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Enrico M. Clini
Francesca Degli Antoni
Michele Vitacca
Ernesto Crisafulli
Mara Paneroni
Sheila Chezzi-Silva
Maurizio Moretti
Ludovico Trianni
Leonardo M. Fabbri

Intrapulmonary percussive ventilation in tracheostomized patients: a randomized controlled trial

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E. M. Clini (✉) · F. D. Antoni · E. Crisafulli · L. Trianni · L. M. Fabbri
University of Modena, and Ospedale Villa Pineta, Department of Pulmonary Rehabilitation,
Via Gaiato 127, 41020 Pavullo, Italy
e-mail: clini.enrico@unimore.it
Tel.: +39-0536-42039
Fax: +39-0536-42039

E. M. Clini · M. Moretti · L. M. Fabbri
University of Modena-Reggio Emilia, Section of Respiratory Diseases, Department of Oncology, Hematology and Pneumonology,
Modena, Italy

M. Vitacca · M. Paneroni · S. Chezzi-Silva
Division of Pneumonology, Fondazione Salvatore Maugeri IRCCS,
Gussago/Lumezzane, Italy

Abstract *Objective:* To investigate whether the addition of intrapulmonary percussive ventilation to the usual chest physiotherapy improves gas exchange and lung mechanics in tracheostomized patients. *Design and setting:* Randomized multicenter trial in two weaning centers in northern Italy. *Patients and participants:* 46 tracheostomized patients (age 70 ± 7 years, 28 men, arterial blood pH 7.436 ± 0.06, PaO_2/FIO_2 238 ± 46) weaned from mechanical ventilation. *Interventions:* Patients were assigned to two treatment groups performing chest physiotherapy (control), or percussive ventilation (IMP2 Breas, Sweden) 10 min twice/day in addition to chest physiotherapy (intervention). *Measurements and results:* Arterial blood gases, PaO_2/FIO_2 ratio, and maximal expiratory pressure were assessed every 5th day for 15 day. Treatment complications that showed up in 1 month of follow-up were recorded. At 15 days the intervention group had a significantly better PaO_2/FIO_2 ratio and higher maximal expiratory pressure; after follow-up this group also had a lower incidence of pneumonia. *Conclusions:* The addition of percussive ventilation to the usual chest physiotherapy regimen in tracheostomized patients improves gas exchange and expiratory muscle performance and reduces the incidence of pneumonia.

Keywords Mechanical ventilation · Chest physiotherapy · Weaning · Tracheostomy

Introduction

Respiratory care and physiotherapy are important components in the treatment of critically ill patients. In particular, early intervention may prove effective in avoiding complications and improving the prognosis for patients admitted to intensive care units (ICUs) [1, 2]. Chest physiotherapy is one of the most popular interventions delivered to patients recovering from the acute phase of their illness [1]. Bed rest and prolonged mechanical ventilation are conditions frequently associated with inadequate mucus clearance and other complications, such

as pneumonia and atelectasis, due to retention of bronchial secretions [3]. Assisted mucus-clearing techniques are usually performed daily by skilled physiotherapists and include forced expiratory technique, assisted cough, mechanical insufflation–exsufflation, breathing techniques, and air stacking [4, 5, 6]. The advantages of these methods are well known [1, 2], as are their relative inefficacy in atelectasis and their frequent inability to clear peripheral secretions, especially in patients with underlying neuromuscular disease [7].

Intrapulmonary percussive ventilation is a new technique designed to create a global effect of internal percussion of the lungs which aims at clearing the peripheral bronchial tree [8]. To date percussive ventilation has been successfully used to remove secretions in patients with cystic fibrosis [9] or neuromuscular disease [10] and to ventilate patients with adult respiratory distress syndrome [11, 12] as well as to treat acute lobar atelectasis [13]. Still there is a lack of information about the physiological and clinical effectiveness of this technique when applied as a means of chest physiotherapy in critically ill patients.

We have therefore hypothesized that percussive ventilation is a feasible and effective method to remove secretions in intubated ICU patients with hypersecretions and high risk of complications based on mucus plugging. The aim of the present study was to investigate whether the addition of percussive ventilation to the chest physiotherapy regimen would improve lung physiology and reduce the rate of complications when used for bronchial drainage in tracheostomized patients recently weaned from mechanical ventilation.

Methods

Patients

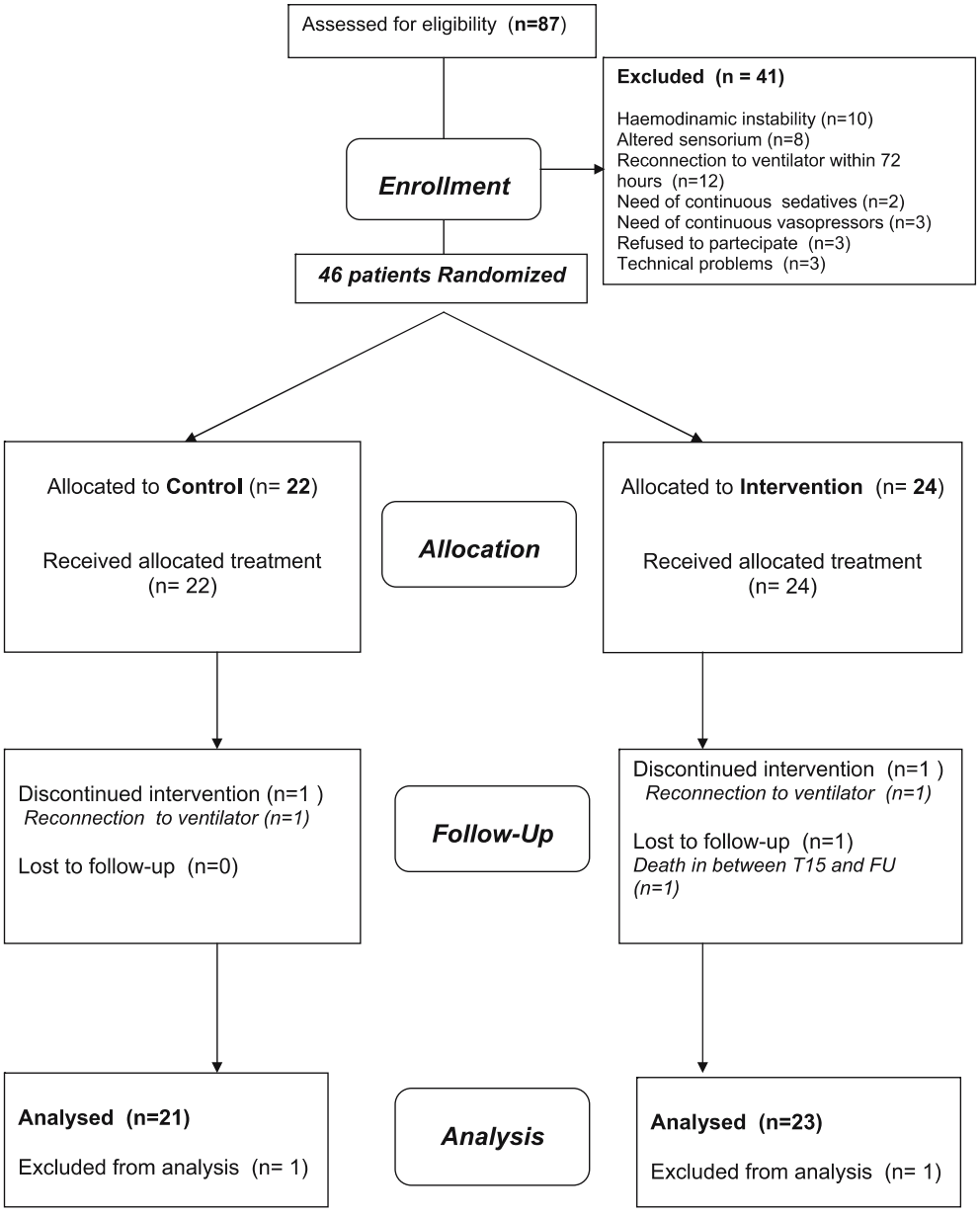
The study group consisted of 46 consecutive tracheostomized patients admitted between January 2004 and September 2005 to the weaning units of two regional centers in northern Italy (Ospedale Villa Pineta, Pavullo, and Fondazione Maugeri IRCCS, Lumezzane/Gussago). Table 1 shows the baseline characteristics of patients when treatment was allocated. All the patients admitted for weaning at both centers who successfully passed the spontaneous breathing trial were considered for eligibility. The patients enrolled in the study accounted for 53% of the total number of eligible patients (55% and 50% in the centers of Pavullo and Lumezzane/Gussago, respectively). Reasons for exclusion are shown in Fig. 1. Two patients (one in each group) withdrew before the last days of treatment because they had to have their ventilators reconnected, and the drop-out rate was thus 4.5% and 4.1% in the control and intervention groups, respectively. Additionally, one patient in the intervention group was lost to follow-up because of sudden death while still in the hospital. All the patients who completed the treatment period were discharged from the units (18 at home and 26 at other facilities including hospice and rehabilitation ward). Most of them (95%) had the tracheostoma occluded within the month following; among the three long-term tracheostomized patients one maintained the stoma opened due to severely impaired swallowing function. Long-term home mechanical ventilators were provided in nine cases (seven noninvasive, two through tracheostomy).

Table 1 Baseline characteristics and functional data of patients (*APACHE* Acute Physiology and Chronic Health Evaluation, PaO_2 partial artery oxygen pressure, FIO_2 fractional inspired oxygen concentration, *COPD* chronic obstructive pulmonary disease; *CRI* chronic respiratory insufficiency

	Control ($n = 22$)	Intervention ($n = 24$)
Sex: M/F	13/9	15/9
Age (years)	70 ± 8	68 ± 10
APACHE II score	13 ± 5	13 ± 3
Kelly-Matthay score	1.7 ± 2.0	1.9 ± 1.4
FIO_2 (%)	30 ± 6	30 ± 5
PaO_2/FIO_2	240 ± 34	238 ± 51
Primary diagnosis		
COPD	5 (23%)	6 (25%)
CRI	5 (23%)	6 (25%)
Pulmonary fibrosis	1 (4%)	2 (8%)
Cardiac surgery	3 (14%)	3 (13%)
Pneumonectomy/lobectomy	2 (9%)	2 (8%)
Sepsis	2 (9%)	1 (4%)
Neurological events, diseases	4 (18%)[a]	4 (17%)[b]

[a] Stroke, 1 patient; tetraparesis, 2 patients; multiple sclerosis, 1 patient; [b] Stroke, 1 patient; tetraparesis, 1 patient; amyotrophic lateral sclerosis, 1 patient; myasthenia gravis, 1 patient

Fig. 1 Trial profile



Tracheostomy had been performed on these patients as a means to facilitate weaning from mechanical ventilator at the ICUs from which they were transferred after recovering from the acute phase of their illness. All of them had been mechanically ventilated for at least 14 days; 25% suffered from critical illness neuropathy as diagnosed by means of electromyography performed in the ICUs of provenience. At our facility weaning was conducted by skilled personnel, and a similar protocol [14] was used at both centers. At the beginning of the study patients had been on spontaneous unassisted breathing for at least 72 h, were stable and conscious, were able to adhere to active physiotherapy treatment, and showed excessive production (more than 40 ml/day) and retention of secretions. At this time tracheostoma has been retained due to their inability to take deep breaths, impaired cough reflex and a need of more than two suctions/day [15].

Patients with persistent alterations of the sensorium, hemodynamic instability (including major cardiac arrhythmias), a need for vasopressors and/or sedatives, or instability of the respiratory system needing further ventilatory assistance were excluded from the study. All procedures in the study were performed according to the Declaration of Helsinki. The ethics committees of both centers approved the protocol, and informed consent was obtained from all patients.

Study protocol

Study subjects were randomly assigned to one of two groups. The random sequence was obtained from a central list of patients at both centers using a random number table with a block sequence by six patients. The 15-day therapeutic regimens for the two groups were as follows. The control group participated in two 1-h chest physiotherapy sessions per day (see below). The intervention group was similarly treated, with the addition of two sessions of percussive ventilation via tracheostomy in sequence with the other techniques adopted. The two groups did not differ significantly in anthropometric or clinical data or in primary diagnosis. In particular, there were no differences in terms of medication which may have interfered with expected variation in outcome measures (i. e., assumption of systemic steroids). Outcome variables were assessed at baseline (t_0) and 5 (t_5), 10 (t_{10}), and 15 days (t_{15}) after randomization. Following the treatment period patients were then managed according to any clinical need up to discharge. A 1-month period of follow-up of all patients in the study was carried out at the end of active treatment to assess the incidence of pulmonary complications.

Treatments

Chest physiotherapy was performed by skilled respiratory therapists unaware of the study's purposes. Procedures were performed according the suggested evidence and best practice as previously reported [1].

Intrapulmonary percussive ventilation was delivered immediately before the chest physiotherapy sequences by means of an IMP2 ventilator (Breas Medical, Mölnlycke, Sweden). The machine was connected by its circuit through the external opening of the cannula while the cuff was deflated, thus allowing the patient to breathe. Further details on the study treatments are provided in the Electronic Supplementary Material (ESM).

Study endpoints

The primary endpoint of the study was to establish the physiological effectiveness (gas exchange and expiratory muscles pressure) of percussive ventilation when added to the chest physiotherapy regimen in the study population. The secondary endpoint was to assess the short- and long-term (1-month) rate of respiratory complications associated with treatments.

Measurements

General measures

The study subjects were classified according to their primary diagnosis, and the usual anthropometric and demographic measures were applied. The severity-of-illness status at enrollment was assessed by means of the Acute Physiology and Chronic Health Evaluation II score [16] and level of consciousness by means of the Kelly-Matthay [17] scale.

Outcomes

At baseline and after 5, 10, and 15 days of treatment the following measurements were recorded in both groups. An arterial blood sample was taken from each patient's radial artery to measure $PaCO_2$, PaO_2/FIO_2, and pH (model 850; Chiron Diagnostics, Medfield, Mass., USA). Arterial sampling was performed in the morning before any intervention, while the patient breathed spontaneously in a semirecumbent position at his or her predetermined inspiratory oxygen fraction that was able to maintain a transcutaneous oxygen saturation level above 92%. A 30-min period of stabilization was required before sampling.

Respiratory muscle performance was assessed by measuring maximal expiratory pressure (MEP) [18] using a portable differential pressure transducer (Honeywell 300 cmH_2O manometer Freeport, Ill., USA). The patient breathed through a one-way valve that had a tubular piece, which was connected to the tracheostomy cannula. Patients were instructed to exert maximal expiratory effort during each measurement; pressures had to be maintained for a sufficient time to reliably record a maximum pressure sustained for 1 s [19] and checked by the respiratory therapist by means of a manual chronometer. Five consecutive efforts were recorded, with a 1-min pause between each effort. The best measurement was used for statistical analysis. All the measurements were performed by respiratory therapists from the two centers who were unaware of the study's purposes. The reference values used were those of Bruschi et al. [20].

During the treatment period and the follow-up the incidence of pulmonary complications (airway hemorrhage, pneumonia, and lung atelectasis) were recorded for all patients. Chest radiography was performed on a weekly basis (or when any radiological change was suspected by the increase in body temperature or white blood cell count, or the evidence of purulent secretions) to monitor the occurrence of both atelectasis and pneumonia. Diagnosis of nosocomial pneumonia was based on the current definition [21]. The number of bronchoscopic procedures performed during the treatment period to remove excess secretions in both groups was also recorded. Decision to perform bronchoscopy was based on the judgment of the attending physicians who were unaware of the study's purposes.

Statistical analysis

Although this study included several outcome measures, only one was considered for sample size calculation to de-

Table 2 Time course of outcome measures in the two study groups (PaO_2 partial artery oxygen pressure, $PaCO_2$ partial artery carbon dioxide pressure, FIO_2 fractional inspired oxygen concentration, *MEP* maximal expiratory pressure)

	Control ($n = 21$)				Intervention ($n = 23$)			
	t_0	t_5	t_{10}	t_{15}	t_0	t_5	t_{10}	t_{15}
$PaCO_2$ (mmHg)	47 ± 12	48 ± 13	47 ± 11	47 ± 9	50 ± 15	48 ± 11	48 ± 12	48 ± 13
PaO_2 (mmHg)	71 ± 12	71 ± 11	72 ± 10	72 ± 9	69 ± 8	76 ± 18*	74 ± 10	76 ± 9*
PaO_2/FIO_2	240 ± 34	245 ± 55	252 ± 47	255 ± 38*	238 ± 51	284 ± 96**,***	280***,4* ± 54	289 ± 52***,4*
pH	7.43 ± 0.08	7.41 ± 0.07	7.42 ± 0.05	7.42 ± 0.04	7.44 ± 0.06	7.42 ± 0.05	7.43 ± 0.07	7.42 ± 0.06
MEP (cmH_2O)	32 (13)	30 (14)	32 (15)	34 (15)	34 (12)	35 (15)	38* (15)	47 (1%)***,4*

*$p \leq 0.05$ vs. t_0, **$p \leq 0.01$ vs. t_0, ***$p \leq 0.005$ vs. t_0, ^{4}*$p \leq 0.05$ vs. chest physiotherapy regimen

termine a minimum sample able to ensure powerful testing of the effects of treatment. This calculation was based on the minimal expected change in the PaO_2/FIO_2 ratio which was the variable selected among those included in the primary end-point of the study, in the usual (control) condition; this change accounted by a minimum increase by 30 points. We calculated that a sample size of 22 in each group would give a 90% power to detect a difference of 30 points in PaO_2/FIO_2 between the two treatment groups, assuming that the common standard deviation is 30 points and using a two-group *t* test with a 5% two-tailed significance level. Hence we aimed to recruit 23 patients per group.

Data are presented as mean ± standard deviation and/or 95% confidence interval (CI), frequency, and/or percentage distribution. Data were analyzed by SPSS 8.0 for Windows statistical software. A *p* value less than 0.05 was considered statistically significant. Per-protocol analysis of outcomes was made between treatment and times using analysis of variance for repeated measures; the post-hoc test was then applied as appropriate. The group comparison of changes after 5, 10, or 15 days of therapy was performed using an analysis of variance model that included the baseline value as the covariate: the differences between treatment were expressed as the mean difference for all the variables, with 95% CI throughout. The group difference in values obtained between admission (t_0) and end of treatment (t_{15}) was used for presentation of data (see below).

Results

The time course of the physiological outcomes measured during the treatment period is shown in Table 2. PaO_2, PaO_2/FIO_2, and MEP progressively improved only in patients in the intervention group. Analysis of group differences confirmed that there was significant improvement in both the oxygenation index (PaO_2/FIO_2) and MEP in patients treated by percussive ventilation (Table 3).

Table 4 gives the number of patients in whom pulmonary complications occurred at the various time points. No patient in either group reported airway hemorrhage, while the number of patients with atelectasis were similar in the two groups. The number of those who developed nosocomial pneumonia (see above) was significantly

Table 3 Group differences in arterial blood gases, oxygenation, and expiratory muscle pressure change during the treatment period (t_0–t_{15}) (PaO_2 partial artery oxygen pressure, $PaCO_2$ partial artery carbon dioxide pressure, FIO_2 fractional inspired oxygen concentration, *MEP* maximal expiratory pressure)

	Mean difference	95% CI	*p*
PaO_2 (mmHg)	2.32	–6.91 to 11.56	NS
$PaCO_2$ (mmHg)	–5.54	–12.73 to 1.65	NS
PaO_2/FIO_2	21.65	–11.75 to 55.05	0.038
pH	0.013	–0.011 to 0.011	NS
MEP (cmH_2O)	9.26	1.98 to 16.54	0.014

Table 4 Number of patients with pulmonary complications in the two study groups (*FU* follow-up)

Variable	Control					Intervention				
	t_0	t_5	t_{10}	t_{15}	FU	t_0	t_5	t_{10}	t_{15}	FU
Acute hemorrhage	NA	0	0	0	0	NA	0	0	0	0
Pneumonia (nosocomial)*	NA	5	3	2	2	NA	3	2	1	0
Atelectasis	NA	3	1	0	0	NA	2	1	0	0

*$p \leq 0.05$ between groups (χ^2 analysis considering all the time points)

lower ($p \leq 0.05$) in the intervention group (Table 4). The number of patients needing bronchoscopic procedures in the treatment period to remove excess of secretions (10 and 12, respectively) did not differ significantly between the two groups.

Discussion

The results of this randomized study show that intrapulmonary percussive ventilation is a feasible technique able to enhance the physiological effects of chest physiotherapy in tracheostomized patients completing weaning from mechanical ventilation. Moreover, its use is associated with a lower rate of pneumonia.

We used percussive ventilation as a means to promote the mechanical clearing of the peripheral bronchial tree, thus creating the global effect of internal percussion of the lungs [8]. This application of the device may be useful for critically ill patients. The prolonged bed stay and overall muscle weakness and wasting, with increased amounts of bronchial secretions, led to an increased risk of developing both lung atelectasis and pneumonia [2]. The major effect induced by percussive ventilation in our study was the significant improvement in the patients' oxygenation (PaO_2/FIO_2 ratio) which is highly correlated with a lesser degree of early and late complications [1]. This improvement was enhanced (Table 3) and speeded up (Table 2) compared with the usual physiotherapy, and it is likely that this effect depends on the mechanically induced high flow rate [22], which provides a more rapid and profound removal of secretions.

The effect of mucus removal might have been assessed by quantifying the amount of secretions. It is likely that emptying the trachea of a tracheostomized patient by suctioning makes it easier to obtain a valid measurement of the weight of secretions. However, the secretions in a tracheostomized patient cannot be precisely quantified because of the high water content of their mucus. Therefore this measurement was not considered in the present research. Despite the fact that percussive ventilation has been shown to increase the weight of tracheal secretions in hypersecretive patients by 69% [10], it is notable that a standardized method to quantify the collected sputum still does not exist. Whether the wet or the dry secretions should be weighed is still questionable [23]. Alternatively, the number of suctions per day could have been used to quantify bronchial drainage in our tracheostomized patients. However, the global secretions thus obtained would depend largely on the attitude of nursing staff toward clearance, the patients' own requests, and so on. Nonetheless, the quantification of sputum was beyond the scope of our study, and instead we therefore assessed the physiological effect (PaO_2/FIO_2) whose variation was attributable to airway clearing.

It is also possible that the faster improvement in PaO_2/FIO_2 in the intervention group was related in part to the ventilatory effect of the device used. Percussive ventilation has previously been applied as a ventilatory technique [24]. In a recent randomized, controlled study [25] of patients with exacerbated chronic obstructive pulmonary disease, percussive ventilation was shown to prevent the deterioration associated with initial respiratory acidosis, thus avoiding the use of mechanical ventilation.

Apart from improved mucus clearance, potential mechanisms of action could include enhanced alveolar recruitment and/or a direct high-frequency oscillatory ventilationlike effect [24]. The role of percussive ventilation as a ventilatory support system when delivered at breathing frequency of 250 cycles/min has also been effective in reducing the diaphragmatic work of breathing, both in normal subjects [26] and in stable patients with chronic obstructive pulmonary disease [27]. In our study the percussive ventilator was set at a breathing frequency between 200 and 300 cycles/min, which is between the optimal ventilatory effect (low frequency and high inspiratory-expiratory ratio) and the percussive effect (high frequency and low inspiratory-expiratory ratio) [10]. Both these effects might also explain the improvement in MEP obtained by using percussive ventilation and not by physiotherapy alone (Table 2). The improvement in MEP was far from a trivial effect in these patients. Improvement in MEP values has been proposed as an index for extubation and discontinuation from mechanical ventilation [28, 29] or for decannulation [15] in critically ill patients.

Our findings also show that percussive ventilation is associated with a lower occurrence and a lower rate of later-onset pneumonia during the treatment period and follow-up than the usual chest physiotherapy (Table 4). This finding underlines the positive role of the early use of this device, especially in preventing lung infections [30, 31, 32] that may significantly worsen the prognosis of patients admitted to ICUs [33].

Percussive ventilation has also proved to be safe. None of the patients in the intervention, as in the control group, experienced dangerous effects such as acute airway hemorrhage during treatment or thereafter (Table 4). The drop-out rates in the control and intervention groups were similar and did not depend on any side effect induced by the treatment.

Notwithstanding, our study presents some important limitations which need to be addressed. First, giving fixed rather than individualized settings for percussive ventilation might be worthwhile for a clinical study such as the present one. However, the tolerance of intrapulmonary percussive ventilation differs among individuals [8, 10, 13] particularly in different diseases (as in our study population). Therefore individually adjusted settings are often better tolerated and possibly more effective. All

patients included in the intervention group tolerated the percussive ventilator very well. The values of the "comfort" scale and the visual analogue scale [34] obtained from these patients did not differ from those recorded in patients whose breathing was unassisted (data not shown). Second, the improvement in MEP only indirectly indicates the clearance of respiratory tract. It is likely that this result, together with the improvement in oxygenation, would have been associated with improvement in lung compliance and resistance. However, a formal "invasive" measurement of lung mechanics has not been performed. Additionally, other very pertinent lung parameters such as inspiratory muscle pressure and peak cough flow [35] and vital capacity [36] would have been measured to assess any physiological change. It has been reported that a simple acute upper respiratory tract infection in patients with neuromuscular disease can cause a vital capacity decrease related to a reduction in respiratory muscle strength, followed by a prompt improvement in that lung volume in parallel with resolution of the infection [37]. Third, although percussive ventilator is known to be easily used by skilled professionals [10], the exact time consumed was not considered in the present trial.

To conclude, the results of our study suggest that percussive ventilation can be routinely used to enhance and speed the favorable effects of chest physiotherapy in patients admitted to ICUs. However, both our physiological and clinical findings only warrant further study of subgroups of critically ill patients with different characteristics or different diagnoses to confirm these results.

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