Acute effect of the use of cycle ergometer during physical therapy treatment in mechanically ventilated critically ill patients

Efeito agudo da utilização do cicloergômetro durante atendimento fisioterapêutico em pacientes críticos ventilados mecanicamente

Efectos agudos de la utilización del cicloergómetro durante la fisioterapia en pacientes críticos ventilados mecánicamente

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ABSTRACT | Mechanically ventilated patients admitted to intensive care units (ICU) usually have muscle dysfunction due to physical inactivity, inflammatory processes, and to the use of pharmacological agents. The objective of this study was to compare the intense use of cycle ergometer in critical mechanically ventilated patients admitted to the intensive care unit (ICU). This is a randomized clinical trial with 25 mechanically ventilated ICU patients from Porto Alegre Teaching Hospital. We collected, pre- and post-intervention, hemodynamic and respiratory variables, and we also assessed the C-reactive protein, through the arterial blood gas test, and lactate levels and gas exchange. The protocol included upper and lower extremity diagonals from the Proprioceptive Neuromuscular Facilitation method and bronchial hygiene exercises when necessary. In the intervention group, in addition of the abovementioned physiotherapy, the group underwent passive cycle ergometer exercises. The analysis was carried out using SPSS 18.0. We used mean and standard deviation to describe continuous data and adopted significance level of 5%. Statistically significant change was observed for peak pressure (pre=25.1±5.9 and post=21.0±2.7 cmH₂O; p=0.03) in the conventional group and for bicarbonate (pre: 23.5±4.3 and post: 20.6±3.0; p=0.002) in the intervention group. We concluded

thus that neither does cycle ergometer in a protocol for early mobilization alter hemodynamic and respiratory mechanics, nor does it result in acute physiological responses.

Keywords | Artificial Respiration; Intensive Care Units.

RESUMO | Pacientes internados em unidades de terapia intensiva (UTI) e ventilados mecanicamente comumente apresentam disfunção muscular devido à inatividade física, à presença de processos inflamatórios e ao uso de agentes farmacológicos. O objetivo deste estudo foi comparar a utilização aguda do cicloergômetro em pacientes críticos ventilados mecanicamente internados em UTI. Trata-se de um ensaio clínico randomizado, no qual foram incluídos 25 pacientes em ventilação mecânica na UTI do Hospital de Clínicas de Porto Alegre. Foram coletadas, pré e pós-intervenção, variáveis hemodinâmicas e respiratórias, bem como foram avaliadas a troca gasosa, por meio da gasometria arterial, os níveis de lactato e proteína C reativa. O protocolo consistiu de diagonais do método de Facilitação Neuromuscular Proprioceptiva de membros superiores e inferiores e técnicas de higiene brônguica, guando necessário. Já no grupo intervenção foi realizado, além da fisioterapia descrita previamente, o cicloergômetro passivo. A análise foi realizada mediante

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o programa SPSS 18.0. Os dados contínuos foram expressos em média e desvio-padrão, e o nível de significância adotado foi de 5%. Observou-se alteração estatisticamente significativa em relação à pressão de pico (pré: 25,1±5,9; pós: 21,0±2,7cmH₂O; p=0,03) no grupo convencional e ao bicarbonato (pré: 23,5±4,3; pós: 20,6±3,0; p=0,002) no grupo intervenção. Concluiu-se que a utilização do cicloergômetro num protocolo de mobilização precoce não altera a mecânica respiratória, nem a hemodinâmica e não resulta em respostas fisiológicas agudas.

Descritores | Respiração Artificial; Unidades de Terapia Intensiva.

RESUMEN | Los pacientes hospitalizados en unidades de cuidados intensivos (UCI) y ventilados mecánicamente en general presentan disfunción muscular debido a la falta de practicar actividad física, a la presencia de procesos inflamatorios y a la utilización de fármacos. En este estudio se comparó el uso agudo del cicloergómetro en pacientes críticos ventilados mecánicamente hospitalizados en UCI. Se trata de un estudio clínico aleatorio, en el cual se incluyeron 25 pacientes en ventilación mecánica en la UCI del Hospital de Clínicas de Porto

Alegre, Brasil. Se recolectaron, pré y posintervención, las variables hemodinámicas y respiratorias, así como se evaluaron el cambio de gases, mediante la gasometría arterial, los niveles de lactato y la proteína C reactiva. El protocolo estaba formado de diagonales del método de Facilitación Neuromuscular Propioceptiva de los miembros superiores e inferiores y técnicas de higienización de los bronquios, cuando necesarios. En el grupo intervención se realizó, además de la fisioterapia descriptiva preestablecida, el cicloergómetro pasivo. Se realizó el análisis a través del programa SPSS 18.0. Los datos fueron expresados en promedio y desviación-estándar, y el nivel de significación fue de 5%. Se observó alteraciones significativas estadísticamente en relación a la presión máxima (pré: 25,1±5,9; pos: 21,0±2,7cmH₂O; p=0,03) en el grupo convencional y al bicarbonato (pré: 23,5±4,3; pos: 20,6±3,0; p=0,002) en el grupo intervención. Se concluyó que el empleo del cicloergómetro en el protocolo de movilización precoz no altera la mecánica respiratoria, la hemodinámica y tampoco resulta en respuestas fisiológicas agudas.

Palabras clave | Respiración Artificial; Unidades de Cuidados Intensivos.

INTRODUCTION

Muscle dysfunction is common in mechanically ventilated ICU patients due to physical inactivity, inflammatory processes, and the use of pharmacological agents, e.g., corticosteroids, neuromuscular blocking drugs, and antibiotics¹⁻¹⁴. Neuromuscular disorders are especially common in these patients, with an average prevalence of 57%¹⁵. In most cases, the necessity of prolonged mechanical ventilation (MV) contributes to these alterations, decreasing the functionality state and, consequently, the quality of life of these patients after hospital discharge¹⁶. MV is associated with increased periods of hospitalization and ICU stay, and also increased mortality^{7-14,17,18}.

ICUs in Brazil and worldwide have been searching for alternative therapies to help assisting patients¹⁹⁻²¹. In this context, early mobilization has been more used as a therapeutic choice in treatment centers. Recent studies demonstrated that early mobilization is feasible and safe for mechanically ventilated patients. They also demonstrated that this procedure decreases ICU stay, hospitalization period and of MV^{7,22,23}. Moreover, when early mobilization is not practiced in the ICU, there are increased rates of hospital readmission and death within the first year after hospital discharge^{24,25}. The use of a cycle ergometer was a good alternative on early intervention for critically ill patients, increasing functional capacity, self-perception, and quadriceps strength¹². Therefore, the objective of this study was to compare the intense use of a cycle ergometer in mechanically ventilated critically ill ICU patients regarding hemodynamic effects, respiratory mechanics, and lactate levels before and after it was used.

METHODOLOGY

This is a randomized clinical trial, conducted at the Porto Alegre Teaching Hospital, from May to December 2013. The study population was composed of ICU patients from Porto Alegre Teaching Hospital. We included patients aged 18 years and older, male and female, admitted to the ICU at HCPA with at least 24 hours and not more than 48 hours of invasive mechanical ventilation (IMV). Patients came from emergency department or inpatient unit, with no more than 1 week of hospitalization. This study was approved by the Research Ethics Committee of the Porto Alegre Teaching Hospital, report No. 415.748, and the informed consent form was signed by the person responsible for the patient.

Exclusion criteria include patients with neuromuscular diseases who presented motor deficit, such as cerebrovascular accident, multiple sclerosis, amyotrophic lateral sclerosis, myasthenia gravis, and Guillain-Barré syndrome. Similarly, we excluded patients extubated in less than 48 hours after being included in the study and who had hemodynamic instability (noradrenaline >0.5 mc/kg/min for a mean arterial pressure >60 mmHg), complications during the protocol (pneumothorax, deep vein thrombosis, and pulmonary embolism), Shilley catheter in the femoral vein, need for reintubation, prolonged weaning (3 failed spontaneous breathing trials), body mass index (BMI) >35 kg/m², and development of eschar in the calcaneal during the protocol.

The final sample of 25 individuals had its selected individuals randomly placed in groups of 10 using the website Randomization (www.randomization.com) on intervention group (IG) or conventional group (CG).

Patients from both groups were seen for 30 to 45 minutes and the difference between the groups was the use of the cycle ergometer. The cycle ergometer used was an in-bed simple Cajumoro[®] Flexmotor (São Paulo, Brazil).

Physical therapy care protocol for conventional group: 30-minute physiotherapy session. The protocol included upper and lower extremity diagonals from the Proprioceptive Neuromuscular Facilitation method (two series of 10 repetitions for each bilateral diagonal), and bronchial hygiene exercises such as vibrocompression, manual hyperinflation, and aspiration of secretions when necessary. The intervention group underwent the abovementioned physiotherapy and passive cycle ergometer exercises. Patients were submitted to the exercise with 20 cycles per minute for 20 minutes before conventional physiotherapy. The patient was in supine position to use the cycle ergometer and the bed was elevated to 30 degrees.

For hemodynamic evaluation, we used heart rate (HR) and mean arterial pressure (MAP) measures, which were obtained from the ICU multi-parametric monitor (Infinity Kappa, Dräger, Germany). Respiratory variables analyzed were tidal volume (Vt), respiratory frequency (RF), positive end expiratory pressure (PEEP), and fraction of inspired oxygen (FiO₂), obtained from the mechanical ventilators monitor (Servo, Maquet, Sweden and Evita-4, Dräger, Germany). We also measured gas exchange using the arterial blood gas test and C-reactive protein and lactate levels.

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Statistical analysis was carried out using SPSS 18.0. We used mean and standard deviation to describe continuous data and absolute and percentage values to categorical data. We used Student's t-test or Mann-Whitney test to compare quantitative variables between groups. We adopted a 5% significance level.

RESULTS

During the pre-established period for data collection, 25 patients met the study inclusion criteria. After randomization, 14 patients were included in the intervention group (IG) and 11 in the conventional group (CG). Average age of the patients was 55.21±23.1 (IG) and 61.8±22.6 (CG) years and the percentage of females was 57.1% and 45.4%, respectively. Mean duration of mechanical ventilation was 11.8±8.8 (IG) and 12.6±5.1 (CG) days and the average ICU length of stay was 20.1±15.1 and 20.1±9.3 days, respectively. APACHE II, which predicts the risk of death during the first 24 hours of ICU admission, mean scores were 23.6±9.6 (IG) and 27.8±4.9 (CG). (Table I).

Table 1.	Demographic	variables
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Variables	IG	CG	р
Age (years)	61,8±22,6	55,2±29,1	0,481
Gender, female	5 (45,4%)	8 (57,1%)	-
Height (m)	1,62±0,07	1,58±0,09	0,237
Weight (Kg)	60,8±15,9	70,0±14,0	0,092
BMI (Kg/m²)	22,4±4,9	28,7±6,4	0,012
Duration, MV (days)	12,6±5,1	11,4±8,8	0,682
Period, ICU (days)	20,1±9,3	20,1±15,1	0,984
Period, hospital (days)	25,8±12,9	21,08±11,8	0,333
Apache II	27,8±4,9	23,6±7,6	0,125
Death	6 (54,5%)	2 (14,20%)	-

m: meter; Kg: kilograms; MV: mechanical ventilation; ICU: intensive care unit

Pre- and post-intervention values regarding respiratory mechanics revealed a statistically significant change for peak pressure, maximum inspiratory pressure (pre= 25.1 ± 5.9 and post= 21.0 ± 2.7 cmH₂O; p=0.03– Table II) in the conventional group. The ABG test revealed a significant difference for bicarbonate (pre: 23.5 ± 4.3 and post: 20.6 ± 3.0 ; p=0.002 – Table III) in the intervention group. Lactate and C-reactive protein levels revealed no significant difference in both groups when we compared pre- and post-intervention values (Table IV).

Table 2. Comparison of respiratory and hemodynamic variables

Variable		IG			CG	
	Pre	Post	р	Pre	Post	р
Ppeak	25,1±5,9	21,0±2,7	0,03	26,7±5,3	25,1±5,1	0,481
Vt	455±132,4	431±86,4	0,595	506±164	537±167	0,638
PEEP	7,6±2,9	6,6±1,1	0,271	8,8±2,5	9,0±2,7	0,846
FiO2	42,7±2,6	39,4±9,5	0,201	40,7±6,3	40,0±5,3	0,791
RF	21,7±5,1	20,3±3,7	0,314	18,8±3,9	20,2±4,7	0,414
HR	84,1±16,1	89,3±10,8	0,340	93,0±12,3	90,1±13,4	0,543
MAP	84,5±15,6	82,7±19,4	0,795	79,2±13,9	79,1±13,7	0,953

Ppeak: Peak pressure; Vt: Tidal volume; PEEP: Positive end-expiratory pressure; FIO₂: Fraction of Inspired Oxygen; RF: Respiratory Frequency; HR: Heart rate; MAP: Mean arterial pressure

Table 3. Arterial blood gas test

Variable		IG	CG			
	Pre	Post	р	Pre	Post	р
рН	7,41±0,09	7,41±0,06	1,00	7,34±0,09	7,38±0,07	0,223
PaO2	111,4±35,4	127,2±70,0	0,465	103,8±36,7	82,8±21,6	0,09
PaCO2	41,7±10,6	46,5±13,3	0,305	43,7±9,1	50,5±8,4	0,060
HCO3	25,9±5,6	29,6±7,9	0,17	23,5±4,3	20,6±3,0	0,002

pH: Power of hydrogen; PaO_2: Partial pressure of oxygen; PaCO_2: Partial pressure of carbon dioxide; HCO_3 : Bicarbonate

Table 4.	Comparison	of ph	nysiol	ogical	variables

	IG			CG		
Pre	Post	р	Pre	Post	р	
1,40±0,53	1,17±0,24	0,165	1,01±0,37	1,06±0,59	0,758	
751,7±86,1	137,7±56,8	0,645	304,6±103,8	215,0±167,7	0,114	
113,3±62,8	103,8±66,9	0,707	103,6±73,3	105,2±53,1	0,939	
10,1±4,4	10,5±5,8	0,825	15,9±9,2	13,8±6,1	0,512	
	1,40±0,53 751,7±86,1 113,3±62,8	Pre Post 1,40±0,53 1,17±0,24 751,7±86,1 137,7±56,8 113,3±62,8 103,8±66,9	Pre Post p 1,40±0,53 1,17±0,24 0,165 751,7±86,1 137,7±56,8 0,645 113,3±62,8 103,8±66,9 0,707	Pre Post p Pre 1,40±0,53 1,17±0,24 0,165 1,01±0,37 751,7±86,1 137,7±56,8 0,645 304,6±103,8 113,3±62,8 103,8±66,9 0,707 103,6±73,3	Pre Post p Pre Post 1,40±0,53 1,17±0,24 0,165 1,01±0,37 1,06±0,59 751,7±86,1 137,7±56,8 0,645 304,6±103,8 215,0±167,7 113,3±62,8 103,8±66,9 0,707 103,6±73,3 105,2±53,1	

CRP: C-reactive protein

From total sample, seven patients were diagnosed with sepsis, 3 from the intervention group and 4 from the control group. Demographic data of these patients revealed statistically significant differences for age (IG=61.1±10.5 and CG=81.6±5.1 years – p=0.0001), weight (IG=73.5±15.6 and CG=54.0±17.8 kg – p=0.005), and body mass index (BMI) (IG=29.9±7.9 and CG=20.4±5.6 – p=0.002). Duration of mechanical ventilation, period of hospitalization, and ICU length of stay revealed no significant differences, as shown in Table V.

Non-septic patients from both groups showed no significant differences for abovementioned demographic and temporal variables.

Table 5. Comparison of demographic variables of septic patients	
from both groups	

nom both groups			
Variables	IG	CG	р
Age (years)	81,6±5,1	61,1±10,5	0,0001
Gender, male	4 (80%) 36?	3 (42%) 21?	-
Height (m)	1,62±0,08	1,58±0,05	0,07
Weight (Kg)	54,0±17,8	73,5±15,6	0,0058
BMI (Kg/m²)	20,4±5,6	29,9±7,9	0,002
Duration, MV (days)	10,2±5,1	12,0±5,3	0,380
Period, ICU (days)	21,0±9,2	24,2±16,6	0,559
Period, hospital (days)	23,8±5,0	19,6±9,4	0,194
Death	4 (80%)	1 (14,2%)	-

DISCUSSION

The main finding of this study is that the use of a protocol for early mobilization and the cycle ergometer did not cause cardiorespiratory changes, neither changed physiological variables in mechanically ventilated patients, however, we did not observe a reduction in ICU length of stay and period of hospitalization when we compared it to the early mobilization protocol without the use of cycle ergometer. The study found a significant decrease in peak pressure pre- and post-intervention in the conventional group. Moreover, we found significant differences between the two groups in age, weight, and BMI of patients who were diagnosed with sepsis.

Critical mechanically ventilated patients usually stayed in the hospital bed, or because of their insecurity, or unpreparedness of healthcare team, both an obstacle to mobility. These patients also suffered with sleep deprivation, social isolation, poor nutritional status, sedation, and other consequences from ICU stay, which affected the functionality of these patients²⁶.

Early mobilization, however, has been proving itself beneficial to reduce the duration of mechanical ventilation and to improve the functionality of patients. More recently, early physical activity has been used in critically ill patients with neurological and cardiorespiratory stability²⁷. Early mobilization includes progressive therapeutic exercises, e.g., bed exercises, sitting at the edge of bed, orthostatism, transfer from sit to stand, and ambulation²⁸.

Dantas et al.²⁹ administered an early mobilization protocol to 14 mechanically ventilated patients and evaluated its effect on peripheral and respiratory muscles. The authors gathered evidence that inspiratory and peripheral muscles strength increased significantly. They also analyzed the duration of mechanical ventilation, period of hospitalization, and ICU length of stay. They did not detect significant differences between the two groups, corroborating findings from our study.

Pires-Neto et al.³⁰ assessed hemodynamic, respiratory, and metabolic effects of early use of the cycle ergometer in critically ill patients. The authors used the equipment in the first 72 hours of mechanical ventilation in 19 patients and did not observe significant changes in the variables analyzed. In this study, however, we observed a significant decrease of bicarbonate in the intervention group arterial blood gas test, comparing pre- and postintervention values. We must point out that there is no clinical explanation for this fact, for there was no significant change in any other arterial blood gas test variable.

APACHE II score predicts the risk of death during the first 24 hours of ICU admission. This score is a severity-of-disease classification system³¹ and may influence critical patients prognosis. Soares et al.³² assessed in a longitudinal study the effects of taking 51 ICU patients from bed. The authors, analyzing APACHE II scores, noted that patients who were removed from hospital bed were in better conditions than patients who were not removed. When the authors analyzed the actual mortality and predicted mortality rates, i.e., what APACHE II score predicted and what was clinically found, they also found statistically significant differences when comparing patients removed from the hospital bed and patients not removed: rates were higher for patients not removed.

In this study there was no significant difference in APACHE II scores between the two groups, therefore, it was not possible to determine how the variables were related.

In an observational study, Gael et al.¹¹ analyzed the physiological effects of early mobilization on 20 critical patients, who were included because they stayed in ICU for 7 days and received mechanical ventilation for at least 2 days. Exercises included sitting out of bed, standing with assistance of a tilt table, and ambulation. Authors observed significantly decreased heart rate (HR) and respiratory frequency (RF) after sitting out of bed exercises. Aforementioned variables, however, significantly increased during standing with assistance of a tilt table and ambulation, in the latter there was a significant decrease in peripheral oxygen saturation.

Chris et al.¹² used a mobility protocol consisting of respiratory and motor physiotherapy exercises, in which the cycle ergometer was also used (20 minutes every day) in the intervention group. The authors assessed quadriceps muscle strength and functionality state of patients after ICU and hospital discharge. We administered the six-minute walk test after hospital discharge. We did not observe significant differences at ICU discharge comparing the two groups for abovementioned variables. Intervention group, however, presented significantly higher six-minute walk test results at hospital discharge for quadriceps strength and functionality state.

CONCLUSION

The limitations of our study is its small sample size and impossibility of analyzing factors affecting muscle function. On the other hand, the strength of our study is the comparison of two acute physical therapy care protocols using cycle ergometer in mechanically ventilated critically ill patients, which we hope will call healthcare professionals attention to its use, since there was no significant variation regarding variables analyzed in this study. It is also worth mentioning that unmodified outcomes (duration of MV and period of hospitalization) may be related to this study design, which focused on the acute effect of adding the use of cycle ergometer to a physical therapy protocol on intensive care unit patients.

Therefore, results obtained in this study demonstrated that neither does the use of cycle ergometer in a protocol for early mobilization alter hemodynamic and respiratory mechanics, nor does it result in acute physiological responses.

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