The responsiveness of the Chelsea Critical Care Physical Assessment tool in measuring functional recovery in the burns critical care population: An observational study.

Evelyn Corner[1,2], Louise Hichens[3], Kate Attrill[3] , Marcela Vizcaychipi[2,4], Stephen Brett[2,5], Jonathan Handy[2,4]

[1]Clinical Lead Respiratory Physiotherapist and Clinical Research Fellow, Chelsea and Westminster NHS Foundation Trust, Chelsea and Westminster Hospital, 369 Fulham Road, London SW10 9NH, England

[2]Imperial College London, Chelsea and Westminster Hospital, 369 Fulham Road, London, SW10 9NH, England.

[3]Senior Burn's Specialist Physiotherapist, Chelsea and Westminster NHS Foundation Trust, Chelsea and Westminster Hospital, 369 Fulham Road, London SW10 9NH, England

[4]Consultant in Intensive Care Medicine and Honorary Senior Lecturer, Chelsea and Westminster NHS Foundation Trust, Chelsea and Westminster Hospital, 369 Fulham Road, London SW10 9NH, England

[5]Consultant in Intensive Care Medicine and Reader in Critical Care, Centre for Perioperative Medicine and Critical Care Research, Imperial College NHS Healthcare Trust, Hammersmith Hospital, Du Cane Road, London W12 0HS, England, UK

Email addresses:
e.corner13@imperial.ac.uk
Louise.Hichens@nbt.nhs.uk
kate.attrill@chelwest.nhs.uk
m.vizcaychipi@imperial.ac.uk,
stephen.brett@imperial.ac.uk
j.m.handy@imperial.ac.uk

Correspondence to:

Evelyn Corner

Email: e.corner13@imperial.ac.uk

Telephone: (+44) 2033155689

Mobile: (+44) 7817901140

Fax number: 02033156069

Postal address: Therapies Department, Ground floor, Chelsea and Westminster Hospital, 369 Fulham Road, London, SW10 9NH, England.

Abstract

Introduction
Severe burn injury leads to a state of hypercatabolism, resulting in rapid muscle loss and long-term disability. As survival rates from severe burn injury are improving, early rehabilitation is essential to facilitate functional recovery. However there is no way of measuring the degree of disability in the acute stages, hence, no marker of functional recovery. This hampers both communication and research into interventions to improve functional outcomes.

The Chelsea Critical Care Physical Assessment tool (CPAx) is a simple objective measure of function, designed and validated in the general Intensive Care Unit (ICU) cohort. The aim of this study was to test the responsiveness of the CPAx in the burns ICU (BICU) cohort and validate its use.

Methods
Observational study of 52 BICU patients admitted for over 48 hours. All patients were assessed on the CPAx retrospectively for pre-admission, and prospectively at ICU admission, ICU discharge (or final ICU assessment for non-survivors) and hospital discharge.

Analysis of variance, post hoc between group differences in median CPAx score, and floor and ceiling effect (i.e. the percentage of patients scoring full marks (50), or zero) for the four time points was completed. Minimal Clinically Important Difference (MCID) was estimated as half of the standard deviation of the CPAx score at ICU discharge.

Results
A total of 30 patients were included in the final analysis; mean age 47.1 (SD 21.2), 63.3% were male, with a median burn total body surface area (TBSA) of 30% (IQR 11.3-48.8). There was a significant difference in on analysis of variance in median CPAx scores at all four time-points ($p<.001$). In survivors, the differences in CPAx scores post hoc was significant for all time-points ($p<.05$), aside from ICU discharge and hospital discharge. The CPAx MCID for BICU patients was six.

Twenty-three (86.7%) of patients scored full marks or zero on the CPAx pre-admission. For survivors, no patients scored full marks or zero on the CPAx at ICU and hospital discharge. On ICU admission 66.7% (n=20) scored zero on the CPAx and no patients scored 50.

Conclusions
The CPAx score appears to be able to detect improvements in physical function as patients recover from acute severe burn injury. It has a limited floor and ceiling effect in the acute setting and a change in CPAx score of 6 represents clinically important progress. Further work is required in a larger cohort.

Key words: burns; rehabilitation; critical care; outcome measure, physiotherapy; disability evaluation.

Abbreviations: SIRS, systemic inflammatory response syndrome; CPAx, Chelsea Critical care Physical Assessment tool; ICU, Intensive Care Unit; TBSA, total body surface area; BOBI, Belgium Outcomes in Burns Injury score; TENS, toxic epidermal necrolysis syndrome; MCID, minimal clinically important difference; SEN, standard error of measurement; FAB, Functional Assessment in Burns; FIM, Functional Independence Measure; BI, Barthel Index.

Introduction

There are around 16,100 people admitted to hospital with burn injuries in the UK annually, and around 300 of those have severe, complex burns, which are likely to require admission to the BICU [1,2]. Over the past 20 years, standard practice has been to perform early debridement of burnt skin in patients with acute major burn injuries. This practice has evolved in hand with the philosophy that burnt tissue acts as a motor for systemic inflammation and organ failure; it has coincided with improvements in outcome following burn injury and is likely to be a major influence in this change.

In general, surgery and grafting will take place as early as possible as there is usually a narrow window before the major complications of SIRS and sepsis develop. Invasive organ support is frequently required in this cohort. Early nutrition is a vital component to long-term recovery and healing; aggressive calorific management is commenced immediately and continues for months in order to aid healing and rehabilitation [3]. Both the acute and chronic phases of major burn injury are characterized by massive energy requirements to allow regeneration of the extensive muscle mass that is lost during the acute catabolic stages. Enforced bed rest and the presence of infections/sepsis further perpetuate muscle loss [4]. As a result early rehabilitation for burns survivors' is vital, complex and specialized; beyond that of the general ICU population.

Burns rehabilitation is a multi-disciplinary team (MDT) approach, with the therapeutic objective of minimizing long-term disability. One of the challenges to the MDT has been the lack of an accurate measure of function that is inclusive and reflective of the burns patients' complex needs. As physical function cannot be directly measured per se, it is considered a latent trait in measurement theory and as such, requires development and validation of an appropriate tool comprised of relevant functional tasks, broken down and graded appropriately to allow a composite score to be calculated. Without such a tool to measure the degree of functional impairment, it is difficult to perform objective assessment of disability, monitor that disability as it changes over time, compare functional outcomes in interventional studies, and communicate the level of disability concisely between professionals, patients and family.

Previous studies have utilized the Functional Independence Measure (FIM), the Barthel Index (BI) and the Functional Assessment for Burns (FAB) to measure disability in the severe burns population in the ward and rehabilitation stages [5,6,7], however no measure has been utilized in BICU; this may be due to a perceived floor effect at this time. For example, the FAB grades patients on a Guttmann scale from one to five (dependence to independence) in the following activities: feeding, washing, toileting, transfers, dressing, walking and climbing stairs. This measure has been through initial psychometric testing, demonstrating predictive validity for final hospital discharge location from BICU discharge, but due to the composite tasks, it is likely to have a floor effect on the BICU [7]. Further psychometric evaluation of this measure would be beneficial, to ensure that it has inter-rater reliability.

The Chelsea Critical Care Physical Assessment (CPAx) tool is a functional scoring system designed and validated for general ICU patients [8,9]. It is comprised of ten commonly assessed components of physical function, which are graded on a Guttman scale from dependent to independent (0-5), giving an overall score from zero to fifty. These are: respiratory function; cough; bed mobility; supine to sitting on the edge of the bed; sitting balance; sit to stand; transfers from bed to chair; standing balance; stepping and grip strength. As the CPAx was specifically designed to detect change in low functioning patients, thus have a minimal floor effect; it may be a useful functional measurement system in the BICU. However, due to the different rehabilitation needs of this specialized group it is vital that the validity of the CPAx in BICU is tested to ensure that the tools composite parts and their grading systems are valid in this cohort. As there is no current 'gold standard' in the functional assessment of BICU patients to compare the CPAx to, the

validation process becomes more complex, and surrogates such as level of care must be used as a measure of clinical improvement instead.

The primary aim of this study was to test the responsiveness of the CPAx in the BICU population. This is broken down into three key components;

1. to see if the CPAx can detect change through clinically important time points from, predicted preadmission score to ICU admission, ICU discharge (or final ICU assessment for non-survivors) and hospital discharge;
2. to establish an estimated minimal clinically important difference (MCID) in CPAx score in burns patients.
3. to analyze the floor and ceiling effect of the CPAx at these time points.

Methods:

As the CPAx score is already in clinical use in the BICU of this hospital, this work was classified as service evaluation and, as such, ethical approval was not sought. All data was collected as part of routine clinical care and was anonymised for analysis; the need for patient consent was waived.

Inclusion criteria were all patients admitted to the BICU for over 48 hours with completed CPAx scores. Toxic epidermal necrolysis syndrome (TENS) patients, although managed on the BICU, were excluded due to the unique nature of the condition and its management. All patients were over sixteen years old.

Data were collected from a two-bedded specialty BICU in central London over a 31-month time period from 16th September 2011 to 30th March 2014. All patients admitted to the BICU are assessed for TBSA, burn depth, inhalation injury and need for surgery according to recognized Emergency Management of Severe Burns Course/Adult Trauma Life Support protocols. Patients are fluid resuscitated using the parkland formula and monitored for urine output and resuscitation outcomes such as blood gas assessment and vitals. If inhalation injury is suspected patients undergo a bronchoscopy and a respiratory physiotherapy assessment within 24 hours. Patients with need for debridement are taken to theatres for definitive skin cover within 24 hours and covered with autograft or allograft if there is need to temporise the wound or there is insufficient donor site. The patient is then reviewed every 48 hours for graft viability and wound assessment. Staples are removed at day 6 and after day 10 the patient is then assessed for donor site healing/re-cropping. Immediate escharotomies are performed if there is evidence of circumferential burns or compartment syndromes, followed by stabilization and grafting. The therapy service has a model of daily therapy review for all inpatients (from ICU to ward care). This is a 'hands on' assessment and treatment, which includes: respiratory therapy; physical therapy (i.e. exercise and functional rehabilitation); and, scar management.

The lead burns physiotherapists were taught how to use the CPAx tool by the primary developer (EC) in a case based tutorial. As many of the burns therapy staff rotate between teams, the lead burns physiotherapist taught new staff members how to use the CPAx tool. The CPAx has been shown to have good inter-rater reliability [8] so no further testing was completed in this study. The full content of the CPAx can be found in previously published work [8].

The CPAx score was assessed at four key time points that represent clinically important progress for patients (see table 1): predicted preadmission score based on patient and proxy reporting; ICU admission CPAx score; ICU discharge CPAx score; and hospital discharge CPAx score. For patients that died on the ICU, the final CPAx assessment was included as the ICU discharge score. These data were used to analyze the ability of the CPAx to detect change, or lack thereof, through this patient journey.

If the patients' level of care was stepped down over the weekend, the score was taken on the following Monday due to the pragmatics of training up non-specialist weekend staff to complete the assessments. As the CPAx score includes grip strength dynamometry, and this could not be assessed for the pre-admission CPAx score, an average (mean) of the nine other CPAx components was used. This is a recommended method of accounting for missing scale subsections [10]. Where available, follow up CPAx scores in the outpatient setting were also collated, however this was not part of the initial plan due to transfer of care elsewhere, loss to follow up, and the structure of the clinic setting. These data are reported descriptively for the readers' interest.

The following demographic data were also collected: age; length of stay (hospital and ICU); the number of days of mechanical ventilation; type of burn (i.e. flame, scald, chemical, and contact); Total Body Surface Area of burn (TBSA); percentage of deep dermal or full thickness burns; number of theatre trips; Belgium Outcomes in Burn Injury score (BOBI); severity of burn (American Burns Association criteria), location of burn; presence of inhalation injury; predicted pre-admission CPAx score; the number of days post burn when the CPAx score returned to predicted preadmission level.

Data analysis

Statistical analysis was performed with Excel (version 2010, Microsoft Corporation, Seattle) and Prism (version 5, GraphPad Software, San Diego). Data were assessed for normality using the D'Agostino & Pearson omnibus normality test and are presented as mean (±standard deviation) or median (range [inter-quartile range]), parametric or non-parametric equivalent tests were used as appropriate.

Statistical differences between time points were assessed by analysis of variance (Kruskal-Wallace), Dunn's multiple comparison test was used to analyze the individual differences between groups post hoc. The primary level of significance was set at $p < 0.05$ adjusted for multiple comparisons.

Half of the largest standard deviation of CPAx score and the standard error of measurement (SEM) were used as measures of minimal clinical important difference (MCID) [11,12].

The percentage of patients scoring zero or fifty on the CPAx score at the four time points is reported as a measure of floor and ceiling effect. The CPAx is an ordinal scale so median (range [inter-quartile range]) CPAx scores are reported.

Results

Thirty patients were included in the final analysis, with 22 excluded. Patient attrition is displayed in the "Consort" diagram in Figure 1. Of the four patients whom did not have a CPAx score; one was palliated prior to a physiotherapy review and the rest did not have a score due to staff shortages and temporary staff who had not been inducted into using the CPAx tool. The average age was 47.1 (SD21.2), 63.3% were male, the median TBSA was 30% (IQR 11.3-48.8). Full demographic data of all admissions and the study cohort are presented in table 2.

Only the CPAx scores at ICU discharge were normally distributed ($p<0.05$) and as the CPAx score is an ordinal scale, non-parametric inferential statistical analysis was completed.

Responsiveness and floor and ceiling effect

Figures 2 and 3 demonstrates the change in CPAx score as the care needs of the patient reduce from ICU admission to hospital discharge, as well as predicted pre-admission scores. These are presented as raw data demonstrating individual recovery trajectories. Figure 2 includes all patients and figure 3 represents survivors only.

Predicted pre-admission CPAx scores were high (median 50, IQR 50-50, range 13-50), with 86.7% (n=26) of patients scoring 50. No patients' scored zero on the CPAx score prior to admission.

At ICU admission CPAx scores were at their lowest (median 0, IQR 0-1, range 0-40), with 66.7% (n=20) of patients scoring zero. No patients scored fifty on the CPAx score at ICU admission.

At ICU discharge 13.3% (n=4) of patients scored zero on the CPAx, all of whom died on ICU. No patients scored full marks of 50. For survivors, no patients scored either 0 or 50 on the CPAx at ICU discharge (median 18, IQR 14-32.0; range 9-45).

No survivors at hospital discharge scored zero or 50 on the CPAx (median 44.0, IQR 42.0-45.0, range 22-48). Where known, the number of days post burn when the CPAx score returned to pre-morbid level in survivors ranged from 27 to 216 days (median 68 [IQR 41-146]) (n=9).

Analysis of variance showed statistically significant differences between time points for all patients (n=30) ($p<.0001$, $H(2)= 88.53$), this was also significant for survivors alone (n=23) ($p<.0001$, $H(2) = 87.69$).

Post hoc comparisons for differences between time points are shown in table 3, all differences between groups were significant, apart from two. The difference between median ICU admission and discharge CPAx scores in all patients; and the difference between ICU discharge CPAx scores and ward/hospital discharge CPAx score in survivors.

Minimal clinically important difference

As the ICU discharge CPAx score was the only normally distributed time point, and had the largest standard deviation, this was used to give an estimate of MCID. The mean CPAx score on ICU discharge for survivors was 23.65 (SD 12.08), therefore the estimated MCID is a change in CPAx score of 6.04, however as CPAx score is calculated in integers, this has been rounded to 6, which is 12% of the total CPAx scale. The standard error of the measurement at this time point was 2.518, thus a change of 3 (rounded up) is likely to represent a true change in the CPAx score for the burns cohort.

Discussion

These data from a small cohort of burns patients suggest that the CPAx is responsive to change in BICU from hospital admission to discharge. A change in CPAx score of six is likely to reflect clinically meaningful progress, and a change of three represents a true change in score. There is a floor effect of the CPAx on admission to ICU, however this may reflect the patients' severity of illness. The CPAx has limited floor and ceiling effect in the acute setting.

Responsiveness is an important psychometric quality of any clinical scoring system. It determines whether the measure is able to detect changes in the construct in which it is designed to measure, in the environment and cohort that it was intended for. Unlike sensitivity, responsiveness specifies that any change detected must be clinically relevant. If a tool is able to detect when a clinically meaningful change

has occurred or, equally as importantly, remains static in the absence of meaningful change, then it can be used as a validated outcome in both clinical practice and research.

Importantly, it must be acknowledged that no scoring system of function will ever be able to span the spectrum from complete dependence to independence and stay responsive in a linear fashion to clinically important progress. To elaborate, imagine the full spectrum of physical function ranging from a bed bound patient unable to breath independently with no active muscle activity (e.g. ICUAW) at the lowest end, to an Olympic athlete at the peak. The ability to breathe independently would be considered clinical progress in the ICU patient, but a pre-requisite to participation in sport even at the most amateur level.

For this reason, it is vitally important that scales are only used in the population for which they are intended or validated for, and at the time point in which they are responsive. If used out of context in, it would be both detrimental to research and clinical practice. To establish where the floor and ceiling effect of a measure lies, is important in determining its validity and use.

Due to the level of disability observed in general and burns ICU patients, lack of responsiveness in the more disabled patient is the primary reason that most existing functional scoring systems may fail; this is reflected in their clinical uptake. The CPAx was specifically developed to detect change at this very low level of function. Zero on the CPAx can only be scored in a patient not breathing, coughing or moving in any way, hence arguably hits the floor of physical function. The authors would contest that zero on the CPAx is *the floor*, not *the floor effect* of the tool. These data support this demonstrating that on BICU admission, the median CPAx score was zero (IQR 0-1) with 66.7% of patients scoring zero on the CPAx. Likewise on BICU discharge, four patients scored zero, however all of these died within 24 hours of the score being recorded.

As the patients recovered the average CPAx score improved significantly through to BICU and hospital discharge, however on post hoc testing between individual time points, the difference between BICU admission and BICU discharge was only significant for survivors. An explanation could be that non-survivors will not have improved functionally from ICU admission to death, and hence ICU discharge. In survivors that had full outpatient follow up (n=9) it took a median of 68 days [IQR 41-146] after discharge for them to return to their predicted pre-morbid level of function on the CPAx score; demonstrating how significant severe burn related disability can be. Although, it should also be acknowledged that in severe major burns 68 days to full recovery may be considered fast; hence these data may represent a ceiling effect of the CPAx at this time point.

The MCID in CPAx score was equated as six and a change in score of three represents a true change in CPAx score. The MCID means that when a patients' score has improved by six points, it represents a clinically important improvement in the patients' function. In a clinical setting, this would be informative for the patient and clinicians; it may help in therapy goal setting; it could be used to demonstrate the cost effectiveness of a service and facilitate business planning for additional staff. The MCID is also of value in the research setting. If the CPAx were used as a primary outcome in a randomized controlled trial into early burns therapy interventions; awareness of the MCID will help the researcher to establish if there is a true difference in outcome between intervention and control group. This will help to identify the most effective treatment strategies on the BICU. Caution should be taken if using the CPAx tool as an outcome for interventional studies in the later stages/rehabilitation setting as further data are required to analyse the true ceiling effect, which may lead to type 2 errors.

These data, in a small and specialized cohort demonstrate that as the patient progresses through the system, recovers from their injury and as the levels of care are reduced; their function on the CPAx improves, indicating that the CPAx is responsive to change in the Burns population. However due to the negative skew of data at hospital discharge, it may be more appropriate to start to use a functional scale

designed to detect change at a higher level of function following the acute stages, for example, the Functional Assessment for Burns (FAB). [7].

Unlike the general critical care population; all burns patients that died, died on the ICU and had a last recorded CPAx score of zero or one, indicating that if patient survive the acute stage of illness, they are likely to survive until hospital discharge.

Limitations

This was a service improvement initiative at one adult burns ICU in central London, so should be generalized with caution. The hospital is the lead center for the development of the CPAx tool and hence has strong local champions, which may influence compliance with completion of the score.

There was no blinding of the treating therapists, that were both scoring patients on the CPAx score as part of clinical care and making the clinical decisions about rehabilitation need and ongoing therapy input. It is considered unlikely that the CPAx score would have influenced decisions about clinical care, in absence of prognostic evidence. It should however be noted that there was an empirical association between return to work date and CPAx scores returning to predicted pre-morbid level. Hence, the CPAx scores cannot be ruled out as confounders to this decision. This association supports the validity of the CPAx tool in the burns population.

It was not possible to complete grip strength assessments for the predicted pre admission CPAx scores. Hence the score for grip component section was predicted by using the average of the other 9 components of the CPAx, as recommended for the management of missing data [10]. This may affect the accuracy of this CPAx measurement.

No CPAx scores were taken over the weekend and four patients did not have any CPAx scores data; three of which due to staffing issues and training. Over the weekends, the burns ICU is staffed by non-specialist therapists, for pragmatic reasons these staff were not asked to complete the score at the weekend. This may have influenced the accuracy of the recovery trajectory data. There is only follow up outpatient data reported for nine patients, as this did not form part of the initial study plan. These scores were completed out of clinician choice and are reported purely as an interest to the reader. Further follow up data on the CPAx in the outpatient setting would be beneficial.

Conclusions

The CPAx appears to be able to detect clinically important progress in the patients' functional status as they progress through their journey from ICU admission to hospital discharge. The CPAx has a limited floor and ceiling effect from ICU admission to hospital discharge in survivors of severe burn injury, however it may have a ceiling effect in the outpatient rehabilitation setting. A change in CPAx score of three is a true change in the score, and a change in CPAx score of six represents the minimal clinically important difference in severe burn injuries.

The CPAx may be a useful measure of physical function in severe burns injury, and may help healthcare professionals to monitor recovery in an objective manner. This could inform burns survivors about their recovery and facilitate interventional studies into physiotherapy techniques.

Further studies are needed to establish the validity of the CPAx in the burns population in a larger cohort from multiple centers, and to test the CPAx as an outcome for interventional studies.

Authors' contributions
EC was the primary developer of the CPAx. All authors contributed to the conception and design of this study, data analysis and interpretation, draft and revised manuscript development and approval of the final version for publication.

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Table 1: Level of care needs of patients at each inpatient time point.

	Level of care needs.
ICU (level 3 care)	Two organ systems failing and/or requiring advanced respiratory support. 1:1 nurse to patient ratio
ICU discharge (i.e. level 1 or 2 care)	Single organ failing or patients at risk of deterioration. Either 1:4 or 1:2 nurse to patient ratio
Ward (level 0 care)	Patients' needs can be met through normal ward care. 1:6 nurse to patient ratio.

Table 2: patient demographic data

	Whole population (n=52)	Study cohort (n=30)
Age, mean (SD)	50 (22.9)	47.1 (21.2)
Male, n (%)	29 (55.7%)	19 (63.3%)
Female, n (%)	23 (44.2%)	11 (36.6%)
Type of burn - Flame - Scald - Electrical - Contact - TENS - Chemical	 39 (75%) 2 (4%) 3 (6%) 3 (6%) 4 (8%) 1 (2%)	 25 (83.3%) 2 (6.6%) 2 (6.6%) 0 (0%) 0 (0%) 1 (3.3%)
TBSA, Median (range [IQR]) Burn severity (ABA injury severity grading system) n(%) - Severe - Moderate - Mild	 25 (1.5-100 [6.8-54.8]) 33 (63.5%) 9 (17.3%) 10 (19.2%)	 30 (1.5-88 [11.3-48.8]) 22 (73.3%) 5 (16.7%) 3 (10%)
Percentage of DD/FT, Median (range [IQR])	12.3 (0-95 [3.8-30])	19 (0-88 [6.25-34.1])
BOBI score Mean (SD) Median (range [IQR])	 3.7 (2.1) 3.5 (0-8 [2-6])	 4.0 (2.1) 4 (0-8 [2.3-6])
Inhalation injury present, n (%)	28 (53%)	21 (70%)
Length of stay, median (range [IQR]) - Hospital - ICU - Days of MV	 23 (1-321[9.8-61.3]) 5 (1-94 [2-29.5]) 5 (0-94 [1-28.5])	 32 (2-312 [17.5-93.8]) 17 (2-94 [4.3-43.3]) 14 (0-94 [3.3-31.5])
Number of theatre trips, Median (range [IQR]) Number of surgical procedures, Median (range [IQR])	1 (0-39 [1-4]) 1 (0-15 [1-3])	3.5 (0-39[1-5.5]) 3 (0-15 [1-4.5])
Deaths on ICU, n (%) Deaths on ward, n (%)	13 (25%) 0 (0%)	7 (22.3%) 0 (0%)

TBSA= total body surface area; ABA= American Burn Association (*Hartford CE, Kealey CP. Care of outpatient burns. In: Total Burn Care, 3rd ed, Herndon DN (Ed), Elsevier, Philadelphia 2007..)* DD = deep dermal; FT= full thickness; MV = mechanical ventilation; BOBI score= Belgium Outcomes in Burn Injury.

Table 3: Dunn's post hoc multiple comparison test for individual differences between time points

	Mean rank difference in all patients (n=30)	Mean rank difference in survivors (n=23)
Pre-admission CPAx vs ICU admission CPAx	72.82*	70.02*
Pre-admission CPAx vs ICU discharge CPAx	51.79*	43.63*
Pre-admission CPAx vs ward/hospital discharge CPAx	24.20*	24.19*
ICU admission CPAx vs ICU discharge CPAx	-21.03	-26.38*
ICU admission CPAx vs ward/hospital discharge CPAx	-48.62*	-45.83*
ICU discharge CPAx vs ward/hospital discharge CPAx	-27.59*	-19.45

* = $p<.05$

Figure 1

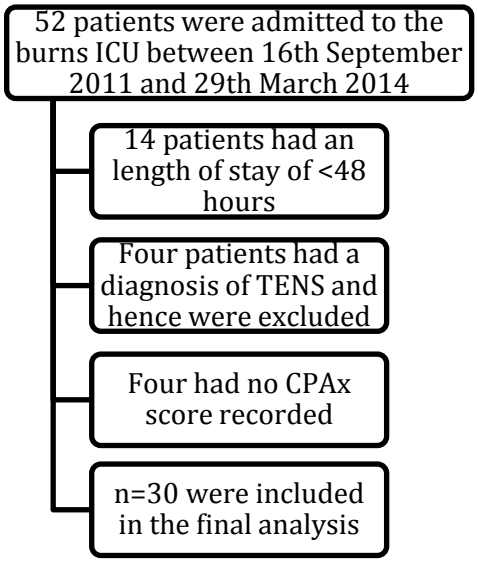
52 patients were admitted to the burns ICU between 16th September 2011 and 29th March 2014
14 patients had an length of stay of <48 hours
Four patients had a diagnosis of TENS and hence were excluded
Four had no CPAx score recorded
n=30 were included in the final analysis

Figure 2

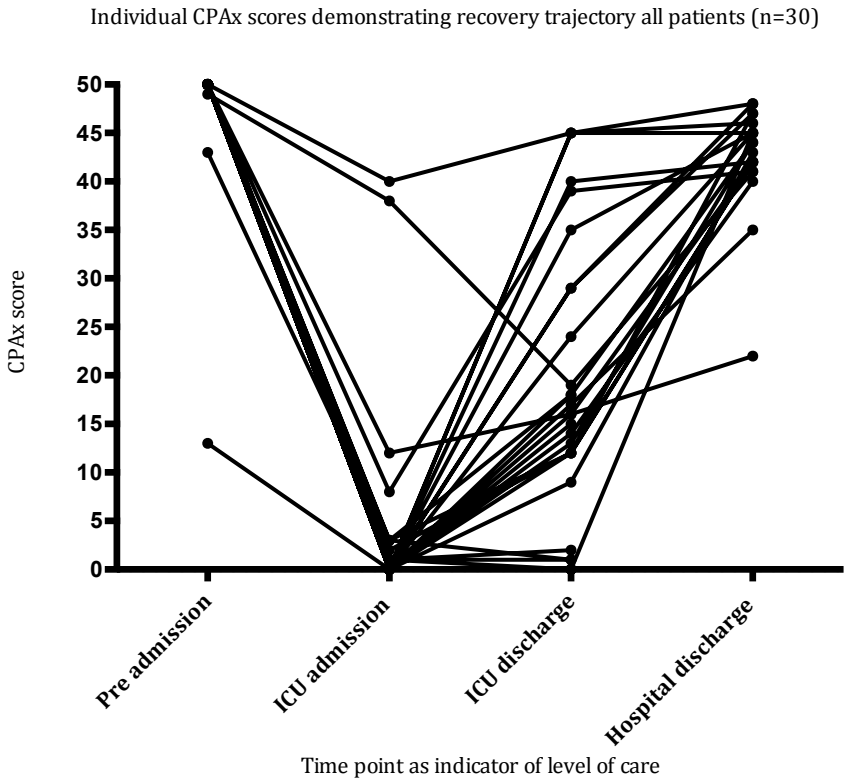

Figure 3