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Research paper

Effect of minimally invasive endotracheal tube suctioning on physiological indices in adult intubated patients: An open-labelled randomised controlled trial

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ABSTRACT

Background: Endotracheal tube suctioning (ETS) is one of the most frequent procedures performed by nurses in intensive care units. Nevertheless, some suctioning practices are still being performed that do not provide any benefit for patients.
Objectives: To investigate the effects of minimally invasive ETS (MIETS) versus routine ETS (RETS) on physiological indices in adult intubated patients.
Methods: In this single centre parallel randomised controlled, open label trial, 64 adult intubated patients in the four intensive care units of Alzahra University hospital, Isfahan, Iran, were randomly allocated to a MIETS or a RETS group. Physiological indices including systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, and peripheral oxygen saturation were assessed immediately before, immediately after, and 10 min after ETS in both groups. The chi-square test, independent t-test, and repeated measures analysis of variance were used to analyse the data.
Results: Sixty-four patients were randomised and analysed. There were no significant differences in mean heart rate between the both groups across the three time points. However, there was a significant drop in peripheral oxygen saturation across the three time points in the RETS group compared to the MIETS group. Furthermore, there was a significant increase in systolic blood pressure, diastolic blood pressure, and mean arterial pressure across the three time points in the RETS group compared to the MIETS group.
Conclusion: The results of this study indicate that the use of MIETS has less effect on the alterations of physiological indices and consequently fewer adverse effects than RETS.

1. Introduction

Endotracheal tube suctioning (ETS) is required in patients undergoing mechanical ventilation to maintain a patent airway to prevent hypoxia, pulmonary infections, blockage of the airway, and atelectasis from retention of accumulated pulmonary secretions.[1–3] However, it can potentially lead to complications such as hypoxaemia, airway mucosal trauma, pain, pneumonia, fluctuations in physiological indices, bronchoconstriction, atelectasis, and increase in intracranial pressure.[1,4,5]

The most common complication associated with ETS is hypoxaemia.[6] During suctioning, heart rate (HR) and blood pressure (BP) may be affected due to acute hypoxaemia, airway stimulation, and coughing.[7] Conflicting findings have been reported regarding

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changes in BP, HR, and arterial oxygenation.[8,9] One study indicated no significant changes in BP and HR,[2] while other studies have shown significantly lower incidence of increased HR,[10] BP,[3,5] and drop in oxygen saturation levels[1,10] in minimally invasive ETS (MIETS) versus routine ETS (RETS).

Because of the severe adverse complications associated with ETS, it is one of the most important responsibilities of the nurses working in the intensive care units (ICUs) to ensure that it is carried out in the best possible way.[11,12] Nevertheless, some suctioning practices are still being performed regardless of evidence that indicates that they are of no benefit.[13,14] Studies have shown that invasive techniques such as hyperinflation using a manual resuscitator bag[1,4] and instillation of normal saline solution via the endotracheal tube prior to suctioning[2,6,15] do not facilitate removal of airway secretions during ETS. However, these techniques are routinely implemented in some ICUs.[13,14]

Furthermore, there are significant inconsistencies regarding the negative pressure chosen by nurses performing ETS.[16] There is, however, no clinical study that indicates an exact maximum pressure to be applied during ETS.[4] In the literature, acceptable levels of negative pressure vary between 80 and 170 mmHg.[6] However, a meta-analysis indicates that a negative pressure of 80–120 mmHg is commonly used during ETS.[17] There are also inconsistencies regarding the depth of catheter insertion during ETS. Some studies recommended that the suction catheter should be inserted to the carina and retracted 1–2 cm before applying suction.[4,14] While other studies have recommended using shallow suctioning, in which the suction catheter is inserted to the length of endotracheal tube.[1,4,6] Some systematic reviews of ETS shows that manual hyperinflation, installation of normal saline, high negative pressure, and deep ETS result in alterations in HR and BP and a decrease in oxygen saturation.[4,10,14]

Although several studies on ETS procedures have been published, most of them have investigated the effect of one single intervention, such as ETS with and without normal saline,[18] closed suctioning versus open suctioning,[19] or shallow suctioning versus deep suctioning.[1,12] We have developed a MIETS procedure that combines the best current research evidences related to ETS (using shallow suctioning, lowest negative pressure, avoiding installation of normal saline, and manual hyperinflation) that potentially will prevent complications of ETS, ensuring safer suctioning practices and improved standards of care. Moreover, Shamali et al.[20] has shown that using MIETS caused a lower incidence of airway traumatisation and lower suction-related pain in short-term. Therefore, the aim of the present study was to investigate the effects of the MIETS versus the RETS procedure on physiological indices in adult intubated patients.

2. Materials and methods

2.1. Study design and participants

This study was a single centre parallel randomised controlled, open label trial conducted from March to August 2015. Participants were recruited from adult patients admitted to the four ICUs of Alzahra University hospital, Isfahan, Iran. The four ICUs consisted of one surgical ICU (8 beds), two trauma ICU (23 and 20 beds), and one medical ICU (23 beds). Patients who met the inclusion criteria and gave written consent were consecutively enrolled in the trial. These patients were then randomly allocated to an experimental group, MIETS, or a control group, RETS. To ensure allocation concealment, a central randomisation unit was contacted by phone to assign the enrolled patient to experimental group or control group. The central randomisation unit had prepared a list of numbers from 1 to 64 that were allocated randomly to two equal groups by using a computer-generated list of random numbers in two columns. Before randomisation, the first column was considered the MIETS group and the second column the RETS group.

The sample size was based on a power analysis for repeated-measures ANOVA with three measurements and a medium effect size ($F = 0.23$) to achieve a power of 0.80 and $\alpha = 0.05$. Statistical power analysis was performed using the G*Power 3.1.9.2 program.[21] In G*Power, "F-tests" were selected with "analysis of variance, repeated measures, within–between interaction" in two groups and three measurements. Thus, 64 patients should be included in the study, 32 in the MIETS group (experimental) and 32 in the RETS group (controls).

The inclusion criteria were age over 18 years, intubation and mechanical ventilation for more than 24 h and less than 2 weeks, Positive end-expiratory pressure (PEEP) of 5 cm H_2O on mechanical ventilation's mode, an open suction system, no evidence of chronic respiratory disease, agreement of the patient or their relatives to participate in the study, and absence of cardiac arrhythmia and dysrhythmia. Patients were excluded if they refused to remain in the study, the endotracheal tube was removed during the study, or the patient's condition deteriorated (bradycardia: HR < 60 beats per minute, arrhythmia, cyanosis, and extreme loss of arterial oxygen: SpO_2 < 86%).

2.2. Data measurement form and collection procedure

A measurement form was developed for data collection. The first part included demographic and clinical information: age, sex, patient's diagnosis, duration of intubation, numbers of suctioning episode, and mode of mechanical ventilation. The second part included measurements of the physiological indices assessed immediately before, immediately after, and 10 min after ETS. Physiological indices were defined as systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), HR, and peripheral oxygen saturation (SpO_2). Measurement of physiological indices was performed using the vital signs monitoring system (Alborz B9 monitor, Saadat Co., Tehran, Iran). Oxygen saturation was measured continuously by pulse oximetry. A non-invasive BP cuff was used to measure SBP, DBP, and MAP. Continuous cardiac monitoring was used to acquire beat-to-beat HR data by surface electrocardiographic electrodes. This data measurement form was developed based on the relevant literature, and its content and face validity were confirmed by eight faculty members at the Isfahan University of Medical Sciences, Isfahan, Iran.

The first author, MS, was present in the ICUs every day and randomly allocated the enrolled patients to the MIETS or RETS groups by telephoning the allocation centre. Before suctioning, second author, MA, extracted demographic and clinical information from the hospital records and entered it into the first part of the data measurement form. Then, in the second part of the form, data immediately before, immediately after, and 10 min after the ETS were recorded. To do this, we evaluated the patients' requirement for ETS by physical assessment including auscultation and palpation of the chest, presence of coarse crackles over the trachea, and/or a sawtooth pattern on the flow-volume loop on the monitor screen of the ventilator. ETS was performed using the MIETS procedure in the experimental group and the RETS procedure in the control group. MS performed all endotracheal tube suctioning procedures, and MA measured and recorded data needed in the data measurement form.

2.3. Interventions

Open ETS was performed in both groups with a suction catheter that was half of the internal diameter of the endotracheal tube.[4,6] After each suctioning of the endotracheal tube, the patient's

airway was assessed with a stethoscope to ensure effective cleaning. If the airway secretions were not cleaned properly, ETS was performed again for 10 s up to a maximum of three times,[6,14] at an interval of 3 min.[4] Data were measured and recorded only in respect to the first suctioning.

In the RETS group, after disconnecting the patients from the ventilator, manual hyperoxygenation and hyperinflation were carried out for 1 min.[4] Then a suction catheter with an adequate length was introduced into the endotracheal tube until resistance was met (reached the carina), after which it was retracted 1 cm,[6,14] and a negative pressure (100–200 mmHg)[4] was applied for a maximum of 10 s while removing the catheter. Manual hyperinflation was applied between the cycles of suctioning. Before each suctioning, 8 ml of sterile normal saline solution was instilled.[6]

In the MIETS group, patients were hyperoxygenated by ventilator for 1 min. A suction catheter appropriate to the length of endotracheal tube was made by marking on a catheter with a sterile device. Hence, it was impossible to touch the trachea or bronchi with the suction catheter. Then, the patient was removed from the ventilator and the marked suction catheter with the appropriate length was introduced into only the end of the endotracheal tube, and a negative pressure (80–120 mmHg)[4] was applied for a maximum duration of 10 s while removing the catheter. Manual hyperinflation, hyperoxygenation, and installation of normal saline were not applied in this group.

2.4. Ethical considerations

This study was performed in accordance with the Declaration of Helsinki (1964) and approved by the Ethics Committee of Isfahan University of Medical Sciences (No: 294003). Also, the recorded code in the registration centre of clinical trials is IRCT2015072423314N1. The required permissions were obtained from the hospital and the wards authorities. All patients/relatives were informed about the aim and the length of the study, and a written informed consent was obtained from all study participants. If the patient was not able to give written consent, his/her closest relative was informed and asked for consent.

2.5. Data analysis

All analyses were performed using the IBM SPSS Statistics (version 22). For all statistical analysis, the significance level was $p < 0.05$. The chi-square test and the independent t-test were used to compare demographic and clinical characteristics between the two groups. RMANOVA was used to evaluate changes in SBP, DBP, MAP, HR, and SpO_2 at three time points (immediately before, immediately after, and 10 min after the ETS) in each group and the interaction between the two groups and time. The Mauchly test of sphericity was conducted to test the homogeneity of variance between conditions. If the Mauchly test was significant ($p < 0.05$), the F ratio was corrected using the Greenhouse–Geisser (if $e < 0.75$) or the Huynh–Feldt (if $e > 0.75$) corrections.

3. Results

3.1. Patient characteristics

In the present study, 64 patients were studied, 32 in the MIETS group and 32 in the RETS group (Fig. 1). The mean ages of the

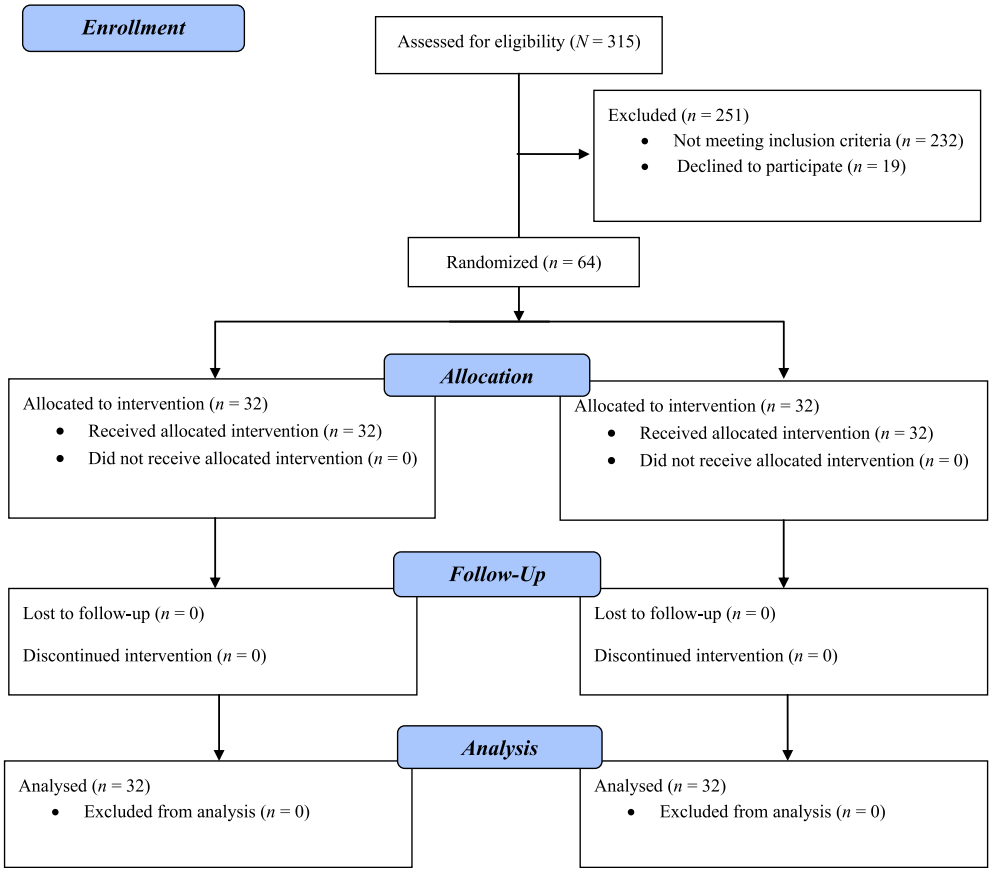

Fig. 1. The study consort flow diagram.

patients in the MIETS and RETS groups were 49.06 and 45.46 years, respectively. Men comprised 68.8% of the patients in the MIETS group and 78.1% of the patients in the RETS group. Trauma was the main diagnosis in both groups, 50% in the MIETS group and 46.9% in the RETS group. The mean hours of intubation were 54.68 in the MIETS group and 60.81 in the RETS group. For most of the patients in both groups, one suction procedure was sufficient to effectively clear the airway, 71.9% in the MIETS group and 78.1% in the RETS group. In addition, the most frequent mode of ventilation was synchronised intermittent mandatory ventilation, 46.9% in the MIETS group and 53.1% in the RETS group. Chi-square and independent *t*-tests showed that there were no significant differences in demographic or clinical characteristics between the two groups ($p > 0.05$; Table 1).

3.2. Effects on heart rate

Compared to baseline values both techniques led to an increase in mean HR immediately after ETS, with largest increase immediately after ETS in the RETS group, followed by a decrease 10 min after ETS. RMANOVA within each group showed a statistically significant difference in mean HR across the three time points in the MIETS group [$F\,(2, 64) = 12.207$; $p < 0.001$; Table 2] and the RETS group [$F\,(2, 64) = 9.753$; $p < 0.001$; Table 2]. But, the interaction between mean HR in the two groups and time failed to reach statistical significance [$F\,(2, 124) = 0.230$; $p = 0.795$; Table 2].

3.3. Effects on oxygen saturation (SpO_2)

Compared to the baseline values both techniques led to a decrease in SpO_2 immediately after ETS, with largest decrease immediately after ETS in the RETS group, followed by an increase 10 min after ETS. RMANOVA within each group showed a statistically significant difference in the SpO_2 across the three time points in the MIETS group [$F\,(2, 64) = 24.997$; $p < 0.001$; Table 2] and the RETS group [$F\,(2, 64) = 13.358$; $p < 0.001$; Table 2]. In addition, there was a statistically significant interaction between mean SpO_2 in the two groups and time [$F\,(2, 124) = 9.247$; $p = 0.003$; Table 2].

Table 1
Patients' demographic characteristics.[a]

Characteristics	MIETS	RETS	*p* value	TEST
Sex			0.396[b]	0.721[b]
Male	22 (68.8)	25 (78.1)		
Female	10 (31.3)	7 (21.9)		
Age, y	49.06 ± 15.95	45.46 ± 17.32	0.391[c]	0.863[c]
Patient's diagnosis			0.852[b]	0.321[b]
Trauma	16 (50)	15 (46.9)		
Medical	8 (25)	7 (21.9)		
Surgical	8 (25)	10 (31.2)		
Duration of intubation, h	54.68 ± 20.42	60.81 ± 24.79	0.285[c]	−1.07[c]
Modes of mechanical ventilation			0.854[b]	0.783[b]
SIMV	15 (46.9)	17 (53.1)		
CPAP	12 (37.5)	10 (31.2)		
AC	2 (6.2)	1 (3.1)		
Other	3 (9.4)	4 (12.5)		
Number of suctioning episodes			0.387[b]	0.333[b]
Once	23 (71.9)	25 (78.1)		
Twice	9 (28.1)	7 (21.9)		

y = year; h = hour; SIMV = synchronised intermittent mandatory ventilation; CPAP = continuous positive airway pressure; AC = assist control; MIETS = minimally invasive endotracheal tube suctioning; RETS = routine endotracheal tube suctioning; SD = standard deviation.
[a] Data are presented as No. (%) or mean ± SD.
[b] The results of chi-square test.
[c] The results of independent *t*-test.

Table 2
Physiological indices in the experimental (MIETS) and control (RETS) groups immediately before, immediately after, and 10 min after the endotracheal tube suctioning.[a]

Variable	Immediately before	Immediately after	10 min after	RMANOVA[b]
HR				
Experimental group	90.65 ± 14.70	94.00 ± 13.63	92.65 ± 13.59	$P^d < 0.001$, $F = 12.207$
Control group	91.78 ± 16.13	95.81 ± 15.60	94.46 ± 15.79	$P^d < 0.001$, $F = 9.753$
RMANOVA[b]	$P^c = 0.795$ $F = 0.230$			
SpO_2				
Experimental group	98.71 ± 0.07	97.12 ± 1.49	97.21 ± 1.23	$P^d < 0.001$, $F = 24.997$
Control group	97.75 ± 1.27	95.78 ± 2.51	96.62 ± 2.04	$P^d < 0.001$, $F = 13.358$
RMANOVA[b]	$P^c = 0.003$ $F = 9.247$			
SBP				
Experimental group	121.34 ± 15.82	123.65 ± 16.40	120.34 ± 16.32	$P^d = 0.341$, $F^e = 1.058$
Control group	126.81 ± 13.98	138.93 ± 16.58	133.96 ± 17.53	$P^d < 0.001$, $F = 10.278$
	$P^c = 0.002$ $F = 10.881$			
DBP				
Experimental group	73.71 ± 14.55	75.00 ± 13.20	70.65 ± 8.98	$P^d = 0.087$, $F = 2.536$
Control group	74.75 ± 11.62	82.25 ± 13.04	81.96 ± 16.24	$P^d = 0.003$, $F = 6.434$
RMANOVA[b]	$P^c = 0.021$ $F = 5.602$			
MAP				
Experimental group	90.31 ± 14.74	89.43 ± 13.13	89.37 ± 12.86	$P^d = 0.664$, $F^e = 0.412$
Control group	93.56 ± 10.66	102.09 ± 14.28	100.56 ± 16.04	$P^d < 0.001$, $F = 10.813$
RMANOVA[b]	$P^c = 0.003$, $F = 9.764$			

MIETS = minimally invasive endotracheal tube suctioning; RETS = routine endotracheal tube suctioning; HR = heart rate; SpO_2 = blood oxygen saturation; SBP = systolic blood pressure; DBP = diastolic blood pressure; MAP = mean arterial pressure; SD = standard deviation.
[a] All data are presented as mean ± SD.
[b] Repeated measures analysis of variance.
[c] Interaction between groups and time.
[d] Values changes within groups.
[e] Significant Mauchly's test of sphericity ($p < 0.05$, $e > 0.75$; Huynh–Feldt corrections of *F* ratios were performed).

3.4. Effects on blood pressure

With respect to the SBP, as compared to the baseline values, both techniques led to an increase in SBP immediately after ETS, with largest increase immediately after ETS in the RETS group. While 10 min after ETS, SBP values decreased in both groups. RMANOVA showed no significant difference in mean SBP changes across the three time points in the MIETS group [$F\,(1.660, 51.448) = 1.058$; $p = 0.341$; Table 2]. In contrast, mean SBP changes in the RETS group were statistically significant across the three time points [$F\,(2, 62) = 10.278$; $p < 0.001$; Table 2]. In addition, there was a statistically significant interaction between mean SBP in the two groups and time [$F\,(2, 124) = 10.881$; $p = 0.002$; Table 2].

With respect to the DBP, as compared to the baseline values both techniques led to an increase in DBP immediately after ETS, with largest increase immediately after ETS in the RETS group. While 10 min after ETS, DBP values declined in both groups. RMANOVA showed no significant difference in mean DBP changes across the three time points in the MIETS group [$F\,(2, 62) = 2.536$; $p = 0.087$; Table 2]. In contrast, mean DBP changes in the RETS group were statistically significant across the three time points [$F\,(2, 62) = 6.434$; $p = 0.003$; Table 2]. In addition, there was a statistically significant interaction between mean DBP in the two groups and time [$F\,(2, 124) = 5.602$; $p = 0.021$; Table 2].

With respect to the MAP, as compared to the baseline values, there was an increase in MAP immediately after ETS in the RETS group and a decrease 10 min after ETS. While in the MIETS group, there was a decrease in MAP immediately after ETS and 10 min after ETS. RMANOVA showed no significant difference in mean MAP changes across the three time points in the MIETS group [F (1.767, 54.764) = 0.412; p = 0.664; Table 2]. In contrast, the mean MAP changes in the RETS group were statistically significant across the three time points [F (2, 62) = 10.813; $p < 0.001$; Table 2]. In addition, there was a statistically significant interaction between mean MAP in the two groups and time [F (2, 124) = 9.764; p = 0.003; Table 2].

4. Discussion

The main finding in this study is that there were several statistically significant differences in mean SBP, DBP, MAP, and SpO_2 across three time points in patients undergoing MIETS compared with RETS. In contrast, we found no significant differences between the two groups with regard to mean HR across the three time points.

Mean HR in the present study was significantly increased in both groups, especially immediately after ETS, but the differences between the groups were not significant. Hence, both MIETS and RETS had a similar effect on HR during and after ETS. In line with our study, Irajpour et al.[8] reported a significant increase in HR after both deep and shallow ETS, but without significant differences between the two groups. Jongerden et al.[9] also showed a significant increase in mean HR immediately after the ETS. Moreover, the results of two other studies showed no significant differences in HR responses between two groups of infants undergoing deep or shallow ETS.[22,23] ETS is thought to increase HR because of mechanical stimulation from the catheter and the pain and stress experienced by patients during the procedure.[19]

In this study, we found a statistically significant decrease in SpO_2 in patients undergoing RETS compared to MIETS. Similarly, a systematic review study[5] and a randomised clinical trial[1] showed that MIETS, compared to RETS, results in fewer adverse effects such as a drop in oxygen saturation levels. In contrast, some studies indicated no significant differences in SpO_2 when shallow and deep suctioning methods were compared.[12] Furthermore, the statistically significant drop in SpO_2 (1.97% in RETS) may be considered as clinically insignificant in some patients. However, when SpO_2 ranges from 90% to 100%, according to the oxyhaemoglobin dissociation curve, 1% reduction in SpO_2 results in decrease of PaO_2 by 4 mmHg,[24] which may be considered as a clinically important in some critically ill patients. A decrease in SpO_2 is assumed to be a common event after ETS.[9] Hypoxaemia has been reported as the most frequent adverse complication of ETS,[4] and preoxygenation is recommended prior to ETS in all patients.[14] A meta-analysis showed that the use of hyperoxygenation declined the rate of suction-induced hypoxia by 30%.[17] The statistically significant drop in SpO_2 in association with RETS compared to the MIETS may be attributed to the instillation of normal saline prior to ETS in the RETS group. Some studies showed patients receiving a bolus of normal saline before ETS suffered a much greater fall in SpO_2.[2,25,26] Another contributing factor may be the manual hyperoxygenation used in the RETS group. Hyperoxygenation by mechanical ventilator has been reported to be more effective than the manual resuscitator bag in controlling hypoxaemia in ETS.[14]

The present study showed a statistically significant increase in SBP, DBP, and MAP in patients in the RETS group compared to those in the MIETS group. Consistent with the current study's results, a systematic review study[5] and a randomised clinical trial[1] showed that RETS, compared to MIETS, results in a significant increase in SBP. Hyperinflation with manual resuscitator bag has been shown to increase significantly the MAP.[14] In addition, the high negative pressure and deep ETS in RETS may also affect BP. More tracheal stimulation in RETS leads to severe cough, resulting in increased intra-thoracic and intra-abdominal pressures, and accordingly, increases cardiac output and left ventricular load and elevates BP.[19] The tracheal stimulation may also cause a significant imbalance in autonomic modulation of HR (decrease in parasympathetic efferent activity with/without increased sympathetic efferent activity) and consequently may contribute to the increase in HR and BP during ETS.[7]

Regarding the implications for the clinical practice, it is important to consider our results that are statistically significant as also clinically important in some patients. For example, alterations in BP are clinically important in the patients with increased intracranial pressure as well as decreases in SpO_2 in the patients with acute respiratory distress syndrome. These patients are particularly susceptible to the slight changes of the haemodynamic parameters. Therefore, it seems that MIETS is safer practice in patient who needs meticulous control of BP or SpO_2. We have changed practice in our ICUs to use MIETS. However, in very rare cases, because of the large amounts of secretions in the lower airways, deep ETS was inevitable. Therefore, prospective studies are recommended to investigate further the impact of MIETS in long-term on patient outcomes.

This study has several limitations. First, the results of our study can only be applied to the type of patient and ETS methods we studied, and they should be generalised with caution to other type of patients and different methods of ETS such as close suction system. Furthermore, the study was a single centre trial; therefore, the findings may not be broadly applicable. Accordingly, a large multicentre trial is recommended. In addition, the study could not be blinded, either from the patient or the researcher. Finally, we only measured the physiological indices during the first episode of ETS, and data were not measured if ETS was performed again for second time. This might be a potential source of bias.

5. Conclusion

The results of our study demonstrate that the use of MIETS versus RETS in adult intubated patients caused less alteration in SBP, DBP, MAP, and SpO_2, but not in HR, both immediately after ETS and 10 min after ETS. Presumably, these differences are due to less physical stimulation, lower negative pressure, no installation of normal saline, and no use of manual hyperoxygenation and hyperinflation in the MIETS group.

Clinical trial registration number

The study was registered in Iranian Registry of Clinical Trials (www.irct.ir) with following number: IRCT2015072423314N1.

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Authors' contribution

Mahdi Shamali contributed to study concept and design; Mahdi Shamali and Mohammad Abbasinia contributed to acquisition of data; Mahdi Shamali, Mohammad Abbasinia, Birte Østergaard, and Hanne Konradsen contributed to analysis and interpretation of

data, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted.

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