Comparison between lignocaine 2% gel and water-based lubricant in reducing post intubation sore throat

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ABSTRACT

Introduction: Sore throat following tracheal intubation is a common postoperative complaint with a reported incidence of up to 90%. We performed a prospective randomised double-blind clinical trial to compare the effectiveness of lignocaine 2% gel with water-based lubricant (KY Jelly) in reducing post-intubation sore throat. **Materials and Methods:** One hundred and fifty one patients with American Society of Anaesthesiologists (ASA) physical status I or II undergoing elective surgery under general anaesthesia with tracheal intubation were enrolled into this study. Cuffed endotracheal tubes were lubricated with either lignocaine 2% (Group A) or a water-based lubricant (Group B). Patients were assessed at three intervals (1, 12, and 24 h after surgery) by a blinded investigator for presence of sore throat, severity of sore throat and throat related complaints. **Results:** Significantly larger number of patients in Group A complained of throat dryness at 1 h (p=0.035) and sore throat at 12 h (p=0.001). Incidences of sore throat and throat related complaints were comparable at other time intervals. No differences in severity of sore throat were observed, and none of the patients required further treatment. **Conclusion:** Lignocaine 2% gel was not effective in reducing post-intubation sore throat in comparison with water-based lubricant.

Keywords: Lubricant, lignocaine gel, water-based lubricant, sore throat, post-intubation, complications

INTRODUCTION

Sore throat is a common postoperative complaint following tracheal intubation, with a reported incidence ranging from 30 to 90%. [1-14] Although this is often regarded as a minor complication, it is distressing for the patient and often remain as unpleasant memories of the procedure. Therefore, lessening of the symptoms is worth striving for.

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In our institution, both lignocaine 2% gel and water-based lubricants are used for lubricating endotracheal tube (ETT). Local anaesthetic gels are postulated to limit po-

tential damage to tracheal mucosa by suppressing bucking on ETT, but their role post-intubation sore throat prevention is inconclusive. It have been shown that there was a higher incidence of sore throat associated with lignocaine 2% gel when compared to water-based lubricant or no lubricant. [1, 2] Another study found that lignocaine gel reduced the incidence of postoperative sore throat but not cough or hoarseness of voice compared with the control group. [9]

This study was thus undertaken to compare the effectiveness of lignocaine 2% gel with water-based lubricant in reducing post-intubation sore throat and other throat-related complaints.

MATERIALS AND METHODS

This prospective, double-blind, randomised clinical trial was carried out following approval from the institution's Research and Ethnics Committee. One hundred and fifty one patients with American Society of Anaesthesiologists (ASA) physical status I or II, aged between 18 to 60 years old and scheduled for elective surgery under general anaesthesia with tracheal intubation were enrolled in the study. The anticipated duration of surgery was between 2 to 4 hours, and intraoperative position was supine with the head in the neutral position. Obstetric patients, smokers, and those with preoperative sore throat or respiratory infection, anticipated difficult airway, history of neck, throat or airway surgery, and known allergy to medications used in study were excluded. Anaesthetic management in the operation theatre was carried out by anaesthetic trainees with more than five years experience in anaesthesia. Data collection and postoperative assessment were carried out by a blinded independent observer.

Explanation and written informed consent were obtained from patients recruited into the study. Patients were fasted overnight. Oral midazolam was prescribed as night sedation as well as premedication when patients were transferred to the operation theatre. Patients were randomised into two groups, Group A and Group B, by means of computer-generated random table. Cuffed ETT (Euro Care®, Belford Limited, London, United Kingdom) was selected based on the patient's gender and body size (7.0-7.5 for females, 7.5-8.0 for males). The ETT tip and its cuff were lubricated with either 3 ml of Lignocaine 2% Sterile Gel (Axcel, Malaysia) in Group A, or 3 ml of water-based lubricant KY Jelly (Johnson & Johnson, India) in Group B by the anaesthetic assistant according to the patients' group allocation.

Patients were placed supine and in the optimal intubating position on the operating table. Routine standard monitoring, consisting of electrocardiography, non invasive blood pressure monitor, pulse oximetry and capnography, was established. Anaesthesia was induced with IV fentanyl 2 µg/kg and propofol 2 mg/kg, followed by rocuronium 0.6 mg/kg to facilitate endotracheal intubation. Mask ventilation was carried out for 3 minutes with sevoflurane in 100% oxygen to achieve minimal alveolar concentration (MAC) of 1-1.2, in order to ensure an adequate depth of anaesthesia and relaxation before laryngoscopy and endotracheal intubation. No oropharyngeal airway was inserted unless mask ventilation was difficult as a result of airway obstruction caused by the tongue. An appropriate sized MacIntosh laryngoscope blade was used dur-

ing the intubation process, and the number of intubation attempts was noted. Patients who required more than two intubation attempts or required insertion of oropharyngeal airway, gum elastic bougie or nasogastric tube were excluded from the study.

After successful intubation, the ETT cuff was inflated with air to a minimal occlusion volume, checked by minimal air leak around the ETT at airway pressure of 20 cm H_2O. Cuff inflation pressure was monitored at hourly intervals and kept below 25 cm H_2O throughout the surgery. Maintenance of anaesthesia was provided by air and oxygen with sevoflurane at 1.0-1.2 MAC. Morphine 0.1-0.2 mg/kg was administered for intraoperative analgesia.

At the end of the surgery, neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Gentle oropharyngeal suction was carried out using Yaunkeur suction device. Endotracheal tube was removed following return of adequate spontaneous ventilation and consciousness with eye opening to verbal command. Duration of anaesthesia (induction to extubation interval) and the volume of air aspirated from ETT cuff on extubation were documented. Any adverse events occurring during or immediately after extubation, such as laryngospasm, stridor or oxygen desaturation (SpO_2 < 95%), were noted and managed accordingly.

Patients were assessed by a blinded observer at 3 intervals – first 1, 12, and 24 h after surgery. Assessment was carried out by direct questioning: "Do you have sore throat since operation?" If present, its severity was graded by means of Visual Analogue Scale (VAS) from 1 to 10, 1 being mild pain and 10 being the most severe pain imaginable. Those who complained of severe sore throat (VAS > 5) would be prescribed throat lozenges or gargles. Presence of other complaints such as throat dryness, cough and hoarseness were also assessed by direct questioning.

Statistical Analysis: The α value was set at 0.05 and power of study at 80%. Calculation was based on Soltani's reported percentage of sore throat with lignocaine 2% gel at 50% and that with water-based lubricant at 25%.[2] Sample size was calculated from 'Power and Sample Size Calculations' (Informer Technologies, Inc). Case sample size for Fisher's exact test or corrected Chi-square test was 66. Allowing for a drop-out rate of 15%, the total sample size was 151.

Data Analysis was carried out using SPSS 13 for Windows (LEAD Technologies, Inc). Student's t test was used for parametric demographic data such as age, weight, height, volume of air aspirated and duration of anaesthesia. Qualitative demographic data was analysed by Chi-square test. Chi-square test was used for incidence of sore throat and other throat-related complaints. Mann-Whitney U test was used to analyse the severity of sore throat. A p value of <0.05 was considered to be statistically significant.

RESULTS

No patients were excluded from the analysis. Both groups were comparable in terms of demographic data and intra-operative details (Table 1).

Table 2 shows the incidence of sore

throat and throat-related complaints during the study period. During the first hour, sore throat was present in 51% of patients in Group A and 39% in Group B, a difference which did not achieve statistical significance. A significantly greater number of patients in Group A experienced throat dryness (p= 0.035), while none of the patients complained of cough or hoarseness of voice. No adverse events, such as laryngospasm, stridor or oxygen desaturation were documented during or immediately after extubation.

At 12 h after surgery after surgery, sore throat continued to be present in 28% of patients in Group A, compared to 3% of patients in Group B (p=0.001). The incidence of throat dryness had reduced, and the intergroup difference observed in the first hour was no longer present. No patient had other throat-related complaints during this period.

At 24 h after surgery, there was a further decrease in the incidence of sore throat in Group A, from 28% to 2%. No significant differences in sore throat and throat-related complaints were observed during this assessment interval. Two patients in Group A complained of hoarseness of voice, but their symptoms resolved the next day without any treatment.

Even though the incidence of sore throat was significantly higher in Group A, there was no difference in terms of severity between 2 groups at 12 h following surgery (Table 3). Similarly, no significant differences in severity were observed during the other two assessment periods. None of the patients complained of severe sore throat (VAS>5) and no treatment was necessary.

DISCUSSION

Postoperative sore throat, dryness, cough and hoarseness are common and can be uncomfortable and distressing following endotracheal intubation. Even though such complaints are almost always self-limiting and respond to over-the-counter (OTC) local anaesthetic-based throat lozenges, there are cases of severe pain that are associated with additional symptoms such as hoarseness of voice.

Proposed aetiologies of sore throat in-

Table 1: Demographic Data and Intraoperative Details, values expressed as mean ± SD or number (%) where appropriate.

	Group A (n=80)	**Group B (n=71)**
Age (years)	41.4 ± 13.3	44.4 ± 13.2
Weight (kg)	64.9 ± 10.4	62.9 ± 6.8
Height (m)	1.7 ± 0.1	1.7± 0.1
Body mass index (kg/m^2)	23.4 ± 2.5	23.4 ± 2.0
Race		
Malay	47 (59)	39 (55)
Chinese	22 (28)	18 (25)
Indian	4 (5)	10 (14)
Others	7 (9)	4 (6)
Gender		
Male	53 (66)	45 (63)
Female	27 (37)	26 (37)
Cuff volume during extubation (ml)	4.7 ± 0.5	4.6 ± 0.6
Duration of anaesthesia (min)	162.5 ± 47.9	151.6 ± 36.0

Table 2: Sore throat and throat related symptoms.

Time post-surgery	1 h		12 h		24 h	
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
Sore throat	41 (51)	28 (39)	22 (28)[#]	2 (3)[#]	2 (2)	2 (3)
Throat dryness	32 (40)[*]	17 (24)[*]	8 (10)	4 (6)	0 (0)	0 (0)
Hoarseness	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Expressed as frequency and percentages (%)

Table 3: Severity of sore throat.

Time post-surgery	1 h		12 h		24 h	
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
n	41	28	22	2	2	2
VAS score (range)	2.1 (1-4)	2.0 (1-3)	1.9 (1-3)	2.0 (1-3)	1.5 (1-2)	1.5 (1-2)

clude mucosal erosion from the cuff of the ETT, friction between tracheal mucosa and the ETT, mucosal dehydration, and trauma as a result of patient bucking and coughing whilst on ETT. [13, 16, 17] There are numerous factors which can potentially influence the incidence of sore throat; ETT diameter, cuff design and pressure, intubation procedure, movement of the ETT during surgery, bucking or coughing, and excessive pharyngeal suctioning during extubation. [1-3] Other factors include age, gender, respiratory tract disease, previous postoperative nausea and vomiting, as well as duration of anaesthesia. [14] Mencke *et al*. found that the quality of tracheal intubation contributed to laryngeal morbidity, and excellent conditions were less frequently associated with postoperative hoarseness and vocal cord sequelae. [15]

Attempts to reduce post-intubation sore throat include the use of local anaesthetic agents as well as other medications such as steroids, [9, 10] non-steroidal anti-inflammatory drugs (NSAIDs), [14] and ketamine. [18] In appropriate cases, endotracheal intubation can be avoided with the use of supraglottic airway devices, which have been associated with significantly lower incidence of sore throat. [13, 14]

Various formulations of lignocaine can be administered by different means. It can be applied as a lubricant on to the cuff and tip of ETT, administered intravenously prior to airway manipulation, used as a topical spray on the vocal cords during direct laryngoscopy, and instilled into the ETT cuff following endotracheal intubation. The postulated mechanisms of action have been varied, ranging from lubrication to prevent trauma during intubation, reduction of friction between ETT cuff and tracheal mucosa during anaesthesia, suppression of coughing or bucking on the ETT thus limiting damage to tracheal mucosa, suppression of excitation of airway sensory C-fibres and reduction of neuropeptide release.

[13] The effectiveness of lignocaine appeared to be affected by drug concentration and route of administration, management of cuff pressure during anaesthesia, patient population, and the types of outcome measured. [13]

There are conflicting results regarding the effectiveness of lignocaine in preventing postoperative sore throat and throat-related complaints. Sumathi *et al*., found that lignocaine gel reduced the incidence of postoperative sore throat but not cough or hoarseness. [9] In contrast, lignocaine gel was found to be associated with a higher incidence of postoperative cough and hoarseness by Selvaraj *et al*., [10] and sore throat by Loeser *et al.,* [11] when compared to water-based lubricants. The latter studies were in accordance with the findings of our study.

In the first hour following surgery, the incidence of sore throat (51% with lignocaine and 39% with water-based lubricant) in our study was consistent with reported incidence. [1-14] Klemola *et al*. postulated that postoperative sore throat was due to certain impurities in the lignocaine preparation, [13] but this was not substantiated by other authors. We also found that the incidence of throat dryness to be higher in the lignocaine group. However, this complaint was self-limiting and abated without treatment.

We did not find any significant difference in the severity of sore throat or the incidence of other throat-related complaints between the two groups. Two patients in the lignocaine group experienced hoarseness 12 h after surgery. These patients were followed up in view of report of an association between hoarseness and arytenoid subluxation. [12] Their symptoms resolved the next day without any treatment.

Differences in findings between various studies could be due to differences in the assessment technique, scoring system for pain, drug preparation, and the absence of validated reliable measure for diagnosing postoperative sore throat and various protocols in pooled relative risk estimation. In our study, assessment was done by means of direct questioning on the presence of sore throat, throat dryness and hoarseness. This method of questioning could have affected our results, since a significantly higher incidence of sore throat could be obtained by direct as compared to indirect questioning. [5]

Our demographic and intra-operative data were comparable in both groups. We were able to exclude possible confounding factors such as ETT size, cuff pressure and duration of anaesthesia. However, we did not standardise other factors, such as the type of surgery, postoperative analgesia and resumption of oral intake. The adequacy of postoperative analgesia may affect the presence and severity of sore throat, while delayed resumption of oral intake may affect the hydration status of patients and sensation of throat dryness. These differences could have affected the accuracy of our results.

In conclusion, our study showed that lignocaine 2% gel was not effective in reducing post-intubation sore throat in comparison with water-based lubricant. These complaints were self-limiting and resolved within 24 hours.

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American Society of Anaesthesiologist (ASA) Classification

ASA	I	Normal healthy patients
	II	Patients with mild systemic disease
	III	Patients with severe systemic disease that is limiting but not incapacitating
	IV	Patients with incapacitating disease which is a constant threat to life
	V	Moribund patients not expected to live more 24 hours
	VI	A declared brain-dead patient whose organs are being removed for donor purposes