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Title: The Diagnostic Accuracy of Cross-Sectional Imaging for Detecting Acute Scaphoid Fractures in Children: A Systematic Review

Running Title: Imaging Suspected Scaphoid Fracture in Children: A Systematic Review

Type of Article: Systematic Review

Abstract

Objectives

To determine the diagnostic accuracy of cross-sectional imaging for the diagnosis of acute scaphoid fractures in children.

Methods

A systematic review of Medline, Embase and Cochrane databases between 1980 and July 2017 was independently performed by two observers. Criteria for study inclusion in a meta-analysis and assessment of the quality of such studies using the QADAS tool, were predetermined.

Results

No studies were eligible for inclusion in a meta-analysis. Three studies (of low quality when assessed against the STARD guidelines for reporting of studies of diagnostic accuracy) assessed MRI (performed between Days 2 and 10 after acute injury) for the diagnosis of scaphoid fractures in a total of 119 children (age range 6 to 16 years). Study 1 (45 children) reported inter-observer reliability of radiographs and MRI of 0.53 and 0.95 respectively. Study 3 (18 children) reported a negative predictive value of MRI (even as early as Day 2), of 100%. No measure of diagnostic accuracy or observer reliability was reported in Study 2 (56 children). In all 3 studies, MRI identified more scaphoid fractures (and other carpal injuries) than radiographs. Study 3 showed that follow-up MRI between Days 38 and 45 added no new information compared to initial MRI.

Conclusion

Based on a systematic review of the literature, there is currently no evidence on which to suggest an imaging protocol for suspected scaphoid fracture in children. Until such evidence is available, existing guidelines (which are based on expert opinion from adult studies) should be followed.

Advances in Knowledge

1. There is low quality evidence regarding the diagnostic accuracy of cross-sectional imaging for suspected scaphoid fractures in children and no evidence on which to propose an optimal imaging strategy
2. Until such evidence is available, current guidelines (based predominantly on findings in adults and expert opinion) should be followed

Introduction

The scaphoid plays an important role in the proper mechanics of wrist function.[1] The reported annual UK incidence of scaphoid fractures in children is 11 to 15 per 100,000, commoner in boys than girls[2,3] and accounting for 0.34% of all and 0.45% of upper limb fractures.[4] Historically fractures have most frequently involved the distal pole in children, however, increasing body mass index and earlier and more intense sporting activities are resulting in patterns of scaphoid fracture in children mirroring those in adults i.e. occurring more proximally and worsening the prognosis.[2,3,5,6]

Currently, when scaphoid fractures are clinically suspected, conventional radiography (CR) is the first line investigation; AP and lateral wrist radiographs are standard. Additional views (the so called, "scaphoid series") vary between institutions, but may include up to 4 projections with x-ray tube angulation utilised to elongate and improve visualisation of the scaphoid.[7,8] Because of the low rate of true fractures, many patients receive a cast unnecessarily, and authors of one adult study recently calculated the costs involved in treating suspected scaphoid fractures to be greater than those of MRI.[9] The American College of Radiology (ACR), the Guidelines in Emergency Medicine Network (GEMNet) and the Royal College of Radiology (RCR), do not have specific paediatric guidelines, but may be summarised as recommending initial radiographs followed by radiographs, unenhanced magnetic resonance imaging (MRI) or unenhanced computed tomography (CT) for follow-up imaging if a fracture continues to be suspected.[10-12] The National Institute for Health and Care Excellence (NICE) also does not have specific paediatric guidelines but (in contrast to the ACR, GEMNet and RCR) recommends MRI as the first line investigation following a "thorough" clinical examination.[13]

Concerned with poor results of a local audit indicating extensive patient follow-up and imaging, we conducted a systematic review to ascertain the most appropriate protocol for diagnosis of acute scaphoid fractures in children.

Materials and Methods

Review Question: "What is the diagnostic accuracy of cross-sectional imaging for the diagnosis of acute scaphoid fractures in children?"

Search Strategy: Using [MeSH] terms and limiting to Date 1980 to July 2017 and Language English), titles and abstracts were searched as follows:

Search 1: EMBASE Limiting to Human Age Groups Child unspecified age or Preschool Child 1 to 6 years or School Child 7 to 12 years or Adolescent 13 to 17 years, (Scaphoid bone OR scaphoid fracture AND Ultrasound OR X-ray OR Radiodiagnosis OR Nuclear Magnetic Resonance Imaging OR Computer Assisted Tomography)

Search 2: Medline Limiting to Age Groups Child, preschool or Child or Adolescent or Young adult (Carpal bones OR Scaphoid bone AND Fractures, bone OR Ultrasound OR X-rays OR Magnetic resonance imaging OR Radiography OR Tomography, x-ray computed)

The Cochrane database (all years) was also searched:

Search 3: (Scaphoid [Title, Abstract, Keywords] AND Child [All Text])

Search 4: (Scaphoid [Title, Abstract, Keywords] AND Diagnosis [All Text])

The following inclusion criteria were predetermined; 1) A clinical study of diagnostic accuracy that included CT and/or ultrasound and/or MRI to allow diagnosis of acute scaphoid fracture based on observer visualisation of abnormality, 2) The study used a clearly defined reference standard, 3) The full text paper was published in English, 4) If the study included adults, then results for children below 16 years of age were presented separately, 5) there was sufficient data to construct a 2x2 contingency table (or 2x2x2 if 2 or 3 modalities were compared).

The two study authors independently performed the searches and extracted and evaluated abstracts and full text articles. Results were then compared, pooled and agreed in consensus.

The quality of included articles to be agreed by consensus, using the Quality Assessment tool for

Diagnostic Accuracy Studies (QUADAS-2).[14,15]

Any papers specific to paediatrics but not eligible for inclusion in a systematic review and meta-analysis to be summarised and assessed against the STAndards for the Reporting of Diagnostic accuracy studies (STARD)[16] criteria to formally document reasons for their ineligibility for inclusion in a meta-analysis.

The study did not require Research Ethics Committee approval.

Statistical Analysis

SPSS V21 for Mac was used to summarise descriptive statistics.

Results

Of the 457 identified articles, 51 were duplicated and 384 eliminated based on either their title or abstract, so that 22 full text articles were retrieved. A hand search of their references yielded 1 additional paper; therefore, a total of 23 full text articles were reviewed.[6,17-38] Of these 23 articles, none fulfilled our inclusion criteria for a meta-analysis. Figure 1 is a flow diagram summarising the results of the search strategy. The 23 eliminated articles and the reasons for their elimination are summarised in Table 1.

Of the 23 ineligible papers, 3 were specific to paediatrics.[38-40] The findings of these papers and their compliance with the STARD checklist[16] are summarised in Tables 2 and 3 respectively.

Discussion

A systematic review of the literature identified no papers allowing the recommendation of an imaging strategy for scaphoid fractures in children. This is a significant evidence gap because the most frequent wrist fracture mechanism is a fall onto the outstretched hand[4,41,42] and the scaphoid is the commonest of the carpal bones to fracture following such a fall.[41,43]

A recent meta-analysis concluded that anatomical snuffbox (ASB) tenderness was the most sensitive clinical test (albeit with a specificity of only 3%) and that the low specificity of clinical tests potentially results in significant overtreatment.[6] Some researchers have attempted to develop clinical decision rules or scoring systems,[44,45] however these studies relate to adults and their applicability to children is uncertain. Clinical findings shown to be significant predictors of scaphoid fracture in children include volar tenderness, pain with radial deviation of the wrist and pain with active range of motion,[46] however scaphoid fractures are identified in only 6.7%-11.5% of children in whom they are initially suspected on clinical grounds.[2,3]

Typical first line imaging in this context is the scaphoid series, the radiation dose of which is about 8μSv (2 days of background radiation).[47] The fracture may appear as a break in the cortex, a radiolucent line or frank displacement of fragments. The false negative rate of initial radiographs in children is 12.5%-37%.[4,43,48] Misdiagnosis is high compared to adults because scaphoid fractures are less common and the immature skeleton is harder to interpret.[49,50] For these reasons, if clinical suspicion remains, the general policy is to place the wrist in a cast and repeat radiographs after 7 to 14 days, by which time it is hoped that sclerosis from healing will render the fracture more prominent.[47,51] However, sensitivity, negative predictive value and observer reliability of delayed radiographs is also low.[52] The situation is further complicated by anecdotal evidence (discussion with colleagues at other national and international centres) that scaphoid series and imaging protocols vary from centre to centre and indeed not all centres have a protocol in place for imaging suspected scaphoid fractures in children.

Magnetic resonance imaging (MRI) does not expose the child to ionising radiation, and sedation may not always be required. Asesssment of MRI protocols was outside the scope of this review, however one recommended protocol includes coronal T1 and STIR with diagnostic features being high signal on STIR from bruising/haemorrhage and a low signal fracture line on T1.[53] Many authors perceive MRI to be the "gold standard", however acute MRI services have significant infrastructural and organisational issues to overcome[51] and the use of MRI as the first line investigation of suspected scaphoid fractures (as recommended by NICE[13]) may not be a short or even medium-term option for many centres. It has been suggested that a short MRI protocol (with a low field strength magnet) following radiography for initial evaluation of adult patients with acute wrist trauma does not identify those patients who can be discharged without further follow-up.[54] Therefore, irrespective of scanner availability, the clinical and cost effectiveness of MRI in the management of scaphoid fractures in children needs to be assessed.

Computed tomography (CT) is widely available, of moderate cost and can be used in the acute setting. Image reconstruction at sub-mm thickness is possible and the acute fracture appears as a cortical disruption[52], however specificity is said to be reduced due to the resemblance between normal intertrabecular channels and fracture lines.[55-57] The radiation dose is 30µSv (1 week of background).[58] We did not find any studies comparing CT to radiographs for the diagnosis of scaphoid fractures in children.

Like MRI, ultrasound does not use ionising radiation. Ultrasound is widely available and relatively cheap; however, it is user-dependent. Currently there is no evidence to support its use and diagnostic accuracy and cost effectiveness of ultrasound would have to be prospectively assessed before this could be recommended as a routine first or second line investigation in children.

Nuclear medicine (NM) scanning involves radioisotope being taken up (4-6 hours after intravenous injection) by active osteoblasts during fracture healing; to return positive results, scans should not be performed until 1 to 3 days following trauma.[59,60] Therefore, although NM has 100% sensitivity, this delay, the high radiation dose of up to 4000µSv (2 years of background)[53] and expense[61] render NM an unattractive option. We did not include the term "nuclear medicine" in our search for these reasons and because we were concerned with cross-sectional methods that could potentially be employed on the day of initial presentation.

The American College of Radiology (ACR), the Guidelines in Emergency Medicine Network (GEMNet) and the Royal College of Radiology (RCR) all recommend initial radiographs. If negative but clinical suspicion is high, then the patient receives a cast. In this scenario, the ACR recommends Day 10-14 MRI, scaphoid series or unenhanced CT.[10-12] The GEMNet and RCR also suggest cross-sectional imaging for follow-up without specifying the timing. None of the guidelines are specifically for children; the title of the GEMNet suggests it is for adults, but within the text it is stated that the guidelines are for anyone aged over 8 years (however there is only one sentence referring to children in the entire 32-page document).

Three studies[38-40] were specific to children, but either did not include an external reference standard for the confirmation of scaphoid fracture or were not explicit as to the nature of the reference standard. All three scored poorly against the STARD checklist (it should be mentioned that two of the papers[38, 39] predate the 2003 publication of the initial STARD tool). However, had they complied with the STARD guidelines, they would also have been eligible for inclusion in a meta-analysis, underscoring the importance of adequate reporting of studies of diagnostic accuracy.

Although not explicitly stated, it would seem that Cook et al used serial radiographs as their reference standard.[40] If this is the case, then based on the data the authors present, both the sensitivity and specificity of MRI are 100%. This should be interpreted with caution, not only because of the small study population (18 patients), but also because it isn't clear exactly how many radiographs each child had and over what period of time (maximum follow-up was 1 year), neither is it clear what the end-point was that determined the follow-up period for each child. The lack of a reference standard was highlighted by Kavanaki et al in their discussion.[38] The very test that they (and Johnson et al[39]) were assessing, is also what they took as their reference standard.

We accept that the design of a robust prospective study to address the research question may be difficult and suggest that a suitable reference standard for such a study might be Day 10 to 14 MRI (to ensure some resolution of potentially confounding oedema on early scans and using a "long protocol" MRI) against which earlier (Day 1) imaging, other modalities and/or "short protocol" MRI can be assessed. Another option for such a prospective study might be to employ alternative methods of data analysis, developed for medical tests for which there are no reference/gold standards.[62]

Conclusion

This systematic review identified no studies that allow the recommendation of an evidence-based diagnostic imaging pathway for children with suspected scaphoid fracture. Optional pathways based on existing ACR,[10] GEMNet,[11] RCR[12] and NICE[13] guidelines are summarised in Figure 2. Until evidence-based results are available, it is left to the reader's discretion to follow the guideline that is most compatible with their local practice, facilities and expertise.

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Table and Figure Legends

Figures

Figure 1:

Flow diagram showing outcome of systematic review. No eligible studies were found for inclusion in a meta-analysis

Figure 2:

Summary of existing guidelines for imaging of suspected scaphoid fracture

Tables

Table 1:

Full text papers retrieved and subsequently excluded from the systematic review and reason(s) for their exclusion

Table 2:

Summary of papers evaluating MRI for the diagnosis of scaphoid fracture in children.

MRI = magnetic resonance imaging. X-ray = radiograph(s)

Table 3:

Assessment of papers evaluating MRI for the diagnosis of scaphoid fracture in children against the STARD-2 checklist

Table 1: Summary of Excluded Articles

Reference	1st Author/Year of Publication	Reason(s) for Exclusion
17	Ring D/2008	Single case report
18	Bedford AF/1982	The ultrasound diagnosis of fracture depended on the patients' subjective responses to pain caused by the ultrasonic vibrations rather than visual identification of the fracture Recruited both children and adults; data for children is not separately extractable
19	Da Cruz DJ/1988	
20	Christiansen TG/1991	
21	Tibrewal S/2012	Age of recruits is not stated
22	Herneth AM/2001	Recruited both children and adults; data for children is not separately extractable
23	Hauger O/2002	
24	Senall JA/2004	
25	Nguyen Q/2008	
26	Welling RD/2008	
27	Balci A/2015	The lower end of the age range for study participants is 17 years
28	de Zwart AD/2016	The lower end of the age range for study participants is 18 years
29	Fusetti C/2005	Recruited adults only
30	Nakamura R/1991	
31	You JS/2007	
32	Jenkins PJ/2008	
33	Ilica AT/2011	
34	de Zwart AD/2012	
6	Mallee WH/2014	Systematic reviews of studies that include both children and adults; data for children is not separately extractable
35	YinZ-G/2010	
36	YinZ-G/2012	
37	Mallee WH/2015	
38	Kanavaki A/2016	No defined reference standard for confirmation of scaphoid fracture

Table 2: Summary of 3 studies evaluating MRI for diagnosis of scaphoid fracture in children

Parameter	Kavanaki et al, 2016 [38]	Johnson et al, 2000 [39]	Cook et al, 1997 [40]
Design	Retrospective	Uncertain – Prospective?	Prospective
Sample size	45 children/45 scans	56 children/57 scans	18 children/36 scans
Age range (years)	8-16 (mean =12.7, SD = 2)	6-11 (mean = 12.5, median = 11.6)	Girls: 10-14 (mean = 12) Boys: 8-15 (mean = 11)
MRI field strength	1.5T	1.5T	1.5T
MRI protocol	Coronal T1, Coronal STIR	Coronal T1, Coronal T2, Sagittal STIR	Coronal T1, Coronal GRE, Sagittal T1, Axial PD, Axial T2
Day of MRI	3-10	2-10	Initial: 2-10 (mean = 6) Follow-up: 38-45 (mean = 41)
MRI in all patients	Yes	No	Yes (initial and follow-up)
Inter-observer reliability (kappa)	Radiograph = 0.53 MRI = 0.95	Not calculated	Not calculated
Diagnostic accuracy	Not calculated No reference standard	Not calculated No reference standard	Normal MRI (even at 2 days) has a negative predictive value of 100%
MR compared to radiographic findings	For Reader AN: *Radiograph* No fracture = 17 Fracture/equivocal = 28 *MRI* No fracture = 22 Fracture/equivocal = 23 For Reader BN: *Radiograph* No fracture = 26 Fracture/equivocal = 19 *MRI* No fracture = 21 Fracture/equivocal = 24	MRI was normal in 27 cases where radiography was normal MRI detected 17 scaphoid and/or carpal fractures where radiography was normal MRI was normal in 6 cases where radiography was equivocal MRI identified 2 scaphoid and 2 other fractures where radiography was equivocal MRI identified 3 scaphoid fractures where radiography also identified scaphoid fracture	Initial MRI detected 6 fractures of which 4 had normal initial radiographs (fractures confirmed on subsequent radiographs) No child with marrow oedema but absent fracture line on initial MRI progressed to radiographic fracture Obliteration of the scaphoid fat stripe was seen on radiographs of 11 children, only 5 of whom had a scaphoid fracture on MRI Compared to the initial MRI, follow-up MRI yielded no new information

Table 3: Assessment of studies evaluating MRI for diagnosis of scaphoid fracture in children against STARD 2015 checklist[16]

Section & Topic	No	Item	Reported on page #		
			Kavanaki et al, 2016 [38]	Johnson et al, 2000 [39]	Cook et al, 1997 [40]
TITLE OR ABSTRACT	**Section & Topic**				
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	Abstract mentions NPV*. #495	No	Abstract mentions NPV. #511
ABSTRACT					
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Yes. #495	Yes. #685	Yes. #511
INTRODUCTION					
	3	Scientific and clinical background, including the intended use and clinical role of the index test	Yes. #495 It seems that MRI is the index test	Yes. #685 It seems that MRI is the index test	Yes. #512
	4	Study objectives and hypotheses	Yes. #495	Yes. #495	Yes. #512
METHODS					
Study design	**5**	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Retrospective	Not explicitly stated – seems prospective	Prospective. #512
Participants	**6**	Eligibility criteria	#495	Not explicitly stated	Skeletally immature as confirmed from radiographs. #512
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Pain ASB/scaphoid Had “early” MRI (early = between days 3 and 10)	Suspected scaphoid fracture #686. No further detail	Suspected scaphoid fracture (point tenderness ASB/scaphoid or soft tissue swelling. #512
	8	Where and when potentially eligible participants were identified (setting, location and dates)	Case note review of those who attended ED 2009-2012	ED #686. No dates	ED #512

	9	Whether participants formed a consecutive, random or convenience series	Not explicitly stated; presumed consecutive	Not explicitly stated; presumed consecutive	Not explicitly stated; presumed consecutive
Test methods	**10a**	Index test, in sufficient detail to allow replication	Yes. # 496	Yes. # 686	Yes. #512
	10b	Reference standard, in sufficient detail to allow replication	No clear reference standard (if we assume that MRI is the index test)	No clear reference standard (if we assume that MRI is the index test)	Partially: Serial radiographs at intervals of 2-3 weeks with last at 1 year; uncertain how many in total (it is doubtful that images were obtained every 2-3 weeks throughout the year). #512
	11	Rationale for choosing the reference standard (if alternatives exist)	No	No	Reference standard of serial radiographs not explicitly stated – presumably selected as standard of care
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	No	No	Yes. #512
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	No	No	Yes. #512
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	Yes – aware of age clinical suspicion of scaphoid fracture #496	Yes. #687	Neither clinical nor radiographic information available. #512
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	No clear reference standard (they propose an MRI protocol	No clear reference standard (they propose an MRI protocol but	Clinical information but not MRI information available. #512

			but do not assess it against an external reference standard)	do not assess it against an external reference standard)	
Analysis	**14**	Methods for estimating or comparing measures of diagnostic accuracy	Not assessed	Not assessed	NPV. #511
	15	How indeterminate index test or reference standard results were handled	Consensus #496	No indeterminate tests	No
	16	How missing data on the index test and reference standard were handled	Not discussed	Not discussed	No missing data
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	No	No	No
	18	Intended sample size and how it was determined	No power calculation. 45 children recruited	No power calculation. 56 children recruited	No power calculation. 18 children recruited
RESULTS					
Participants	**19**	Flow of participants, using a diagram	No	No	No
	20	Baseline demographic and clinical characteristics of participants	#496	#686	#512
	21a	Distribution of severity of disease in those with the target condition	N/A	N/A	N/A
	21b	Distribution of alternative diagnoses in those without the target condition	#496	#686	#512, #513
	22	Time interval and any clinical interventions between index test and reference standard	No clear reference standard	No clear reference standard	#512
Test results	**23**	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	No	No	No
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	No	No	No (NPV of MRI presented)
	25	Any adverse events from performing the index test or the reference standard	N/A	N/A	N/A
DISCUSSION					
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Yes. #499	No	Brief discussion. #514
	27	Implications for practice, including the intended use and clinical role of the index test	Yes. #499	Yes. #688	Yes. #514, #515
OTHER INFORMATION					
	28	Registration number and name of registry	No	No	No
	29	Where the full study protocol can be accessed	No	No	No
	30	Sources of funding and other support; role of funders	No	No	No

* NPV = negative predictive value