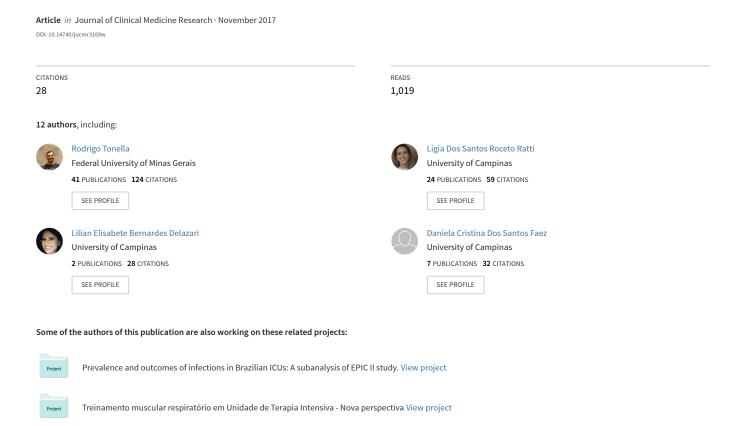
## Inspiratory Muscle Training in the Intensive Care Unit: A New Perspective





# Inspiratory Muscle Training in the Intensive Care Unit: A New Perspective

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#### **Abstract**

**Background:** Prolonged use of mechanical ventilation (MV) leads to weakening of the respiratory muscles, especially in patients subjected to sedation, but this effect seems to be preventable or more quickly reversible using respiratory muscle training. The aims of the study were to assess variations in respiratory and hemodinamic parameters with electronic inspiratory muscle training (EIMT) in tracheostomized patients requiring MV and to compare these variations with those in a group of patients subjected to an intermittent nebulization program (INP).

**Methods:** This was a pilot, prospective, randomized study of tracheostomized patients requiring MV in one intensive care unit (ICU). Twenty-one patients were randomized: 11 into the INP group and 10 into the EIMT group. Two patients were excluded in experimental group because of hemodynamic instability.

**Results:** In the EIMT group, maximal inspiratory pressure (MIP) after training was significantly higher than that before (P = 0.017), there were no hemodynamic changes, and the total weaning time was shorter than in the INP group (P = 0.0192).

**Conclusion:** The EIMT device is safe, promotes an increase in MIP, and leads to a shorter ventilator weaning time than that seen in patients treated using INP.

**Keywords:** Diaphragm; Respiratory insufficiency; Ventilator weaning; Intensive care

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#### Introduction

The main goals of invasive ventilatory support are to promote normal alveolar ventilation and effective gas exchange, to treat the underlying disease, and to reverse respiratory failure [1]. However, the disuse of the respiratory muscles that occurs alongside such controlled ventilation weakens the muscles [2] and decreases diaphragm strength in a manner that is logarithmically proportional to the duration of mechanical ventilation (MV) [3] and to the use of sedation and muscle blockers [4]. Episodes of sepsis, extended MV, and severe polyneuropathy [5] exacerbate the harmful effects on respiratory muscular function and can lead to long dependence from MV [6].

The process of weaning from MV involves the patient initially spending approximately 40% of their time on MV [7]. Unfortunately, especially when the weaning process started late, the significant loss of muscle strength means that between 5% and 15% of patients being weaned repeatedly fail to regain respiratory autonomy [6].

The extended use of MV is associated with high daily cost of hospitalization and a higher mortality [8]; therefore, pulmonary rehabilitation interventions have been decreasing hospitalization time and substantially reducing hospital costs [9].

Respiratory muscle training reverses weakness and improves endurance [10]. The training can result in a significant increase in the maximal inspiratory pressure (MIP) [11], as well as successful weaning of patients who have failed repeatedly [12]. Muscle training is safe, with no adverse hemodynamic or respiratory repercussions that would necessitate discontinuing the procedure, even in patients whose condition is severe [13].

New technologies are available for respiratory muscle training. Electronic devices play a key role in increasing the respiratory performance of recreational runners [14]. The safety of these devices using inspiratory loads of up to 60% MIP has been confirmed in normal individuals. Specifically, when this limit was applied, the resulting hemodynamic variations were within the normal range [15].

Souza et al [16] used an electronic device for inspiratory muscle training (IMT) in a tracheostomized patient on MV who had a neuromuscular disease; the investigators observed an increase in MIP, detected no significant hemodynamic repercus-

Table 1. Inclusion Criteria

Criteria	Requirements		
Age	> 18 years old		
Partial arterial oxygen tension	> 60 mm Hg		
Fraction of inspired oxygen	≤ 0.6		
Oxygen saturation index	≥ 100		
Mean arterial pressure	$\geq 80~mm~Hg \leq 110~mm~Hg$		
Analgesia and sedation	Without analgesia/sedation more than 24 h		
Ventilatory modality	Assisted/controlled or spontaneous		
Pressure support ventilation	$\geq 10 \text{ cm H}_2\text{O}$		
Positive end-expiratory pressure	$\leq 10 \text{ cm H}_2\text{O}$		
Respiratory rate	≤ 30 breaths/min		
Arterial oxygen saturation	≥ 90%		
Body temperature	≥ 36.5 °C ≤ 38.5 °C		
Body mass index	$\leq 40 \text{ kg/m}^2$		

sions, and reported successful invasive weaning from MV.

With this in mind, we assessed variation in respiratory and hemodynamic parameters in tracheostomized patients who were subjected to electronic IMT (EIMT). Further, this group was compared with a group of patients subjected to an intermittent nebulization program (INP); the groups were compared in terms of MIP, rapid shallow breathing index (RSBI), duration of MV, and total weaning time.

#### Methods

This was a pilot, prospective, randomized study involving tracheostomized patients hospitalized in the intensive care unit (ICU) of the Clinical Hospital at the State University of Campinas. The Research Ethics Committee of the same institution (report No. 403/626) approved this study. The patients' legal representatives read, accepted, and signed an informed consent form (ICF), allowing patient enrollment in the study (registered in The Brazilian Clinical Trials - REBeC, number U1111-1156-3177).

From October 2013 to January 2014, 25 consecutive patients were selected. Twenty-one tracheostomized patients meeting the inclusion criteria were enrolled (Table 1). Patients were excluded from this study when presented injury of phrenic nerve, neuromuscular disease, or musculoskeletal disorders, necessity of more than 1 aspiration per hour, or who had used home MV before hospitalization.

The patients were randomized into two groups: INP and EIMT. The randomization was performed using closed envelopes, the selection being performed by one of the authors of the study accompanied by an employee of the same institution who was not participating in the research. Weaning success was defined as breathing without MV for 48 consecutive hours. Prior to data collection, each patient received physical therapy comprising bronchial hygiene therapy, tracheal and oral cavity aspiration, and positioning in bed with the head

lifted at an angle of at least 30°.

Three MIP readings were obtained from each patient daily using a digital manovacuometer (MVD300; GlobalMed<sup>®</sup>, MDI Produtos e Sistemas Ltda Novo, Hamburgo, Brazil). The measurement involved a one-way valve connected to both the tracheostomy tube and the equipment, a 20-s occlusion, a 1-min break between measurements, and selection of the highest MIP value. The RSBI was also checked daily using a ventilometer (Wright<sup>®</sup> Mark-8, inspector inspire health Ltd, Hertford, England).

The fraction of inspired oxygen was adjusted to 100% for 2 min before the MIP and RSBI measurements were obtained.

In the INP group following institutional protocol, the patients were subjected to an INP using a T-piece for a progressively increasing duration, until they had completed 48 h of respiratory autonomy on continuous nebulization. INP was discontinued when the patient showed two or more of the clinical criteria characterizing respiratory failure: respiratory rate over than 35 cycles/min; oxygen arterial saturation less than 90%; heart rate over than 130 beats/min; systolic blood pressure over than 180 mm Hg or less than 90 mm Hg; signs and symptoms like agitation, sweating, change in consciousness level and thoracoabdominal asynchrony.

In the EIMT group, patients underwent training using a POWER breathe<sup>®</sup> KH2 (IMT Technologies Ltd, Birmingham, England) electronic inspiratory training device. The manual mode was selected and 30 repetitions were divided into three series of 10 with a 1-min break between each series. EIMT was performed twice a day using a resistive load of 30% of the initial MIP and readjusted daily, with a 10% increase on each training day.

Hemodynamic and respiratory parameters were monitored before and after each training session: heart rate (HR), mean arterial pressure (MAP), arterial oxygen saturation (SpO<sub>2</sub>), and respiratory rate (RR). Additionally, in the EIMT group, hemodynamic and respiratory parameters were monitored during training (Table 2).

In the EIMT group, the training was to be discontinued if

Demographics	INP group (N = 8)	EIMT group (N = 11)	
Median age (years)	46.5	58.0	
Gender			
Male	N = 7	N = 8	
Female	N = 1	N = 3	
TI rationale			
Respiratory failure	N = 4	N = 4	
Decrease in consciousness level	N = 3	N = 5	
Post-operative complications	N = 1	N = 2	
	$Mean \pm SD$	$Mean \pm SD$	
APACHE II	$20.2 \pm 7.2$	$20.9 \pm 5.4$	
SOFA	$7.7 \pm 4.4$	$7.13 \pm 5.8$	

**Table 2.** Demographics of the Studied Population

INP: intermittent nebulization program; EIMT: electronic inspiratory muscle training; N: number of patients; TI: tracheal intubation; SD: standard deviation; APACHE II: acute physiology and chronic health disease classification system II; SOFA: sequential organ failure assessment.

the patient showed two or more of the clinical criteria characterizing respiratory failure: respiratory rate over than 35 cycles/min; oxygen arterial saturation less than 90%; heart heat over than 130 beats/min; systolic blood pressure over than 180 mm Hg or less than 90 mm Hg; signs and symptoms like agitation, sweating, change in consciousness level, and thoracoabdominal asynchrony.

SPSS version 13.0 for Windows was used for statistical analysis. No normal variable distribution was found using the Kolmogorov-Smirnov test. A descriptive analysis of numerical and categorical variables was performed in both groups. The Wilcoxon test was used to compare related variables, and the Mann-Whitney test for independent samples. P values < 0.05 were considered statistically significant.

Figure 1 shows the study flowchart, as well as the number of patients studied.

#### Results

Twenty-five patients were selected from October 2013 to January 2014; four were excluded because they failed to submit an ICF signed by legal representatives. Twenty-one patients were randomized: 11 into the INP group and 10 into the EIMT group. Two patients were excluded in experimental group because of hemodynamic instability. In both groups, one patient died (Fig. 1). The demographics of the study population are presented in Table 2. There were no significant differences between the groups in terms of demographics.

Although the HR, MAP, RR, and SpO<sub>2</sub> showed variation during training in the EIMT group, these were within normal values and did not necessitate discontinuation of the treatment.

Table 3 shows the RSBI and MIP values obtained before and after training in both groups. The groups did not differ in terms of RSBI values either before or after the respective treatment. In both groups, MIP increased after the training; however, the increase was significant only in the EIMT group

when the value before training was compared with that after training (P < 0.017).

The groups did not differ in terms of MV time with  $21.8 \pm 9.8$  days to INP group and  $14.5 \pm 10$  days for EIMT group (P = 0.082); however, the total weaning time was shorter in the EIMT group than in the INP group (P = 0.0192), with  $9.4 \pm 6.47$  days for INP group and  $3.5 \pm 1.6$  days for EIMT group.

#### Discussion

Our findings suggest that EIMT can be used safely and possibly effectively in tracheostomized patients who are on MV and are being treated in the ICU, as the HR, MAP, RR, and SpO<sub>2</sub> were within normal values.

Selection of the study population was made easy owing to the large number of patients needing a tracheostomy tube because of difficulties with weaning. This is in accordance with the study by Cader et al [17], which treated intubated patients using a respiratory muscle training protocol, with a view to increasing the extubation success rate; however, of the 198 patients selected for their study, only 28 were randomized, as the majority of the population was subject to tracheostomy tube or died.

The selection of a 30% resistive load during EIMT was supported by the findings of Bissett et al [10], who evaluated patients on MV for 7 days or more and successfully weaned them from ventilation. The same authors noted that respiratory muscle endurance was reduced in a third of the studied patients immediately after MV withdrawal.

The findings of Cader et al [18] also supported the resistive load selected in our study. In a randomized assay, these authors employed IMT twice a day using a load that was equivalent to 30% of the MIP, with a daily 10% increase in the training load. They found an increase in the MIP and a decrease in weaning time; 87.5% of the patients in the training group were discharged from the ICU with no need for ventilatory support. Similar results were obtained in this study; total weaning

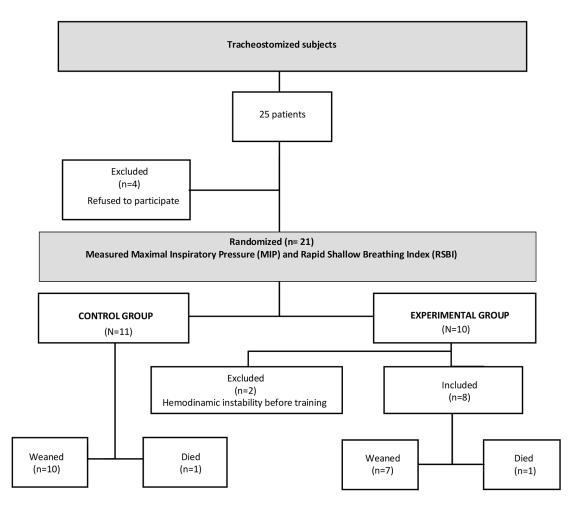


Figure 1. Study flowchart and the number of patients studied.

time was shorter in the EIMT group, and this was associated with significant MIP increase over the pre-training values (P = 0.017). The proportion of ICU discharges showed a similar trend in this study, because all patients who had achieved respiratory autonomy were discharged from the ICU.

In a prospective study, Epstein et al [19] found that MV-dependent patients who had been successfully weaned had an average MIP of 40 cm  $\rm H_2O$ . In contrast, patients for whom weaning had failed presented an average MIP of 20 cm  $\rm H_2O$ . In our study, the initial mean MIPs were 43  $\pm$  16 cm  $\rm H_2O$  and

Table 3. Distribution of MIP and RSBI Values in Both Groups

	INP group		EIMT group	
	Before	After	Before	After
RSBI (cycles/min/L)	97 ± 47	80 ± 34	49 ± 16	48 ± 10
	P = 0.49		P = 0.249	
MIP (cm H <sub>2</sub> O)	$43 \pm 16$	$53 \pm 19$	$54 \pm 20$	$61 \pm 17$
	P = 0.304		P = 0.017	

INP: intermittent nebulization program; EIMT: electronic inspiratory muscle training; MIP: maximal inspiratory pressure; RSBI: rapid shallow breathing index.

 $54 \pm 20$  cm  $H_2O$  for the INP and EIMT groups, respectively. Taken together, this may explain the successful weaning and respiratory autonomy reached in both groups.

Jubran et al [20] compared patients weaned using decreasing support pressure with those weaned using INP at specific times daily. Weaning time in the INP group was shorter than that in the support pressure group. Conversely, the weaning time in the EIMT group in our study was shorter than that of the INP group.

In our study, RSBI was not significantly different between the two groups, both before and after training; this is in contrast to the study by Cader et al [18]. However, the population in their study was mainly composed of elderly individuals who were on MV for a shorter period and were trained while still on tracheal intubation; both these factors may have contributed to the significant decrease in RSBI. In our study, each patient had been tracheostomized and had an MV time of  $21.8 \pm 9.8$  days in the INP group, and  $14.5 \pm 10$  days in the EIMT group; it is likely for this reason that the RSBI did not decrease. Furthermore, the RSBI value in the EIMT group in our study was already within the predictive value for successful ventilatory weaning, i.e., less than 104 cycles/min/L, with a mean of  $49 \pm 16$  cycles/min/L. However, patients were not yet able to acquire

respiratory autonomy without respiratory muscle training.

With regards to the safety of the electronic device, the present study was in accordance with several previous studies [11, 21, 22], all of which used the Threshold® IMT device in patients dependent on MV in the ICU. In contrast, we used the POWERbreathe® KH2 in such patients. Therefore, the POWERbreathe® KH2 is equally safe, because it did not significantly or sustainably affect the HR, MAP, RR, or SpO<sub>2</sub> of the patients enrolled in this study, during or after training.

It is important to highlight that the POWERbreathe® was initially meant exclusively for IMT in healthy and fit individuals (16 recreational runner athletes) [15]. Thus, it was necessary to determine the safety and applicability of the instrument in this "off-label" use, namely, the weaning of tracheostomy patients. Information is still scarce in the literature regarding the utility of electronic IMT devices in patients whose condition is severe. In a case study involving tracheostomized patient with neuromuscular disease who had been MV-dependent for 14 days, Souza et al [16] reported successful IMT using the POWERbreathe®; the study was carried out in an intermediate care unit. A 30-cm H<sub>2</sub>O increase in MIP was observed after 2 weeks, allowing MV discontinuation, decannulation, and initiation of non-invasive MV. Therefore, in accordance with the results of their study, the authors concluded that IMT was safe, as hemodynamic variables did not change to the point of interrupting the IMT, and there was no need to administer supplemental oxygen. More studies are necessary to understand when, how and for how long we need to implement the muscular training in intensive care medicine before and after weaning [23].

#### **Conclusions**

It can be concluded that the electronic IMT device is safe, as it did not adversely affect HR, MAP, and SpO<sub>2</sub> variations. In addition, it may be effective since it led to an increase in MIP over pre-training values, and weaning time was shorter than in the INP group. Shorter weaning times in particular may contribute to a decrease in the incidence of MV-associated pneumonia and in hospital-acquired infection, as well as to shorter hospitalization times and, consequently, lower morbidity and mortality and decreased hospitalization-related costs.

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