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Functional electrical stimulation with cycling in the critically ill: A pilot case-matched control study

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ABSTRACT

Purpose: The purpose was to determine (*a*) safety and feasibility of functional electrical stimulation (FES)-cycling and (*b*) compare FES-cycling to case-matched controls in terms of functional recovery and delirium outcomes.
Materials and methods: Sixteen adult intensive care unit patients with sepsis ventilated for more than 48 hours and in the intensive care unit for at least 4 days were included. Eight subjects underwent FES-cycling in addition to usual care and were compared to 8 case-matched control individuals. Primary outcomes were safety and feasibility of FES-cycling. Secondary outcomes were Physical Function in Intensive Care Test scored on awakening, time to reach functional milestones, and incidence and duration of delirium.
Results: One minor adverse event was recorded. Sixty-nine out of total possible 95 FES sessions (73%) were completed. A visible or palpable contraction was present 80% of the time. There was an improvement in Physical Function in Intensive Care Test score of 3.9/10 points in the intervention cohort with faster recovery of functional milestones. There was also a shorter duration of delirium in the intervention cohort.
Conclusions: The delivery of FES-cycling is both safe and feasible. The preliminary findings suggest that FES-cycling may improve function and reduce delirium. Further research is required to confirm the findings of this study and evaluate the efficacy of FES-cycling.

1. Introduction

The initial insult of a critical illness has lingering repercussions for patients admitted to the intensive care unit (ICU) resulting in skeletal muscle wasting and weakness. This is particularly so for individuals with sepsis who experience high rates of intensive care unit-acquired weakness (ICU-AW) [1] and prolonged diminution of their physical capabilities and cognitive functioning [2,3]. Importantly, an improvement in survival rates and increasing awareness of post–intensive care syndrome [4] have resulted in a paradigm shift from mortality-based outcomes to include patient-centered outcomes around activity limitation, disability, participation, and quality of life [5].

Early mobility is shown to lead to improvements in physical function and delirium [6–9]. However, there is often a delay in commencement of therapy due to the inability of patients to participate as a result of sedation or delirium. There is increased interest in the use of assistive technology to aid early rehabilitation, without the need for volitional patient engagement [10]. A recent systematic review evaluating electrical muscle stimulation (EMS) in critically ill patients concluded that the outcomes of using EMS in this cohort were inconclusive because of the heterogeneity of the studies and outcome measures but that EMS may have a beneficial role in the ICU [11]. The studies to date have examined EMS in nonfunctional resting positions using isolated muscle groups, such as the quadriceps muscles [12–14]. Functional electrical stimulation (FES) is different to EMS, as it recruits several muscles concurrently in functional patterns that mimic voluntary muscle activation. Use of FES-cycling compared with EMS enables cyclical muscle contraction of large lower limb muscle groups including quadriceps, hamstrings, gluteals, and calf muscles. It is hypothesized that coordinated muscle contraction increases the muscle workload, facilitating increased training of strength and force while minimizing muscle fatigue [15]. Electrical stimulation using FES-cycling can translate to improvements in other functional tasks such as walking in other patient populations [16].

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This is the first study to investigate the use of FES-cycling in critically ill patients. The primary aims of this study were to determine the safety and feasibility of FES-cycling; secondary aims were to assess its effects on physical function, ICU length of stay (LOS), and delirium compared to a matched-case control cohort.

2. Materials and methods

2.1. Study design

This was a single-center interventional observational study of critically ill patients with case-matched control comparisons at a quaternary ICU in Melbourne, Australia. Individuals were recruited into the intervention (FES-cycling) over a 4-month period (January, March, May-June, July-August 2012). Institutional ethical approval was obtained for the pilot evaluation of FES-cycling. Written informed consent was obtained from the patient's proxy in the first instance followed by continuation of consent from the patient once he or she was able to provide consent. Retrospective case matching to identify control comparisons took place between January and December 2012. The institutional ethics committee approved a waiver of consent for case-matched controls.

2.2. Screening and eligibility

Subjects were initially included if they were adults at least 18 years of age; were admitted with a diagnosis of *sepsis* or *severe sepsis* as defined by the American College of Chest Physicians Consensus Conference Guidelines [17]; and were predicted, by the senior ICU physician on admission, to be mechanically ventilated (MV) for more than 48 hours and remain in the ICU for at least 4 days. The senior ICU physician made the prediction independent from the research team. Additionally, those screened to have the intervention were excluded if there were physical reasons for the intervention not to be applied such as the presence of an external fixator, pacemaker or defibrillator, open wound or skin abrasions, or obesity (body mass index >40 [weight too high for cycle machine]), or if the treating senior ICU physician deemed the patient to be approaching imminent death.

A control was identified for each of the 8 subjects who underwent the interventional program (FES-cycling). Matching was performed according to 3 a priori–identified matching criteria. The order of matching priority and subcategories for matching were as follows: (1) Acute Physiology and Chronic Health Evaluation II score—4 categories (a: <18 mild, b: 18-22 moderate, c: 23-27 severe, d: ≥28 very severe); (2) MV hours—3 categories (a: <72 hours, b: 72 hours-7 days, and c: >7 days); and (3) age ± 15 years. If more than one matched participant was identified, the matched case control was randomly selected using computer-generated random numbers. Severity of illness, mechanical ventilation time, and age have been associated with increased risk of intensive care acquired weakness; and thus, to minimize confounding, individuals were matched on these 3 criteria.

2.3. Study procedures

2.3.1. Protocols of care

Patients were managed in the unit according to institutional protocols for resuscitation and sepsis management including antibiotic treatment, sedation, delirium, and nutritional support. All care was under the direct supervision of senior ICU physicians and critical care qualified nursing staff with a nurse to patient ratio of 1:1.

2.3.1.1. Usual care. Physiotherapists routinely screened daily for awakening and presence of delirium using the De Jonghe 5-point criteria (*awake* defined as a score of greater than 3 out of 5) [18] and the cognitive assessment method for ICU [19], respectively. Once awake, patients commenced rehabilitation involving early mobility activities such as sitting on the edge of bed, sitting out of bed, standing, marching in place, and walking (if able) for up to a maximum of 15 minutes in duration per day.

2.3.1.2. Intervention. In addition to the usual care described above, 8 subjects received FES-cycling, which aimed to commence within 96 hours of admission and continue daily until ICU discharge. The FES-cycling intervention involved a supine motorized cycle ergometer attached to a current-controlled stimulator (RT-300 supine model and SAGE stimulator; Restorative Therapies, Ltd, Baltimore, MD) (Fig. 1).

Disposable adhesive gel electrodes were placed over the major muscles of the lower limb bilaterally including quadriceps, hamstrings, gluteals, and calf muscles. The FES-cycling was conducted for a minimum of 20 to a maximum of 60 minutes daily 5 times a week. Muscles were stimulated at specific stages throughout the cycling

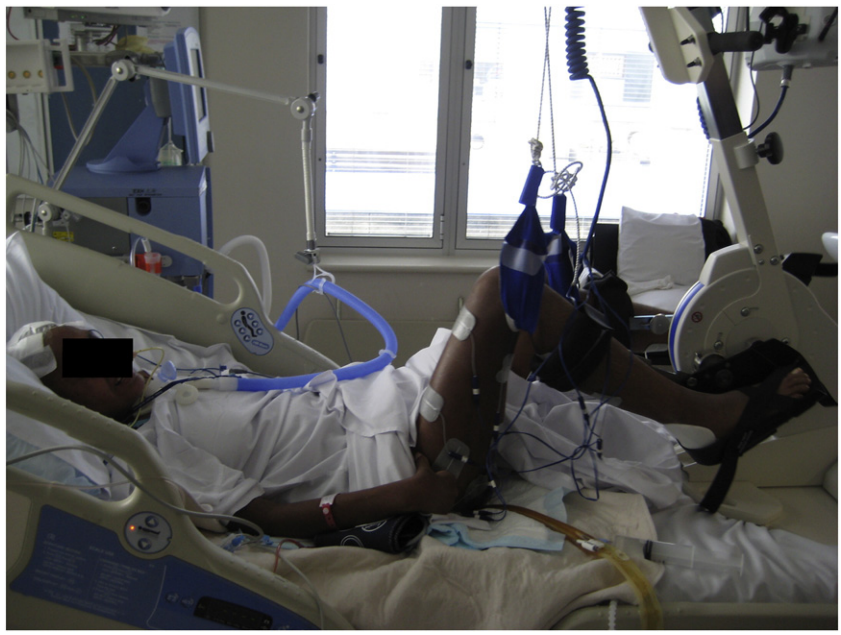

Fig. 1. FES-cycling machine (RT-300 supine model and SAGE stimulator; Restorative Therapies, Ltd, Baltimore, MD).