Journal of Associated Medical Sciences 2021; 54 (1): 58-66

JAMS
Journal of Associated Medical Sciences

Thai-Journal Citation Index Centre (TCI) & ASEAN Citation Index (ACI)

Journal of Associated Medical Sciences

Journal homepage: https://www.tci-thaijo.org/index.php/bulletinAMS/index



Impact of inspiratory muscle training and early mobilization program during the peri-weaning period on body composition in critically ill surgical patients: A pilot randomized controlled trial

Attalekha Thammata[1] Salinee Worraphan[1] Kaweesak Chittawatanarat[2] Kanokkarn Juntaping[2] Mujalin Prasannarong[1*]

[1]Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai Province, Thailand
[2]Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai Province, Thailand

ARTICLE INFO

Article history:
Received 11 October 2020
Accepted as revised 18 December 2020
Available online 18 December 2020

Keywords:
Body composition, early mobilization, mechanical ventilation, respiratory muscle training

ABSTRACT

Background: A long period of mechanical ventilation and bed rest cause alterations in body composition which are associated with higher mortality. In particular there is an association with loss in muscle mass. Inspiratory muscle training (IMT) and early mobilization (EM) have been used to increase muscle activity, which leads to improvement in muscle mass and strength. IMT and EM have been shown to prevent intensive care unit-acquired weakness in critically ill patients. However, it is still not known whether they have any effect on body composition in critically ill patients.

Objectives: To evaluate the effects of IMT and EM on body composition in critically ill surgical patients.

Materials and methods: Surgical patients at a single center in whom there had been failure at the first attempt of short weaning were randomized into two groups, a control group (n=12) and an experimental group (n=15). Usual care, IMT, and EM were provided in the experimental group, and only usual care was provided for the control group. Both groups were treated twice a day until 48 hours after extubation. The body composition was measured by bioelectrical impedance analysis before and after the treatment.

Results: After treatment, there were significant decreases from baseline in skeletal muscle mass (SMM), segmental lean of right arm (SLRA), segmental lean of left arm (SLLA), and segmental lean of trunk (SLTR) in the experimental group. In the control group, SLRA and SLTR showed significant decreases from baseline. However, there were no significant changes in segmental lean of right leg (SLRL), and segmental lean of left leg (SLLL), fat mass, and percent of body fat (PBF) in either group from baseline to after treatment. The multivariate regression analysis with adjustment for confounding factors showed no significant differences between the groups as regards body composition.

Conclusion: Inspiratory muscle training and early mobilization in conjunction with usual care did not improve body composition when compared to solely usual care in critically ill surgical patients.

* **Corresponding author.**
Author's Address: *Department of Physical Therapy, Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai Province, Thailand*
** **E-mail address:** mujalinp@gmail.com
doi: 10.14456/jams.2021.8
E-ISSN: 2539-6056

Introduction

In the intensive care unit (ICU), alterations in body composition including respiratory and limb muscle loss[1, 2] and increased adiposity[3] are substantial due to prolonged bed rest and mechanical ventilation (MV). In addition, prolonged MV also subsequently leads to prolonged bed rest which causes alterations in body composition.[1] Alteration of body composition in mechanically ventilated critically ill patients, in particular muscle mass loss which is the critical contributor of ICU-acquired weakness (ICUAW) is associated with longer bed rest[1] and higher mortality.[4, 5] Muscle loss in critically ill patients is the result of the occurrence of the disease itself and also a rapid increased in muscle protein breakdown.[6-8] During intensive care, a reduction in muscle mass is noticeable within 3 days and progressively declines.[9] Prolonged bed rest in critically ill patients decreases limb muscle mass by 13-21% within a week of admission.[10] Furthermore, prolonged bed rest causes a decrease in the cross-sectional area of diaphragm fibers[11] and in the thickness of diaphragm muscle[12], which leads to long duration of MV.[1, 2]

Inspiratory muscle training (IMT) and early mobilization program (EM) have been provided for critically ill patients. IMT in mechanically ventilated patients increases inspiratory muscle activity[13] which leads to improved inspiratory muscle strength.[14-16] In a similar way, EM increases skeletal muscle activity[17, 18] which results in prevention or reduction of the occurrence of ICUAW[19] and improvement in muscle strength after discharge from ICU.[20] In elderly chronic obstructive pulmonary disease (COPD) patients, EM has been shown to improve thigh lean mass and strength.[21] It has also been shown to restore muscle mass after bed rest in healthy elderly[22] and after immobilization in healthy adults.[23]

It is widely accepted that physical therapy including IMT or EM prevents ICUAW and improves physical function in critically ill patients.[19, 24-26] Importantly, these treatments are safe and feasible in critically ill patients.[14, 27] The early mobilization program involves substantial treatment which is recommended for assisting improvement of functional outcomes and respiratory conditions resulting from prolonged bed rest.[28, 29] Inspiratory muscle training has been shown to reduce MV duration[14-16] which may lead to a shorter periods of bed rest. Taken together, the combined treatments of IMT and EM may further promote MV weaning, prevent prolonged bed rest, and subsequently prevent muscle loss in critically ill patients. To date, there have been no studies which evaluate the combined effects of IMT and EM on the body composition in critically ill surgical patients.

Objective

To study the changes in body composition in critically ill surgical patients who have received IMT with EM and usual care.

Materials and methods

Study design

A pilot randomized controlled trial was conducted at the surgical ICU and critical care unit (CCU) of Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand. The Research Ethics Committee, Faculty of Medicine, Chiang Mai University (SUR-2561-05554) approved this study. A physical therapist (PT), specializing in critical care, visited daily to identify and recruit eligible patients, and obtain informed consent from the patients. Patients were allocated to either control group or experimental group (1:1 ratio) using thick opaque sealed envelopes in random block sizes of six within each stratum. A system involving a list of computer-generated random numbers, and preparation and sequential numbering of the envelopes was used by a researcher who was not involved in the data collection or treatment. Usual care alone was provided for the control group. Usual care with IMT and EM were provided for the experimental group. Both groups were treated twice a day until 48 hours after extubation by the same PT who recruited eligible patients. The physicians who were blinded to the allocation made a decision regarding extubation according to the standardized weaning protocol.[30] The body composition was measured before and after the treatment periods by a single assessor blinded to the grouping of the patients. This study was presented in accordance with the CONSORT guidelines.

Participants

Adults surgical patients (aged≥18 years) who were on an endotracheal tube (ETT) and whom there had been failure at the first attempt of short weaning from MV (Weaning according to a New Definition (WIND) classification). Short weaning is defined as termination of weaning after the first attempt within 24 hours.[31] Additional criteria were patients had to be alert with good cooperation (-1 to +1 of the Richmond Agitation–Sedation Scale (RASS)), did not have active sepsis or hyperthermia, were in a stable respiratory condition (FiO_2<0.60, oxygen saturation>92%, no use of respiratory-depressant drugs), were hemodynamically stable (no hypotension, systolic blood pressure (SBP) 90-170 mmHg, mean arterial pressure (MAP) not varying by>10 mmHg, had no need for vasopressors or were using very low levels (dopamine<5 μg/kg/min or levophed 0.01-0.1 mg/kg/min), had no significant chronic congestive heart failure, and no life-threatening cardiac arrhythmia. In addition, patients were eligible for inclusion when their causes for respiratory failure were resolved, when the underlying disease was stable, and when the patients remained psychologically steady.

Patients with neurological diseases and those in the end stage of lung cancer were excluded. Patients with the following conditions were also excluded: musculoskeletal pathology impacting chest wall movement, severe orthopedic problems (unstable spine, severe scoliosis, ribs fracture, hip fracture); hypothyroidism; malnutrition; ascites; obesity (BMI≥40 kg/m^2); pregnancy; significant pain or distress impacting breathing capacity; and palliation. Additionally, exclusion criteria included an inability to walk without assistance (except using a cane or walker) before admission to ICU, cardiopulmonary resuscitation (CPR) at admission, and readmission to the ICU within the current hospitalization.

Usual care

Usual care included a combination of secretion clearing techniques, breathing exercises, chest mobilization, bed mobility training, upper and lower limb exercises without external weight in Fowler's position (5-10 repetitions),

ankle pump exercises, and sitting balance training. Usual care was provided twice a day until 48 hours after extubation. The vital signs including heart rate (HR), blood pressure (BP), respiratory rate (RR), oxygen saturation, and rate perceived exertion (RPE) were recorded before and after training.

Inspiratory muscle training

An electric inspiratory training device (POWERbreathe KH2, POWERbreathe International Ltd, UK) was used in the training procedure. The IMT was carried out with patients in Fowler's position. The intensity of training was set at 40-60% of the daily maximal inspiratory pressure (MIP). The measurement of MIP was repeated three times (differences between values<10%), and the most negative value was recorded.[32]

Patients were encouraged to inhale quickly and forcefully against the device with full exhalation for every breath. The program consisted of 30 breaths per session which was divided into 10 breaths per set with a one-minute rest between each set, and each session was repeated twice a day. During each resting period, MV was permitted. The termination of training included presentation of any of the following: RR>35 breaths per min, oxygen saturation<90%, HR>140 beats per min or >20% at the start, SBP>180 mmHg or <80 mmHg, paradoxical breathing, agitation, hemoptysis, depression, or sweating.[33] The vital signs were recorded before and after training.

Table 1 Early mobilization program.

Levels of EM	Testing	Training
Level I	• Alert	• AAROM exercise or AROM exercise of UE&LE 5-10 reps, twice a day
	• Follow simple command for upright position	• Sitting balance training
Level II	• Elbow flexors and extensors grade >3/5 (MRC scale)	• UE: resistance exercise (weight ≤500 g) 5-10 reps, twice a day
	• At least fair grade of sitting balance testing for sitting over the edge of the bed	• LE: active exercise 5-10 reps, twice a day
		• Gross motor function training (supine to side lying, side lying to sitting)
Level III	• At least antigravity of bridging on bed	• Standing balance training
	• Knee extensors grade >3/5	• Less than 40% of HRR or Borg scale <3 (10-point scale) of aerobic exercise while standing 10-15 minutes, twice a day
	• At least fair grade of standing balance testing for actively sit to stand beside the bed	

Note: *AAROM: active-assisted range of motion, AROM: active range of motion, EM: early mobilization, UE: upper extremity, LE: lower extremity, reps: repetitions, MRC: Medical Research Council, g: grams, HRR: heart rate reserve.*

Early mobilization program

The EM program was modified from Morris et al. [34] and divided into three levels (Table 1). Before the training, manual muscle testing (MMT) using the Medical Research Council (MRC) scale[35] and balance assessment were performed. Balance was assessed when the MRC scale was >3/5. Each patient received a level of EM according to their grade of MMT and balance. Patients were progressed to the next level when their grade of MMT and balance improved. The criteria used to determine termination of training included the following conditions: hypoxia with oxygen saturation<88%, hypotension (MAP<65 mmHg), new vasopressor administration, new documented myocardial infarction, requirement of administration of a new antiarrhythmic agent, needing a change of MV mode into assist control mode or an increase in the positive end-expiratory pressure (PEEP) (no absolute limit regarding PEEP and FiO_2 to terminate the training). Re-assessment was performed the next day if the EM was terminated. The training was initiated again when patients were in a stable clinical.[34] During training, other events such as falling or ETT dislocation were also documented. The vital signs were recorded before and after training.

Body composition

The bioelectrical impedance analysis (BIA) (InBody S10®, InBody Co., Ltd, Seoul, South Korea) was used for measurement the body composition. In critically ill patients, the BIA has been successfully used for body composition assessment and monitoring.[36, 37] Before each measurement, manual inputs of patient information including age, height, weight, and sex were recorded.[38] The arms were separated naturally from the trunk at approximately 15 degrees, and the legs were separated approximately shoulder width apart. Touch-type electrodes were placed in contact with the patient's thumbs and middle fingers. The foot electrodes were placed between the patient's ankle bones and heels. The procedure was performed for 10-15 minutes in a supine position.

Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) Version 17 (IBM Inc., Armonk, NY, USA). The Shapiro-Wilk test was used to analyze the normality of distribution. An unpaired t-test or the Mann-Whitney U test was used to examine differences between groups in the case of continuous variables. The chi-square test was used for analysis of categorical variables. Multivariate regression analysis was used for analysis of possible confounding factors of the outcomes. Significance level was set at $p<0.05$.

Results

Characteristics of the patients

The period of recruitment and follow-up was from December 2018 to July 2019. Thirty patients were enrolled onto study. Three were excluded after the initial enrolment and the remainder were randomized into the control (n=12) and the experimental group (n=15) (Figure 1). There was no loss to follow-up. Body composition was measured before and after treatment. The three patients excluded after enrolment was in the control group were not measured for the following reasons: had a metal implant (n=1) and had skin lesions at site where the electrodes were placed (n=2). The MV duration in the control and the experimental groups were 5.00±2.70 and 3.93±1.49 days, respectively. Upon admission, primary diagnoses of patients in both groups were gastrointestinal surgery (59.26%), thoracic surgery (25.93%), urinary tract surgery (3.70%), and vascular surgery (11.11%). The mean values and standard deviations of pain visual analog scale (VAS) in the control and experimental groups were 0.00±1.56 and -0.40±1.45, respectively. There was no significant difference between the groups. The percentages of patients in the control and experimental groups that completed total sessions of the treatment were 91.42% and 89.89%, respectively. Incompletion of the treatment sessions included unstable clinical conditions and other events not related to the treatment, such as bedside bronchial suctioning. The minimum and maximum treatment days of the EM program were three and five. The percentages of patients at each training were as follows: 1) Day 1: 33.33% of level II and 66.67% of level III; 2) Day 2: 20% of level II and 80% of level III; 3) Day 3: 20% of level II and 80% of level III; 4) Day 4: 6.67% of level II and III; and 5) Day 5: 6.67% of level III. None of the patients started EM at level I. The mean intensity of IMT (cmH_2O) on each day of treatment was as follows: 16.57 (Day 1); 19.09 (Day 2); 18.67 (Day 3); 21.76 (Day 4); and 21.31 (Day 5). There were no adverse effects from the treatments in this study. There were no significant differences in baseline characteristics between the groups of the patients apart from the BMI which was significantly different (p=0.04) (Table 2).

The MIP at baseline, after treatment, and mean changes are presented in Table 2. After treatment, the mean changes in MIP showed an increasing trend in the experimental group. Although the MIP in the experimental group was higher than the control group, there was significant difference between groups at baseline. Therefore, a multivariate regression analysis adjusted with potentially confounding variables was performed, including Model 1 (MIP at baseline) and Model 2 (MIP at baseline, age, and BMI). Both models of the multivariate regression analysis showed that the treatments significantly increased MIP by 12.83 cmH_2O p=0.01) and 13.12 cmH_2O (p=0.02) in the experimental group when compared to the control group.

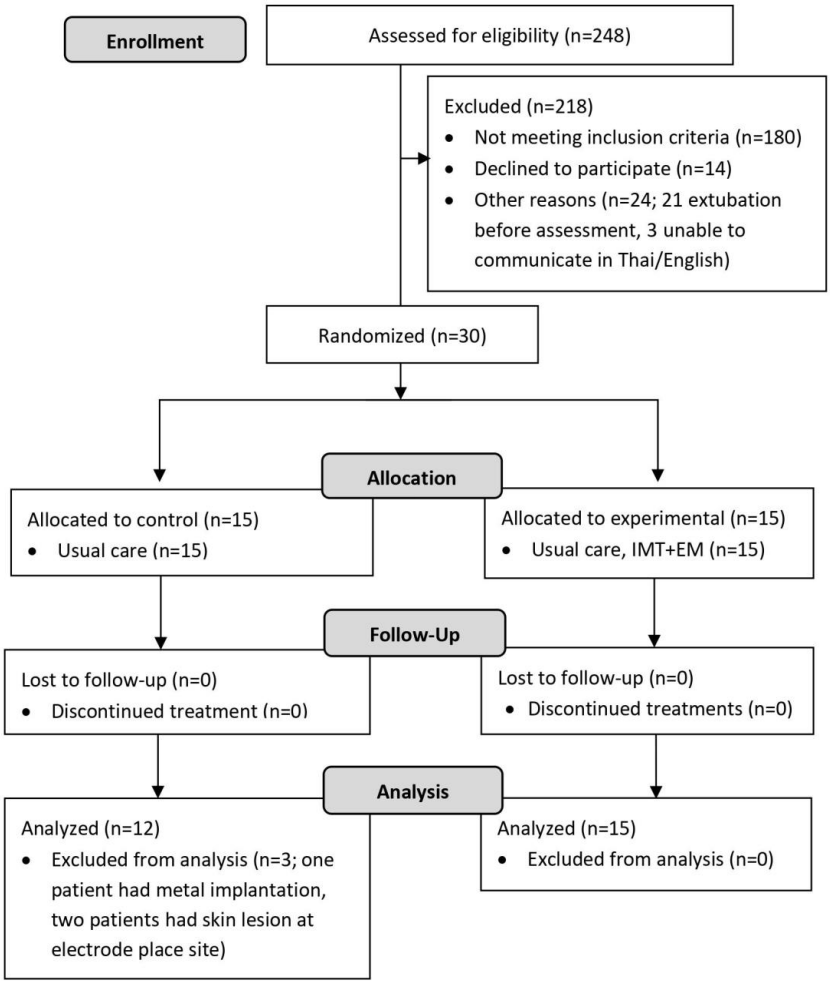


Figure 1. *Flow diagram of the procedure (CONSORT). IMT=inspiratory muscle training; EM=early mobilization.*

Table 2 Characteristics of the patients.

Parameters	Control (n=12)	Experimental (n=15)	*p* value
Sex, male, n (%)	5 (41.67)	7 (46.67)	0.55†
Age, years‡	65.75±12.90	61.27±5.95	0.28
Height, m‡	1.56±7.14	1.59±9.52	0.52
Weight, kg‡	50.58±12.57	57.80±13.40	0.22
BMI, kg/m²‡	19.90±3.72	23.29±5.17	0.04*
Primary diagnosis category at admission, n (%)			
Gastrointestinal surgery	9 (75.00)	7 (46.67)	0.25
Thoracic surgery	3 (25.00)	4 (26.66)	
Urinary tract surgery	0 (0.00)	1 (6.67)	
Vascular surgery	0 (0.00)	3 (20.00)	
MV mode, n (%)			
PCV	0 (0.00)	1 (6.67)	0.36†
PSV	12 (100.00)	14 (93.33)	
MV duration, days‡	5.00±2.70	3.93±1.49	0.52
Treatment day, days‡	4.25±2.42	3.20±0.56	0.52
MIP, cmH_2O			
Baseline‡	23.00±10.24	34.23±13.78	0.03ϕ
After treatment‡	19.54±8.80#	39.18±15.83	<0.01ϕ
Mean changes‡	-3.47±4.98	4.95±15.29	0.06
Regression models of MIP	**Coefficient (95% CI)**		***P***
Model 1: MIP at baseline	12.83 (3.03 to 22.63)		0.01Ж
Model 2: MIP at baseline, age, BMI	13.12 (2.44 to 23.80)		0.02Ж

Note: *‡Data are presented as the mean±SD. m=meters, kg=kilograms, BMI=body mass index, MV=mechanical ventilation, PSV=pressure-support ventilation, PCV=pressure-control ventilation, MIP=maximal inspiratory pressure. †P by chi-square test of control versus experimental groups, *P<0.05 by Mann-Whitney U test of control versus experimental groups, ϕP<0.05 by T-test of control versus experimental groups, #P<0.05 by T-test of baseline versus after treatment in the control group, ЖP<0.05 by multivariate regression analysis.*

Effects of IMT and EM on the body composition

The changes in body composition are presented in Table 3. After treatment, no significant changes of the segmental lean of right leg (SLRL), segmental lean of left leg (SLLL), fat mass, and percent of body fat (PBF) were found in either group. However, decreases in skeletal muscle mass (SMM), segmental lean of right arm (SLRA), segmental lean of left arm (SLLA), and segmental lean of trunk (SLTR) were found in the experimental group after treatment. In the control group, decreases in SLRA and SLTR were found. Baseline values of SMM, SLRA, SLLA, and SLTR in the experimental group were significantly higher than the control group. Therefore, multivariate regression analysis with adjusted confounding factors (Model 1 and 2), was performed. The body composition at baseline was used for adjusting in Model 1 and the body composition at baseline, age, and BMI were used in Model 2. The results showed that no significant differences between the groups (Table 4).

Table 3 Body composition at baseline and after treatment, and mean changes between baseline and after treatment in the control and experimental groups.

Parameters	Control (n=12)			Experimental (n=15)			#*p* value
	Baseline	After treatment	Mean changes	Baseline	After treatment	Mean changes	
Fat mass, kg	10.13±8.66	10.53±9.54	0.41±4.53	10.97±9.87	12.21±9.61	1.24±2.56	0.55
PBF, %	17.89±13.05	19.01±14.82	1.12±8.35	17.50±10.74	19.80±10.93	2.30±4.27	0.64
SMM, kg	20.91±4.20	20.39±5.39	-0.52±2.67	24.87±3.91ϕ	23.92±4.04†	-0.95±1.32	0.59
SLRA, kg	2.26±0.72	1.91±0.72†	-0.35±0.39	3.07±0.71ϕ	2.68±0.60*	-0.38±0.25	0.77
SLLA, kg	2.21±0.86	1.91±0.90	-0.30±0.48	2.96±0.74ϕ	2.52±0.49*	-0.44±0.34	0.38
SLTR, kg	18.37±4.59	16.65±4.58†	-1.72±2.29	22.73±3.99ϕ	20.57±2.96*	-2.16±1.43	0.54
SLRL, kg	5.43±1.22	5.91±2.21	0.48±1.64	6.22±1.64	6.47±1.20	0.24±0.76	0.91
SLLL, kg	5.36±1.23	5.92±2.36	0.55±1.70	6.33±1.68	6.56±2.09	0.23±0.86	0.98

Note: *Data are presented as coefficients with 95% CIs of multivariate regression analysis with adjusted confounding factors of body composition. BMI: body mass index, CI: confidence interval, PBF: percentage of body fat, SMM: skeletal muscle mass, SLRA: segmental lean of right arm, SLLA: segmental lean of left arm, SLTR: segmental lean of trunk, SLRL: segmental lean of right leg, SLLL: segmental lean of left leg. ϕP<0.05 by T-test of control versus experimental groups at baseline, †P<0.05 by T-test of baseline versus after treatment in the experimental and control groups, *P<0.01 by T-test of baseline versus after treatment in the experimental group, #P by T-test of mean changes of control versus experimental groups.*

Table 4 Correlation coefficient of overall scores, and the MDADI-TH subscale scores between test-retest; and intra-class correlation coefficient of the MDADI-TH (N=29).

Parameters	Regression models of body composition	Coefficient (95% CI)	*p value*
Fat mass	Model 1: Fat mass at baseline	0.87 (-2.02 to 3.76)	0.54
	Model 2: Fat mass at baseline, age, BMI	0.78 (-2.68 to 4.23)	0.65
PBF	Model 1: PBF at baseline	1.16 (-4.03 to 6.35)	0.65
	Model 2: PBF at baseline, age, BMI	0.88 (-5.26 to 7.03)	0.77
SMM	Model 1: SMM at baseline	-0.61 (-2.46 to 1.24)	0.50
	Model 2: SMM at baseline, age, BMI	-0.59 (-2.57 to 1.39)	0.54
SLRA	Model 1: SLRA at baseline	0.11 (-0.16 to 0.39)	0.41
	Model 2: SLRA at baseline, age, BMI	0.13 (-0.16 to 0.42)	0.37
SLLA	Model 1: SLLA at baseline	0.41 (-0.09 to 0.92)	0.10
	Model 2: SLLA at baseline, age, BMI	0.35 (-0.21 to 0.91)	0.21
SLTR	Model 1: SLTR at baseline	0.45 (-1.06 to 1.97)	0.54
	Model 2: SLTR at baseline, age, BMI	0.54 (-1.09 to 2.17)	0.50
SLRL	Model 1: SLRL at baseline	-0.87 (-2.18 to 0.43)	0.18
	Model 2: SLRL at baseline, age, BMI	-1.03 (-2.35 to 0.29)	0.12
SLLL	Model 1: SLLL at baseline	-0.53 (-1.61 to 0.56)	0.33
	Model 2: SLLL at baseline, age, BMI	-0.76 (-1.91 to 0.39)	0.19

Note: *Data are presented as coefficients with 95% CIs of multivariate regression analysis with adjusted confounding factors of body composition. BMI: body mass index, CI: confidence interval, PBF: percentage of body fat, SMM: skeletal muscle mass, SLRA: segmental lean of right arm, SLLA: segmental lean of left arm, SLTR: segmental lean of trunk, SLRL: segmental lean of right leg, SLLL: segmental lean of left leg.*

Discussion

This study aimed to investigate the differences in body composition between critically ill surgical patients with either usual care alone or IMT with EM in addition to usual care. Although this study found significant decreases in muscle mass or lean mass in the control and experimental groups, the multivariate regression analysis showed no significant differences in body composition between the groups.

Significant decreases in SMM, SLRA, SLLA, and SLTR were found in the experimental group after treatment. Significant decreases in the SLRA and SLTR were observed in the control group. These results were similar to the findings published in a study by Puthucheary *et al*.[9] which stated that a reduction in muscle mass noticeably starts within 3 days and progressively declines during intensive care. However, the multivariate regression analysis in the present study showed that there were no significant differences in SMM, SLRA, SLLA, SLTR, SLRL, and SLLL between the groups. These results could be explained by the short weaning period (the mean was only 3 days) which consequently shortens the study period.

According to American College of Sports Medicine (ACSM), several weeks of resistance training are needed for the enhancement of muscle mass in healthy individuals.[39] However, the effects of EM on muscle mass after bed rest and immobilization in healthy subjects, COPD patients, and breast cancer patients have been reported.[21-23, 40] EM restores and increases lean muscle mass or cross-sectional area of thigh muscle after 6 or 8 or 15 weeks of training. Additionally, type and intensity of EM training between previous studies and this study were not similar. In the experimental group in our study, 80% of patients reached the highest level of EM (level III) which was focused on the aerobic training while standing with low intensity. COPD patients[21, 41] and healthy subjects[22, 23] underwent the training with maximal intensity isokinetic resistance, once a day for 3 sessions per week. Breast cancer patients underwent combined aerobic and resistance training with intensity at 40-60% of maximal HR, once a day, 2 days per week.[40] Inspiratory muscle training led to significantly increased MIP in the experimental group when compared to the control group after treatment. Increased MIP may involve the improvement of diaphragm muscle thickness.[42-44] Although diaphragm muscle is the essential skeletal muscle for respiration, the muscles are thin and may not affect body composition, especially as regards the SMM. This might explain why the muscle mass was unaffected.

This pilot study did not find significant differences in fat mass and PBF between groups. These might be also because of the short training period. Similar to enhancement of muscle mass, several weeks of aerobic training or active physical activity are required to reduce body fat.[39] In active adults, endurance types of physical activities have been shown to limit fat mass gain when compared with sedentary adults. The physical activities, such as jogging, tennis, gymnastics, skiing, and swimming were performed for >2 months at moderate- or high-intensity level at least 3 hours a week to show results regarding reduction in body fat.[45] Early

mobilization has also been shown to decrease fat mass and PBF after 20 weeks of training in older women, again over a longer period than this study. The program comprised 5 minutes of warm-up, 30 minutes of resistance training, 30 minutes of moderate-intensity aerobic training, and 5 minutes of stretching at the end. The training took place for approximately 70 minutes a day, twice a week.[46] Liao *et al*.[47] demonstrated that resistance training decreased fat mass and PBF in older women with sarcopenic obesity after 12 weeks of training. Subjects were trained using progressive elastic bands for 30-45 minutes per session, 3 sessions a week. In addition, home-based physical training decreased visceral abdominal fat in patients with coronary artery disease after 8 weeks of training. That training comprised 13 minutes of warm-up, 15-20 minutes of strength training, 35-45 minutes of endurance training, and 6 minutes of stretching. The patients were trained with 60-70% of maximal HR, once a day, 3 times a week.[48] In comparison, this pilot study involved only a short training period, and in addition the experimental group seemed to have lower level of physical activity and lighter intensity of training than the previous studies. This might explain why the fat mass and PBF were no different between groups.

Limitations

One limitation of this study was that the population was too small to achieve any statistically significant differences in body composition. A larger population may result in a significant difference in the outcomes. Incision pain in critically ill patients is a factor that limits physical activity and voluntary force generation during inspiratory muscle training and measurement. Therefore, pain management has been provided in patients who underwent the surgery[49], this would limit the ability of the patient to generate muscle force in the same way as a non-critically ill surgical patient. However, pain did not affect the measurement and training in the present study. This study did not match fluid balance between patients as it is difficult to control fluid levels in critically ill patients. However, this study did not find differences in fluid balance between the groups. Early nutritional support plays an important role in the physical and functional recovery of critically ill patients and would need to be included in a further study as the nutrition was not controlled in patients in this study.[50] This might be another reason why no improvement in body composition was found.

Conclusion

The conclusion of this pilot study is that a combination of inspiratory muscle training and early mobilization in conjunction with usual care did not improve body composition when compared to the usual care alone in critically ill surgical patients. After treatment, a decrease in segmental lean of arm and segmental lean of trunk were found in both groups. The multivariate regression analysis adjusted for confounding factors showed no significant differences in body composition between the groups.

Conflicts of interests

The authors declare that there is no conflict of interest

Clinical trial registration number

TCTR20181220005

Funding

The study was supported by the Faculty of Associated Medical Sciences and Graduate School, Chiang Mai University, Chiang Mai, Thailand. The funders claimed no role in this study.

References

[1] De Jonghe B, Sharshar T, Lefaucheur JP, Authier FJ, Durand-Zaleski I, Boussarsar M, et al. Paresis acquired in the intensive care unit: a prospective multicenter study. Jama. 2002;288:2859-67. doi: https://doi.org/10.1001/jama.288.22.2859.

[2] Doorduin J, van der Hoeven JG, Heunks LM. The differential diagnosis for failure to wean from mechanical ventilation. Curr Opin Anaesthesiol. 2016; 29: 150-7. doi: https://doi.org/10.1097/aco.0000000000000297.

[3] Nelson JE, Cox CE, Hope AA, Carson SS. Chronic critical illness. Am J Respir Crit Care Med. 2010; 182(4): 446-54. doi: 10.1164/rccm.201002-0210CI.

[4] Ali NA, O'Brien JM, Jr., Hoffmann SP, Phillips G, Garland A, Finley JC, et al. Acquired weakness, handgrip strength, and mortality in critically ill patients. Am J Respir Crit Care Med. 2008; 178(3): 261-8. doi: 10.1164/rccm.200712-1829OC.

[5] Weijs PJM, Looijaard WGPM, Dekker IM, Stapel SN, Girbes AR, Oudemans-van Straaten HM, et al. Low skeletal muscle area is a risk factor for mortality in mechanically ventilated critically ill patients. Criti Care. 2014; 18(2): R12-R. doi: 10.1186/cc13189.

[6] Dres M, Goligher EC, Heunks LMA, Brochard LJ. Critical illness-associated diaphragm weakness. Intensive Care Med. 2017; 43: 1441-52. doi: http://dx.doi.org/10.1007/s00134-017-4928-4.

[7] Powers SK, Kavazis AN, DeRuisseau KC. Mechanisms of disuse muscle atrophy: role of oxidative stress. Am J Physiol Regul Integr Comp Physiol. 2005; 288: R337-44. doi: https://doi.org/10.1152/ajpregu.00469.2004.

[8] van Gassel RJJ, Baggerman MR, van de Poll MCG. Metabolic aspects of muscle wasting during critical illness. Curr Opin Clin Nutr Metab Care. 2020; 23(2): 96-101. doi: 10.1097/MCO.0000000000000628.

[9] Puthucheary ZA, Rawal J, McPhail M, Connolly B, Ratnayake G, Chan P, et al. Acute skeletal muscle wasting in critical illness. Jama. 2013; 310(15): 1591-600. doi: https://doi.org/10.1001/jama.2013.278481.

[10] Nakanishi N, Tsutsumi R, Okayama Y, Takashima T, Ueno Y, Itagaki T, et al. Monitoring of muscle mass in critically ill patients: comparison of ultrasound and two bioelectrical impedance analysis devices. Journal of intensive care. 2019; 7: 61-. doi: 10.1186/s40560-019-0416-y.

[11] Levine S, Nguyen T, Taylor N, Friscia ME, Budak MT, Rothenberg P, et al. Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans. N Engl J Med. 2008; 358: 1327-35. doi: https://doi.org/10.1056/NEJMoa070447.

[12] Goligher EC, Fan E, Herridge MS, Murray A, Vorona S, Brace D, et al. Evolution of diaphragm thickness during mechanical ventilation. Impact of inspiratory effort. Am J Respir Crit Care Med. 2015; 192(9): 1080-8. doi: https://doi.org/10.1164/rccm.201503-0620OC.

[13] Sprague SS, Hopkins PD. Use of inspiratory strength training to wean six patients who were ventilator-dependent. Phys Ther. 2003; 83: 171-81. doi: https://doi.org/10.1093/ptj/83.2.171.

[14] Elkins M, Dentice R. Inspiratory muscle training facilitates weaning from mechanical ventilation among patients in the intensive care unit: a systematic review. J Physiother. 2015; 61: 125-34. doi: https://doi.org/10.1016/j.jphys.2015.05.016.

[15] Magalhaes PAF, Camillo CA, Langer D, Andrade LB, Duarte M, Gosselink R. Weaning failure and respiratory muscle function: what has been done and what can be improved? Respir Med. 2018; 134: 54-61. doi: https://doi.org/10.1016/j.rmed.2017.11.023.

[16] Vorona S, Sabatini U, Al-Maqbali S, Bertoni M, Dres M, Bissett B, et al. Inspiratory muscle rehabilitation in critically ill adults. a systematic review and meta-analysis. Ann Am Thorac Soc. 2018; 15: 735-44. doi: https://doi.org/10.1513/AnnalsATS.201712-961OC.

[17] Needham DM. Mobilizing patients in the intensive care unit: improving neuromuscular weakness and physical function. Jama. 2008; 300(14): 1685-90. doi: 10.1001/jama.300.14.1685.

[18] Winkelman C. Inactivity and inflammation in the critically ill patient. Crit Care Clin. 2007; 23(1): 21-34. doi: 10.1016/j.ccc.2006.11.002.

[19] Zang K, Chen B, Wang M, Chen D, Hui L, Guo S, et al. The effect of early mobilization in critically ill patients: A meta-analysis. Nurs Crit Care. 2019;n/a(n/a). doi: 10.1111/nicc.12455.

[20] Tipping CJ, Harrold M, Holland A, Romero L, Nisbet T, Hodgson CL. The effects of active mobilisation and rehabilitation in ICU on mortality and function: a systematic review. Intensive Care Med. 2017; 43: 171-83. doi: https://doi.org/10.1007/s00134-016-4612-0.

[21] Constantin D, Menon MK, Houchen-Wolloff L, Morgan MD, Singh SJ, Greenhaff P, et al. Skeletal muscle molecular responses to resistance training and dietary supplementation in COPD. Thorax. 2013; 68(7): 625. doi: 10.1136/thoraxjnl-2012-202764.

[22] Tanner RE, Brunker LB, Agergaard J, Barrows KM, Briggs RA, Kwon OS, et al. Age-related differences in lean mass, protein synthesis and skeletal muscle markers of proteolysis after bed rest and exercise rehabilitation. The Journal of physiology. 2015; 593(18): 4259-73. doi: 10.1113/JP270699.

[23] Jones SW, Hill RJ, Krasney PA, O'Conner B, Peirce N, Greenhaff PL. Disuse atrophy and exercise rehabilitation in humans profoundly affects the expression of genes associated with the regulation of skeletal muscle mass. Faseb j. 2004; 18(9): 1025-7. doi: 10.1096/fj.03-1228fje.

[24] Franca EE, Ferrari F, Fernandes P, Cavalcanti R, Duarte A, Martinez BP, et al. Physical therapy in critically ill adult patients: recommendations from the Brazilian Association of Intensive Care Medicine Department of Physical Therapy. Rev Bras Ter Intensiva. 2012; 24: 6-22. doi: http://dx.doi.org/10.1590/S0103-507X2012000100003

[25] Hodgin KE, Nordon-Craft A, McFann KK, Mealer ML, Moss M. Physical therapy utilization in intensive care units: results from a national survey. Crit Care Med. 2009; 37: 561-6; quiz 6-8. doi: https://doi.org/10.1097/CCM.0b013e3181957449.

[26] Jang MH, Shin M-J, Shin YB. Pulmonary and Physical Rehabilitation in Critically Ill Patients. Acute and critical care. 2019; 34(1): 1-13. doi: 10.4266/acc.2019.00444.

[27] Nydahl P, Ewers A, Brodda D. Complications related to early mobilization of mechanically ventilated patients on intensive care units. Nurs Crit Care. 2014. doi: https://doi.org/10.1111/nicc.12134.

[28] Ambrosino N, Venturelli E, Vagheggini G, Clini E. Rehabilitation, weaning and physical therapy strategies in chronic critically ill patients. European Respiratory Journal. 2012; 39(2): 487. doi: 10.1183/09031936.00094411.

[29] Schweickert WD, Pohlman MC, Pohlman AS, Nigos C, Pawlik AJ, Esbrook CL, et al. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. Lancet. 2009; 373: 1874-82. doi: https://doi.org/10.1016/s0140-6736(09)60658-9.

[30] Chittawatanarat K, Thongchai C. Spontaneous breathing trial with low pressure support protocol for weaning respirator in surgical ICU. J Med Assoc Thai. 2009;92:1306-12. doi:

[31] Beduneau G, Pham T, Schortgen F, Piquilloud L, Zogheib E, Jonas M, et al. Epidemiology of weaning outcome according to a new definition. The WIND study. Am J Respir Crit Care Med. 2017; 195: 772-83. doi: https://doi.org/10.1164/rccm.201602-0320OC.

[32] Langer D, Charususin N, Jacome C, Hoffman M, McConnell A, Decramer M, et al. Efficacy of a novel method for inspiratory muscle training in people with chronic obstructive pulmonary disease. Phys Ther. 2015; 95: 1264-73. doi: https://doi.org/10.2522/ptj.20140245.

[33] Caruso P, Denari SD, Ruiz SA, Bernal KG, Manfrin GM, Friedrich C, et al. Inspiratory muscle training is ineffective in mechanically ventilated critically ill patients. Clinics (Sao Paulo). 2005; 60: 479-84. doi: https://doi.org/10.1590/s1807-59322005000600009.

[34] Morris PE, Goad A, Thompson C, Taylor K, Harry B, Passmore L, et al. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. Crit Care Med. 2008; 36: 2238-43. doi: https://doi.org/10.1097/CCM.0b013e318180b90e.

[35] Medical Research Council. MRC Muscle Scale London1976 [cited 2018 May 9]. Available from: https://mrc.ukri.org/research/facilities-and-resources-for-researchers/mrc-scales/mrc-muscle-scale/.

[36] Kim D, Sun JS, Lee YH, Lee JH, Hong J, Lee JM. Comparative assessment of skeletal muscle mass using computerized tomography and bioelectrical impedance analysis in critically ill patients. Clin Nutr. 2018. doi: https://doi.org/10.1016/j.clnu.2018.12.002.

[37] Looijaard WGPM, Molinger J, Weijs PJM. Measuring and monitoring lean body mass in critical illness. Curr Opin Crit Care. 2018;24:241-7. doi: https://doi.org/10.1097/MCC.0000000000000511.

[38] InBody UK. InBody S10 user's manual 2017 [updated 18 October 2017; cited 2019 26 August]. Available from: https://uk.inbody.com/support/download-center/.

[39] Nelson ME, Rejeski WJ, Blair SN, Duncan PW, Judge JO, King AC, et al. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc. 2007; 39(8): 1435-45. doi: 10.1249/mss.0b013e3180616aa2.

[40] Battaglini C, Bottaro M, Dennehy C, Rae L, Shields E, Kirk D, et al. The effects of an individualized exercise intervention on body composition in breast cancer patients undergoing treatment. Sao Paulo Med J. 2007; 125(1): 22-8. doi: 10.1590/s1516-31802007000100005.

[41] Menon MK, Houchen L, Harrison S, Singh SJ, Morgan MD, Steiner MC. Ultrasound assessment of lower limb muscle mass in response to resistance training in COPD. Respiratory research. 2012; 13(1): 119-. doi: 10.1186/1465-9921-13-119.

[42] Chiappa GR, Roseguini BT, Vieira PJ, Alves CN, Tavares A, Winkelmann ER, et al. Inspiratory muscle training improves blood flow to resting and exercising limbs in patients with chronic heart failure. J Am Coll Cardiol. 2008; 51(17): 1663-71. doi: 10.1016/j.jacc.2007.12.045.

[43] Downey AE, Chenoweth LM, Townsend DK, Ranum JD, Ferguson CS, Harms CA. Effects of inspiratory muscle training on exercise responses in normoxia and hypoxia. Respir Physiol Neurobiol. 2007; 156(2): 137-46. doi: 10.1016/j.resp.2006.08.006.

[44] Souza H, Rocha T, Pessoa M, Rattes C, Brandão D, Fregonezi G, et al. Effects of inspiratory muscle training in elderly women on respiratory muscle strength, diaphragm thickness and mobility. J Gerontol A Biol Sci Med Sci. 2014; 69(12): 1545-53. doi: 10.1093/gerona/glu182.

[45] Kyle UG, Gremion G, Genton L, Slosman DO, Golay A, Pichard C. Physical activity and fat-free and fat mass by bioelectrical impedance in 3853 adults. Med Sci Sports Exerc. 2001; 33(4): 576-84. doi: 10.1097/00005768-200104000-00011.

[46] Rossi FE, Lecca AR, Martins LGP, Takahashi LSO, Christofaro DGD, Gobbo LA, et al. Physical exercise programs at Basic Healthcare Units decrease body fat and improve the functional capacity of women over 50 years old. Journal of exercise rehabilitation. 2017; 13(3): 315-21. doi: 10.12965/jer.1734986.493.

[47] Liao CD, Tsauo JY, Lin LF, Huang SW, Ku JW, Chou LC, et al. Effects of elastic resistance exercise on body composition and physical capacity in older women with sarcopenic obesity: A CONSORT-compliant prospective randomized controlled trial. Medicine (Baltimore). 2017; 96(23): e7115. doi: 10.1097/md.0000000000007115.

[48] Noites A, Pinto J, Freitas CP, Melo C, Albuquerque A, Teixeira M, et al. Effects of microcurrents and physical exercise on the abdominal fat in patients with coronary artery disease. Eur J Integr Med. 2015; 7(5): 499-507. doi: https://doi.org/10.1016/j.eujim.2015.06.002.

[49] Shoar S, Esmaeili S, Safari S. Pain management after surgery: a brief review. Anesthesiology and pain medicine. 2012; 1(3): 184-6. doi: 10.5812/kowsar.22287523.3443.

[50] Bear DE, Wandrag L, Merriweather JL, Connolly B, Hart N, Grocott MPW, et al. The role of nutritional support in the physical and functional recovery of critically ill patients: a narrative review. Critical care (London, England). 2017; 21(1): 226-. doi: 10.1186/s13054-017-1810-2.