International Journal of Health Sciences and Research
www.ijhsr.org ISSN: 2249-9571

Original Research Article

Evaluation of Postoperative Sore Throat and Hoarseness of Voice with Three Variants of Laryngeal Mask Airway

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Received: 19/02/2015 *Revised: 29/06/2015* *Accepted: 30/06/2015*

ABSTRACT

Background: Modifications in LMA design could alter the pressure characteristics on the pharyngeal structures resulting in sore throat and hoarseness.
Methods: We studied the incidence and severity of postoperative sore throat and hoarseness of voice in the first 24 hours with LMA Classic, LMA Proseal and LMA Unique in 153 adult patients posted for elective surgical procedures under general anaesthesia after taking care of the confounding factors that could contribute to sore throat and hoarseness.
Results: LMA insertion was successful in first or second attempt in all patients. Mean surgical duration was 45.08 min, 51.55 min, and 51.25 min in LMA Classic, LMA Proseal and LMA Unique groups respectively. Incidence of sore throat at 6- 8h post LMA removal was 5.9%, 1.9% and 1.9%; at 18- 24h was 3.9%, 1.9% and 0% in LMA Classic, LMA Proseal and LMA Unique group respectively. Incidence of hoarseness of voice at 6- 8h was 3.9%, 0% and 9.8%; at 18- 24h was 0%, 0% and 3.9% in LMA Classic, LMA Proseal and LMA Unique group respectively. The incidence, severity of sore throat as assessed using VAS, and hoarseness of voice was comparable in all groups of patients.
Conclusions: LMA Classic, LMA Proseal or LMA Unique produces a low yet comparable incidence and severity of postoperative sore throat and hoarseness of voice in the first 24 hours following general anaesthesia with spontaneous ventilation provided that the confounding factors are strictly identified and addressed.

Key-words: Sore throat, Hoarseness, LMA Classic, LMA Proseal, LMA Unique

Key Messages: Classic LMA has been modified to introduce prototypes by alteration of the design. These modifications could alter the pressure characteristics on the pharyngeal structures resulting in sore throat and hoarseness. We investigated to see if the modification in the design of the LMAs could contribute to the same after ensuring that the confounding factors for sore throat and hoarseness were strictly controlled.

INTRODUCTION

Airway management is one of the most important skills in the field of anaesthesia. Laryngeal Mask Airway (LMA) is a supraglottic airway device that has gained immense popularity and

revolutionised airway management ever since its introduction.

LMA has continued to develop since the time of its invention and many variants have been developed subsequently. These variants have incorporated several modifications in the design of the airway tube, cuff, additional drain port, epiglottis elevating bar etc. which could result in subtle to significant differences in the mask fit or opposition to the pharyngeal wall. All these modifications could change the post-operative complications like sore throat or hoarseness. In this prospective randomised, double blind study three LMA variants are evaluated with respect to postoperative sore throat and hoarseness of voice.

Aim: To compare the incidence and severity of postoperative sore throat and hoarseness of voice in the first 24 hours with LMA Classic, LMA Proseal and LMA Unique in adult patients following general anaesthesia with spontaneous ventilation.

MATERIALS AND METHODS

After obtaining institutional ethical committee clearance, 153 adult patients undergoing elective surgeries in supine or lithotomy position under general anaesthesia requiring LMA insertion were included in the study with 51 in each of the three groups. They were randomly allocated into one of the following three groups. Group Classic, Group Proseal, and Group Unique depending on the LMA variant to be used. The sample size was determined assuming to detect a difference in sore throat of 10% between the LMA prototypes based on historical data, [1,2] a two-sided test, for a statistical power of 80% and for an α error of 0.05 including allowing of a 20% drop out rate. The variant of LMA to be inserted was decided by computer generated random number sequence and allocation concealment ensured using sequentially-numbered, opaque, sealed envelopes.

Adult patients aged between 18 to 60 years of either gender, belonging to American Society of Anesthesiologists Physical Status (ASA PS) 1 or 2, with Body Mass Index (BMI) $\leq$ 30 kg/m^2 undergoing elective surgeries lasting more than 30 minutes requiring general anaesthesia and spontaneous ventilation were included in the study. Patients with high risk of aspiration, anticipated difficult airway, reactive airway disease, head and neck surgeries, and any position other than supine or lithotomy were excluded.

In order to overcome confounding factors that could contribute to postoperative sore throat and hoarseness, we had done following changes

Administration of anti-sialogogue (glycopyrrolate) was avoided; all the insertions were done by consultant anesthesiologists who have more than 100 insertion experience in each of the three types of LMA; number of insertion attempts were limited to two; intra-cuff pressure was monitored continuously with anaeroid manometer and maintained in the range of 40- 60 cm H_2O; insertion of oropharyngeal airway or deep oropharyngeal suction was not done in any of these patients. All the LMA introductions and removal was made with the cuff fully deflated.

The study involved two observers. Observer 1, consultant anaesthesiologist (first author) who was blinded to the type of LMA inserted, conducted preoperative evaluation and postoperative sore throat assessment and observer 2, consultant anaesthesiologist (either second or third co-author) who had experience of more than 100 insertion in each of the three types of LMA, performed LMA insertions.

On the day before the scheduled surgery, the preoperative visit was done by observer 1 and inclusion and exclusion criteria were evaluated, written informed consent was taken from all eligible patients

and, Visual Analogue Scale (VAS) and the post-operative evaluation process was explained.

All patients were premedicated with oral alprazolam 0.25mg (body weight < 50 kg) or 0.5mg (body weight > 50 kg) on the night before and on the morning of surgery. All of them were kept nil by mouth for a period of six hours for solids and three hours for clear fluids. In the operating room, after recording baseline vitals and preoxygenation, anaesthesia was induced with IV propofol (2 mg/ kg) and IV fentanyl (2µg/ kg) and deepened with 2% isoflurane in oxygen for two minutes with face mask ventilation. After ensuring adequate depth of anaesthesia, as per the group allocated LMA type was lubricated with sterile water soluble jelly and inserted smoothly as per the recommended standard technique. Number of attempts taken for successful insertion was recorded. LMA size was chosen as per the patient's body weight (< 50 kg - size 3 and > 50 kg - size 4). LMA cuff was inflated with air to achieve a cuff pressure of 40 cm H_2O and proper positioning of LMA was confirmed with gentle assisted ventilation and appearance of a normal capnographic trace. The cuff pressure was maintained at 40-60 cm H_2O throughout the intraoperative period. Anaesthesia was maintained with 1.5 - 2% isoflurane in oxygen (40%), and nitrous Oxide (60%) with the patients breathing spontaneously through a semi- closed circle absorber system. At the end of surgery all patients were allowed to breathe spontaneously with 100% oxygen. Once the patient started responding to verbal commands LMA was removed after full deflation of the cuff. LMA was examined for blood stain indicating pharyngeal injury. Oropharyngeal suctioning was avoided and those patients requiring oropharyngeal suctioning or oropharyngeal airway in the perioperative period were excluded from further evaluation. Non-steroidal anti-inflammatory drugs were avoided in these patients during perioperative period and analgesia was provided by fentanyl. All Patients were kept nil by mouth for a period of four hours in the postoperative period.

Postoperatively all patients were evaluated for sore throat and hoarseness of voice between 6-8 hours and 18-24 hours postoperatively. Sore throat was graded as per the sore throat grading criteria (*Table 1*).

***Table 1*: Grading of postoperative sore throat and hoarseness of voice**

Grading of postoperative sore throat	
Grade 0	No sore throat
Grade 1	Mild sore throat – Pain on swallowing solids
Grade 2	Moderate sore throat – Pain on swallowing liquids
Grade 3	Severe sore throat – Continuous pain independent of swallowing
Grading of postoperative hoarseness of voice	
Grade 0:	No hoarseness
Grade 1:	Mild hoarseness – Change in voice as observed by the patient
Grade 2:	Moderate hoarseness – Change in voice as observed by the observer
Grade 3:	Severe hoarseness – Aphonia

Subjective assessment of sore throat as per patient's assessment was done using 10 point VAS score. A VAS score of 0 indicated no sore throat and a score of 10 indicated severe sore throat.

The results were analysed using the SPSS™ v17 statistical package. Nonparametric data (ASA-PS, Mallampati grade, blood stain on the LMA, number of attempts taken for insertion, sore throat, VAS grade and hoarseness) were analysed using chi-square test and parametric data (age, BMI, duration of LMA in situ) were

analysed using ANOVA. A p value < 0.05 was considered as statistically significant.

RESULTS

Demographic data of patients included is presented in *Table 2*.

Table 2: **Demographic data**

	Classic (n= 51)	Proseal(n= 51)	Unique (n= 51)	p value
Age in years Mean (SEM)	35.16(1.782)	39.94 (1.619)	37.51 (1.512)	0.123*
Sex: M/ F	35/ 15	32/ 19	39/ 12	
BMI kg. m^{-2} Mean (SEM)	22.01 (0.37)	22.74 (0.42)	22.04 (0.45)	0.375*
ASA- PS 1/ 2	49/ 2	43/ 3	46/ 5	0.136 †
Mallampati classification I/ II/ III/ IV	19/ 30/ 2/ 0	19/ 27/ 5/ 0	12/ 33/ 6/ 0	0.335*

ASA- PS: American Society of Anesthesiologists Physical Status
SEM: Standard error of mean *ANOVA † Chi-square test

All three groups were comparable with respect to age, gender distribution, BMI, ASA physical status and mallampati classification.

LMA insertion was successful on first or second attempt in all patients. Five patients in Classic group, three patients in Proseal group and six patients in Unique group required second attempt for successful placement.

The mean duration of the surgical procedure was 45.1 minutes in LMA Classic group, 51.6 minutes in group Proseal and 51.3 minutes in the Unique LMA group [p value of 0.255, ANOVA].

Blood stain on the LMA was noticed in four patients (three in group Classic and one in group Proseal). There was no significant difference in the incidence of oropharyngeal trauma [p value of 0.325, Chi-square test].

The incidence and severity grade of postoperative sore throat (*Table 3*)

***Table 3*: Incidence and grade of severity of postoperative sore throat**

	Grade	Classic (n= 51)	Proseal (n= 51)	Unique (n= 51)	p value
Sore throat at 6- 8 h post LMA removal	0	48	50	50	0.620 †
	1	0	0	1	
	2	0	1	0	
	3	3	0	0	
	Incidence (%)	5.9	1.9	1.9	
Sore throat at 18- 24 h post LMA removal	0	49	50	51	0.419 †
	1	1	1	0	
	2	0	0	0	
	3	1	0	0	
	Incidence (%)	3.9	1.9	0	

† - Chi-square test, p value- not significant

Severity of sore throat as per patients assessment using VAS (*Table 4*)

***Table 4*: Severity of postoperative sore throat assessed using VAS**

	VAS score	Classic (n= 51)	Proseal (n= 51)	Unique (n= 51)	p value
Sore throat at 6- 8 h post LMA removal	0	48	50	50	0.635 †
	0.1- 3	2	1	1	
	> 3	1	0	0	
Sore throat at 18- 24 h post LMA removal	0	49	50	51	0.361 †
	0.1- 3	2	1	0	
	> 3	0	0	0	

† - Chi-square test, p value- not significant

Incidence and severity grade of hoarseness of voice (*Table 5*),

***Table 5*: Incidence and grade of severity of postoperative hoarseness of voice**

	Grade	Classic (n= 51)	Proseal (n= 51)	Unique (n= 51)	p value
Hoarseness at 6- 8 h post LMA removal	0	49	51	46	0.133 †
	1	2	0	3	
	2	0	0	2	
	3	0	0	0	
	Incidence	3.9%	0%	9.8%	
Hoarseness at 18- 24 h post LMA removal	0	51	51	49	0.365 †
	1	0	0	2	
	2	0	0	0	
	3	0	0	0	
	Incidence	0%	0%	3.9%	

† - Chi-square test, p value- not significant

DISCUSSION

The use of an LMA has become a universally accepted option in anaesthesia practice. Sore throat and change in voice are frequently encountered problems following the use of LMA. The reported incidence of sore throat widely varies between various investigators. [3,4] McHardy et al. discussed several possible factors such as not using heat and moisture exchangers in the gas delivery circuit, oropharyngeal suctioning, insertion of LMA by residents and staff with a wide range of experience and cuff pressures not being monitored as factors which could influence the varied incidence of sore throat. [5] As there are several variants of LMA available and some of them are more popular than the LMA Classic. This study focuses on evaluating the incidence of sore throat and change in voice during the first 24 hours following the use of three different variants of LMA.

The incidence of postoperative sore throat at 2 hour postoperative period was higher with LMA Classic (30%) compared to LMA Soft Seal (10%) as reported by Dipasri et al. [4] Authors attributed the higher incidence to the increase in cuff pressure due to diffusion of nitrous oxide in LMA Classic and higher incidence of trauma. The higher incidence of trauma was indicated by a significantly higher number of blood stain in LMA Classic group (8% vs none) compared to LMA Soft Seal. In a similar study Van Zundert et al, assessed the incidence of sore throat after 2 hour postoperatively and the incidence was significantly higher with LMA Classic compared to LMA Soft Seal. [6] However at 24 hours the sore throat incidence was similar. They noted increase in intracuff pressure in LMA classic group compared to LMA Soft Seal group as a result of diffusion of nitrous oxide. Inflating the LMA cuff to the maximum recommended volume of air as per manufacturer's guidelines, often results in high intracuff pressure. Brimacombe et al, reported higher incidence of postoperative sore throat and hoarseness of voice when LMA Classic cuff was inflated with a higher volume compared to a lower volume (30 mL vs 15 mL for size 4 and 40 mL vs 20 mL for size 5). [7] Burgard et al. used LMA Classic in 200 adult female patients undergoing gynaecological procedures. [8] They used 65% nitrous oxide with 35% oxygen and observed a study increase in cuff pressure till 60 minutes in one group where as in the other group the volume was reduced to control pressure. The sore throat incidence was significantly lower (0% vs. 8%) in group where pressure was controlled. In another randomised trial involving 839 patients, Molt et al. reported higher incidence of sore throat with LMA Classic in women, older patients or after

multiple insertion attempts. [9] Seet et al, observed a lower incidence (13.4 vs. 45.6%) of composite pharyngolaryngeal complications in the pressure limitedgroup LMA Classic (intracuff pressure 44± 6 mmHg) versus the routine care group (114 ± 57 mmHg). [10] In contrast to above studies, Rieger et al. did not find any difference in the incidence of sore throat, dysphagia and hoarseness between high (180 mmHg) and low (30 mmHg) intracuff pressure groups. [11] Unlike most other studies they had removed the LMA while they were still asleep avoiding any coughing.

O Brien et al. investigated the effect of LMA Classic removal with or without deflating the cuff on postoperative sore throat and hoarseness of voice in 126 day care patients. [12] The incidence of sore throat was identical in both groups though there was higher incidence of blood stain (21% vs 13%) on the LMA cuff and hoarseness of voice (22% vs 9%) in the group where LMA was removed without deflating the cuff.

Figueredo et al. [13] investigated the postoperative laryngopharyngeal discomfort in 70 adult patients equally divided into LMA Proseal and Laryngeal tube group. There were no differences in the incidence of intolerance, sore throat, dysphagia, and/or dysphonia between the two devices.

In our study the incidence of sore throat at 6- 8 hours was 5.9% with LMA Classic, 1.9% each with LMA Proseal and LMA Unique. At 18-24 hours the incidence reduced to 3.9% in LMA Classic, 1.9% in LMA Proseal and 0% in LMA Unique. Addressing the confounding factors as identified by earlier studies like insertion performed by experienced operators and limiting the cuff pressures between 40-60 cmH_2O, not using oropharyngeal suction etc. might have resulted in significantly lower incidence of sore throat in our patients compared to most of the historical data. Although only 3 patients had sore throat in group Classic, all of them had severe sore throat at 6- 8 hours as per the sore throat grading criteria. We tried to grade the sore throat and hoarseness of voice using visual analog scale (VAS) as per patient's perception. Among the five patients who had a sore throat during 6-8h evaluation, most of them graded it as 3 or less on a scale of 10 except one patient in LMA Classic group who graded it as 5.2. The patient who graded it as 5.2 was found to be had two attempts at insertion and laryngeal trauma was evident by the presence of blood on LMA removal. On 18-24h evaluation, all three patients who were found to be having sore throat, graded their sore throat as 3 or less on a scale of 10.

The average time of LMA in situ in our study was about 45 to 50 minutes (range of 30 to 150 minutes) which could have contributed to the lower incidence of post operative complications. We had limited our evaluation to the first 24 hours so further incidence of sore throat or hoarseness of voice was not evaluated. Our study model had controlled conditions like experienced operators inserting LMA, limiting the number of attempts to two, avoiding oral airway or suction etc these factors might have contributed to the lower incidence and it may be difficult to replicate this in actual clinical practice. However by controlling the confounding factors the pharyngo-laryngeal complications can be reduced significantly. As the overall incidence and severity of the complications being comparable, we could assume that the structural modifications in the LMAs per-se have not resulted in any difference in the pharyngo-laryngeal complications.

CONCLUSION

The use of LMA Classic, LMA Proseal or LMA Unique results in a low yet comparable incidence and severity of

postoperative sore throat and hoarseness of voice in the first 24 hours in nonparalised anaesthetised adults. Understanding the confounding factors like avoiding repeated insertion attempts and controlling intracuff pressure will help in minimising sore throat and hoarseness of voice.

ACKNOWLEDGEMENT

The authors acknowledge the encouragement and support of Manipal University in clinical research.

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How to cite this article: Kiran BR, Prasad KN, Manjunath P. Evaluation of postoperative sore throat and hoarseness of voice with three variants of laryngeal mask airway. Int J Health Sci Res. 2015; 5(7):94-100.

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