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Mechanical insufflation/exsufflation improves respiratory mechanics in critical care: Randomized crossover trial

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ABSTRACT

This study evaluated the ventilatory and haemodynamic effects of the mechanical insufflator-exsufflator (MI-E) in critically ill patients. Sixteen mechanically ventilated patients performed three protocols: MI-E (-30/+30 cmH_2O) plus endotracheal suctioning; 50S: MI-E (−50/+50 cmH2O) plus endotracheal suctioning; and isolated endotracheal suctioning (IES). The protocols were applied randomly in all subjects, with 3 -h intervals in between. Peak airway pressure (Ppeak), plateau pressure (Pplat), airway resistance (Raw), static compliance (Cst), heart rate (HR), systolic (SBP) and diastolic (DBP) blood pressure, peripheral oxygen saturation (SpO_2) and amount of removed secretions were evaluated before (PRE), immediately after (POST) and 10 min after (10' POST) each protocol. The 50S protocol reduced Ppeak and Raw and increased Cst immediately after its application. Moreover, this protocol provided the largest amount of removed secretions and held SBP, DBP and SpO_2 at basal values. The MI-E at high pressures promotes benefits to respiratory mechanics, is more effective in removing pulmonary secretions and it does not lead to hemodynamic repercussions.

1. Introduction

Patients admitted to the Intensive Care Unit (ICU) often require invasive ventilatory support (Carvalho et al., 2007), which is related to the retention of pulmonary secretions due to impairment of mucociliary transport and cough (Branson, 2007). This accumulation of secretions induces increased airway resistance and obstruction, alveolar hypoventilation, atelectasis, hypoxemia and increased respiratory muscle work as well as creating a favourable environment for bacterial colonisation and development of pulmonary infections (Branson, 2007; Konrad et al., 1994).

Manual physiotherapeutic techniques or devices that promote airway clearance of patients in critical care maintain airway permeability, promote tissue oxygenation and pulmonary ventilation and prevent pulmonary complications (Ciesla, 1996; Stiller, 2000). In this context, the mechanical insufflator-exsufflator (MI-E) simulates physiological coughing, providing respiratory cycles that alternate positive pressures and abrupt changes at negative pressures (Toussaint, 2011). This device provides pressures up to -70/+70 cmH_2O, and some studies demonstrate the production of assisted cough well tolerated and safe by patients with pressures of −30/+30 cmH_2O to −50/+50 cmH_2O (Miske, 2004). The use of the MI-E has shown favourable results in the removal of pulmonary secretions from patients with neuromuscular diseases (Fauroux et al., 2008). However, endotracheal suctioning is not efficient in removing peripheral airway secretion and may be unable to prevent complications related to secretory accumulation

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(American Association for Respiratory, 2010).

Although there is evidence of positive results regarding its effectiveness in airway clearance (Pillastrini et al., 2006; Sancho et al., 2003), the use of the MI-E in patients in intensive care is still uncommon in clinical practice. Moreover, studies demonstrating its effects on cardiovascular and respiratory systems are scarce, especially in critically ill patients. Therefore, the aim of this study was primarily to evaluate the effects of the use of the MI-E at two different pressures of insufflation/exsufflation (I/E) on respiratory mechanics of adults receiving invasive mechanical ventilation (IMV) with an orotracheal tube (OTT). Moreover, we also propose to analyse its effects on haemodynamics and clearance of bronchial secretions of these patients and to compare these effects to those achieved with isolated endotracheal suctioning.

2. Material and methods

2.1. Study characteristics and ethical aspects

This randomized crossover study was performed for three months (May to August 2016) in the clinical ICU of Nossa Senhora da Conceição Hospital in Porto Alegre, Rio Grande do Sul, Brazil. The study was approved by the Ethical Committee of the Federal University of Pampa – Unipampa (process number: 37094914.0.0000.5323) and its institutional review board, and all the necessary participation consents were given. This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans, with the ethical aspects of research described in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals and the good clinical research guidelines published by the National Health Council (Resolution 466/12).

2.2. Subjects

The sample, determined by sample size calculation for the analysis of quantitative variables of a proportion of a population of infinite size, considering a 95% confidence level, a 5% maximum error of estimation, and an estimated prevalence of 50%, was composed of patients who met the following criteria: older than 18 years on mechanical ventilation for more than 24 h through an OTT in assist-control mode without ventilatory drive (Table 3), with a RASS Richmond Agitation-Sedation Scale (RASS) score of -4 or -5 (Nassar et al., 2008) and hemodynamically stable (defined as Systolic Blood Pressure - SBP - ranging from 90 to 160 mmHg or Diastolic Blood Pressure - DBP - ranging from 50 to 110 mmHg). Subjects with acute respiratory distress syndrome (ARDS), exacerbated chronic obstructive pulmonary disease (COPD), bronchopleural fistula or risk of pneumothorax, intracranial hypertension, in a postoperative state, hemodynamically unstable (requiring the use of noradrenaline > 0,1 mcg/kg/min or in association with another cardiovascular drug), trauma victims and patients in palliative care were excluded from the study.

2.3. Interventions

To perform I/E, the *Cough Assist®* device *(Philips-Respironics, USA)* was used connected to a one meter long corrugated trachea, which was directly connected to the patient's OTT. An antibacterial and viral filter *(MedFlex®, Brazil)* was fitted between the trachea and the device according to the manufacturer's specifications.

All patients participated in the three protocols, with a 3-h application interval between each and a sequence defined by block randomisation. The protocols were: a) 30S – MI-E with I/E pressures of −30/+30 cmH_2O followed by endotracheal suctioning; b) 50S – MI-E with I/E pressures of −50/+50 cmH_2O followed by endotracheal suctioning; and c) isolated endotracheal suctioning (IES). All protocols were performed with the patients in the dorsal decubitus position. All patients remained with the cuff inflated with pressure between 25–35 cmH_2O during protocols.

The 30S and 50S protocols were performed in automatic mode, with 4 sequences of 4 respiratory cycles each and a 20 s interval between each sequence. Respiratory cycles were adjusted with inspiratory time of 2.5 s, a pause of 0.5 s and expiratory time of 1.5 s, according to manufacturer's suggestions. The protocols were followed by only an open-endotracheal suctioning manoeuvre performed according to the recommendations of the American Association for Respiratory Care (AARC) (American Association for Respiratory, 2010), which recommends a closed suction system, suction catheter with maximal internal-to-external diameter ratio of 0.5, delivery of 100% oxygen 30 s immediately before and 1 min after the procedure, duration of 15 s, and vacuum pressure of ± 150 mmHg. All the suctioning procedures were performed by the same physiotherapist.

Secretions were collected immediately after the end of the procedure, using a sputum trap attached to the suction system. Sterile saline (10 mL) was flushed through the suction tubing into the trap to clear any secretions in the catheter. The volume of sputum was recorded by subtracting the saline volume from the total volume in the trap. The secretion was stored in a collecting bowl *(Psimon®, Brazil)* and the total volume of secretion collected was weighed on a precision scale (*500-Diamond, Diamond, Korea*) by subtracting the weight of the disposable collector from the total measurement. In the IES protocol, only endotracheal suctioning was performed.

Two hours before the first stage of the experiment, patients underwent a single endotracheal suctioning manoeuvre in order to normalise their previous condition and avoid the bias of excessive secretions in airways. In addition, the ICU team was instructed to neither perform body hygiene 1 h prior to the application of protocols nor perform bronchial hygiene therapy in the intervals between protocols.

2.4. Outcomes

Respiratory mechanics was the primary outcome and it was evaluated through changes in a single measure of peak airway pressure (Ppeak), plateau pressure (Pplat), airway resistance (Raw) and static compliance (Cst), whose data were collected by performing an inspiratory pause of 2–3 s, where variables were extracted for further calculation of respiratory mechanics, according to the recommendations of the Brazilian Guidelines on Mechanical Ventilation (AMIB, 2013). Secondary outcomes included changes promoted by the different protocols in hemodynamic parameters, such as heart rate (HR), SBP, DBP and peripheral oxygen saturation (SpO2) provided by a standard ICU multiparameter monitor (*Infinity Kappa, Dräger, Germany*); and evaluation of the amount of removed secretions by weighing the collected secretions. The parameters evaluated in each protocol were collected in three periods: 5 min before the execution (PRE), immediately after (POST) and 10 min after (10′ POST) each protocol.

2.5. Data analysis

Data are expressed as mean ± SD. Statistical analysis was performed using the D'Agostino and Pearson omnibus normality test, one-way or two-way ANOVA followed by the Fisher post hoc test using *GraphPad Prism®* 6 software (New Zealand). Values with $p < 0.05$ were considered statistically significant.

3. Results

Eighteen patients were recruited, two of whom were excluded because of hemodynamic instability (Fig. 1). Finally, 16 patients (10 women) participated in the study. Clinical characteristics of the participants are described in Tables 1 and 2.

Concerning the assessment of respiratory mechanics, there was a slight increase, but not significant, in Ppeak immediately after the

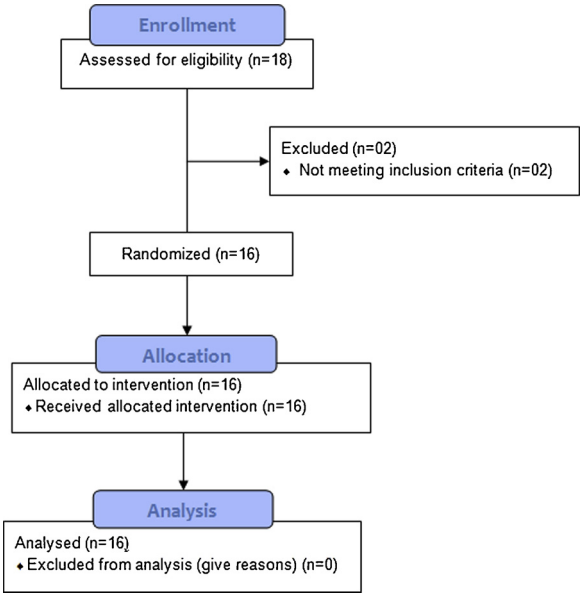

Fig. 1. Flowchart of inclusion of patients.

Table 1
Clinical data of the study subjects.

	N (16)	%	Mean ± SD	Min-Max
Age (years)	–	–	57.6 ± 19.1	27–87
Simplified Acute Physiology Score-SAPS III (%)	–	–	42.3 ± 21.6	7–84
Cause of Hospitalization				
Sepsis/Septic shock	8	50		
Lowering of consciousness	3	18.8	–	–
Others	5	31.2		
Comorbidities				
Hypertension	8	50		
Obesity	4	25		
Smoking	4	25		
Heart Failure	3	18.8	–	–
Diabetes Mellitus	2	12.5		
Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS)	2	12.5		
Others	10	62		
Medication used				
Sedative/Hypnotic drugs	13	81.2		
Antibiotics	12	75	–	–
Vasoactive drugs	4	25		
Diuretics	3	18.8		

application of I/E with pressures of −30/+30 cmH_2O and the execution of isolated endotracheal suctioning, both of which returned to the baseline values 10 min after the implementation of the protocols (Fig. 2A, p = 0.06). However, there was a reduction in Ppeak immediately after the application of I/E with pressures of −50/+50 cmH_2O, which was maintained 10 min after the protocol was performed (Fig. 2A, p = 0.03). No changes were observed in Pplat in the different protocols and periods evaluated (Fig. 2B, p = 0.9).

As for Raw, it increased immediately after the execution of isolated endotracheal suctioning (Fig. 2C, p = 0.04) and remained unchanged during the application of I/E with pressures of -30/+30 cmH_2O (Fig. 2C, p = 0.8). On the other hand, there was a reduction in this parameter immediately after the application of I/E with pressures of -50/+50 cmH_2O, which remained reduced 10 min after the execution of the protocol (Fig. 2C, p = 0.03). Regarding Cst, no changes were observed after the use of I/E with pressures of −30/+30 cmH_2O and the execution of isolated endotracheal suctioning (Fig. 2D, p = 0.5). However, I/E with pressures of -50/+50 cmH_2O was able to increase this variable immediately after its application (Fig. 2D, p = 0.005).

In the assessment of haemodynamic parameters, the HR was similar in the different protocols and periods analysed (Fig. 3A, p = 0.2). Regarding the blood pressure, both SBP and DBP had similar behaviours and showed a significant increase immediately after the application of I/E with pressures of -30/+30 cmH_2O and execution of isolated endotracheal suctioning, returning to the baseline values 10 min after the protocols were performed (Figs. 3B and 1 C, p = 0.0006). On the other hand, the execution of I/E with pressures of -50/+50 cmH_2O did not induce significant changes in blood pressure (Fig. 3B and C, p = 0.8).

With respect to SpO2, both the use of I/E with pressures of -30/+30 cmH_2O and the execution of isolated endotracheal suctioning reduced the SpO2 immediately after the application of the protocols, returning to baseline values 10 min after the end of them (Fig. 4, p = 0.0001). The use of I/E with pressures of -50/+50 cmH_2O did not change the SpO2, and their values remained similar to basal levels at all periods evaluated (Fig. 4, p = 0.5).

Moreover, I/E with pressures of -50/+50 cmH_2O was the protocol that provided the largest amount (in g) of removed secretions when compared to the other protocols (Fig. 5, p = 0.003; Table 2).

4. Discussion

Our findings demonstrate that the use of I/E at high pressures promotes greater benefits in respiratory mechanics and removal of pulmonary secretions from critically ill patients on IMV when compared to I/E at lower pressures or IES. In addition, I/E at higher levels of pressures does not lead to significant haemodynamic repercussions, differently from the use of low pressures or IES.

The use of the MI-E is on the rise (Toussaint, 2011) and currently some research shows benefits in using this device as a facilitator of IMV weaning (Bach et al., 2015). In this context, Gonçalves et al. (2012) presents interesting results in clinical practice in patients who performed 3 daily sessions of MI-E, where they had lower extubation rates and lower mean time of ICU stay than the control group.

The use of the MI-E in patients on IMV with the goal of increasing secretion withdrawal is not yet a consensus. Corroborating our findings, de Camillis et al., 2018, using the MI-E in patients with IMV, observed a higher volume of secretions removed and an improvement in pulmonary compliance with the MI-E when compared to standard respiratory physiotherapy. However, different from this study, we used higher pressure levels in the MI-E, in addition to showing improvement in Raw with the use of the equipment.

The MI-E was also used in critical patients on IMV by Coutinho et al., 2018; however, differently from our study, no difference was found in the volume of removed secretions after the use of the MI-E compared to IES alone. A possible explanation for this controversy would be the fact that, in the aforementioned study, the authors did not perform the previous suctioning to guarantee the homogeneity of the patients before the application of the protocols. In addition, the protocols were performed on different days, which may have influenced the volume of secretions presented by the patients.

Another important point in the form of application of the MI-E is the time of the inspiratory and expiratory phase. We used an inspiratory time greater than the expiratory time, simulating a physiological cough. The manoeuvre with slow insufflation and rapid exsufflation has been shown to be effective in removing secretions, as it generates a greater peak expiratory flow (Volpe et al., 2018).

Regard to the ventilatory parameters evaluated, the use of the MI-E with pressures of -50/+50 cmH_2O reduced the Ppeak. We suggest that the use of higher pressures promotes better alveolar recruitment and keeps the alveoli expanded longer when compared to the use of lower I/E pressures or to the achievement of IES.

Likewise, the use of the MI-E with pressures of -50/+50 cmH_2O was the only protocol that promoted a sustained reduction in Raw as well as increased Cst of the lung after its execution. These data corroborate previous studies, which showed a greater recruitment of collapsed lung

Table 2
Arterial gasometry, PaO_2/FiO_2 ratio, endotracheal tube size and absolute weight of secretion (g) for each protocol.

Subject	pH	PaO_2	$PaCO_2$	HCO_3	PaO_2/FiO_2	ETT size	weight of secretion (g)		
		(mmHg)	(mmHg)	(mEq/L)		(mm)	IES	30S	50S
1	7.4	103	53.5	35.5	257	9	0.2	0.9	2.4
2	7.4	100	54.7	32.2	200	8	0.3	0.2	0.6
3	7.5	176	27.6	27.9	440	8.5	1.0	0.1	0.7
4	7.4	83.1	48.9	32.3	207	8.5	0.1	0.5	0.4
5	7.4	111	40.6	27.7	222	8	0.1	0.1	0.3
6	7.4	97.1	43.4	27.7	242.7	8	0.4	0.6	0.9
7	7.3	83.4	42.3	22	208.5	8.5	0.6	1.7	2.3
8	7.4	80.5	44.7	24.6	201.2	8	0.3	0.5	1.2
9	7.3	155	57.1	29.7	387.5	8.5	0.01	0.03	0.6
10	7.4	221	32.4	21.5	368.3	8	0.1	0.9	0.8
11	7.3	111	52.7	27.5	201	8	0.5	0.9	0.4
12	7.4	125	32.5	21.2	357.1	8.5	0.1	0.4	0.3
13	7.4	111	44.1	29.4	370	8.5	0.2	3.6	2.2
14	7.4	114	41.6	25.1	285	8.5	0.9	0.6	1.2
15	7.5	119	45.9	33.9	238	8	0.3	0.1	0.2
16	7.4	112	30.3	17	280	8	0.1	0.6	1.2

pH: negative logarithm of hydrogen ion concentration [H+]; PaO_2: partial pressure of oxygen; $PaCO_2$: partial pressure of carbon dioxide; HCO_3: base excess; PaO_2/FiO2: ratio of PaO_2 to inhaled O_2; ETT: endotracheal tube size; IES: isolated endotracheal suctioning; 30S: MI-E with I/E pressures of -30/+30 cmH2O followed by endotracheal suctioning 50S: MI-E with I/E pressures of -50/+50 cmH2O followed by endotracheal suctioning.

Table 3
Baseline ventilator parameters (assisted volume controlled mode).

Patient	Tidal Volume (ml)	PEEP (cmH_2O)	f (bpm)	FiO_2 (%)	Flow (L/min)
1	450	6	18	40	30
2	400	6	15	40	26
3	490	11	22	35	35
4	450	8	15	40	31
5	530	6	18	40	31
6	500	6	18	40	33
7	530	5	20	40	39
8	440	6	18	46	29
9	490	8	15	30	31
10	520	7	22	40	40
11	490	8	19	40	35
12	480	6	16	35	31
13	520	5	20	40	38
14	280	6	16	55	17
15	400	8	22	40	33
16	600	10	15	40	28

PEEP: Positive end-expiratory pressure; f: respiratory rate in breath per minute; FiO_2: Fraction of inspired oxygen.

areas and greater removal of tracheal secretions after the use of the MI-E in mechanically ventilated patients, reflecting improvements in peak cough flow and respiratory mechanics (Miske, 2004; Winck et al., 2004). On the other hand, the IES increased the Raw, which contrasts with previous findings that showed a reduction in Raw of mechanically ventilated patients with ventilatory drive (Choi and Jones, 2005; Rosa et al., 2007), and corroborates with studies of patients on IMV in controlled mode (Guglichninotti et al., 1998). The increase in Raw observed could be related to transient bronchoconstriction being triggered by constriction of the bronchial muscles in response to direct stimulation of the bronchial stretch receptors during the suctioning manoeuvre (Woodburne and Powaser, 1980), especially when performed in the open system, as in our study.

Previously, we analysed the cardiorespiratory effects from the use of the MI-E with pressures of −30/+30 cmH_2O and -50/+50 cmH_2O in healthy subjects and compared them to those caused by spontaneous coughing, demonstrating that for these individuals none of the applied pressures had haemodynamic or ventilatory repercussions and did not differ from spontaneous coughing (de Cássia Nunes et al., 2016). This study had relevance, as it ensured safety in the use of the device at both low and high pressures when applied in subjects without diseases and associated comorbidities. However, the efficacy and safety of the MI-E in critically ill patients was unclear.

Regarding the haemodynamic effects, we observed that IES and pressures of -30/+30 cmH_2O, increased SBP and DBP immediately after the execution of the protocols, which was not observed using pressures of -50/+50 cmH_2O. A hypothesis for such behaviour is that pressures of -50/+50 cmH_2O generate elevated intra-thoracic pressure levels by reducing cardiac output (Schuster et al., 1990), preventing the increase in blood pressure provided by posterior endotracheal suctioning. Probably, lower pressure levels at -30/+30 cmH_2O are not sufficient to promote significant cardiac output changes, which would explain the increase in blood pressure after suctioning.

In our study, the SpO2 after the endotracheal suctioning manoeuvre and the use of I/E with pressures of -30/+30 cmH_2O did not present clinically relevant changes, as in other studies (Mohammadpour et al., 2015).

Finally, concerning the removal of pulmonary secretions, the use of the MI-E at high pressures was the protocol that removed the largest amount of secretions when compared to the use of lower pressures and IES. It is known that the MI-E is effective in eliminating pulmonary secretions by generating adequate airflow in proximal and distal airways, which mobilises secretions by increasing peak cough flow (Bach et al., 2013). We observed that the application of higher I/E pressures promotes a greater mobilisation of secretions and possibly is the factor responsible for the improvements in respiratory mechanics observed, such as the sustained reduction in Ppeak and Raw and the increase in Cst.

The limitations of the study lie in the small sample of patients. Another limiting factor is the fact that patients are not curarized for the evaluations of respiratory mechanics; however, care was taken to observe the absence of respiratory muscular effort by the curves of the mechanical ventilator. In addition, even though we have used the manufacturer's recommended MI-E settings, the best parameters still pose a challenge to practice, since the rate of I/E interferes with the volume of mobilised secretions (Volpe et al., 2018).

In summary, the use of the MI-E at high pressures promotes benefits to respiratory mechanics and is more effective in removing pulmonary secretions from patients on IMV. In addition, it does not lead to significant haemodynamic repercussions, constituting the safest form of application to critically ill patients. Our results have important clinical implications, as they provide a basis for the adequate application of the MI-E by health professionals in the context of intensive care. Future

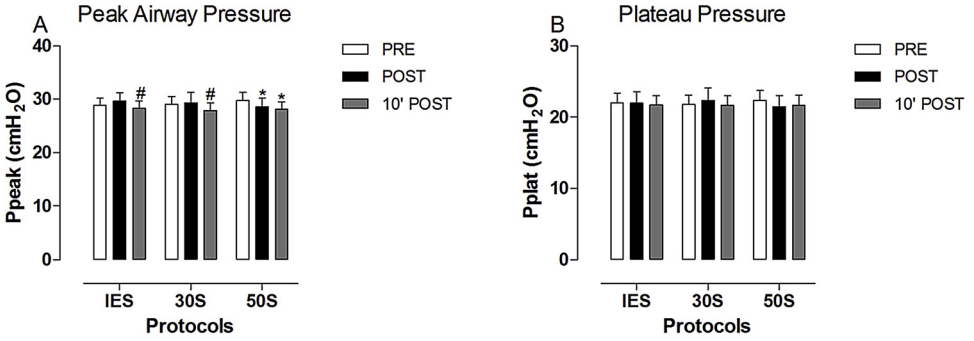

Fig. 2. Peak airway pressure (Ppeak) (A), plateau pressure (Pplat) (B), airway resistance (Raw) (C) and static compliance (Cst) (D) variability for study subjects before (PRE), immediately after (POST) and 10 min after (10' POST) the application of different protocols. 30S: MI-E protocol with pressures of -30/+30 cmH_2O followed by endotracheal suctioning, 50S: MI-E protocol with pressures of -50/+50 cmH_2O followed by endotracheal suctioning, IES: Isolated endotracheal suctioning protocol (*p < 0.05 *vs* PRE; #p < 0.05 *vs* POST).

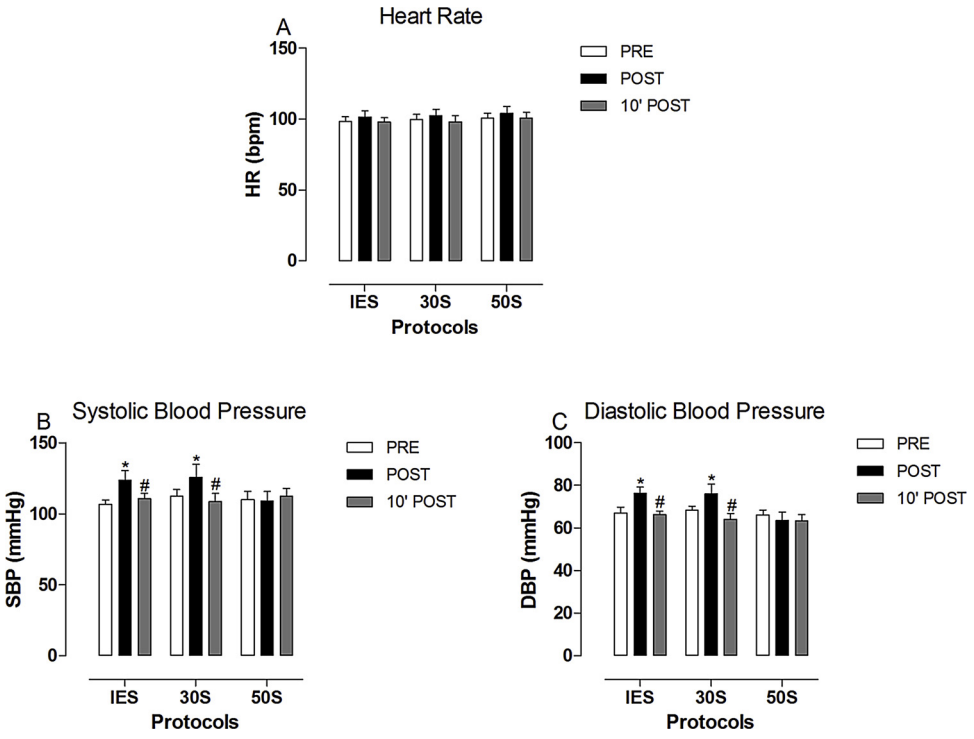

Fig. 3. Heart rate (HR) (A), systolic (SBP) (B) and diastolic (DBP) (C) blood pressure variability for study subjects before (PRE), immediately after (POST) and 10 min after (10' POST) the application of different protocols. 30S: MI-E protocol with pressures of -30/+30 cmH_2O followed by endotracheal suctioning, 50S: MI-E protocol with pressures of -50/+50 cmH_2O followed by endotracheal suctioning, IES: Isolated endotracheal suctioning protocol (*p < 0.05 *vs* PRE; #p < 0.05 *vs* POST).

studies may clarify the long-term effects of the MI-E on outcomes, such as IMV time and rates of both ventilator-associated pneumonia and reintubation.

Declarations of interest

None.

Author contributions

Literature search: LCN, DN, DAR, GAW, FMP; Data collection: LCN, DN, FNV, FMK; Study design: FMP, GAW, DAR, FNV, FMK; Analysis of data: DAR, FMP, GAW; Manuscript preparation: LCN, DN, DAR, GAW, FMP; Review of manuscript: FMP, GAW, DAR. All authors have approved the final manuscript. FMP has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

This research was carried out in the clinical ICU of Nossa Senhora da

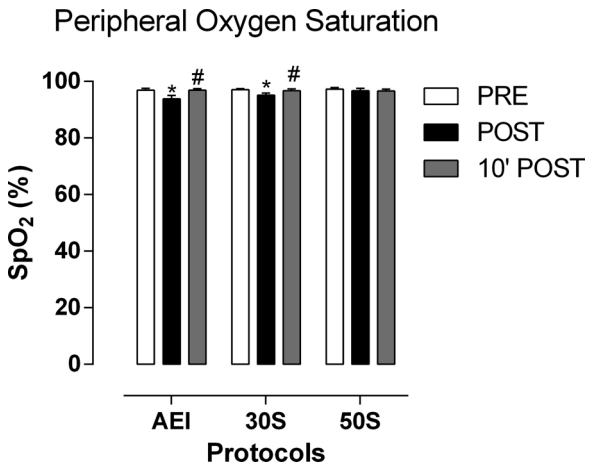

Fig. 4. Peripheral oxygen saturation (SpO2) variability for study subjects before (PRE), immediately after (POST) and 10 min after (10' POST) the application of different protocols. 30S: MI-E protocol with pressures of -30/+30 cmH_2O followed by endotracheal suctioning, 50S: MI-E protocol with pressures of -50/+50 cmH_2O followed by endotracheal suctioning, IES: Isolated endotracheal suctioning protocol (*p < 0.05 *vs* PRE; #p < 0.05 *vs* POST).

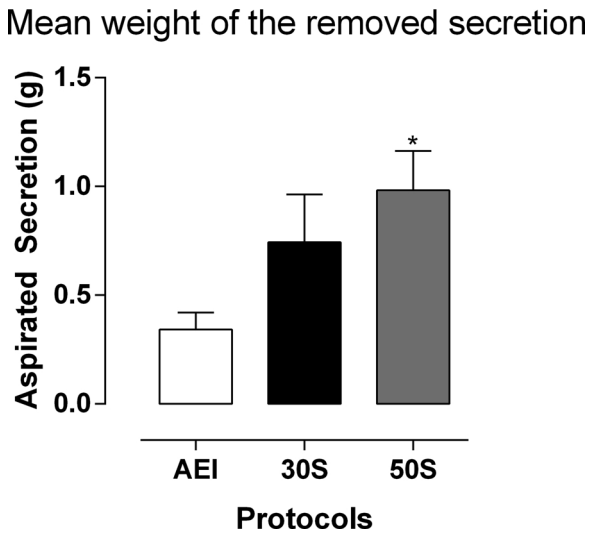

Fig. 5. Amount (g) of removed secretion from study subjects after application of different protocols. 30S: MI-E protocol with pressures of -30/+30 cmH_2O followed by endotracheal suctioning, 50S: MI-E protocol with pressures of -50/+50 cmH_2O followed by endotracheal suctioning, IES: Isolated endotracheal suctioning protocol (*p < 0.05 *vs* PRE).

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