in the intensive care unit; who had magnetic resonance imaging (MRI) as the primary neuroimaging study; patients who received sedative agents or intubation primarily for the medical management of severe head injuries or multitrauma pre-hospital or in the ED; and who received benzodiazepines for seizure management, i.e. where sedation was a side effect of the anticonvulsants used.

Methods and Outcomes

Using the APHIRST database, which includes all patients with any severity of head injury, patients who underwent a CTB for investigation of their head injury were identified. Their medical records were reviewed for age, sex and developmental background, clinical presentation including Glasgow Coma Scale (GCS)[18] or modified paediatric GCS for those under 4 years of age[17] and whether sedatives were used for the CT scan. In those who were sedated for imaging, information about type and dose of sedatives, fasting status, medical personnel ordering sedation and adverse events was collected. In situations where multiple teams were involved in the initial care of the patient, the prescriber was documented as the team present at the time.

The adverse events were listed and defined using Bhatt et al's Consensus-Based Recommendations for Standardising Terminology and Reporting Adverse Events for Emergency Department Procedural Sedation and Analgesia in Children[19]. CT findings and neurosurgical interventions were reviewed and extracted.

Prior to November 2011, scans were carried out using a 16-slice CT scanner (Sensation 16, Siemens Healthcare, Forchheim Germany), and from November 2011 a 128-slice dual source CT scanner was used (Definition Flash, Siemens Healthcare, Forchheim, Germany).. This reduced CT head scanning times from at least 20

seconds to 8 seconds per scan. The sedation rates of patients in both scanners were analysed for a possible reduction in the sedation rate due to differences in the scanning times required.

Data extraction was performed by a trained abstractor using a piloted clinical report form. Inclusion criteria and the variables used were defined. The abstractor was not blinded to the study question[20].

Definitions

Our definitions and categorization of a traumatic brain injury on CT are taken from the definitions used by the Pediatric Emergency Care Applied Research Network (PECARN) head injury rules[3]. Traumatic brain injury on CT was defined by any of the following descriptions: Intracranial haemorrhage or contusion, cerebral edema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus or skull fracture depressed by at least the width of the table of the skull.

Sedated patients were categorized as sedation without intubation or sedation with intubation using information available in the medical notes. Sedation with intubation was regarded as general anaesthesia. Opioids given alone were not regarded as sedation.

The time of CT scanning was taken from the radiology database. This was the time when the images were uploaded to the radiology viewing system which occurs within minutes of completion of the scan. A CT scan was labelled as a failed study if this was documented as such in the medical or nursing notes.

Statistical Analysis

We entered the data into an Excel database (Microsoft, Redmond, Wash., USA) and analysed the data using Stata (Statacorp, College Station, Tx., USA). Key percentages are presented with 95% confidence intervals (CI). Continuous data is

presented as a mean with a standard deviation (SD) or median with interquartile range (IQR). We compared proportions using odds ratios (OR) with 95% CI. We conducted pre-determined comparisons of the sedation rates of children less than and ≥5 years of age, GCS ≤12 and 13-15 and CTBs conducted using 16-slice or 128-slice CT scanners.

RESULTS

Characteristics of study subjects

During the study period 5709 patients were identified as having received a head injury of any severity. We identified 561 patients as having neuroimaging post head injury during the study period. Of those, 84 were excluded; six had an MRI as their initial investigation, 57 had neuroimaging at another hospital prior to transfer, 11 had a CTB after admission to the wards and 10 medical records were incomplete. The ED neuroimaging rate for head injuries therefore was 8.5% (477 of 5636).

Of the remaining 477 patients, 35 were sedated or intubated primarily for medical management of their head injury or multitrauma. Nineteen of these were intubated prior to arrival in ED and 14 were intubated in ED. Two further patients received midazolam as treatment for head injury related seizures and were sedated as a side effect of the anticonvulsants. These patients were excluded from analysis because they were not sedated primarily for imaging (Figure 1). The final study population of 442 patients had a mean age of 8.4 years (SD 5.3) with a median GCS of 15 (IQR 14-15). The patient population is further described in Table 1.

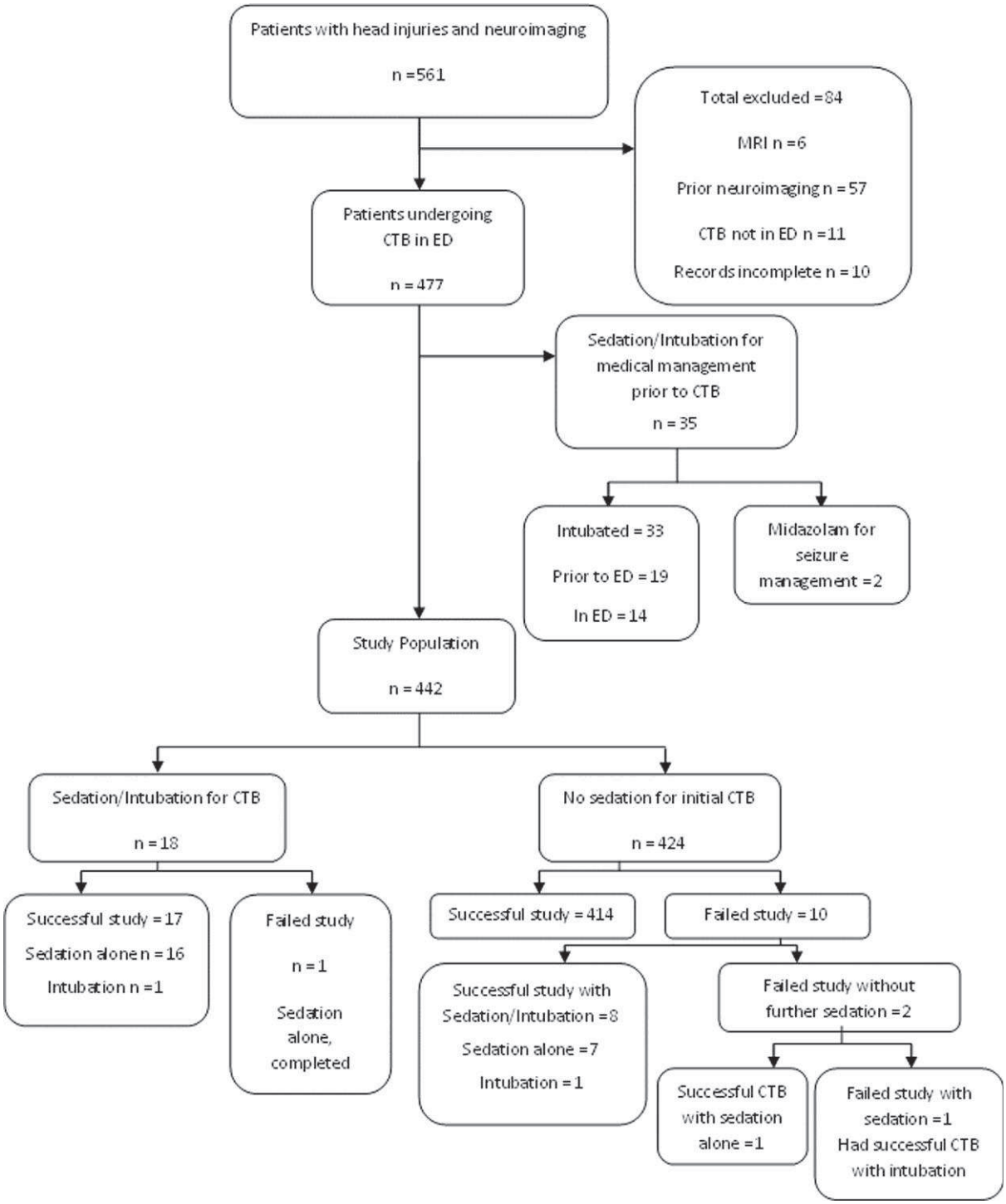

Figure 1 Patient flowchart. CTB, computed tomography of the brain; MRI, magnetic resonance imaging; ED, emergency department

Table 1. Patient Characteristics, Computed Tomography Findings and Neurosurgical Intervention of Sedated and Non-Sedated Patients

	Total	Sedated	Not Sedated
n (%)	442	28 (6.3%)	414 (93.7%)
Age			
< 2	60 (13.6%)	18 (64.3%)	42 (10.1%)
2 – 5	76 (17.2%)	7 (25.0%)	69 (16.7%)
5 – 10	96 (21.7%)	2 (7.1%)	94 (22.7%)
10 – 18	210 (47.5%)	1 (3.6%)	209 (50.5%)
Sex			
Male	298 (67.4%)	18 (64.3%)	280 (67.6%)
Initial GCS			
3 – 8	0	0	0
9 – 12	27 (6.1%)	1 (3.6%)	26 (6.3%)
13	30 (6.8%)	2 (7.1%)	28 (6.8%)
14 – 15	375 (84.8%)	24 (85.7%)	351 (84.8%)
Not recorded	10 (2.3%)	1 (3.6%)	9 (2.2%)
Lowest GCS			
3 – 8	2 (0.5%)	0	2 (0.5%)
9 – 12	43 (9.7%)	2 (7.1%)	41 (9.9%)
13	50 (11.3%)	2 (7.1%)	48 (11.6%)
14 – 15	337 (76.2%)	23 (82.1%)	314 (75.8%)
Not recorded	10 (2.3%)	1 (3.6%)	9 (2.2%)
Severity of head injury[16]			
Mild	89 (20.1%)	9 (32.1%)	80 (19.3%)
Moderate	340 (76.9%)	16 (5.7%)	324 (78.3%)
Severe	13 (2.9%)	3 (10.7%)	10 (2.4%)
CT findings			
Normal	306 (69.2%)	12 (42.9%)	294 (71.0%)
Abnormal	136 (30.8%)	16 (57.1%)	120 (29.0%)
Intracranial haemorrhage/contusion	57 (41.9%)	6 (37.5%)	51 (42.5%)
Cerebral Oedema	7 (5.1%)	0	7 (5.8%)
Diffuse Axonal Injury	5 (3.7%)	2 (12.5%)	3 (2.5%)
Midline Shift or Brain Herniation	1 (0.7%)	0	1 (0.8%)
Diastasis of Skull	7 (5.1%)	1 (6.25%)	6 (5.0%)
Pneumocephalus	20 (14.7%)	0	20 (16.7%)
Skull Fracture	108 (79.4%)	14 (87.5%)	94 (78.3%)
Traumatic brain injury on CT (PECARN)	67 (49.3%)	6 (37.5%)	61 (50.8%)
Neurosurgery			
None	433 (98.0%)	28 (6.5%)	405 (93.5%)
Any	9 (2.0%)	0	9 (100.0%)
Elevation of depressed skull fracture	2 (22.2%)	0	2 (22.2%)
Haematoma Evacuation	8 (88.9%)	0	8 (88.9%)
Dura Repair	3 (33.3%)	0	3 (33.3%)

CT, computed tomography; GCS, Glasgow Coma Scale; PECARN, Pediatric Emergency Care Applied Research Network

Main results: Sedation Rate and Association with Age and GCS

Overall, 28 (6.3%, 95% CI 4.2% – 9.0%) patients were sedated for CTB. Eighteen patients were initially sedated for their scan, of which one was intubated for the CTB. One patient failed the study and went on to have a successful scan two and a half hours later without further sedatives.

Ten patients failed their initial scan without sedation. Eight patients were sedated for the second attempt and had a successful scan, of these one was intubated. Two patients failed a further attempt without sedation. On the third attempt, both these patients were sedated. One had a successful scan. The other failed and had a successful scan following anaesthesia and intubation. All patients who failed a CTB were under 5 years old, one had an initial GCS in ED of 13 and the others had an initial GCS in ED of 15.

The mean age of children sedated for CTB was 1.9 years (SD 2.9) (Figure 2). Children under 5 years of age had a significantly higher sedation rate than those 5 years of age or older (18.4% vs. 1.0%, OR 22.8, 95% CI 6.7 – 119.1, $p < 0.001$). Of the 3 patients over 5 years who were sedated, two had behavioural and developmental issues and one was sedated for CT and pain management for open leg fractures.

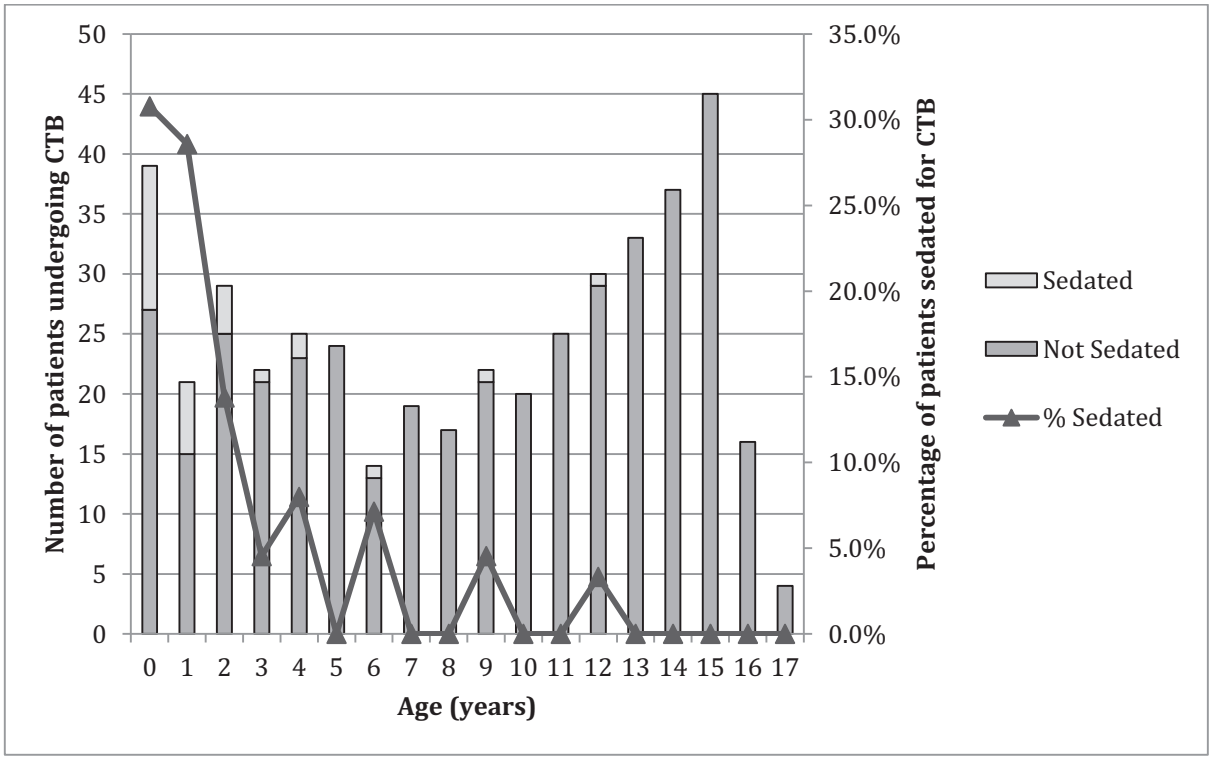

Figure 2. Number of patients undergoing CTB in each age group and percentage given sedation. CTB, computed tomography of the brain

The median initial ED GCS of patients who received sedation was 15 (IQR 15 - 15). Children with a GCS over 12 were sedated more frequently than children with a GCS of 12 or under but this was not statistically significant (10.1% vs. 3.7%, OR 0.34 , 95% CI 0.1 - 2.2, p = 0.27).

Sedation Agents and Adverse Events

The agents used in the 28 sedated patients were chloral hydrate in 18, IV Midazolam in four, oral Midazolam in one, Propofol in four, sevoflurane in one and ketamine in one. No adverse events or complications were recorded during any of the sedations. Four of these patients had also received opioids (intravenous 3 and oral 1). Paralytic agents were used in the 2 patients who were intubated.

Neurosurgery and Type of CT Scanner

We found an abnormal CTB in 57.1% of patients who were sedated versus 29.0% non-sedated (OR 3.3, 95% CI 1.4 – 7.8, p = 0.002). No patients who was sedated for CTB required neurosurgery compared to 9 (2.2%) in the non-sedated group. Sedation was given to 5.8% of patients using the 16-slice scanner and 6.6% were sedated for the 128-slice scanner (OR 1.1, 95% CI 0.5 – 3.1, p = 0.8).

DICUSSION

This study of children with head injuries of all severities found the sedation rate for children undergoing CTB to be low. Only 6% of patients required sedation to perform a CTB, once patients intubated pre-hospital or in ED and patients who received benzodiazepines for seizure management are excluded. Few patients (2.3%) failed an initial unsedated CTB attempt. As was anticipated, the younger the child, the higher the sedation rate; however, even in the under 2 year old group, the sedation rate was relatively low (30.0%). In patients not initially intubated for their medical management, GCS did not appear to be a major determinant for sedation use. In addition, while CTBs are generally brief procedures, the shorter procedure time with the faster CT scanner did not appear to change the sedation rate.

A recent multicentre study of sedation for CTB after mild head injury (GCS 14 and 15) from the United States found a sedation rate of 3%[15]. While toddlers represent the peak age to requires sedated CTs in both studies (1.7 years[15] vs. 1.9 years), the US data are based on a much higher CT rate with a CT scan rate of 35% vs. 9% in our study and a lower rate of identifying traumatic brain injury on sedated CTs of 8% vs. 57% in our study. We note that the CTB rate for head injuries at our centre may be similar to UK and European rates and is lower than what has been reported in North American studies [3,4,5]. Although the starting points of the US study and our data are different in terms of head injury severity, more “well”

children may undergo a CTB in North America in absolute terms and may therefore need to be sedated.

In our setting a play therapist was frequently available to assist with scans during business hours. His or her job was to introduce the child to the scanner in a non-threatening way and accompany them to the scanner. This may have contributed to the overall low sedation rates in the preschool and lower primary school children. Infants were often scanned after the use of a "feed and wrap" where the infant was given a breast or bottle feed and wrapped, often falling asleep for the CT scan.

Given the low sedation rate and the small number of sedative agents used, it is not possible to draw conclusions as to ideal agent for sedation in CTBs in children after head injury. It is of note that the majority of sedated patients could be managed without intubation. In the US study[15] the most frequently used sedative agents were chloral hydrate and pentobarbital, an agent not used in our setting. We did not include opioids as single agents in our definition of sedation which had been administered to one quarter of patients at some time prior to the CTB. Whilst it is possible that the opioids had some sedative effect on the patients which may have assisted with obtaining a CTB, we believe that they were not primarily prescribed for sedation in these cases.

No sedated patient had documentation of an adverse event or airway intervention. With our low sedation numbers this is not unexpected based on published adverse events rates from other sedation series[,10,21]. Documentation of vital signs was often incomplete during the CTB period of the sedations; this was also identified in the US study on sedation for head trauma[15]. The brevity of the procedure may leave little time for documentation of vital signs during the scan itself. At our institution sedated patients are routinely accompanied to the CT scanner by a nurse and a physician with continuous cardiac and saturation monitoring in place.

Limitation

This study has a number of limitations. We focused on the patients sedated for CTB by excluding patients who were sedated and intubated for the medical management of their head injuries. While this is obvious for patients intubated pre-hospital (n=19) there were 14 patients who were intubated in ED prior to their CTB. While the indication for the intubation may have included sedation for CTB, 9 had an initial GCS of 8 or less and were intubated as recommended in hospital and international guidelines[16,22]. Another had a GCS of 11 and was intubated for respiratory compromise. The remaining 4 patients had an initial GCS of 12; one had significant facial fractures, one had a penetrating head injury and two were combative and aggressive and at risk of causing harm to themselves during their initial assessments.

While the documentation of medication given, especially sedatives and general anaesthetics, is likely good even in a retrospective study, other factors such as staff interventions by play therapy or parental presence and support were insufficiently documented. We may have also underestimated the frequency of failed CTBs due to a lack of documentation in the medical or nursing notes or the non-recording of CTB attempts in the radiology data base. A prospective study would provide a better understanding of these factors.

Conclusions

In summary, children undergoing CTB after head injury infrequently require sedation to complete the scan. When sedation is needed it is generally for the younger child, and the child with a normal GCS. Unless patients need to be intubated for the management of their head injuries or multi-trauma, sedated CTBs can generally be performed without general anaesthesia and intubation. These data will be useful in assessing CTB associated risks and the allocation of resources for CTB in children.

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6.2.5 Infrared device to reduce head computed tomography

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ORIGINAL PAPER

The use of handheld near-infrared device (Infrascanner) for detecting intracranial haemorrhages in children with minor head injury

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Abstract
Objective A handheld device using near-infrared technology (Infrascanner) has shown good accuracy for detection of traumatic intracranial haemorrhages in adults. This study aims to determine the feasibility of use of Infrascanner in children with minor head injury (MHI) in the Emergency Department (ED). Secondary aim was to assess its potential usefulness to reduce CT scan rate.
Methods Prospective pilot study conducted in two paediatric EDs, including children at high or intermediate risk for clinically important traumatic brain injury (ciTBI) according to the adapted PECARN rule in use. Completion of Infrascanner measurements and time to completion were recorded. Decision on CT scan and CT scan reporting were performed independently and blinded to Infrascanner results.
Results Completion of the Infrascanner measurement was successfully achieved in 103 (94 %) of 110 patients enrolled, after a mean of 4.4±2.9 min. A CT scan was performed in 18 (17.5 %) children. Only one had an intracranial haemorrhage that was correctly identified by the Infrascanner. The exploratory analysis showed a specificity of 93 % (95 % CI, 86.5–96.6) and a negative predictive value of 100 % (95 % CI, 81.6–100) for ciTBI. The use of Infrascanner would have led to avoid ten CT scan, reducing the CT scan rate by 58.8 %.
Conclusions Infrascanner seems an easy-to-use tool for children presenting to the ED following a MHI, given the high completion rate and short time to completion. Our preliminary results suggest that Infrascanner is worthy of further investigation as a potential tool to decrease the CT scan rate in children with MHI.

Keywords Minor head injury · Near-infrared spectroscopy · CT scan · Children

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Introduction

Minor head injuries (MHI) continue to be a major problem in paediatrics, representing one of the most common reasons for visits to the Paediatric Emergency Department (PED) [19, 5, 7], however only a small number are at risk of identifiable poor outcome [6, 14, 22].

The use of head CT for the detection of traumatic intracranial injuries in children should be balanced against the risks related to radiation [1, 18, 21], and risk of sedation of uncooperative patients [4, 17]. In addition, it leads to an increased resource utilization [20].

Despite recent availability of high-quality clinical decision rules to assist decision-making on CT scan in paediatric MHI [6, 14, 22], the rate of unnecessary neuroimaging is far from being optimal [16].

In the study centres we implemented the rule by the Paediatric Emergency Care Applied Research Network (PECARN) [14] that provides differentiated algorithms for

children younger and older than 2 years of age (Fig. 1) This rule, derived and validated in the largest multicentre study with high methodological standards, appears to be the best rule to accurately identify children at very low risk of clinically important traumatic brain injuries (ciTBIs) for whom a CT scan can safely be avoided. For children at intermediate and high risk of ciTBI however, the rate of CT scan is still considerable with a rate of unnecessary CTs of approximately 20 % in our setting [2], and more than double in the United States [14].

In the effort of further optimizing the use of head CT scan in children with MHI new management strategies should be investigated, such as the additional use of non-radiating tools for the identification of patients with potentially clinically important intracranial haemorrhages.

Near-infrared spectroscopy (NIRS) technology devices have shown good accuracy for the detection of traumatic intracranial haemorrhages in adults [8–13, 15], with a sensitivity ranging from approximately 70 to 100 % and a specificity equal or greater than 80 %.

Promising results have also recently been reported in children [3, 25]. However, data are still limited and no studies have specifically assessed the feasibility of NIRS technology in detecting intracranial haemorrhages in the most challenging group of children with MHI in the emergency department (ED) setting.

The aim of this study was to determine the feasibility of use of NIRS technology for children with MHI in the ED. We hypothesised that the use of a handheld, non-radiating, painless, near-infrared technology device (Infrascanner) would be time efficient, and could be easily used in a busy ED also in young children.

As a secondary aim we explored whether Infrascanner could help reduce the number of unnecessary CT scan in this population and is worth of further larger multicenter studies.

Methods

Study design and setting

A prospective observational pilot study was carried out over a 9-month period (June 2011–February 2012) in the PED of the Woman's and Child's Health Department of Padova Hospital and over 7 months (September 2012–March 2013) in the Paediatric Unit of Treviso Hospital, in Italy. The PEDs of Padova and Treviso share clinical protocols and they collaborate in common research projects. Their yearly census is approximately 25,000 and 15,000 visits of children younger than 15 years. Both study centres use an adapted version of the

ciTBI predictors	Age < 2 years of age	Age ≥ 2 years of age
High-risk	Altered mental status[a] Palpable skull fracture	Altered mental status[a] Signs of basilar skull fracture
Intermediate-risk	Severe injury mechanism[b] Loss of consciousness > 5 secs Non-frontal hematoma Not acting right as per parents	Severe injury mechanism[b] Any loss of consciousness Vomiting Severe headache Amnesia[c]
Very low risk	None	None

[a] GCS 14, agitation, sleepiness, slow response or repetitive questioning

[b] Motor vehicle crash with patient ejection, death of another passenger or rollover, pedestrian or bicyclist without helmet struck by motorized vehicle, falls (of >3 feet for children < 2 years of age or > 5 feet for children ≥ 2 years) or head struck by high impact object

[c] Predictor added at the study sites, based on consensus, in the adapted PECARN rules in use

***ciTBI**: death from traumatic brain injury, neurosurgery, intubation for more than 24 h for traumatic brain injury, or hospital admission of 2 nights or more associated with traumatic brain injury on CT (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull)*

Fig. 1 PECARN minor head injury age-based clinical prediction rules: high, intermediate and very low risk groups for clinically important traumatic brain injury (*ciTBI*)

PECARN rule for the management of children with MHI (Fig. 1).

Inclusion and exclusion criteria

A convenience sample of children younger than 15 years of age presenting to the ED following a MHI at high or intermediate PECARN risk of ciTBI were enrolled [2, 14]. Neurologic or bleeding disorders were part of the inclusion criteria, as children with these conditions are more likely to undergo CT scan, independent of their risk group. According to the instructions of the manufacturer, only children who sustained the head injury within the 12 h prior to presentation were eligible to undergo the Infrascanner measurement. This time restriction was recommended to warrant optimal sensitivity.

Exclusion criteria were: performance of neuroimaging at another hospital before assessment in the study PEDs, low risk of intracranial injury or trivial injury, as defined by the PECARN study [14], large scalp lacerations or blood over one or more sites of NIRS measurement or suspicion of abuse (for the most likely subacute/chronic nature of possible intracranial injuries), previous craniotomy [12].

Definitions

MHI: blunt head injury with GCS≥14 at the time of ED assessment.

ciTBI: death from head injury, neurosurgery, intubation for more than 24 h for the head injury or hospital admission of two nights or more associated with traumatic brain injury on CT scan [14] (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull).

Trivial injuries: ground-level falls or walking or running into stationary objects, and no signs or symptoms of head trauma other than scalp abrasions and lacerations [14].

Study outcomes

Feasibility of NIRS technology: defined as

- Completion of Infrascanner measurements: performance of the measurements in all the four pre-selected pairs of locations (frontal, temporal, parietal and occipital regions).
- Time to completion: time to complete all the measurements, including repeat of the measurements in case of a positive result (see below).

Possible usefulness of NIRS technology in reducing CT scans: defined as

- Ability to predict negative CT scans in children with negative NIRS
- Ability to predict children without ciTBI as assessed by either CT scan or results of follow-up for children who did not undergo CT scan on initial assessment.

Clinical evaluation and management

Decisions on CT scan and disposition (discharge, observation in ED, length of observation or hospitalization) were made independently by the treating physician, who was blinded to the Infrascanner measurements results. Treating physician's decision-making on whether to CT scan was not influenced by the Infrascanner results. CT scan findings were reported by an attending neuroradiologist who was unaware of the current study and Infrascanner measurements results.

Data collection and study procedures

In both centres, patients were enrolled only when a study operator was available, i.e., weekdays during day time (8 am–6 pm). The electronic data system of each PED was monitored to identify eligible patients.

Data on demographics, mechanism of injury, clinical findings, PECARN risk group and disposition were prospectively collected at the time of initial assessment in the ED. Information on hair characteristics was also collected. Results of CT scans were retrospectively collected from the report of the attending neuroradiologist.

Trained NIRS operators were physicians working in the two centres and they were available to recruit patients during weekdays study hours, while on clinical duty. Their training consisted of a 3-h course provided by the distributor of the device. The course included a brief lecture, a demonstration of the device, followed by supervision of practice examinations on normal individuals. The demonstration was videotaped and videos were made available for review by the operators.

The Infrascanner measurements were performed before neuroimaging, in patients undergoing CT scanning. Results of the Infrascanner measurement were collected along with all the other patients' data on a dedicated clinical report form.

Telephone follow-up, between 7 and 90 days after ED visit, as well as monitoring of the electronic PED medical records for return visits, were carried out for the patients who did not undergo a CT scan. This was done in order to exclude initially missed ciTBI.

NIRS device and examination procedures

NIRS technology identifies intracranial haematomas by comparing the optical density (OD) of infrared light absorption between symmetrical regions in the two sides of the head. The extravascular blood of the haematomas absorbs NIR light more than intravascular blood. This is due to the higher concentration of haeme-based proteins, such as haemoglobin, in the haematoma compared with normal brain tissue, where blood is contained within vessels. Under normal circumstances, the brain's absorption is symmetrical. When a haematoma is present on one side of the brain a difference in light absorption is detected and recorded by the NIRS device. The examination includes a set of four pairs of measurements of four regions of the brain (frontal, temporal, parietal and occipital), where the device is placed in sequence on the left and right side over pre-selected locations.

A commercially available handheld NIRS device was used based on the manufacturer's instructions (Infrascanner, Model 1000, InfraScan Inc.). This device includes a sensor and a personal digital assistant (PDA) for data collection and processing. The sensor includes an 808-nm near-infrared diode laser light source and a detector of absorbance, placed 4 cm apart. Both are optically coupled to the patient's head through a disposable sensor cap provided with two light guides and an extra plastic support designed so that it can ensure adequate sensor contact in areas with and without hair and minimize background light interference. Acquired signals from the detector are digitized and transmitted via Bluetooth to the PDA. Absorbance of light is measured and the OD within the various regions is determined. The difference in OD (ΔOD) of the various regions is electronically calculated using the following formula:

$$\Delta \mathrm{OD} = \log_{10} \frac{I_N}{I_H}$$

In this formula, I_N is the intensity of the reflected light on the presumed normal side, and I_H is the intensity reflected light on the presumed abnormal side. Based on previous studies [24], a positive test result was defined by a difference in optical density (ΔOD) >0.2 between two symmetric regions. The detection limits of the device for intracranial haematomas are a volume of blood ≥3.5 mL, within a depth of 2.5 cm of the brain surface.

When a positive scan was obtained during the study, the measurement was repeated to confirm the findings and reduce the chances of a false reading due to trapped hair under the light guides, or inadequate sensor contact with the head. If the repeat scan did not match the original results, a third measurement was performed; the outcome found twice was considered the final result for the study. Negative findings were not repeated, as possible false negative results from impaired coupling of the sensor with the scalp are extremely unlikely.

Statistical analysis

Normally distributed continuous variables are presented as means ± standard deviation. Comparison between continuous variables was carried out using the *t* test. Categorical variables are reported as absolute numbers and percentages. As this was a pilot study no formal sample size calculation was performed. An exploratory calculation of sensitivity, specificity, positive and negative predictive values (PPV and NPV) was performed with their 95 % confidence interval (CI). Statistical analyses were conducted using the statistical program MedCalc 11.1.

Ethics approval

This study was approved by the ethics committees of both Padova and Treviso Hospital and informed written consent was obtained by parents or legal guardians, as well as assent from capable patients.

Results

Population characteristics

A total of 1,083 children were assessed for MHI in both centres during the study period. Of these, 844 were ineligible because they had either trivial injuries or they belonged to the very-low-risk group. Of the 349 children meeting the criteria for MHI at intermediate or high risk, 175 presented outside the recruitment hours. Of those presenting during the recruitment hours 37 were excluded as the injury had occurred more than 12 h prior to the ED visit. One patient was excluded because neuroimaging was performed at another centre before arrival and one had a large scalp laceration overlying the sites of the Infrascanner measurement. Of the 135 eligible patients, 115 were approached for participation in the study. Five patients refused to participate, and a total of 110 patients were finally enrolled (Fig. 2).

Feasibility

Of the 110 children enrolled in the study, 103 (94 %) had a complete successful Infrascanner examination. Demographics and clinical characteristics of these subjects are presented in Table 1. Forty-six children were younger than 2 years of age, 57 (55.3 %) were male and 42 (40.8 %) sustained a frontal impact to the head. Thirteen patients belonged to the high-risk PECARN group.

Infants were preferentially assessed either when asleep or when breast/bottle feeding. Older children were able to

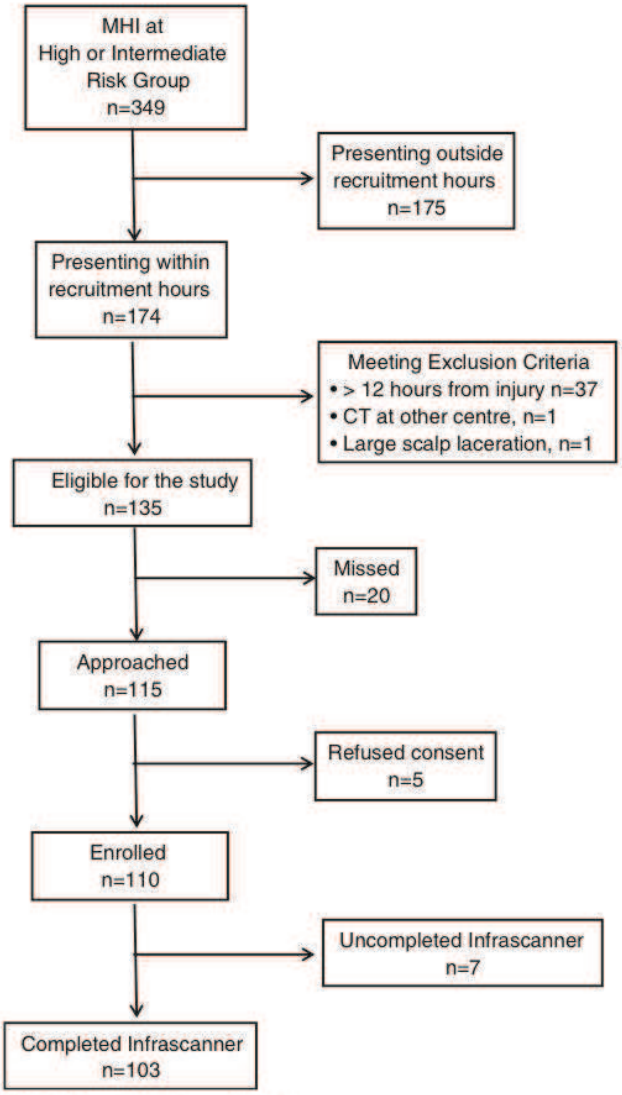

Fig. 2 Flow-chart of enrolled patients

Table 1 Demographics and clinical characteristics of study subjects ($n=103$)

	No.	Percent
Age<2 years	46	45
Gender (M)	57	55.3
Site of impact		
Frontal	42	40.8
Temporal	5	4.9
Parietal	11	10.7
Occipital	27	26.2
Unknown	18	17.5
Severe mechanism of injury	69	67
Loss of consciousness	7	6.8
Amnesia (>2 years of age)	6	5.8
Vomiting (>2 years of age)	12	11.7
Headaches (>2 years of age)	13	12.6
Not acting normally per parent (<2 years of age)	12	11.7
Large scalp haematoma (<2 years of age)	8	7.8
Signs of basal or skull fracture	1	1
Altered mental status	9	8.7
GCS 14	9	8.7
Risk group		
Intermediate	90	87.4
High	13	12.6
Hair colour		
Light	53	51.5
Dark	39	37.9
Black	11	10.7
Skin colour		
White	95	92.2
Dark	4	3.9
Black	4	3.9
Hair thickness		
Thin	30	29.1
Normal	65	63.1
Thick	8	7.8

tolerate the performance of measurements after simple explanation and instructions. We were unable to complete the examination in seven children. Of these, one had thick hair that impaired proper coupling of the sensor with the patient's head and six were uncooperative. These six were less than 2 years old, leading to a success rate of 88.5 % in children younger than 2 years of age. Overall the mean time to complete the examination was 4.4±2.9 min. The completion time was longer in children younger than 2 years compared with the older group (5.5±3.1 min and 3.5±2.2 min, respectively, $p=0.018$).

Potential usefulness in reducing CT scans

Eight patients had a positive Infrascanner measurement in one or more locations. Of these only one underwent a CT scan that showed a parietal extradural haemorrhage corresponding to the site of the positive measurement. None of the seven patients with positive Infrascanner examination, who did not undergo a CT scan, had a missed ciTBI, as ascertained by telephone follow-up (Fig. 3). Of these patients, four had large scalp haematomas overlying the sites of measurement.

The Infrascanner results were negative for intracranial haematomas in 95 (92.2 %) children. Of these 17 underwent a CT scan. All 17 CTs were negative for intracranial injury. The remaining 78 patients did not undergo CT scanning. Review of return visits and telephone follow-up ascertained that ciTBI were not missed in any of these children (Fig. 3).

NIRS technology correctly identified 17/17 (100 %) patients without intracranial haemorrhages, as ascertained by CT

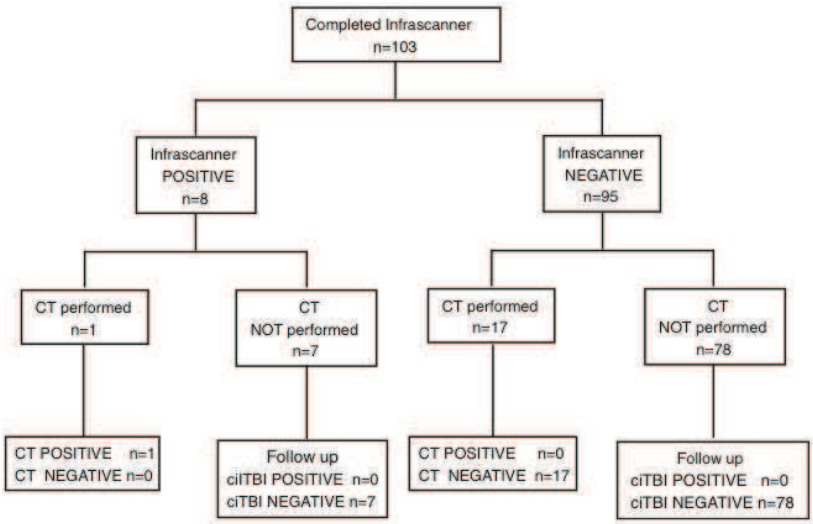

Fig. 3 Results of Infrascanner examination, CT scan performance and follow up. *ciTBI* clinically significant traumatic brain injury

scan. The remaining 78, who did not have CT turned out to be ciTBI negative (100 %).

The sensitivity, specificity, PPV and NPV for prediction of intracranial haemorrhages identified on CT scan were 100 % (95 % CI, 20.7–100), 100 % (95 % CI, 81.6–100), 100 % (95 % CI, 20.7–100) and 100 % (95 % CI, 81.6–100), respectively.

The sensitivity, specificity, PPV and NPV for prediction of ciTBI identified by either CT or follow-up were 100 % (95 % CI, 20.7–100), 93.1 % (95 % CI, 86.5–96.6), 12.5 % (95 % CI, 2.2–47.1) and 100 % (95 % CI, 96.1–100), respectively.

According to this exploratory analysis, if the result of the NIRS examination had been used for clinical decision making, this would have led to a net avoidance of ten CT unnecessary scans (as seven unnecessary scans would have been performed based on the positive Infrascanner results). The CT scan rate would have reduced by 58.8 %, from 17.5 % (18/103) to 7.7 % (8/103).

Discussion

Our results show that Infrascanner examination is feasible in children with MHI in the ED, even in the younger group of children aged less than 2 years of age, with a success rate above 90 % overall and nearly 90 % in younger children. Study operators obtained these very good results after only a limited required training of 3 h. The relatively short time to completion, 4.4±2.9 min, makes this examination a potentially easy to use tool in the ED setting. Our study showed a longer time to completion in children younger than 2 years, 5.5±3.1 min; this is to be expected because of their lack of cooperation and need of repeat measurement. However, even in this age group the average time to completion did not interfere with the high-pace ED clinical activity. This study is the first to assess times to completion in children with MHI in the setting of an ED. A recent study including 28 children admitted to a paediatric intensive care unit, who received a CT scan as part of their routine clinical care, showed a NIRS completion rate of 79 %, and a completion time up to 15 min [25]. The different population included in this study (more severely injured patients, as well as patients with conditions other than trauma) likely explains the difference in the results. The other studies including both adults and children [3, 23, 24] did not report specific data on completion rate or time to completion for children. Studies mainly conducted in adults report a time for NIRS examination completion of 2 to 3 min [12, 14, 15] or less than 10 min [23].

Our study population included a large proportion of children younger than 2 years of age (45 %) that may represent a more challenging group in clinical practice, especially for adult emergency physicians who may have to take care of children in community hospitals.

A small proportion of the study subjects, approximately 10 %, had thick, darkly coloured hair or dark-black skin. These factors may affect performance of an optical method such as NIRS [12, 26]. Improvement in the technology and device design over time likely account for the good results of our study. We were unable to complete the examination in only one child, who had thick hair that impaired proper coupling of the sensor with the patient's head.

In the study population, a CT scan was performed in 18 (17.5 %) children. Only one had an intracranial haemorrhage that was correctly identified by the Infrascanner measurement. Of the 95 (92 %) patients who had a negative Infrascanner result, 17 had a negative CT scan and 78 had no missed ciTBI, as ascertained by follow-up.

According to our exploratory analysis Infrascanner might be a useful tool in further optimizing the selection of CT scan in children with MHI and is worth additional investigation in

future larger multicentre studies. The very high specificity and NPV found for both intracranial haemorrhages and ciTBI means that a negative result on the Infrascanner examination seems highly predictive of the lack of intracranial haemorrhage and ciTBI in children with MHI. As for sensitivity and PPV, our exploratory analysis failed to provide sufficient data for their proper calculation, as shown by the broad confidence intervals. However, if NIRS examination had been used for clinical decision making, it would have led to a net CT scan reduction of nearly 60 %. If these results were confirmed by future larger studies, this would have important implications for clinical practice in terms of reduction of children's lifetime risk of cancer due to radiation, as well as in important savings for the healthcare system, especially in settings with higher CT scan rates.

Previous studies assessing NIRS accuracy for traumatic intracranial haemorrhages in different populations have reported a good sensitivity and a specificity mostly greater than 85 and 75 %, respectively, with a wide range of PPV (18 to 100 %) and good to very good NPV (80–98 %) [3, 9, 13, 15, 24, 25]. The only studies providing separate data on children have found a specificity ranging from 64 to 80 % and a NPV ranging from 80 to 98 % [3, 25]. However, the inclusion of different populations [3, 25], as well as the little details provided on the clinical characteristics of paediatric patients in the study by Coksun and colleagues [3] limit the applicability of these results to the population of children with MHI assessed in the ED.

In children with PECARN MHI the great majority do not have intracranial injuries, with a prevalence of ciTBI ranging from 1 to 5 % according to the risk group [14]. The influence of the large prevalence of disease-free subjects on NPV values likely accounts for the optimal results we obtained in our convenience sample.

Despite the advantages of portable NIRS technology and the potential role in the management with children with MHI, this technology is not designed to substitute CT scan and its intrinsic limitations should be noted.

First of all the detection limits of the device for intracranial haematomas are a volume of blood ≥3.5 mL, within a depth of 2.5 cm of the brain surface. This does not allow for reliably screening for deep haematomas or contusions, or very small superficial bleeding.

Second, bilateral haematomas cannot be reliably identified by near-infrared technology, as the technique relies on comparison of light absorption between the two hemispheres.

Third, the utility of NIRS in detecting subacute or chronic haematomas is limited, since this technology is based on the absorption characteristics of acute bleeding and haemoglobin breakdown products that develop in the following hours do not have the same absorption characteristics. This was the reason why in our study the Infrascanner examination had to be performed within 12 h of the head injury, according to the instructions of the manufacturer, for optimal sensitivity.

Fourth, scalp haematomas are confounding factors for near-infrared technology measurements. Blood contained within a scalp haematoma can alter the difference in optical density and cause a false-positive result. Despite symmetrical measurements can be performed at the edges of the haematoma, this limit questions the applicability of near-infrared technology to the challenging group of children younger than 2 years of age with large isolated scalp haematomas.

Furthermore, thick hair may affect examination performance, while cervical collars may limit the ability to perform the measurements in the occipital pair of locations.

However, NIRS technology in children with MHI is not meant to be used in isolation, but incorporated into clinical decision rules, as a screening tool to further guide clinical management.

Our study is limited by the small sample size. This limit is intrinsic to the study design, being designed as a pilot study based on the resources available, to inform on possible opportunities for larger multicentre studies.

Furthermore, a CT scan was not performed in all patients. However, follow-up was carried out in all patients who did not receive a CT scan, in order to exclude initially missed ciTBI. ciTBI is a more clinically relevant outcome, compared to CT findings alone, and it was previously used in the PECARN study [14].

The results of our study suggest that Infrascanner examination is feasible in the ED even for children younger than 2 years of age and is worth of further investigation as a potential tool to reduce CT scan rate in children with MHI when used in conjunction with a clinical prediction rule. This tool might help decision making in symptomatic children who sustained a MHI up to 12 h from presentation, who neither have large scalp haematomas or lacerations affecting the measurement nor obvious signs of injuries that require CT scan investigation independently of the presence of an intracranial haemorrhage (such as obviously depressed skull fracture or signs of base of skull fracture). Larger multicentre studies are needed to appropriately assess the Infrascanner accuracy for the management of children with MHI in the ED, as data on false negative results should be carefully analysed in order to minimize the risk of missing ciTBI while optimizing the selection of patients who need a CT scan. In addition, it would be interesting to assess the possible impact of negative NIRS results on the duration of observation in the ED or in the ED-based observation unit, following a MHI.

Conclusions

Infrascanner seems an easy-to-use tool for children presenting to the ED following a MHI, given the high completion rate and short time to completion. Our preliminary results suggest

that Infrascanner is worthy of further investigation as a potential tool to decrease the CT scan rate in children with MHI.

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Conflict of interest statements The authors have no conflicts of interest to disclose. The authors have not received any financial support, salary or other personal benefits by SEDA S.p.A. for the present study and do not hold stock in the company. The Infrascanner devices and necessary equipment were provided free-of-charge by the distributor, SEDA S.p.A, for the purpose of this study.

Contributorship SB conceived the idea of the study, searched the literature, interpreted the final results and drafted the manuscript. MD, FM, DD and FM substantially contributed to the study design, data collection and drafting of the manuscript. IPS substantially contributed by reviewing the literature, interpreting final results and critically reviewing the manuscript. LDD substantially contributed to the conception and design of the study, supervised study conduct, contributed to interpretation of final results and critically reviewed the manuscript.

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6.2.6 Management of sport-related concussion

To be submitted

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On-field management and return-to-play in sports-related concussion in children: Are children managed appropriately?

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ABSTRACT

Background/Aim On-field management and return-to-play guidelines aim to ensure the identification and appropriate management of the concussed athlete. Compliance with current guidelines in many settings is unknown. We assessed whether key components of current concussion guidelines are being followed in child athletes.

Methods Prospective observational study of children (5 to 18 years) presenting to a paediatric emergency department (ED) with sport-related concussions. Data were collected via researcher-administered surveys in ED and during follow-up phone-call. On discharge all patients received a return to sports factsheet based on the International Concussion in Sports Group.

Results 93 had sustained a concussion (mean age 12.7 (±0.27) years, 83% male). Sports played included Australian Football (47%), soccer (12%), rugby (9%) basketball (8%), other (25%). 82% participated in organised sports. Concussive signs or symptoms included loss of consciousness (41%), disorientation (36%), vomiting (23%), amnesia (30%), headache (60%). For concussive injury in organized sports (n=76), overall 42% were not managed according to recommended guidelines: 19% were not immediately removed from play, 29% were allowed to return to play on the same day and 27% were not assessed by qualified personnel. 93% of parents

and 96% of patients overall were unaware of concussion or return-to-play guidelines from their organisations. Overall, 72% were compliant with provided return-to-play guidelines.

Conclusions Many children with sports related-concussion are not formally assessed on-field and continue to play. On-field concussion management and return to play practices are often suboptimal. Awareness and education of coaches, teachers, parents and children need to be improved.

INTRODUCTION

Sports-related concussion has received a growing amount of media and scientific attention in recent years for its increasing incidence and possible short and long-term sequelae.[1] Children are particularly vulnerable with 65% of all sport-related head injuries presenting to US emergency departments (EDs) being in persons aged 5 to 18 years.[2] In Australia, the impact of concussion on the child and on the health sector is not well described, despite 63% of school-aged children participating in at least 1 organised sport outside school hours.[3]

Concussed athletes, who return to play whilst still symptomatic have an increased risk of recurrent injury and associated complications. This is due to a pathophysiological window of brain vulnerability post-concussion, as well as a post-concussion reduction in reaction time, information processing and speed, exposing the athlete to the demands of sport with a reduced capacity for evasive and defensive actions, with resultant increased risk of recurrent brain injury.[4,5]

The main issues of concern therefore are concussion management at the time of injury and timing of return to play. The International Concussion In Sport Group (CISG) consensus statement[5],and position statements from the American Medical Society for Sports Medicine (AMSSM)[6] and the American Academy of Neurology (AAN)[7] all advocate prohibition of athletes returning to play/train on the same day as their injury.

In Australia, both the Australian Football League (AFL) and the National Rugby League (NRL) recommend immediate removal from play, first aid management and assessment by medical personnel for athletes with suspected concussion, as per the CISG 2012 Consensus Statement on Concussion in Sport.[5,8,9] In Australian Football, junior leagues are required to have a person with current first aid qualifications available at all games. [8] Once concussion has been diagnosed, both sporting bodies mandate a graduated return-to-play process commencing once the athlete is asymptomatic, progressing to normal game play in a minimum of 6 days. No evidence based guidelines for safe return-to-play following sport-related head injury have been validated for children, and the current guidelines are modelled on those for adults recommended in the CISG 2012 Consensus Statement[5,10]

It remains unclear if general or sports specific guidelines for concussion management translate into changed on field practice, and how much players and parents know about the management of concussion and return to play instructions. There have been few studies assessing on-field management of head injuries in children and youth, or coach awareness and understanding of recommended guidelines. A recent survey of community AFL and NRL coaches and sports trainers identified knowledge gaps in key aspects of on-field management and the importance of a graduated return-to-play.[11] International studies have recognised similar gaps in both coach and player knowledge.[12,13]

Involvement in sport is highly encouraged for children to improve health, fitness, confidence and teamwork skills. However it is crucial that sport is also safe for children who are rapidly developing both cognitively and physically. This study aimed to identify: 1. compliance with on-field management guidelines for concussion; 2.parent and player awareness of return-to-play guidelines; and 3. parent and player compliance with return-to-play guidelines supplied to them. With a plan to assess differences between sports, and between organised and unorganised sporting activities

METHODS

Children aged between 5 and 18 years presenting to the emergency department (ED) at The Royal Children's Hospital Melbourne (RCH) with sport-related concussion between May 2013 and November 2013 were recruited for the study. The RCH is a paediatric tertiary referral hospital and paediatric trauma centre for the state of Victoria, Australia, with an annual ED census of 82,000 patients. The study was approved by the local human research ethics committee.

Sports included both organised and non-organised sports, and included recreational activities such as motor-cycle riding, bicycle riding, skateboarding, horse-riding and ice-skating. Injuries sustained while playing on a playground or during games involving running but not involving a ball were not included.

We enrolled concussive injuries defined as a blow to the head resulting in one or more of the following: loss of consciousness, headache, vomiting, amnesia, disorientation, seizure or focal neurology.[5] We excluded lacerations or bruises to the head or face without concussive signs or symptoms.

Procedures

Eligible children were identified at initial presentation to the ED. Verbal consent was obtained for initial data collection and follow-up phone call, which was completed with parents between 3 weeks and 3 months after recruitment.

All families were provided with the hospital's return-to-sports factsheet,[14] outlining the graduated return-to-play protocol recommended by the CISG 2008 Consensus Statement,[15] and a general advice for head injury factsheet[16] on discharge.

Even though the CISG statement is and the head injury fact sheet was more detailed in its recommendations, we defined a patient as "compliant" with CISG on field management if they were removed immediately from play, assessed by qualified personnel and not allowed to return to play on the same day. We defined

a patient as “compliant” with CISG RTP if they at least followed two of the steps of the step wise return to play and did not return to play while still experiencing symptoms.

Statistical methods

Analysis was descriptive with categorical variables presented as percentages and 95% confidence intervals for relevant key percentages, and continuous variables described as mean and standard deviation or median and interquartile range according to their parametric or non-parametric distribution. Results for Australian Football (AF) and non AF sports played were dichotomized.

RESULTS

During the study period, there were 1115 HIs of any severity that presented to the ED. A total of 271 sport-related HIs among children aged 5 to 18 years were identified. Of these, 169 were missed during prospective recruitment, mostly while researchers were unavailable to approach patients for enrolment.

A total of 102 patients with sports related head injuries were approached; 9 were excluded as they had soft tissue or neck injuries without concussive symptoms and 93 had concussion (the study group). No patient who was approached refused consent for participation. Of enrolled patients with concussion, 8 were lost to follow up. The average number of days until follow up was 32 (±5.2) days. **Figure 1** shows the study recruitment process.

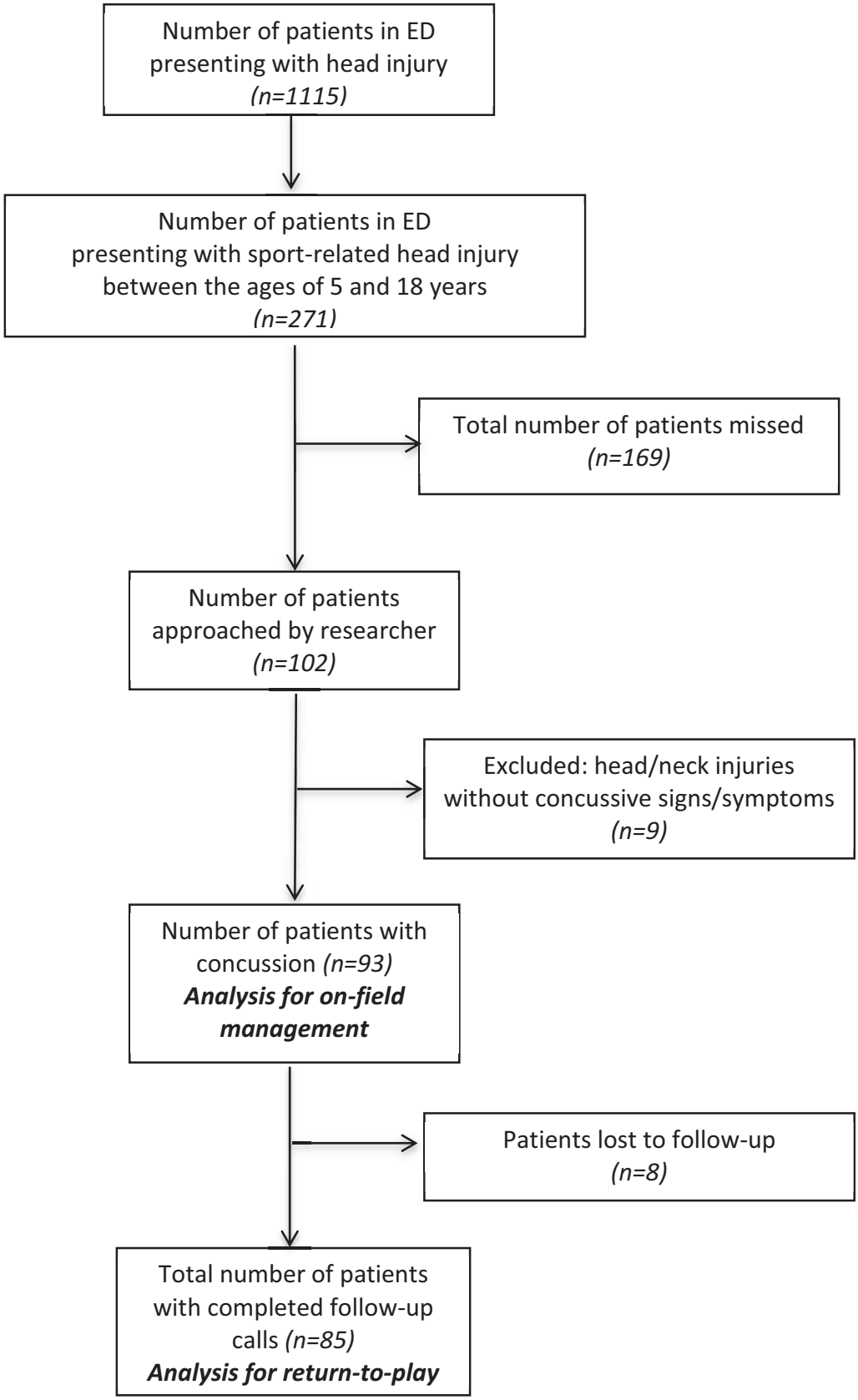

Figure 1. Patient flow chart

Injury and player characteristics

Demographics and signs and symptoms at presentation of the 93 enrolled children are presented in Table 1. Children arrived by ambulance in 51% and apart from one patient arriving by air ambulance the remainder arrived in private car. Mean age of the children with concussion was 12.7 (SD±0.27) years. Sports played were 47% were playing Australian Football (AF) soccer (12%), rugby (9%) basketball (8%) and other sports (25%).including baseball, gymnastics, ice-skating, speed ice-skating, horse-riding, handball, hockey, taekwando, motocross, and riding a scooter, bicycle, skateboard or quadbike. Most children (82%) were involved in organised sports. Of the organized sports (54%; 95% CI 42% to 66%) were playing AF. The average number of years children had been competing in their sport for was 3.7 years (SD±0.3). Protective equipment was worn by 52% (95% CI 41% to 62%), mainly mouth guards (81%) and helmets (25%). Only 2% of AF players and 22% of non AF players wore a helmet.

Signs and symptoms of concussions and management of children prospectively enrolled who were playing AF is compared with those playing non-AF sports in Table 1. The most frequent concussive symptoms and signs were headache (60%), and LOC (41%). Neuroimaging was performed in 18/93 (19%) of patients with none showing intracranial injury. Thirty percent were observed in a short stay unit and 15% were admitted to an inpatient ward. Mean length of stay was 4 hours, with a range 0.3 and 11.3 hours. None required neurosurgery.

Table 1. Demographics and signs and symptoms of children with sports related concussion

	Australian Football (n=44)	Non Australian Football (n=49)	Total (n=93)
Gender			
Male	43 (97.7%)	34 (69.4%)	77 (82.8%)
Female	1 (2.3%)	15 (30.6%)	16 (17.2 %)
Age (years)			
5-7	3 (6.8%)	1 (2.0%)	4 (3.9%)
8-10	4 (9.1%)	9 (18.4%)	13 (14.7%)
11-15	35 (79.5%)	32 (65.3%)	67 (70.6%)
16-18	2 (4.5%)	7 (14.3%)	9 (10.8%)
Organiser			
Club	36 (81.9%)	23 (46.9%)	59 (63.4%)
School	5 (11.4 %)	12 (24.3%)	17 (18.3%)
Non-Organised	3 (6.8%)	14 (28.6%)	17 (18.3%)
Nature of organised play			
Competition	40 (90.9%)	22 (44.9%)	62 (66.7%)
Friendly	1 (2.3%)	4 (8.2%)	5 (5.4%)
Training/Physical Education	0	8 (16.3%)	8 (8.6%)
NA	3 (6.8%)	17 (34.7%)	18 (19.4%)
Competition level			
Suburban	31 (70.5%)	11 (22.4%)	42 (45.2%)
Interschool	4 (9.1%)	6 (12.2%)	10 (10.8%)
Other*	6 (13.6%)	11 (22.4%)	17 (18.3%)
NA	3 (6.8%)	21 (42.9%)	24 (25.8%)
Competition experience			
Nil	3 (6.8%)	13 (26.5%)	16 (17.2%)
≤1 year	4 (9.1%)	9 (18.4%)	13 (14.0%)
1-5 years	21 (47.7%)	14 (28.6%)	35 (37.6%)
>5 years	16 (36.4%)	13 (26.5%)	29 (31.2%)
Concussive signs and symptom			
Loss of consciousness			
Disorientation	17 (38.6%)	21 (42.9%)	38 (40.9%)
Vomiting	18 (40.9%)	15(30.6%)	33 (35.5%)
Amnesia	9 (20.5%)	12 (24.5%)	21 (22.6%)
Headache	15 (34.1%)	13 (26.5%)	28 (30.1%)
Seizure activity	25 (56.9%)	31 (63.2%)	56 (60.2%)
Focal neurological deficit	1 (2.3%)	1 (2.0%)	2 (2.2%)
	1 (2.3%)	4 (8.2%)	5 (5.4%)
Disposition			
Treated and discharged	30 (68.2%)	21 (42.9%)	51 (54.8%)
Observed in Short Stay Unit	11 (25.0%)	17 (34.7%)	28 (30.1%)
Admitted	3 (6.8%)	11 (22.4%)	14 (15.1%)

*Other levels of competition included state, regional, rural and age group levels.

NA = Not applicable

On-field management analysis

Important factors regarding on field management of concussive injuries are shown in Table 2.

For most injuries a coach or medical staff attended and assessed the patient. Ten percent of patients did not report their head injuries at the time and were therefore not assessed on field. Symptom checklist use could only be determined definitively in ~50% of cases overall as 20% of patients did not know if the checklist had been used.

When compliance with on-field management practices was defined as performing all tasks recommended by the CISG statement, 32/76 (42%; 95% CI 31% to 54%) children involved in organised-sports were not managed appropriately. This included 14/76 19% (95% CI 10% to 31%) not removed immediately from play; 21/76 (27%; 95% CI 17% to 40%) not assessed by qualified personnel; and 22/76 (29%; 95% CI 18% to 41%) allowed to return to play same day, with 6/76 (8%, 95% CI 4%-16%) were allowed to return to play after less than 30 minutes.

Table 2. On field management of concussive injuries

	Organised sports (n=76)		Non-organised sports	Total
	AF (n=41)	Non-AF (n=35)	(n=17)	(n=93)
Personnel attending injury				
No	1 (2.4%)	3 (8.6%)	5 (29.4%)	9 (9.7%)
Yes	36 (87.8%)	29 (82.9%)	9 (52.9%)	74 (79.6%)
Coach	21	21	0	42
Medical staff	33	15	5	53
Other	5	4	2	11
Didn't report head injury	4 (9.8.%)	4 (11.4%)	3 (17.6%)	11 (11.8%)
Personnel assessing injury				
No	4 (9.8%)	9 (25.7%)	6 (35.3%)	19 (20.4%)
Yes	32 (78.0%)	21 (60.0%)	8 (47.1%)	61 (65.6%)
Coach	16	11	0	27
Medical staff	24	15	6	45
Other	2	6	1	9
Unknown	1 (2.4%)	1 (2.9%)	0	2 (2.2%)
Didn't report head injury	4 (9.8%)	4 (11.4%)	3 (17.6%)	11 (11.8%)

Field-side assessment using symptom checklist				
No	10 (24.4%)	17 (48.6%)	NA	27 (29.0%)
Yes	15 (36.6%)	7 (20.0%)	NA	22 (23.7%)
Unknown	12 (29.3%)	7 (20.0%	NA	19 (20.4%)
Didn't report head injury	4 (9.8%)	4 (11.4%)	NA	8 (8.6%)
NA, Non-Organised	0	0	17	17 (18.3%)
Stoppage of play				
No	18 (43.9%)	7 (20.0%)	NA	25 (32.9%)
Yes	18 (43.9%)	22 (62.9%)	NA	40 (52.7%)
NA	5 (12.2%)	6 (17.1%)	NA	11 (14.5%)
Didn't report head injury	4	3	NA	7
End of game	1	1	NA	2
Non team sports	0	2	NA	2
Immediate removal from play				
No	4 (9.8%)	3 (8.6%)	NA	7 (9.2%)
Yes	33 (80.5%)	29 (82.9%)	NA	62 (81.6%)
Didn't report head injury	4 (9.8%)	3 (8.6%)	NA	7 (9.2%)
Stand down time				
<15min	2 (4.9%)	1 (2.9%)	NA	3 (3.9%)
15-30min	2 (4.9%)	1 (2.9%)	NA	3 (3.9%)
Unknown	0	1 (2.9%)	NA	1 (1.3%)
NA	37 (90.2%)	31 (88.6%)	NA	68 (89.5%)
Kept playing	7	6	NA	13
Did not return to play	30	25	NA	55
Return to play since head injury				
No	29 (70.7%)	25 (71.4%)	12 (70.1%)	66 (71.0%)
Yes	12 (29.3%)	10 (28.6%)	4 (23.5%)	26 (28.0%)
Kept playing	8	6	3	15
Same game	4	2	0	6
Unknown	0	0	1 (5.9%)	1 (1.1%)
Management between field and emergency department				
No	9 (22.0%)	14 (40.0%)	4 (23.5%)	27 (29.0%)
Yes	32 (78.0%)	21 (60.0%)	13 (76.5%)	66 (71.0%)
Paramedic	22	15	9	46
Other Doctor/Hospital	10	4	6	20
Other	3	4	1	8
Transport to emergency department	17 (41.5%)	20 (57.1%	8 (47.1%)	45 (48.4%)
Personal car	23 (56.1%)	15 (42.9%)	9 (52.9%)	47 (50.5%)
Ambulance	1 (2.4%)	0	0	1 (1.1%)
Air transport				
Parent supervision				
No	4 (9.8%)	13 (37.1%)	11 (64.7%)	28 (30.1%)
Yes	30 (73.2%)	21 (60.0%)	4 (23.5%)	55 (59.1%)
Unknown	7 (17.1%)	1 (2.9%)	2 (11.8%)	10 (10.8%)

Return To Play

Follow-up calls were completed for 85 children. Of these 85 children, 42 (49%) played AF. Overall 65 children (77%; 95% CI 66% to 85%) experienced post-concussive symptoms.

Table 3 shows frequency and duration of post-concussive symptoms in children playing AF and non-AF sports. Fatigue and headache were the most frequently experienced symptoms reported in 57% of all children at follow up.

Forty-nine children/85 (58%, 95% CI 46% to 68%) experience symptoms for fewer than 7 days, and 7 (9%, 95% CI 11% to 29%) experienced symptoms for 10 days or more after their injury.

Compliance rates with components of RCH return-to-play guidelines are shown in Table 4.

None of the 85 patients followed the CISG based step-wise process exactly as set out in terms of a 6 step staged process or with progression to the next step every 24 hours. However, as set out in methods, we defined compliance with RTP guidelines in a modification of the 2008 CISG guidelines.[15] Seventy children (82%, 95% CI 73% to 89%) (57 organised, 13 non-organised) followed at least two steps of the step-wise RTP process. One of these children playing organised AF did not complete each step for at least 24 hours, and 13/85 (16%, 95% CI 10% to 26%children, 12 playing organised sports, returned to play whilst still experiencing symptoms. A further two children who had followed a step-wise RTP, both playing organised AF, experienced symptoms during their RTP process but did not rest for at least 24 hours until asymptomatic, as prescribed by the CISG protocol. Fifty five percent of children had followed a RTP and returned to sport and six were still symptomatic and had not yet returned to sport. Therefore, overall 61/85 (72%; 95% CI 61% to 81%) were broadly compliant with our RTP guidelines. In organised sports, 47/70 (67%; 95% CI 55% to 78%) were compliant with our RTP guidelines. In most measures of compliance there was little difference between the different

organized sports or un-organised sport. However more children who played organized AFL received medical clearance before returning to play.

Table 3. Post-concussive symptoms experienced in Australian Football (AF) and non-AF sports

	AF concussions (n=42)		Non-AF concussions (n=43)		Total (n=85)
	n, (%)	Median duration (days)	n, (%)	Median duration (days)	
Headache	25 (59.5%)	2	23 (53.5%)	2.5	48 (56.5%)
Neck pain	11 (26.2%)	3	11 (235.6%)	7	22 (25.9%)
Nausea or vomiting	4 (9.5%)	2	5 (11.6%)	2	9 (10.6%)
Dizziness	3 (7.1%)	7	7 (16.3%)	3	10 (11.8%)
Blurred vision	3 (7.1%)	4.5	2 (4.7%)	3	5 (5.9%)
Balance problems	1 (2.4%)	5	1 (2.3%)	21.5	2 (2.4%)
Sensitivity to light	6 (14.3%)	3	6 (14.0%)	30	12 (14.1%)
Sensitivity to noise	5 (11.9%)	1.5	5 (11.6%)	18.5	10 (11.8%)
Feeling slowed down	2 (4.8%)	7	2 (4.7%)	30	4 (4.7%)
Feeling like in a fog	1 (2.4%)	7	2 (4.7%)	15.5	3 (3.5%)
Don't feel right	2 (4.8%)	1	6 (14.0%)	7	8 (9.4%)
Difficulty concentrating	7 (16,7%)	4	8 (18.6%)	5	15 (17.6%)
Difficulty remembering	5 (11.9%)	14	8 (18.6%)	5	13 (15.3%)
Fatigue	23 (54.8%)	5	26 (60.5%)	4	49 (57.6%)
Confusion	1 (2.4%)	0	3 (7.0%)	30	4 (4.7%)
Drowsiness	2 (4.8%)	2	2 (4.7%)	30	4 (4.7%)
Trouble falling asleep	1 (2.4%)	2	2 (4.7%)	15.5	3 (3.5%)
More emotional	4 (9.5%)	3	7 (16.3%)	10.5	11 (12.9%)
Irritability	8 (19.0%)	3	5 (11.6%)	14	13 (15.3%)
Sadness	2 (4.8%)	2	3 (7.0%)	30	5 (5.9%)
Nervous/Anxious	2 (4.8%)	14	3 (7.0%)	30	5 (5.9%)

Awareness/Knowledge

Prior to presentation for this injury, 41/85 (48%; 95% CI 38% to 59%) of parents were aware of some HI information. However, 71/76 (93%; 95% CI 85% to 98%) of parents and 73/76, 96% (95% CI 89% to 99%) of children involved in organised sports were unaware of head injury information from their own organisation. Of the 17 children with a previous sport-related HI in organised sports, only 1 child and parent were aware of head injury information from their organisation.

At follow-up, all parents (100%) were aware of the hospital provided RTP guidelines as reported in the head injury handout they received. However, 52/70 (74%; 95% CI 62% to 84%) of parents with completed follow-up calls, whose children participated in organised

sports, were unaware of any RTP guidelines from their organisation. Of those participating in club sports, 15/54 (28%; 95% CI 17% to 42%) were aware of RTP information from their club and of those participating in school sports, 3/16 (19%; 95% CI 4% to 46%) were aware of RTP information from their school. One child was aware of both school and club guidelines.

Table 4. Return to play (RTP) protocol followed in children with concussive injury in organised Australian Football (AF), organised non-AF sports and non-organised sports, including second head injury

	Organised Sports (n=70)		Non-organised Sports (n=15)	Total (n=85)
	AF (n=39)	Non-AF (n=31)		
Attempted any RTP				
No	2 (5.1%)	3 (9.7%)	1 (6.7%)	6 (7.1%)
Yes	37 (94.9%)	28 (90.3%)	14 (93.3%)	79 (92.9%)
First full gameplay RTP attempt				
Not yet full RTP	4 (10.3%)	10 (32.3%)	4 (26.7%)	18 (21.2%)
<7days post-concussion	0	1 (3.2%)	1 (6.7%)	2 (2.4%)
≥7days post-concussion	35 (89.7%)	20 (64.5%)	10 (66.7%)	65 (76.5%)
Attempted step-wise RTP				
No	4 (10.3%)	4 (12.9%)	1 (6.7%)	9 (10.6%)
Yes	33 (84.6%)	24 (77.4%)	13 (86.7%)	70 (82.4%)
NA, not yet RTP	2 (5.1%)	3 (9.7%)	1 (6.7%)	6 (7.1%)
Contact RTP with medical clearance				
No	21 (53.8%)	22 (71.0%)	8 (53.3%)	51 (60.0%)
Yes	14 (35.9%)	3 (9.7%)	4 (26.7%)	21 (24.7%)
NA, not yet returned to contact sports	4 (10.3%)	6 (19.4%)	3 (20.0%)	13 (15.3%)
RTP whilst symptomatic				
No	31 (79.5%)	22 (71.0%)	13 (86.7%)	66 (77.6%)
Yes	6 (15.4%)	6 (19.4%)	1 (6.7%)	13 (15.3%)
NA	2 (5.1%)	3 (9.7%)	1 (6.7%)	6 (7.1%)
Symptoms during RTP and action taken:				
No symptoms	28 (71.8%)	21 (67.7%)	13 (86.7%)	62 (81.2%)
Experienced symptoms	9 (23.1%)	7 (22.6%)	1 (6.7%)	17 (11.8%)
Continued RTP without rest	5	3	1	9
Rested until asymptomatic for ≥24hrs	4	4	NA	8
NA	2 (5.1%)	3 (9.7%)	1 (6.7%)	6 (7.1%)

NA not applicable

DISCUSSION

It is accepted that same day return to play in concussed athletes, can cause prolonged symptoms, and increase the risk of both complications and recurrent HI.[7,17] CISG consensus recommendations[5] have been adopted by Australian sporting codes such as AFL[8],[28] and NRL.[9] They mandate the use of an approved sideline assessment tool (SAT) and trained personnel to assess concussive injury. This study was designed to assess the implementation of these guidelines in children's sport, the knowledge of participants of these guidelines, and concussed patient compliance with return to play guidelines. The underlying sports activities in this study were dominated by AF, a sport mainly played in the southern hemisphere winter months when the study was conducted.

This study highlights that, while these international sports related concussion guidelines have been adopted by sporting organisations, they have not been not been put into place at many sporting fields with 40% of children who sustained a concussion playing sport not receiving on field management outlined in the CISG recommendations.[5] Deficiencies in management were evident at all points of the guideline - players were not immediately removed from play, were allowed to return to play on the same day, or were not assessed by qualified personnel. International studies have been conducted assessing youth sporting staff awareness and knowledge of concussion management guidelines.[11,12,13,24,25,] and have identified gaps in coach and trainer sports related concussion management. This study indicates that these knowledge gaps translate into inappropriate on field management and premature return to play in youth athletes.

Despite the largest sporting codes adopting best practice concussion management guidelines, only 7% of parents or children in this study were aware of any pre-injury concussion instructions or RTP guidelines from their sporting organization, suggesting current implementation of the guidelines is inadequate. We also found that a number of children did not report their head injury during the game. The problem of underreporting of HI by youth athletes has been

previously identified, with higher rates of underreporting in studies in the US and New Zealand compared to the present study.[26,27] Though reasons for not reporting at the time of injury were not collected, the lack of awareness of concussion guidelines, and the presumed lack of knowledge of the significance of a sports related concussion may have contributed.

Most children recovered within 7 days with 81% reporting no post-concussive symptoms 7 days from their injury. Previous literature has demonstrated higher rates of post-concussive problems.[18,19,20] However, these studies used detailed neuropsychological testing to assess cognitive recovery whilst the present study used a researcher administered symptom checklist only. While over two thirds complied to some degree with the CISG[5] based RTP information provided at hospital discharge, only 8.2% complied with all 6 steps of the protocol. The concerning outcome of this is that 17.6% of children either returned to play whilst symptomatic or did not follow appropriate remedial action after experiencing symptoms during their RTP process. Explanations for this inadequate response include parental understanding, lack of medical supervision during the step-wise program or the difficulty of using a process primarily designed for adult athletes in a non-professional paediatric sports setting. Generally, the literature shows poor compliance rates with RTP guidelines among youth athletes.[26,27,29,30,31] An American study of concussed high school athletes found that at least 40% were noncompliant, however it was unclear whether all athletes were aware of RTP guidelines.[26] A recent Australian study of mostly adult athletes found a rate of noncompliance of 87%.[30]

Despite the poor compliance with the RTP steps the majority of children in this study waited until they were asymptomatic for at least 6 days before returning to full gameplay and followed the appropriate sections of RTP recommendation if they experienced symptoms during any stage of RTP. These rates are higher than those previously reported.[26,27,29,30,31] Previous studies however have looked at all sports related head injuries and concussion, and our cohort was perhaps the more

severe end as it included only those presenting to hospital after a head injury. Previously the non-compliance with RTP guidelines in youth athletes is often explained by the sporting culture of 'not letting the team down'. Thirty-two percent of high school rugby players from New Zealand believed a concussed player on their team had been under pressure to return to play.[27] `At follow-up no parent in our study reported that their child had been under any such pressure.

Our findings reinforce that appropriate on-field management of sports related HI is not being universally followed, and RTP guidelines are not being adequate followed, or adequately supervised by clubs or medical personnel. These practices leave children at greater risk of complications of concussion. Considering the focus of a number of sporting organizations on improving care for possible concussion through their websites and freely provided materials[28] there appears to be a problem with both the transfer of information from the sporting organization to the individual clubs, coaches, parents and players, and the implementation of the recommendations. In the US state laws mandate compliance with concussion education and return to play rules, [32] no such laws exist in Australia. Before considering legislative changes the community, sporting clubs, and sporting organisations need to accept there are ongoing issues and address the knowledge deficits and implementation deficits in managing sports related concussion

Limitations

Findings are limited in their generalisability due to a focus on a single, paediatric tertiary referral hospital. The results were dominated by AFL injuries as there was a weekend and winter seasonal focus which is the main season for football playing in the southern hemisphere. This may have resulted in a study population dominated by AF. Selection bias may have been introduced as recruitment was based on researcher availability. Although very few sideline assessment tools appeared to have been used on-field information on the use of these tools may be better collected by targeting coaches and team staff rather

than parents and child athletes, who may not be aware if the tools are being used. The population studied is hospital based and findings cannot be generalize to all field-side concussions, particularly those not transferred to hospital.

CONCLUSION

On-field concussion management and return to play practices are often suboptimal and awareness and education of coaches, teachers, parents and children and actual practice on the sports fields need to be improved. Many children with sports related concussion are not being appropriately assessed on-field and continue to play despite signs or symptoms of concussion, increasing the risks of complications and further head injury.

Summary: What are the new findings?

1. On field management of children after sports related concussion in this study did not follow international concussion in sports guidelines in 42%.
2. Parents and patients generally were not aware of concussion guidelines or information from their sports organisations.
3. Although most patients attempted a graduated return to play, none followed the step wise return in detail.

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6.2.7 Concussion recovery trajectories

Bressan S, Anderson V, Davis GA, Babl FE. Take CARe (Concussion Assessment and Recovery Research) project – preliminary results from a pilot study.

Take CARe (Concussion Assessment and Recovery Research) project – preliminary results from a pilot study

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INTRODUCTION

Head injuries (HI) are one of the most common presentations for children to the Emergency Department (ED) in developed countries.[1] According to recent Australian data approximately 4% of ED presentations are for a HI, and nearly 3000 children present to the Paediatric ED for HI of all severities on a yearly basis at the Royal Children's Hospital (RCH) in Melbourne.[2]

The great majority of children, approximately 90%, sustain a minor HI.[3] Of these, only a very low percentage will have an intracranial lesion on computed tomography (CT) scan and an even smaller number will need acute neurosurgical intervention, intubation or prolonged hospitalization for life-threatening intracranial complications.[4-6]

Given the potentially severe or unfavourable outcome resulting from intracranial injuries, the main goal of the acute management of children with HI has traditionally been considered the timely identification of possible intracranial complications. The growing body of scientific concern regarding the increased incidence of malignancy[7-10] and possible neurodevelopmental outcomes[11] related to CT scan radiation exposure, as well as the sedation-associated risks for uncooperative children, has prompted the research effort to derive and validate clinical prediction rules to help emergency physicians in this challenging decision-making process.[12]

More and more, however, recent research has highlighted that a substantial minority of children with either no documented intracranial injury on CT or at very

low risk of intracranial injury suffer from prolonged post-concussive symptoms (PCS).[13-17] These symptoms include headaches, dizziness, visual disturbance, memory/concentration deficits, mental slowness, confusion, fatigability, irritability, light/noise sensitivity, sleep disturbances, depression and anxiety.[18]

Paediatric studies have reported an incidence of PCS varying between 6% and 35% in the first 3 months following a mild traumatic brain injury.[13,15,17,19] In nearly 90% of these children PCS will resolve in 3 months, and less than 5% will be still symptomatic at 1 year.[13] However those who are affected can develop significant disability, which may interfere with children's school achievements and social activities. Inability to lead their normal lives may contribute to the development of more persistent cognitive symptoms, including reduced concentration and memory problems.[20]

Given the large number of children who are assessed in the ED following a HI, emergency physicians may play a key role not only in the timely identification of possible acute intracranial complications, but also in the early identification of those children at high risk of significant PCS, who will benefit from closer follow up in a dedicated concussion clinic.

Only few studies have investigated risk factors or predictors for developing PCS in children, leading to different results. A recent systematic review carried out to identify prognosticators of persistent symptoms following paediatric concussion has included 15 relevant studies.[17] However, pooling and interpreting of data was precluded by the excessive heterogeneity in the populations studied, outcomes measured, definitions of cases, and follow-up intervals. The few most recently published studies, not included in the above mentioned systematic review, suffer from the same limitations and do not provide clinicians with definite answers as to which are the best predictors to identify those children who will develop significant PCS.[15,21-25]

Simple and accurate clinical prediction rules based on pre-injury and injury-related data would facilitate identification of children at higher risk of significant PCS in the ED and prioritize their follow up in a dedicated concussion clinic.

We aim to address this knowledge gap by developing a large multicentre prospective study to derive and validate a clinical prediction rule to be used in the ED for identifying children at higher risk of significant PCS following a concussion.

In order to test the feasibility and improve the protocol for the multicentre study we set out to conduct a pilot study. The results of the pilot will allow for a more accurate sample size estimation and planning of the final study, as well as refinement of study procedures.

METHODS

Study design, setting and structure

This is was a prospective longitudinal pilot study including children aged 5 to 18 years old and their parents.

The pilot was being conducted at the RCH and Murdoch Children's Research Institute (MCRI) as a single-centre study.

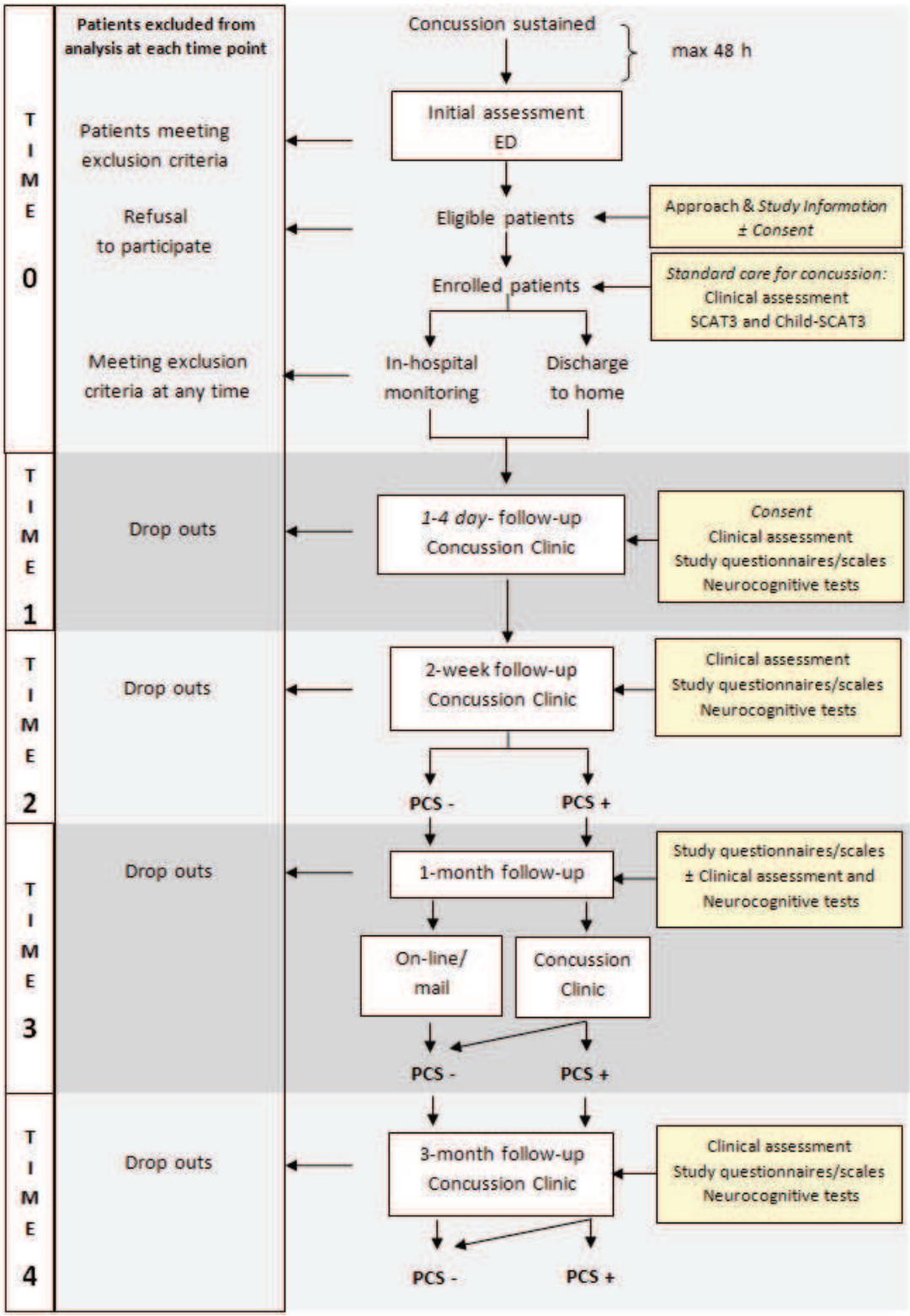
The study included repeated assessments over time. The recruitment and the first assessment happened at the time of the ED visit, while all subjects were expected to have a total of at least 3 follow-up visits in the Concussion Clinic, which was set up for the purpose of this study. All patients were reviewed in the Concussion Clinic at 1-4 days following the ED presentation (T1); at 2 weeks post-injury (T2), and at 3 months from injury (T4). At 1-month (T3) subjects who were found to be significantly symptomatic at 2 weeks were reviewed in the clinic, while the other patients completed paper or on-line questionnaires at home. The study procedures included a joint research and clinical assessment at each Concussion Clinic visit.

A detailed description of the study procedures is reported in figure 1.

Outcome measures

The primary outcome for feasibility was the ability to enroll patients in a busy ED and complete follow up procedures to estimate recruitment and completion rate for the larger study.

The primary clinical outcome was the presence of clinically significant post concussive symptoms (see definition section below) at 2 weeks (T2), 1 month (T3), and 3 months (T4) post injury.



ED= Emergency Department. PCS+= clinically significant post-concussive symptoms; PCS-= asymptomatic or improving patients

Figure 1. Study design diagram

Definitions

Concussion: was defined according to the Zurich Consensus Statement on Concussion in sport.[26] This definition is reported in section 3.3.2.

Clinically significant post concussive symptoms: for the purpose of this study this was defined as an increase in 3 or more symptoms and in the total severity score compared with the pre-injury level (as rated on the post concussive symptom inventory), in addition to a lack of significant improvement in symptom burden over time (as ascertained through a clinical interview carried out by medical staff experienced in concussion management).

Recruitment

Eligible patients were identified through surveillance of the ED electronic visits database by trained Research Assistants (RA) or study investigators.

The RA verified with the treating clinician whether the patients met inclusion criteria and patient and family were suitable to be approached.

Eligibility Criteria

Patients aged 5-18 years who presented to the ED for a concussion sustained in the previous 48 hours were eligible for the study.

The following patients were excluded: intubated patients, need of neurosurgical operative intervention or general anaesthesia for injury management, presence of structural/haemorrhagic intracranial injury on CT scan, clinical evidence of CSF leak, intellectual disability with inability to complete the testing measures, injury resulting from child abuse or assault, alcohol or drug intoxication at time of presentation to the ED, insufficient understanding of English as per assessment by the treating physician/research assistant in the ED, more than 1 hour drive from the hospital (unless family willing to come back despite distance), multiple trauma, presence of fever at time of initial assessment (T>37.5°), no clear history of trauma as primary event (eg, seizure, syncope or migraine as primary event), and already enrolled in the study.

Study visits and procedures schedule

A summary of the study procedures and assessments tools for each study time point is reported in table 1.

Table 1 Summary of study procedures and follow up timing

Timeline	T0 Presentation	T1 1-4 days	T2 2-weeks	T3 1-month	T4 3-months
Location	ED	Concussion Clinic	Concussion Clinic	Home/ Concussion Clinic	Concussion Clinic
Approach and study information	X				
Consent	X	X			
Demographics	X				
Pre-injury data					
-Questionnaire		X			
-PCSI (retrospective)		X			
Injury-related data					
- APHIRST CRF	X				
Clinical assessment					
- SCAT3/Child-SCAT3	X	X	X	(X)	X
- PCSI		X	X	X	(X)
Neurocognitive tests					
- CogSport		X	X	(X)	X
Quality of life					
-PedsQL		X		X	X
Medical assessment		X	X	(X)	X

(X) = procedures for patients significantly symptomatic at T2 only

List of abbreviations used in the table (reported in alphabetical order): APHIRST –Australasian Prospective Head Injury Study; CRF- Clinical Report Form; ED= Emergency department; PCSI- Post Concussive Symptom Inventory; PedsQL – Pediatric Quality of Life Inventory; SCAT- Sport Concussion Assessment Tool

Clinical assessments and data collection

Data collection included the common data elements selection of measures chosen by expert opinion by the Pediatric TBI (Traumatic Brain Injury) Demographics and Clinical Assessment Working Group through the National Institutes of Health.[27] This standardization of data collection will permit comparison of results and high-quality meta-analysis in the future.

Demographic, pre-injury and injury-related data were collected in dedicated clinical report forms. The Australasian Prospective Head Injury Rule Study (APHIRST- see chapter 7, section 7.9) clinical report form was used for collection of injury-related data and was completed by the treating clinician in ED.

A detailed description of specific questionnaires used for the other data is reported below.

The *Post Concussive Symptom Inventory (PCSI)* is a 20-item scale that measures physical, cognitive, emotional and sleep-related symptoms. We used both the parent report, and the age-based self-report form for children. PCSI has shown good reliability and validity.[28] The PCSI was selected as a supplemental measure by the Paediatric Common Data Element (CDE) Traumatic Brain Injury (TBI) Outcomes Workgroup, because of its sound psychometric characteristics, promising indications of validity in distinguishing mild TBI from other injuries, applicability to younger children, and availability in the public domain. It was selected as a supplemental rather than a core measure because, compared to the Health and Behaviour Inventory, it had less empirical validation. However new data have recently been published confirming its strong psychometric characteristics and contributing to its empirical validation.[29] Administration time is ~10–15 min.[30] The Post Concussive Symptom Inventory (PCSI), retrospective pre-injury report, is completed at T1 to collect information on pre-injury "baseline" symptom occurrence.

The third version of the *Sport Concussion Assessment Tool (SCAT3)* is a multimodal test battery to be used for acute assessment of sport concussions, currently recommended by the Zurich Consensus Statement on Concussion in sport.[26] It includes a version for children aged 13 years and over (SCAT3) and a separate version for children aged 5-12 years (Child-SCAT3).
The main components of these tools include:

(i) Symptom evaluation.

The symptom scales used differ in the SCAT3 and Child SCAT3.

The SCAT 3 includes the Post Concussive Symptom Scale (PCSS). This is a 22-item self-report scale of the severity of concussion-related symptoms on a 7-point Likert scale, from 0 (no symptoms) to 6 (severe symptoms). Previous studies have shown good reliability and validity for self-report PCSS.[28]

The childSCAT3 includes the Health and Behavioural Inventory (HBI). This is a 20-item scale that measures the frequency of a variety of somatic, affective, cognitive and behavioural symptoms, on a 4-point scale, from 0 (never) to 3 (often). It includes a child and a parent report form.[18,28] The HBI was selected, by the Paediatric CDE TBI Outcomes Workgroup as a core measure, based on its sound psychometric characteristics, validity in distinguishing mild TBI from other injuries, and availability in the public domain. The scale has been used to investigate the outcomes of mild-to-severe TBI, and it is sensitive to various markers of injury severity. Administration time is ~ 5–10min.[30]

(ii) Cognitive assessment

The Standardized Assessment of Concussion (SAC) and its child version (SAC-C) is a rapid cognitive assessment tool. It includes an orientation, an immediate memory, a concentration and a delayed recall test.[31,32] These items slightly differ for children younger and older than 13 years, but the maximum possible score (equal to the number of correct answers for the different items) is 30 in both age groups. A higher score represents a better performance. SAC has been shown to be a valid instrument for detecting the immediate effects of a concussion both in adults[33,34] and in children (Davis G et al., 2013- unpublished data).

(iii) Physical assessment

The modified Balance error scoring system (BESS) is used to assess postural stability. It includes single, double, and tandem stance assessments, each held for 20 seconds, with the patient hands on hips and eyes closed.[35,36] The BEES score equals to the number of total errors made by the patient in the stances included in the test with a maximum of 10 errors for any single condition (total maximum score possible is 20 for children younger than 13 years and 30 for older children).

Coordination is assessed by the finger- to-nose task that measures the numbers of correct repetitions of the task over 4 seconds. The test is scored as 1 (passed) if five correct repetitions are performed in less than four seconds.

CogState® is a series of computerized cognitive tests, derived from theoretical and developmentally sensitive principles that have been validated widely in adults, and is also appropriate for use in children. Prior research has demonstrated the sensitivity of these tests to adult mild TBI.[34] The reliability and metric properties of the tests in adults have been described.[34,37,38]

The CogSport[39] is one of the stable of CogState® tests, developed specifically for application in sport, and in the context of concussion specifically. It includes a series of tasks based on a 'playing-card' paradigm testing the domains of processing speed, attention, learning and working memory. Within each test, participants are shown a picture of a playing card and asked to answer a question about the card. Different tests are created by changing the question. A summary of the tasks included in the CogSport battery and the cognitive domain assessed by the task is reported below.

Detection task – processing speed. A card is presented face down at the center of the computer screen. The participant is instructed to 'Press Yes' as soon as a card turns face up. After a randomized delay, the next card flips face up, and the participant must press the 'Yes' key as quickly as possible.

Identification task – attention. A card is presented face down at center screen, and the participant is asked: 'Is the face-up card red?' and responds by pressing 'Yes'. After a randomized delay, the next card flips face up, and the participant must respond 'Yes' (red card) or 'No' (other color).

One Back task - working memory. A card is presented face up at center screen. The participant is asked 'Does the face up card exactly match the one before?' The card then goes to the back of the pack and after a random delay the next card is revealed. If the card is identical to the card before it, the participant presses 'Yes' key, if not, 'No'.

One Card Learning task - learning / memory. A card is presented face down at centre screen. The participant is asked 'Have you seen this card before in this task?' After a randomized delay, the card flips face up. For each card, participants must decide whether they have seen that card before in the task and respond 'Yes' or 'No'.

For processing speed and attention the outcome measure is the reaction time in millisecond. A shorter response time shows a better performance. For

learning the outcome measure is accuracy in the response and a higher percentage shows a better performance. For working memory both reaction time and accuracy are reported.

The simple, game-like nature of the CogSport tasks, combined with the consistent response mechanism, ensures that these tests are appropriate for use in children. Prior research has demonstrated that these tests are sensitive to the effects of stimulant medication in ADHD[40], and are appropriate for administration to children as young as 5 years of age.[41,42] The reliability of the tests in paediatric populations has also been described.[41,42] Paediatric normative data are currently available for children older than 9 years. Children included in this study undergo a practice test at T1 before the actual test battery is administered. This is to avoid poor performance related to unfamiliarity with the test requirements and functioning. The CogSport test battery was administered only on two computers with identical hardware and software characteristics.

The *Pediatric Quality of Life Inventory* is a 23-item measure that is used to assess quality of life in children. The measure includes items in the domains of physical, emotional, social and school functioning. Age-appropriate child forms are used. Respondents indicate how much each item has been a problem in the past month; responses for 8-18 year old children and for parents are rated in a 5-point Likert scale, while younger children rate their responses on a 3-point scale. A total score and two summary scores for physical health and psychosocial health can be calculated. Scales scores are computed as the sum of items divided by the number of items answered; this accounts for missing data. The total score is on a scale from 1-100, with higher scores indicating a higher health-related quality of life. Summary scores and scores for each subscale are computed by averaging the component item responses, and range between 0-4. Administration time is ~5 minutes. This tool is currently recommended by the by the Paediatric CDE TBI Outcomes Workgroup.[30]

Statistical analysis

Based on estimates from the available literature between 20 and 30% of children still experience symptoms at 1 month and 5-10% are symptomatic at 3 months. In order to test study procedures in a sufficient number of symptomatic patients we aimed to recruit 100 subjects with complete follow-up data. Based on data from APHIRST, an average recruitment time of 60 hours per week, and the seasonal variation in sport-related concussions we estimated a study duration of 12-18 months. Data from this pilot study will be used for the sample size calculation of the larger study.

Categorical variables were described as percentages and 95% confidence intervals for main results. Continuous variables were described as mean and standard deviation or median and interquartile range, according to their parametric or non-parametric distribution respectively. Comparisons were performed by means of Chi-square test of Fisher's exact test, as appropriate, for categorical variables. Mann-Whitney test was used to compare variables with non-parametric distribution in independents samples. P values <0.05 are considered statistically significant. Wilcoxon pairwise comparisons of medians using a Bonferroni adjustment to compensate for the multiplicity of testing were used to compare groups with repeated continuous non-parametric variables over time. Data for the 1-month questionnaires were collected by using REDCap (version 5.10.2) for patients who were not scheduled for an appointment in the Concussion Clinic and preferred to complete the questionnaires on-line. All data were entered into an Excel database and were analysed using Stata (version 13.0, StataCorp, College Station, Tex, USA).

RESULTS

This section covers both feasibility issues with establishing and setting up the study structure and procedures, and results on patient characteristics of the pilot study, including prevalence of clinically significant post concussive symptoms and recovery trajectories.

The results presented in this thesis include data of patients enrolled between 1 August 2013 and 30 June 2014, with follow up assessments completed by 11 July 2014.

Feasibility results

The pilot study was structured as a staged process to gradually increase the recruitment and follow up capacity and improve the study procedures.

1. The first three months were dedicated to testing study procedures and administration. The principal investigator undertook recruitment whilst working as a clinician in the ED. This provided opportunity to comprehensively test recruitment and follow up procedures in a small number of patients. Four patients were enrolled during this first stage of the pilot study. In this period we set the basis for the collaboration with multidisciplinary professionals for assessment of participants in the newly established Concussion Clinic within the project.
2. The following three-month period was dedicated to increasing recruitment and follow up capacity, to test and refine study procedures and logistics in a larger number of patients. Study procedures were undertaken by the principal investigator and two trained interns in Psychology. A patient logbook for screening of patients and monitoring of recruitment rate was initiated. Recruitment occurred during daytime from Monday to Friday and over the weekends only when the principal investigator was rostered to work as a clinician in the ED. The average recruitment time was approximately 40 hours per week. During this stage 27 patients were enrolled in the study. Staff from the Rehabilitation team became routinely involved in the clinical

assessment of the patients, with input from Mental Health, Neuropsychology and Neurosurgery as needed.

3. The third three-month stage focused on increasing enrolment of participants by increasing the weekly recruitment time. Undergraduate and postgraduate volunteer staff underwent formal training to be involved in the recruitment procedures in the ED during evenings and weekends. Each staff member was involved in the study for an average of 20 hours a month, allowing for an increase in recruitment time to 60 hours per week. A total of 36 patients were recruited during this stage.
4. The last stage was dedicated to increasing staffing to undertake the larger number of follow up study assessments in the Concussion Clinic and entering data into an electronic excel database. Undergraduate and postgraduate volunteer staff have been involved in this stage of the study after formal training. In the last two months of this ongoing study 21 participants were enrolled.

Overall, nearly 50% of the 365 patients suitable for approach during stages 2 to 4 were approached by research staff and half of these (49%, 95% CI 41%-57%) were enrolled in the study (Figure 2). After including the four patients who were enrolled during stage 1 and excluding four patients who met exclusion criteria after enrolment, a total of 81 patients were finally included in this pilot study.

Of the 80 patients who refused participation to the study, 71 (89%) provided a reason and 43 (61%) of these reported the study procedures, in particular the follow up visits, to be too time consuming to commit to the study.

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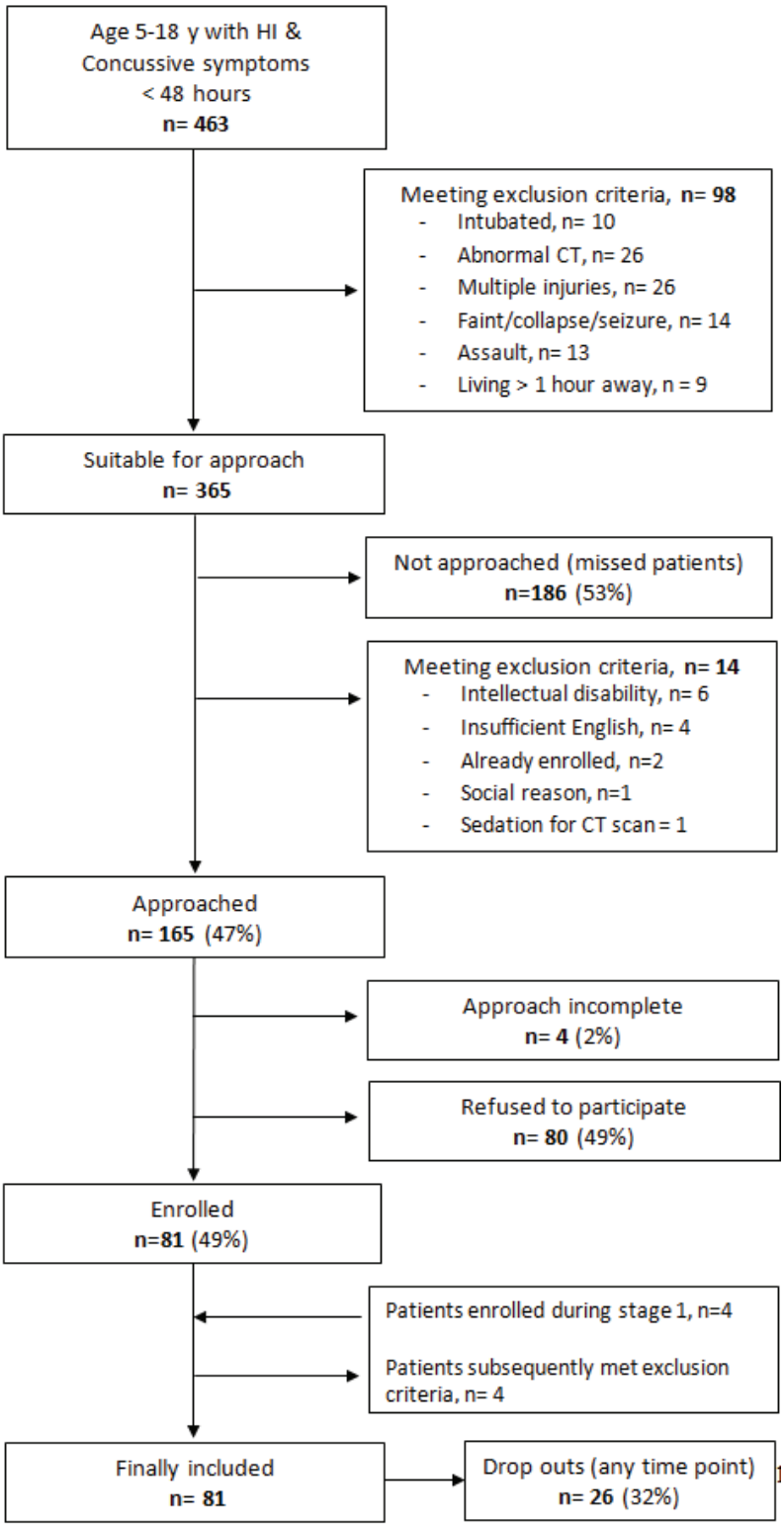

HI= Head Injury; CT= Computed Tomography

Figure 2. Patient flow chart for stages 2 to 4 of the study. Patients from stage 1 (n=4) are included at the bottom of the flow chart.

During stage 3 a higher number of patients were approached (56% vs 45%, p=0.047), but a higher percentage of the approached patients refused participation to the study, leading to a lower recruitment rate.

Comparison data on recruitment during stages 2 and 3 of the study are reported in Table 2.

Table 2. Comparison of recruitment data for the stages 2 and 3 of the study

	Stage 2 November 2013 – January 2014 n, (%)	**Stage 3** February 2014 – April 2014 n, (%)
Weekly recruitment hours	40	60
Patients meeting inclusion criteria	136	189
Patients meeting exclusion criteria	47	37
Patients suitable for approach	89	152
Missed patients	51 (58%)	67 (44%)
Enrolled patients	27 (30%)	36 (24%)
Refused to participate	11 (12%)	49 (32%)

The reasons behind the missed opportunities for approaching patients during stage 3 of the study are reported in Table 3.

Table 3. Analysis of reasons behind missed opportunities for approaching patients during stage 3 of the study

Reason	**n**	**%**
Screening challenges *	23	34
Presented outside recruitment hours	20	30
Staff busy doing follow up assessments	8	12
Too short ED stay (< 40 min)	6	9
Recruitment shift not covered (public holidays, sick leave, annual leave)	6	9
Other	5	7
Total	**67**	**100**

* Including staff not recognizing eligible patients from "triage complaint" field of ED database, as well as ambiguous triage complaints and incorrect/incomplete information received from clinical staff when screening for patients.

ED = Emergency Department

A summary of patients with completed study follow up assessments for each time point is reported in Table 4.

Table 4. Summary of patients with completed study follow up assessments for each time point.

Study Time Point			Follow up due¥	Completed assessment §	
			n, (%)	n, (%)	95% CI
ED presentation	T0	within 48 hours from injury	81 (100%)	69 (85%)	76%-92%
1st follow up	T1	1-4 days from ED presentation	81 (100%)	68 (84%)	74%-91%
2nd follow up	T2	2 weeks post injury	78 (96%)	59 (76%)	65%-85%
3rd follow up	T3	1 month post injury	70 (86%)	46 (66%)	53%-77%
4th follow up	T4	3 months post injury	53 (65%)	33 (62%)	48%-75%

¥ refers to patients whose follow up occurred until 11 July 2014 (cut-off date for follow up for the purpose of the preliminary analysis presented in this thesis)
§ percentage calculated on number of patients whose follow up fell by July 11th 2014 (cut-off date for follow up for the purpose of the preliminary analysis presented in this thesis)
ED = Emergency Department

Overall 12 patients did not have the study procedures completed in the ED at T0, because they either were too unwell to undertake the study assessment or presented when no research staff was available. The latter group of patients were referred to the project by the treating clinician in ED.

A total of 26 patients dropped out since the beginning of the study: 13 (50%) did not present to the first follow up visit, 5 (19%) did not undertake the second assessment, 3 (12%) did not complete the third assessment and decided to leave the study at that point, and 5 (19%) did not present at the final follow up visit. There was no significant difference in the age and sex distribution of patients who dropped out compared with those who completed or are still in the study (median age 9.5 (IQR 7-13) vs 12 (IQR 9-14), p =0.170; proportion of males 73% vs 75%, p=0.888).

Overall, complete study data were available for 30% (95% CI 23%-38%) of the approached patients at the time of the analysis.

Summary data of the actual time of each study follow-up visit are reported in Table 5. This parameter was monitored to assess how closely patients could be seen for their study visits considering child and families obligations.

Table 5. Summary of actual time of completed study follow up assessments in the Concussion Clinic.

Study Time Point		Expected time of visit	N of patients with complete assessments	Actual time of assessment in days Median, (IQR)
1st follow up	T1	1-4 days from ED presentation	68	3 (2-4)
2nd follow up	T2	2 weeks post injury	59	16 (15-20)
3rd follow up	T3	1 month post injury	14*	35 (31-38)
4th follow up	T4	3 months post injury	33	95 (93-102)

IQR= interquartile Range; ED= Emergency Department

* Significantly symptomatic patients only. Patients asymptomatic or improving at T2 were asked to completed an online/paper questionnaire at T3.

Characteristics of study population

A total of 81 patients were enrolled. Of these 61 (74%) were males, and the median age was 11 years (IQR 8-13). Patients younger than 13 years were 47 (58%).

Clinical and injury characteristics of all the enrolled patients are reported in Table 6. This information was collected by the treating clinician on the same clinical report form used for the APHIRST study. Overall the great majority of patients (75%) were assessed in the ED within 3 hours from their injury. Falls from standing height or from an elevation were by far the most common mechanism of injury (in 57% of the study population).

The most common symptom was headache, reported in 74% of patients, followed by disorientation (47%), amnesia (35%), vomit (28%) and loss of consciousness (19%), while only one patient had a seizure. Symptoms were similar in children younger and older than 13 years of age. Only the vomiting rate was significantly higher in younger children (39% vs 12%, p=0.008).

The great majority of children (83%) had a GCS of 15 on arrival in the ED.

Overall nearly one third of patients underwent a CT scan. The CT scan rate was higher in older children (41% vs 21%, p=0.05).

On discharge 11% of patients had persistent neck tenderness with normal cervical-spine x-rays and were discharged to home with a semi-rigid collar. None of these children was found to have a significant injury at the time of the orthopaedic follow up, 7-10 days after the ED assessment.

Data on sport participation and past medical history were collected at the first follow up visit (T1) and were available for 68 patients. These data are summarized in table 7.

More than half of the included children (55%) sustained their injury while playing sport, with football, basketball and cycling being the most common sports played at the time of injury.

Overall approximately 40% of the children regularly played sport twice a week or more. A total of 10 patients (15%) had sustained at least one concussion in the past year, with a significantly higher rate in older children (30% vs 3%, p=0.002).

Use of regular medications was reported in 16% of patients and was significantly higher in children aged 13 years and over (37% vs 0%, p<0.001). They mostly included analgesic and anti-asthmatic medications, with only one patient on antidepressants.

All the other pre-injury characteristics did not differ significantly between the two age groups.

Table 6. Demographics and injury-related characteristics of enrolled patients.

Demographics and injury related data (collected at T0 in the ED)	**< 13 y n=47**	**≥ 13 y n=34**	**Total n=81**
Age (median, IQR)	9 (7-11)	14 (13-15)	11 (8-13)
Gender (M) (n, %)	32 (68%)	29 (85%)	61 (75%)
Time from injury (median, IQR)	1 (1-2)	2 (1-3)	2 (1-3)
Mechanism of injury (n, %)			
Fall from standing height	20 (43%)	13 (38%)	33 (41%)
Fall from height	10 (21%)	3 (9%)	13 (16%)
Collision with other child	7 (15%)	4 (12%)	11 (14%)
Hit by an object	2 (4%)	7 (21%)	9 (11%)
Fall off non-motorized RV	4 (9%)	5 (15%)	9 (11%)
Road accident	4 (9%)	1 (3%)	5 (6%)
Fall off motorbike	0 (0%)	1 (3%)	1 (3%)
Symptoms (n, %)			
LOC (n=80)			
Yes	5 (11%)	10 (29%)	15 (19%)
Duration			
< 5 s	4 (9%)	2 (6%)	6 (7%)
5s -5m	3 (6%)	8 (24%)	11 (14%)
>5m	0 (0%)	1 (3%)	1 (1%)
Unknown	2 (2%)	1 (3%)	3 (4%)
Suspected	6 (13%)	2 (6%)	8 (10%)
No	35 (76%)	21 (62%)	56 (69%)
Unknown	0 (0%)	1 (3%)	1 (1%)
Witnessed disorientation (n=79)			
Yes	16 (36%)	20 (59%)	37 (47%)
No	24 (53%)	13 (38%)	36 (46%)
Unknown	3 (7%)	1 (3%)	4 (5%)
Vomit			

Yes	18 (39%)	4 (12%)	22 (28%)
> 1	14 (30%)	4 (12%)	18 (38%)
≥ 3	10 (21%)	3 (9%)	13 (16%)
No	28 (61%)	29 (88%)	57 (72%)
Unknown	0 (0%)	0 (0%)	0 (0%)
Amnesia (n=73)			
Yes	15 (32%)	13 (38%)	28 (35%)
≤ 5 m	7 (15%)	5 (15%)	12 (15%)
> 5m	4 (9%)	7 (21%)	11 (14%)
Unknown	2 (4%)	0 (0%)	2 (2%)
No	26 (55%)	14 (41%)	40 (49%)
Unknown	3 (6%)	2 (6%)	5 (6%)
Seizure (n, %)			
Yes	1(2%)	0 (0%)	1(1%)
No	45 (96%)	32 (94%)	77 (95%)
Unknown	1(2%)	2 (6%)	3 (4%)
Headache in ED			
Yes	33 (70%)	27 (79%)	60 (74%)
No	10 (21%)	5 (15%)	15 (19%)
Unknown	3 (6%)	1 (3%)	4 (5%)
Headache severity (n=77)			
Mild	15 (42%)	9 (33%)	24 (38%)
Moderate	14 (39%)	10 (37%)	24 (38%)
Severe	3 (8%)	5 (19%)	8 (13%0
Unknown	1 (350	2 (7%)	3 (5%)
Physical findings (n, %)			
GCS on initial medical assessment			
15	37 (82%)	29 (88%)	65 (83%)
14	7 (16%)	2 (6%)	9 (12%)
13	1 (2%)	0 (0%)	1 (1%)
Irritable or agitated (n=80)			
Yes	5 (11%)	4 (12%)	9 (11%)
No	40 (87%)	30 (88%)	70 (88%)
Unknown	1 (2%)	0 (0%)	1 (1%)
Drowsy/difficult to wake			
Yes	10 (22%)	2 (6%)	12 (15%)
No	35 (76%)	32 (94%)	67 (84%)
Unknown	1 (2%)	0 (0%)	1 (1%)
Repetitive questions			
Yes	4 (9%)	3 (9%)	7 (9%)
No	41 (89%)	29 (85%)	70 (88%)
Unknown	1 (2%)	2 (6%)	3 (4%)
Slow to respond to speech			
Yes	11 (24%)	3 (9%)	14 (18%)
No	33 (72%)	29 (85%)	62 (78%)
Unknown	2 (4%)	2 (6%)	4 (5%)
Altered Mental Status			
Yes	9 (20%)	3 (9%)	12 (15%)
No	34 (74%)	30 (88%)	64 (80%)
Unknown	3 (6%)	1 (3%)	4 (5%)
Dispositions (n, %)			
CT performed in ED	10 (21%)	14 (41%)	24 (29%)
Discharged with neck brace	3 (7%)	5 (17%)	8 (11%)
Admitted to the ED observation unit	28 (60%)	22 (65%)	50 (62%)
Admitted to the ward	4 (9%)	2 (6%)	6 (7%)

CT=computed tomography; ED= emergency department; GCS= Glasgow Coma Scale; IQR= Interquartile range; LOC= loss of consciousness; RV=recreational vehicle.

Table 7. General demographics, sport participation and past medical history of patients attending the first follow up visit (information collected through parent reports).

Pre-Injury data (collected at T1)	**< 13 y** n=38	**≥ 13 y** n=30	**Total** n=68
Dominant hand, n (%)			
Left	3 (8%)	3 (10%)	6 (9%)
Right	35 (92%)	25 (83%)	60 (88%)
Both	0 (0%)	2 (7%)	2 (3%)
Sport at time of injury, n (%)			
Yes	17 (46%)	20 (67%)	37 (55%)
Type of sport at time of injury n (%)			
Football	5 (28%)	8 (40%)	13 (34%)
Basketball	3 (17%)	2 (10%)	5 (13%)
Cycling	1 (6%)	2 (10%)	3 (8%)
Other	8 (47%)	8 (40%)	16 (43%)
Playing sport regularly, n (%)			
No	5 (14%)	2 (7%)	7 (10%)
Once a week	6 (16%)	4 (13%)	10 (15%)
Twice a week	7 (19%)	5 (17%)	12 (18%)
3 times a week	7 (19%)	10 (33%)	17 (25%)
> 3 times a week	12 (32%)	9 (30%)	21 (31%)
Previous concussions, n (%)			
Yes	5 (13%)	13 (43%)	18 (26%)
Number of concussions in the past year, n (%)			
None	4 (11%)	4 (13%)	8 (12%)
1	1 (3%)	7 (23%)	8 (12%)
2	0 (0%)	2 (7%)	2 (3%)
Past hospital stay (any reason), n (%)			
Once	10 (26%)	10 (33%)	20 (29%)
More than once	9 (24%)	10 (33%)	19 (28%)
No	19 (50%)	10 (33%)	29 (43%)
Past admissions to intensive care (any reason), n (%)			
Yes	5 (13%)	2 (7%)	7 (10%)
No	33 (87%)	27 (90%)	60 (88%)
Unknown	0 (0%)	1 (3%)	1 (1%)
Diagnosis of migraine, n (%)			
Yes	2 (5%)	6 (20%)	8 (12%)
No	36 (95%)	24 (80%)	60 (88%)
Unknown	0 (0%)	0 (0%)	0 (0%)
Learning disability/dyslexia/ADHD, n (%)			
Yes	3 (8%)	3 (10%)	6 (9%)
No	33 (87%)	26 (87%)	59 (87%)
Unknown	2 (5%)	1 (3%)	3 (4%)
Depression, anxiety, psychiatric conditions, n (%)			
Yes	0 (0%)	4 (7%)	4 (6%)
No	37 (97%)	23 (77%)	60 (88%)
Unknown	1 (3%)	3 (10%)	4 (6%)
Depression, anxiety, psychiatric conditions in the family			
Yes	13 (34%)	11 (37%)	24 (35%)
No	24 (63%)	17 (57%)	41 (60%)
Unknown	1 (3%)	2 (7%)	3 (5%)
Motion sickness, n (%)			
Yes	9 (24%)	11 (37%)	20 (29%)

No	26 (68%)	17 (57%)	43 (63%)
Unknown	3 (8%)	2 (7%)	5 (8%)
Frequent vomit, n (%)			
No	30 (79%)	26 (87%)	56 (82%)
Once a year or less	6 (16%)	1 (3%)	7 (10%)
Once a month or less	1 (3%)	2 (7%)	3 (4%)
Once a week or less	0 (%)	0 (0%)	0 (0%)
Unknown	1 (3%)	1 (3%)	2 (3%)
Abdominal pain, n (%)			
No	18 (47%)	23 (77%)	41 (60%)
Once a year or less	7 (18%)	3(10%)	10 (15%)
Once a month or less	8 (21%)	3 (10%)	11 (16%)
Once a week or less	4 (11%)	1 (3%)	5 (7%)
More than once a week	1 (3%)	0 (0%)	1 (1%)
Troubles falling asleep, n (%)			
No	27 (71%)	19 (63%)	46 (68%)
Once a year or less	4 (11)	1 (3%)	5 (7%)
Once a month or less	2 (5%)	5 (17%)	7 (10%)
Once a week or less	3 (8%)	4 (13%)	7 (10%)
More than once a week	2 (5%)	1 (3%)	3 (4%)
Nightmares, n (%)			
No	22 (58%)	22 (73%)	44 (65%)
Once a year or less	7 (18%)	3 (10%)	10 (15%)
Once a month or less	6 (16%)	2 (7%)	8 (12%)
Once a week or less	3 (8%)	2 (7%)	5 (7%)
More than once a week	0 (0%)	1 (3%)	1 (1%)
Regular medications, n (%)			
Yes	0 (0%)	11 (37%)	11 (16%)
Unknown	0 (0%)	1 (3%)	1 (1%)
Protective gear at time of injury, n (%)			
Yes	5 (13%)	5 (17%)	10 (15%)

ADHD: Attention deficit hyperactivity disorder

A summary of parents' characteristics is reported in Table 8. The mother was the parent who most often responded to the questionnaires at the first follow up visit (79%). Most of the parents were between the age of 30 and 50 (91%) and English was the language spoken at home in 85% of cases.

The great majority of parents who attended the visit had a high-school or bachelor degree education (78%) and most of them were working (81%).

Table 8. Characteristics of parents of patients attending the first follow up visit.

Pre-Injury data (collected at T1)	**< 13 y** n=38	**≥ 13 y** n=30	**Total** n=68
Parent-related data*			
Parent responding to questions, n (%)			
Mother	32 (84%)	22 (73%)	54 (79%)
Parent age, n (%)			
20-30	1 (3%)	0 (0%)	1 (1%)
31-40	11 (29%)	5 (17%)	16 (23%)
41-50	23 (60%)	23 (77%)	46 (68%)
>50	3(8%)	2 (7%)	5 (7%)
Language spoken at home, n (%)			
English	30 (79%)	28 (93%)	58 (85%)
Other	8 (21%)	2 (7%)	10 (15%)
Parent education, n (%)			
Primary school	1 (3%)	0 (0%)	1 (1%)
High school	14 (37%)	12 (40%)	26 (38%)
Bachelor's degree/vocational training	17 (45%)	12 (40%)	29 (43%)
Postgraduate degree	6 (14%)	1 (3%)	7 (10%)
Other	0 (0%)	5 (17%)	5 (7%)
Family employment status, n (%)			
Working	31 (82%)	24 (80%)	55 (81%)
On a pension	1 (3%)	1 (3%)	2 (3%)
Keeping house	4 (11%)	1 (3%)	5 (7%)
Student	2 (5%)	2 (7%)	4 (6%)
Other	0 (%)	2 (7%)	2 (3%)

* refers to parent completing the questionnaire at T1

A total of 19 out of 59 patients (30%, 95% CI 21%-46%) who completed the 2-week (T2) assessment were identified as having clinically significant post-concussive symptoms and were invited to be reviewed in the Concussion Clinic at 1 month post-injury (T3). Of these, two had their follow up appointment due after the data collection cut-off date used for the purpose of the present analysis. Out of the 17 who had their T3 follow up due by the data analysis cut-off date, 13 attended their T3 appointment in the Concussion Clinic, 1 patient dropped out of the study and 3 patients completed the paper/on-line questionnaires at T3, as they could not present to their appointment.

The comparison of main pre-injury and injury-related characteristics in patients with clinically significant post-concussive symptoms (PCS) at 2 weeks versus asymptomatic/improving patients is reported in table 9.

Table 9. Comparison of pre-injury and injury-related characteristics between patients with clinically significant post-concussive symptoms (PCS) and those asymptomatic/improving at 2 weeks.

	Clinically significant PCS n=19	**Asymptomatic/ improving n=40**	**p**
Pre-injury characteristics			
Age (median, IQR)	11 (9-13)	11 (7.5-14)	0.994
Gender (M) (n, %)	12 (63%)	31 (78%)	0.247
Concussion in the past year (n, %)	3 (16%)	5 (13%)	0.730
Past hospital stay (n, %)	10 (53%)	24 (60%)	0.593
Past admission to intensive care (n, %)	1 (5%)	4 (10%)	0.294
Diagnosis of migraine (n, %)	3 (16%)	4 (10%)	0.521
Learning disability/dyslexia/ADHD (n, %)	2 (11%)	2 (5%)	0.616
Depression/anxiety/psychiatric condition (n, %)			
Patient	4 (21%)	0 (0%)	0.011
Family	8 (42%)	13 (33%)	0.515
Motion sickness (n, %)	6 (32%)	13 (33%)	0.255
Recurrent abdominal pain (n, %)			
Weekly	4 (21%)	2 (5%)	0.057
Frequent troubles falling asleep (n, %)			
Weekly	4 (21%)	6 (15%)	0.563
Frequent nightmares (n, %)			
Weekly	4 (13%)	9 (24%)	0.900
Injury-related characteristics			
Mechanism of injury (n, %)			
Road accident	3 (16%)	1 (3%)	0.058
Symptoms (n, %)			
LOC	3 (16%)	7 (18%)	0.870
Witnessed disorientation	7 (39%)	19 (49%)	0.441
Vomit	5 (28%)	9 (23%)	0.664
Amnesia	5 (26%)	15 (38%)	0.369
Headache	16 (84%)	30 (75%)	0.425
Physical findings (n, %)			
GCS < 15	4 (22%)	4 (10%)	0.247
Irritable or agitated	3 (17%)	3 (8%)	0.325
Drowsy/difficult to wake	2 (11%)	8 (20%)	0.365
Repetitive questions	0 (0%)	5 (13%)	0.107
Slow to respond to speech	5 (28%)	7 (18%)	0.432
Altered mental status	2 (11%)	7 (18%)	0.486
Dispositions (n, %)			
CT performed in ED	9 (47%)	12 (30%)	0.193
Discharged with neck brace	1 (6%)	6 (17%)	0.280
Admitted to the ED observation unit	13 (68%)	24 (60%)	0.532
Admitted to the ward	4 (21%)	1 (3%)	0.017

CT= computed tomography; ED= emergency department; GCS = Glasgow coma scale; IQR=interquartile range; LOC = loss of consciousness

Of the pre-injury characteristics only the rate of depression/anxiety/psychiatric conditions was significantly higher in symptomatic subjects, while a history of recurrent abdominal pain was borderline for statistical significance.

Among the injury-related characteristics the only difference found was a higher admission rate in symptomatic subjects. Being involved in a road accident showed a borderline statistical significance.

At 1-month post injury 16/19 patients significantly symptomatic at 2 weeks either attended the follow up appointment in the Concussion Clinic or completed the PCSI at home. Of these, 9 patients were still significantly symptomatic. However one of these patients sustained a second concussion between the T2 and T3 follow-up visits. The prevalence of clinically significant post-concussive symptoms in patients who completed the follow up procedures at 1 month was 20% (95% CI 10%-35%). A total of 5 patients were still significantly symptomatic at 3 months corresponding to 15% (95% CI 5%-32%) of patients who completed the follow up at that time point.

Recovery trajectories

Recovery trajectories are presented for symptom burden, balance, neurocognitive performance and health related quality of life. A detailed description of the tools used to assess these domains and their time of administration is reported in the Methods section. A brief summary is provided below to facilitate interpretation of the results presented in this section.

a) The Sport Concussion Assessment Tool (SCAT3) and ChildSCAT3 include child self-report age-based symptom scales, a rapid cognitive assessment tool and a balance assessment. These tools were administered by research staff at the time of ED presentation (T0), at 1-4 days following ED presentation (T1), at 2 weeks (T2) and at 3 months post injury (T4) for all patients. Only patients with clinically significant symptoms at T2 were reviewed in the Concussion Clinic at T3 and were administered the ChildSCAT3/SCAT3 at this time point. Patients who were asymptomatic or improving at T2 completed a paper or on-line questionnaire at T3 and were not administered the ChildSCAT3/SCAT3.

b) The Post Concussive symptom Inventory (PCSI) is a symptom scale that collects number and severity of post concussive symptoms. This scale was completed by patients and their parents at T1 (including retrospective completion of the pre-injury status), T2, T3 and T4 for all patients (independently of their symptoms at T2). Only the results of the parent report will be presented, as the child age-based form includes three different versions and results would have been too fragmented for the preliminary analysis.

c) The CogSport computerised neurocognitive test was administered by research staff during the assessment in the Concussion Clinic at T1, T2 and T4 to all study participants. As for the ChildSCAT3 and SCAT3 tools, this test was administered at T3 only to those patients who were significantly symptomatic at T2 and were reviewed in the Concussion Clinic at T3.

d) The Pediatric Quality of Life Inventory (PedsQL) was used to measure the health related quality of life and was completed by the child and the parent at T1 (intended to reflect pre-injury status), T3 and T4 for all patients (independently of their symptoms at T2).

a) *ChildSCAT3 and SCAT3*

The results of the ChildSCAT3 (for children younger than 13 years) and SCAT3 (for children older than 13 years) are reported separately for the following main components: (i) symptom scale; (ii) standardised assessment of concussion (SAC) and (iii) balance error scoring system (BEES). A detailed description of the ChildSCAT3 and SCAT3 tools is reported in the methods section. A brief description of the main items assessed is reported below to facilitate interpretation of the results.

The symptom scale included in the ChildSCAT3 is the Health Behavioral Inventory. This includes 20 items that can be scored on a 4-point scale from 0 to 3 for a maximum possible symptom severity score of 60.

The SCAT3 includes the Post Concussive Symptom Scale. This scale has a total number of 22 items that can be scored on a 7-point scale from 0 to 6 for a maximum possible symptom severity score of 132.

Both scales are patient self-reports.

The SAC score is equal to the number of correct answers to the orientation, immediate memory, concentration and delayed recall items. These items slightly differ for children younger and older than 13 years, but the maximum possible score is 30 in both age groups. A higher score represents a better performance.

The BEES score equals to the number of total errors made by the patient in the stances included in the test (double leg stance and tandem leg stance for children younger than 13 years, while an additional single leg stance is included for older children). A higher number of errors represents a worse performance. The maximum possible score is 20 for children younger than 13 years and 30 for older children.

The ChildSCAT3 and SCAT3 results are summarized in Table 10 and 11 respectively.

Table 10. ChildSCAT3 results for each study time point.

ChildSCAT3 (children <13 years)	**T0**	**T1**	**T2**	**T3**	**T4**
	ED	1-4 d post ED	2 weeks	1 month	3 months
All available results for each time point	n=40	n=37	n=33	n=7	n=14
			Median (IQR)		
Symptoms number	14(10.5-16)*	11(5-17)**	7(4-13)	11(0-14)	8(2-14)
Symptoms severity score	27 (18-30)	23 (7-31)	13 (4-24)	17 (0-27)	8.5(3-30)
SAC	21 (18-23)	23 (21-25)	25 (23-26)	26 (23-27)	22.5(21-26)
BESS	2 (1-4.5)#	4 (1-5)	2.5 (1-4)	1 (0-1)	3 (1-4)

* data available for 39 patients
** data available for 35 patients
# data available for 36 patients
BEES= balance error scoring system; ED = emergency department; IQR= interquartile range; SAC=standardised assessment of concussion

Pairwise comparison of medians of symptom numbers indicated that the biggest differences in medians were found between T0 and T2 and T1 and T2 ($p=0.002$ and $p<0.001$), showing a significant decrease in the number of symptoms between the first and second week post-injury. The same comparison performed for symptom severity showed the biggest differences between T0 and T2 ($p=0.002$), T0 and T4 ($p=0.015$), and T1 and T2 ($p=0.014$). These results show a significant reduction in symptom severity between the first and second week following the injury.

Children who were significantly symptomatic at T2 (2 weeks) and attended the T3 (1-month) follow up visit seemed to have a higher number and severity of

symptoms. However these were not significantly different from the symptom number and severity distribution at the other time points.

Pairwise comparison of medians for the SAC score found a significant improvement between T0 and T1, T0 and T2 and T1 and T2 ($p<0.001$ for all the three comparisons). These results show a progressive improvement in the SAC scores in the first two weeks following the concussion.

In contrast to the improvement in symptoms and SAC score, we found no evidence of individual differences between medians with respect to the BEES over time.

Table 11. SCAT3 results for each study time point.

SCAT3 (children ≥ 13 years) *All available results for each time point*	**T0** ED n=29	**T1** 1-4d post ED n=28	**T2** 2 weeks n=24	**T3** 1 month n=6	**T4** 3 months n=18
			Median (IQR)		
Symptoms number, median (IQR)	13(10-17)	9.5(5-14.5)	3.5(1-10.5)	11(0-14)	2(2-9)
Symptoms severity score, median (IQR)	45 (22-60)	12.5 (6.5-32)	0.5 (4-20.5)	33 (13-55)	2.5(0-13)
SAC, median (IQR)	24 (21-25)	24 (23-26)	26 (25-28)	26 (23-27)	25(23-27)
BESS, median (IQR)	7 (4-10)#	6 (3-7.5)	6 (3-7.5)	7 (2-10)	4 (1-6)

data available for 21 patients

BEES= balance error scoring system; ED=emergency department; IQR= interquartile range; SAC=standardised assessment of concussion

Pairwise comparison of medians indicated that the biggest differences were found between T0 and T2 ($p=0.002$), T1 and T2 ($p=0.003$), T0 and T4 ($p=0.002$) and T1 and T4 ($p=0.012$). These results show a significant reduction in symptom number between the first and second week after the injury that is maintained at 3 months post injury in the overall population. The same comparison performed for symptom severity showed the biggest differences between T0 and T1 ($p=0.002$), T0 and T2 ($p=0.001$) T0 and T4 ($p<0.001$). These results show a significant reduction in the severity of symptoms from the first days following the injury.

Children older than 13 years who were significantly symptomatic at T2 (2-weeks) and attended the T3 (1-month) follow up visit seemed to report a higher number of symptoms and symptom severity at T3, as well as a higher number of errors in the BEES. However these data were not statistically different from the other time points.

The pairwise comparison of SAC score medians found a significant improvement between T0 and T2 (p=0.003), T1 and T2 (p=0.001), with weaker evidence of difference also between T0 and T4 (p=0.016) and T1 and T4 (p=0.025). These results showed an improvement in the SAC scores between the first and second week post injury. The improvement was maintained at 3 months post injury in the overall population.

In contrast to the improvement in symptoms and SAC score and similarly to the younger age group, we found no evidence of individual differences between medians with respect to the BEES over time.

A graphic representation of the ChildSCAT3 and SCAT3 results is presented in Figures 3 and 4 respectively.

All the figures in this results section include box plot graphic summaries of a variable for the different study time points. A box-plot is a graphic representation of the distribution of a variable. The horizontal line inside the box represents the median of the distribution. The top and bottom lines of the box are the 25^{th} and 75^{th} quartile and represent the interquartile range (IQR). The ends of the whiskers are the lowest and highest data within 1.5 IQR of the lower and upper quartile.

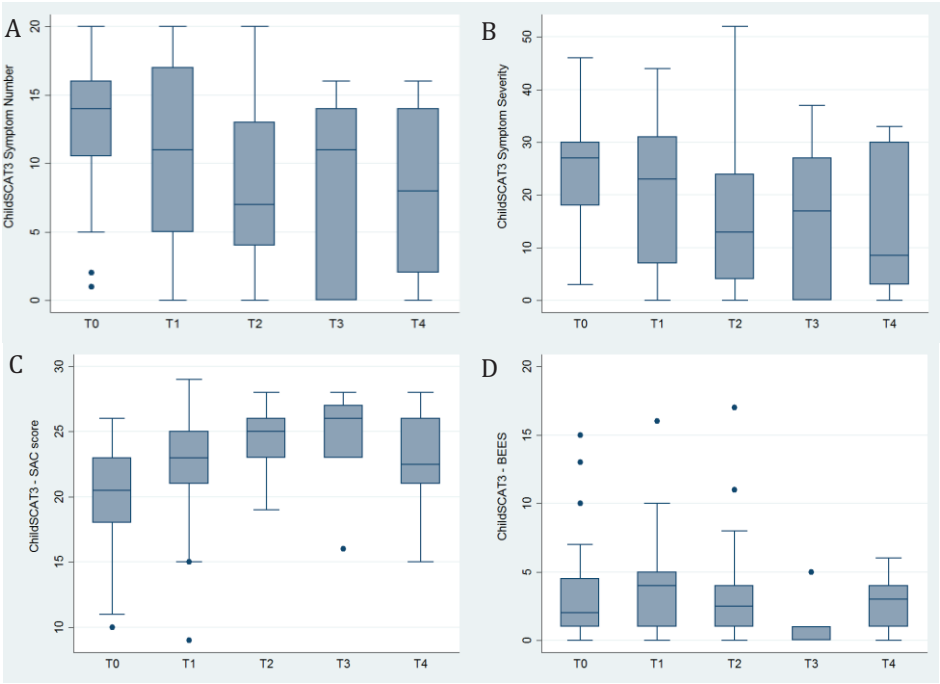

Figure 3. Box plots of each ChildSCAT3 main test for each time point. A = Symptom number; B = Symptom severity; C = Standardised Assessment of Concussion (SAC) score; D = Balance Error Scoring System (BEES).

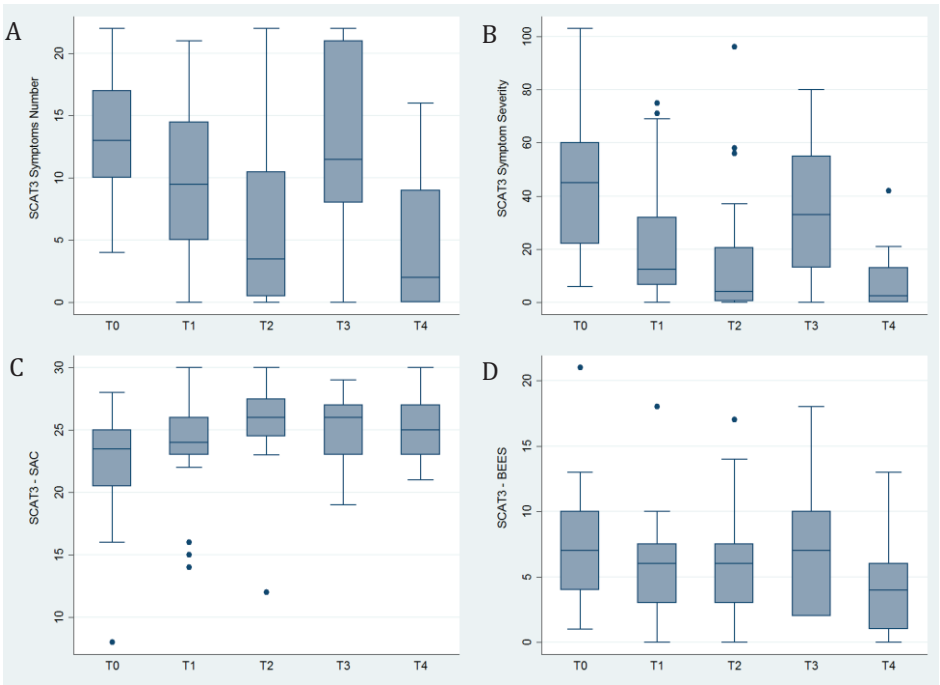

Figure 4. Box plots of each SCAT3 main test for each time point. A= Symptom number; B= Symptom severity; C=Standardised Assessment of Concussion (SAC) score; D= Balance Error Scoring System (BEES).

b) *PCSI parent report*

The PCSI version for parents does not differ with the child's age. This is a 20-item scale, where each item can be scored on a 7-point scale from 0 to 6, for a total possible maximum score of 120. It also includes a dedicated section to rate pre-injury symptoms retrospectively.

The results of the PCSI parent report are shown in Table 12, including separate T3 data for patients who were significantly symptomatic versus those who were asymptomatic/improving at T2.

Table 12. Summary of patients' symptoms as rated by parents in the PCSI at different study time points.

PCSI Parent Report	**Pre-Injury§**	**T1** 1-4 d post ED	**T2** 2 weeks	**T3** 1 month	**T4** 3 months
All available results for each time point	n=67	n=68	n=59	n=41	n=33
Number of symptoms, median (IQR)	3 (0-7)	9 (4-14.5)	3 (1-7)	2 (0-6)	3 (0-6)
Sum of Symptom Severity, median (IQR)	4 (0-13)	19 (6.5-37)	5 (1-11)	2 (0-10)	4 (0-10)

IQR= interquartile range; PCSI=post concussive symptom inventory
§retrospectively completed at T1

The pairwise comparison of medians indicated a very strong evidence of increase in symptom number and severity between the retrospectively rated pre-injury symptoms and the symptoms present at T1 ($p<0.001$ for both variables). There was a significant decrease in symptom number and severity between T1 and each following follow-up time point ($p<0.001$ for each comparison for both variables). These results show a significant peak in symptoms in the first week after the injury and a significant improvement following this time point in the overall population.

The graphic representation of the PCSI summary results for all patients at the different time points is reported in Figure 5. The T3 time point includes data of all patients, both those significantly symptomatic and those asymptomatic or improving at T2.

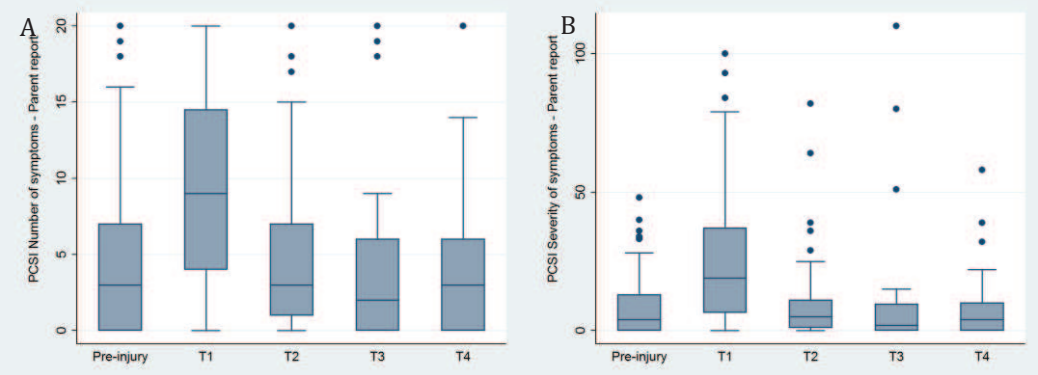

Figure 5. Box plots of symptoms number and severity according to the PCSI parent-report. A= Symptom number; B= Symptom severity.

c) *CogSport*

A detailed description of the CogSport test battery is reported in the methods section. Results are presented for each of the cognitive domains assessed by the four tasks of the test: processing speed, attention, learning and working memory. For processing speed and attention the outcome measure is the reaction time in millisecond. A shorter response time shows a better performance. For learning the outcome measure is accuracy in the response and a higher percentage shows a better performance. For working memory both reaction time and accuracy are reported.

All the results presented are the summary of each task raw data and are not corrected by age-based norms of healthy subjects. Age based norms are currently available only for children older than 9 years. Only results that passed the completion and integrity checks were used for analysis.

As the CogSport test battery did not differ according to the patient's age group the results are presented for the whole study population. A summary of the CogSport tasks results is shown in Table 13.

Table 13. Summary of CogSport battery results per cognitive domain for the different study time points.

CogSport	T1 1-4 d post ED	T2 2 weeks	T3 1-month	T4 3 months
*All available results for each time point**				
Processing speed (milliseconds)	n=57	n=47	n=11	n=31
Median	363.7	372.2	419.6	345.9
IQR	(307.9-454.5)	(318.4-473.3)	(368.5-478.8)	(311.9-419.4)
Attention, speed (milliseconds)	n=59	n=52	n=11	n=31
Median	611.6	616.7	660.1	625.1
IQR	(526.5-763.8)	(545.9-768.1)	(613.6-773.9)	(504.9-720.1)
Learning, accuracy (%)	n=59	n=53	n=12	n=30
Median	67.4%	72.1%	73.8%	71.8%
IQR	(57.1-76.2)	(64.3-78.6)	(65.8-82.3)	(64.3-78.6)
Working memory				
Speed (milliseconds)	n=55	n=48	n=10	n=26
Median	928.7	885.5	1009.7	759.4
IQR	(709.7-1099.8)	(693.7-1053.1)	(745.0-1133.7)	(685.5-899.5)
Accuracy (%)	n=55	n=48	n=10	n=26
Median	93.9%	93.9%	91.2%	96.9%
IQR	(86.1-1)	(89.9-96.9)	(83.8-96.9)	(91.2-1)

*Only valid results included (completion and integrity checks passed)
IQR Interquartile range

The pairwise comparison of medians for each task indicated a significant worsening in the processing speed at T3 (subjects who were identified as having clinically significant post-concussive symptoms at T2), compared with the results of the overall population at each of the other time points (p=0.077 for comparison with T1, p=0.028 for comparison with T2, and p=0.012 for comparison with T4).

There was also a strong evidence of improvement in the learning task from T1 to T2 (p=0.007). There was weak evidence of improvement in the working memory processing speed at T4 compared to T3 (p=0.024), and a weak evidence of worse performance in the attention task at T3 in symptomatic subjects, compared with the overall population at T2 (p=0.028). No differences were found in the performance of the attention, learning and working memory tasks between other time points.

The graphic representation of the CogSport summary results per cognitive domain across the different study time points is reported in figure 6 for all study patients.

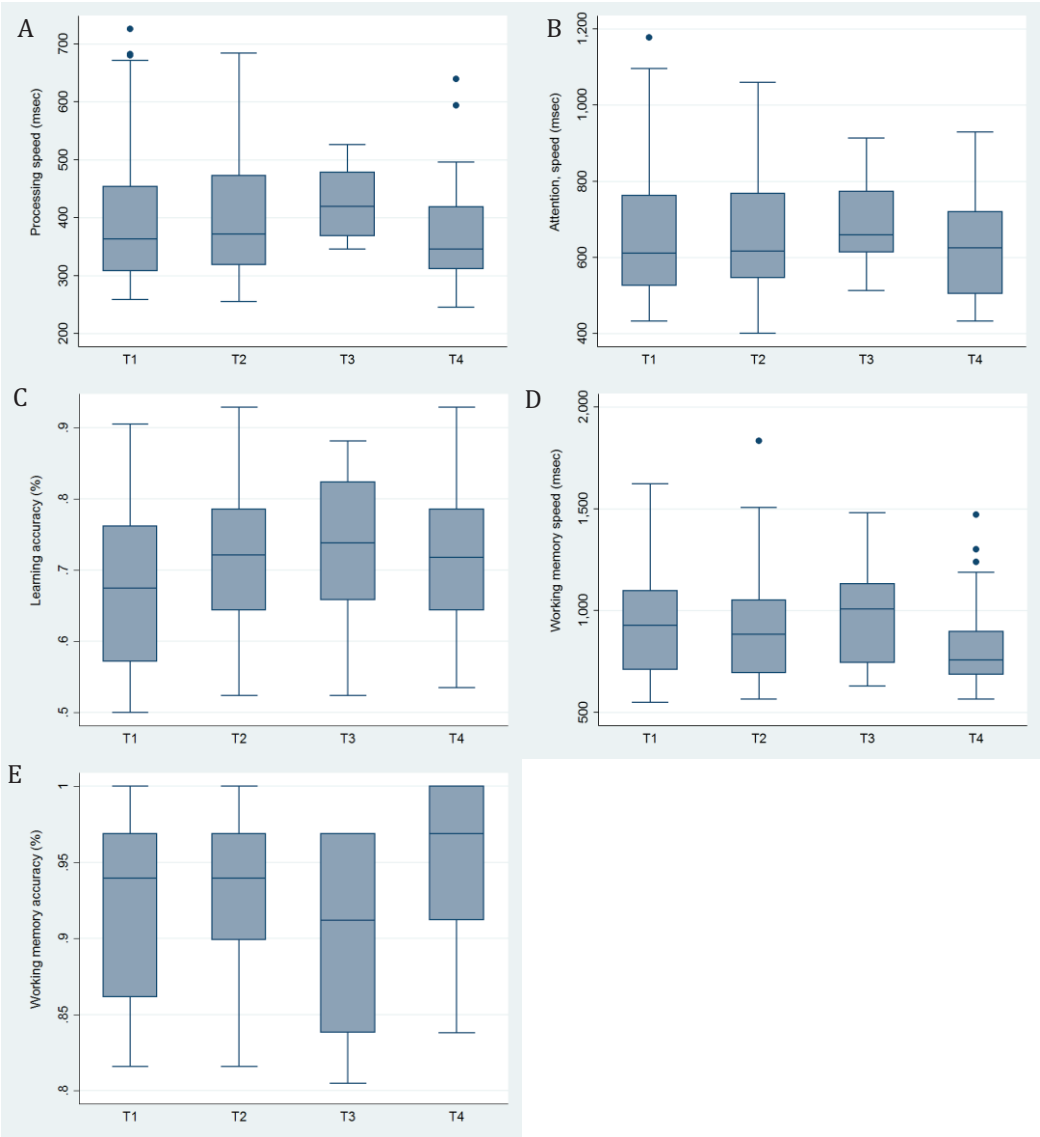

Figure 6. CogSport summary results for each cognitive domain for the different study time point. A= Processing speed; B= Attention speed; C=Learning accuracy; D= Working memory speed; E= Working memory accuracy.

A sub-analysis of patients who had complete CogSport data at T1, T2 and T4 satisfying both the integrity and completion checks for each task (n=21) showed only a significant improvement in the learning domain between T1 and T2, but no difference in the other tasks at every time point.

d) *PedsQL*

The PedsQL results for the total generic score over time are presented in table 14.

Table 14. PedsQL results at the different study time points.

PedsQL	**Pre-injury§**	**T3** 1 month	**T4** 3 months
Child self report	n=68	n=44	n=33
Median	83.7	91.3	91.3
IQR	(71.7-91.3)	(75.0-97.8)	(76.1-97.8)
Parent proxy report	n=58	n=44	n=32
Median	85.4	85.9	93.0
IQR	(78.3-93.5)	(71.6-94.6)	(78.8-96.2)

§ retrospectively completed at T1 (respondents had to indicate how much each item had been a problem in the month prior to the injury)
IQR= interquartile range

The pairwise comparison of medians found no difference in the PedsQL scores at the different time points for both parent and child reports.

The comparison of all the study tests between subjects who were identified as having clinically significant symptoms and those asymptomatic/improving at 2 weeks is presented in Table 15 and Table 16 for each study time point at which the tests were administered.

Table 15. Comparison of results of ChildSCAT3, SCAT3, and CogSport at each time point between subjects with clinically significant symptoms and those asymptomatic/improving at 2 weeks.

8	T0			T1			T2			T3			T4		
	PCS+	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**
ChildSCAT3	n=10	n=21		n=11	n=22		n=11	n=23		n=7			n=6	n=8	
Symptom number	17 (9-18)	13(11-15)	0.397	13 (9-19)	6 (2-11)	0.164	9 (5-13)	6 (1-14)	0.242	11 (0-14)	NA	NA	12 (7-14)	3 (1-13)	0.268
Symptom severity	28 (18-33)	27(19-30)	0.703	24(15-38)	20 (9-28)	0.183	14 (8-27)	8 (1-24)	0.267	17 (0-27)	NA	NA	13 (7-30)	4 (1-24)	0.331
SAC	20 (15-22)	21(19-24)	0.320	24(22-26)	22(21-25)	0.310	26(22-26)	25(23-26)	0.928	26 (27-30)	NA	NA	22(20-25)	23 (21-26)	0.434
BESS	1 (0-3) §	3 (1-5) §	0.081	4 (2-6)	4 (1-5)	0.700	2 (1-7)	3 (1-4)	0.911	1 (0-1)	NA	NA	2 (0-3)	3 (2-4)	0.291
SCAT3	n=5	n=16		n=7	n=17		n=7	n=17		n=6			n=5	n=12	
Symptom number	13 (12-17)	13 (8-19)	0.772	11(10-21)	9 (5-16)	0.123	17 (5-20)	2 (0-5)	**0.005**	11 (0-14)	NA	NA	6 (1-9)	0 (0-6)	0.181
Symptom severity	54 (37-63)	35(21-56)	0.409	26(20-71)	12 (7-24)	**0.059**	37 96-58)	3 (0-5)	**0.004**	33 (13-55)	NA	NA	13 (2-13)	0 (0-8)	0.164
SAC	24 (24-26)	23(20-25)	0.361	23 15-25)	24(23-27)	0.102	26(24-27)	26 (25-28)	0.585	26 (23-27)	NA	NA	25 (25-26)	25 (23-27)	0.521
BESS	12 (2-21) §	7 (5-10) §	0.854	6 (3-10)	6 (3-7)	0.686	7 (4-14)	6 (2-7)	0.370	7 (2-10)	NA	NA	6 (4-6)	3 (0-4)	0.135
CogSport*															
				n=14	n=34		n=13	n=34		n=11			n=11	n=19	
Processing speed (ms)	NA	NA	NA	364 (328-501)	365 (311-454)	0.570	403 (346-428)	350 (313-479)	0.366	419 (369-479)	NA	NA	361 (312-430)	338 (308-419)	0.254
				n=16	n=36		n=16	n=36		n=11			n=11	n=19	
Attention (ms)	NA	NA	NA	629 (527-841)	618 (547-767)	0.706	635 (578-790)	613 (527-747)	0.538	660 (614-774)	NA	NA	634 (500-795)	594 (505-720)	0.651
				n=14	n=38		n=18	n=35		n=12			n=11	n=18	
Learning (%)	NA	NA	NA	64 (57-76)	67 (57-74)	0.796	69 (62-76)	74 (64-79)	0.665	74 (66-82)	NA	NA	69 (57-72)	75 (67-79)	0.075
Working memory				n=14	n=34		n=15	n=33		n=10			n=10	n=15	
speed (ms)	NA	NA	NA	859 (696-1087)	919 (710-1129)	0.717	952 (740-1065)	884 (684-1041)	0.556	1010 (745-1134)	NA	NA	781 (699-938)	760 (657-900)	0.824
accuracy (%)	NA	NA	NA	93 (84-97)	94 (86-97)	0.497	94 (89-94)	94 (91-97)	0.367	91 (84-97)	NA	NA	94 (86-97)	97 (91-100)	0.444

* Only valid results included (completion and integrity checks passed)

§ Possible for 8 patients in the PCS+ group and 19 patients in the PCS- group 2 for the ChildSCAT3; possible for 2 patients in the PCS+ group and 12 patients in the PCS- group for the SCAT3

BESS= balance error scoring system; ChildSCAT3= Sport Concussion Assessment Tool version 3 for children younger than 13 years; NA= not applicable; PCS+= clinically significant post concussive symptoms at 2 weeks; PCS - = asymptomatic/improving at 2 weeks; SAC= standardised assessment of concussion; SCAT 3= Sport Concussion Assessment Tool version 3 for children aged 13 years and above

Table 16. Comparison of results of PCSI (parent report) and PedsQL (child and parent report) at each time point between subjects with clinically significant symptoms and those asymptomatic/improving at 2 weeks.

	Pre-injury*			T1			T2			T3			T4		
	PCS+	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**	**PCS+**	**PCS -**	**p**
	n=19	n=40		n=19	n=40		n=17	n=40		n=16	n=27		n=12	n=20	
PCSI parent report															
Symptom number	4 (1-8)	4 (0-8)	0.251	15 (7-19)	9 (5-13)	**0.034**	6 (4-14)	2 (0-6)	**0.000**	5 (0-18)	2 (0-6)	0.229	3 (1-17)	4 (1-5)	0.454
Symptom severity	7 (1-18)	5 (0-11)	0.168	53 (10-67)	18 (7-32)	**0.038**	12 (8-36)	2 (0-9)	**0.000**	6 (0-37)	2 (0-6)	0.116	3 (1-27)	5 (1-9)	0.651
PedsQL															
Child report	78 (67-90)	85 (72-92)	0.205	NA	NA	NA	NA	NA	NA	68 (55-89)	96(90-100)	**0.000**	83 (69-92)	97 (81-100)	**0.021**
Parent report	84 (67-95)	85 (78-95)	0.720	NA	NA	NA	NA	NA	NA	71 (55-82)	89 (79-95)	**0.002**	91 (56-96)	94 (79-98)	0.444

* Completed retrospectively at T1

NA= not applicable; PCS+= clinically significant post concussive symptoms at 2 weeks; PCS - = asymptomatic/improving at 2 weeks; PCSI= post concussive symptom inventory

Subjects who were identified as significantly symptomatic at T2 had higher scores in symptom number and severity on the PCSI parent report at T1. There was also a borderline significance for symptom severity at T1 as rated in the post-concussive symptom scale of the SCAT3 for children aged 13 and older. Self-rated symptom number and severity scores on this scale correlated with the results of the PCSI parent form, as shown by the significantly higher scores reported in symptomatic subjects at T2. In contrast, no difference was noted in the scores of the self-rated health behavioural symptom inventory scale included in the ChildSCAT3.

No difference between significantly symptomatic and asymptomatic/improving patients at 2 weeks was noted on the SAC and BESS scores at any time point. Similarly non difference was found for any of the CogSport tasks between the two groups at any time point.

Children with significant symptoms at 2 weeks showed significantly worse scores on the self-rated PedsQL scale at 1 and 3 months post-injury, while a similar difference was found only at 1 month for the parent report. There was no difference in the pre-injury scores between the two groups according to both the child and parent report. PedsQL scores significantly improved between the 1-month and 3-month assessments according to child report ($p=0.031$), while this difference was not found for the parent report ($p=0.071$).

DISCUSSION

The preliminary results of our pilot study provides useful information to assess the feasibility for the larger study and to identify challenges and opportunities for improvement. From a clinical perspective we found that the majority of children recovered within 2 weeks post injury, with no difference between children younger and older than 13 years. Clinically significant post-concussive symptoms were identified in nearly one third of patients at 2 weeks and halved at 3 months. Children with clinically significant symptoms at 2 weeks showed a worse health related quality of life (HRQOL) at 1 and 3 months post injury.

With regards to feasibility we could estimate the recruitment rate for the larger study to be between 41% and 57%. This is lower compared to previous

longitudinal studies on concussion or mild traumatic brain injury (TBI) that recruited patients in the ED, but included only telephone interviews or online questionnaires as part of the follow-up procedures.[13,15,43-45] As most parents reported follow-up study procedures to be too time consuming as a main barrier to study participation, it may be worth including the option of on-line and telephone interview completion of questionnaires in the future. It is unclear why the proportion of refusal to participate increased during stage 3, when recruitment hours were extended to include research staff cover until 10 pm. Patients and parents approached during the evening hours may be more tired and thus less receptive and less inclined to commit to research projects. Possible strategies to address this challenge in the future may include a follow-up telephone call 24 hours post discharge to provide better explanations on the study procedures and/or answer the questions that parents may have on the information statement provided in the ED.

Almost one third of eligible patients were assessed or presented between 10 pm and 10 am, outside the study recruitment hours. Targeted education to improve engagement of clinical staff in the ED may be beneficial to provide patients with initial information on the study and ask for consent for telephone approach by research staff within 24 hours from discharge.

In addition, approximately one third of patients during stage 3 were missed because of screening challenges. Regular updates with review of missed case presentations were circulated among research staff in order to improve identification of eligible patients. Continuous education of clinical staff with respect to concussion definition and reminders on the project is essential to help minimize miscommunication and avoid missed opportunities for case identification. Suboptimal training in concussion recognition and management, as well as ambiguity with terminology and definitions used by clinicians is well recognised in the medical literature.[46-48]

Approximately two thirds of the enrolled patients completed the study procedures. Our completion rate is lower compared with the 80-90% of previous longitudinal studies including telephone interviews or on-line questionnaires only,[13,15,22,45] but similar to studies including follow up visits.[49] The highest rate of patient drop out was recorded at T1. Reasons reported by parents of patients who dropped out at T1 included transport related issues, family organization issues or

not realizing how much of a commitment the study was at the time of the approach in the ED. Early telephone contact within 24 hours after discharge may help in rearranging the first follow-up appointment on a date and time that best suits family commitments and obligations in order to facilitate retainment in the study.

Similarly to previous paediatric studies on head injury and TBI, our sample was characterised by a male predominance; falls were the most common mechanism of injury and a considerable proportion was sport-related.[13,16,44,50] As previously found in our study assessing compliance with on field concussion management and return to play guidelines (section 6.2.6), football was the sport most commonly involved. Less than 10% of children in our sample sustained a concussion as a result of a road traffic accident. However this type of mechanism seemed to be associated with the presence of clinically significant symptoms at 2 weeks. Albeit our limited numbers do not allow for definitive conclusions, it is reasonable to believe that a post-traumatic distress symptom component may contribute to symptom duration in these children and this should be investigated further in the future.

Almost one third of the study subjects underwent a CT scan in the ED. This rate is almost three times that recorded at our institution for the whole population of children assessed for any head injury in the ED.[2] Older children had a significantly higher CT scan rate despite reporting similar symptom and GCS to younger children. It is unclear what factors might have played a role in this decision making, whether the mechanism of injury was perceived as more severe or whether symptoms worsened during the stay in ED. For the larger study we should collect information on the symptom progress during the ED stay, to investigate whether not only the symptom burden, but also the duration and progress in the ED might play a role in predicting delayed recovery.

A history of previous concussion in the past year was present in 15% of the overall study subjects, with a significantly higher rate in older children (30%). These data are similar to those reported by Eisemberg et al.[44] in patients between 11 and 22 years of age presenting to the ED with an acute concussion. They found that patients with a previous concussion in the past year had nearly 3 times the median duration of symptoms compared with those who had no previous concussion, or whose more recent concussion occurred > 1 year prior. However, our preliminary

results did not show an association of a history of concussion in the past year with presence of clinically significant post-concussive symptoms at 2 weeks.

Almost one third of the study population suffered from motion sickness, slightly more than 10% suffered from migraine and less than 10% suffered from vomiting or abdominal pain on a weekly basis. This information was collected to explore whether recurrent symptoms may influence post-concussive symptom duration. It has been shown that a history of motion sickness, or recurrent headache in children or their family is associated with post-traumatic vomiting following a head injury.[51] Cyclic vomiting syndrome and motion sickness are examples of abnormal activation of the vomiting centre; the threshold of the vomiting centre might be lower in these affected patients. In children with cyclic vomiting, trauma has been reported as a precipitating factor of attacks, in addition to stress and intercurrent infections.[52] Similarities between recurrent vomiting and other recurrent symptoms, such as motion sickness and migraine, have been described, on the basis of parallel temporal patterns, associated symptoms, positive family history of migraine, and the strong association of these symptoms or the progression from one to another within the same individuals.[53,54] Whether a history of recurrent symptoms may exacerbate post-concussive symptoms has not been explored yet. In our sample the only recurrent symptom that seemed to have a higher prevalence in children with clinically significant symptoms at 2 weeks was abdominal pain. Somatization and psychological co-morbidies, such as anxiety and depression, are often recognised as a cause of recurrent abdominal pain in children and adolescents[55] and may contribute to exacerbating post-concussive symptoms. The actual strength of association between recurrent symptoms and post-concussive symptoms duration and burden will be better investigated in the larger study.

Data on previous hospital stay and intensive care admission was collected to investigate the possible influence of previous traumatizing hospital experience on development of significant post-concussive symptoms. Surprisingly more than 50% of our sample had previously received care in hospital at least once and 10% of patients were admitted to intensive care in the past. The reasons of previous admissions to hospital and the age at admission were not systematically collected. However we found no difference in the rate of previous admissions, including

intensive care, between children with clinically significant symptoms and those asymptomatic/improving at 2 weeks.

The only pre-injury characteristic that was associated with being significantly symptomatic at 2 weeks was a personal history of depression, anxiety or psychiatric conditions. This is consistent with existing literature.[26] In contrast with previous studies we found no difference in age between significantly symptomatic and asymptomatic/improving children at 2 weeks. Conflicting evidence exists on the role of age on duration of post-concussive symptoms,[13-15,20,44] with some recent studies suggesting a more prolonged recovery in adolescents compared to younger children. [15,44]

Of the injury-related characteristics only being admitted to the ward for the concussion was significantly associated with the presence of clinically significant symptoms at 2 weeks. This suggests that more severe clinical symptoms during the acute phase following a concussion may be associated with delayed recovery. Admission to the ward may be considered a proxy marker of clinical severity of symptoms that reflects progression over time, which cannot be captured with a single administration of the ChildSCAT3/SCAT3 in the ED.

Our preliminary analysis showed that while the majority of children completely recovered or significantly improved within 2 weeks post injury, almost one third had clinically significant symptoms at 2 weeks. In adults, collegiate and high school athletes, symptoms have shown to generally resolve in 7-10 days.[56-59] Only limited research on recovery trajectories in the first 2 weeks post injury exists in children. Results of the few available studies are consistent with our findings and showed a marked reduction in symptoms at 1 week post-injury.[44,49] Studies that assessed post-concussive symptoms in children with mild TBI or concussion in the longer term found variable results, with a proportion between 10% and 30% of patients still symptomatic at 1 and 3 months post injury.[13,15,16,43,44] These data are similar to what we found in our study.

Ours is the first study to have used the ChildSCAT3 and SCAT3 tools for repeat post-injury assessments over time. Our results showed a trend towards higher symptom number and severity at 1 month for children who were significantly symptomatic at 2 weeks. However the difference was not significant. While the child SCAT3 symptom scale showed a significantly higher number and

severity of symptoms in subjects with clinically significant symptoms at two weeks, the same was not true for the symptom scale used in the ChildSCAT3 for younger children. Variability of results when using different symptom rating tools is well recognized in the literature and highlighted as a barrier to compare results of existing research on concussion.[17] Collection of information from the younger age group is especially challenging due to their different developmental level and use of age-appropriate tools is essential. However, information reported by children needs to be complemented by the parent perspective in order to properly assess the burden of symptoms, especially in the younger age group. It has been shown that parents and children display modest to moderate agreement when reporting post-concussive symptoms. Lower agreement may result from parents' unawareness of certain symptoms, or from unwillingness or inability of children to verbalize particular symptoms.[60] The performance of a clinical assessment by medical staff experienced in the management of concussion, in conjunction to the use of reliable and validated symptom collection tools is essential in order to correctly interpret the burden of symptoms reported by children and their parents.

A significant improvement on the SAC scores was found between the time of assessment in ED and 2 weeks post injury for both children younger and older than 13 years, with stable performance thereafter. This is consistent with previous studies that demonstrated the usefulness of the SAC tool to detect immediate effects of concussion in adults.[33,34]

According to our preliminary results we could not document obvious neurocognitive impairment related to symptom burden for most of the domains assessed by the CogSport test battery, with no significant change in the tests performance over time. Processing speed at 1 month of subjects with clinically significant symptoms at 2 weeks was worse compared with the overall population at the other time points, while learning accuracy significantly improved from T1 to T2 and remained stable thereafter. The use of raw data as well as the statistical analysis used may not have allowed the detection of more subtle neurocognitive changes. Comparison of results with baseline pre-concussion testing remains the optimal method to assess concussion-related cognitive impairment.[61] In the absence of baseline tests comparison with age-based norms can be used. However, no normative data were available for children younger than 9 years at the time of

the present study. These are expected to be published by the end of 2014, allowing for corrected analysis based on age-based norms in the final study dataset

Studies in adults using the BESS have identified acute postural stability deficits lasting approximately 72 hours following sport-related concussion.[26] This test has been shown to be reliable and valid in adults to objectively assess the motor domain neurological functioning after a concussion.[35] Our results showed no statistically significant improvement in the BESS over time for both children younger and older than 13 years. However the BESS score was missing at T0 for nearly 30% of the study subjects. Half of these did not have the whole SCAT3/ChildSCAT3 performed because either no research staff was available or the patients were too unwell to undergo the test; the other half was able to complete all the other ChildSCAT3/SCAT3 items but the BESS, because either they were too unwell to stand (e.g. having headache) or they had to adhere to spinal precautions during the time when research staff was available to do this test.

Our results showed no significant variation of health related quality of life (HRQOL) over time and compared to pre-injury rating in the overall population. These results were consistent for both the child and the parent reports. However patients who had clinically significant post concussive symptoms at 2 weeks post-injury had a significantly worse HRQOL at 1 and 3 months post injury compared with subjects who were asymptomatic or improving at 2 weeks. Similar results were found for the parent report at 1 month, but not at 3 months. Analysis of the pre-injury scores found no difference between these two groups of patients for both the child and parent reports. These preliminary results suggest that the symptom burden, rather than pre-injury functioning, may contribute to a worse HRQOL at 1 and 3 months post injury in subjects who still experience significant symptoms at 2 weeks. This is also supported by the significant improvement at 3 months, when the symptom burden is further decreased.

Previous research on HRQOL following traumatic brain injuries (TBI) in children has mainly focused on the moderate and severe end of the spectrum.[62-65] The findings from these studies showed that most of the deficits are noticeable within a year and tend to improve over time, with persistent long-term impairment being more common in severe cases[64,66] Only limited literature has specifically evaluated HRQOL in the mild TBI spectrum,[67-69] while no study has selectively assessed

HRQOL in children with concussion according to the Zurich Consensus Statement definition.[26] Available studies used different definitions of mild TBI, different tools to assess the HRQOL, with some of them only including the parent report.[67-69] Similarly to our results the studies by Petersen at al.[67] and Pieper et al.[69] found no significant changes of HRQOL at different time points post-injury and from pre-injury ratings. Only the study by Moran et al.[68] assessed the impact of post-concussive symptoms on HRQOL. Similar to our results they found that higher levels of post-concussive symptoms shortly after injury were associated with lower HRQOL at 3 months post injury in children with mild TBI. This association was maintained at 12 months post-injury showing that children who experience higher levels of post-concussive symptoms after mild TBI are at risk for significant lasting declines in HRQOL. However their study population was characterized by a higher spectrum of severity, including only patients with a GCS of 13 and 14, as well as patients with intracranial injuries on neuroimaging not requiring neurosurgical intervention. They also used different tools for the assessment of post-concussive symptoms and HRQOL and included only the parent report. In contrast to our findings, and in line with other research from the same group,[70] their study found that pre-injury HRQOL was a stronger predictor of post-injury HRQOL than either post-concussive symptoms or mild TBI. Their results suggest that pre-injury functioning strongly influences the post-injury HRQOL. However our results are based on a small number of patients and do not allow us to draw definitive conclusions on this matter.

Despite these differences, both our results and Moran's[68] support that intervention is indicated for children who display significant post-concussive symptoms.

Study strengths and limitations

In our study we used a clinically relevant outcome to measure not only the presence and severity of post-concussive symptoms, but also their impact on patient's life in between the assessments. The study outcome was assigned by medical staff experienced in the management of concussion during the assessment in the Concussion Clinic, after reviewing symptom scale ratings compared to pre-injury scores and information collected through a clinical interview. The simple rating of the number and severity of symptoms at given time points, although

useful in monitoring progression over time, may not be as accurate in reflecting the actual burden of symptoms for the patient and their family in between the assessments. Our clinically oriented outcome was used to decide which children needed to be reviewed in the Concussion Clinic at 1 month post-injury. By using this outcome we will be able to develop a clinical decision rule able to identify not only children with persistent symptoms, but especially those who will mostly benefit from early follow-up in a dedicated Concussion Clinic. Patients who were still symptomatic compared to the pre-injury level, but whose symptoms significantly improved in the two weeks post-injury were not classified as having clinically significant symptoms at T2. They were asked to contact the clinic if any worsening in symptoms was noted over the following 2 weeks. None of these patients contacted the clinic for a review and all returned to their pre-injury status according to their 1-month questionnaire.

Our study has several limitations. The low recruitment rate and the high drop-out rate may lead to selection bias. The differences in the characteristics of enrolled patients compared with missed patients, patients who refused to participate and patients who droped out has not been analysed as part of the pilot results presented in this thesis, but will be calculated for the final dataset. Selection bias has implications for generalizability of our results.

The retrospective collection of pre-injury data might be subject to recall bias. However, this information has been obtained only a few days after the injury, thus reducing the chances of possible recall bias. To further minimize this possibility in the future, questionnaires on pre injury data may be administered at the time of the ED assessment.

We did not include a control group of children with extra-cranial injuries. However previous studies including control groups of children with minor orthopaedic injuries consistently showed a higher rate and duration of post-concussive symptoms in children with mild TBI, validating post concussive syndrome as a diagnosis apart from other forms of recovery from trauma.[13,14,16,49,71]

Approximately 15% of the study population did not have the ChildSCAT3/SCAT3 at the time of ED presentation. This was related either to unavailability of research staff at the time of presentation or to patients being too unwell to do the test. In addition another 15% of patients were not able to complete the BESS score,

because either they felt to unwell to stand or they had to adhere to spinal precautions at the time when research staff was available to do the test. This limitation is intrinsic to studies conducted in an ED setting, and reflects the more severe spectrum of concussion assessed in the ED compared to the sport field.

Finally, results of subdomains of the PedsQL questionnaires were not analysed as part of this preliminary analysis. Understanding the trend and possible differences in the physical, psychosocial and cognitive fatigue domains will provide further insight on the impact of symptom burden and specific type of symptoms on HRQOL, thus allowing for planning of targeted effective interventions. These data will be analysed as part of the final analysis on the complete study dataset.

CONCLUSIONS

This pilot study provided important data on the feasibility of a larger study, identifying opportunities for improvement, estimating the prevalence of the study outcome for sample size calculation purposes and exploring recruitment and completion rates to better estimate the duration of the final study.

Despite the majority of children recovering within two weeks from their concussion, approximately one third suffered clinically significant post-concussive symptoms that halved at 3 months post-injury. While improvement on the rapid neurocognitive assessment was clearly noted within two weeks from the concussion, the pattern of recovery on neurocognitive computerized testing and postural stability needs to be explored further. Patients with clinically significant post-concussive symptoms showed a worse health related quality of life at 1 month post-injury that improved with symptom resolution.

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6.2.8 Recreational vehicle-related head injuries and helmet use

To be submitted

Bressan S, Daverio M, Barker R, Babl FE. Epidemiology, helmet use and characteristics of children presenting to the Emergency Department for recreational vehicle-related head injuries.

Epidemiology, helmet use and characteristics of children presenting to the Emergency Department for recreational vehicle-related head injuries

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ABSTRACT

Objective: Recreational vehicles (RV) are an important cause of head injuries (HIs) in children. Helmet use is an established preventative strategy that has been mandated in a variety of settings to reduce HI severity when riding an RV. Information regarding RV-related HIs and helmet use in the paediatric population is scarce. This study examined the use of helmet and characteristics of children presenting to the Emergency Department (ED) with a RV-related HI.

Study Design: Retrospective study conducted in a tertiary care ED including children who presented with an RV-related HI between April 2011 and January 2014.

Results: Of 8,469 HIs of any cause, 647 (7.6%) were RV-related. Bicycles were the most commonly involved (36.3%), followed by push-scooters (18.5%), motorcycles (18.4%), horses (11.7%), skateboards (11.6%), all-terrain vehicles (2.8%) and go-karts (0.6%). Motorized vehicles were associated with a higher need for neurosurgery (5.7% vs. 1.2%, p=0.001). Helmet use was documented in 85.3%, with a positive use in 66.7%. The highest rates of documentation and use were recorded for

motorcycles (97.5% and 83.2%), horses (92.1% and 82.9%) and bicycles (94.5% and 65.1%). Computed tomography and neurosurgery rates were higher in non-helmeted children (37.0% vs. 20.1%, $p<0.001$, and 5.4% vs. 0.8%, $p<0.001$, respectively).

Conclusion: Helmet documentation and use varied by RV with highest rates amongst children riding motorcycles or horses. Motorized RVs accounted for a small proportion of cases overall, but the majority of neurosurgical interventions. Helmet use was associated with less severe HIs and should be encouraged through legislative and social marketing strategies.

INTRODUCTION

Head injury (HI) is one of the most common reasons for presentation to the paediatric Emergency Department (ED) and the leading cause of death and disability in children older than 1 year.[1] Trauma associated with the use of recreational vehicles (RV), defined for the purposes of this paper as a motorcycle, all-terrain vehicle (ATV), go-kart, bicycle, scooter, skateboard, or horse, represents a growing cause of HIs and therefore a public health concern.[2-5]

Of all the RV-related injuries, HI in both adults and children, is associated with the highest rates of admission, long-term disability and death.[3,5-8] Helmet use reduces the risk of death and severe head trauma in both non-motorized (e.g. bicycles,[6,9-11] and horses[12,13] and motorized (e.g. motorcycles[14] and 'all-terrain vehicles'[2,4,15,16] RVs-related incidents. As such, RV-related helmet use in Australia is mandated across a spectrum of activities and settings and in a variety of ways. The state of Victoria in Australia was the first state in the world to introduce a mandatory motorcycle helmet law for road users in 1961.[17] This state law was later superseded by the Australian Road Rules, a nationally standardised set of road use regulations that are regularly revised and enacted into legislation across all states

and territories in Australia.[18] In 1990 the Helmet law became mandatory also for cyclists and their passengers.[19] For the purpose of the Australian Road Rules, a person in or on a wheeled recreational device or wheeled toy (i.e. skateboard and scooters) is a pedestrian, and the use of helmet is not compulsory.[18] For horse riders younger than 18 years of age helmet use is compulsory but rarely enforced.[20] Helmet and other personal protective equipment use are also mandated in many competition settings, particularly motorcycle and horse-related events. In the absence of comprehensive legislation, helmet use in children riding bicycles, push scooters or skateboards was found to be less than 50% from direct observation of children riding a RV in the community.[21,22]

Introduction of mandatory helmet laws has proven effective in increasing helmet use in bicycle riders in a number of jurisdictions in Canada, United States and Australia.[23-26] Data on paediatric RV-related HI presentations to the ED and associated helmet use are scarce, both in settings with and without mandatory helmet laws. Most of the studies include data on a mixed paediatric and adult population,[4,15,22,27,28] focus on broader paediatric HI populations,[27,29] on specific RVs,[4,13,15,30,31] or examine helmet use alone.[21,22] The aim of our study was to describe the epidemiology and characteristics of children presenting to the ED with a RV-related HI with a special focus on helmet use.

MATERIALS AND METHODS

Study design

We performed a single centre retrospective study of patients presenting to the ED of the Royal Children's Hospital (RCH), Melbourne, Australia for HIs related to the use of a RV.

Study setting

The RCH is a tertiary-care teaching hospital and the only paediatric trauma centre in the state of Victoria. It also serves as the principal health-care service for children of the metropolitan area of Melbourne and receives children from Tasmania and parts of southern New South Wales. The state of Victoria covers approximately 227,000 km^2 with a population of 5.3 million, of which around 1.3 million are children younger than 18 years of age.[32] The RCH ED has a yearly census of 82000 visits of children less than 18 years.

Study Population

We included all children under 18 years who presented to the ED between April 2011 and January 2014 with a RV related HI. Study subjects were identified by searching the field "triage presentation complaint" of the electronic ED database for the following keywords: bike (for bike, motorbike), quad, ATV (for 'all-terrain vehicle'), kart (for go-kart or karting), cycle (for bicycle and motorcycle), cyclist, bmx, scooter, skateboard, horse, pony, ride, riding, rodeo, gymkhana, and helmet. The list of the keywords was developed with the input of senior author (RB) who is a paediatric emergency physician and injury surveillance and prevention researcher. The ED database does not provide coding to the same extent as inpatient data, where external cause of injury is routinely coded. ED systems predominantly use diagnostic codes (International Classification of Diseases or ICD codes) and children presenting with RV-related injuries could be allocated a single ICD code from a broad range of injury ICD codes. Therefore, our search strategy allowed identification of RV-related presentations where the primary injury may or may not have been a HI.

Exclusion criteria were: no RV-related injuries, RV-related injuries other than HI (i.e. isolated or combined facial/torso/limb injuries as per definition reported below), medical charts not retrievable, patients left without being seeing by the ED physician or representation for the same HI. The final study population was cross-

matched with the database of a prospective study on HIs, running at the RCH ED since April 2011, the Australasian Paediatric Head Injury Rules Study (APHIRST).[33] For the patients enrolled in APHIRST data on demographics, history and mechanism of injury, symptoms, physical findings, imaging performed and results, disposition and follow-up were retrieved by the prospectively completed clinical report forms. In order to ensure consistent data collection for the patients satisfying inclusion criteria, but not enrolled in APHIRST (i.e. non eligible, missed and excluded), the APHIRST clinical report forms were used. Data on helmet use, type of RV involved, and site of impact were not included in the APHIRST clinical report forms and were extracted from chart review for all the patients.

Chart review guidelines were followed.[34] The primary data abstractor (MD) received formal training in medical records review, but was not blinded to the study objectives. Ambiguous data were discussed and reviewed with the senior investigator (FB). In order to minimize possible selection bias, 20% of the overall retrieved records not included in APHIRST were randomly selected and reviewed by a second investigator (SB) to determine inter-rater agreement with respect to meeting study exclusion criteria.

Definitions

Recreational vehicle: for the purpose of this study RVs include bicycles, push scooters, skateboards, horses, motorcycles, ATV, and go-karts.

Helmet: a protective device worn on the head capable of resisting penetration, absorbing impact energy, and with a retention system.

Helmet use: was recorded as "yes" when its use was documented, "no" when notes reported that a helmet was not used, and "not documented" if no information on helmet use was recorded.

Head injury: any trauma involving the head.

RV-related injuries other than HI – isolated or combined facial/torso/limb injuries: chin, lips or dental injuries and injuries below the nasal bridge and the zygomatic prominences/injuries to the chest, abdomen, pelvis/upper or lower limb(s), with documented absence of head injury reported in the medical notes or detailed mechanism description that excluded impact to head.

Associated extra-cranial injuries (for patients finally included in the study): facial, neck, torso or limb injuries as reported in the discharge diagnosis, including lacerations, sprains, fractures/dislocations or internal organ injuries.

Site of impact to head: as reported in the clinical notes based on the history, physical signs of injury on examination or site of damage on the helmet.

Ethical committee

The study was approved by the hospital ethics committee at Royal Children's Hospital.

Statistical Analysis

Categorical variables were reported as percentages and 95% confidence intervals (CI) for main findings. Continuous variables were described as mean and standard deviation or median and interquartile range based on their parametric or non-parametric distribution respectively. Comparisons were performed by means of Chi-square tests for categorical variables, while independent-sample t-tests or Mann-Whitney U-tests were used for continuous variables according to their parametric or non-parametric distribution, respectively. Logistic regression analysis with adjustment for confounders was performed to assess for the association of the site of impact with the presence of intracranial injury on CT, and results were reported as odds ratio (OR) and their 95% CI. The κ-statistic was used to determine inter-rater agreement. Parameters displaying $p \leq 0.05$ were considered statistically significant. Data were entered into a REDCap database (version 5.10.2) and were analysed using Stata (version 13.0, StataCorp, College Station, Tex, USA).

RESULTS

Our search strategy retrieved 3045 records. Of these, we excluded 512 injuries as not RV-related and 1827 RV-related injuries as not associated with a HI. Seven records were representations for the same HI and were excluded from the final population. A total of 647 children were finally included in the study, corresponding to 7.5% of all children presenting for a HI of any severity at the RCH ED during the study period (Figure 1).

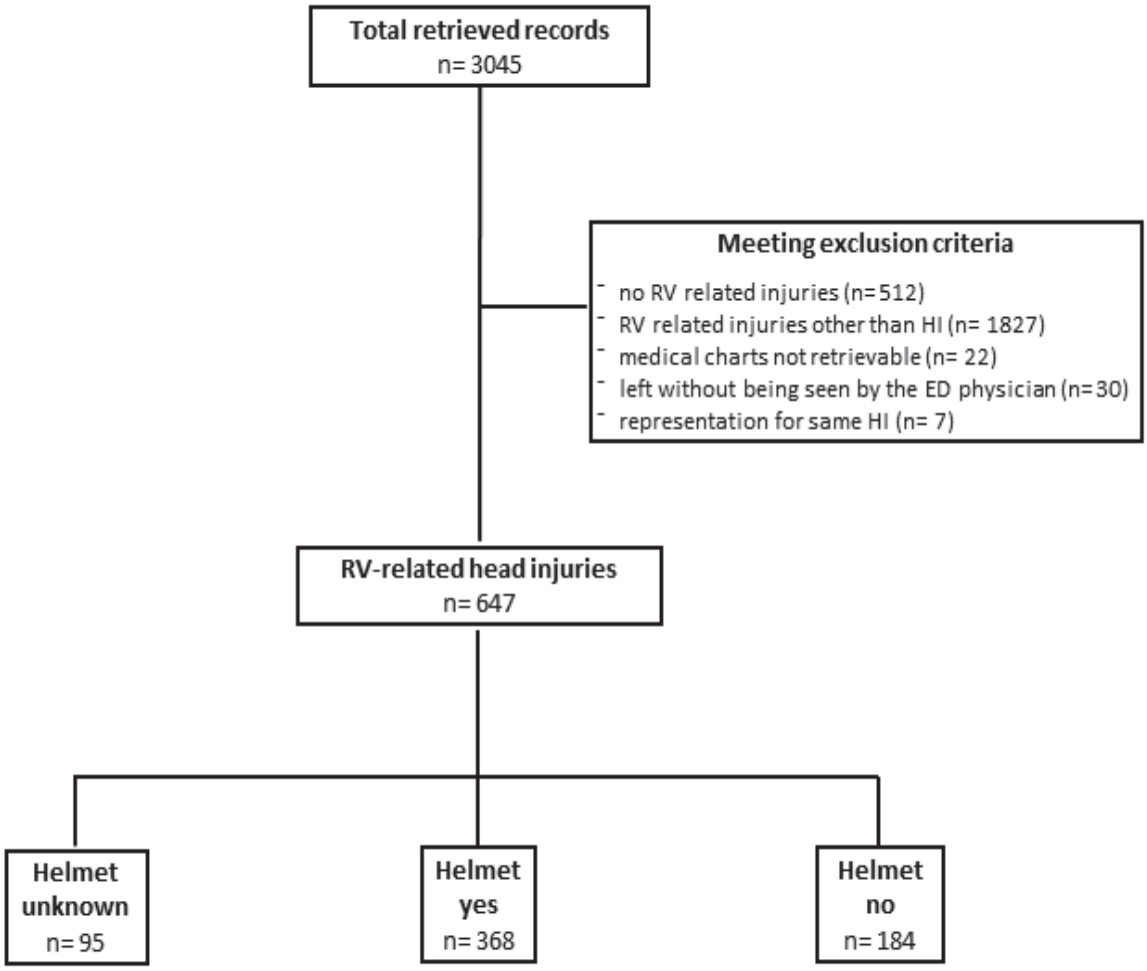

Figure 1. Patients' flow chart

The k value for the inter-rater agreement on the selection process of retrieved records was 0.90 (95% CI 0.87-0.94). The demographics and clinical characteristics of patients according to RV group (motorized vs. non-motorized), type of RV, and helmet documentation and use are reported in Tables 1, 2 and 3 respectively.

The majority of patients, 506 (78.2%, 95% CI 74.8-81.3) sustained a HI while riding a non-motorized vehicle (bicycle, n=235; scooter, n=120; horse, n=76; and skateboard, n=75), while 141 (21.8%, 95% CI 18.7-25.2) were riding a motorized vehicle (motorcycle, n=119; ATV, n=18; and go-kart, n=4) at the time of the incident. The median age of the overall population was 11.8 years (IQR 7.5-14.5), and the majority overall and in all subgroups except in horse riding were males 469 (72.5%, 95% CI 68.9-75.9). Overall helmet use was documented in 552 (85.3%, 95% CI 82.4-88.0) patients, with 368 (66.7%, 95% CI 62.6-70.6) patients wearing a helmet at the time of injury. Children who sustained a HI related to a motorized RV were older and more frequently males. Helmet use was both more frequent and more frequently documented in this group of patients, compared with the non-motorized RV group (76.6% vs. 51.4%, $p<0.0001$ and 95.7% vs. 82.4% respectively, $p<0.0001$). Patients who sustained a HI while riding a motorized vehicle were overall more severely injured as highlighted by the following: lower GCS, higher proportion of associated extra-cranial injuries, of patients transferred from other facilities, of intracranial injuries, of admissions to intensive care, of neurosurgical interventions and longer stays in hospital. Within the motorized vehicle group children riding an ATV were younger and used the helmet less often than the group overall.

Table 1. Demographics and clinical characteristics of head injury patients riding motorized or non-motorized RV

	Motorized RV n= 141	Non-motorized RV n=506	p
Age (median, IQR)	13.16 (11.13—15.02)	10.94 (6.59-14.30)	0.000
Sex % (n)			
- Male	80.1 (113)	70.4 (356)	
- Female	19.86 (28)	29.6 (150)	0.021
Helmet use % (n)			
- YES	76.6 (108)	51.4 (260)	
- NO	19.2 (27)	31.0 (157)	
- Not documented	4.3 (6)	17.6 (89)	0.000
Associated extra-cranial injuries % (n)			
- None	39.0 (55)	59.7 (302)	
- Face/neck	19.9 (28)	24.5 (124)	
- Upper limbs	6.4 (9)	8.9 (45)	
- Torso	17.0 (24)	2.4 (12)	
- Lower limbs	17.7 (25)	4.6 (23)	0.000
GCS # % (n)			
- 14-15	83.0 (117)	92.3 (467)	
- 9-13	7.1 (46)	6.1 (31)	
- 3-8	2.6 (17)	1.6 (8)	0.001
Transfers from other hospital % (n)	19.2 (27)	11.3 (57)	0.014
CT scan performed % (n)			
- at referring hospital	6.4 (9)	5.9 (30)	
- at RCH ED	27.0 (38)	14.2 (72)	0.005
CT findings % (n)			
- Isolated Skull Fractures	0.0 (0)	1.8 (9)	0.111
- Intracranial injuries	13.5 (19)	7.5 (38)	0.027
Disposition % (n)			
- Discharged from ED/SSU	41.8 (59)	76.5 (387)	
- Admitted to WARD only	48.9 (69)	21.5 (109)	
- Admitted to PICU	8.5 (12)	1.6 (8)	0.000
Neurosurgical intervention % (n)	5.7 (8)	1.2 (6)	0.001
Total LOS hours (median, IQR) (n=646)	24 (4.4-87.7)	3.8 (2.2-17.1)	0.000

CT = Computed Tomography; ED = Emergency Department; GCS = Glasgow Coma Scale;
IQR = Interquartile Range; ICU = Intensive Care Unit; LOS = Length of Stay; RV = Recreational Vehicles
*Some patients may have more than 1 site of impact
At time of initial hospital assessment (RCH ED for direct access patients, referring centre for transferred patients)

Table 2. Demographics and clinical characteristics of patients according to type of RV involved

	Total n=647	Bicycle n=235	Scooter n=120	Motorcycle n=119	Horse n=76	Skateboard n=75	ATV n=18	Go-kart n=4
Age (median, IQR)	11.83 (7.41-14.52)	10.92 (5.87-14.63)	7.66 (4.64-10.59)	13.47 (11.45-15.15)	12.80 (9.95-15.17)	13.55 (11.11-15.23)	10.83 (7.53-13.22)	13.39 (9.43-15.07)
Age group % (n)								
- < 5 years	13.8 (89)	20.0 (47)	29.2 (35)	1.7 (2)	1.3 (1)	1.3 (1)	16.7 (3)	0.0 (0)
- ≥ 5 and < 10 years	26.3 (170)	27.2 (64)	44.2 (53)	14.3 (17)	23.7 (18)	16.0 (12)	27.8 (5)	25.0 (1)
- ≥ 10 and <15 years	40.0 (259)	32.8 (77)	23.3 (28)	57.1 (68)	47.4 (36)	54.7 (41)	38.9 (7)	50.0 (2)
- ≥ 15 and < 18 years	19.9 (129)	20.0 (47)	3.3 (4)	26.9 (32)	27.6 (21)	28.0 (21)	16.7 (3)	25.0 (1)
Sex % (n)								
- Male	72.5 (469)	79.6 (187)	75.0 (90)	84.9 (101)	14.5 (11)	90.7 (68)	66.7 (12)	0.0 (0)
- Female	27.5 (178)	20.4 (48)	25.0 (30)	15.1 (18)	85.5 (65)	9.3 (7)	33.3 (6)	100.0 (4)
Site of impact* % (n)								
- Frontal	47.5 (307)	55.32 (130)	65.0 (78)	32.8 (39)	22.4 (17)	45.3 (34)	38.9 (7)	50.0 (2)
- Parietal	8.0 (52)	7.2 (17)	7.5 (9)	7.6 (9)	7.9 (6)	12.0 (9)	11.1 (2)	0.0 (0)
- Temporal	6.3 (41)	6.8 (16)	5.0 (6)	3.4 (4)	7.9 (6)	10.7 (8)	5.6 (1)	0.0 (0)
- Occipital	9.7 (63)	11.1 (26)	7.5 (9)	4.2 (5)	7.9 (6)	18.7 (14)	11.1 (2)	25.0 (1)
- Unknown	29.8 (193)	19.6 (46)	15.8 (19)	55.5 (66)	55.3 (42)	16.0 (12)	38.9 (7)	25.0 (1)
Helmet use % (n)								
- YES	56.9 (368)	65.1 (153)	25.8(31)	83.2 (99)	82.9 (63)	17.3 (13)	38.9 (7)	50.0 (2)
- NO	28.4 (184)	29.4 (69)	37.5 (45)	14.3 (17)	9.2 (7)	48.0 (36)	55.6 (10)	0.0 (0)
- Not documented	14.7 (95)	5.5 (13)	36.7 (44)	2.5 (3)	7.9 (6)	34.7 (26)	5.6 (1)	50.0 (2)
Associated extra-cranial injuries								
- Face/neck	27.2 (176)	27.2 (64)	28.3 (34)	28.6 (34)	35.5 (27)	12.0 (9)	27.8 (5)	75.0 (3)
- Upper limbs	11.0 (71)	8.9 (21)	7.5 (9)	16.8 (20)	6.6 (5)	18.7 (14)	11.1 (2)	0.0 (0)
- Torso	7.4 (48)	6.4 (15)	3.3 (4)	17.7 (21)	4.0 (3)	1.3 (1)	16.7 (3)	25.0 (1)
- Lower limbs	6.5 (42)	1.7 (4)	4.2 (5)	21.9 (26)	1.3 (1)	4.0 (3)	11.1 (2)	25.0 (1)
GCS # % (n)								
- 14-15	90.3 (584)	94.0 (221)	94.2 (113)	84.0 (100)	90.8 (69)	85.3 (64)	72.2 (13)	100.0 (4)
- 9-13	7.1 (46)	4.7 (11)	5.0 (6)	9.2 (11)	7.9 (6)	10.7(8)	22.2 (4)	0.0 (0)
- 3-8	2.6 (17)	1.3 (3)	0.8 (1)	6.7 (8)	1.3 (1)	4.0 (3)	5.6 (1)	0.0 (0)
Transfers from other hospital % (n)	13.0 (84)	11.5 (27)	6.7 (8)	19.3 (23)	14.7 (11)	14.7 (11)	16.7 (3)	25.0 (1)
CT scan performed % (n)								
- at referring hospital	6.0 (39)	5.5 (13)	1.7 (2)	6.7 (8)	7.9 (6)	12.0 (9)	5.6 (1)	0.0 (0)
- at RCH ED	17.0 (110)	13.2 (31)	12.5 (15)	26.1 (31)	14.5 (11)	20.0 (15)	38.9 (7)	0.0 (0)
CT findings % (n)								
- Isolated Skull Fractures	1.4 (9)	2.6 (6)	1.7 (2)	0.0 (0)	0.0 (0)	1.3 (1)	0.0 (0)	0.0 (0)
- Intracranial injuries	8.8 (57)	4.7 (11)	4.2 (5)	12.6 (15)	9.2 (7)	20.0 (15)	22.2 (4)	0.0 (0)
Disposition % (n)								
- Discharged from ED	69.0 (446)	78.3 (184)	85.0 (102)	40.3 (48)	65.3 (49)	69.3 (52)	50.0 (9)	50.0 (2)
- Admitted to WARD only	27.5 (178)	19.6 (46)	14.2 (17)	50.4 (60)	32.9 (25)	28.0 (21)	38.9 (7)	50.0 (2)
- Admitted to PICU	3.1 (20)	1.7 (4)	0.0 (0)	8.4 (10)	2.6 (2)	2.7 (2)	11.1 (2)	0.0 (0)
Neurosurgical intervention % (n)	2.2 (14)	1.3 (3)	0.8 (1)	5.9 (7)	1.3 (1)	1.3 (1)	5.6 (1)	0.0 (0)
Total LOS hours (median, IQR) (n=646)	4.29 (2.50-23.81)	3.96 (2.37-15.69)	2.90 (1.67-4.88)	24.07 (4.38-88.83)	5.51 (2.63-23.81)	3.95 (2.35-25.58)	34.28 (4.31-76.02)	26.87 (4.31-81.70)

ATV= all-terrain vehicles; IQR = Interquartile Range; GCS = Glasgow Coma Scale; CT = Computed Tomography; RCH = Royal Children's Hospital; ED = Emergency Department; PICU = Pediatric Intensive Care Unit; LOS= Length of Stay

*Some patients may have more than 1 site of impact

At time of initial hospital assessment (RCH ED for direct access patients, referring center for transferred patients)

Table 3. Demographics and clinical characteristics of patients with and without documentation of helmet use

	Helmet use documented n=552			Helmet use NOT documented n= 95	
	Helmet YES n = 368	Helmet NO n= 184	p †		p ^
Age (median, IQR)	12.33 (8.85 – 14.81)	11.49 (6.90 – 14.41)	0.046	9.12 (5.71 – 12.48)	<0.001
Age group % (n)					
- < 5 years	12.2 (45)	14.1 (26)		19.0 (18)	
- ≥ 5 and < 10 years	21.2 (78)	28.8 (53)		41.1 (39)	
- ≥ 10 and <15 years	43.5 (160)	38.0 (70)		30.5 (29)	
- ≥ 15 and < 18 years	23.1 (85)	19.0 (35)	0.162	9.5 (9)	<0.001
Sex % (n)					
- Male	70.4 (259)	76.6 (141)		72.6 (69)	
- Female	29.6 (109)	23.4 (43)	0.121	27.4 (26)	0.973
Transfers from other hospital % (n)	14.7 (54)	12.0 (22)	0.382	8.4 (8)	0.152
Time from injury to hospital presentation in hours (median, IQR)	1.93 (1.18 – 3.45)	1.61 (1.11 – 3.21)	0.289	1.57 (1.03 – 3.32)	0.203
Time of presentation (n, %)					
- 8:00-15:59	42.9 (158)	29.4 (54)		31.6 (30)	
- 16:00-23:59	55.2 (203)	67.9 (125)		64.2 (61)	
- 24:00-7:59	1.9 (7)	2.7 (5)	0.008	4.2 (4)	0.262
Site of impact* % (n)					
- Frontal	41.0 (151)	56.5 (104)	0.001	54.7 (52)	0.124
- Parietal	6.8 (25)	11.4 (21)	0.064	6.3 (6)	0.504
- Temporal	5.7 (21)	8.2 (15)	0.273	5.3 (5)	0.642
- Occipital	7.6 (28)	15.8 (29)	0.003	6.3 (6)	0.223
- Unknown	40.8 (150)	8.2 (15)	0.000	29.5 (28)	0.935
Associated extra-cranial injuries					
- Face/neck	29.9 (110)	23.9 (44)	0.140	23.2 (22)	0.338
- Upper limbs	12.8 (47)	7.6 (14)	0.068	10.5 (10)	0.880
- Torso	9.8 (36)	6.0 (11)	0.131	1.1 (1)	0.497
- Lower limbs	7.9 (29)	4.9 (9)	0.191	4.2 (4)	0.005
GCS # % (n)					
- 14-15	90.2 (332)	86.4 (159)		97.9 (93)	
- 9-13	7.6 (28)	9.8 (18)		0.0 (0)	
- 3-8	2.2 (8)	3.8 (7)	0.351	2.1 (2)	0.002
CT scan performed % (n)					
- at referring hospital	5.4 (20)	9.8 (18)	0.057	1.1 (1)	0.032
- at RCH ED	14.7 (54)	27.2 (50)	<0.001	6.3 (6)	0.003
CT findings % (n)					
- Isolated Skull Fractures	1.4 (5)	2.2 (4)	0.476	0.0 (0)	0.210
- Intracranial injuries	5.2 (19)	19.6 (36)	0.000	2.1 (2)	0.013
Disposition % (n)					
- Discharged from ED	66.0 (243)	62.5 (115)	0.389	92.6 (88)	<0.001
- Admitted to WARD only	30.7 (113)	33.2 (61)	0.560	4.2 (4)	<0.001
- Admitted to PICU	2.7 (10)	4.4 (8)	0.309	2.1 (2)	0.753
Neurosurgical intervention % (n)	0.8 (3)	5.4 (10)	<0.001	1.1 (1)	0.705
Total LOS (median, IQR) (n=646)	4.80 (2.79-24.50)	4.74 (2.53-40.95)	0.896	2.88 (1.50-4.53)	<0.001

IQR = Interquartile Range; GCS = Glasgow Coma Scale; CT = Computed Tomography; RCH = Royal Children's Hospital; ED = Emergency Department; PICU = Pediatric Intensive Care Unit; LOS = Length of Stay

† for the comparison between helmet worn and not worn

^ for the comparison between helmet documented and not documented

*Some patients may have more than 1 site of impact

At time of initial hospital assessment (RCH ED for direct access patients, referring center for transferred patients)

Patients with no documentation of helmet use had a less severe HI as shown by the higher GCS, the lower intracranial injuries on CT and neurosurgery rate, and the shorter length of stay (LOS). Recorded helmet use was the lowest for push-scooter and skateboard related HIs. Push scooters-related HIs affected the youngest age group, were most often discharged from the ED and had the shortest LOS. In contrast, skateboard-related HIs more commonly affected teenage boys and had a similar neurosurgical intervention rate and LOS compared with the other non-motorised RVs.

Patients who wore a helmet had a lower rate of CT, intracranial injuries on CT and neurosurgical intervention, but no difference in the rate of admission to intensive care or LOS.

Across all RVs the most common site of impact was the frontal area, especially in non-helmeted patients (56% vs. 41% in the helmeted group, $p=0.001$), while it was mostly unknown in children wearing a helmet (40% vs. 8% in non-helmeted children, $p<0.001$). However, on logistic regression analysis only the parietal site of impact, compared with the other sites, was associated with the presence of an intracranial injury on CT when adjusted for helmet use (OR 3.74, 95% CI 1.21-11.55).

There was only one death in our population; a 15 year old male who had an off-road motorcycle crash against a fixed object whilst reported to be wearing a helmet and sustained unsurvivable head and cervical cord injuries.

DISCUSSION

Our study provides comprehensive epidemiological data on a broad range of RV-related HIs in children presenting to the ED. The key findings in this study were that the majority of RV related HIs were due to non-motorised RVs yet motorized RVs accounted for the majority of severe HI. Documentation of helmet use and helmet use overall was high, but lower where its use was not legally

mandated, such as in push scooters, skateboards and in ATV bikes. Helmet use was associated with less severe HIs.

With the exception of horse-related RV injuries, more males than females presented following a RV-related HI. These results are consistent with previous studies.[3,4,13,16,21,22,31,35,36] The age distribution was skewed towards late childhood and adolescence as expected by the developmental skills required to ride most of the RVs included in our study. Younger children most often sustained a HI while riding a push-scooter or a bicycle, as also reported by previous research.[2,21,36-39]

Motorized vehicles were responsible for the most severe HIs despite the higher helmet use, as shown by the higher positive CT findings and neurosurgical intervention rate. They also accounted for most of the associated extra-cranial injuries, as expected by the more severe dynamic of trauma that characterizes this category of vehicles.

Overall, the documentation of helmet use was high (85%) considering the retrospective nature of the data set and mostly missing for children injured whilst riding a push-scooter or a skateboard, where there is no legal obligation or code requiring helmet use in the local setting. For bicycles and motorcycles, where on-road helmet use is nationally legislated, the documentation was greater than 95% and was higher compared with previous studies reporting rates between 50 and 70%.[3,30,40] This is despite the fact that for the paediatric population, motorcycle use is almost exclusively off-road, where the Australian Road Rules do not apply. In Victoria, children under the age of 18 years are unable to obtain a motorcycle licence for on-road use.[35,41] Whilst helmet use is also legislated for on-road horse riding, the majority of time is spent riding off-road.[20,42] However, there is a strong culture both within the horse and motorcycle-riding communities of helmet use, particularly in competition settings, with rules regarding helmet and other personal protective equipment use, and guidelines regarding renewing helmets after an impact[43]. In particular, that they are aware of the significant impact of helmet use in reducing HI severity and are therefore likely to both document and incorporate

this information in their decision making process in clinical practice. A helmet was worn by two thirds of the patients in our study with wide variation across RV types. Wearing a helmet was associated with a reduced risk of severe HI across all RV types, consistent with other research.[2,9,10,13,15] The lack of impact of helmet use on the admission rate and total LOS may be explained by the care needs of the associated extra-cranial injuries, which were most often reported in the motorized vehicles group.

We found a very high rate of positive helmet use for motorcycle and horse riders. The pattern of positive helmet use has increased over time compared to previous studies conducted at our institution (from 73% to 83% for motorcycles and from 50% to 83% for horse-related HIs).[27,30] In contrast a helmet was worn in less than 40% of children who sustained a ATV-related HI. ATVs may be conditionally registered for on-road use, predominantly for movements between properties; however, the majority of riding time for both adults and children occurs off-road, where the helmet requirements of the Australian Road Rules do not apply.[18] The low rate of positive helmet use in children riding an ATV compared with that for motorcycle and horse riders is striking. This may be explained by the false community perception that ATVs are more stable and therefore less dangerous vehicles. In addition, in contrast to the large recreational industry in the United States, ATV riding in Australia, for both adults and children, is still predominantly related to work or informal recreational use and not competition-related[44], where again, competition codes might encourage personal protective equipment use.

Positive helmet use amongst children presenting with a bicycle-related HI was only 65%, and lower than the estimated 75% usage rate (for bicyclists of all ages) reported in the year following the introduction of mandatory helmet wearing regulation in 1990.[35] However our data may not be representative of the general population, as children who present to the ED of a tertiary care and sole state trauma centre, may be more severely injured as a consequence of wearing the

helmet less often. While studies on push scooter-related injuries showed that an injury to the head is sustained in approximately 30% of patients,[45] scarce data are available on the severity and helmet use of scooter-related HIs. We found that despite the low helmet use, push-scooter related HIs are less severe compared with other RVs. The younger age of children riding this RV may account for a lower-risk taking behaviour and a lower energy mechanism of injury. The lack of documentation of helmet use in more than one third of these patients, however, may also account for the low HI severity, as actual helmet use might have not been documented in patients with asymptomatic HI as a result of helmet protection.

Presentations due to skateboard and horse-related HIs were similar in number in our sample. Compared with horse-related HI skateboarders had a higher rate of CT scan and intracranial injuries on CT. This result may be explained by a lower rate of helmet use in this group of patients (17 compared to 83%). Our results also show that despite the most common site of impact is frontal, the parietal site is the one mostly associated with intracranial injury even after adjusting for helmet use, suggesting that this area may need to be better protected when manufacturing helmets. In our study we considered presence of intracranial injury on CT, neurosurgical intervention rate, admission rate (including intensive care) and total LOS as markers of severity. Nevertheless prolonged post-concussive symptoms and brain dysfunction following intracranial injuries that are treated conservatively also significantly impact on patients' life and future studies should investigate whether helmet use has any impact on these outcomes.

Limitations

Children wearing helmets may, in the event of a HI, be less likely to present to ED, particularly if the incident involved a HI in isolation and they were not symptomatic. This presentation bias may select for children not wearing helmets, and may account for the lower than expected positive helmet use particularly

amongst young cyclists. The sensitive search strategy used to identify children who sustained a RV-related HI ensured broad data capture and reduced the possibility of selection bias in data collection.

In addition as the majority of our cases were also prospectively identified through the APHIRST study, which was designed to capture HI of any severity, and no APHIRST patients were missed in the retrospective search strategy, we believe this selection bias may be less significant than compared with an entirely retrospective cohort.

While we followed recommendations for high quality medical record review[34] the retrospective design has limitations in particular with clinical information recorded with a focus on management. A prospective study would also allow the collection of additional information that would facilitate a better understanding of helmet efficacy; make, model, impact history, and fit, position on head and fixation at the time of injury.

CONCLUSIONS

Our findings show that RV-related HIs in children account for significant morbidity and hospital resource utilization. The most common RVs involved are bicycles, but motorized vehicles, mainly motorcycles, account for the most severe injuries. In addition, this study provides useful information on the pattern and documentation of helmet use in this population. Documentation of helmet use is overall high but overlooked for scooters and skateboards. Helmet use varies across RVs categories and is highest for motorcycles and horses. The use of helmet is associated with less severe HIs and should be encouraged through various routes.

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7. DISCUSSION

The results of the studies included in this thesis provide a valuable addition to the existing paediatric literature on head injury and concussion, with particular focus on the diagnosis of intracranial injuries, concussion management and recovery, as well as ED burden and prevention of RV-related HI.

With regards to the diagnosis of possible intracranial injuries, we externally validated the PECARN rule[3] for decision-making on head CT in children with minor HI. These results support its wide implementation into clinical practice. We described the successful implementation of an adapted PECARN rule in the Italian setting and its effects and use in clinical practice. We reported sedation use and practice for head CT scan in children with HI showing that it is required in a small number of patients, and mainly for children younger than 5 years of age. We explored the use of an infrared device to detect intracranial traumatic haematomas and better select patients who need a head CT scan, finding that this tool can be used in children in the ED and has potential for reducing CT rate.

Our research on concussion management and recovery showed that compliance with current guidelines for on-field management of sport-related concussion is not optimal and needs to be improved. In addition, a lack of patients and parents awareness on return-to-play guidelines following a concussion was highlighted. We found that most of the children who sustain a concussion recover within 2 weeks post-injury. Approximately a third still suffer from clinically significant post concussive symptoms at this time point and this is associated with a reduced HRQOL at 1 and 3 months post-injury compared with asymptomatic patients.

Our study on RV-related HIs showed that they place a non-negligible burden on the ED service and described variation of helmet use documentation, positive use and HI severity, across different RV types. This information will be useful for injury prevention purposes.

Overall our results may contribute to improving patient care, as well as health care resource utilization. The use of clinical decision rules (CDRs) to support decision making in clinical practice is well recognised to optimize patient's outcome and use of resources.[3,38] Despite our research in the Italian setting focused on the PECARN CDR for minor HI,[3] two other high-quality CDRs have been published in the literature.[17,22] Their characteristics have been examined in detail in the general introduction. A recent US study[41] externally validated the three rules in the same cohort finding that PECARN and baseline physician ordering outperformed the other CDRs. However, this study suffered from several limitations and whether PECARN truly outperforms the other rules in clinical practice will be tested by the larger multicentre prospective Australasian Prospective Head Injury Rule Study (APHIRST) study[226] that is led by our research team at the Royal Children's Hospital (RCH) and Murdoch Children's Research Institute (MCRI) in Melbourne. The results of APHIRST, that will be available in 2015, will clarify which rule will be the most accurate and most suitable for wide implementation in clinical practice. A cost-effectiveness analysis will provide useful information around potential reduction of resource utilization and costs.

Close monitoring of the effects of implementing any of the rules in clinical practice is essential for quality improvement and patient safety surveillance purposes. The actual use of CDRs by clinicians may be different from what originally intended and possible deviation from expected results needs to be promptly detected.

Similarly to recent literature[54,227] we found that sedation is required in less than 10% of children who undergo a head CT for HI and is often provided by ED staff with good success, using medications with a wide margin of safety (most often chloral hydrate). Potential adverse effects related to sedation use infrequently play a role in the risk-benefit balance that influences decision-making on CT scanning children with HI.

Decision-making is often complex and multifactorial. Understanding which factors play a major role in this process may help identify key areas for improvement through targeted interventions. While this process may be more straightforward for patients who sit at the two ends of the severity spectrum, it may be particularly challenging for patients who are at intermediate risk of a given outcome. In these circumstances, the support to decision-making provided by CDRs can be improved and refined by complementing clinical findings with specific screening tests results. According to recent studies, bedside skull ultrasound seems accurate in detecting skull fractures in children who sustained a head trauma.[228] Children with a skull fracture have a higher risk of intracranial injury[229] (40% vs 3% in children with no skull fracture on CT, $p<0.001$ based on the PECARN rule dataset; [N. Kuppermann personal communication]). Identification of skull fractures on ultrasound may provide additional information to better estimate the patient risk of intracranial injury, thus further supporting decision making. Similarly, the use of a handheld infrared device can identify acute traumatic intracranial haematomas[55,56] [230] and better select patients who need a CT scan. We demonstrated the feasibility of use and potential usefulness of this non-irradiating tool in reducing CT rate in children with minor HI. Our results support further research should be conducted on this area. Both skull ultrasound and infrared devices could be incorporated as additional items of existing CDR to optimize CT performance in the future.

With regards to concussion management we found that approximately one fifth of children were not immediately removed from play and one third returned to play the same day. Our data are similar to those of a recent US study,[231] which also found that paediatric patients are mostly compliant with concussion instructions given in the ED. These results highlight the importance of providing concussion education in the ED, in order to avoid premature return to play. This is associated to longer post-concussive symptom duration and risk of re-injury.[84] Our research group, in conjunction with the MCRI health technology team ("Curve

Tomorrow") has recently developed an app (HeadCheck™) for concussion recognition and initial management advice, based on the Zurich consensus statement recommendations. The app has also been endorsed by RCH, the University of Melbourne and the Australian football league concussion working group and can be downloaded for free from the App store. This app is meant to increase public awareness of concussion effects and improve compliance with current on-field management guidelines.

We also set up a joint research and clinical project for the study of concussion recovery. This project aims to develop a CDR to be used in the ED to identify children at higher risk of clinically significant post-concussive symptoms, who will benefit from early follow-up in a dedicated concussion clinic. Appropriate prioritisation of follow-up for children who sustain a concussion is essential to deliver best care to patients mostly in need, while optimising utilisation of resources. The feasibility data from our pilot project will help with the planning and conduct of a larger study to develop evidence-based guidelines for concussion management.

Finally our data on RV-related HIs and helmet use highlighted opportunities to reinforce injury prevention education on helmet use, especially targeting specific types of RV (i.e. skateboards, scooters and quadbikes). For children riding motorised vehicles, who most often sustained severe HIs despite wearing a helmet, injury prevention strategies should also aim to reduce risk taking behaviours to avoid high-energy mechanisms of injury.

Specific limitations have been reported for each study in the dedicated sections. A common limitation to all the studies is the tertiary care paediatric setting where they were conducted. This limits their generalizability to different settings. The population presenting to our EDs is generally a more severely ill population compared to that presenting to non-referral centres. However, the purpose of our projects was to provide emergency physicians with evidence based

information to guide their practice in the management of head injuries in general, as well as concussion.

Retrospective data collection has been used for many of the projects and might be associated with a selection bias. However recommendations on methodology for chart review in emergency medicine[217] were followed, although data abstractors were not blinded to the study outcomes.

8. CONCLUSIONS

Our results provide useful information to guide emergency physicians practice on the management of HIs in general, as well as concussion.

The external validation of the PECARN CDR for minor HI provides evidence for wide implementation in clinical practice.

Implementation in clinical practice of an adapted PECARN rule was successful with respect to patient outcome, resource utilisation and satisfaction of medical staff with its use.

PECARN intermediate-risk predictors did not seem to be associated with decision to perform a CT scan, while a patient age of less than 3 months seemed a major contributing factor to this decision. Further research should explore how CDRs on HI are used in clinical practice and what factors mostly influence physicians' decision making.

Sedation for head CT scan in children with HI was infrequently needed and children younger than five years were more likely to need sedation.

The use of an infrared device to detect intracranial traumatic haematomas seemed useful to better select patients who need to be scanned for a HI, and deserves further exploration as a potential additional item to be incorporated in existing CDRs.

Compliance with current guidelines for on-field management of sport-related concussion was not optimal and needs to be improved. The lack of patients and parents awareness on return-to-play guidelines following a concussion highlighted the need of increasing general public education on this topic. The satisfactory compliance with return to play instructions given in the ED suggested that education on concussion provided in the ED may be effective and should be encouraged.

Most of the children recovered within 2 weeks following their concussion. Approximately a third still suffered from clinically significant post concussive symptoms at this time point. Presence of clinically significant symptoms at 2 weeks was associated with a reduced health related quality of life at 1 and 3 months post-injury compared with asymptomatic patients.

In children with a recreational vehicle-related injury documentation of helmet use and positive use varied across RVs categories and was highest for motorcycles and horses. Its use was associated was associated with less severe HIs and should be mostly encouraged in children riding a skateboard, a quadbike or a push-scooter.

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APPENDICES

Appendix I. Sport Concussion Assessment Tool – 3rd edition

SCAT3™

Sport Concussion Assessment Tool – 3rd Edition

For use by medical professionals only

Name | Date/Time of Injury: Date of Assessment: | Examiner:

What is the SCAT3?[1]

The SCAT3 is a standardized tool for evaluating injured athletes for concussion and can be used in athletes aged from 13 years and older. It supersedes the original SCAT and the SCAT2 published in 2005 and 2009, respectively[2]. For younger persons, ages 12 and under, please use the Child SCAT3. The SCAT3 is designed for use by medical professionals. If you are not qualified, please use the Sport Concussion Recognition Tool[3]. Preseason baseline testing with the SCAT3 can be helpful for interpreting post-injury test scores.

Specific instructions for use of the SCAT3 are provided on page 3. If you are not familiar with the SCAT3, please read through these instructions carefully. This tool may be freely copied in its current form for distribution to individuals, teams, groups and organizations. Any revision or any reproduction in a digital form requires approval by the Concussion in Sport Group.

NOTE: The diagnosis of a concussion is a clinical judgment, ideally made by a medical professional. The SCAT3 should not be used solely to make, or exclude, the diagnosis of concussion in the absence of clinical judgement. An athlete may have a concussion even if their SCAT3 is "normal".

What is a concussion?

A concussion is a disturbance in brain function caused by a direct or indirect force to the head. It results in a variety of non-specific signs and/or symptoms (some examples listed below) and most often does not involve loss of consciousness. Concussion should be suspected in the presence of **any one or more** of the following:

- Symptoms (e.g., headache), or
- Physical signs (e.g., unsteadiness), or
- Impaired brain function (e.g. confusion) or
- Abnormal behaviour (e.g., change in personality).

SIDELINE ASSESSMENT

Indications for Emergency Management

NOTE: A hit to the head can sometimes be associated with a more serious brain injury. Any of the following warrants consideration of activating emergency procedures and urgent transportation to the nearest hospital:

- Glasgow Coma score less than 15
- Deteriorating mental status
- Potential spinal injury
- Progressive, worsening symptoms or new neurologic signs

Potential signs of concussion?

If any of the following signs are observed after a direct or indirect blow to the head, the athlete should stop participation, be evaluated by a medical professional and **should not be permitted to return to sport the same day** if a concussion is suspected.

Any loss of consciousness?	☐ Y ☐ N
"If so, how long?"	_____
Balance or motor incoordination (stumbles, slow/laboured movements, etc.)?	☐ Y ☐ N
Disorientation or confusion (inability to respond appropriately to questions)?	☐ Y ☐ N
Loss of memory:	☐ Y ☐ N
"If so, how long?"	_____
"Before or after the injury?"	_____
Blank or vacant look:	☐ Y ☐ N
Visible facial injury in combination with any of the above:	☐ Y ☐ N

1 Glasgow coma scale (GCS)

Best eye response (E)	
No eye opening	1
Eye opening in response to pain	2
Eye opening to speech	3
Eyes opening spontaneously	4
Best verbal response (V)	
No verbal response	1
Incomprehensible sounds	2
Inappropriate words	3
Confused	4
Oriented	5
Best motor response (M)	
No motor response	1
Extension to pain	2
Abnormal flexion to pain	3
Flexion/Withdrawal to pain	4
Localizes to pain	5
Obeys commands	6
Glasgow Coma score (E + V + M)	of 15

GCS should be recorded for all athletes in case of subsequent deterioration.

2 Maddocks Score[3]

"I am going to ask you a few questions, please listen carefully and give your best effort."

Modified Maddocks questions (1 point for each correct answer)

What venue are we at today?	0	1
Which half is it now?	0	1
Who scored last in this match?	0	1
What team did you play last week/game?	0	1
Did your team win the last game?	0	1
Maddocks score		of 5

Maddocks score is validated for sideline diagnosis of concussion only and is not used for serial testing.

Notes: Mechanism of Injury ("tell me what happened"?):

Any athlete with a suspected concussion should be REMOVED FROM PLAY, medically assessed, monitored for deterioration (i.e., should not be left alone) and should not drive a motor vehicle until cleared to do so by a medical professional. No athlete diagnosed with concussion should be returned to sports participation on the day of Injury.

BACKGROUND

Name: _____ Date: _____

Examiner: _____

Sport/team/school: _____ Date/time of injury: _____

Age: _____ Gender: ☐ M ☐ F

Years of education completed: _____

Dominant hand: ☐ right ☐ left ☐ neither

How many concussions do you think you have had in the past? _____

When was the most recent concussion? _____

How long was your recovery from the most recent concussion? _____

Have you ever been hospitalized or had medical imaging done for a head injury?	☐ Y ☐ N
Have you ever been diagnosed with headaches or migraines?	☐ Y ☐ N
Do you have a learning disability, dyslexia, ADD/ADHD?	☐ Y ☐ N
Have you ever been diagnosed with depression, anxiety or other psychiatric disorder?	☐ Y ☐ N
Has anyone in your family ever been diagnosed with any of these problems?	☐ Y ☐ N
Are you on any medications? If yes, please list:	☐ Y ☐ N

_____

SCAT3 to be done in resting state. Best done 10 or more minutes post excercise.

SYMPTOM EVALUATION

3 How do you feel?

"You should score yourself on the following symptoms, based on how you feel now".

	none	mild		moderate		severe	
Headache	0	1	2	3	4	5	6
"Pressure in head"	0	1	2	3	4	5	6
Neck Pain	0	1	2	3	4	5	6
Nausea or vomiting	0	1	2	3	4	5	6
Dizziness	0	1	2	3	4	5	6
Blurred vision	0	1	2	3	4	5	6
Balance problems	0	1	2	3	4	5	6
Sensitivity to light	0	1	2	3	4	5	6
Sensitivity to noise	0	1	2	3	4	5	6
Feeling slowed down	0	1	2	3	4	5	6
Feeling like "in a fog"	0	1	2	3	4	5	6
"Don't feel right"	0	1	2	3	4	5	6
Difficulty concentrating	0	1	2	3	4	5	6
Difficulty remembering	0	1	2	3	4	5	6
Fatigue or low energy	0	1	2	3	4	5	6
Confusion	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
Trouble falling asleep	0	1	2	3	4	5	6
More emotional	0	1	2	3	4	5	6
Irritability	0	1	2	3	4	5	6
Sadness	0	1	2	3	4	5	6
Nervous or Anxious	0	1	2	3	4	5	6

Total number of symptoms (Maximum possible 22) _____

Symptom severity score (Maximum possible 132) _____

Do the symptoms get worse with physical activity? ☐ Y ☐ N

Do the symptoms get worse with mental activity? ☐ Y ☐ N

☐ self rated ☐ self rated and clinician monitored

☐ clinician interview ☐ self rated with parent input

Overall rating: If you know the athlete well prior to the injury, how different is the athlete acting compared to his/her usual self?

Please circle one response:

no different	very different	unsure	N/A

Scoring on the SCAT3 should not be used as a stand-alone method to diagnose concussion, measure recovery or make decisions about an athlete's readiness to return to competition after concussion. Since signs and symptoms may evolve over time, it is important to consider repeat evaluation in the acute assessment of concussion.

COGNITIVE & PHYSICAL EVALUATION

4 Cognitive assessment

Standardized Assessment of Concussion (SAC)[4]

Orientation (1 point for each correct answer)

What month is it?	0	1
What is the date today?	0	1
What is the day of the week?	0	1
What year is it?	0	1
What time is it right now? (within 1 hour)	0	1
Orientation score		of 5

Immediate memory

List	Trial 1		Trial 2		Trial 3		Alternative word list		
elbow	0	1	0	1	0	1	candle	baby	finger
apple	0	1	0	1	0	1	paper	monkey	penny
carpet	0	1	0	1	0	1	sugar	perfume	blanket
saddle	0	1	0	1	0	1	sandwich	sunset	lemon
bubble	0	1	0	1	0	1	wagon	iron	insect
Total									

Immediate memory score total of 15

Concentration: Digits Backward

List	Trial 1		Alternative digit list		
4-9-3	0	1	6-2-9	5-2-6	4-1-5
3-8-1-4	0	1	3-2-7-9	1-7-9-5	4-9-6-8
6-2-9-7-1	0	1	1-5-2-8-6	3-8-5-2-7	6-1-8-4-3
7-1-8-4-6-2	0	1	5-3-9-1-4-8	8-3-1-9-6-4	7-2-4-8-5-6
Total of 4					

Concentration: Month in Reverse Order (1 pt. for entire sequence correct)

Dec-Nov-Oct-Sept-Aug-Jul-Jun-May-Apr-Mar-Feb-Jan	0	1
Concentration score		of 5

5 Neck Examination:

Range of motion Tenderness Upper and lower limb sensation & strength

Findings: _____

6 Balance examination

Do one or both of the following tests.

Footwear (shoes, barefoot, braces, tape, etc.) _____

Modified Balance Error Scoring System (BESS) testing[5]

Which foot was tested (i.e. which is the **non-dominant** foot) ☐ Left ☐ Right

Testing surface (hard floor, field, etc.) _____

Condition

Double leg stance:	Errors
Single leg stance (non-dominant foot):	Errors
Tandem stance (non-dominant foot at back):	Errors

And/Or

Tandem gait[6,7]

Time (best of 4 trials): _____ seconds

7 Coordination examination

Upper limb coordination

Which arm was tested: ☐ Left ☐ Right

Coordination score of 1

8 SAC Delayed Recall[4]

Delayed recall score of 5

INSTRUCTIONS

Words in *Italics* throughout the SCAT3 are the instructions given to the athlete by the tester.

Symptom Scale

"You should score yourself on the following symptoms, based on how you feel now".

To be completed by the athlete. In situations where the symptom scale is being completed after exercise, it should still be done in a resting state, at least 10 minutes post exercise.

For total number of symptoms, maximum possible is 22.

For Symptom severity score, add all scores in table, maximum possible is 22 x 6 = 132.

SAC[4]

Immediate Memory

"I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order."

Trials 2 & 3:

"I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Complete all 3 trials regardless of score on trial 1 & 2. Read the words at a rate of one per second. **Score 1 pt. for each correct response.** Total score equals sum across all 3 trials. Do not inform the athlete that delayed recall will be tested.

Concentration

Digits backward

"I am going to read you a string of numbers and when I am done, you repeat them back to me backwards, in reverse order of how I read them to you. For example, if I say 7-1-9, you would say 9-1-7."

If correct, go to next string length. If incorrect, read trial 2. **One point possible for each string length**. Stop after incorrect on both trials. The digits should be read at the rate of one per second.

Months in reverse order

"Now tell me the months of the year in reverse order. Start with the last month and go backward. So you'll say December, November … Go ahead"

1 pt. for entire sequence correct

Delayed Recall

The delayed recall should be performed after completion of the Balance and Coordination Examination.

"Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order."

Score 1 pt. for each correct response

Balance Examination

Modified Balance Error Scoring System (BESS) testing[5]

This balance testing is based on a modified version of the Balance Error Scoring System (BESS)[5]. A stopwatch or watch with a second hand is required for this testing.

"I am now going to test your balance. Please take your shoes off, roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of three twenty second tests with different stances."

(a) Double leg stance:

"The first stance is standing with your feet together with your hands on your hips and with your eyes closed. You should try to maintain stability in that position for 20 seconds. I will be counting the number of times you move out of this position. I will start timing when you are set and have closed your eyes."

(b) Single leg stance:

"If you were to kick a ball, which foot would you use? [This will be the dominant foot] Now stand on your non-dominant foot. The dominant leg should be held in approximately 30 degrees of hip flexion and 45 degrees of knee flexion. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

(c) Tandem stance:

"Now stand heel-to-toe with your non-dominant foot in back. Your weight should be evenly distributed across both feet. Again, you should try to maintain stability for 20 seconds with your hands on your hips and your eyes closed. I will be counting the number of times you move out of this position. If you stumble out of this position, open your eyes and return to the start position and continue balancing. I will start timing when you are set and have closed your eyes."

Balance testing – types of errors

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hip into > 30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position > 5 sec

Each of the 20-second trials is scored by counting the errors, or deviations from the proper stance, accumulated by the athlete. The examiner will begin counting errors only after the individual has assumed the proper start position. **The modified BESS is calculated by adding one error point for each error during the three 20-second tests. The maximum total number of errors for any single condition is 10.** If a athlete commits multiple errors simultaneously, only one error is recorded but the athlete should quickly return to the testing position, and counting should resume once subject is set. Subjects that are unable to maintain the testing procedure for a minimum of **five seconds** at the start are assigned the highest possible score, ten, for that testing condition.

OPTION: For further assessment, the same 3 stances can be performed on a surface of medium density foam (e.g., approximately 50 cm x 40 cm x 6 cm).

Tandem Gait[6,7]

Participants are instructed to stand with their feet together behind a starting line (the test is best done with footwear removed). Then, they walk in a forward direction as quickly and as accurately as possible along a 38mm wide (sports tape), 3 meter line with an alternate foot heel-to-toe gait ensuring that they approximate their heel and toe on each step. Once they cross the end of the 3m line, they turn 180 degrees and return to the starting point using the same gait. A total of 4 trials are done and the best time is retained. Athletes should complete the test in 14 seconds. Athletes fail the test if they step off the line, have a separation between their heel and toe, or if they touch or grab the examiner or an object. In this case, the time is not recorded and the trial repeated, if appropriate.

Coordination Examination

Upper limb coordination

Finger-to-nose (FTN) task:

"I am going to test your coordination now. Please sit comfortably on the chair with your eyes open and your arm (either right or left) outstretched (shoulder flexed to 90 degrees and elbow and fingers extended), pointing in front of you. When I give a start signal, I would like you to perform five successive finger to nose repetitions using your index finger to touch the tip of the nose, and then return to the starting position, as quickly and as accurately as possible."

Scoring: 5 correct repetitions in < 4 seconds = 1

Note for testers: Athletes fail the test if they do not touch their nose, do not fully extend their elbow or do not perform five repetitions. **Failure should be scored as 0.**

References & Footnotes

1. This tool has been developed by a group of international experts at the 4th International Consensus meeting on Concussion in Sport held in Zurich, Switzerland in November 2012. The full details of the conference outcomes and the authors of the tool are published in The BJSM Injury Prevention and Health Protection, 2013, Volume 47, Issue 5. The outcome paper will also be simultaneously co-published in other leading biomedical journals with the copyright held by the Concussion in Sport Group, to allow unrestricted distribution, providing no alterations are made.

2. McCrory P et al., Consensus Statement on Concussion in Sport – the 3rd International Conference on Concussion in Sport held in Zurich, November 2008. British Journal of Sports Medicine 2009; 43: i76-89.

3. Maddocks, DL; Dicker, GD; Saling, MM. The assessment of orientation following concussion in athletes. Clinical Journal of Sport Medicine. 1995; 5(1): 32–3.

4. McCrea M. Standardized mental status testing of acute concussion. Clinical Journal of Sport Medicine. 2001; 11: 176–181.

5. Guskiewicz KM. Assessment of postural stability following sport-related concussion. Current Sports Medicine Reports. 2003; 2: 24–30.

6. Schneiders, A.G., Sullivan, S.J., Gray, A., Hammond-Tooke, G.&McCrory, P. Normative values for 16-37 year old subjects for three clinical measures of motor performance used in the assessment of sports concussions. Journal of Science and Medicine in Sport. 2010; 13(2): 196–201.

7. Schneiders, A.G., Sullivan, S.J., Kvarnstrom. J.K., Olsson, M., Yden. T.&Marshall, S.W. The effect of footwear and sports-surface on dynamic neurological screening in sport-related concussion. Journal of Science and Medicine in Sport. 2010; 13(4): 382–386

ATHLETE INFORMATION

Any athlete suspected of having a concussion should be removed from play, and then seek medical evaluation.

Signs to watch for

Problems could arise over the first 24–48 hours. The athlete should not be left alone and must go to a hospital at once if they:

- Have a headache that gets worse
- Are very drowsy or can't be awakened
- Can't recognize people or places
- Have repeated vomiting
- Behave unusually or seem confused; are very irritable
- Have seizures (arms and legs jerk uncontrollably)
- Have weak or numb arms or legs
- Are unsteady on their feet; have slurred speech

Remember, it is better to be safe.
Consult your doctor after a suspected concussion.

Return to play

Athletes should not be returned to play the same day of injury.
When returning athletes to play, they should be **medically cleared and then follow a stepwise supervised program,** with stages of progression.

For example:

Rehabilitation stage	Functional exercise at each stage of rehabilitation	Objective of each stage
No activity	Physical and cognitive rest	Recovery
Light aerobic exercise	Walking, swimming or stationary cycling keeping intensity, 70% maximum predicted heart rate. No resistance training	Increase heart rate
Sport-specific exercise	Skating drills in ice hockey, running drills in soccer. No head impact activities	Add movement
Non-contact training drills	Progression to more complex training drills, eg passing drills in football and ice hockey. May start progressive resistance training	Exercise, coordination, and cognitive load
Full contact practice	Following medical clearance participate in normal training activities	Restore confidence and assess functional skills by coaching staff
Return to play	Normal game play	

There should be at least 24 hours (or longer) for each stage and if symptoms recur the athlete should rest until they resolve once again and then resume the program at the previous asymptomatic stage. Resistance training should only be added in the later stages.

If the athlete is symptomatic for more than 10 days, then consultation by a medical practitioner who is expert in the management of concussion, is recommended.

Medical clearance should be given before return to play.

Scoring Summary:

Test Domain	Score		
	Date:	Date:	Date:
Number of Symptoms of 22			
Symptom Severity Score of 132			
Orientation of 5			
Immediate Memory of 15			
Concentration of 5			
Delayed Recall of 5			
SAC Total			
BESS (total errors)			
Tandem Gait (seconds)			
Coordination of 1			

Notes:

CONCUSSION INJURY ADVICE

(To be given to the **person monitoring** the concussed athlete)

This patient has received an injury to the head. A careful medical examination has been carried out and no sign of any serious complications has been found. Recovery time is variable across individuals and the patient will need monitoring for a further period by a responsible adult. Your treating physician will provide guidance as to this timeframe.

If you notice any change in behaviour, vomiting, dizziness, worsening headache, double vision or excessive drowsiness, please contact your doctor or the nearest hospital emergency department immediately.

Other important points:

- Rest (physically and mentally), including training or playing sports until symptoms resolve and you are medically cleared
- No alcohol
- No prescription or non-prescription drugs without medical supervision. Specifically:
  - No sleeping tablets
  - Do not use aspirin, anti-inflammatory medication or sedating pain killers
- Do not drive until medically cleared
- Do not train or play sport until medically cleared

Clinic phone number

Patient's name _____

Date/time of injury _____

Date/time of medical review _____

Treating physician _____

Contact details or stamp

Appendix II. Sport Concussion Assessment Tool for children

Child-SCAT3™

Sport Concussion Assessment Tool for children ages 5 to12 years

For use by medical professionals only

What is childSCAT3?[1]

The ChildSCAT3 is a standardized tool for evaluating injured children for concussion and can be used in children aged from 5 to 12 years. It supersedes the original SCAT and the SCAT2 published in 2005 and 2009, respectively[2]. For older persons, ages 13 years and over, please use the SCAT3. The ChildSCAT3 is designed for use by medical professionals. If you are not qualified, please use the Sport Concussion Recognition Tool[1].Preseason baseline testing with the ChildSCAT3 can be helpful for interpreting post-injury test scores.

Specific instructions for use of the ChildSCAT3 are provided on page 3. If you are not familiar with the ChildSCAT3, please read through these instructions carefully. This tool may be freely copied in its current form for distribution to individuals, teams, groups and organizations. Any revision and any reproduction in a digital form require approval by the Concussion in Sport Group.
NOTE: The diagnosis of a concussion is a clinical judgment, ideally made by a medical professional. The ChildSCAT3 should not be used solely to make, or exclude, the diagnosis of concussion in the absence of clinical judgement. An athlete may have a concussion even if their ChildSCAT3 is "normal".

What is a concussion?

A concussion is a disturbance in brain function caused by a direct or indirect force to the head. It results in a variety of non-specific signs and/or symptoms (like those listed below) and most often does not involve loss of consciousness. Concussion should be suspected in the presence of any one or more of the following:

-Symptoms (e.g., headache), or
-Physical signs (e.g., unsteadiness), or
-Impaired brain function (e.g. confusion) or
-Abnormal behaviour (e.g., change in personality).

SIDELINE ASSESSMENT

Indications for Emergency Management

NOTE: A hit to the head can sometimes be associated with a more severe brain injury. If the concussed child displays any of the following, then do not proceed with the ChildSCAT3; instead activate emergency procedures and urgent transportation to the nearest hospital:

- Glasgow Coma score less than 15
- Deteriorating mental status
- Potential spinal injury
- Progressive, worsening symptoms or new neurologic signs
- Persistent vomiting
- Evidence of skull fracture
- Post traumatic seizures
- Coagulopathy
- History of Neurosurgery (eg Shunt)
- Multiple injuries

1 Glasgow coma scale (GCS)

Best eye response (E)	
No eye opening	1
Eye opening in response to pain	2
Eye opening to speech	3
Eyes opening spontaneously	4
Best verbal response (V)	
No verbal response	1
Incomprehensible sounds	2
Inappropriate words	3
Confused	4
Oriented	5
Best motor response (M)	
No motor response	1
Extension to pain	2
Abnormal flexion to pain	3
Flexion/Withdrawal to pain	4
Localizes to pain	5
Obeys commands	6
Glasgow Coma score (E + V + M)	of 15

GCS should be recorded for all athletes in case of subsequent deterioration.

Potential signs of concussion?

If any of the following signs are observed after a direct or indirect blow to the head, the child should stop participation, be evaluated by a medical professional and **should not be permitted to return to sport the same day** if a concussion is suspected.

Any loss of consciousness?	Y N
"If so, how long?"	
Balance or motor incoordination (stumbles, slow/laboured movements, etc.)?	Y N
Disorientation or confusion (inability to respond appropriately to questions)?	Y N
Loss of memory:	Y N
"If so, how long?"	
"Before or after the injury?"	
Blank or vacant look:	Y N
Visible facial injury in combination with any of the above:	Y N

2 Sideline Assessment – child-Maddocks Score[3]

"I am going to ask you a few questions, please listen carefully and give your best effort."

Modified Maddocks questions (1 point for each correct answer)

Where are we at now?	0	1
Is it before or after lunch?	0	1
What did you have last lesson/class?	0	1
What is your teacher's name?	0	1
child-Maddocks score		of 4

Child-Maddocks score is for sideline diagnosis of concussion only and is not used for serial testing.

Any child with a suspected concussion should be REMOVED FROM PLAY, medically assessed and monitored for deterioration (i.e., should not be left alone). No child diagnosed with concussion should be returned to sports participation on the day of injury.

BACKGROUND

Name: _____ Date/Time of Injury: _____
Examiner: _____ Date of Assessment: _____
Sport/team/school: _____
Age: _____ Gender: M F
Current school year/grade: _____
Dominant hand: right left neither
Mechanism of Injury ("tell me what happened"?): _____

For Parent/carer to complete:

How many concussions has the child had in the past?	
When was the most recent concussion?	
How long was the recovery from the most recent concussion?	
Has the child ever been hospitalized or had medical imaging done (CT or MRI) for a head injury?	Y N
Has the child ever been diagnosed with headaches or migraines?	Y N
Does the child have a learning disability, dyslexia, ADD/ADHD, seizure disorder?	Y N
Has the child ever been diagnosed with depression, anxiety or other psychiatric disorder?	Y N
Has anyone in the family ever been diagnosed with any of these problems?	Y N
Is the child on any medications? If yes, please list:	Y N

SYMPTOM EVALUATION

3 Child report

Name: _____

	never	rarely	sometimes	often
I have trouble paying attention	0	1	2	3
I get distracted easily	0	1	2	3
I have a hard time concentrating	0	1	2	3
I have problems remembering what people tell me	0	1	2	3
I have problems following directions	0	1	2	3
I daydream too much	0	1	2	3
I get confused	0	1	2	3
I forget things	0	1	2	3
I have problems finishing things	0	1	2	3
I have trouble figuring things out	0	1	2	3
It's hard for me to learn new things	0	1	2	3
I have headaches	0	1	2	3
I feel dizzy	0	1	2	3
I feel like the room is spinning	0	1	2	3
I feel like I'm going to faint	0	1	2	3
Things are blurry when I look at them	0	1	2	3
I see double	0	1	2	3
I feel sick to my stomach	0	1	2	3
I get tired a lot	0	1	2	3
I get tired easily	0	1	2	3

Total number of symptoms (Maximum possible 20) _____

Symptom severity score (Maximum possible 20 x 3 = 60) _____

☐ self rated ☐ clinician interview ☐ self rated and clinician monitored

4 Parent report

The child	never	rarely	sometimes	often
has trouble sustaining attention	0	1	2	3
Is easily distracted	0	1	2	3
has difficulty concentrating	0	1	2	3
has problems remembering what he/she is told	0	1	2	3
has difficulty following directions	0	1	2	3
tends to daydream	0	1	2	3
gets confused	0	1	2	3
is forgetful	0	1	2	3
has difficulty completeing tasks	0	1	2	3
has poor problem solving skills	0	1	2	3
has problems learning	0	1	2	3
has headaches	0	1	2	3
feels dizzy	0	1	2	3
has a feeling that the room is spinning	0	1	2	3
feels faint	0	1	2	3
has blurred vision	0	1	2	3
has double vision	0	1	2	3
experiences nausea	0	1	2	3
gets tired a lot	0	1	2	3
gets tired easily	0	1	2	3

Total number of symptoms (Maximum possible 20) _____

Symptom severity score (Maximum possible 20 x 3 = 60) _____

Do the symptoms get worse with physical activity? ☐ Y ☐ N

Do the symptoms get worse with mental activity? ☐ Y ☐ N

☐ parent self rated ☐ clinician interview ☐ parent self rated and clinician monitored

Overall rating for parent/teacher/coach/carer to answer.
How different is the child acting compared to his/her usual self?
Please circle one response:

no different	very different	unsure	N/A

Name of person completing Parent-report: _____

Relationship to child of person completing Parent-report: _____

Scoring on the ChildSCAT3 should not be used as a stand-alone method to diagnose concussion, measure recovery or make decisions about an athlete's readiness to return to competition after concussion.

COGNITIVE & PHYSICAL EVALUATION

5 Cognitive assessment

Standardized Assessment of Concussion – Child Version (SAC-C)[4]

Orientation (1 point for each correct answer)

What month is it?	0	1
What is the date today?	0	1
What is the day of the week?	0	1
What year is it?	0	1

Orientation score _____ of 4

Immediate memory

List	Trial 1		Trial 2		Trial 3		Alternative word list		
elbow	0	1	0	1	0	1	candle	baby	finger
apple	0	1	0	1	0	1	paper	monkey	penny
carpet	0	1	0	1	0	1	sugar	perfume	blanket
saddle	0	1	0	1	0	1	sandwich	sunset	lemon
bubble	0	1	0	1	0	1	wagon	iron	insect
Total									

Immediate memory score total _____ of 15

Concentration: Digits Backward

List	Trial 1	Alternative digit list		
6-2	0 1	5-2	4-1	4-9
4-9-3	0 1	6-2-9	5-2-6	4-1-5
3-8-1-4	0 1	3-2-7-9	1-7-9-5	4-9-6-8
6-2-9-7-1	0 1	1-5-2-8-6	3-8-5-2-7	6-1-8-4-3
7-1-8-4-6-2	0 1	5-3-9-1-4-8	8-3-1-9-6-4	7-2-4-8-5-6
Total of 5				

Concentration: Days in Reverse Order (1 pt. for entire sequence correct)

Sunday-Saturday-Friday-Thursday-Wednesday-Tuesday-Monday	0	1

Concentration score _____ of 6

6 Neck Examination:

Range of motion Tenderness Upper and lower limb sensation & strength

Findings: _____

7 Balance examination

Do one or both of the following tests.

Footwear (shoes, barefoot, braces, tape, etc.) _____

Modified Balance Error Scoring System (BESS) testing[5]

Which foot was tested (i.e. which is the **non-dominant** foot) ☐ Left ☐ Right

Testing surface (hard floor, field, etc.) _____

Condition

Double leg stance:	Errors
Tandem stance (non-dominant foot at back):	Errors

Tandem gait[6,7]

Time taken to complete (best of 4 trials): _____ seconds

If child attempted, but unable to complete tandem gait, mark here ☐

8 Coordination examination

Upper limb coordination

Which arm was tested: ☐ Left ☐ Right

Coordination score _____ of 1

9 SAC Delayed Recall[4]

Delayed recall score _____ of 5

Since signs and symptoms may evolve over time, it is important to consider repeat evaluation in the acute assessment of concussion.

INSTRUCTIONS

Words in *Italics* throughout the ChildSCAT3 are the instructions given to the child by the tester.

Sideline Assessment – child-Maddocks Score

To be completed on the sideline/in the playground, immediately following concussion. There is no requirement to repeat these questions at follow-up.

Symptom Scale[8]

In situations where the symptom scale is being completed after exercise, it should still be done in a resting state, at least 10 minutes post exercise.

On the day of injury

- the child is to complete the Child Report, according to how he/she feels now.

On all subsequent days

- the child is to complete the Child Report, according to how he/she feels today, **and**
- the parent/carer is to complete the Parent Report according to how the child has been over the previous 24 hours.

Standardized Assessment of Concussion – Child Version (SAC-C)[4]

Orientation

Ask each question on the score sheet. A correct answer for **each question scores 1 point.** If the child does not understand the question, gives an incorrect answer, or no answer, then the score for that question is 0 points.

Immediate memory

"I am going to test your memory. I will read you a list of words and when I am done, repeat back as many words as you can remember, in any order."

Trials 2 & 3:

"I am going to repeat the same list again. Repeat back as many words as you can remember in any order, even if you said the word before."

Complete all 3 trials regardless of score on trial 1 & 2. Read the words at a rate of one per second. **Score 1 pt. for each correct response.** Total score equals sum across all 3 trials. Do not inform the child that delayed recall will be tested.

Concentration

Digits Backward:

"I am going to read you a string of numbers and when I am done, you repeat them back to me backwards, in reverse order of how I read them to you. For example, if I say 7-1, you would say 1-7."

If correct, go to next string length. If incorrect, read trial 2. **One point possible for each string length.** Stop after incorrect on both trials. The digits should be read at the rate of one per second.

Days in Reverse Order:

"Now tell me the days of the week in reverse order. Start with Sunday and go backward. So you'll say Sunday, Saturday .... Go ahead"

1 pt. for entire sequence correct

Delayed recall

The delayed recall should be performed after completion of the Balance and Coordination Examination.

"Do you remember that list of words I read a few times earlier? Tell me as many words from the list as you can remember in any order."

Circle each word correctly recalled. **Total score equals number of words recalled.**

Balance examination

These instructions are to be read by the person administering the childSCAT3, and each balance task **should be demonstrated to the child**. The child should then be asked to copy what the examiner demonstrated.

Modified Balance Error Scoring System (BESS) testing[5]

This balance testing is based on a modified version of the Balance Error Scoring System (BESS)[5]. A stopwatch or watch with a second hand is required for this testing.

"I am now going to test your balance. Please take your shoes off, roll up your pant legs above ankle (if applicable), and remove any ankle taping (if applicable). This test will consist of two different parts."

(a) Double leg stance:

The first stance is standing with the feet together with hands on hips and with eyes closed. The child should try to maintain stability in that position for 20 seconds. You should inform the child that you will be counting the number of times the child moves out of this position. You should start timing when the child is set and the eyes are closed.

(b) Tandem stance:

Instruct the child to stand heel-to-toe with the non-dominant foot in the back. Weight should be evenly distributed across both feet. Again, the child should try to maintain stability for 20 seconds with hands on hips and eyes closed. You should inform the child that you will be counting the number of times the child moves out of this position. If the child stumbles out of this position, instruct him/her to open the eyes and return to the start position and continue balancing. You should start timing when the child is set and the eyes are closed.

Balance testing – types of errors - Parts (a) and (b)

1. Hands lifted off iliac crest
2. Opening eyes
3. Step, stumble, or fall
4. Moving hip into > 30 degrees abduction
5. Lifting forefoot or heel
6. Remaining out of test position > 5 sec

Each of the 20-second trials is scored by counting the errors, or deviations from the proper stance, accumulated by the child. The examiner will begin counting errors only after the child has assumed the proper start position. **The modified BESS is calculated by adding one error point for each error during the two 20-second tests. The maximum total number of errors for any single condition is 10.** If a child commits multiple errors simultaneously, only one error is recorded but the child should quickly return to the testing position, and counting should resume once subject is set. Children who are unable to maintain the testing procedure for a minimum of **five seconds** at the start are assigned the highest possible score, ten, for that testing condition.

OPTION: For further assessment, the same 2 stances can be performed on a surface of medium density foam (e.g., approximately 50cm x 40cm x 6cm).

Tandem Gait[6,7]

Use a clock (with a second hand) or stopwatch to measure the time taken to complete this task. Instruction for the examiner – **Demonstrate the following to the child**:

The child is instructed to stand with their feet together behind a starting line (the test is best done with footwear removed). Then, they walk in a forward direction as quickly and as accurately as possible along a 38mm wide (sports tape), 3 meter line with an alternate foot heel-to-toe gait ensuring that they approximate their heel and toe on each step. Once they cross the end of the 3m line, they turn 180 degrees and return to the starting point using the same gait. ***A total of 4 trials are done and the best time is retained****. Children fail the test if they step off the line, have a separation between their heel and toe, or if they touch or grab the examiner or an object. In this case, the time is not recorded and the trial repeated, if appropriate.*

Explain to the child that you will time how long it takes them to walk to the end of the line and back.

Coordination examination

Upper limb coordination

Finger-to-nose (FTN) task:

The tester should **demonstrate it to the child**.

"I am going to test your coordination now. Please sit comfortably on the chair with your eyes open and your arm (either right or left) outstretched (shoulder flexed to 90 degrees and elbow and fingers extended). When I give a start signal, I would like you to perform five successive finger to nose repetitions using your index finger to touch the tip of the nose as quickly and as accurately as possible."

Scoring: 5 correct repetitions in < 4 seconds = 1
Note for testers: Children fail the test if they do not touch their nose, do not fully extend their elbow or do not perform five repetitions. **Failure should be scored as 0.**

References & Footnotes

1. This tool has been developed by a group of international experts at the 4th International Consensus meeting on Concussion in Sport held in Zurich, Switzerland in November 2012. The full details of the conference outcomes and the authors of the tool are published in The BJSM Injury Prevention and Health Protection, 2013, Volume 47, Issue 5. The outcome paper will also be simultaneously co-published in other leading biomedical journals with the copyright held by the Concussion in Sport Group, to allow unrestricted distribution, providing no alterations are made.

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CHILD ATHLETE INFORMATION

Any child suspected of having a concussion should be removed from play, and then seek medical evaluation. The child must NOT return to play or sport on the same day as the suspected concussion.

Signs to watch for

Problems could arise over the first 24–48 hours. The child should not be left alone and must go to a hospital at once if they develop any of the following:

- New Headache, or Headache gets worse
- Persistent or increasing neck pain
- Becomes drowsy or can't be woken up
- Can not recognise people or places
- Has Nausea or Vomiting
- Behaves unusually, seems confused, or is irritable
- Has any seizures (arms and/or legs jerk uncontrollably)
- Has weakness, numbness or tingling (arms, legs or face)
- Is unsteady walking or standing
- Has slurred speech
- Has difficulty understanding speech or directions

Remember, it is better to be safe.
Always consult your doctor after a suspected concussion.

Return to school

Concussion may impact on the child's cognitive ability to learn at school. This must be considered, and medical clearance is required before the child may return to school. **It is reasonable for a child to miss a day or two of school after concussion, but extended absence is uncommon.** In some children, a graduated return to school program will need to be developed for the child. The child will progress through the return to school program provided that there is no worsening of symptoms. If any particular activity worsens symptoms, the child will abstain from that activity until it no longer causes symptom worsening. Use of computers and internet should follow a similar graduated program, provided that it does not worsen symptoms. This program should include communication between the parents, teachers, and health professionals and will vary from child to child. The return to school program should consider:

- Extra time to complete assignments/tests
- Quiet room to complete assignments/tests
- Avoidance of noisy areas such as cafeterias, assembly halls, sporting events, music class, shop class, etc
- Frequent breaks during class, homework, tests
- No more than one exam/day
- Shorter assignments
- Repetition/memory cues
- Use of peer helper/tutor
- Reassurance from teachers that student will be supported through recovery through accommodations, workload reduction, alternate forms of testing
- Later start times, half days, only certain classes

The child is not to return to play or sport until he/she has successfully returned to school/learning, without worsening of symptoms. Medical clearance should be given before return to play.

If there are any doubts, management should be referred to a qualified health practitioner, expert in the management of concussion in children.

Return to sport

There should be no return to play until the child has successfully returned to school/learning, without worsening of symptoms.
Children must not be returned to play the same day of injury.
When returning children to play, they should **medically cleared and then follow a stepwise supervised program,** with stages of progression.

For example:

Rehabilitation stage	Functional exercise at each stage of rehabilitation	Objective of each stage
No activity	Physical and cognitive rest	Recovery
Light aerobic exercise	Walking, swimming or stationary cycling keeping intensity, 70 % maximum predicted heart rate. No resistance training	Increase heart rate
Sport-specific exercise	Skating drills in ice hockey, running drills in soccer. No head impact activities	Add movement
Non-contact training drills	Progression to more complex training drills, eg passing drills in football and ice hockey. May start progressive resistance training	Exercise, coordination, and cognitive load
Full contact practice	Following medical clearance participate in normal training activities	Restore confidence and assess functional skills by coaching staff
Return to play	Normal game play	

There should be approximately 24 hours (or longer) for each stage and the child should drop back to the previous asymptomatic level if any post-concussive symptoms recur. Resistance training should only be added in the later stages.
If the child is symptomatic for more than 10 days, then review by a health practitioner, expert in the management of concussion, is recommended.
Medical clearance should be given before return to play.

Notes:

CONCUSSION INJURY ADVICE FOR THE CHILD AND PARENTS / CARERS

(To be given to the **person monitoring** the concussed child)

This child has received an injury to the head. A careful medical examination has been carried out and no sign of any serious complications has been found. It is expected that recovery will be rapid, but the child will need monitoring for the next 24 hours by a responsible adult.

If you notice any change in behavior, vomiting, dizziness, worsening headache, double vision or excessive drowsiness, please call an ambulance to transport the child to hospital immediately.

Other important points:

- Following concussion, the child should rest for at least 24 hours.
- The child should avoid any computer, internet or electronic gaming activity if these activities make symptoms worse.
- The child should not be given any medications, including pain killers, unless prescribed by a medical practitioner.
- The child must not return to school until medically cleared.
- The child must not return to sport or play until medically cleared.

Clinic phone number

Patient's name

Date/time of injury

Date/time of medical review

Treating physician

Contact details or stamp

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