EFFECT OF PROTOCOL-BASED EARLY MOBILIZATION ON MUSCLE STRENGTH AND ENDURANCE IN PATIENTS ON MECHANICAL VENTILATION

Vladislav Bonev
National Sports Academy, "Vassil Levski", Sofia, Bulgaria

ORCID
Vladislav Bonev
https://orcid.org/0009-0002-0807-6045
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ABSTRACT
Introduction: Patients with critical illness can lose more than 15% of muscle mass in one week, and this can have long-term detrimental effects on activities of daily living and quality of life. Early mobilization (EM) therapy has emerged as a crucial aspect of intensive care unit (ICU) management, aiming to counteract the detrimental effects of prolonged immobility in critically ill patients.
Aim: To study the effects of a protocol-based EM versus standard EM on muscle strength and endurance in mechanically ventilated (MV) patients.
Methodology: 70 ICU trauma patients, on prolonged MV, were separated randomly into two groups: experimental (EG), where we used a protocol-based EM, and a control group (CG), where we used standard clinic EM. The Physical Function in the ICU score (PFITs) was used twice to assess muscle strength and endurance when patients could first engage actively in physiotherapy and again at ICU discharge.
Results: Statistically significant intergroup difference is observed in favor of the EG in terms of the "sit-to-stand"(p = .000) and "cadance" (p = .009) components as well as the total score of the PFITs (p = .005), compared to the CG.
Conclusion: Protocol-based EM resulted in better muscle strength and endurance at ICU discharge in the experimental group compared to the standard EM in the control group.

Keywords: *immobility, muscle strength, early mobilization*

INTRODUCTION

While advancements in medical technology have significantly improved intensive care unit (ICU) patient survival rates, studies have highlighted that ICU treatments, particularly mechanical ventilation, often result in reductions in muscle mass and function (Balke et al., 2022). Patients with critical illness can lose more than 15% of muscle mass in one week, and this can have long-term detrimental effects (Fazzini et al., 2023)

One of the most debilitating consequences of critical illness and prolonged ICU stay is Intensive Care Unit-Acquired Weakness (ICU-AW). It is characterized by symmetrical and predominantly proximal limb weakness with typical sparing of facial muscles and overall reduction in osteo-tendon reflexes in patients with critical illness and has no underlying cause other than the critical illness itself. Respiratory muscles can also be affected (Hermans & Van den Berghe, 2015; Fazzini et al., 2023).

ICU-AW is a medium- and long-term complication in critically ill patients that impacts quality of life by increasing morbidity and healthcare costs. About 20 million people worldwide require ICU admissions each year. Among this group, the incidence of ICU-AW is estimated to be around 25–30%, meaning 3–6 million patients are affected annually. The rate is even higher in surgical ICUs, with some studies reporting rates between 50% and 70% (Wang et al., 2020).

Several risk factors have been identified for developing ICU-AW, including mechanical ventilation (MV) (Vanhorebeek et al., 2020; Lu et al., 2024; Sinha et al., 2024), immobilization (Parry& Puthucheary, 2015; Hermans, Van den Berghe, 2015; Wang et al., 2020; Akan, 2021), poor glycemic control (Bercker et al., 2005), sepsis (Evans et al., 2021), higher age, and female sex (Geense et al., 2021; Meyer-Friessem et al., 2021; Hajeb et al., 2021)

Early mobilization (EM) has emerged as a crucial aspect of ICU management, aiming to counteract the detrimental effects of prolonged immobility in critically ill patients (Singam, 2024). EM has been shown to improve functional outcomes, muscle strength, shorten ICU and hospital lengths of stay, and enhance survivors' overall quality of life (Tipping et al., 2017; De Queiroz et al., 2018; Phelan et al., 2018; Clarissa et al., 2019; Zhang et al., 2019; Monsees et al., 2023)

Aim and Objective

The present study aims to evaluate the effects of a protocol-based EM on muscle strength and endurance in mechanically ventilated patients.

METHODOLOGY

Seventy ICU polytrauma patients, each on mechanical ventilation for at least 72 hours, were randomly assigned to two groups. The experimental group, with a mean age of 43.14±18.9 years, received protocol-based early mobilization (EM), while the control group, with a mean age of 47.94±19.3 years, received standard clinical EM. The Physical Function in the ICU test score was used to evaluate muscle strength and endurance twice: once when the patient was first awake and cooperative, and again at ICU discharge. Characteristics of the patient cohort are presented in Table 1.

Table 1. *Characteristics of the patients in the two groups*

Group	EG	CG	*p*	Total
Sex				
Men	28 (80%)	23 (65.7%)		51 (72.86%)
Women	7 (44%)	12 (34.3%)		19 (27.14%)
Total:	35	35		
Mean age (years)	43.1418.9	47.94±19.3	.397	45.54±19.1
<40 years	15(42.86%)	14 (40%)		29 (41.43%)
41-60 years	12 (34.28%)	13 (37.14%)		25 (35.71%)
>61 years	8 (22.85%)	8 (22.85%)		16 (22.86%)

Notes. Experimental group (EG), patients undergoing early mobilization according to the Surgical Intensive care unit Optimal mobilization score; Control group (CG), patients undergoing ward-standard early mobilization; p, degree of significant differences between the two groups, determined by Mann-Whitney U-criterion for nonparametric and Student's t-criterion for parametric variables.

In the EG, we applied the Surgical Intensive Care Unit optimal mobilization score (SOMS) twice daily (Table 2). This score ranges from '0' to '4', with '0' indicating "No activity" and '4' representing 'Ambulation.' The goal was to achieve the highest possible functional status and early verticalization while patients were still on mechanical ventilation (MV). A SOMS level 0 score applies to patients who cannot be mobilized due to several contraindications, such as inability to maintain adequate arterial blood pressure even with catecholamine support or meet target saturation; increased risk of death within the next 24 hours; or unstable spinal fractures that could affect the spinal cord. Level 1 activities include passive range of motion and sitting in bed. Level 2 involves moving the patient to a chair with a mechanical lift or sitting on the edge of the bed. It is crucial that patients are cooperative and able to voluntarily perform limb movements. Level 3 activities include verticalization, such as standing next to the bed. Level 4 involves walking around, with support if needed (Meyer et al., 2013).

Table 2. *Surgical Intensive care unit optimal mobilization score (Meyer et al., 2013)*

	SOMS Algorithm				
	No mobilization (0)	**PROM (1)**	**Sitting (2)**	**Standing (3)**	**Ambulation (4)**
Safety criteria for advancing mobilisation	1) Stable spine 2) No excessive predicted mortality in the next 24 hours 3) ICP <20 cm H_2O	1) Follows 1-step commands 2) Volitional movements 3) No SCI, open lumbar drains, open EVD, femoral vein access for CVVH	1) ≥3/5 bilateral quadriceps strength 2) Sits with no support 3) No WB restrictions	1) Stands twice with minimal assist 2) Steps-in-place with minimal assist	
	Attempt to maintain blood pressure and heart rate within a clinically appropriate range during mobilization; consider using vasopressors, adjusting fluid volume, administering vasodilators, and prescribing pain medication as indicated. If unsuccessful in achieving hemodynamic stabilization, do not advance.				

Notes. ICP - intracranial pressure; SCI - spinal cord injury; EVD - external ventricular drain; CVVH - continuous veno-venous hemofiltration; WB - weight-bearing.

For patients in the CG, we applied standard for the ward physiotherapy twice every day, which

included: inbed range of motion exercises for the limbs (for the upper limbs: shoulder joint flexion, extension, abduction and adduction, elbow joint flexion, extension, supination and pronation, wrist and fingers flexion and extension; for the lower limb: hip joint flexion, extension, abduction and adduction, knee extension, ankle planter and dorsal flexion, toes flexion and extension), 10 times for each movement and progressing from passive, to active-assisted and active, breathing exercises (such as chest extensions, inhalation with raising of the upper limbs and exhalation combined with lowering them, manual chest percussion), hip bridges, rolling in bed and maintaining an upper body position of 30-45 degrees. Verticalization to sitting on the edge of the bed and standing out of bed, as well as activities in these positions, were delayed until patients no longer needed MV.

Patients' inclusion criteria are: trauma patients aged 18 or older; on mechanical ventilation (MV) for at least 72 hours; independent in activities of daily living before admission; no missing limbs or parts of limbs; contact, compliant, and cooperative; and able to give informed consent to participate in the study. The exclusion criteria are: patients who required amputation of a limb or part of a limb during their ICU stay; patients who refused to participate in the study; patients with spinal cord injuries and irreversible neurological deficits; patients receiving palliative care; and patients with significant cognitive deficits.

The Physical Function in the Intensive Care Unit Test Score (PFIT-s) is a scale used to assess physical capabilities such as muscle strength and endurance in the ICU (Table 3) (Denehy et al., 2013). The test involves evaluating four components: shoulder strength, assessed by evaluating shoulder flexion according to the Oxford Scale for grading muscle strength; knee strength, assessed by evaluating knee extension using the Oxford Scale; sit-to-stand assistance, determining the number of people needed to help the patient stand; and cadence, which refers to the number of steps per minute.

Table 3. *Physical Function in the intensive care unit test-score (Denehy et al., 2013)*

PFIT Scoring	0	1	2	3	TOTAL	
Shoulder strength (grade)	0, 1 or 2	3	4	5		**TOTAL PFIT Score:**
Knee strength (grade)	0, 1 or 2	3	4	5		
Sit-to-stand Assistance	Unable	Assist x2	Assist x1	No assist		(0-12)
Cadence (steps/min)	Unable	>0-49	50≤80	80+		

Statistical analysis

All statistical analyses were performed using SPSS for Windows, Version 19.0. The level of significance was set at $p < .05$. All data subsets were assessed for the presence of a normal distribution (Shapiro-Wilk test $p > .05$) and for homogeneity with Levene's test for equality of variance before using parametric analysis. Differences between data at the PFIT-s and SOMS levels were assessed using repeated measures analysis of variance with post hoc multiple comparisons by t-test with Bonferroni corrections.

RESULTS

The changes in upper and lower limb muscle strength and muscular endurance reported with the Physical Function in ICU test score are shown in Table 4.

Table 4. *Mean values and changes in muscle strength and endurance assessed by PFIT-s in both groups over the course of the ICU stay.*

Component	Group	n_1	$M_1 \pm SD$	n_2	$M_2 \pm SD$
Shoulder Strength	CG	35	1.19±1.22	32	2.52±0.89***
	EG	35	1.76±1.35	34	2.76±0.65***
	p		.072		.119
Knee Strength	CG	35	1.81±1.25	32	2.72±0.73***
	EG	35	2.06±1.2	34	2.88±0.54***
	p		.419		.301
Sit-to-stand	CG	35	0.00±0.00	32	1.45±1.06***
	EG	35	0.00±0.00	34	1.76±0.98***
	p		1.0		**< .001**
Cadence	CG	35	0.00±0.00	32	0.25±0.44***
	EG	35	0.00±0.00	34	0.67±0.84***
	p		1.0		**.009**
PFIT-s общо	CG	35	3.46±2.16	32	6.22±2.32***
	EG	35	4.20±2.47	34	7.79±2.13***
	p		0.185		**.005**

*Notes. M_1 and M_2, mean values of the four tests; SD, standard deviation of the parameters; EG, experimental group; CG, control group; n_1 - number of patients at the first assessment; n_2 - number of patients at ICU discharge; *** p<.001, ** p<.005,*p<.05, significance level determined by Student t-test for dependent and Independent samples, Mann-Whitney, and Wilcoxon for dependent and independent samples.*

At ICU discharge, there is a statistically significant intragroup improvement in muscle strength and endurance in both patient groups ($p < .001$), and a statistically significant intergroup difference is found in the total score, favoring the EG ($p < .005$). Significant improvements were found in shoulder strength, knee strength, sit-to-stand ability, and cadence in both patient groups ($p < .001$). Regarding sit-to-stand and cadence, we report a significant intergroup difference ($p < .001$) in favor of the patients in the experimental group.

From the above, we can conclude that the EG patients were characterized by better strength and greater endurance at discharge from the ICU, compared to the CG, where a standard early mobilization approach was applied.

The distribution of patients by the maximally achieved SOMS level at ICU discharge is presented in Table 5.

Table 5. *Distribution of patients by maximum achieved SOMS level at ICU discharge*

SOMS level	Group	N
Level 1 (inbed)	EG (*n*=34)	1 (2.9%)
	CG (*n*=31)	1 (2.9%)
Level 2 (Sitting)	EG (*n*=34)	13 (37.1%)
	CG (*n*=31)	19 (54.3%)
Level 3 (Standing)	EG (*n*=34)	9 (25.7%)
	CG (*n*=31)	6 (17.1%)
Level 4 (Ambulation)	EG (*n*=34)	11 (31.4%)
	CG (*n*=31)	5 (14.3%)

Notes. EG - experimental group; CG - control group; N - number of patients; SOMS - Surgical ICU optimal mobility scale.

From Table 5, we found that 11 (31.4%) of the EG patients undergoing protocol-based EM achieved a SOMS level 4 (walking) in the ICU, whereas only 5 (14.3%) of the CG patients achieved a SOMS level 4 during their ICU stay. Consequently, twice as many patients in the EG were discharged from the ICU with the maximum SOMS level compared with those in the CG who received ward-standard EM.

The comparative analysis of the mean level of SOMS mobilization achieved in the EG and the CG is shown in Table 6.

Table 6. *Comparative analysis of the mean level of SOMS achieved in the EG and the CG*

Test	Group	n_1	$M_1 \pm SD$	n_2	$M_2 \pm SD$
Mean SOMS achieved	EG	35	1.00±0.00	34	2.88±0.91***
	CG	35	1.00±0.00	31	2.48±0.81***
	p		1.00		.069

*Notes. M_1 and M_2, mean values of the two tests; SD, standard deviation of the parameters; CG, control group; EG, experimental group; n_1 - number of patients at the first assessment; n_2 - number of patients at ICU discharge; *** p<.001,** p<.01, * p<.05- significant differences from postoperative values determined by Student t-test for dependent samples; P-statistical significance by independent samples, Mann Withney and Wilcoxon for dependent and independent samples.*

There was an increase in absolute mean SOMS values in both patient groups at discharge from the ICU. The improvement in values for the CG was on average 1.48 ± 0.81 points, and for the EG, it was on average 1.88 ± 0.91 points, compared to the baseline. There was no significant intergroup difference in the level of mobilization achieved at ICU discharge for patients in the two groups, but, in absolute terms, the EG had higher mean scores at ICU discharge.

DISCUSSION

In a study by Parry et al. (2015) with 66 patients (40 males and 26 females), the mean age was 58 ± 17 years. They required intensive care for an average of 8 days (range 5-15 days), with an average of 5 days on mechanical ventilation (range 3-10 days). The patients achieved a mean PFIT-s of 4.7±2.3 points at first contact after awakening from sedation. In our study, at first contact after awakening from sedation, patients in the control group (CG) had a mean PFIT-s of 3.46 ± 2.16 points, while the experimental group (EG) had a mean PFIT-s of 4.20 ± 2.47 points. Therefore, our patients show a lower baseline score compared to those in Parry et al. (2015). We believe this difference results from the later initiation of early mobility (EM) in our study, occurring at a mean of 19.71 ± 13.78 days (with the EG at 16.17 ± 10.16 days and the CG at 23.26 ± 16.03 days) from ICU admission and start of mechanical ventilation. Parry et al. (2015) did not specify the exact day EM was started after ICU admission, but their ICU stay averaged 8 days, with 5 days on MV. We believe that the delay in EM in our study is due to the more severe condition of our patients and the need for prolonged sedation. Notably, the mean age of our cohort was lower, at 45.54 ± 19.1 years (EG: 43.14 ± 18.9 years; CG: 47.94 ± 19.3 years), compared to 58 ± 17 years in Parry et al. (2015). Between the two assessments - upon awakening and at ICU discharge- patients in Parry et al. (2015) underwent standard ICU physiotherapy, including bed mobility, sitting on the bed's edge, standing, marching in place, and walking. At ICU discharge, they reported a PFIT-s score of 6.3 ± 2.2 points (mean difference = 1.59, 95% CI = 1.12, 2.06, $p < .005$). In our study, CG results were similar, at 6.22 ± 2015. 32, while the EG achieved a mean PFIT-s of 7.79 ± 2.13 points ($p = .005$). We attribute the higher PFIT-s score in the EG to our implementation of upper extremity resistance exercises- both manual and with free weights- and early verticalization efforts while patients were still on MV. This approach included lower extremity exercises against gravity, such as standing, sitting, marching in place, stair climbing, and walking with or without aids.

Higher PFIT-s scores at waking from sedation (OR = 1.59, $p = .004$) and younger age are significant factors in determining whether a patient will be discharged home or to a long-term rehabilitation center, as noted in studies by Denehy et al. (2013) and Nordon-Craft et al. (2014). Furthermore, according to Berney et al. (2012) and Denehy et al. (2013), PFIT-s can be used to guide exercise selection in ICU patients as well as to monitor their functional recovery.

In a study by Dos Reis et al. (2022) in the ICU of the Federal University of Santa Catarina's University Hospital with 122 patients, the mean age was 56 years (47-66 years), and the mean ICU length of stay was 7 days (5-11), with an average of 5 days (3-8) on mechanical ventilation (MV). Patients scored a mean PFIT-s of 8 (5-10) points at ICU discharge. In comparison, EG patients in our study had a mean PFIT-s of 7.79 ± 2.13 points at ICU discharge, which is close to the score reported by Dos Reis et al. (2022). It is important to note that Dos Reis et al. (2022) do not specify the exact type of early mobilization used in their study. We believe that our results are due to the protocol-based early mobilization we implemented, which aims to achieve the highest level of motor independence within the ICU while patients are still on MV.

CONCLUSION

The use of protocol-based progressive mobilization, with an emphasis on early verticalization, in the EG resulted in a more significant increase in muscle strength and endurance. Further research is needed to determine the optimal time to initiate early mobilization as well as the best safety criteria to progress in the intensity.

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Corresponding author:
Vladislav Bonev,
"Department of Physiotherapy and Rehabilitation",
National Sports Academy "Vassil Levski"
Sofia, Bulgaria
E-mail: v.bonev@nsa.bg

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