Golestan University of Medical Sciences
Journal of Research Development in Nursing and Midwifery
(J Res Dev Nurs Midw)
Online ISSN: 2588-3038

Effect of Warm Saline Solution Gargle on Sore Throat after Extubation in Open Heart Surgery Patients: A Randomized Clinical Trial

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Abstract

Background: Sore throat is one of the most common complications of endotracheal intubation, which interferes with patient's normal breathing and oral feeding process. This may ultimately delay the patient's discharge from the hospital. The aim of this study was to determine effect of warm normal saline solution gargling on sore throat in open heart surgery patients after estuation.

Methods: This clinical trial was performed in 2016 on 60 patients undergoing open heart surgery at the Amir Al-Momenin Hospital in Kordkoy, Northeast of Iran. The subjects were selected by convenience sampling method and randomly assigned to an intervention and a control group. Patients with sore throat were assessed using the Numerical Pain Rating Scale (NPRS 0–10) one hour after endotracheal tube removal and then every 6 hours for 24 hours. An overall score of zero, 1-3, 4-6, and 6-10 indicated no pain, mild pain, moderate pain, and severe pain, respectively. Data were analyzed with SPSS (version 18) using the Shapiro–Wilk test, independent t-test, Fisher's exact test, Chi-square test, and Friedman test. All analyses were carried out at significance of 0.05.

Results: At the beginning of the study, there was no statistically significant difference between the two groups in terms of age, sex, ethnicity, history of addiction, and sore throat severity ($p > 0.05$). Six hours after the intervention, pain intensity did not differ significantly between the two groups ($p < 0.05$). However, pain intensity was significantly lower in the intervention group compared with the control group 12, 18, and 24 hours after the intervention ($p<0.001$).

Conclusion: The results indicate that warm normal saline solution gargling after removal of the endotracheal tube is a practical, simple, and cheap approach to relieve sore throat in patients undergoing open heart surgery.

ARTICLE HISTORY

Received: Feb 07 2020
Received in revised form: Feb 20 2021
Accepted: Jul 15 2021
Published online: Feb 16 2022
DOI: 10.29252/jgbfnm.19.1.21

Keywords:
Endotracheal Intubation
Cardiac Surgical Procedures
Pharyngitis
Saline Solution
Gargling

Article Type: Original Article

Highlights:

What is current knowledge?

According to the existing literature, no study has examined effect of warm Saline solution gargle on sore throat after extubating in open heart surgery patients.

What is new here?

This study show that warm saline solution gargling after removal of the endotracheal tube is a practical, simple, and cheap approach to relieve sore throat in patients undergoing open heart surgery.

Introduction

According to the World Health Organization and the American Heart Association, cardiovascular disease was the leading cause of death worldwide in 2019 (1, 2). These diseases impose a significant burden on healthcare as many of the cases require surgical intervention (3-5). In Iran, cardiovascular diseases are considered as one of the most important causes of death, and about 40,000 open heart surgeries are performed annually in the county (6). Open heart surgery is classified as a complex and complicated surgery (7). In this surgery, patients are placed under general anesthesia and immediately transferred to the intensive care unit after the operation where they recover from anesthesia. Endotracheal intubation is essential for the management and maintenance of the airway under general anesthesia (8). Almost all patients who are intubated during surgery suffer from some degree of airway injury often 12 to 24 hours after the extubating that may resolve after five to seven days (9). The main causes of postoperative sore throat are damage to the mucosa by endotracheal tube cuff, trauma during intubation, and mucosal dehydration. Factors such as coughing, friction between the tracheal mucus, the tracheal tube size and type, and the cuff pressure of the endotracheal tube are also related to postoperative sore throat (10). Sore throat after endotracheal intubation is one of the most common reasons of patient dissatisfaction (9). In fact, the prevalence of postoperative sore throat is between 30 and 70% (11). Poor management of postoperative complications leads to increased catabolism, tachycardia, hypertension, tachypnea, immunosuppression, coagulation disorders, postoperative pain, nausea, vomiting, restlessness, decreased patient satisfaction, and additional treatment costs. It also increases the length of hospital stay as well as the possibility of hospital returns (12). Patients undergoing cardiac surgery may face several complications, which are exacerbated by other conditions such as sore throat that may interfere with the patient's breathing, oral nutrition, and hemodynamic stability. This may ultimately delay discharge from the hospital (7, 13, 14). Different non-pharmacological and pharmacological methods have been suggested to reduce this complication. Using a smaller endotracheal tube, performing endotracheal intubation after complete muscle relaxation, minimum pressure inside the cuff, and removing the endotracheal tube when the endotracheal tube cuff is completely emptied are non-pharmacological ways to reduce postoperative sore throat. Therapeutic interventions include inhalation of budesonide or beclomethasone, intravenous dexamethasone administration, use of topical betamethasone gel, use of ketamine, topical and systemic lidocaine, and magnesium sulfate. Moreover, the use of advanced devices to induce anesthesia such as video laryngoscopes, supraglottic airways, transesophageal echocardiography, and novel anesthetics such as muscle relaxants (remifentanil and rocurium bromide) have been also suggested for reducing risk of postoperative sore throat. However, most conventional treatments have relative effects and are not completely effective (15). Normal saline is an inexpensive, low-risk solution that is readily available. The use of normal saline solution has been suggested to prevent post-extubation sore throat. This involves rinsing the mouth with normal saline before endotracheal tube removal (16) or normal saline gargling before intubation (17), and soaking the tip of the endotracheal tube in normal saline (18). Normal saline reduces inflammatory mediators and thins the

mucus. In addition, heat can relieve pain and promote healing of damaged tissues (19). Nursing textbooks also emphasize on gargling with warm saline solution to relieve sore throat (20). Therefore, this study was performed to determine effects of gargling warm normal saline solution on sore throat after endotracheal tube removal in open heart surgery patients.

Methods

This clinical trial was conducted during October 2018 to February 2019 in Amir Al-Momenin Educational and Medical Center, Kordkuy, Northeast of Iran. The number of required samples was calculated according to the study of Jafari et al. (21) at 95% confidence level, with a test power of 80%, and using the following formula:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (SD_1^2 + SD_2^2)}{(\mu_1 - \mu_2)^2}$$

$$\mu_1 = 1.2414$$
$$\mu_2 = 1.746$$
$$SD_1 = 0.47$$
$$SD_2 = 0.87$$

In this study, 60 patients who were candidates for open heart surgery were selected using convenience sampling method and allocated through block randomization. Written informed consent was obtained from all participants a day before surgery. Inclusion criteria were age between 30 and 65 years, no sore throat or cold in the past weeks, ability to communicate, endotracheal intubation under 30 seconds (22), and Mallampati score of 2 (23). Cricoid pressure during anesthesia, any attempt for re-intubation, respiratory infection, intubation for more than 16 hours in the intensive care unit, bleeding, cardiac dysrhythmia, and decreased level of consciousness were considered as the exclusion criteria (21) .

Demographic characteristics including age, sex, ethnicity, and history of addiction were recorded. The level of pain in patients was recorded using the Numerical Pain Rating Scale (NPRS). A score of zero, 1-3, 4-6 and 7-10 indicated no pain, mild pain, moderate pain and severe pain, respectively (24). The same method of anesthesia induction was carried out by the same anesthesiologist for both groups. All endotracheal tubes used in the study were cuffed and 7-8 mm in diameter. The surgeries were also performed by a same cardiovascular surgeon. After the surgery, the patients were transferred to the cardiac intensive care unit. After stabilization of hemodynamic status, the endotracheal tube was removed in the same manner for all patients. The level of sore throat was measured using the NPRS scale one hour after extubating for both groups (before the intervention). Next, normal saline solution was placed in a warmer at 40 °C. Then, the intervention group (n=30) gargled 30 ml of the warm saline solution every three hours. The severity of sore throat was measured every six hours for 24 hours using the NPRS scale (25). Patients in the control group (n=30) received routine care.

Data were entered into the SPSS software (version 18). Pain scores were analyzed qualitatively. Qualitative variables were expressed in form of number and percentage, and quantitative variables were expressed as mean and standard deviation. Normality of quantitative data distribution was analyzed using the Shapiro-Wilk test. The independent t-test was used to compare quantitative variables between the two groups. The Fisher's exact test and Chi-square test were used to compare the level of sore throat at different time intervals between groups (intervention and control). The intergroup changes of sore throat intensity were assessed using the Friedman test. All analyses were performed at significance level of 0.05.

Results

The mean age of subjects in the intervention group and the control group was 53.58 ± 8.30 years and 61.70 ± 9.11 years, respectively (p=0.15). Table 1 shows the frequency distribution of demographic characteristics among the subjects.

Table 1: Frequency distribution of demographic characteristics of patients in the intervention and control groups

Variable		N (%)	N (%)	
Gender	Female	7 (23.3)	10(33.3)	0.39*
	Male	23(76.7)	20(66.7)	
History of addiction	Yes	13(43.3)	11(36.7)	0.598*
	No	17(56.7)	19(63.3)	
Ethnicity	Persian	16(53.3)	15(50)	0.241**
	Turkmen	8(26.7)	6(20)	
	Sistani	1(3.3)	6(20)	
	Other	5(16.7)	3(10)	

*Chi-square Test, ** Fisher's exact test

After extubation, 66.7% of patients in the intervention group and 33.3% of patients in the control group had severe sore throat, and 26.7% of patients in the intervention group and 40% of patients in the control group had moderate sore throat. Results of the Fisher's exact test did not show a statistically significant difference in sore throat severity between the two groups before the intervention (p<0.05). However, the results indicated that the sore throat frequency was significantly lower in the intervention group than in the control group 12, 18 and 24 hours after the intervention (Table 2).

The mean score of sore throat was highest before the intervention and lowest 24 hours after the intervention in both groups. The mean scores of sore throat increased six and 12 hours after the intervention in the control group, while the mean pain score decreased continuously in the intervention group (Table 3).

Table 2: Comparison of sore throat intensity between the study groups before the intervention and 6, 12, 18 and 24 hours after the intervention

Measurement time points	Intensity of sore throat	Control		
		N (%)	N (%)	P-value
Before intervention	No	0(0)	1(3.3)	0.058*
	Mild	1(3.3)	3(10)	
	Moderate	8(26.7)	12(40)	
	Severe	21(70)	14(46.6)	
6 hours after the intervention	No	4(13.3)	1(3.3)	0.066*
	Mild	17(56.7)	11(36.7)	
	Moderate	9(30)	16(53.3)	
	Severe	0(0)	2(6.7)	
12 hours after the intervention	No	14(46.7)	1(3.3)	<0.001*
	Mild	15(50)	16(53.3)	
	Moderate	1(3.3)	11(36.7)	
	Severe	0(0)	2(6.7)	
18 hours after the intervention	No	23(76.7)	4(13.3)	<0.001*
	Mild	6(20)	18(60)	
	Moderate	1(3.3)	7(23.3)	
	Severe	0(0)	1(3.3)	
24 hours after the intervention	No	28(93.3)	15(50)	<0.001*
	Mild	2(6.7)	12(40)	
	Moderate	0(0)	2(6.7)	
	Severe	0(0)	1(3.3)	

* Chi-Square test

Table 3. Comparison of the mean score of sore throat in the study groups before the intervention and 6, 12, 18, and 24 hours after the intervention

Time of measurement	Intervention	Control
	Mean score	Mean score
Before intervention	2.70±0.59	2.43±0.97
6 hours after the intervention	2.16±0./64	2.63±0.66
12 hours after the intervention	1.5±0.56	2.46±0.68
18 hours after the intervention	1.2±0.52	2.16±0.69
24 hours after the intervention	1.06±0.25	1.63±0/76

Discussion

Based on the results, the severity of sore throat after endotracheal tube removal in both groups did not differ significantly. Various studies reported that pain can start immediately after endotracheal tube removal or can be delayed due to damage to the tracheal mucosa. However, sore throat can often be masked in the first hour after the endotracheal tube removal due to the effects of analgesics and general anesthesia (26).

There was a negligible difference in the pain severity between the two groups six hours after the intervention. This finding is in line with findings of a study by Jafari et al. on the effect of green tea gargle on sore throat in patients undergoing coronary artery bypass graft surgery (21). Twelve hours after the intervention, none of the patients in the intervention group had severe pain, while the patients in the control group reported mild to severe pain. Similarly, the pain intensity was significantly lower in the intervention group compared with the control group at 18 and 24 hours after the intervention. These results are consistent with findings of the study of Jafari et al. (21). The increase in pain intensity in the control group could be due to the reduced effect of analgesics after anesthesia. Zare et al. also found that the severity of sore throat was significantly reduced six and 12 hours after endotracheal tube removal. However, they observed no statistically significant difference in the severity of sore throat between the intervention and control groups immediately, one hour, and 24 hours after the removal(9) . In our study, the severity of sore throat differed significantly between the two groups despite the decreasing course of pain intensity. There was also a statistically significant difference in the mean score of sore throat severity before and after the intervention. The mean score of sore throat severity increased six hours after the intervention and then decreased after 12 to 24 hours, but this decrease was milder in the control group than in the intervention group. It seems that the pain

intensity increased gradually over time due to the reduced effects of anesthetics and analgesics. In the intervention group, the pain intensity reduced due to the effects of warm normal saline solution gargling. Warm saline solution gargle has been regarded as a common treatment for sore throat that acts by reducing throat muscle spasm (20).

In a double-blind clinical trial, Ruetzler et al. (2013) found that licorice gargling before endotracheal intubation significantly reduced postoperative sore throat (27). Another study investigated the preventive effects of lidocaine and beclomethasone spray on sore throat and cough caused by intubation in patients undergoing mastectomy. One hour after endotracheal tube removal, the incidence of sore throat was 10% in the beclomethasone group, 23% in the lidocaine group, and 36.7% in the control group. After 24 hours, this rate remain constant in the treatment groups but increased to 50% in the control group (28).

In a clinical trial in 2020, the effects of pre-treatment with cold steam and ice cubes on sore throat and postoperative hoarseness were investigated on 120 patients. The study found that the use of cold steam was more effective in reducing sore throat than other methods (13). In general, most studies have investigated the effects of both pharmaceutical and non-pharmaceutical methods on postoperative sore throat prior to endotracheal intubation, which may not be possible in practice due to operating room conditions and the stress associated with operating room congestion. However, our results indicate that warm saline solution gargling after removal of the endotracheal tube is a practical and simple approach to relieve sore throat after open heart surgery. One of the factors that affect sore throat is the amount of tracheal tube cuff pressure. In our study, due to the lack of access to a special manometer we could not accurately measure this factor, which is a limitation of our study.

Conclusion

The results indicate that warm saline solution gargling after removal of the endotracheal tube is a practical, simple, and cheap approach to relieve sore throat in patients undergoing open heart surgery. Therefore, it is recommended to implement this safe and simple method in the cardiac intensive care unit to reduce postoperative sore throat after endotracheal tube removal.

Acknowledgements

This article has been derived from results of a master's thesis in intensive care nursing at the Golestan University of Medical Sciences, Iran. The authors would like to express their sincere gratitude to the Vice Chancellor for Research of Golestan University of Medical Sciences for supporting the study, and the staff of the cardiac intensive care unit of Amir Al-Momenin Hospital in Kordkuy as well as all patients who participated in this study.

Funding source

This research has been supported and funded by the Golestan University of Medical Sciences, Gorgan, Iran (project code: 110634).

Ethical statement

This protocol study has been approved by the Research Ethics Committee of Golestan University of Medical Sciences
(Ethical code: IR.GOUMS.REC.1398.177) & (code: IRCT20190311043014N1)

Conflict of interest

The authors declare that there is no conflict of interest.

Author contributions

All authors have contributed significantly to this study. Eri and Yazdi designed the project, performed the data collection and wrote the manuscript, Mehrbakhsh analyzed data, Riahi & Ahmadi supervised execution of the study and data collection, Yazdi also supervised the study. All the authors approved the content of the manuscript.

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How to Cite:
Golbahar Iri, Khadijeh Yazdi, Gholamali Riahi, Zahra Mehrbakhsh, Mohammad Ahmadi. Effect of Warm Saline Solution Gargle on Sore Throat after Extubation in Open Heart Surgery Patients: A Randomized Clinical Trial. *Journal of Research Development in Nursing & Midwifery*, 2022; 19 (1): 21-24