Effects of early passive cycling exercise on quadriceps femoris thickness in critically ill patients: a controlled randomized pilot study

Efeitos do exercício passivo precoce em cicloergômetro na espessura muscular do quadríceps femoral de pacientes críticos: estudo-piloto randomizado controlado

Efectos del ejercicio pasivo precoz en cicloergómetro en el espesor muscular del cuádriceps femoral de pacientes críticos: un estudio piloto aleatorizado controlado

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ABSTRACT | The objective of this study was to evaluate the effects of early passive cycling exercise on quadriceps femoris thickness (QFT) in critically ill patients admitted in the intensive care unit (ICU) of a tertiary care university hospital. A controlled randomized pilot study was conducted with a sample of 24 patients (51±18.11 years, 16 male), on mechanical ventilation (MV) from 24 to 48 hours, who were randomly divided into two groups: control group (n=12), receiving conventional physical therapy; and an intervention one (n=12), receiving passive cycle ergometer, once a day, throughout seven days of protocol, in addition to conventional physical therapy. The QFT was measured by ultrasonography. The first ultrasonographic measurement was performed within 48 hours after the start of MV, and the second at the end of the protocol. There were no significant differences in QFT of the left (27.29±5.86mm vs 25.95±10.89mm; p=0.558) and right (24.96±5.59mm vs 25.9±9.21mm; p=0.682) in the control group, and in QFT of the left (27.2±7.38mm vs 29.57±7.89mm; p=0.299) and right (26.67±8.16mm vs 28.65±8.04mm; p=0.381) in the intervention group. There were no significant between-groups differences for left QFT (3.61±1.07mm; p=0.248) and right QFT (2.75±0.85mm; p=0.738). The results of this pilot study demonstrate that application of early passive cycle ergometer exercises has not significantly change the muscle layer thickness. However, our findings indicate that conventional physical therapy is able to preserve the quadriceps femoris thickness in critically ill patients admitted in ICU.

Keywords | Physical Therapy Modalities; Intensive Care Units; Ultrasonography; Exercise Therapy; Early Ambulation.

RESUMO | O objetivo deste estudo foi avaliar os efeitos do exercício passivo precoce em cicloergômetro na espessura muscular (EM) do quadríceps femoral (EMQ) de pacientes críticos admitidos em uma Unidade de Terapia Intensiva (UTI) de um hospital universitário terciário. O método utilizado foi um estudo-piloto randomizado controlado conduzido em uma amostra de 24 pacientes (51±18,11 anos, 16 do sexo masculino), com 24 a 48 horas de ventilação mecânica (VM), aleatoriamente divididos em dois grupos: grupo-controle (n=12), que recebeu a fisioterapia convencional; e grupo-intervenção (n=12), que...
recebeu o exercício passivo em cicloergômetro, uma vez ao
daia, durante o período de sete dias do protocolo, em adição
à fisioterapia convencional. A EMQ foi mensurada através
da ultrassonografia. A primeira medida ultrassonográfica foi
realizada entre as primeiras 48 horas de VM e a segunda ao
término do protocolo. Não houve diferenças significativas na
EMQ esquerda (27,29±5,86mm vs. 25,95±10,89mm; p=0,558)
e direita (24,96±5,59mm vs 25,9±9,21mm; p=0,682) do grupo-
controle e na EMQ esquerda (27,2±7,38mm vs 29,57±7,89mm;
p=0,299) e direita (26,67±8,16mm vs 28,65±8,04mm; p=0,381) do grupo-intervenção. Na comparação entre os
grupos, não houve alterações significativas em relação à
EMQ esquerda (3,61±1,07mm; p=0,248) e a EMQ direita
(2,75±0,85mm; p=0,738). Os resultados deste estudo-piloto
demonstraram que a aplicação precoce do exercício passivo
em cicloergômetro não promoveu mudanças significativas
na espessura da camada muscular avaliada. No entanto,
nossos achados sinalizam que a fisioterapia convencional foi
capaz de preservar a EMQ de pacientes críticos admitidos
em UTI.

Descritores | Modalidades de Fisioterapia; Unidades de Terapia
Intensiva; Ultrassonografia; Terapia por Exercício; Deambulação
Precoce.

RESUMEN | El presente estudio tuvo como objetivo evaluar
los efectos del ejercicio pasivo precoz en cicloergómetro en
el espesor muscular (EM) del cuádriceps femoral (EMC) de
pacientes críticos ingresados en una Unidad de Cuidados
Intensivos (UCI) de un hospital universitario terciario. Se utilizó
como método un estudio piloto aleatorizado controlado con una
muestra de 24 pacientes (51±18,1 años, 16 varones), con 24 a 48
horas de ventilación mecánica (VM), quienes fueron divididos
aleatoriamente en dos grupos: grupo de control (n=12), que
recibió fisioterapia convencional; y grupo intervención (n=12),
que recibió el ejercicio pasivo en cicloergómetro una vez al
daia durante el período de protocolo de siete días, además de
la fisioterapia convencional. El EMC se midió por ecografía.
La primera medición ecográfica se realizó entre las primeras
48 horas de VM, y la segunda al final del protocolo. No hubo
diferencias significativas en el EMC izquierdo (27,29±5,86 mm
vs. 25,95±10,89mm; p=0,558) y derecho (24,96±5,59mm vs
25,9±9,21mm; p=0,682) del grupo de control; y en el EMC
izquierdo (27,2±7,38mm vs 29,57±7,89mm; p=0,299) y
derecho (26,67±8,16mm vs 28,65±8,04mm; p=0,381) del grupo
intervención. En la comparación entre grupos, no hubo cambios
significativos en el EMC izquierdo (3,61±1,07 mm; p=0,248) y
en el EMC derecho (2,75±0,85 mm, p=0,738). Los resultados
de este estudio piloto demostraron que la aplicación precoz
del ejercicio pasivo en cicloergómetro no promovió cambios
significativos en el espesor de la capa muscular evaluada.
Sin embargo, nuestros hallazgos indican que la fisioterapia
convencional pudo preservar el EMC de pacientes críticos
ingresados en la UCI.

Palabras clave | Modalidades de Fisioterapia; Unidades de Cuidados
Intensivos; Ultrasonografía; Terapia por Ejercicio; Ambulación
Precoz.

INTRODUCTION

The rapid decayz of the skeletal muscle mass is the
main factor for common physical deficiency in critical
patients of mechanical ventilation (MV)1. Early muscle
disfunction occurs in hours to days, specifically in the
first 7 to 10 days of hospitalization in the intensive
care nit (ICU), there is decay in quadriceps femoris
thickness (QFT)2,3.

The quantification of peripheral muscle thickness
(MT) may be performed by muscle ultrasound (US). This
tool represents an attractive way for early application in
critical patients, once it is a safe, non-invasive technique
that can predict muscle volume and evaluate intervention
effectiveness4-6.

Among the resources used in the prophylaxis
for quadriceps femoris atrophy, lower limb cycling is
highlighted. This device is used passively, specially in the
first ICU hospitalization days, allowing for patients with
reduced level of consciousness to perform it7. Previous
studies have shown that performing continuous passive
cycling mobilization, besides being a feasible and safe
activity, helps recovering peripheral muscle strength for
critical ICU patients8,9.

Supposing that the first ICU hospitalization week
is a decisive period regarding peripheral MT decay,
specially for the quadriceps femoris, it is necessary
to apply resources preventing muscle atrophy. The
objective of this study was, thus, to investigate the
effects of early passive cycling exercise associated
to conventional physical therapy on QFT for ICU
patients.
METHODOLOGY

A clinical randomized pilot essay with blind outcome evaluators, carried out in the Adult ICU of the University Hospital of Santa Maria (HUSM) of the Universidade Federal de Santa Maria (UFSM), in Santa Maria, Rio Grande do Sul, Brazil, between June and October 2015. All participants or their family members have signed the Informed Consent Form before being included in the study, as established by the Resolution no. 466/2012 of the Brazilian National Health Council.

It was included in the study both male and female patients, who were older than 18 years-old, between 24 and 48 MV hours after being admitted into the ICU, with deep sedation level assessed by the Richmond Agitation Sedation Scale 10 (RASS=-4) and hemodynamically stable. It was excluded from the study patients receiving palliative care, amputees or with lower limb fracture, with neuromuscular or neurological diseases, motor sequelae, just as patients who were unable to use the cycle ergometer due to pre-existing articular and/or muscle-skeletal disfunctions.

Randomization and intervention

The subjects were allocated based on a random numbers table, computer-generated, with a randomization sequence designed by the software Random Number Generator (Pro v2.00, Segobit, Issaquah, WA, USA). All participants had the intervention applied by two physical therapists. Due to the intervention’s nature, the physical therapists responsible for early cycling mobilization were not blind regarding the patients’ randomization. However, outcome evaluators were blinded regarding the allocation, given that they did not participate in the study’s interventions.

The patients who met inclusion criteria were allocated in the intervention group (IG) or control group (CG). The CG was submitted to conventional physical therapy, while the intervention group also received passive exercise sessions with the use of lower limb cycle ergometer (MOTOmed letto 2, RECK-Technik GmbH & Co.KG, Betzenweiler, Germany). Therefore, passive cycling sessions were performed with the patient in decubitus position and head elevation at 30°, for 20 minutes, with a fixed cadence of 20 cycles/min. once a day, during the first ICU hospitalization week. Aiming to ensure the performance of passive exercise, the equipment’s screen, which allows for the visualization/analysis of the practice and detects active movements, was constantly monitored during the protocol.

Conventional physical therapy (respiratory and motor therapy) was conducted by ICU physical therapists twice a day, for around 30 minutes for 7 days. The protocol included vibrocompression maneuvers, hyperinflation through mechanical ventilator and tracheal suctioning, if needed, besides motor exercises for upper and lower limbs, passive and active-assisted ones, according to the patient’s clinical evolution.

During and after the protocol application, cardiovascular parameters were constantly monitored, such as: peripheral oxygen saturation (SpO₂), heart rate (HR), mean blood pressure (MBP), systolic and diastolic blood pressure, in a non-invasive way by observing the multiparametric monitor DX 2022 (Dixtal Biomédica, Manaus, Brazil). The criteria for interrupting the protocol were: hemodynamic instability (MBP<60 or >125 mmHg), SPO₂<88%, HR>130 bpm or <40 bpm, and respiratory discomfort signs.

Evaluating quadriceps femoris thickness

QFT was evaluated by high resolution US (Mindray Ultrasound, portable DP-2022), in B mode, with a micro-convex echocardiologic transductor (65C15EA 5, 0-9.0 MHz, 4W). The initial QFT evaluation was performed during the first 48 MV hours, and the second one 7 days after the mobilization (end of the protocol).

The protocol for US evaluation was based on the study by Fivez et al. 12. The patient was positioned in decubitus, with outstretched lower limbs. After that, the transductor was positioned perpendicularly to the mean quadriceps femoris point, which was identified by a measuring tape. After detecting the ultrasound image in a resolution fit for muscle visualization (Figure 1), it was captured and the measures, expressed in millimeters, were taken. QFT was determined through transversal images measuring the distance between the external femoral edge and the upper aponeurosis of the rectus femoris muscle.
Sample size calculation

The sample for this pilot study was used for sample inference of the randomized clinical essay. It was estimated to obtain a 5% significance level (p<0.05), and 80% power (WinPepi program, version 10.5), considering a difference of 2.37mm in QFT and a sample of 64 patients for each group.

Statistical analysis

The statistical analysis was performed with the use of the program IBM SPSS Statistics, version 2.0 (IBM Corporation, Armonk, NY, USA). Variable normality was evaluated by the Shapiro-Wilk test. Continuous variables were presented as mean ± standard-deviation and confidence interval of 95% (CI 95%), while the categories were presented in absolute frequencies and percentages. To compare pre and post-intervention moments within the group, the paired Student’s t-test was used. The comparison between groups was performed by a two-way ANOVA test followed by the Bonferroni post-hoc test. The effect size was determined by the Cohen to $f^2$ compare the groups and classify them as great, moderate, and small $^{13}$. For statistically significance, it was considered a value of p<0.05.

RESULTS

In the studied period, 76 patients were admitted in the institution’s Adult ICU, 32 of them met the inclusion criteria, being randomized in CG (n=16) and IG (n=16). Later on, 4 patients in the CG deceased, as well as 4 patients in the IG. Therefore, the final sample was composed by 24 patients, with a total sum of 12 for each group (Figure 2).

Table 1 presents the sample’s general characterization, which was homogeneous for most variables, except for the gender. The IG had more men when compared to the CG (p=0.009). During the study, there was no need to interrupt the protocol nor was any adverse event observed during and after its application.

QFT remained unchanged in both groups after implementing the protocol. There were no significant differences in the left QFT (27.29±5.86mm vs. 25.95±10.89mm; p=0.558; CI 95%: −3.53 to 6.20) and right QFT (24.96±5.59mm vs. 25.9±9.21mm; p=0.682; CI 95%: −5.82 to 3.95) of the CG; and in the IG’s left QFT (27.2±7.38mm vs. 29.57±7.89mm; p=0.299; CI 95%: −6.92 to 2.34) and right QFT (26.67±8.16mm vs. 28.65±8.04mm; p=0.381; CI 95%: −6.77 to 2.80). When comparing both groups, there were no significant changes regarding the left QFT (3.61±1.07mm; p=0.248; CI 95%: −4.16 to 11.40) and the right one (2.75±0.85mm; p=0.738; IC 95%: −4.69 to 10.21) with great effect size (Cohen $f^2$=0.634) (Figure 3).
Figure 2. Study flowchart

Table 1. Clinical and demographical characteristics of the patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control group (n=12)</th>
<th>Intervention group (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54.17±16.71</td>
<td>47.83±19.61</td>
</tr>
<tr>
<td>Males, (n/%)*</td>
<td>5 (31.2)</td>
<td>11 (68.8)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25.58±5.93</td>
<td>25.58±4.84</td>
</tr>
<tr>
<td>APACHE II score</td>
<td>16.00±5.84</td>
<td>14.42±6.25</td>
</tr>
<tr>
<td>Primary cause for admission into the ICU (n/%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>0 (0.0)</td>
<td>1 (8.33)</td>
</tr>
<tr>
<td>Abdominal</td>
<td>5 (41.66)</td>
<td>2 (16.66)</td>
</tr>
<tr>
<td>Neurologic</td>
<td>3 (25)</td>
<td>5 (41.66)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2 (16.66)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Others</td>
<td>2 (16.66)</td>
<td>4 (33.33)</td>
</tr>
<tr>
<td>Medicines (n/%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuromuscular blocking agents</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>5 (41.7)</td>
<td>3 (25.0)</td>
</tr>
<tr>
<td>Vasopressors</td>
<td>5 (41.7)</td>
<td>5 (41.7)</td>
</tr>
</tbody>
</table>

Apache II: acute physiology and chronic health evaluation II. All comparisons were performed by Student’s t-test, except for the ones indicated by an asterisk (Mann-Whitney U test).
DISCUSSION

To the best of our knowledge, this is the first randomized pilot study that investigate the effects of early passive cycling exercise associated to conventional physical therapy on critical patients’ QFT. After implementing the protocol, there were no significant changes in the thickness of the muscle layer both for the CG and the IG, however, it was observed that conventional physical therapy, performed with both groups, has promoted QFT preservation.

Studies performed in ICUs have demonstrated that 17% to 30% of muscle mass may be lost in the 10 first hospitalization days for critical patients3,14. Considering the lack of evidence regarding the effects of early passive cycling exercise on QFT, it is important to mention the randomized pilot clinical essay carried out by Gruther et al.15, in which it was investigated, during the first week in the ICU, the efficacy of neuromuscular electrical stimulation on the prevention of peripheral muscle atrophy, however, a significant reduction in QFT was observed, demonstrating that the early intervention did not prevent the loss of muscle mass. In our study, the mobilization through cycle ergometer did not promote additional affects to the traditional physical therapy protocol, on the other hand, it was concluded that implementing this protocol has preserved QFT.

Studies performed in ICUs have demonstrated that implementing early rehabilitation promotes anabolic stimulation to peripheral muscle fibers19,20. In the study performed by Burtin et al.21, it was observed an increase in quadriceps strength after combining passive and active mobilization associated to early cycling exercise. In this study, all patients were in deep sedation (Richmond agitation and sedation scale=−4), a factor that made it impossible to measure muscle strength. In this context, as described by Puthucheary et al.22, ultrasound can replace other resources when evaluating peripheral muscle strength, such as the Medical Research Council, specially when patients are unable to follow verbal commands; besides that, this is a promising tool used for muscle-skeletal evaluation and its success owes to the reduction of bias created by conventional anthropometric measurements23-26.

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CONCLUSION

The results of this pilot study have demonstrated that early application of passive cycling exercise associated to conventional physical therapy did not promote changes in quadriceps femoris thickness. However, our findings indicate that conventional therapy helped preserving muscle deterioration18, however, these outcomes were not assessed in this study.

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In our sample, there was predominance of men, given that, male individuals physiologically present higher muscle mass when compared to females, however, it is highlighted that this aspect does not protect muscle thickness27. In the observational study conducted by Turton et al.1, in which there was also prevalence of men, the ultrasound evaluations performed in the 10 first ICU days have demonstrated a significant decay of QFT.

Our study has some limitations. Firstly, the outcome was restricted to the evaluation of QFT in the first ICU week, therefore, it is not possible to confirm if the QFT preservation would be maintained until medical discharge. Secondly, other parameters involved in muscle architecture, such as pennation angle, fascicle length and cross-sectional area, were not measured, considering that most studies in literature performed with critical patients use only the QFT parameter12,15,26,27. In third place, a share of the sample received corticosteroids, however, the casual relation between neuromuscular disfunctions and the use of corticosteroids is not well-stablished, probably since these disfunction are related to more complex mechanisms, such as: dose, time, and concomitant glycemic control28.
thickness for critical patients in the first ICU week. It is hoped that increasing the sample size may indicate significant results regarding the increase of muscle thickness with the use of passive cycle ergometer, given that there was a great effect size along with this intervention.

REFERENCES


