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ORIGINAL RESEARCH

The effect of the addition of in-bed leg cycling using a MOTOmed device to standard rehabilitation on the length of mechanical ventilation: a randomized clinical trial

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Abstract

Successful weaning from mechanical ventilation (MV) belongs to the challenges in critical care. The study evaluated the effect of the addition of in-bed leg cycling using a MOTOmed device to standard rehabilitation on the length of MV. Randomized open-label clinical trial. Sixty-seven mechanically ventilated patients were random allocated in the in-bed leg cycling MOTOmed group (m-group) and the control group (c-group). The standard physiotherapy was carried out twice a day in both groups. The m-group received additional in-bed leg cycling rehabilitation using a MOTOmed device once daily. We included 20 patients in m-group and 19 in c-group in the final analysis. In the m-group, a non-significant reduction in both total length of MV (21.0 $\pm$ 9.78 *vs.* 24.4 $\pm$ 10.88 days, $p = 0.915$) and length of MV from randomization (5.4 $\pm$ 6.17 *vs.* 8.7 $\pm$ 8.00 days, $p = 0.860$) was observed. Both groups had significant muscle strength improvement (knee joint extension, handgrip). However, the m-group patients reached the same muscle strength level in a shorter time (8.70 $\pm$ 6.44 *vs.* 6.8 $\pm$ 4.3 days, $p = 0.534$). In our study, adding the MOTOmed device in-bed leg cycling to standard rehabilitation did not significantly reduce mechanical ventilation length in critically ill patients.

Keywords

In-bed cycling; Rehabilitation; Mechanical ventilation; Critical care; Weaning

1. Introduction

Intensive Care Unit-Acquired Weakness (ICU-Acquired Weakness) is the most frequent complication in critically ill mechanically ventilated patients [1–3]. It usually leads to mechanical ventilation dependence causing prolonged intensive care unit length of stay and increased morbidity and mortality [2]. Clinically manifested peripheral muscle weakness has been reported in 25% to 33% of patients on at least four days of mechanical ventilation [4, 5], and in up to 76% of patients with sepsis [6–10]. ICU-Acquired Weakness is associated with increased mortality [3]. In 2009, the "Enhanced early physiotherapy rehabilitation protocol in the intensive care unit" concept was formulated to improve the mortality and morbidity of mechanically ventilated critically ill patients [11].

Early rehabilitation tailored to the patient's general condition, consciousness, and cooperation is appropriate for preventing ICU-Acquired Weakness. ICU-physiotherapy, including general body rehabilitation and mobilization, can be safely performed in critically ill patients requiring mechanical ventilation [12–15]. Since then, several studies have shown that early physical activity can improve outcomes if applied in the very early within three days of mechanical ventilation [14, 15]. Concerning the in-bed leg cycling, a non-beneficial data related to the outcomes (non-significant influence on muscle wasting, cardiovascular performance and respiratory mechanics) in critically ill patients was recently published [16, 17].

The main objective of our study was to evaluate the potentially beneficial influence of the addition of in-bed leg cycling using a MOTOmed device to standard physiotherapy on weaning from mechanical ventilation. The primary outcome was the overall length of mechanical ventilation (number of ventilator days) and mechanical ventilation length from the randomization. Secondary outcomes were (1) change in intensity of muscle strength and speed of its recovery, (2) a frequency of adverse alterations of vital (respiratory and cardiovascular) parameters related to use of cycling device.

2. Materials and methods

TABLE 1. Inclusion and exclusion criteria.

Inclusion criteria:
• age $\geq$18 years
• ICU admission
• weaning from mechanical ventilation initiation
Exclusion criteria:
• inability to use cycling exercise: trauma or operation of lower limbs, pelvis, open abdomen, failure to cooperate (qualitative and quantitative disturbance of consciousness)
• encephalopathy (ischemic, traumatic)
• cardiac arrest
• symptomatic chronic neuromuscular disorders
• extreme obesity (body mass index $\geq$40 kg/m^2)
• anticipated survival time $\leq$7 days
• patient height $\leq$1.5 m

ICU—intensive care unit.

2.1 Study design and setting

The trial was conducted between the 1st of September 2018 and the 31st of December 2019 at the department of anesthesiology and intensive care, university hospital of Ostrava.

2.2 Participants

Following their admission to the ICU, all patients on mechanical ventilation expected to last five days and more were screened. At the time of weaning from mechanical ventilation initiation, the study physician and rehabilitation worker assessed the patients' eligibility using the criteria shown in Table 1. The cause of mechanical ventilation was noted see Table 2. According to the mobility protocol, standard rehabilitation was started within 48 hours after mechanical ventilation initiation.

2.3 Interventions and randomization

The weaning from mechanical ventilation was considered immediately after cardiorespiratory stability was achieved. The stability was defined as absence of low dose of vasopressors (norepinephrine <8 μg/min), inspiratory fraction of oxygen (FiO_2 $<60\%$) and positive end-expiratory pressure (PEEP <10 cm H_2O). At the time of the beginning of weaning the patients were randomly allocated into the in-bed leg cycling group (m-group) undergoing standard rehabilitation together with in-bed cycling exercise and a control group (c-group) receiving only rehabilitation. The intended allocation ratio was 1:1. The randomization was performed by randomly pulling out the unmarked sealed envelopes pre-filled with the fixed number of group-specific designations.

In all randomized patients, the weaning was performed strictly according to local standard of care, including gradual reduction of synchronized intermittent mandatory ventilatory support (pressure control and PEEP), followed by spontaneous breathing on pressure support ventilation and intermittent T piece trials. We followed cooperative analgosedation concepts (target: richmond agitation and sedation score about 0 to –2) to during the weaning period using titrated dosage of opiates (sufentanil, S2CD02, Chilsi Pharmaceuticals, Austria) and short-term sedatives (dexmedetomidine, 2112311, Hameln Pharmaceuticals BBraun Melsungen AG, Spain), (propofol, 211138071, Hameln Pharmaceuticals BBraun Melsungen AG, Germany). Discontinuation of mechanical ventilation was considered after two successful consecutive spontaneous breathing trials.

At the randomization, the informed consent was signed by two study-independent physicians in unconscious patients and obtained directly from the patients conscious enough to approve the study participation. The study physician collected the baseline, clinical, and outcome characteristics in all randomized patients (see Table 3) and stored them in the secure analog database.

Muscle strength was assessed in both groups by study rehabilitation worker at the two-time points: the time of randomization and the end of rehabilitation when each patient was discharged from the intensive care unit. The medical research council manual muscle testing scale was used [18]. The strength was measured by a dynamometer (microFET2, Hoggan Scientific LCC, Salt Lake, UT, USA). The wrist flexors on the upper extremity and the knee extensors were evaluated three times, 4 seconds each measurement, and then the average was calculated.

Rehabilitation was carried out twice a day in both groups. The standard rehabilitation included: (1) chest physiotherapy encompassing manual therapy, ventilation support (contact breathing, activation of diaphragm, reflex stimulation of breathing), and airway clearance techniques (vibration, breathing exercises on the side or in sitting position, cough assistance, instrument support-vest airway clearance system), and (2) functional mobility training using recondition (reeducation of the range of motion and muscle strength, coordination and endurance training), mobilization according to the mobility protocol. In passive patients, we performed a passive exercise to prevent secondary changes. In-bed cycling was performed once daily only in the m-group 5 days a week except for Saturday and Sunday. The cycling device was the MOTOmed Letto 2 (RECK–Technik GmbH, Betzenweiler,

TABLE 2. The causes for mechanical ventilation in m-group and c-group.

Cause	m-group (n = 20)	c-group (n = 19)	*p*-value
pulmonary			
Pneumonia % (n)	42.86 (9)	10.53 (2)	0.022
Exacerbation of chronic pulmonary disease % (n)	4.76 (1)	5.26 (1)	1.00
Aspiration % (n)	0	0	
Pleural cavity disorders (pneumothorax, fluidothorax) % (n)	9.52 (2)	5.26 (1)	1.00
other % (n)	0	5.26 (1)	0.475
extrapulmonary			
Multiple trauma % (n)	4.76 (1)	0	1.00
Isolated chest wall trauma % (n)	0	0	
Sepsis % (n)	4.76 (1)	26.32 (5)	0.085
Major surgery % (n)	9.52 (2)	21.05 (4)	0.398
Cardiogenic pulmonary edema % (n)		5.26 (1)	0.475
Burns % (n)	0	0	
other % (n)	23.81 (5)	21.05 (4)	1.00

Nominal values are stated as absolute numbers and relative frequencies (in %). p-values correspond to the tests of significant differences between research group a control group.
M-group—MOTOmed group; C-group—control group.

Germany). The therapy was targeted to at least 10 minutes of active cycling in (1) servo mode, (2) without resistance, or (3) against dosed resistance, depending on their current ability in the m-group [19].

Before release from the intensive care unit, a cycling test was performed in both groups (10 minutes in the primary mode without resistance), as was the barthel index for activities of daily living.

2.4 Ethics and outcomes

The code of ethics of the world medical association (Declaration of Helsinki) for human subjects experiments was pursued.

We followed (1) overall length of mechanical ventilation (number of ventilator days) and mechanical ventilation length from the randomization, (2) change in intensity of muscle strength and speed of its recovery, (3) presence of adverse alterations of vital (respiratory and cardiovascular) parameters related to use of cycling device.

2.5 Statistical analysis

The sample was characterized using descriptive statistics (the median, arithmetic mean, standard deviation, frequency tables). The distribution of quantitative data was tested for normality by using shapiro-wilk normality test, data was not normal distributed. Selected characteristics (methods) were compared between m-group and c-group using the nonparametric test. Mann-whitney was used for testing the quantitative data and chi-squared test for qualitative data or, where the criteria for chi-squared test using not accepted, fisher's exact test was performed. The data were graphically depicted as box plots. The level of significance was set at 5%. The analyses were performed by certified statistician using Stata 13 software application.

3. Results

A total of 508 critically ill patients underwent mechanical ventilation during the study period. We randomized a total of 67 patients. In the final analysis, we included 39 patients (m-group, n = 20, and c-group, n = 19). For more details concerning patient selection, please see the consort flow diagram (Fig. 1). The baseline, clinical, and relevant outcome characteristics are summarized in Table 3.

3.1 Primary outcome

The mechanical ventilation length did not significantly differ between the m-group and the c-group (21.0 ± 9.78 *vs.* 24.4 ± 10.88 days, respectively, $p = 0.915$). The mechanical ventilation length from randomization to the discontinuation of mechanical ventilation did not significantly differ between groups (5.4 ± 6.17 *vs.* 8.7 ± 8.00 days, respectively, $p = 0.860$; Fig. 2).

3.2 Secondary outcomes

M-group and c-group patients' dynamometric values did not significantly differ in both measured groups of muscles (knee joint extensors, wrist flexors) at the time of randomization. However, comparing values at randomization, we observed a significant improvement in muscle strength at the time of ICU discharge in both groups. Dynamometric evaluation of knee joint extension revealed a significant improvement in the m-group respondents in both the left (LLE) and right lower extremity (RLE) ($p = 0.004$ and 0.015, respectively). Apart from the RUE ($p = 0.576$), the same significant improvement in

TABLE 3. The baseline, clinical and outcome characteristics in m-group and c-group.

Characteristics	m-group	c-group	*p*-value
	(n = 21)	(n = 19)	
baseline			
Age (years)	53.0 ± 16.02	67.0 ± 12.59	0.036
Sex (male % (n))	52 (11)	58 (11)	0.726
Sex (female % (n))	48 (10)	42 (8)	
Body weight (kg)	83.0 ± 17.34	80 ± 22.6	0.744
Height (cm)	170.0 ± 8.67	170 ± 8.91	0.453
BMI (cm/m^2)	29.4 ± 6.12	27.5 ± 6.33	0.652
Diabetes mellitus (% (n))	23.81 (5)	26.32 (5)	0.855
Chronic coronary artery disease (% (n))	4.76 (1)	31.58 (6)	0.04
Chronic obstructive pulmonary disease (% (n))	14.29 (3)	10.53 (2)	1.00
Stroke (% (n))	0 (0)	10.53 (2)	0.219
Cancer (% (n))	28.57 (6)	21.05 (4)	0.721
Liver cirrhosis (% (n))	0	0	0
Chronic kidney disease (% (n))	14.29 (3)	31.58 (6)	0.265
clinical			
APACHE II*	12.0 ± 2.1	12 ± 2.3	0.760
SOFA score**	12.0 ± 2.1	12 ± 2.3	0.760
Kreatinin (µmol/L)**	83.95 ± 80.12	161.47 ± 139.38	0.0086
Billirubin (µmol/L))**	17.52 ± 6.68	14.57 ± 4.55	0.1293
Platelets (×10^3/µL))**	248.90 ± 106.94	278.74 ± 240.06	0.5156
PaO_2/ FiO_2 (mmHg)**	281.15 ± 77.21	270.84 ± 77.35	0.8179
SpO_2/ FiO_2**	2.97 ± 0.50	2.92 ± 0.45	0.9136
Richmond Agitation and Sedation Scale**	–2.48 ± 1.75	–2.74 ± 1.56	0.7406
outcome			
Rehabilitation days (n)	10.75 ± 6.69	9.95 ± 4.97	0.8217
Total length of mechanical ventilation (days)	21.0 ± 9.78	24.4 ± 10.88	0.915
Length of mechanical ventilation since randomization (days)	5.4 ± 6.17	8.7 ± 8.00	0.860
Intubation to randomization (days)	15.3 ± 6.82	15.7 ± 8.41	0.008
ICU admission to beginning physiotherapy (days)	3.0 ± 3.56	1.0 ± 4.92	0.288
ICU admission to randomization (days)	14.0 ± 9.71	9.0 ± 6.96	0.170
Randomization to discharge from ICU (days)	11.0 ± 7.91	11.0 ± 12.19	0.616
Randomization to end of physiotherapy (days)	18 ± 12.94	28 ± 37.91	0.103
Absence of physiotherapy (days)	3 ± 2.78	0.5 ± 1.55	0.050
Barthel Index for Activities of Daily Living	35 ± 19.1	33 ± 24.04	0.610
ICU length of stay (days)	25 ± 37.93	28 ± 11.00	0.832
ICU mortality (n (%))	0 (0)	3 (8)	0.234

Nominal values are stated as absolute numbers and relative frequencies (in %), numeric values with the mean ± standard deviation (SD). p-values correspond to the tests of significant differences between research group a control group.
SOFA—sequential organ failure assessment; m-group—MOTOmed group; c-group—control group; ICU—intensive care unit; PaO_2—partial pressure of oxygen; SpO_2—peripheral oxygen saturation.
** The parameters were calculated from the worst values during the first 24 hours after admission; ** The parameters were calculated or noted at the day of the weaning initiation.*

muscle strength was observed in handgrip values: in the LUE in the m-group (p = 0.004) and both upper extremities (LUE and RUE) in the c-group (p = 0.011 and 0.017, respectively), see Table 4. The m-group patients reached the same muscle

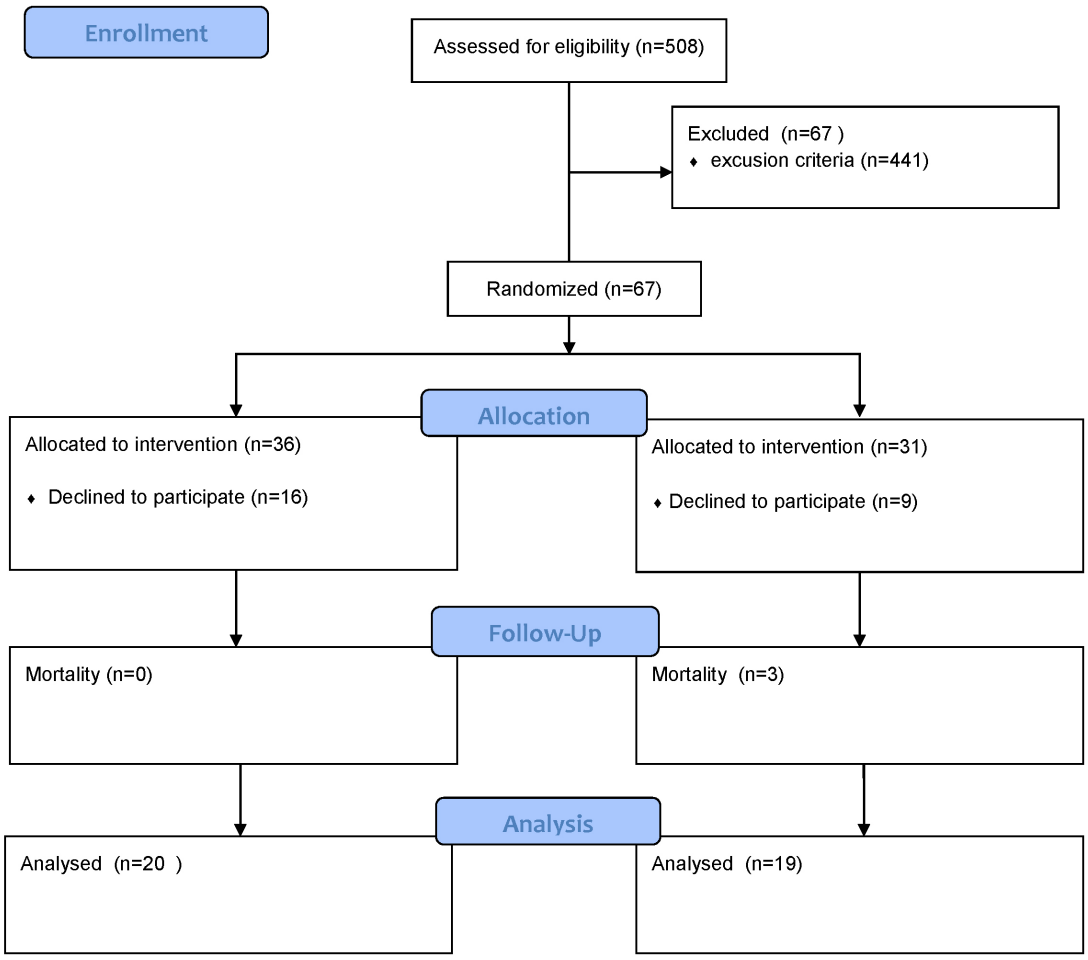

FIGURE 1. Consort flow diagram. CONSORT—Consolidated standards of reporting trials.

strength level in a non-significantly shorter time (8.70 ± 6.44 *vs.* 6.8 ± 4.3 days, $p = 0.534$). The result was achieved even when the interval of rehabilitation absence was significantly longer in the m-group (3 ± 2.78 *vs.* 0.5 ± 1.55 days, $p = 0.050$). The average duration of physiotherapy lasted 18 ± 12.94 days in the m-group compared to 28 ± 37.91 days in the c-group ($p = 0.103$).

We found no adverse alteration in physiological respiratory and cardiovascular parameters (respiratory rate, pulse oximetry, heart rate, mean arterial blood pressure, frequency of heart arrhythmias) in all patients from m-group, leading to procedure interruption.

The m-group patients had non-significantly higher scores on the Barthel test than the c-group (35 ± 19.1 *vs.* 33 ± 24.04, $p = 0.610$). The ICU length of stay was non-significantly shorter in the m-group than in the c-group (25 ± 38.9 days and 28 ± 11.0 days, respectively, $p = 0.813$). No death was observed in the m-group, while the ICU mortality rate was 8 % ($p = 0.234$) in c-group.

4. Discussion

Our study's results demonstrated that adding the MOTOmed device has not a statistically significant beneficial influence on the overall length of mechanical ventilation and length of mechanical ventilation since randomization. We also observed a non-significant difference in the recovery of muscle strength. No vital functions adverse events were observed in m-group. However, although a statistical significance was not achieved, a trend to better results could be observed in all followed primary and secondary outcomes, rendering using the MOTOmed device in mechanically ventilated critically ill patients as promising.

4.1 Mechanical ventilation and in-bed cycling

Our study belongs to a few interventional studies reporting the influence of in-bed leg cycling on the length of mechanical ventilation in critically ill patients. The most similar trial was performed by Yu *et al.* [20], enrolling the patients almost simultaneously. They found a statistically significant difference in ICU length of stay, the average length of mechanical ventilation, and the Barthel index favored the intervention group [20]. Our study showed a beneficial effect of in-bed leg cycling exercise in the same parameters. Compared the methodology of the Yu *et al.* [20] study, the reasons for our non-significant results were most probably as follows: (1) smaller number of patients enrolled, as the main factor, (2) our patients were almost all intubated before admission to ICU, which might bias the results due to the unknown possible adverse effect of previous treatment strategy, and (3) the length of mechanical ventilation in Yu *et al.* [20] study

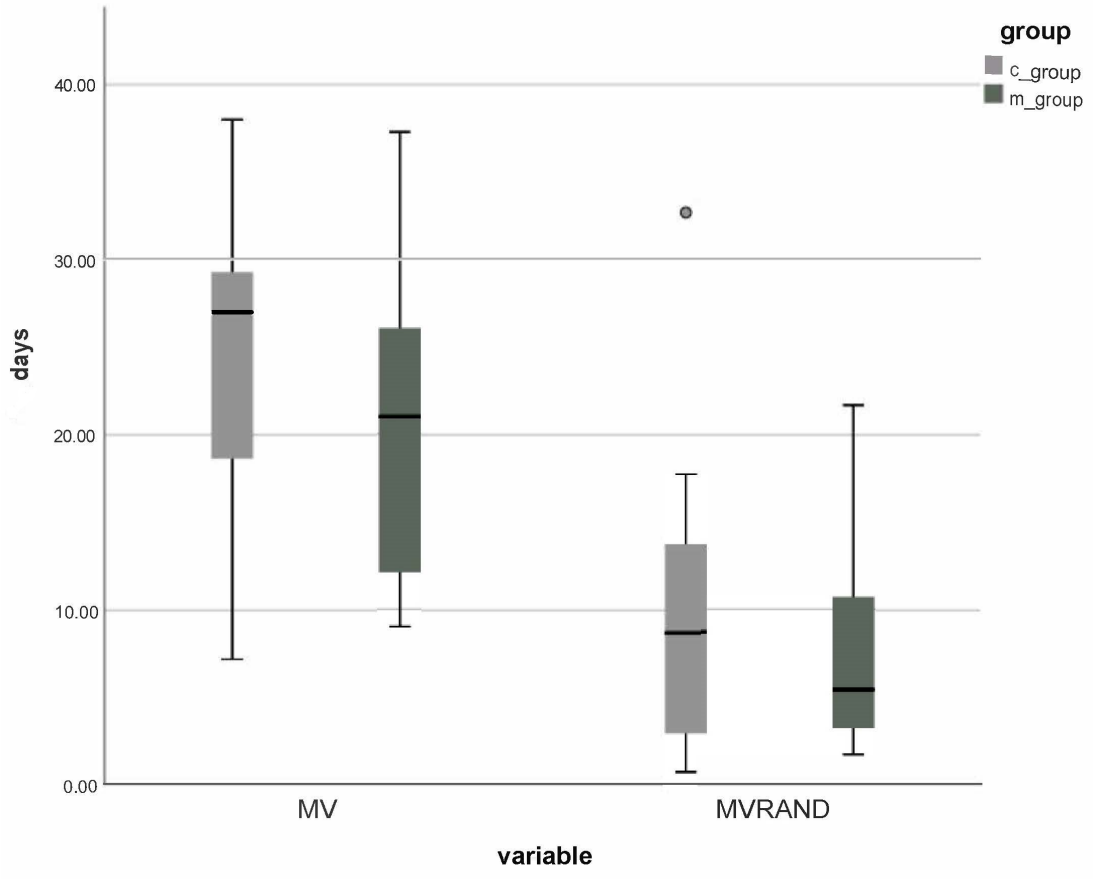

FIGURE 2. Comparison of total length of mechanical ventilation in m-group and c-group and of length of mechanical ventilation from randomization in m-group and c-group. m-group—MOTOmed group; c-group—control group; MV—mechanical ventilation; MVRAND—mechanical ventilation from randomization.

TABLE 4. Comparison of dynamometry results in m-group and c-group.

Dynamometry (kilogram-force; kgf)	m-group	c-group	*p*-value
Knee joint extension			
LLE 1	2.3 ± 2.89	2.2 ± 1.85	0.86
LLE 2	3.4 ± 3.46	3.5 ± 3.22	0.703
p-value	0.015	0.011	
RLE 1	1.8 ± 2.96	1.8 ± 2.12	0.978
RLE 2	3.3 ± 3.29	4.0 ± 3.36	0.855
p-value	0.004	0.005	
Hand grip			
LUE 1	1.7 ± 1.33	2.2 ± 1.90	0.523
LUE 2	3.3 ± 1.62	3.0 ± 2.27	0.855
p-value	0.005	0.011	
RUE 1	1.6 ± 7.37	2.3 ± 1.45	0.342
RUE 2	2.8 ± 2.25	2.9 ± 1.96	0.563
p-value	0.0576	0.017	

The dynamometry measurement was performed at the time of randomization (1) and at the end of rehabilitation; (2) p-values in the rows present significance of muscle power improvement, while p-value in the column describes comparison between study groups; numeric values with the mean ± standard deviation; p-values correspond to the tests of significant differences between m- group and c-group.
LLE—left low extremity; RLE—right low extremity; LUE—left upper extremity; RUE—right upper extremity.

was almost twice shorter than in our study (8 to 10 days *vs*. 21 to 24 days, respectively) implying that we enrolled more ill patients possibly influencing the results. Machado *et al*. [21] evaluated MOTOmed-based passive cycling in a randomized fashion in mechanically ventilated patients. In consent with our results, they found improvement in muscle strength in both study groups, with a more pronounced increase in the intervention group. They also analyzed data from a small number of patients (n = 36) and did not find a significant mechanical ventilation length difference. They even observed that the length of mechanical ventilation was three days longer in the intervention group, while our results showed 3.4 days short interval.

Schweickert *et al*. [15] pursued the efficacy of combining daily interruption of sedation with physical and occupational therapy on functional outcomes of mechanically ventilated intensive care patients (n = 104). Among other results, they found significantly more ventilator-free days on the 28th day of hospital stay in a study group with daily interruption and physical and occupational activity (2.5 days difference). They also found a significant reduction in the overall length of mechanical ventilation. Compared to our results, the length of mechanical ventilation in the study was almost five times shorter.The possible explanation of why the authors found a significant difference in mechanical ventilation length might include the daily interruption of sedation or that the study included less severely ill patients with better rehabilitation ability.

4.2 Cycling and non-mechanical ventilation outcome

Pires-Neto *et al*. [10] evaluated physiological changes and safety of an earlier cycling intervention (<72 hours of mechanical ventilation) in critically ill patients. They found that early passive cycling exercise in sedated, critically ill, mechanically ventilated patients was not associated with significant alterations in hemodynamic, respiratory, or metabolic variables [10]. Our study also did not observe any adverse changes in physiological variables leading to in-bed cycling premature interruption.

In consent with other studies [21], we demonstrated a significant favorable influence of early physiotherapy on muscle strength improvement. The isometric handgrip, elbow joint flexion, and knee joint extension methods using portable dynamometers were used to evaluate muscle strength. It has been demonstrated that dynamometry can provide reliable measurements in critically ill patients. However, it should be considered that moderate changes in strength may be required to overcome measurement error during the acute recovery period [22].

In actual clinical practice, various respiratory physiotherapy elements are used to activate weakened respiratory muscles and help with airway hygiene, thereby supporting ventilation and contributing to the patient's early disconnection from mechanical ventilation. The long-term rehabilitation plan included trunk stabilization exercises; passive, active, and resistance exercises with a thera-band; cycling exercises; sitting and standing exercises; walking between parallel bars; and walking upstairs, all five times a week for 30–60 minutes. After rehabilitation, significant improvements were noted in increased muscular strength in the upper and lower extremities, improved locomotion, and walking up and down the stairs (and time to disconnect from mechanical ventilation) [23]. In a prospective, randomized, controlled study, Chih-Cheng *et al*. [24] investigated the effects of 6 weeks of respiratory exercise and upper and lower limb exercise in patients with long-term mechanical ventilation. The program was developed as a 5-week workout, focusing on respiratory muscle exercises, limb exercises, functional training, and walking. In the rehabilitated group, functional status and muscle strength improved significantly compared with the control group, in which an apparent decrease in both values was observed. A shorter time to disconnecting from mechanical ventilation was recorded in the intervention group [24]. Our data show that daily addition of in-bed cycling physiotherapy to standard physiotherapy increases muscle strength to a similar degree in both groups but in a shorter time than routine rehabilitation.

4.3 Study limitations

Our study's limitations included the small number of subjects, which decreases the results' generalizability and limits the chance to prove statistical significance. However, the addition of in-bed cycling exercise to standard physiotherapy showed an unequivocal trend to benefit in all followed end-points (length of mechanical ventilation, muscle strength, Barthel index for activities of daily living, ICU length of stay) without significant physiologic adverse effects. The loss of subjects to follow-up also belongs to study limitations, further decreasing sample size and potentially introducing bias.

5. Conclusion

We observed no significant reduction in the length of mechanical ventilation between groups. However, the trend to shorten the length of mechanical ventilation and the time to improve muscle strength, without concurrent adverse physiological effects, might indicate a possible beneficial effect of the combination of in-bed cycling exercise and the standard physiotherapy in m-group mechanically ventilated critically ill patients. However, a large multicenter randomized trial is needed to confirm the effectiveness of in-bed leg cycling in critical care.

AUTHOR CONTRIBUTIONS

JM designed the research study and wrote the manuscript. CI performed the research and collected data. FI performed the research, KL performed the research, KM performed the research, NI performed the research and collected data, KZ collected data and processed data, ZR designed the research and co-wrote the manuscript, all authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethics committee approved this prospective, randomized, controlled, open-label clinical trial of the university hospital of Ostrava (Ref: 404/2017), registered at clinicaltrial.gov (ID: NCT03581760). The informed consent was signed by two study-independent physicians in unconscious patients and obtained directly from the patients conscious enough to approve the study participation.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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