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Physical function and activity of patients after open abdominal surgery: a prospective cohort study comparing the clinimetric properties of two outcome measures☆

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Abstract

Objectives To measure and compare the clinimetric properties of the Chelsea Critical Care Physical Assessment (CPAx) and Physical Function in Intensive Care Test-scored (PFIT-s) for assessment of physical function and activity.
Design Prospective cohort design using crossover-randomisation of the sequence in which participants were assessed with CPAx and PFIT-s.
Setting Surgical and transplant intensive care units (ICU) in an academic hospital.
Participants Adults who underwent elective open abdominal surgery. Consecutive sampling was used to enrol 69 participants.
Interventions Physical function and activity were assessed on ICU days one, three, five and at ICU discharge using the CPAx and PFIT-s in random order.
Main outcome measures Responsiveness to change, minimal clinically important difference (MCID), floor and ceiling effect, and convergent validity.
Results CPAx demonstrated a large responsiveness (effect size index (ESI)= 0.83) and PFIT-s moderate responsiveness (ESI=0.73) to change in scores. MCID for CPAx was 2.1 (standard error of measurement (SEM) 1.1) and for PFIT-s 0.6 (SEM=0.3). CPAx had no floor effect and a small ceiling effect (9%, n = 6) at ICU discharge compared to 2% (n = 1) floor and 48% (n = 32) ceiling effects of PFIT-s. Moderate convergent validity was found for both tools at ICU admission (n = 67, r = 0.62, p < 0.001) and discharge (n = 67, r = 0.51, p < 0.001).
Conclusion CPAx is most responsive to changes in physical function and activity scores, has no floor and limited ceiling effects and moderate convergent validity, and is recommended for similar cohorts.
Contribution of the paper

- This paper describes clinimetric properties of CPAx compared to PFIT-s for a cohort of middle-aged patients who had elective open abdominal surgery and contributes to the limited existing evidence.
- It reports MCID for CPAx and PFIT-s for this elective surgery cohort.

Keywords: CPAx; PFIT-s; Activity; Abdominal surgery; Responsiveness; Minimum clinically important difference

Introduction

Globally the number of major surgeries performed annually is rising as is surgical morbidity [1]. Approximately one third to half of adult patients who undergo open

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abdominal surgery develop postoperative complications such as pneumonia and atelectasis which predisposes them to increased length of stay and risk of mortality [2,3]. Early postoperative “out of bed” mobilisation improves respiratory function [4] and physical function performance for enhanced early recovery [5]. It therefore becomes important to assess and monitor the progression of physical function and activity in patients after elective open abdominal surgery utilising accepted outcome measures.

The responsiveness of an outcome measure indicates its ability to detect change in a patient’s function and activity every time that the specific measurement tool is administered [6,7]. The minimal clinically important difference (MCID) is the smallest detectable change in a score that has an implication in patient management [8].

The Chelsea Critical Care Physical Assessment (CPAx) tool comprises of 10 items. Activity is assessed with five items from moving in bed to stepping. Physical function such as balance (dynamic sitting and standing), grip strength, respiratory function, and ability to cough, is assessed with the remaining five items [6,9]. The clinimetric properties of the CPAx tool and its impact on patients’ clinical outcomes have been tested in medico-surgical and trauma adult intensive care unit (ICU) populations [6,10–12]. The Physical Function in ICU Test-scored (PFIT-s) comprises of four items. Two items evaluate physical function (e.g. shoulder flexion and knee extension strength, and upper extremity endurance) and two items evaluate activity (e.g. sit-to-stand transfer and marching on the spot) [13,14]. The clinimetric properties of the PFIT-s have been tested in mixed adult ICU populations and were found to be responsive to change [13–15]. A recent systematic review reported that both tools perform strongly as assessment measures for impairments in body function and structure (e.g. muscle strength) and activity limitations (e.g. mobility) in the critically ill patient [16]. South African physiotherapists often use body function and structure-related outcome measures in clinical practice [17,18] with less frequent use of activity-related tools [18]. Time-constraints is a frequently reported obstacle to their use [17,19]. The clinimetric properties of the CPAx and PFIT-s have not been tested in an adult population after elective open abdominal surgery. Such patients may have specific activity-based rehabilitation needs.

The study objectives were to measure and compare the a) responsiveness to detect change; b) MCID; c) floor and ceiling effects; and d) convergent validity for scores obtained with the CPAx and PFIT-s tools for adults after elective open abdominal surgery. Identifying a tool that is responsive and demonstrates MCID for this population may assist physiotherapists to prioritise goal-directed progressive therapy sessions for improved functional patient outcomes and to provide time-efficient services. Strengthening the Reporting of Observational Studies in Epidemiology guidelines were used in reporting this study.

Methods

Study design

This was a prospective observational longitudinal cohort study. The sequence with which the CPAx and PFIT-s tools were administered to each participant during their ICU stay was randomised to prevent any learning effects by participants. It is reasonable to assume that patients who undergo elective open abdominal surgery would be able to resume physical function and activity early after surgery [4]. The authors hypothesised that PFIT-s would have a larger responsiveness to change than CPAx in adults who had elective open abdominal surgery.

Study setting

The X hospital situated in X is a 190-bed private academic teaching hospital that offers elective surgery. Potential participants were recruited from the transplant and surgical ICUs. The standard mobilisation protocol in these ICUs for patients after open abdominal surgery is aimed at early, active mobilisation if the patient is stable enough. Most patients sit in a chair day one postoperatively, progressing to walking on the spot, walking in the ICU and then mobilising out of the ICU. All patients are treated by the physiotherapists to promote physical function and activity and to prevent postoperative pulmonary complications (PPC).

Study population

Consecutive sampling was done to recruit potential participants during the period August to November 2019. Patients were included if they were admitted to ICU for longer than 24 hours, were older than 18 years of age, had elective open abdominal surgery (including general-, colorectal- or transplantation surgery), could follow instructions, scored at least three out of five on the Standardised Five Questions test (assessment of the level of cooperation), and were ready to mobilise out of bed on postoperative day one. Those who presented with unstable cardiac function such as myocardial ischaemia or pulmonary emboli, had undergone continuous dialysis therapy, had an amputation affecting functional performance, current encephalopathy, and presenting with ongoing or history of neurological disease, were excluded.

The estimated sample size was 63 based on the previous 12-months admissions to the participating ICUs (total n = 176) for open abdominal surgery. Sample sizes of more than 50 participants are recommended for studies assessing clinimetric properties of measurements to enhance the generalisability of findings [15].

Materials

A Camry Model EH101 electronic hand dynamometer was used to obtain the grip strength of participants for CPAx strength assessment. A Medalist JS3212 stopwatch was used for the cadence assessment for PFIT-s. Study-specific individual recording sheets were used to capture information on duration of mechanical ventilation (MV), ICU length of stay (LOS), diagnosis, pain management, postoperative complications, number of theatre trips, CPAx and PFIT-s scores, and other relevant demographics.

Procedure

Approval for this study was granted by X ethics committee and the chief executive officer and ICU director of X. A trained research assistant screened potential participants for inclusion against the study criteria and approached them for consent. On obtaining written consent, the research assistant determined the sequence of participant assessment with the CPAx and PFIT-s tools using a computer-generated randomisation list and sealed envelope allocation. The research assistant informed two identified physiotherapists (assessors), experienced in using CPAx and PFIT-s and responsible for participant assessment, of each participant's randomisation allocation (e.g. Day 1 participant A received CPAx first, then PFIT-s; Day 3 PFIT-s first then CPAx, etc.). Each participant was assessed with both CPAx and PFIT-s. Participants were assessed by one of the two assessors on the mornings of days one, three, and five postoperatively and on ICU discharge. The first allocated assessment was performed prior to the regular physiotherapy treatment session on the days stipulated above. The second allocated assessment was delivered two hours after treatment completion on those days to allow participants to recover prior to testing. The assessors followed through with the participants and were not involved in delivery of postoperative patient care to any participants. During assessment participants were monitored for adverse events such as pulling out of drip lines, drop in blood pressure, desaturation, falling, opening of the wound or excessive drainage from the wound site. Any adverse events experienced by participants were recorded. Any complications that the participants developed, diagnosed by medical officers in their records, and that impacted their ability to participate in physical function and activity assessment, were recorded. Throughout their ICU stay, individualised physiotherapy care was provided to participants by one of three physiotherapists, each with more than three years of clinical work experience in the participating ICUs, who were not involved in the participant assessments done as part of this study. After ICU discharge, CPAx and PFIT-s assessments were terminated but physiotherapy patient care continued on the general wards until discharge.

Outcomes

The primary outcomes for this cohort study were the responsiveness of CPAx and PFIT-s to changes in physical function scores [effect size index (ESI)] and MCID. Secondary outcomes were floor and ceiling effects and convergent validity.

Statistical analysis

Data were captured in Excel and analysis was done with IBM® Statistical Package for Social Sciences® version 28. Continuous variables were assessed for normality of distribution (Shapiro-Wilk) and are summarised as median and interquartile ranges. Categorical variables and floor and ceiling effects are summarised as numbers and percentages. The floor effect is reflected as the percentage of participants who scored zero on the CPAx or PFIT-s and the ceiling effect is reflected as the percentage of participants who had a full score on the CPAx or PFIT-s.

The CPAx and PFIT-s scores were compared at ICU Day 1 and ICU discharge to determine their responsiveness to change in physical function and activity using the Friedman test with a post-hoc Bonferroni correction to determine the Z-score for each tool. Responsiveness was assessed by determining each tool's ESI [13]. The ESI was calculated for each tool using $r = Z$ and divided by the square root of the sample size [6,13]. A positive ESI reflects an improvement in functional status. Effect size indexes of < 0.5, 0.5–0.8, > 0.8 reflect small, moderate, and large responsiveness to change respectively [13,20].

The MCID was calculated with distribution-based methods using the standard error of measurement (SEM) for CPAx and PFIT-s scores at ICU Day 1. Sedaghat [8] justifies using $\text{MCID} = 1.96 * \text{SEM}$ for cohort studies as with this equation the MCID is beyond the 95%CI of expected random variation in scores.

For this study, the construct is physical function and activity scores. Convergent validity was assessed with the Spearman's rank correlation to evaluate whether the CPAx and PFIT-s have similar underlying constructs [13]. Interpretation of the correlation was done according to the stratification described by Schober et al. [21]. Scatterplots illustrate the distribution of scores at ICU Day 1 and ICU discharge.

If any participants withdrew or didn't complete their ICU assessment, the last recorded CPAx and PFIT-s scores obtained were carried forward and utilised as that participant's ICU discharge score.

Results

Ninety-seven patients had elective open abdominal surgery during the study period. Sixty-nine were recruited and

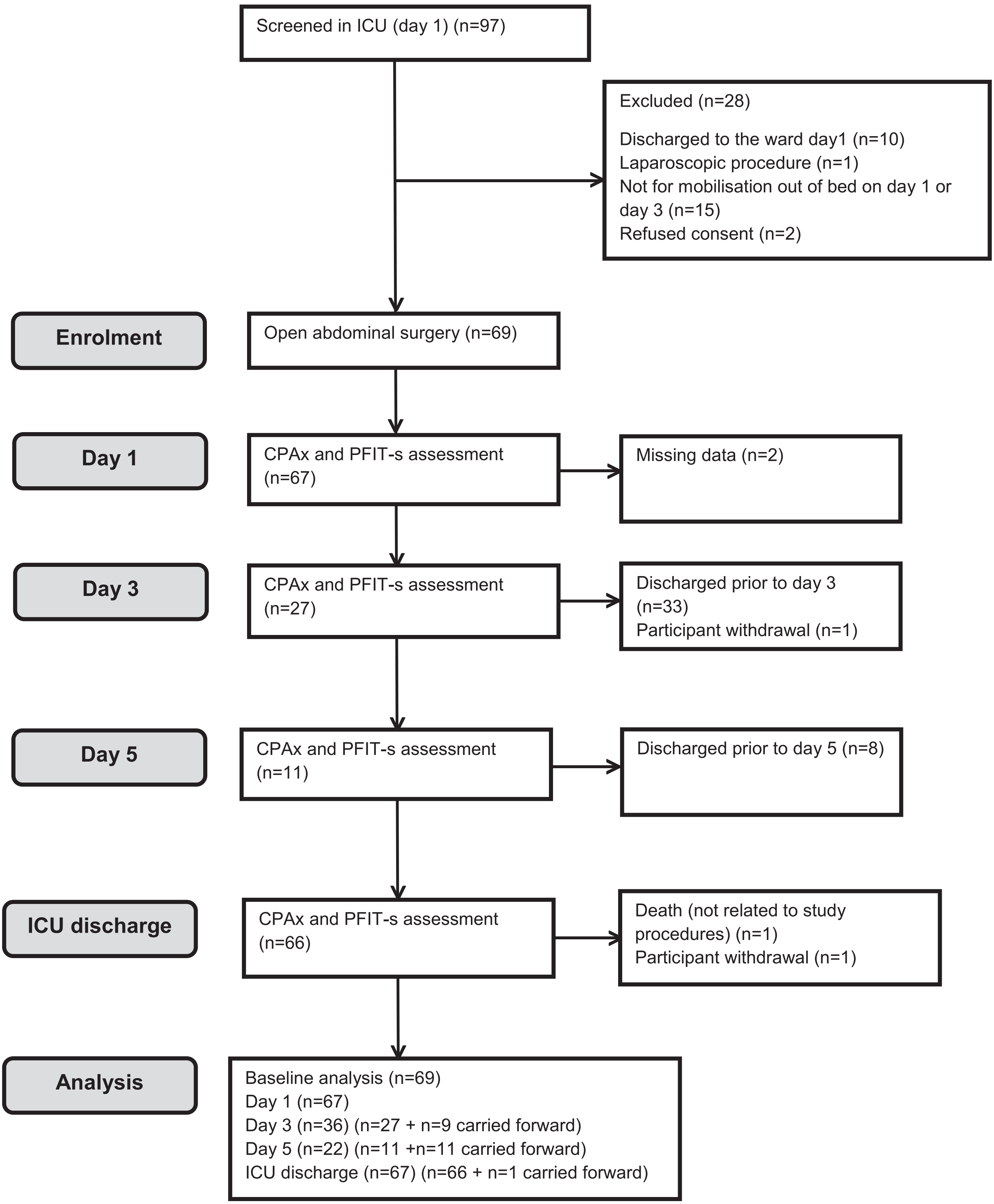

Fig. 1. A summary of participant flow for this elective open abdominal surgery cohort.

Table 1
Characteristics and clinical information of surgical cohort (n = 69).

	Results
Age (years): median (IQR) (minimum; maximum)	54 (39-66) (18; 82)
Sex: n (%)	
Male	26 (38)
Female	43 (62)
Diagnosis category: n (%)	
Bowel obstruction	8 (12)
Cancer	29 (42)
Diverticulitis	5 (7)
Fistula	2 (3)
Gastroesophageal reflux	1 (1)
Kidney disease	3 (4)
Kidney transplant	5 (7)
Liver disease	5 (7)
Liver transplant	5 (7)
Portal hypertension	2 (3)
Rectal prolapse	1 (1)
Duration of surgery (hours): median (IQR) (minimum; maximum)	5 (3-6) (1; 10)
Duration of mechanical ventilation (hours): median (IQR) (minimum; maximum)	5 (3-6) (1; 41)
ICU length of stay (days): median (IQR) (minimum; maximum)	3 (2-6) (1; 22)
Pain medication administration on day 1 post surgery: n (%)	
Intravenous	65 (94)
Oral	24 (35)
Rectal sheath	27 (39)
Pain medication administration at ICU discharge: n (%)	
Intravenous	40 (60)
Oral	38 (57)
Rectal sheath	22 (33)
Physiotherapy treatment sessions received in ICU: median (IQR) (minimum; maximum)	4 (3-7) (1; 26)

IQR, interquartile range; ICU, intensive care unit

67 completed the study. Fig. 1 summarises the flow of participants for this cohort study. Participants' characteristics and clinical information are summarised in Table 1. All participants had a laparotomy, and most were female. The most common reason for surgery was cancer. The median duration of surgery was five hours and ICU LOS was three days. All participants received MV from the start to end of surgery; therefore, duration of surgery can be interpreted as anaesthetic time. One participant was on MV for 41 hours. Participants received a median of four physiotherapy treatment sessions during their ICU stay. Postoperative complications that influenced participants' physical function and activity were recorded and are summarised in Fig. 2. Hypotension was the most common postoperative complication, followed by pain and low haemoglobin levels. No adverse events were reported during assessment with CPAx or PFIT-s.

Responsiveness of CPAx and PFIT-s

Changes in physical function and activity assessed with CPAx and PFIT-s from ICU Day 1 (ICU admission score) until ICU discharge are summarised in Table 2. Median (IQR) CPAx was 38 (35–41) at ICU Day 1 and 47 (44–48) at ICU discharge with a median difference of 9 points (95% CI 7 to 10) and ESI of 0.83. Median (IQR) PFIT-s was 9 (7–11) at ICU Day 1 and 11 (10–12) at ICU discharge with a median difference of 2 points (95% CI 2 to 3) and ESI of 0.73. The CPAx thus had a large responsiveness to change in physical function and activity, and the PFIT-s a moderate responsiveness to change.

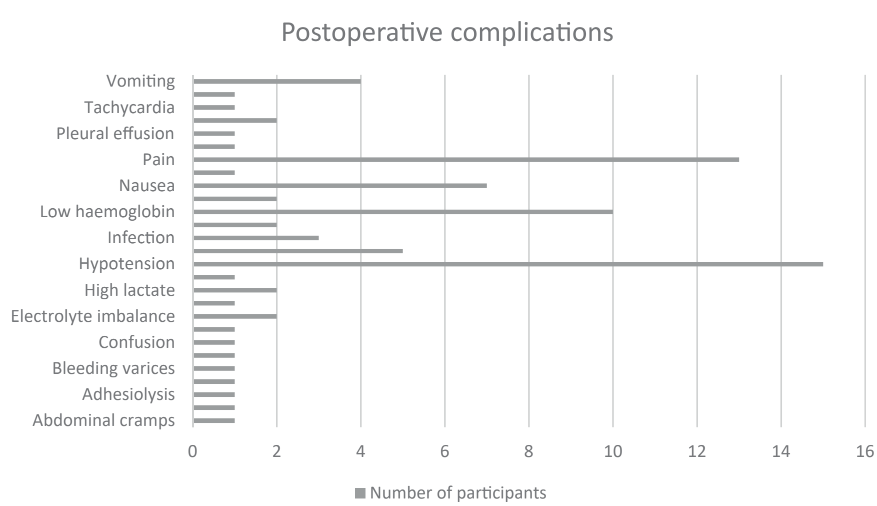

Fig. 2. Postoperative complications reported for the cohort.

Table 2
Physical function and activity assessed with the CPAx and PFIT-s tools from ICU admission until discharge.

Assessment timeline	Tool	Median (IQR)	Minimum	Maximum
ICU Day 1	CPAx	38 (35-41)	10	49
(admission) (n = 67)	PFIT-s	9 (7-11)	2	12
ICU Day 3 (n = 36)	CPAx	41 (36-46)	7	49
	PFIT-s	10 (8-12)	1	12
ICU Day 5	CPAx	44 (38-47)	4	50
(n = 22)	PFIT-s	10 (8-12)	0	12
ICU discharge	CPAx	47 (44-48)	32	50
(n = 67)	PFIT-s	11 (10-12)	0	12

CPAx, Chelsea Critical Care Physical Assessment; ICU, intensive care unit; PFIT-s, Physical Function in ICU test-scored

Minimal clinically important difference in physical function

The CPAx and PFIT-s ICU Day 1 scores were used to estimate the MCID. The CPAx SEM was 1.1 and PFIT-s SEM was 0.3. This resulted in CPAx MCID of 2.1 and PFIT-s MCID of 0.6.

Floor and ceiling effects

The median (IQR) CPAx score was 38 (35–41) on ICU Day 1 and the median (IQR) PFIT-s score was 9 (7–11) (Table 2). No participants scored 0 on either tool on ICU Day 1, thus indicating 0% floor effect. No participants achieved a full score for the CPAx on ICU Day 1, but the PFIT-s demonstrated a ceiling effect of 6% as four of 67 participants scored 12/12. At ICU discharge, the median (IQR) CPAx score was 47 (44–48) and the median (IQR) PFIT-s score was 11 (10–12). The CPAx had no floor effect but a ceiling effect of 9% (n = 6). The PFIT-s had a floor effect of 2% (n = 1) and a ceiling effect of 48% (n = 32). Five participants (7%) had full scores with both CPAx and PFIT-s at ICU discharge.

Convergent validity

The construct for this cohort was physical function and activity scores. Convergent validity was assessed using Spearman's rank correlation to evaluate whether CPAx and PFIT-s had similar underlying constructs. The distribution of scores for ICU Day 1 and ICU discharge are illustrated in Figs. 3 and 4. A positive linear relationship between CPAx and PFIT-s scores was found for ICU Day 1 and ICU discharge. The CPAx and PFIT-s ICU Day 1 scores demonstrated $r = 0.62$ ($n = 67$, $p < 0.001$) and CPAx and PFIT-s ICU discharge scores $r = 0.51$ ($n = 67$, $p < 0.001$) indicating moderate convergent validity.

Discussion

This prospective cohort study assessed the clinimetric properties of two commonly used outcome measures of physical function and activity in intubated, extubated, and non-MV patients after elective open abdominal surgery, managed in an ICU setting. The CPAx was found to have a large responsiveness to change in scores, no floor effect and limited ceiling effect when used for this specific cohort at ICU Day 1 and discharge, compared to the PFIT-s.

Major surgery inflicts stress on the human body such as sterile injury (e.g. incision, excision, organ manipulation, suturing), pathogen invasion (e.g. gut bacterial translocation) and/or anaesthesia [1]. Furthermore, open surgery imposes a greater stress response to the body than less invasive surgical techniques [1]. Surgical stress causes tissue hypoxia and ischaemia which leads to mitochondrial dysfunction and subsequently increased oxidant stress in peripheral tissues which predisposes

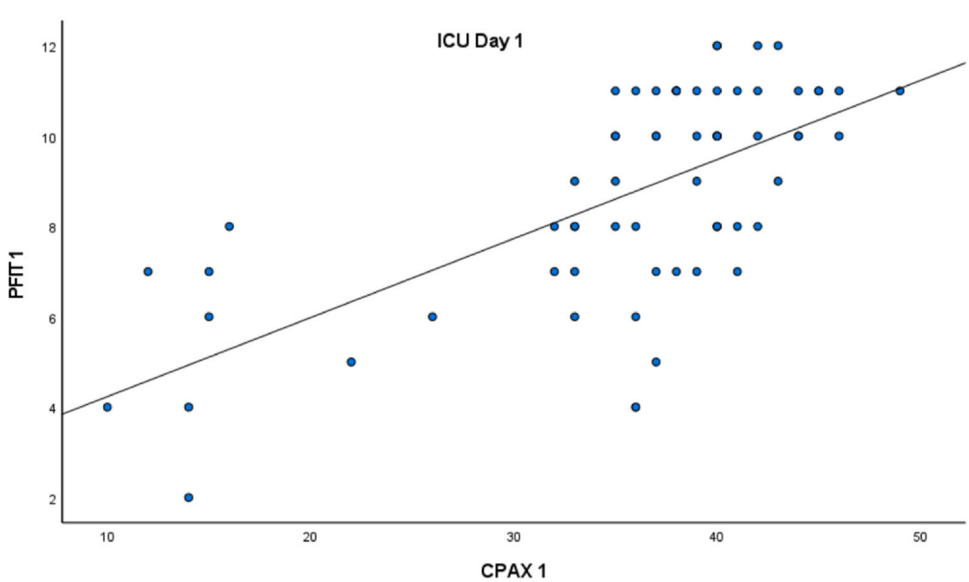

Fig. 3. Distribution of CPAx and PFIT-s scores at day 1 of ICU stay.

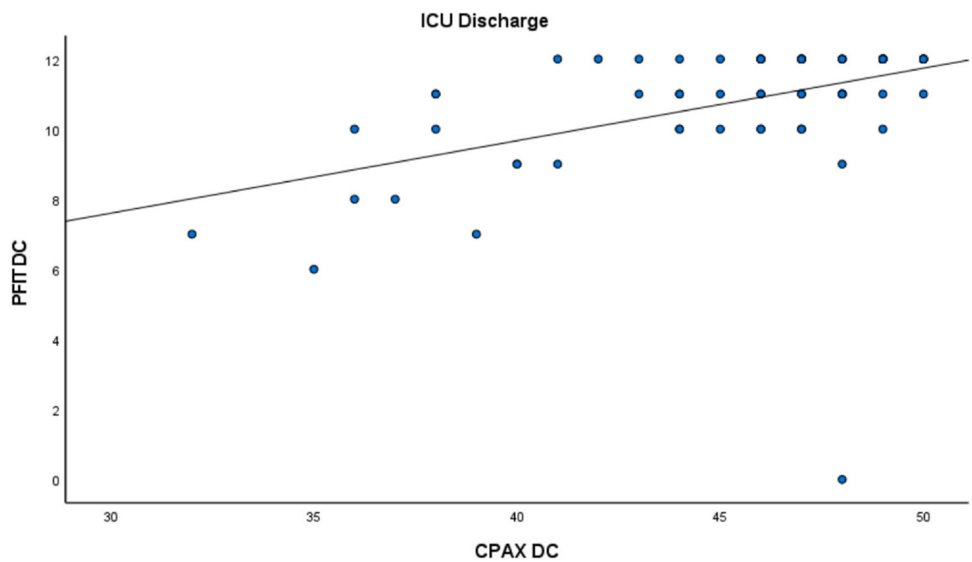

Fig. 4. Distribution of CPAx and PFIT-s scores at ICU discharge.

to skeletal muscle atrophy and impacts on physical function [1,22]. Major surgery, such as open abdominal surgery, is associated with an increased risk for the development of PPC [1–3]. This study cohort underwent elective open abdominal surgery predominantly for cancer, bowel obstruction, and organ transplantation. It is unique as it was exclusively surgical and had diagnoses associated with preoperative frailty and sarcopenia [16–18]. Therefore, this middle-aged cohort is at particular risk of impaired physical function, pulmonary complications, and prolonged hospital stay in the postoperative phase [23–25]. CPAx considers the effect of respiratory function on an individual's physical function, which the PFIT-s does not take into consideration. It is thus apparent that CPAx is more appropriate to use for assessment of postoperative physical function and activity in these participants.

Commonly reported postoperative complications that influenced physical function and activity outcomes included hypotension, pain, and low haemoglobin. The median intraoperative time was five hours which may have predisposed participants to higher risk of bleeding, common in those undergoing major non-cardiac surgery, and resultant lower haemoglobin and hypotension postoperatively [26]. The type of pain medication administered postoperatively could have contributed to the presence of hypotension [27].

The CPAx had a large responsiveness to change in scores compared to the moderate responsiveness of PFIT-s. Although the impact of CPAx on patients' clinical outcomes had been reported [6, 10, 11 12, 20], this is the first study to report on its responsiveness to changes in physical function and activity for a middle-aged elective open abdominal surgery cohort. Parry et al. [15] reported moderate responsiveness to changes in physical function for postoperative patients who were slightly older and had longer ICU LOS compared to this cohort. In contrast, Denehy et al. [13] and Nordon-Craft et al. [14] reported large responsiveness for PFIT-s in their mixed ICU participants; however, their participants had a longer duration of MV and ICU LOS.

There was no floor effect and a small ceiling effect (9%) at ICU discharge with CPAx. Similarly, Astrup et al. [20] reported no floor or ceiling effects for CPAx when tested in a Danish medico-surgical ICU cohort. Corner et al. [7] reported a floor effect of 3.2% and ceiling effect of 0.8% for medico-surgical ICU patients who had a similar median ICU LOS (2.6 days) to this cohort. A high ceiling effect of 48% was recorded with PFIT-s at ICU discharge. This contrasts with findings of others who reported ceiling effects ranging from 5–22% in medical and medico-surgical ICU cohorts, respectively [13–15]. Patient characteristics are known to influence floor and ceiling effect findings [13]. This cohort had elective open abdominal surgery, were mostly female, and had a short duration of MV and ICU LOS. This could explain the high ceiling effect observed, especially for five participants who had full scores on both outcome measures at ICU discharge.

Both CPAx and PFIT-s demonstrated moderate convergent validity. Physical activity in the form of mobility is measured in both tools which may explain their relationship but needs further exploration.

The MCID for CPAx was 2.1 and for PFIT-s 0.6. Others have reported MCID of 1–1.5 for PFIT-s in medico-surgical cohorts [14,15]. These participants were slightly older (median 58 and 59 years respectively) and had a longer ICU LOS (median 7 and 8 days respectively) than in this study. No studies have reported MCID for CPAx in medico-surgical or surgical ICU patients.

Study limitations

This study has some limitations. As stated earlier, a sample of 50 participants is sufficient for assessment of clinimetric properties of measurement tools [15]. This study exceeded its estimated sample size of 63 participants, but the participants were recruited from a single centre. Utilising a surgical cohort from a single centre might have affected the outcomes generated and thus limits the extent of generalisation of findings. A strength is that all participants were assessed with both the CPAx and PFIT-s in random order, to control the impact of learning effects on outcomes generated, which limits reporting bias. Participants were not assessed at hospital discharge and therefore the responsiveness of both tools to detect changes in physical function and activity beyond ICU discharge, is unknown. The ESI reports statistical significance but not the validity of the score changes and limits the interpretation of findings. Lastly, a distribution-based method [8,28] was used to determine MCID for this surgical cohort instead of anchor-based methods, or a combination of methods [29]. This was done to enable comparison of our MCID results with those of others who used similar methodology [6,13]. The distribution-based method does not assess what patients perceive as a meaningful change and highlights the need for further studies.

Conclusion

The CPAx showed a large responsiveness to change and no floor and limited ceiling effects and is recommended for use in middle-aged adults who undergo elective open abdominal surgery. The use of CPAx could enable physiotherapists to apply sustainable physical function and activity-related outcomes to goal-directed progressive therapy to optimise patient recovery after surgery.

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Conflict of interest: The authors declare that they have no conflict of interest in reporting the results of this study.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.physio.2024.02.001.

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