

Comparison of Postoperative Sore Throat Following Endotracheal Intubation with or without Water-Based Lubricating Jelly

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Abstract

Background: Water-soluble lubricant gel (X–Y jelly) was evaluated for its ability to lessen the common throat pain that follows tracheal intubation under general anesthesia. **Materials and Methods:** scheduled for elective surgery under general anesthesia requiring endotracheal intubation, Were enrolled in a prospective, randomized, double-blind comparative study. They were split evenly into two-member cohorts. One cohort received 3 mL of water-soluble X–Y gel smeared from the cuff tip to 15 cm up the tracheal tube, whereas the other cohort had no gel. Sore-throat presence and severity were assessed 1, 4, 12 and 24 hours after tube removal. **Results:** Patients who received the X–Y gel reported noticeably milder and less frequent throat discomfort 4 and 12 hours after surgery ($P < 0.05$), whereas the two groups were comparable at the 1- and 24-hour checks. **Conclusion:** Endotracheal tube lubrication with water-based jelly significantly reduces POST at 4 and 12 hours postoperatively.

Keywords: Postoperative complications, sore throat, anesthesia, general, endotracheal intubation, lubricants, randomized controlled trial, double-blind method

INTRODUCTION

Major surgical operations are associated with undesirable postoperative sequelae [1, 2]. Several postoperative complications arise because of endotracheal intubation [3]. Among them, postoperative sore throat (POST), coughing, and hoarseness of voice are common and undesirable outcomes following tracheal intubation. It can cause discomfort and dissatisfaction to the patient. Different studies have shown different incidence of sore throat which varies from 14.4–70% [4, 5].

Cough, sore throat, and hoarseness of voice are caused by the mucosal injury of the airway following endotracheal intubation. Inflammation of the airway often occurs due to mechanical irritation from instrumentation or the presence of foreign objects such as endotracheal tubes [6]. Postoperative sore

throat (POST) may result from localized trauma to the pharyngeal and tracheal mucosa caused by laryngoscopy, intubation, or endotracheal tube cuff inflation [7]. Sore throat and hoarseness within the first 24 hours after surgery are among the most frequent complications associated with endotracheal intubation.

A comparison between patients using endotracheal tubes and those with laryngeal mask airways revealed that postoperative sore throat and hoarseness were more frequent among individuals with endotracheal tubes [8]. Although the laryngeal mask airway is linked to a lower incidence of these complications, its use is limited in many surgical procedures because it does not offer a fully secure

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airway. Water-based lubricating jelly can be applied to endotracheal tubes before insertion to minimize irritation. This jelly is a water-soluble, biologically inert lubricant that is free from colorants and fragrances and is widely utilized in medical practice. A study demonstrated that the use of water-based lubricating jelly significantly reduced the occurrence of sore throat, cough, and hoarseness, showing better results than betamethasone gel, which itself was more effective than lidocaine jelly [9].

In our setup, lidocaine jelly is commonly used for inserting nasogastric (NG) tubes and Foley catheters, but endotracheal tubes (ETT) are usually inserted without any lubrication. We currently do not employ any specific measures to reduce the incidence of postoperative sore throat (POST). In fact, sore throat is often overlooked and not treated as a significant concern, and there's very limited data available on its occurrence after intubation. This study was, therefore, conducted to evaluate how water-based lubricating jelly affects the incidence and severity of sore throat following endotracheal anesthesia.

METHODS

This prospective, randomized, double-blind study was carried out at Bir Hospital between July 16, 2018, and February 15, 2019. A total of 74 patients, aged 18 to 65 years, of either sex, classified as American Society of Anesthesiologists Physical Status (ASA-PS) I or II, and scheduled for elective surgeries under general anesthesia requiring endotracheal intubation, were included. The sample size was determined based on a study by Thapa et al. (2011) [3], which reported a 25% incidence of sore throat following endotracheal intubation. To detect a 15% reduction in incidence with a 95% confidence level, a minimum of 32 patients per group were required. Considering a 10% potential dropout rate, the final sample size was increased to 37 patients in each group. The sample size was calculated using the following formula:

$$\text{Sample Size (n)} = Z_{\alpha}^2 * P * Q / d^2$$

where n = required sample size, Z_{α} = 1.96% for 95% reliability, P = prevalence rate of sore throat, d = effect size = 15% reduction.

Patients were excluded from the study if they met any of the following criteria: refusal to participate, known hypersensitivity to medications, presence of an upper respiratory tract infection, preexisting throat pain, hoarseness, or cough, use of steroid therapy, or a history of hyperreactive airway diseases such as asthma. Additionally, patients requiring nasogastric tubes or throat packs, those undergoing surgeries lasting more than three hours, nasotracheal intubation, anticipated difficult or rapid sequence intubation, head and neck surgeries, or with a previous history of general anesthesia involving endotracheal intubation were excluded. Individuals with a Mallampati score greater than II were also omitted, as these factors are associated with a higher likelihood of developing postoperative sore throat [6].

After obtaining approval from the Institutional Review Board, a pre-anesthetic evaluation was conducted one day before surgery, and written informed consent was obtained from all participants after explaining the study and procedure in detail. Patients were instructed to remain nil per oral (NPO) for at least six hours before surgery.

Participants were randomly allocated into two groups using a paper ballot method. In Group X–Y, the endotracheal tube (ETT) was lubricated with X–Y® water-based lubricating jelly (R and R Company), whereas in Group C, the ETT was inserted without lubrication. The low-pressure, high-volume polyvinyl chloride (PVC) endotracheal tube, Curity® (Covidien Company), was coated with 3 ml of X–Y jelly from the distal cuff up to 15 cm along the shaft, ensuring uniform application under aseptic conditions.

Patient was brought to operation theatre. Non-invasive monitors including blood pressure, pulse oximetry, electrocardiography were attached and baseline vitals were recorded.

Patient sedation was achieved using midazolam at a dose of 0.04 mg/kg, while analgesia was provided with fentanyl 2 µg/kg. Anesthesia induction was carried out with propofol 2 mg/kg. Once manual ventilation was confirmed to be adequate, muscle relaxation was facilitated with rocuronium 1.2 mg/kg. After 1.5 minutes of bag and mask ventilation, tracheal intubation was performed using a Curity® polyvinyl chloride endotracheal tube by a qualified anesthesiologist, with tube sizes of 7.5 mm and 7.0 mm internal diameter for male and female patients, respectively. Following intubation and verification of tube placement, the cuff was inflated with room air to achieve just enough pressure to seal the trachea. Anesthesia was maintained using isoflurane at 1.2% concentration with oxygen at a flow rate of 3 L/min, and ventilation was controlled mechanically.

At the conclusion of surgery, once spontaneous breathing efforts resumed, neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.02 mg/kg. The airway was gently suctioned, and extubating was carried out while the patient remained under a deep plane of anesthesia. After the patient regained full consciousness and airway protective reflexes, they were transferred to the post-anesthesia care unit (PACU). The exact time of tracheal extubating was recorded, and the incidence and severity of postoperative sore throat (POST) were evaluated at 1, 4, 12, and 24 hours post-extubating by a non-blinded investigator using a standardized four-point scale as described below.

Postoperative sore throat score [1]:

- 0 = No sore throat at any time since the operation.
- 1 = Minimal sore throat (complains of sore throat only on asking).
- 2 = Moderate sore throat (complains of sore throat on his/her own).
- 3 = Severe sore throat (change of voice or hoarseness, associated with throat pain).

Data collected for the study included demographic information, preoperative vital signs, type of surgery performed, patient positioning during the procedure, number of intubation attempts, duration of intubation, and the size and type of endotracheal tube used. Additionally, the presence and severity of sore throat were recorded using a four-point verbal numerical rating scale, where 0 indicated no sore throat, 1 mild, 2 moderate, and 3 severe.

Data were expressed as frequencies or percentages for categorical variables, and as means with standard deviations for continuous variables. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS). The chi-square test was applied to analyze categorical data, while the student's t-test was used for numerical data. A p-value of less than 0.05 was considered statistically significant.

Data were collected using a structured proforma that included patient demographic details, vital signs, sore throat numerical rating scores, age, duration, and type of surgery. The collected information was analyzed using statistical software such as SPSS (Statistical Package for the Social Sciences) for Windows, applying appropriate statistical tests.

Results were presented in tabular form, with continuous variables expressed as mean ± standard deviation, and categorical variables shown as numbers and percentages. A p-value of less than 0.05 was considered statistically significant.

Student's t-test was employed to analyze continuous variables, such as age, weight, and duration of surgery, while the chi-square test was used to determine associations between groups for categorical variables, including gender, ASA physical status, and the incidence and severity of postoperative sore throat.

RESULTS

A total of seventy-four patients who met the inclusion criteria were enrolled in the study. However, four patients were excluded – two from Group X–Y and two from Group C. One patient was excluded

due to prolonged surgical duration, another because of unanticipated difficult intubation, and two others owing to the intraoperative insertion of a nasogastric tube. Statistical significance was defined as a p-value less than 0.05. The demographic characteristics of patients were found to be comparable between the two groups (Table 1).

Table 1. Demographic data of the patients.

Variables	Group X-Y (n = 35 mean $\pm$ SD)	Group C (n = 35 mean $\pm$ SD)	p-Value
Age (years)	42.29 $\pm$ 12.428	45.37 $\pm$ 14.831	0.349
Sex (M/F)	13/22	15/20	0.626
Weight (kg)	59.86 $\pm$ 9.27	63.11 $\pm$ 9.08	0.142
ASA I/II	29/6	24/11	0.163
Duration of surgery (minutes)	77.51 $\pm$ 23.641	76.57 $\pm$ 21.171	0.861

Incidence of Sore Throat

In this study, the overall incidence of postoperative sore throat was 38.57%. The occurrence of sore throat was 20% in Group X-Y and 57.4% in Group C. The comparison between the two groups revealed a statistically significant difference, with a p-value of 0.001 (Table 2 Figure1).

Table 2. Incidence of Postoperative Sore Throat in Group X-Y and Group C.

Parameter	Group X-Y (n = 35)	Group C (n = 35)	p-Value
Overall incidence	7 (20%)	20 (57.14%)	0.001

Note: Values given in number of patients and percentages.

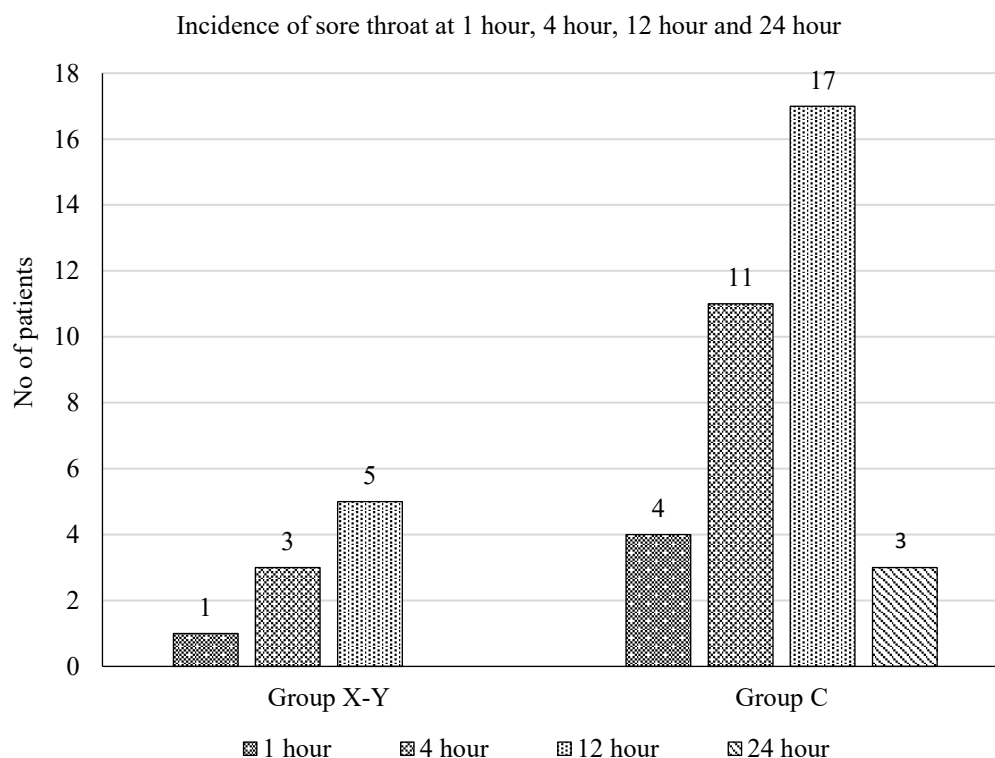


Figure 1. Incidence of sore throat at 1, 4, 12 and 24 hours between two study groups.

At one-hour post-extubating, the incidence of sore throat was 2.9% in Group X-Y and 11.45% in Group C. This difference was not statistically significant, with a p-value of 0.164. The incidence of sore throat at 4 hours was 3 (8.6%) for Group X-Y and 11 (31.4%) for Group C which was statistically

significant ($p = 0.017$). The incidence of sore throat at 12 hours was 5 (14.3%) for Group X–Y and 17 (48.6%) for Group C which was statistically significant ($p = 0.002$). At 24 hours, none of the patients had sore throat in Group X–Y but 3 patients from Group C had sore throat.

Severity of Sore Throat at 1 Hour

At one-hour post-extubating, most patients in both groups reported no sore throat, with no significant difference between them ($p = 0.164$) (Table 3).

Table 3. Severity of sore throat at 1 hour.

Severity Score of POST at 1 Hour	Group X–Y (n = 35) No. of Patients	Group C (n = 35) No. of Patients	p-Value
Severity Score 0	34	31	0.164
Severity Score 1	1	4	
Severity Score 2	0	0	
Severity Score 3	0	0	

Severity of Sore Throat at 4 Hours

At four hours post-extubating, Group X–Y showed significantly fewer cases of sore throat compared to Group C ($p = 0.017$) (Table 4).

Table 4. Severity of sore throat at 4 hours.

Severity Score of POST at 4 Hours	Group X–Y (n = 35) No. of Patients	Group C (n = 35) No. of Patients	p-Value
Severity Score 0	32	24	0.017
Severity Score 1	3	11	
Severity Score 2	0	0	
Severity Score 3	0	0	

Severity of Sore Throat at 12 Hours

At twelve hours post-extubating, Group X–Y had significantly fewer patients with sore throats compared to Group C ($p = 0.004$) (Table 5).

Table 5. Severity of sore throat at 12 hours.

Severity Score of POST at 12 Hours	Group X–Y (n = 35) No. of Patients	Group C (n = 35) No. of Patients	p-Value
Severity Score 0	30	17	0.004
Severity Score 1	5	17	
Severity Score 2	0	1	
Severity Score 3	0	0	

Severity of Sore Throat at 24 Hours

At twenty-four hours post-extubating, most patients in both groups were free of sore throat, with no significant difference between them ($p = 0.077$) (Table 6).

Table 6. Severity of sore throat at 24 hours.

Severity Score of POST at 24 Hours	Group X–Y (n = 35) No. of Patients	Group C (n = 35) No. of Patients	p-Value
Severity Score 0	35	32	0.077
Severity Score 1	0	3	
Severity Score 2	0	0	
Severity Score 3	0	0	

DISCUSSION

Postoperative sore throat and hoarseness of voice were found to be the 8th most undesirable outcome in postoperative period [10]. Though not a major anesthetic complication, sore throat and hoarseness of voice in the postoperative period can be troublesome and lead to major patient dissatisfaction following a relatively uneventful surgery. But in our daily practice, we overlook these common complications until and unless the patient complains.

The findings indicated an increased incidence of postoperative sore throat at four hours after extubating in Group C, which aligns with results observed in similar research [11]. In both the groups, at 1st hour, incidence of sore throat was less probably because patients were sedated due to the residual effects of anesthesia. The other reason could be patients were more aware of their surgical pain than sore throat. Patients receive analgesic immediately in the 1st hour of postoperative period which could be another reason of less incidence of sore throat at 1st hour. The use of analgesic in the first hour of operation might have masked the sore throat. At 4th and 12th hour of extubating, there is significant difference in incidence of POST between Group C and Group X–Y. It might have been because at 4th hour of extubating, patient got out of effect of sedation and anesthesia, so they could complain of sore throat. At 24th hour of extubating, least patients complained of sore throat in both the groups.

This study showed the overall incidence of POST in control group of 57.14% which is higher than the incidence shown in study done by Thapa et al. [3]. The incidence of POST in their study was 33.3%. They have standardized postoperative analgesia in their study and used anxiolytic a day prior to surgery. These might be the other reason for decrease in the incidence of sore throat in their study.

It was observed that in the control group, the overall incidence of postoperative sore throat at 4, 8, and 24 hours was 75%, 60%, and 50%, respectively. These values were considerably higher than those observed in the control group (Group C) of our study, where the incidence of POST was 11.4%, 31.4%, 48.6%, and 8.6% at 1, 4, 12, and 24 hours, respectively. This discrepancy may be attributed to differences such as the use of larger endotracheal tube sizes and the inclusion of nitrous oxide in their anesthetic protocol [12].

When the incidence and severity of postoperative sore throat (POST) were analyzed at different observation intervals, a statistically significant difference was observed at 4 and 12 hours after extubating, with a lower incidence noted in the group that received water-based lubricating jelly. Overall, both the incidence and severity of POST were higher in Group C compared to Group X–Y across all time points. Though the exact mechanism of water-based lubricating jelly is unknown, it is believed to reduce the POST by reducing friction, protecting the mucosa, and making movement smoother [9]. It was found that the overall incidence of postoperative sore throat was 57.5%, which closely matched the incidence observed in the control group at 57.14%. This study showed the significant differences in severity of sore throat at 4 ($p = 0.017$) and 12 hours ($p = 0.002$) which were similar with the results found in the study done by Doukumo et al. [13]. This study showed a higher severity score at 4 and 12 hours on both groups, which was not supported by the findings found on the study done by Thapa et al. [3] which showed higher severity score at only 24 hours. These variations might be due to prolonged inflammatory action of betamethasone and standardization of intra-cuff pressure.

Our study has several limitations. The small sample size made it challenging to determine whether factors, such as age, ASA classification, endotracheal tube size, anesthetist's experience, choice of muscle relaxants, or duration of intubation, had any influence on the incidence of postoperative sore throat (POST) in our population. The first assessment was conducted one hour after extubating, during which some patients might still have been drowsy, potentially affecting the accuracy of their responses regarding the presence and severity of sore throat. Additionally, endotracheal tube cuff pressure was not monitored, meaning consistent cuff pressure was not maintained, which could have introduced

variability in the results. Furthermore, postoperative analgesia was not standardized, which may have influenced patients' perception of sore throat intensity.

CONCLUSIONS

In conclusion, lubricating the endotracheal tube with 3 ml of water-based jelly, applied from the distal cuff up to 15 cm along the tube, effectively reduces both the incidence and severity of postoperative sore throat at 4 and 12 hours after extubating.

Recommendation

It is recommended to use water-based lubricating jelly in any case undergoing general anesthesia with endotracheal intubation to reduce the incidence and severity of POST.

Conflict of Interest

None.

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