



# Effect of Diphenhydramine Gargling on Sore Throat in Patients Undergoing Cataract Surgery with Laryngeal Mask Insertion

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### ABSTRACT

**Introduction:** Sore throat is a common postoperative complication in patients undergoing general anesthesia. Several factors contribute to this complication, and the airway management method plays a pivotal role in this regard. The present study aimed to assess the effect of diphenhydramine gargling on sore throat in patients undergoing cataract surgery with laryngeal mask insertion.

**Methods:** This placebo-controlled, double-blind, clinical trial was conducted on two groups of intervention and control. The patients in the intervention group gargled 8 cc (20 mg) of diphenhydramine diluted to 20 cc with normal saline 20 minutes before anesthesia induction. The control group patients gargled 20 cc of normal saline 20 minutes before anesthesia induction. The score of sore throat severity was determined based on the visual analogue scale during recovery three, six, 12, and 24 hours postoperatively.

**Results:** Initially, 176 candidates of eye surgery using laryngeal mask airway (LMA) were enrolled in the study, and three patients were excluded from the intervention group due to withdrawal. In the intervention group, 36 patients (42.9%) were female, and 48 patients (57.1%) were male. In the control group, 46 patients (52.3%) were female, and 42 patients (47.7%) were male. The mean age of the subjects was  $59.5 \pm 16.74$  and  $57.94 \pm 15.74$  years in the intervention and controls groups, respectively. No significant differences were observed between the groups in terms of age and gender ( $P=0.53$  and  $P=0.29$ , respectively). The mean score of pain severity was  $0.3 \pm 0.14$  and  $1.7 \pm 0.14$  in the intervention and control groups, respectively, which indicated a significant difference between the groups at each measurement point ( $P < 0.001$ ). However, the reported pain severity scores were not correlated with age, gender, mask size, and duration of surgery.

**Conclusion:** Gargling 20 milligrams of diphenhydramine suspension 20 minutes prior to LMA insertion in the patients undergoing eye surgery significantly reduced the post-anesthesia sore throat compared to the control group. Moreover, sore throat had no associations with the age, gender, duration of surgery, and mask size of the patients.

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### Introduction

Sore throat is a common postoperative complication in patients undergoing general anesthesia, which reduces patient satisfaction with healthcare services. Several factors contribute to the development of this complication, and the airway management method plays a pivotal role in this regard. Endotracheal intubation (45.4%) followed by laryngeal mask airway (LMA) insertion (17.5%)

have been reported to be the most important causes of postoperative sore throat. However, sore throat has also been observed with the use of face masks (3.3%). The other influential factors in the incidence of this complication include female gender, age of less than 65 years, neck and pharyngeal surgery, spinal and gynecological surgeries, and use of succinylcholine.

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Postoperative sore throat is often caused by damage to the pharyngeal mucosa, and the lower severity of physical trauma is associated with the decreased incidence of this complication (1, 2). Most of the studies in this regard have recommended the prevention of mucosal trauma while using airway tools and pharyngeal manipulation in order to reduce postoperative sore throat (3). In addition, some studies have suggested pharmacological interventions to reduce postoperative sore throat, while no drugs are routinely used in such practices (4).

Despite the pharmacological and non-pharmacological efforts to relieve pain in the patients experiencing postoperative sore throat, this complication remains disturbing. The present study aimed to evaluate the effect of diphenhydramine gargling on the sore throat of patients undergoing general anesthesia with LMA insertion as the airway management method compared to the controls.

## Methods

This double-blind, randomized, controlled, clinical trial was conducted on 176 patients undergoing cataract surgery with general anesthesia. In all the cases, LMA was used to manage the airway, and the accurate size of each patient was selected based on weight-specific standards.

After the patients were introduced as candidates for eye surgery with general anesthesia by a surgeon, 176 patients were selected based on the inclusion criteria of the study, who provided written informed consent for enrolment. The selected patients were randomly divided into two groups of intervention and control using the random number table. The researcher briefed the patients on all the stages of the trial, asking them to grade their level of pain based on the visual analogue scale (VAS).

The inclusion criteria of the study were as follows: 1) candidates for eye surgery with general anesthesia; 2) age of 18-75 years; 3) ASA-PS classification I and II; 4) BMI < 30 kg/m<sup>2</sup>; 5) no degrees of cold/flu; 6) no drug or alcohol addiction; 7) no use of analgesics within the past 24 hours; 8) no known allergies to diphenhydramine; 9) absence of psychological disorders; 10) fluency in Persian; 11) absence of hearing impairment and 12) basic literacy of Persian texts.

The exclusion criteria were as follows: 1) LMA insertion problems requiring more than two attempts for insertion; 2) lack of proper ventilation with LMA inserted based on weight-specific standards; 3) incidence of general anesthesia complications (e.g., hemodynamic changes by more than 30% of the baseline value, airway spasms, swell-

ing of the pharynx, and glottis leading to respiratory distress); 4) nausea and vomiting requiring treatment with more than one dose of IV ondansetron and 5) pain in the surgery site requiring analgesics.

Due to the nature of the surgery, no premedication was prescribed for the patients. In all the patients, anesthesia was induced by propofol (2.5-3 mg/kg), atracurium (0.25-0.5 mg/kg), fentanyl (1 µg/kg) or an equivalent dose of sufentanil. Afterwards, LMA (Well Lead Co., Ltd.) was selected depending on the body weight of the patients, soaked in 10 cc of normal saline solution, and inserted by one of the researchers with adequate approved skills in LMA insertion. The laryngeal cuff was filled with air at the recommended volume by the manufacturer. Anesthesia was maintained with the infusion of propofol (150-200 µg/kg/min) and O<sub>2</sub>/N<sub>2</sub>O (50/50).

After the surgery and recovery of the patients to normal breathing, LMA was removed following an oral suction when the patient was able to open their eyes upon being called. The researcher informed the patients of the taste of the solution, training them on the correct method of gargling and expressing their pain severity based on the VAS. The intervention group gargled 8 cc (20 mg) of diphenhydramine in 12 cc of normal saline 20 minutes before the LMA insertion, and the control group gargled 20 cc of normal saline 20 minutes before the LMA insertion.

During recovery and three, six, 12, and 24 hours after the surgery, the patients were enquired about the degree and severity of their sore throat based on the VAS, and the obtained data were recorded in prepared forms for evaluation. The VAS is a horizontal line with 10 points (spaced 1 cm apart from each other), starting at score zero on the left (no pain) and ending with score nine on the right (severe pain). The patients were asked to select a number on this line based on the severity of their pain in the throat area.

VAS is a standard measure for pain assessment. Since the length of hospital stay following this type of surgery is less than 24 hours, the patients were interviewed preoperatively and assessed to ensure whether they had properly learned the grading of their sore throat pain based on the VAS. It is also notable that the required permit was obtained to conduct the interviews with the patients. The calls were made by the same researcher who was fully familiar with the VAS criteria with great caution in accordance with the psychological principles of treating patients. The caller explicitly and directly asked all the patients whether they had a sore throat, and in the case of a positive answer, they were asked how they would score their pain

severity within the range of 0-9.

Data analysis was performed in SPSS version 16 using mean and standard deviation to describe the quantitative data and frequency and percentage to describe the qualitative data. In addition, independent t-test was applied to compare the study groups, and the correlations between the qualitative variables were investigated using Chi-square. Repeated measures analysis of variance (rANOVA) was also employed to compare a single outcome at different times in the study groups. Moreover, possible correlations were investigated using the Pearson's correlation-coefficient. In all the statistical analyses, the P-value of less than 0.05 was considered significant.

### Sample Size

According to Canbay et al. (4) (test power: 0.9,  $\alpha=0.05$ ) and based on the pain score as the primary outcome, the sample size of the study was determined to be 88 patients in each group (total: 176).

## Results

Initially, 176 candidates of eye surgery using LMA were enrolled in the study, and three patients were excluded from the intervention group due to withdrawal. In total, 173 patients were fully examined. In the intervention group, 85 patients gargled diphenhydramine, and in the control group, 88 patients gargled normal saline. Among the subjects, 82 were female (47.7%), and 90 were male (52.3%). In the intervention group, 36 patients (42.9%) were female, and 48 patients (57.1%) were male. In the control group, 46 patients (52.3%) were female, and 42 patients (47.7%) were male. According to the results, gender had no significant correlation with the patient group ( $P=0.21$ ).

The mean age of the patients was  $58.7\pm 16.21$  years, with the minimum and maximum age of 20 and 83 years, respectively. The mean age of the patients in the intervention and control groups was  $59.5\pm 16.74$  and  $57.94\pm 15.74$  years, respectively. No significant difference was observed in the mean age of the study groups ( $P=0.53$ ).

Table 1 shows the baseline data of the patients. The mean score of pain was  $0.3\pm 0.14$  and  $1.7\pm 0.14$  in the intervention and control groups, respectively ( $P<0.001$ ) (Figure 1). The intra-group analysis indicated that the mean score of pain in the intervention and control groups was significantly different at various times ( $P<0.001$ ). During recovery and 24 hours postoperatively, the mean score of pain was  $2.07\pm 3$  and  $0.64\pm 1.45$  in the control and  $0.67\pm 1.4$  and  $0.02\pm 0.15$  in the intervention group, respectively (Table 2).

**Table 1.** The patients' underlying characteristics in the control and intervention groups at baseline

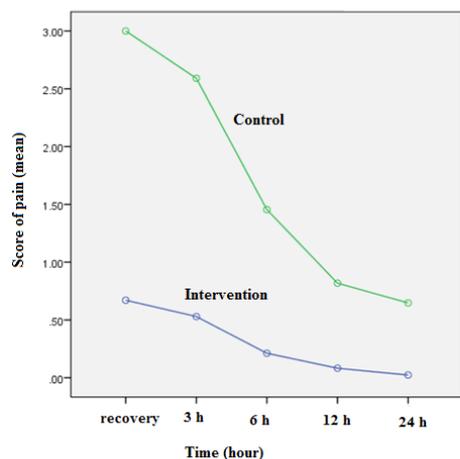
Characteristic	Control Group n=88	Intervention Group n=85	P-Value
Age (years)	15.74±57.94	16.74±59.5	0.53*
Gender (male)	47.7%	57.1%	0.21**
Duration of surgery (min)	11.55±50.17	15.35±53.11	0.15*
Mask size	0.6±3.57	0.65±3.48	0.34*

\* The Independent T-test was used to compare the two groups.

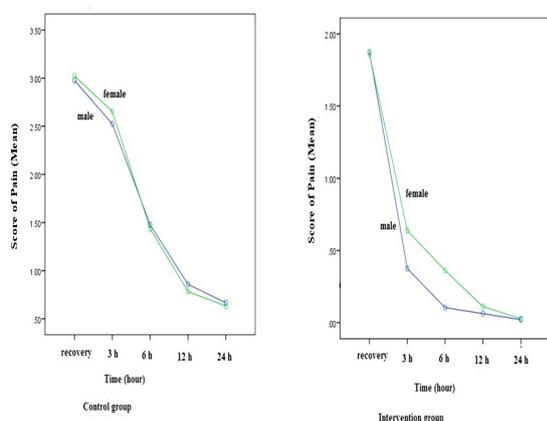
\*\* The Chi-square test was used to compare the two groups.

**Table 2.** The mean score of pain in each group and its comparison at the measurement occasions

Two-by-Two Comparison	Mean Score of Pain in the Control Group	Mean Score of Pain in the Intervention Group	P-Value* Control Group	P-Value* Intervention Group
Recovery - 3 hours after surgery	2.07±3 2.54±2.59	1.4±0.67 1.18±0.52	<0.001	>0.99
Recovery - 6 hours after surgery	2.07±3 1.98±1.45	1.4±0.67 0.86±0.21	<0.001	0.018
Recovery - 12 hours after surgery	2.07±3 1.55±0.81	1.4±0.67 0.38±0.08	<0.001	<0.001
Recovery - 24 hours after surgery	2.07±3 1.45±0.64	1.4±0.67 0.15±0.02	<0.001	<0.001
3 hours after surgery - 6 hours after surgery	2.54±2.59 1.98±1.45	1.18±0.52 0.86±0.21	<0.001	0.017
3 hours after surgery - 12 hours after surgery	2.54±2.59 1.55±0.81	1.18±0.52 0.38±0.08	<0.001	0.003
3 hours after surgery - 24 hours after surgery	2.54±2.59 1.45±0.64	1.18±0.52 0.15±0.02	<0.001	0.001
6 hours after surgery - 12 hours after surgery	1.98±1.45 1.55±0.81	0.86±0.21 0.38±0.08	0.001	0.78
6 hours after surgery - 24 hours after surgery	1.98±1.45 1.45±0.64	0.86±0.21 0.15±0.02	<0.001	0.38
12 hours after surgery - 24 hours after surgery	1.55±0.81 1.45±0.64	0.38±0.08 0.15±0.02	0.31	0.95



**Figure 1.** The reported pain score in the control and intervention groups at the measurement occasions



**Figure 2.** Mean score of pain in male and female patients of the control and intervention groups.

**Table 3.** Correlation between LMA size, Surgery duration and age with pain score mean in intervention group

P- Value	Variable	Correlation Coefficient	Pain Assessment Points
<b>Recovery</b>	LMA Size	0.099	0.37
	Surgery Duration	0.07	0.52
	Age	0.15	0.16
<b>3 hours post operation</b>	LMA Size	0.23	0.03
	Surgery Duration	0.17	0.11
	Age	0.07	0.52
<b>6 hours post operation</b>	LMA Size	0.19	0.08
	Surgery Duration	0.08	0.44
	Age	0.05	0.62
<b>12 hours post operation</b>	LMA Size	0.163	0.14
	Surgery Duration	0.03	0.73
	Age	0.14	0.18
<b>24 hours post operation</b>	LMA Size	0.11	0.29
	Surgery Duration	0.07	0.52
	Age	0.15	0.17

No significant difference was observed in the mean score of pain between the male and female patients in the control and intervention groups ( $P=0.99$  and  $P=0.63$ , respectively) (Figure 2). Furthermore, no significant correlations were denoted between the pain score and LMA size, duration of surgery, and age in the intervention and control groups (Table 3).

### Discussion

The present study was conducted on 173 candidates of eye surgery. To implement the intervention, 85 patients in the intervention group gargled 20 milligrams of diphenhydramine suspension 20 minutes prior to LMA insertion, and 88 patients in the control group gargled normal saline. According to the findings, gargling 20 milligrams of diphenhydramine suspension 20 minutes prior to the insertion of LMA in the patients undergoing eye surgery significantly reduced post-anesthetic sore throat compared to the control group. In addition, the reported incidence of sore throat had no significant correlations with age, gender, duration of surgery, and LMA size.

Although several studies have emphasized the effectiveness of diphenhydramine in the reduction of sore throat caused by infectious pharyngitis, the current research is the first study to evaluate the effect of diphenhydramine on the reduction of sore throat after LMA insertion. Other studies have also demonstrated that diphenhydramine could exert topical anesthetic effects. For instance, Nemazee et al. (2004) suggested that diphenhydramine could positively affect pain alleviation and treatment of pemphigus vulgaris lesions (5). Similarly, Arnstadt et al. reported that the topical anesthetic effects of diphenhydramine are comparable to 1% lidocaine (6). Our findings are consistent with the previous studies in this regard.

In another research, Minamigucci et al. (2014) reported age to be an influential factor in the incidence of sore throat after intubation (3), while no significant correlation was observed between age and pain in the present study. The discrepancy could be due to the narrow age dispersion in the current research in cataract surgery, as well as the fact the number of the young patients was not adequate to confirm the possible association between age and pain.

According to the findings of Higgins et al., gender (female more than male) could affect the incidence of postoperative sore throat in patients with LMA insertion (1). In the present study, no significant difference was observed between the male and female patients in terms of the pain score, which is inconsistent with the mentioned research.

In another study, Minamigucci et al. concluded

that larger-sized LMAs may increase the severity of sore throat (3), while our findings indicated no correlation between the LMA size and increased postoperative sore throat. This could be due to the fact that the mask sizes were selected based on the weight standards recommended by the manufacturer as a standard index offering the optimal classical method of selecting the most appropriate LMA size.

Although previous studies have proposed that the duration of surgery affects the incidence of postoperative sore throat, our findings demonstrated that the duration of surgery had no association with the severity of postoperative sore throat, which could be attributed to the short duration of the surgeries in all the patients (13±51 minutes). Therefore, the lack of adequate dispersion in the duration of surgeries revealed no correlation between this parameter and sore throat.

One of the strengths of the present study was attention to the uniformity of the criteria for the selection of the LMA size and rate of cuff inflation, which led to the elimination of the interference of two major confounding factors. A limitation of the study was that the complication could not be verified in children.

## Conclusion

According to the results, gargling 20 milligrams of diphenhydramine suspension 20 minutes prior to the insertion of LMA in the patients undergoing eye surgery reduced the incidence of post-anesthetic sore throat. If the LMA size is selected based on weight-specific standards and the cuff

is filled in accordance with the instructions of the manufacturer, postoperative sore throat will not be affected by these parameters. By gargling diphenhydramine before surgery, 80% of the patients experienced no pain during recovery, and only moderate pain was reported within 24 hours after the surgery.

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## Conflict of Interest

The authors declare no conflict of interest.

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