Development of a physical function outcome measure (PFIT) and a pilot exercise training protocol for use in intensive care

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ABSTRACT

Objective: To develop an outcome measure as a basis for prescribing and evaluating rehabilitation in the critically ill, and to measure its reliability and responsiveness to change. The study also aimed to assess the feasibility and safety of a pilot exercise training protocol in an intensive care unit.

Methods: We developed a battery of tests (the Physical Function ICU Test [PFIT]) to measure endurance, strength, cardiovascular capacity and functional level. Patients with a tracheostomy who were mechanically ventilated were recruited from a medical–surgical ICU and respiratory weaning unit at a tertiary referral hospital in Melbourne, Victoria, between 2003 and 2005. Patients underwent a pilot exercise training protocol and performed the PFIT when able to stand, and again after weaning from ventilation.

Results: The PFIT demonstrated good reliability and was responsive to change. Twelve patients completed testing and exercise sessions with no adverse events; 50 of 63 possible training sessions (79%) were delivered. Participants increased the marching on the spot result by a mean difference of 86.3 steps and 56 s ($P < 0.05$), and the shoulder flexion result by 8 repetitions ($P < 0.05$). Improvement in function and muscle strength was also observed ($P < 0.05$). Inter-rater reliability for the PFIT was good (intra-class correlation coefficient, 0.996–1.00).

Conclusions: The PFIT is a reliable and responsive outcome measure, and the pilot training protocol was safe and feasible. As exercise may attenuate weakness and functional impairment, the PFIT can be used to prescribe and evaluate exercise and mobilisation. Future research should aim to develop a PFIT score and investigate the ability of the PFIT to predict ICU readmission risk and functional outcome.

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Patients who have been critically ill in the intensive care unit commonly develop weakness,[1,2] musculoskeletal insufficiency and functional impairment.[3] Almost a quarter of patients in the ICU have severe and clinically significant weakness as a result of ICU-acquired paresis,[4] which has been associated with prolongation of weaning from mechanical ventilation and hospital length of stay, and increased mortality and costs.[5-8] Prolonged bed rest also leads to cardiac deconditioning and a reduction in maximal oxygen uptake.[9,10] Patients discharged from the ICU report a poorer quality of life than age-matched controls, particularly in the domain of physical function.[3,11-13] As a result, there is empirical support for providing exercise for patients in the ICU,[1,2,14-19] despite a lack of supporting evidence from randomised controlled trials.[20]

While mobilisation is now commonly used in the ICU,[21-25] no tests for measuring exercise capacity in this population have been described.[25,26] Recent surveys suggest that only a quarter of therapists use any form of outcome measure to evaluate rehabilitation in the ICU,[26,27] in contrast to pulmonary rehabilitation, where the 6-minute walk test is used for patients with chronic obstructive pulmonary disease. This test, along with those described for use in the frail elderly population (eg, the timed "up-and-go" test[28]), cannot be reliably performed in the ICU. Although recent safety guidelines for exercise in critically ill patients have been developed,[29] exercise prescription remains subjective and variable.

The objectives of this pilot study were:

- to develop a clinical exercise outcome measure for use in the ICU;
- to assess its reliability and responsiveness; and
- to assess the feasibility and safety of a pilot exercise training protocol in the ICU.

Methods

The institutional human research ethics committee approved the study, and informed consent was obtained from either patients or their surrogate decision-makers.

Patients were recruited from the mixed medical–surgical ICU and respiratory weaning unit of a large tertiary referral hospital in Melbourne, Victoria, between 2003 and 2005. As there was little previous research on this question from which to generate effect size estimates, the proposed sample size (20) was based on a medium effect size ($d = 0.5$). This effect size would indicate a difference between group means equal to half the value of the pooled standard deviation.[30] An effect of this magnitude was expected to be

clinically meaningful. Patient numbers were truncated to 13 because of the unexpectedly slow recruitment.

Inclusion criteria were:

- presence of a tracheostomy to facilitate weaning;
- presence of mechanical ventilation;
- able to follow commands;
- appropriate to commence exercise as assessed by the treating intensivist and physiotherapist; and
- able to stand up from a chair (with or without assistance).

Exclusion criteria were:

- fraction of inspired oxygen (F_{IO_2}) > 0.6;
- positive end-expiratory pressure (PEEP) > 8 cmH_2O;
- admitted to the ICU with a permanent weakness syndrome (eg, spinal cord injury or stroke);
- admitted to the ICU with injuries precluding exercise (eg, unstable fractures); and
- commenced spontaneous breathing on tracheostomy formation and did not require reinstitution of ventilation.

Withdrawal criteria were:

- recurrence of sepsis resulting in ongoing haemodynamic compromise; and
- medical limitation of patient treatment.

Development of the outcome measure

The Physical Function ICU Test (PFIT) battery was developed by a small group of experienced critical care physiotherapists using a pragmatic approach. Endurance, muscle strength, cardiovascular capacity and functional ability were identified as domains representative of physical function. PFIT components were developed and selected for clinical utility in the ICU and sensitivity to change.

PFIT procedure

When patients were able to sit out of bed, a practice session of standing and marching on the spot (MOS) was performed. Patients were subsequently tested with the PFIT, using standardised instructions (Appendix A).

Patients performed (in order):

1. Sit to stand (from a standardised chair) with assistance recorded as 0–3 people. Gait aid use (eg, gutter frame) was not defined as assistance.
2. MOS as long as possible (while ventilated). Time (seconds), steps and cadence (steps/min) were recorded.
3. Bilateral shoulder flexion (full range of motion) as long as possible. Patients began with hands on their thighs, and measurement ceased when shoulder flexion was < 90°, or > 2 s had elapsed between flexion movements. Time (seconds), repetitions and cadence (reps/min) were recorded.
4. Muscle strength testing (Oxford scale, graded 0–5)[31] for knee extension and shoulder flexion.

Pilot exercise training protocol

Physiotherapists prescribed an exercise training protocol for patients based on the PFIT, using a hierarchical model. In the protocol, patients performed three repetitions of MOS for 70% of their initial PFIT MOS time, progressively increasing to 15 minutes maximum. Patients who MOS or ambulated < 15 minutes practiced sitting to standing until they required additional assistance to stand. If 15 minutes had not elapsed, patients performed upper limb exercises to a total of 15 minutes of exercise.

Exercise was performed with a physiotherapist 6 days a week. Patients exercised once daily while ventilated, increasing to twice daily when the patient was able to tolerate 4 consecutive hours free of the ventilator. Patients were retested with the PFIT after they had been weaned for 48 hours. Weaning from mechanical ventilation was in accordance with the weaning protocol of the ICU.

Safety of the training protocol was assessed by the occurrence of adverse events during training and the ensuing 30 minutes. The rating of perceived exertion (RPE) via the modified BORG scale,[32] oxygen saturation (Spo_2), heart rate and mean arterial blood pressure were monitored during testing and training. These physiological measures were chosen as they have previously been reported as those most commonly monitored by physiotherapists in the ICU.[26]

Adverse events were defined as:

- sustained heart rate < 50 or > 140 beats/min, or development of a new arrhythmia;
- mean arterial blood pressure < 65 mmHg or > 120 mmHg;
- respiratory rate > 35 breaths/min;
- Spo_2 fall > 10% below resting level, or Spo_2 < 85%;
- pale, sweaty or distressed appearance, or new-onset chest pain; or
- a fall.

Reliability

Inter-rater reliability was assessed for 10 PFIT tests. Two therapists concurrently observed patient PFIT performance and recorded separate data for each battery component. Intra-rater reliability was not studied, as ICU patients could not repeat the test in a single session.

Statistical analysis

Data were analysed with SPSS for Windows version 13.0 (SPSS Inc, Chicago, Ill, USA). Paired *t* tests were used for parametric data, and Wilcoxon signed-rank tests for non-parametric data. A $P < 0.05$ was accepted as statistically significant. Data were also expressed as mean difference

Table 1. Ventilation and demographic characteristics of the 12 participants at recruitment

Patient	Age (years)	Sex	APACHE II score	Ventilation	FIO_2	Diagnosis
1	40	M	na	PS 10, PEEP 5	0.4	Repair of dissecting thoracic aortic aneurysm
2	65	M	na	BiPAP	2 L/min O_2	COPD exacerbation
3	64	M	na	PS 12, PEEP 5	0.4	CABG
4	48	M	20	PS 10, PEEP 5	0.5	Pneumonia
5	43	F	15	BiPAP: IPAP 16, EPAP 8	0.3	COPD exacerbation
6	68	M	10	PS 14, PEEP 5	0.5	Pneumonia
7	74	M	na	VCV, 20× 550 mL	3 L/min O_2	Pneumonia
8	65	F	16	PS 17, PEEP 5	0.5	COPD exacerbation
9	51	F	11	PS 15, PEEP 5	0.4	Septic shock/ARDS
10	36	F	25	PS 16, PEEP 5	0.5	Septic shock after gastric bypass
11	64	F	na	VCV, 19× 600 mL	0.5	COPD exacerbation
12	64	M	na	PS 14, PEEP 5	0.5	CABG and lung resection

FIO_2 = fraction of inspired oxygen. na = not available. PS = pressure support (cmH_2O). PEEP = positive end-expiratory pressure (cmH_2O).
BiPAP = bilevel positive airway pressure. COPD = chronic obstructive pulmonary disease. IPAP = inspiratory positive airway pressure (cmH_2O).
CABG = coronary artery bypass graft. EPAP = expiratory positive airway pressure (cmH_2O). VCV = volume-cycled ventilation.
ARDS = acute respiratory distress syndrome.

and 95% confidence interval (CI). Inter-rater reliability was assessed using the intra-class correlation coefficient ($ICC_{2,1}$), and the standard error of the measure (SE measure) calculated according to the equation:

$$\text{SE measure} = SD\sqrt{(1 - ICC)} \times 1.96.$$

Results

Demographic data

Thirteen patients were recruited; one was withdrawn from the study because of treatment limitation, and 12 complete datasets were recorded. Patients included seven men; mean age was 56.8 (SD, 12.5) years. APACHE II scores ranged from 10 to 25, but six patients (three admitted to the respiratory weaning unit) did not have a score calculated. Demographic and ventilation data are reported in Table 1.

PFIT responsiveness

The mean time between tests was 6.2 (SD, 2.33) days. Fifty out of a possible 63 exercise training sessions were delivered (79%), and the mean number of training sessions per patient (excluding testing) was 4.17 (SD, 2.08). Reasons for non-delivery of exercise training were patient complaints of fatigue (4), patient refusal (3), patient medically unstable (3), therapist unavailable (2), and patient unavailable (1).

Patients completed a mean difference of 86.3 more steps (95% CI, 15.8–156.8; $P = 0.02$) after weaning from mechanical ventilation compared with baseline. Patients increased their marching time by a mean difference of 56 s (95% CI, 5.2–102.8; $P = 0.03$), and cadence by a mean difference of 25.4 steps/min (95% CI, –1.7 to 50.3; $P = 0.04$). Patients increased shoulder flexion repetitions by a mean difference of 8 (95% CI, 0.5–25.4; $P = 0.02$). Other differences (cadence and duration of repetitive shoulder flexion) were not significant (Table 2).

The mean assistance required to stand improved from two people required to no stand-by assistance ($P = 0.007$), and muscle strength improved a grade both for knee extension (range pre-training, 3–5, versus post-training, 4–5; $P = 0.008$ for the left and the right knee) and for shoulder flexion (range pre-training, 2–5, versus post-training, 3–5; $P = 0.04$ for the right shoulder and $P = 0.005$ for the left shoulder).

Adverse events

No adverse events occurred during any testing or exercise session. None of the exercise sessions was terminated because of adverse responses.

PFIT reliability

Inter-rater reliability of the PFIT test was good.[33] Table 2 reports the calculated $ICC_{2,1}$ and SE measures.

Discussion

Because of the significant morbidity experienced by ICU survivors, physical rehabilitation in the ICU has gained support.[2,14-25] However, no reliable and responsive outcome measure has been reported for use in the ICU population. Recent surveys showed that ICU physiotherapists predomin-

Table 2. PFIT results before and after weaning from mechanical ventilation and exercise training

Test component	Mean result (SD)		Mean difference	95% CI	*P*	Intra-class correlation coefficient (95% CI)	SE measure
	Before	After					
Marching on the spot							
Steps	37.6 (33.2)	123.8 (129.4)	86.3	15.8–156.8	0.02*	1.000 (0.997–1.000)	
Seconds	34.4 (26)	88.4 (86.5)	56	5.2–102.8	0.03*	1.000 (0.997–1.000)	
Cadence (reps/min)	56.5 (42.4)	80.8 (17.6)	25.4	–1.7–50.3	0.04*	0.999 (0.985–0.999)	0.76
Shoulder flexion							
Reps	15.8 (12.1)	23.8 (16.7)	8	0.5–25.4	0.02*	1.000 (0.999–1.000)	
Seconds	40.3 (38.7)	47.7 (45.8)	5.5	–29.2–44.2	0.16	1.000 (0.999–1.000)	
Cadence (reps/min)	26.4 (12.9)	34.4 (8.6)	7.1	–1.3–17.3	0.08	0.996 (0.971–0.998)	0.61

Reps = repetitions. * Significant difference ($P < 0.05$).

antly use physiological outcome measures, including RPE, blood pressure, respiratory rate, and Spo_2 to evaluate exercise,[26,27] and there are limitations to the use of published functional tests, such as the timed up-and-go test,[28] in the ICU. Critically ill patients often require invasive haemodynamic monitoring and continuous ventilation, making it difficult to perform these tests in a valid manner. The results of this pilot study demonstrate that the PFIT is a responsive and reliable exercise outcome measure when used in ICU patients with a tracheostomy to facilitate weaning from mechanical ventilation. The PFIT can provide a measure of function for prescribing exercise and evaluating rehabilitation in this population.

The PFIT demonstrated responsiveness to change over time and with implementation of an exercise program. Although all patients improved in terms of MOS parameters and shoulder flexion repetitions, the degree of improvement varied, and the wide confidence intervals reflect the small sample size. Prescription of exercise based on the PFIT battery of tests is analogous to the process followed in patients with chronic obstructive pulmonary disease, where the 6-minute walk test is used both as an outcome measure and to prescribe walking exercise. However, in the absence of a control group, the effectiveness of the exercise training protocol cannot be evaluated. Although the use of test components during exercise training may have influenced the magnitude of the observed improvement, these functional exercises were selected on the basis that they are reported to be those most commonly used by physiotherapists in the ICU.[26]

While the PFIT has face validity, validating the test battery remains difficult. Currently, there is no "gold standard" measurement of exercise capacity available for comparison in the critically ill population.

Over the course of the study, patient recruitment became more difficult as the time elapsed between baseline assessment and successful weaning was often too short. This was perhaps a result of the development and implementation of a weaning protocol in the ICU. Retrospective analysis showed a reduction in duration of mechanical ventilation, ICU and hospital length of stay after the introduction of the protocol (unpublished data), which is consistent with previous reports.[1,34,35] However, patients frequently remained weak and dependent when disconnected from mechanical ventilation.

Physiotherapists provide exercise programs both to facilitate weaning and to improve function in weak and deconditioned patients.[1,15,16,18-20,36] Physical function is often a factor in a decision to discharge from the ICU, and poor functional capacity may contribute to ICU readmission.[37] The patients in this study demonstrated clinically significant improvement in endurance, strength and function when retested after weaning from mechanical ventilation. The training and testing protocols were feasible and safe to implement, with 79% of possible exercise sessions delivered. Exercise sessions were prescribed according to the training protocol, and conducted with the patients both receiving and off mechanical ventilation. No adverse events occurred during any testing or training session.

Further investigation of the PFIT using a larger sample size is required. This could occur in the ICU and also in the wards, where equally debilitated patients may require ongoing evaluation and exercise. Future research should be aimed at developing a PFIT score and investigating its use to predict risk of readmission to the ICU and functional outcome. As randomised controlled trials evaluating rehabilitation in ICU survivors appear,[38,39] the PFIT may provide a useful tool to prescribe exercise training and effectively measure exercise outcomes in the ICU.

Exercise in survivors of critical illness is an emerging area, and the importance of functional outcomes is increasingly being recognised. To date, no objective test is available to

measure or prescribe the effects of exercise in this patient population. The PFIT is easy to perform and is a responsive and reliable outcome measure that may be used by clinicians to prescribe and evaluate exercise in weak and debilitated patients in the ICU. A pilot exercise training protocol was feasible and safe to implement in the ICU.

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Appendix A. Instructions for the PFIT test

Marching on the spot component

"Once you are in the standing position, we will ask you to march on the spot. We would like you to march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. This test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."

If applicable (ie, retest), then:

"Last time you performed the test, you marched for . . . and did . . . steps."

Give standardised encouragement every 10 seconds: "Keep going for as long as you can", "You're doing well", "Well done".

Upper limb endurance component

"We would like you to lift your hands up and down above your head for as long as you can. We are going to record how long you can do this for and how many repetitions that you do. This test is designed to record your maximum exercise ability, so it is very important that you lift your arms up and down for as long as you possibly can."

If applicable (ie, retest), then:

"Last time you performed the test, you exercised for . . . and did . . . repetitions."

Give standardised encouragement every 10 seconds: "Keep going for as long as you can", "You're doing well", "Well done". ❑