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Effect of Positioning on the Pressure of Endotracheal Tube Cuff Filled with Air versus Saline: A Double-blind Randomized Clinical Trial

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Abstract

Background: Control and maintenance of endotracheal tube cuff pressure and prevention of sore throat are major concerns in post-anesthesia care.

Aim: This study aimed to evaluate changes in the pressure of the endotracheal tube cuff filled with saline versus air and post-anesthesia sore throat when the position is altered from supine to lateral.

Method: This double-blind randomized clinical trial was performed on 60 participants under lateral hip replacement surgery in an educational, research, and treatment center in the northeast of Iran in 2018-2019. After intubation, the cuffs of the intervention and control groups were filled with saline and air, respectively. Cuff pressures and Visual Analog Scale of sore throat were measured and analyzed using repeated measures ANOVA and Pearson's correlation coefficient in SPSS software, version 20.

Results: The mean ages of the participants in the intervention and control groups were 45.8±11.6 and 40±13.1 years, respectively. Changes in the cuff pressure of different time points were statistically significant in both intervention (P=0.03) and control (P=0.02) groups. Based on the results of the independent sample t-test, the pain score was significantly different between the intervention (0.1±0.4) and control (1.1±2.1) groups 12 h post-surgery (P=0.01). The results of the Pearson's correlation coefficient revealed a significant association between the pain score 12 h post-surgery and pressure difference of the fifth and first stages in the control group (r=0.585, P=0.001). In addition, the 12-h pain score and the pressure difference of the fifth and fourth stages were also significantly correlated in the control group (r=0.479, P=0.01).

Implications for Practice: Based on the findings, in the lateral-position hip surgery, the use of saline to fill the endotracheal tube cuff could lead to better control of cuff pressure and may also reduce the postoperative sore throat.

Keywords: Intubation, Patient positioning, Sore throat

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Introduction

A tracheal tube is applied to manage the airways of patients in the intensive care unit and operation room (1, 2). One of the consequences of tracheal tubes is the elevation of cuff pressure, which can damage the tracheal mucous. Moreover, position change can influence the augmentation of endotracheal tube (ETT) cuff pressure in intubated patients that is unavoidable depending on the needs of patients or operation type (2, 3).

Various studies showed that patients intubated for longer periods suffer from more ETT cuff-related sequels, such as sore throat, tracheal stenosis, and fistula (4). Evaluations by optic fiber revealed a correlation between damage to the tracheal mucus and sore throat. According to the literature, the first sign of the relationship between the high pressure of ETT cuff and injury to the tracheal mucous is sore throat (3, 5, 6).

Diverse investigations have noted that the ETT cuff pressure should be 20-30 cmH_2O. In case this pressure exceeds 30 cmH_2O, the tracheal mucous gets injured as a result of pressure on capillary perfusion. Moreover, a pressure of above 50 cmH_2O leads to complete tracheal obstruction causing tracheal rupture or hemorrhage in some cases (4, 6, 7). On the other hand, not filling the ETT cuff sufficiently (i.e., 20-30 cm H_2O) makes the patient vulnerable to the aspiration condition of secretions, which may result in pneumonia (4, 6, 8).

In a study, it was reported that the risk of ventilator-associated pneumonia might be related to the ETT cuff pressure of lower than 20 cmH_2O (4). Furthermore, some studies recommend the ETT cuff pressure of 20-34 cmH_2O for reducing the consequences of intubation after the surgery (5). The ETT cuff pressure is associated with several factors, namely environmental and therapeutic conditions, which depend on the patient (3, 4, 9).

Any changes in the ETT cuff pressure may depend on the rate of tracheal tube movements (7). Numerous studies have demonstrated that alteration in head position results in a change in tracheal tube location. In addition, the altered position of the patient body causes a significant change in the ETT cuff pressure. In a study addressing laparoscopic surgeries, the ETT cuff pressure elevated in the Trendelenburg position (4, 10).

A shift in the position of the head and neck in the supine position leads to the transposition of ETT. The prone position with a protective pillow for the face, along with the rotation of the head and neck, results in head flexion. Therefore, the movement of the ETT in changing position from supine to prone might cause more sequels. Accordingly, the results of a study performed in 2013 indicated that position alteration from supine to prone resulted in the shift of the tracheal tube and raised the ETT cuff pressure (7).

Another investigation investigated position change from supine to prone revealed that despite the lack of change in the angle between the head and neck, the ETT cuff pressure augmented (8). In a study carried out by Lizy et al., the change of patient position from supine to right lateral was associated with a significant increase in ETT cuff pressure; however, this increase was not significant in the left lateral position (4). Some studies have addressed ETT cuff filled with saline instead of air. These investigations showed a decrease in post-surgical sore throat when using saline instead of air (3, 11). However, N_2O was used to maintain anesthesia in these patients, which may leak into the ETT cuff resulting in an increase in the ETT cuff pressure (3, 12).

To the best of our knowledge, no study in the literature has targetted simultaneously the pressure of ETT cuff, either filled with air or saline, and sore throat in patients undergoing hip replacement surgery with the lateral approach and total intravenous anesthesia for maintenance. We attempted to prevent the reduction or elevation of cuff pressure to more than the standard level. Moreover, this study involved the assessment of the impact of filling cuff with saline on the prevention of sore throat in patients under hip replacement surgery with position change from supine to lateral.

Methods

This double-blind clinical trial was designed based on the CONSORT 2010 guideline. The sampling was completed from 2018-04-30 to 2019-06-02 in the central operation room of an educational, research, and treatment center in the northeast of Iran. The minimum sample size was calculated using the formula of "comparing two independent society" considering ETT cuff pressure as the main variable in the third time point of the pilot study (33.6±7.7 and 27.6±6.8 in the intervention and control groups, respectively). As a result, the sample size was estimated at 23 cases in each group

with a confidence level of 95% and a power of 80%. Considering the possible attrition rate, 33 patients were enrolled in each group.

Therefore, a total of 66 intubated participants who underwent hip replacement surgery under general anesthesia at the lateral position were selected and equally randomized into two groups of intervention and control. The first patient referred was randomly assigned to one group based on tossing coins. Subsequently, every other participant was assigned to one group until the completion of the sampling. The participants and statisticians were blind to the intervention.

The inclusion criteria entailed: 1) no history of surgery or acute and chronic diseases in the pharynx and jaw regions, 2) consciousness, 3) non-intubation at the onset of the study, 4) lack of sore throat in the last 2 weeks, 5) American Society of Anesthesiologists (ASA) classification of < Ⅲ, 6) lateral surgery position, and 7) absence of drug allergy affecting general anesthesia. On the other hand, the exclusion criteria were the Mallampati score of 3 or 4 and the intubation duration of > 20 sec.

Before the trial commencement, all participants were given oral instructions, and a predesigned informed consent was obtained. The cuffs of the intervention and control groups were filled with saline and air until reaching the pressure of 30 cmH_2O after intubation at the supine position, respectively. Afterward, the adjusted cuff pressure was recorded, along with other checklist variables. The checklist for each participant was completed during the course of surgery and included demographic characteristics, participant weight, participant height, operation duration, and position.

The ETT cuff pressure was measured and recorded in five steps, namely immediately after intubation at the supine position, before changing the position to lateral, immediately after changing the position to lateral, 60 min after changing the position to lateral, and immediately after changing the position to supine. In order to measure and adjust the ETT cuff pressure with air, the VBM cuff pressure gauge (Universal model) was used. In addition, a disposable fluid pressure transducer (NORA brand, model CPT-01, Shenzhen Shunmei Medical Co.) was applied in the saline group for the same purpose.

Other symptoms and consequences, such as sore throat (measured based on the Visual Analog Scale by the participants), were assessed at recovery, as well as 12 and 24 h post-surgery, at the department. Ten faculty members of the Department of Anesthesiology and Critical Care, Mashhad University of Medical Sciences, Mashhad, Iran, explored and approved the content validity of these forms. Agreement among observers was calculated using the Cronbach's alpha coefficient to assess the reliability of the entry forms (r=0.81).

The participants were subjected to general anesthesia with propofol, midazolam, atracurium, and fentanyl, followed by the administration of propofol and remifentanil for maintenance. The medications were prescribed based on the weight of the participants at a standard dose. Tracheal tube sizes 8 and 7.5 were applied for men and women, respectively.

The ETT cuffs were of high-volume, low-pressure type. The intubation of the subjects was accomplished using a metal Macintosh laryngoscope blade by a sufficiently skilled person, who was blind to group allocation. The tracheal tube was supported by the anesthesia group during position changing to prevent translocation. Following the operation and the return of spontaneous respiration, the suction on airways was performed cautiously and without causing trauma. Afterwards, the participants were extubated at deep anesthesia. Throughout the trial, 66 patients were followed and analyzed; however, six of them were lost to follow up due to not meeting the inclusion criteria (e.g., ASA classification, duration of the intubation, and body mass index [BMI]).

All data were presented as mean±SD and percentage. The statistical analysis was performed using the descriptive statistics, Kolmogorov-Smirnov, and Shapiro-Wilk tests (to determine the normality of the variables), Chi-square test, Mann-Whitney U, independent t-test, repeated measures ANOVA, and Pearson’s linear correlation. All analyses were carried out in the SPSS software, version 20 (SPSS Inc., Chicago, IL, USA). A p-value less than 0.05 was considered statistically significant.

Results

According to the results, the mean ages of the participants in the intervention and control groups were 45.8±11.6 and 40±13.1 years, respectively. Moreover, the intervention and control groups had the BMIs of 24.1±3.9 and 23.9±2.9, respectively. With regard to the gender, 66.7% and 63.3% of the participants in the intervention and control groups were male, respectively.

The results of the Chi-square test revealed no significant difference between the two groups in terms

of gender (P=0.70). In addition, based on the Mann-Whitney U test, the two groups were not significantly different regarding BMI (P=0.95) and age (P=0.06). Table 1 summarizes the characteristics of the studied participants, including the types of analgesics, time of administering the analgesics, kind of surgery, and time of surgery.

We found in the study that the mean pressures of ETT cuffs measured during five time points in the two groups with repeated measures ANOVA test, P-value = 0.08 but in Intra-group comparison with Repeated measures ANOVA test the result was P-value=0.02 and P-value= 0.03 in the control and intervention groups, respectively. Figure 1 depicts the mean pressure at five time points in the two groups of the intervention and control.

Table 1. Characteristics of research participants

Variables	Group		P-value (between groups)
	Intervention N=30	Control N=30	
	Mean±SD	Mean±SD	
Age	45.8±11.6	40±13.1	0.06**
Body mass index	24.1±3.9	23.9±2.9	0.95**
Time of analgesic injection after surgery	2.5±6.4	1.5±4.7	0.49**
Surgical time (min)	173.7±32.4	168.7±45.7	0.68**
Time of analgesic injection after surgery	3.5±3	5±5.9	0.58**
Gender			0.70*
Male	20 (66.7)	19 (63.3)	
Female	10 (33.3)	11 (36.7)	
Analgesic 1			0.58*
None	8 (26.7)	11 (36.7)	
Opioid analgesic	15 (50)	11 (36.7)	
Non-opioid analgesic	7 (23.3)	8 (26.6)	
Kind of surgery			0.88*
Right hip	14 (46.7)	15 (50)	
Left hip	16 (53.3)	15 (50)	
Analgesic 2			0.76*
None	24 (80)	25 (83.3)	
Opioid analgesic	3 (10)	3 (10)	
Non-opioid analgesic	3 (10)	2 (6.7)	

* Chi-square

** Mann-Whitney U

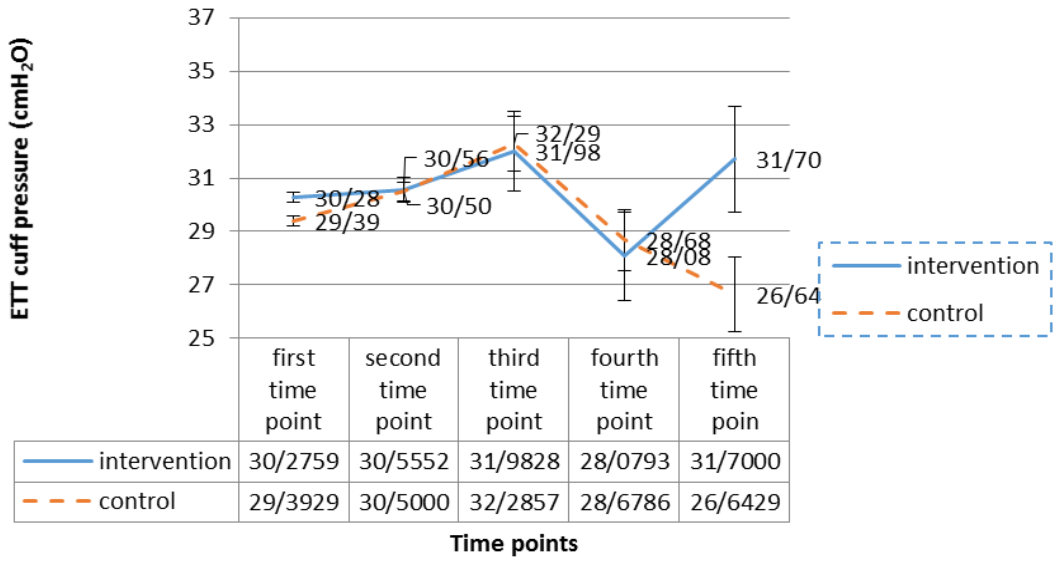
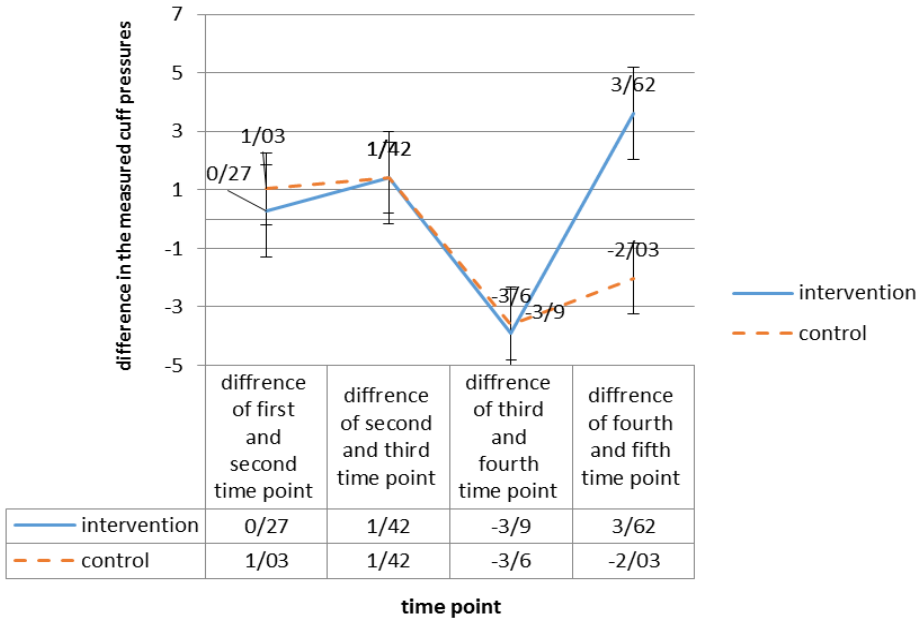


Figure 1. Line chart of the means of tracheal tube cuff pressures in five time points

Additionally, the mean values of difference for the measured pressures at five time points between the two groups of the intervention (0.2±2.6, 1.4±6.7, -3.9±8.4, and 3.6±7.8) and control (1.0±2.3, 1.4±7.3, -3.6±7.4, and -2.0±7.2) were calculated and subsequently analyzed with repeated measures ANOVA test (P=0.04; Figure 2)

Furthermore, the mean values of the sore throat scores during recovery, 12 h post-surgery, and 24 h post-surgery in the intervention group were estimated at 0.8±1.1, 0.1±0.4, and 0.03±0.1, respectively. Regarding the control group, these values were calculated as 2.0±3.0, 1.1±2.1, and 0.4±0.9, respectively. As the results of the repeated measures ANOVA indicated, the two groups were significantly different in this regard (P=0.04; Table 2).



	diffrence of first and second time point	diffrence of second and third time point	diffrence of third and fourth time point	diffrence of fourth and fifth time point
intervention	0/27	1/42	-3/9	3/62
control	1/03	1/42	-3/6	-2/03

Figure 2. Line chart of the means of the difference in the measured pressures during five time points in the two groups

Table 2. Comparison of sore throat post-surgery

Variables	Group				Inter-group p-value
	Intervention		Control		
	N	Mean±SD	N	Mean±SD	
Visual analog scale					0.04*
After surgery in recovery	30	0.8±1.1	30	2.1±3.1	0.05**
12 h after surgery	30	0.1±0.4	30	1.1±2.1	0.012**
24 h after surgery	30	0.03±0.2	30	0.4±0.1	0.041**
Intra-group p-value		0.002*		0.004*	
Multiple comparisons bonferroni correction					

Variables	Difference			P-value***
	Mean±SE	95% Confidence Interval		
		Lower Bound	Upper Bound	
Visual analog scale				
After surgery in recovery- 24 h after surgery	-0.9±.2	-1.4	-0.4	<.001
12 h after surgery - After surgery in recovery	-1.3±.2	-1.9	-0.7	<.001
24 h after surgery - 12 h after surgery	-0.4±.1	-0.7	-0.1	.005

* Repeated measure anova
** Independent t-test
*** Adjustment for multiple comparisons: Bonferroni.

Based on the results of the Pearson's correlation coefficient, a moderate correlation was observed between the difference of the pressure at the fifth and first time points and the sore throat scores 12 h after the surgery in the control group (r=0.58, P=0.001). No correlation, however, was found in the intervention group in this regard (P=0.43). Moreover, the correlation between the difference of the fifth and fourth pressure time points and the score of sore throats 12 h after the surgery was significant in the control group (r=0.47, P=0.01), while no such correlation was observed in the intervention group (P=0.55).

Discussion

As the findings of the current investigation indicated, the score of post-operative sore throat had a significant increase in the control group in comparison with that in the intervention group. Xavier et al. used isoflurane and N_2O for anesthesia maintenance and stated that the prevalence of sore throat in the air-filled cuff group was higher than in the saline group (3). Furthermore, Navvaro et al. compared the prevalence of sore throat between the two groups of air- and lidocaine-filled cuff, using isoflurane and N_2O for anesthesia maintenance. They revealed a higher prevalence of sore throat in the air group (13).

Moslem et al. evaluated the prevalence of sore throat in participants with ETT cuff filled with air versus saline in the supine position. They observed higher sore throat prevalence in the air group, compared to that in the saline group (11). They used N_2O for anesthesia maintenance while in our study, total intravenous anesthesia was applied for maintenance. This gas can raise ETT cuff pressure by accumulating in the cuff (12).

Regarding post-surgical sore throat and position change, Toshiyuki et al. reported that sore throat in changing the position from supine to prone is not related to the translocation of ETT (7). In spite of controlling the movement of ETT in the current study during position changing from supine to lateral, our results indicated an increase in the score of sore throat in the air group, compared to that in the saline group. To the best of our knowledge, no similar study has investigated the effect of changing the position from supine to lateral on the ETT cuff pressure and sore throat during lateral hip replacement surgery.

As mentioned earlier, our findings showed significant changes in ETT cuff pressure in the intragroup assessments. Considering the higher significant difference in pain score 12 h post-surgery, the correlation of this variable with pressure differences was examined in the two groups. The evaluations indicated that the correlation was significant for the pressure difference between the fifth and first stages, as well as between the fifth and fourth stages in the control group.

According to our results, pain score had a positive correlation with pressure changes in the control group. In addition, the ETT cuff pressure alterations in the control group during the five evaluated time points had a higher statistical difference, compared to those in the intervention group. Accordingly, it could be concluded that the use of air for filling ETT cuff leads to more changes in ETT cuff pressure during position changing from supine to lateral in comparison with saline usage. Furthermore, these changes in the ETT cuff pressure had a direct relationship with sore throat.

It should be noted that changes in ETT cuff pressure are different from elevation in ETT cuff pressure and may include decrease, increase, or both of these alterations in the procedure of evaluating ETT cuff pressure. No study was found to assess the relationship between changes in ETT cuff pressure and sore throat. Therefore, it is recommended to perform further investigations in this regard. Based on the results of the current study, the changes in the ETT cuff pressure were significant ($P<0.05$); however, these changes were more prominent in the control group than in the intervention group. Moreover, as could be observed in Table 2, the difference between the pressures of the two groups was statistically significant.

Alzahrani et al. indicated that both conditions of increase or decrease in the ETT cuff pressure are accompanied by some side effects, which should be taken into consideration. Elevated pressure might result in damage to the tracheal tissue, while diminished pressure can lead to the aspiration of the esophagus content to the trachea (6). The results of a study carried out by Hyun-Chang Kim et al. in 2015 revealed that change in the position from supine to lateral rises ETT cuff pressure (14).

Lizy et al. (2015) demonstrated that changing the position of a participant from supine to 90 degrees right lateral increased the ETT cuff pressure. However, these authors noted that changing the position to 90 degrees left lateral did not augment the ETT cuff pressure significantly. They believed that

anatomical differences between the participants could affect the ETT cuff pressure. Nonetheless, no possible reason has been mentioned for the significant elevation in pressure in the right lateral position, compared to that in the left one (4).

Deokkyu et al. showed that changing the position of a participant from supine to prone raised the ETT cuff pressure (8). On the other hand, Toshiyuki et al. reported that changing position from supine to prone reduced ETT cuff pressure. The increase or decrease in ETT cuff pressure due to position change might be attributed to the shift in the place of the cuff in the trachea (7).

In the present study, the anesthesia team performed the needed care to prevent the translocation of ETT during changing the position of the participants. Our evaluations were indicative of more significant alterations in ETT cuff pressure in the air group, compared to that in the saline group. As a result, it could be concluded that in longer surgeries, the risk of aspiration following reduced cuff pressure or tissue injury due to elevated ETT cuff pressure is higher in the air group than in the saline group. However, further investigations in the future are required for confirming this hypothesis.

Concerning the mean ETT cuff pressure, the results of the present study revealed no significant difference between the intervention and control groups in terms of the determined time intervals. Xavier et al. (2001) compared two groups of saline and air. They observed a significant increase in the pressure of air-filled cuff, compared to that in the saline group, which can be attributed to applying N_2O gas in the selected anesthesia method (3).

In the current study, N_2O gas was not utilized. This gas can raise ETT cuff pressure by accumulating in the cuff (12). Moreover, Nasiri et al. (2004) evaluated the change in the pressure of ETT cuff filled with air, lidocaine, and a mixture of oxygen and N_2O. They showed that the elevation in the ETT cuff pressure was lower in the lidocaine and mixture groups in comparison with that in the air group (9). In the mentioned study, N_2O was used for the maintenance of the participants. In the group of oxygen and N_2O mixture, the concentration of the utilized N_2O for filling the cuff was equal to that of the N_2O delivered to the participants for maintenance. Considering the maintenance method and the findings of this study, it is possible that if N_2O gas is not used for maintenance, the ETT cuff pressure will not elevate. Athiraman et al. noted the latter point in their study (12).

Implications for Practice

According to the results of this study, in the lateral-position hip surgery, the use of saline to fill the ETT cuff could better control cuff pressure. Moreover, it may reduce post-surgical sore throat.

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Conflicts of Interest

All authors have disclosed no conflicts of interest.

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