



The Effect of Softening of Endotracheal Tubes on the Decrement of Postoperative Hoarseness and Sore Throat

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Abstract

Background: Hoarseness, cough, and sore throat are the most prevalent complications after removing patients' endotracheal tube and general anesthesia. Various methods have been proposed to reduce these complications after intubation.

Objectives: The present study aimed to assess the effect of softening the endotracheal tube with normal warm saline on reducing post-intubation complications such as sore throat and hoarseness.

Methods: This double-blind, randomized controlled trial was performed on patients undergoing general anesthesia at Rasoul Akram and Firoozgar hospitals in Tehran, Iran. In the present study, 58 patients were randomly divided into 2 groups of 29 patients. All patients underwent the same premedication with fentanyl and lidocaine. Anesthesia was induced with propofol and atracurium. Three to 5 minutes after atracurium injection, the laryngoscopy test was performed. Randomly, some patients were intubated with a thermally softened endotracheal tube, and some were intubated with a normal tube. At the end of the operation, when the spontaneous breathing was adequate, and the patients could carry out oral instructions, the endotracheal tube was removed immediately after suctioning. All patients were evaluated for sore throat and hoarseness before discharge from recovery and 24 hours after surgery. The obtained data were analyzed using SPSS software package version 25.

Results: The mean incidence of sore throat in recovery in the intervention group (20.7%) decreased compared to the control group (75.8%). Moreover, the mean incidence of hoarseness in the intervention group (17.2%) decreased in comparison to the control group (41.4%, $P < 0.029$). Based on the data of our study, we observed that 24 hours after surgery, the mean incidence of sore throat among the patients of the intervention group was significantly lower compared to the control group, where patients in the intervention group did not feel any sore throat ($P < 0.002$). We also observed that 24 hours after surgery, the amount of hoarseness in the intervention group (3.4%) also decreased compared to the control group (24.1%, $P < 0.022$).

Conclusions: Based on the results, it can be concluded that thermal softening of the endotracheal tubes with normal warm saline before intubation could be significantly effective in decrement of sore throat and hoarseness during recovery and 24 hours after surgery.

Keywords: Intubation, Endotracheal Tube, Hoarseness, Sore Throat

1. Background

Endotracheal intubation is essential to control respiration and protect the airways under general anesthesia. Almost all intubated patients for a short time, or for a long time during surgery suffer from some degree of airway damage (1). Sore throat and hoarseness after surgery are common complications following endotracheal intubation and inflammation of the throat, larynx, and trachea (2). The incidence of sore throat in those who have been subjected to general anesthesia with intra-chip intubation has been reported between 14% and 50%, which often oc-

curs 12 to 24 hours after extraction of the tracheal tube and after 5 to 7 days, indicating the role of endotracheal intubation (3). Sore throat is a small complication but leads to patient dissatisfaction. Sore throat is the eighth undesirable complication after surgery for patients (4). Another common complication of endotracheal intubation is hoarseness. In one study, the prevalence of hoarseness was reported to be 11 to 19% in orthopedic surgery (5).

One of the important causes of hoarseness has been reported to be direct trauma to vocal cords and its inflammation caused by endotracheal intubation. It has been stated that intubation can even cause vocal cord paralysis (6). So

far, various drug and non-pharmacological methods have been used to reduce the complications of the tracheal tube, including the use of dexamethasone (7) and lidocaine gel (8), as well as the use of betamethasone gel (9) and gargling of green tea after removal of tracheal tube. Corticosteroid drugs have an anti-inflammatory effect, but the complications of the use of these drugs should not be ignored, including increased blood pressure, the suppression of natural steroid production, and increased blood glucose, especially in diabetic patients, as well as lidocaine gel because of anti-inflammatory properties. Also, lidocaine gel does not have the necessary anti-inflammatory properties and only causes local anesthesia (10). Upon using green tea, the desired effect on hoarseness has not been achieved (11).

2. Objectives

Complications for patients during or after intubation can leave a bad memory of anesthesia and operating room for the patient and, in addition to pain at the surgical site, may bring other pain to the patient, so the purpose of this study was to evaluate the effect of softening the tip of the endotracheal tube with normal warm saline before intubation in reducing the prevalence of hoarseness and sore throat after removal of the tube.

3. Methods

This double-blind, randomized controlled trial was performed on patients undergoing general anesthesia at Rasoul Akram and Firoozgar hospitals in Tehran, Iran, from April 2020 to October 2021. Patients with inclusion and exclusion criteria were included in the study. Inclusion criteria were age 19 to 69 years, surgery on the head and chest, clear hoarseness, previous laryngeal surgery, abnormal position during the operation, sore throat for any reason, history of reflux or use of anti-reflux drugs, and Smoking. Exclusion criteria included pushing, coughing when removing the tube, severe intubation (more than 2 times laryngoscopy), NGT placement, and N₂O intake. The participants (58 people) were categorized into 2 equal groups considering alpha at 0.05, beta at 0.2, P1 at 0.4, and P2 at 0.1. According to the study of Kim et al. (12) and based on the following formula, sample size was calculated:

$$N = [P1(1 - P1)] + [P2(1 - P2)] \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \rightarrow N = (0.4 \times 0.6) + (0.1 \times 0.9) \times 7.8 \rightarrow N = 29$$

$$(P1 - P2)^2 = (0.3)^2$$

3.1. Procedure

Demographic information of patients, including age and sex, type and time of surgery, and other information,

were recorded in a questionnaire prepared by an uninformed technician. The method of study was explained to all eligible patients who were included in the study. Written informed consent was obtained from all the patients who were willing to participate in the study. Sampling was stopped after reaching the required number of patients. Then 58 patients were randomly divided into 2 groups of 29 patients. The first group of patients who underwent general anesthesia with a normal endotracheal tube (as the control group). The second group of patients underwent general anesthesia using trachea heated with normal saline (as the intervention group). In the control group, patients were intubated with unheated tubes and in the intervention group, with trachea softened with normal saline at 40°C. The patients were given 3 - 4 µg of fentanyl per weight and 1.5 mg intravenous lidocaine per weight 3 - 5 minutes before the intubation as a premedication. After administering 100% oxygen for several minutes, anesthesia was induced with propofol and atracurium.

A laryngoscopy test was performed 3 to 5 minutes after atracurium besilate injection, and then an adequate neuromuscular block was established. Intubation was performed with PVC tracheal tube made by Supa Company Tehran (No. 8 for men and No. 7 for women). All patients were intubated by an uninformed resident. The endotracheal tube cuff was inflated until no leakage was heard. Pressure on the cricoid for intubation was avoided. Atracurium, fentanyl, and propofol agents were used as anesthetic agents. Mechanical ventilation was performed with a respiratory rate of 10/min and an initial tv of 10 kg/mL and then adjusted with normocapnia. At the end of the operation, the effect of relaxants with neostigmine and atropine was reversed. When patients were able to breathe spontaneously and carry out oral instructions, the endotracheal tube was removed immediately after suctioning (once before the tube was removed and once after the tube was removed at 100 mmHg). Before removing the endotracheal tube, an airway of appropriate size was placed in the patient's mouth.

All patients were evaluated for sore throat and hoarseness for 20 minutes in recovery and 24 hours after surgery by an uninformed nurse. The severity of sore throat included 0, no sore throat; 1, low; 2, moderate; 3, severe; and the rating of hoarseness were 0, without hoarseness; 1, slight hoarseness in voice; 2 severe hoarseness; and 3, inability to speak.

3.2. Heating the Endotracheal Tubes

As the study is a double-blind, randomized trial, all tubes were selected by an uninformed technician, and their cuffs were checked for accuracy. A one-liter serum containing normal saline was placed in an incubator to

reach a temperature of 40°C. After emptying the tube cuff, 29 tubes (for the intervention group) were sterilely placed in this normal warm saline bottle for 7 to 8 minutes so that the tip of the tube was immersed in water. An insulating layer made of foam and foil was wrapped around the bottles containing normal warm saline to minimize temperature loss.

3.3. Data Analysis

Descriptive statistics, including frequency and percentages, were used to test the hypotheses. Inferential statistics appropriate to the variables, including parametric tests, were used for normal variables, and equivalent nonparametric tests were used for non-normally distributed variables. SPSS statistical software version 25 was used to analyze the data.

3.4. Ethical Considerations

Before participating in the study, patients were given a sufficient explanation that participation in the study was completely optional and there was no obligation to participate in the study. Voluntary informed consent was obtained from patients. It should be noted that in the process of conducting this study, no additional costs were imposed on patients. The questionnaires were also anonymous, the information about the questionnaires was considered confidential, and the results were published only in groups. The study was conducted according to Helsinki's declaration. The Ethics Committee of the Iran University of Medical Sciences approved the study (IR.IUMS.FMD.REC.1399.113).

4. Results

Our study consisted of 58 patients divided into 2 groups of 29 patients. The two groups consisted of 25 males and 33 females. The two groups were similar in terms of basic characteristics such as age, sex, type of surgery, and duration of surgery (Table 1), and there was no statistically significant difference between the two groups ($P > 0.05$).

Table 2 represents the status of hoarseness and sore throat in patients during the recovery phase and 24 hours after the surgery. The results showed that, during the recovery period (1 hour after surgery), the mean incidence of sore throat decreased in the intervention group (20.7%) compared to the control group (75.8%, $P < 0.001$). In the intervention group, most patients either did not have a sore throat or had a sore throat, and no patients were seen with a moderate sore throat. Also, the average incidence of hoarseness decreased in the intervention group (17.2%)

compared to the control group (41.4%) (risk ratio (RR); 95%, CI: 0.408 (0.291 - 0.572), $P < 0.029$). Patients did not experience severe hoarseness during recovery. The results demonstrated that warming the endotracheal tube with normal warm saline reduced the incidence of sore throat during recovery by 55.1% and hoarseness by 24.2%.

Twenty-four hours after the surgery, the mean incidence of sore throat in the intervention group (29.29%) was significantly lower than in the control group, so none of the patients in the intervention group felt sore throat (RR; 95%, CI: (3.496 - 41.515) 12.048, $P < 0.002$). It was also observed that 24 hours after the surgery, the amount of hoarseness decreased in the intervention group (3.4%) compared to the control group (24.1%). Among the 5 patients who claimed to have hoarseness during recovery, only one of them felt a slight hoarseness 24 hours after the surgery ($P < 0.022$). The data from the present study demonstrated that the two studied groups were significantly different based on sore throat and hoarseness after surgery and also the improvement of these complications 24 hours after the surgery ($P < 0.05$, Table 2).

Multivariate logistic regression analysis was used to predict the effect of thermal softening on improvement of sore throat and hoarseness with the variables of gender and age, where data confirmed the effect of the intervention on the improvement of sore throat and hoarseness by adjusting the variables of gender and age (Table 3).

5. Discussion

Complications during or after intubation can be a bad memory for the patient from anesthesia and the operating room and may impose another pain on the patient in addition to the pain at the surgical site. In this study, we aimed to try a new method to reduce the severity of sore throat and hoarseness after removing the tube. In the present study, the results are inconsistent with some previous studies but are consistent with some others. Our study aimed to investigate the efficacy of thermal softening of single-lumen endotracheal tubes on the throat complications that may happen after the surgery. When the intubation procedure was done with double-lumen tubes and nasal endotracheal tubes, it was observed that it could be an effective method in reducing postoperative airway injury (13).

Gender, size, cuff type, intra-cuff pressure, and duration of surgery are effective factors, which affect the occurrence of sore throat and postoperative hoarseness (14-18). It has been revealed that hoarseness is more related to some factors, including intubation duration and smoking history, while sore throat is more related to physical trauma from intubation (19). To put the tubes in the right

Table 1. Basic Information About the Participants ^a

Characteristics	Control Group	Intervention Group	P-Value
Average age (y)	42.13 ± 13.36	45.13 ± 15.64	0.436
Gender distribution			0.791
Male	12 (41.4)	13 (44.8)	
Female	17 (58.6)	16 (55.2)	
Type of surgery			
Appendectomy	5 (17.2)	5 (17.2)	0.999
Breast mass resection	1 (3.4)	2 (6.9)	0.872
Cholecystectomy	8 (27.6)	9 (31.0)	0.887
Hysterectomy	2 (6.9)	1 (3.4)	0.879
Inguinal hernia	3 (10.3)	4 (13.8)	0.889
Laparotomy	2 (6.9)	2 (6.9)	0.999
Mastectomy	2 (6.9)	2 (6.9)	0.999
Orthopedic surgery	2 (6.9)	2 (6.9)	0.999
Close ostomy	4 (13.8)	2 (6.9)	0.756
Average surgery time (h)	3.00 ± 1.29	2.63 ± 0.91	0.213

^a Values are expressed as mean ± SD or No. (%).

Table 2. Assessment of Hoarseness and Sore Throat in Patients During the Recovery Phase and 24 Hours After the Surgery

Items	Control Group	Intervention Group	P-Value	Risk Ratio (95% CI)
The extent of sore throat in recovery			< 0.001	3.388 (1.006 - 11.411)
Not	7 (24.1)	23 (79.3)		
Mild	21 (72.4)	6 (20.7)		
Moderate	1 (3.4)	0 (0.0)		
Sore throat in 24 hours			0.002	12.048 (3.496 - 41.515)
Not	20 (69.0)	29 (100)		
Little	9 (31.0)	0 (0.0)		
Noise violence rate in recovery%			0.029	0.408 (0.291 - 0.572)
No violent sound	17 (58.6)	24 (82.8)		
A little violent sound	10 (34.5)	5 (17.2)		
Intense voice violence	2 (6.9)	0 (0.0)		
Noise violence rate in recovery 24%			0.022	8.909 (1.019 - 77.905)
No violent sound	22 (75.9)	28 (96.6)		
A little violent sound	7 (24.1)	1 (3.4)		

place during the intubation procedure, they should pass through the vocal cords. Since the throat is a very narrow part that is in close contact with the endotracheal tube, the vocal folds are amongst the most vulnerable areas that could be affected by intubation. In addition, stimulation of the mucosa at the cuff end of the endotracheal tube has been identified as the most important complication factor in previous studies. Inflammation from these injuries, as

well as stimulation from traumatic laryngoscopy and cuff contact, can cause postoperative sore throat (20).

Tubes will be more flexible through heating, which is an appropriate option for the decrement of airway trauma during intubation. In addition, immersing the tubes at 40°C normal saline heats up the tubes that may decrease inflammation by suppressing the ion-sensitive ion channel, i.e., transient receptor potential A1 (TRPA1) (21). The re-

Table 3. Prediction of the Efficacy of Thermal Softening on Improving Hoarseness and Sore Throat Based on the Patient's Gender and Age Variables

Items	B	S.E.	Sig.	Exp (B)	95% CI for Exp (B)	
					Lower	Upper
Sore Throat						
Group	3.353	0.861	0.001	28.588	5.290	154.483
Sex	-1.733	0.789	0.028	0.177	0.038	0.829
Age	0.072	0.031	0.020	1.075	1.012	1.143
Hoarseness						
Group	1.875	0.776	0.016	6.520	1.426	29.821
Sex	-2.000	0.820	0.015	0.135	0.027	0.675
Age	0.083	0.031	0.007	1.087	1.023	1.155

sults of the present study revealed that heating the endotracheal tube with normal warm saline reduced the incidence of sore throat in recovery by 55.1% and the incidence of hoarseness by 24.2%. The data from our study also revealed that the two studied groups were significantly different in terms of hoarseness and sore throat after surgery and also the improvement of these complications in 24 hours after surgery. The results of this study were in line with the results of the study of Yu et al. (22), where thermal softening of the endotracheal tubes reduced the incidence of sore throat by 34.1% in comparison to the control group 1 hour after intubation. In addition, the preparation of endotracheal tubes with thermal softening decreases the severity of sore throat by up to 10% per day after the surgery compared to conventional tubes.

Seo et al. (23) found that the incidence of sore throat in the heated endotracheal tube group was significantly lower than in the control group on the first postoperative day, but no difference was found between 2 and 3 days after the operation. Although there were no symptoms of severe soreness in the patients, the severity of sore throat in the thermal softener group was less in comparison to the control group on the first day after surgery. Two and 3 days after the surgery, the severity of the sore throat was similar to each other. Additionally, the differences between the two groups in terms of incidence and intensity of hoarseness were not significant. The results of our study were proved by Seo et al., while in our study, it was only possible to evaluate the severity of sore throat and hoarseness up to 24 hours after the surgery (23). The application of pharmacological methods in the reduction of postoperative airway injury has been evaluated by some recent studies. Medicines that have been used before the surgery include lidocaine spray or benzydamine hydrochloride used for anesthetized parts, magnesium or dexamethasone tablets, betamethasone gel, and ketamine gargling (24-26).

Jiang et al. used intravenous dexamethasone for 13 pa-

tients in the thermal softener group and 12 patients in the control group (24). In their study, it was revealed that post-operative intravenous dexamethasone could effectively decrease the incidence of sore throat (24). However, after elimination of patients taking dexamethasone, the results did not change. Just 1 hour after intubation in the thermal softener group, the incidence rate of sore throat significantly decreased by 17.4% in comparison to the control group (54.4% and 37%), (RR (95% CI) 0.49 (0.26-0.93), (P = 0.04)). Thermal softening of endotracheal tubes is a simple and practical procedure compared to pharmacological methods, with the lowest risk of side effects such as coughing, vomiting, nausea, burning or tingling sensation, and local anesthesia.

The present study also had some limitations. The first limitation was that the population in our study was restricted to the patients without difficult airways who underwent a relatively short operation. Consequently, the results of our study could not be generalized to patients with difficult airways or long-term surgery. In this regard, more detailed studies are required on the effects of thermal softening of endotracheal tubes in patients with difficult airways and that underwent prolonged surgery. Second, sore throat and hoarseness were evaluated in the recovery phase and 24 hours after intubation because usually, on the second day after surgery, patients are discharged. Consequently, more detailed studies should be carried out to confirm the long-term outcomes of thermal softening of the endotracheal tubes. Third, the population considered for the present study was small, so it is recommended that subsequent studies be performed with a larger sample size to generalize findings to a larger population of patients.

5.1. Conclusions

Softening the endotracheal tubes with normal warm saline before intubation could be significantly capable of

reducing the incidence of sore throat and hoarseness during recovery as well as 24 hours after surgery.

Footnotes

Authors' Contribution: Study concept and design: R. F. R.; acquisition of data: M. M.; analysis and interpretation of data: A. Z.; drafting of the manuscript: R. F. R.; critical revision of the manuscript for important intellectual content: N. M.; statistical analysis: M. M.; administrative, technical, and material support: A. Z.; study supervision: R. F. R.

Conflict of Interests: The authors declare no conflict of interest and are employees of Iran University of Medical Sciences.

Data Reproducibility: The data presented in this study are uploaded during submission as a supplementary file and are openly available for readers upon request.

Ethical Approval: The Ethics Committee of the Iran University of Medical Sciences approved the study (IR.IUMS.FMD.REC.1399.113).

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Informed Consent: Written informed consent was obtained from all the patients who were willing to participate in the study.

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