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A comparative evaluation of pharyngolaryngeal morbidity following I-gel insertion after the administration of betamethasone gel versus lidocaine jelly—a prospective study

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Abstract

Background: Post-operative sore throat, cough, and hoarseness of voice constitute the major pharyngolaryngeal morbidities following General anesthesia with an endotracheal tube since its introduction. Pharyngolaryngeal morbidity has been reported following the use of supraglottic airway devices as well, with less frequency and severity. Lidocaine jelly, a time-tested lubricating agent with local anesthetic effects is effective in reducing the incidence and severity of pharyngolaryngeal morbidity. Steroid gel application over the endotracheal tube is an effective alternative. The aim of this work is to compare betamethasone gel and lidocaine jelly in their effects leading to the causation of pharyngolaryngeal morbidity when applied to I-gel, a commonly used supraglottic airway device in practice now.

Results: Both betamethasone gel and Lidocaine jelly were found to be equally efficacious in controlling pharyngolaryngeal morbidity following I-gel insertion. Though the incidence of post-operative sore throat (POST) was lower in the B group in the first 2 h ($P=0.895$) and 6 h ($P=0.582$) postoperatively, it was not significant. Similar results with cough ($P=0.362$) and hoarseness of voice ($P=0.123$) found after 2 h were also not statistically significant.

Conclusions: Both betamethasone gel and lidocaine jelly reduced the incidence and severity of pharyngolaryngeal morbidity following I-gel insertion and was found comparable.

Trial registration: [CTRI/2017/10/010058](https://www.clinicaltrials.gov/ct2/show/study?term=CTRI/2017/10/010058). Registered 11th October 2017.

Keywords: Anesthesia, I-gel, Betamethasone dipropionate 0.05%, 2% lidocaine, Pharyngolaryngeal morbidity

Background

Occurrence of postoperative sore throat (POST), cough, and hoarseness of voice following surgery under general anesthesia (GA) with an endotracheal tube (ETT) is considered the major pharyngolaryngeal

morbidity (PLM) which makes the patient uncomfortable, and the postoperative period distressing with bad memories to recall later during second anesthetic exposure. It delays early enteral feeding, results in disturbed sleep, prolonged hospital stay, and costs. Still, it remains unaddressed because no single treatment modality has proven very effective until now, though many non-pharmacological measures and drugs are being tried. The incidence was found to vary from 14.4 to 50% in general but found significantly less following

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the use of laryngeal mask airway (LMA), a popularly used supraglottic airway devices (SAD) (Endo et al. 2007; Safaeian et al. 2015). The wide variation in these figures may be presumably due to the diversity of the devices used as well as the different techniques of insertion recommended for their use. SADs includes a spectrum of devices with or without an inflatable cuff. Lower cuff pressures are associated with less POST (Seet et al. 2010). I-gel (2nd generation SAD by intersurgical), which is commonly used in practice now, proves to have a lesser POST incidence than LMA (De Montblanc et al. 2014; L'Hermite et al. 2017). However, Belena et al. found that the incidence of POST was high with I-gel when compared with LMA Supreme (Belena et al. 2015). When applied adequately over the ETT, betamethasone gel, a steroid with anti-inflammatory properties, results in significantly less PLM than lidocaine (Sumathi et al. 2008). Our primary objective was to compare the effects of these drugs amounting to PLM when used for lubrication over the I-gel before its insertion.

Methods

The Department of Anaesthesiology of a tertiary cancer hospital conducted an observational study including 118 patients between the age group 18 to 60 years undergoing elective surgery under GA lasting for less than 120 min. Specifically, patients who underwent breast surgeries (Modified radical mastectomy) were included. They were divided into two groups of 59 each and evaluated for PLMs post-operatively. L group received 2 ml of 2% lidocaine jelly (each ml contains 20mg lidocaine HCL so, 2ml is equivalent to 40mg lidocaine HCL) during the study period from October 2017 to February 2018 whereas the B group received 2.5 ml of 0.05% betamethasone gel over the I-gel as the lubricating agent before its insertion following anesthetic induction from March 2018 to August 2018. Those requiring more than two attempts at I-gel insertion, recent upper respiratory tract infection in the form of pharyngitis, sore throat, those on pain medications for the disease, and steroid therapy were excluded from the study.

All the patients were assessed in the pre-anesthesia clinic and were premedicated with oral alprazolam 0.25 mg and pantoprazole 40mg both on the previous day night and the morning of surgery. In the operation theatre, after securing an intravenous (IV) cannula under local anesthesia, induction was done using IV lidocaine 1.5mg/kg, propofol 2mg/kg, and fentanyl 2mcg/kg followed by vecuronium bromide 0.1 mg/kg for adequate muscle relaxation after checking adequacy for mask ventilation. In the B group, an I-gel of appropriate size

according to the weight of the patient was selected and 2.5ml of 0.05% betamethasone gel (BETA GEL 20GM CREAM, MICRO LABS LIMITED) equivalent to 6.25mg was applied to the dorsum of the non-inflatable soft cuff. All the insertions were done by the anesthesiologist who has performed more than 50 I-gel insertions and follows a common standard technique of insertion. Anesthesia was maintained with nitrous oxide and oxygen in a ratio of 2:1 and sevoflurane at 1–2% to attain a MAC of 1. Residual neuromuscular blockade was adequately reversed and the device was removed once the criteria for removal were achieved. Patients were shifted to the post-anesthesia care unit (PACU) and assessed by the duty anesthesiologist for the occurrence of POST, cough, and hoarseness of voice according to a proforma at the end of 2, 6, 12, and 24 h in the postoperative period. The severity of PLM was graded as 0, 1, 2, and 3 taken as nil, mild, moderate, and severe as seen in Fig. 1 (Venugopal et al. 2016b).

The sample size was calculated based on a previous study by Sumathi et al. (2008) in a comparison between betamethasone gel and lidocaine jelly applied over ETT to reduce the incidence of PLM, assuming the power of study as 80% with a confidence level of 95%. The minimum sample size needed was 54 in each group (Sumathi et al. 2008). Considering those requiring more than 2 attempts at I-gel insertion and the duration of surgery exceeding 3 h for unforeseen reasons, an additional 5 patients were added and rounded to 59 in each group. Data obtained were entered into a Statistical Software Package for Analysis (SPSS). Categorical variables were expressed as counts and percentages; and continuous variables as mean \pm standard deviation. Comparison between the study groups was carried out using the unpaired t-test for normally distributed variables and Mann-Whitney *U* test, for otherwise continuous data whereas chi-square tests were done for the categorical data. A *p*-value less than 0.05 was considered significant for all comparisons.

Results

Our study period was from October 2017 to August 18, and 118 patients were observed for 11 months. None of the candidates was excluded from the study, and the flow chart has been illustrated in Fig. 2.

The association between descriptive statistics and the type of gel used observed in the study is depicted in Table 1. Here also, the candidates in the study population were comparable in all aspects.

Table 2 illustrates the association between postoperative symptoms and the type of gel used. We could not find any significant statistical difference in POST, cough, and hoarseness of voice at 2, 6, and 12 h postoperatively

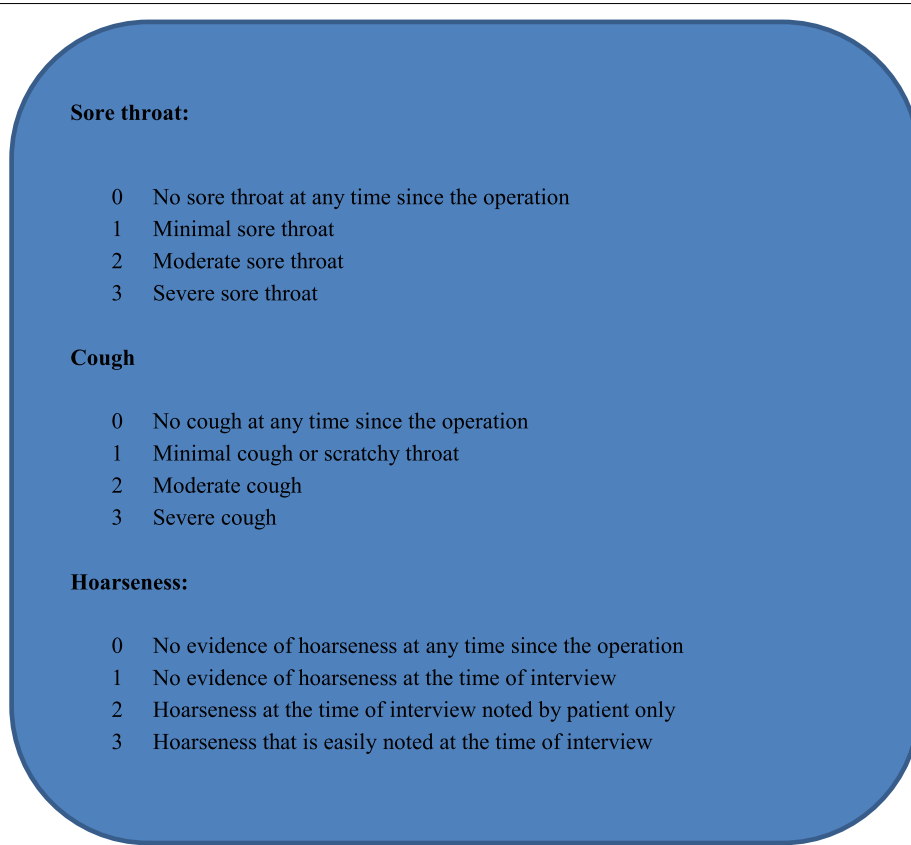


Fig. 1 Pharyngolaryngeal morbidity severity scoring

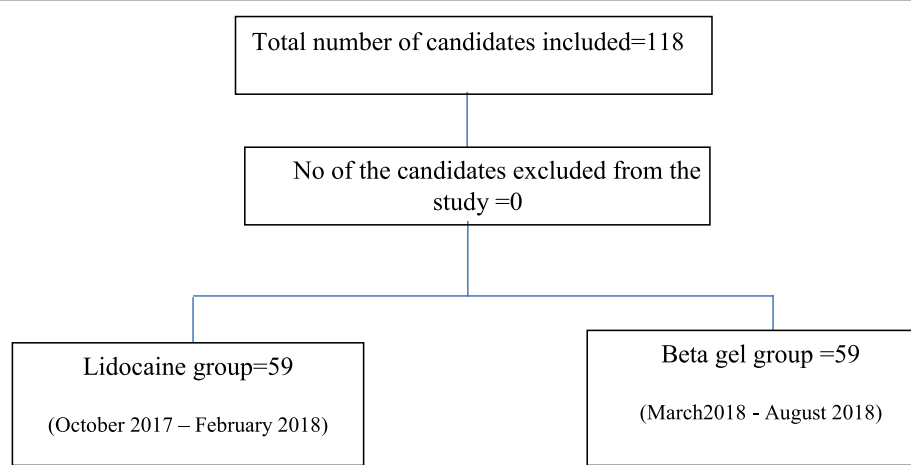


Fig. 2 STROBE flowchart of patients involved in the study

between the groups. At the end of 2 h, 81 patients (41 in B and 40 in L) had no sore throat, mild sore throat corresponding to a score of 1 developed in 15 patients (46.9%of candidates) in the B group and 17 patients (53.1%) of the L group, and the results were found

comparable. Moreover, 5 patients developed moderate sore throat where beta gel had a higher incidence. The difference in the incidence was not found statistically significant ($P=0.895$). None of the patients developed a severe sore throat. Six hours later, 103 patients had no

Table 1 Association between descriptive statistics and type of gel used

Descriptive statistics	Group	Mean ±SD	P-value
Age	B group	49.92 ± 11.05	0.607
	L group	50.95 ± 10.68	
Height	B group	156.32 ± 5.42	0.626
	L group	156.76 ± 4.29	
Weight	B group	59.98 ± 7.45	0.197
	L group	58.19 ± 7.58	
Duration	B group	79.75 ± 16.30	0.172
	L group	90.54 ± 34.91	
Heart rate	B group	83.88 ± 11.08	0.098
	L group	80.61 ± 11.21	
Blood pressure (mean arterial pressure)	B group	70.56 ± 11.33	0.014
	L group	75.53 ± 10.35	
SPO2	B group	99.69 ± 0.534	0.119
	L group	99.58 ± 1.39	
Respiratory rate	B group	12.76 ± 1.00	0.207
	L group	14.63 ± 11.24	
ETCO2	B group	34.98 ± 0.91	0.689
	L group	35.08 ± 1.71	
BMI	B group	24.52 ± 2.52	0.091
	L group	23.67 ± 2.87	

Table 2 Association of postoperative symptoms with both the groups

Postoperative symptoms	Group	Frequency (%)	P-value
Sore throat after 2 h	B group	3 (60.0)	0.895
	L group	2 (40.0)	
Sore throat after 6 h	B group	1 (100.0)	0.582
	L group	0 (0.0)	
Sore throat after 12 h	B group	1 (50.0)	1.000
	L group	1 (50.0)	
Cough after 2 h	B group	4 (33.3)	0.362
	L group	8 (66.7)	
Cough after 6 h	B group	1 (100.0)	1.000
	L group	0 (0.0)	
Cough after 12 h	B group	1 (100.0)	1.000
	L group	0 (0.0)	
Hoarseness after 2 h	B group	4 (57.1)	1.000
	L group	3 (42.9)	
Hoarseness after 6 h	B group	1 (50.0)	0.752
	L group	1 (50.0)	
Hoarseness at 12 h	B group	1 (100.0)	1.000
	L group	0 (0.0)	

sore throat, and 14 patients developed mild sore throat out of which 57.1% belonged to the B group and 42.9% to the L group that was found comparable ($P=0.582$) as

seen in (Table 3). Incidence was nearly the same at 12 h postoperatively.

The overall incidence of cough was 10.1% out of which mild cough (grade 1) was observed in 33.3% in the B group against 66.7% in L during the first 2 h postoperatively which was not statistically significant ($P=0.362$). The mild cough persisted in the Betamethasone group even at the end of 6 and 12 h. No cough was reported in 106 cases (Table 4). Out of the 5.9% of patients reported to have hoarseness of voice, I-gel smeared with betamethasone had a higher incidence (57.1%) than the lidocaine group (42.9%) at the end of 2 h in the postoperative period; again, the observed values were not statistically significant ($P=0.123$) as seen in Table 5.

Discussion

The definition of sore throat varies between anesthesiologists and the severity varies among patients as it is mainly subjective and depends on one's tolerance to pain. The insult is said to be multifactorial in origin including the size of the device selected, cuff design, the pressure generated, duration of surgery being a few leading to mechanical contact, and abrasion by the SAD in and around the glottic area (Endo et al. 2007). In ref (Endo et al. 2007), chose surgeries lasting for about 60 to 120 min under GA as a longer duration per se can contribute to PLM (Endo et al. 2007). Sore throat following the use of a laryngeal mask appears to be related to the technique of insertion, but the high intracuff pressure generated can lead to nerve palsies due to neuropraxia and nerve compression like the hypoglossal nerve palsy

Table 3 Significance of postoperative sore throat at 2, 6, and 12 h

	Group		Total	P-value
	B group	L group		
Sore throat at 2 h				
0	41 (50.6%)	40 (49.4%)	81 (100.0%)	0.895
1	15 (46.9%)	17 (53.1%)	32 (100.0%)	
2	3 (60.0%)	2 (40.0%)	5 (100.0%)	
Total	59 (50.0%)	59 (50.0%)	118 (100.0%)	
Sore throat at 6 h				
0	50 (48.5%)	53 (51.5%)	103(100%)	0.582
1	8 (57.1%)	6 (42.9%)	14 (100%)	
2	1 (100%)	0 (0.0%)	1 (100%)	
Total	59 (50%)	59 (50%)	118 (100%)	
Sore throat at 12 h				
0	58 (50%)	58 (50%)	116 (100%)	1.000
1	1 (50%)	1 (50%)	2 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118 (100%)	

Table 4 Significance of postoperative cough at the end of 2, 6, and 12 h

	Group		Total	P-value
	B group	L group		
Cough at 2 h				
0	55 (51.9%)	51 (48.1%)	106 (100.0%)	0.582
1	4 (33.3%)	8 (66.7%)	12 (100.0%)	
2	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Total	59 (50.0%)	59 (50.0%)	118 (100.0%)	
Cough at 6 h				
0	58 (49.6%)	59 (50.4%)	117 (100%)	1.000
1	1 (100%)	0 (0%)	1 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118 (100%)	
Cough at 12 h				
0	58 (49.6%)	59 (50.4%)	117 (100%)	1.000
1	1 (100%)	0 (0%)	1 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118 (100%)	

Table 5 Significance of hoarseness of voice at the end of 2, 6, and 12 h

	Group		Total	P-value
	B group	L group		
Hoarseness of voice at 2 h				
0	55 (49.5%)	56 (50.5%)	111 (100%)	1.00
1	4 (57.1%)	3 (42.9%)	7 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118 (100%)	
Hoarseness of voice at 6 h				
0	58 (50%)	58 (50%)	116 (100%)	0.752
1	1 (50%)	1 (50%)	2 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118(100%)	
Hoarseness of voice at 12 h				
0	59 (50.4%)	58 (49.6%)	117 (100%)	1.000
1	0 (0%)	1 (100%)	1 (100%)	
2	0 (0%)	0 (0%)	0 (0%)	
Total	59 (50%)	59 (50%)	118 (100%)	

leading to dysphagia, dysarthria, and immobility of the tongue (Endo et al. 2007). SADs are intrinsically more invasive than a facemask but less invasive than tracheal intubation, and careful insertion techniques particularly for laryngeal mask insertion are of paramount importance in the prevention of PLM (Venugopal et al. 2016a). Studies have demonstrated a significant reduction in the

incidence of POST and cough when ETT was smeared with betamethasone gel (Sumathi et al. 2008; Selvaraj and Dhanpal 2002). The beneficial effect of steroid gel application was attributed to the widespread effect of the drug on all portions of the tube that came in contact with the posterior pharyngeal wall, vocal cords, and trachea and not just confined to the tip and cuff of the tracheal tube (Selvaraj and Dhanpal 2002). Since the I-gel does not have a cuff to be inflated, the incidence of PLM is expected to be further less than the LMA in the post-operative period.

PLM is better prevented than treated. The incidence has reduced drastically with the availability of a newer generation of SADs which varies in cuff design, shape, and material, and better lubricating agents available like steroid gel. Cuffless SADs like I-gel provides an optimum seal at the laryngeal aperture with less pressure required for positive pressure ventilation which has recently gained recognition as an airway management device both in elective as well as emergencies. In a significant study of data-based systematic review done by Tanaka et al. using lidocaine as a topical preparation, the incidence of PLM was found to be significantly lower (Tanaka et al. 2015). In another interesting study, the incidence of PLM was found to be higher in women than men (Jansson et al. 2014).

In a study by Kiran.S et al., it was found that betamethasone gel resulted in a significantly lower incidence of PLM compared to 2% Lidocaine jelly, but they used Proseal LMA as the SAD (Kiran et al. 2012). Gupta et al. in their study found that the use of Strepsils lozenges resulted in a 20% reduction in the post-operative cough which was statistically significant (Gupta et al. 2014). Gargling ketamine 50 mg for the 40 s just 5 min before induction of GA and intubation was found to reduce the incidence and severity of POST in a significant way (Rudra et al. 2009). Similar results were also found with the use of oral dispersible Zinc tablets and magnesium lozenges in ameliorating POST (Sarkar and Mandal 2020; Singh et al. 2019). Rieger et al. showed that the incidence of PLMs was not directly related to the intracuff pressure transmitted to the mucosa (Rieger et al. 1997). Although hoarseness of voice seems to be a trivial adverse effect, along with sore throat and dysphagia it can lead to significant patient discomfort, anxiety, and postoperative morbidity following intubation (Ebnesahidi and Mohseni 2010). Like LMA, I-gel insertion can also lead to dislocation of the arytenoid joints causing hoarseness of voice or it may be following vocal cord paralysis which may be unilateral or bilateral (Brimacombe 1997). None of our patients had severe grades of POST according to the questionnaire. Only two cases out of 118 had a traumatic placement which was noted as a bloodstain

on the dorsum of the I-gel at the end of the procedure. SADs with I-gel in particular are expected to have a lower incidence of PLM. Since the device is bulky because of the cuff, it may cause abrasive injuries in the pharyngeal mucosa if not placed gently and well lubricated. Also in patients with limited mouth opening and larger tongue where I-gel is inserted with difficulty, it can lead to abrasive injuries of the mucosa, unlike LMA which requires less space for insertion as the cuff is deflatable. Beta-methasone gel acts as a lubricating agent with additional anti-inflammatory effects at the site of insult like the pharyngeal mucosa. This research work found that the outcome was comparable to lidocaine jelly used I-gel as the SAD which is cuffless and less likely to cause pharyngeal trauma, unlike other studies where either ETT or LMAs were used. But, surprisingly in a cross-sectional observational study on the incidence of POST following LMA and I-gel, it was found that both the incidence and severity were more with I-gel (Lin et al. 2020).

Regarding limitations of our study, chose only breast patients for mastectomy to limit the duration of surgery where positioning is supine and surgical duration is expected to be less than 120 min. A larger study taking other types of cases requiring positioning other than supine, an extended duration of surgery, obesity and pediatric cases taken as subsets or confounding factors may reveal whether they have a higher propensity to PLM. We didn't have a control group with KY jelly applied over the device. We had only one male patient for mastectomy out of 118 cases and hence cannot comment whether the sex of the individual had any role in the contribution of PLM.

Conclusions

This work found that betamethasone gel was equally efficacious and even a better alternative to lidocaine jelly when they were compared to cause PLM following the insertion of I-gel.

Abbreviations

POST: Post-operative sore throat; PLM: Pharyngolaryngeal morbidities; GA: General anesthesia; ETT: Endotracheal tube; SAD: Supraglottic airway devices; MAP: Mean arterial pressure; SPSS: Statistical Software Package for Analysis; PACU: Post anesthesia care unit.

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Authors' contributions

VKE has substantially conducted and contributed to the work, and drafted and revised the manuscript. VGAN conducted and contributed to the work and assisted in the drafting and revision of the manuscript. BRD and JKPMN substantially analyzed the work and revised the intellectual content of the work. All authors have read and approved the final manuscript.

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Availability of data and materials

Based on request will provide data.

Declarations

Ethics approval and consent to participate

Prior approval from the Institutional Review Board and Human Ethics committee belonging to Regional Cancer Centre Thiruvananthapuram (HEC No. 02/2017 dated 10/03/2017) including Dr Paul Sebastian, Dr P Kusumakumary, Dr K Ramachandran, Dr N Geetha. Prior registration of the study, (Registration no: CTRI/2017/10/010058) all procedures were performed in accordance to the ethical guidelines of the Declaration of Helsinki. We obtained an informed written consent to participate from adult patients and telephonic consent from relatives in this multicentric study (there was no need for consent from parent or legal guardian as pediatric patients were excluded from this study).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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