POSTOPERATIVE SORE THROAT IN CHILDREN: COMPARISON BETWEEN PROSEAL™ LMA AND CLASSIC™ LMA

Azlina Mazzita Mohamed Mokhtar*
and Choy Yin Choy**

Abstract

Background: Postoperative sore throat after minor pediatric surgery although uncommon and the symptoms are mild, the incidence may be affected by several factors. This study was designed to compare the frequency and severity of post operative sore throat in children undergoing elective surgery following the use of proseal LMA (PLMA) compared to classic LMA (cLMA).

Methods: Two hundred children, 6 to 12 years old undergoing general anesthesia were selected and randomly divided into two groups which involved the use of the PLMA and the cLMA respectively. Induction of anesthesia was done with fentanyl 1mcg/kg and propofol 2-3mg/kg or sevoflurane 8% depending on the preference of the clinicians. Postoperatively, airway devices were removed when patients were fully awake and given supplemental oxygen via face mask.

Results: At 6 hours postoperatively, the incidence of sore throat was lower in the Proseal LMA group ($p<0.001$).

Conclusion: The incidence of sorethroat was lower in the Proseal LMA group compared to Classic LMA at 6 hours postoperatively.

Key words: Anaesthesia, LMA, sore throat, children, anesthesia.

Sources of financial support: Hospital Universiti Kebangsaan Malaysia.

Conflict of interest: No financial relationships between authors and commercial interests with a vested interest in the outcome of the study.

Introduction

Postoperative sore throat, a minor complaint after general anesthesia is of multifactorial etiology. There are few published studies on postoperative sore throat in children. Furthermore, assessing discomfort and pain in children is more difficult than in adults. In children, Splinter et al. reported an overall incidence of postoperative sore throat of 9% following the use of the Classic™ Laryngeal Mask Airway (cLMA™) compared to the use of the endotracheal tube (ETT), and the

* MD, Department of Anaesthesiology and Intensive Care.
** MD, FANZCA, Department of Anaesthesiology and Intensive Care.
Hospital Universiti Kebangsaan Malaysia, Jalan Yaacob Latiff, Bandar Tun Razak, Cheras, 56000, Kuala Lumpur. Malaysia.
Corresponding author: Clinical Associate Professor. YC Choy, Department of Anaesthesiology and Intensive Care, Hospital Universiti Kebangsaan Malaysia, Jalan Yaacob Latiff, Bandar Tun Razak, Cheras, 56000, Kuala Lumpur. Malaysia. Tel: 006-03-91455783, Fax: 006-03-91456585. E-mail: choy@ppukm.ukm.edu.my/ choyyinchoy@ymail.com

difference between the groups was not statistically significant[1]. They concluded that postoperative sore throat after minor pediatric surgery is uncommon, symptoms are mild and the incidence is unaffected by the choice of an LMA or ETT.

Increasingly the ETT is being replaced by the LMA as it offers an effective method of airway management due to ease of insertion and cost effective considerations. Once it has been properly positioned, it provides an adequate seal around the laryngeal inlet, thereby able to act as a reliable airway, and at the same time minimizes contamination of the environment from leakage of anesthetic gases.

The Proseal LMA (PLMA) has a modified cuff to improve the seal around laryngeal inlet. An esophageal drain tube is available through which a gastric tube can be inserted to empty the stomach thus reduce the risk of gastric aspiration and overcome inadvertent stomach insufflation during mechanical ventilation. In addition, it allows insertion of a bougie to assist in insertion thus it results in a higher success rate of insertion of the device[2]. Studies in adults have also found that PLMA forms a better seal without exerting any higher pressure on the mucosa, as was demonstrated by a higher airway leak pressure compared with the cLMA[2,3,4,5]. However, the standard recommended technique of insertion is association with a higher failure rate at first attempt and has resulted in airway trauma leading to postoperative sore throat in some patients[6]. The pediatric PLMA is available in sizes 1.5, 2 and 2.5 which, and unlike the adult sizes, do not have an additional dorsal cuff. As a result, insertion following the standard recommended technique, the PLMA has been found to be easier. Unlike in adults, bougie-guided technique is seldom required in children to facilitate insertion and proper position of PLMA[2].

This study was designed to compare the frequency and severity of post operative sore throat in children undergoing elective surgery following the use of PLMA (The Laryngeal Mask Company (M) Sdn, Bhd, Kulim, Kedah, Malaysia) compared to cLMA (The Laryngeal Mask Company (M) Sdn, Bhd, Kulim, Kedah, Malaysia). The roles of several factors such as type of airway, technique and multiple attempts at insertion, experience of the anesthetic personnel and duration of surgery were also evaluated.

Methods

This was a randomized controlled clinical trial. The study protocol was approved by the Ethics Committee. Written and informed consent was obtained from the parents. This was a prospective randomized, independent observer study with involvement of multiple operators carried out at Institute Paediatric Hospital Kuala Lumpur and UKMMC.

Two hundred patients aged between 6 to 12 years old with the physical status of ASA I-II and weighing 20-50 kg undergoing general anesthesia for elective non oral surgery were recruited in this study. Exclusion criteria included patients with risk of aspiration, potential difficult airway, communication problems and patients who were considered unsuitable for the use of PLMA or cLMA and smaller children who were unable to self report pain using a four-point categorical pain scale.

Patients were randomized into two groups of 100 patients each to either the PLMA group or cLMA group for airway management. Each patient was allocated to one of two groups using a concealed random number generator. All patients were monitored using an electrocardiogram, pulse oximeter, gas analyzer, non-invasive blood pressure monitor, capnograph, tidal volume monitor and airway pressure monitor during anesthesia.

Anesthesia was induced with intravenous propofol 2-3 mg/kg or inhalational induction with sevoflurane 8% and intravenous fentanyl 1mcg/kg according to the preference of the clinician. Following induction, the patients were ventilated manually using sevoflurane 2-4% in oxygen to achieve MAC of 1.3 and until condition are suitable for airway insertion indicated by presence of apnea, loss of eyelash reflex and lack of response to jaw thrust. The sizes of both devices were selected according to the manufacturer's recommendation.

The PLMA were inserted according to manufacturer's instructions using the introducer tool with the cuff fully deflated. Prior to insertion, lubricant was applied to both PLMA and cLMA. Upon insertion of the PLMA into the pharynx, the cuff was inflated with air until effective ventilation was established or the maximum recommended

inflation volume was reached. Correct positioning of the PLMA was determined by the presence of a square wave capnograph tracing, air bubble formation after placing lubricant over the proximal end of the drain tube and auscultating for esophageal air leak with the adjustable pressure limiting, valve set at 35 cmH_2O with gas flow of 3L/min. Effective ventilation for both LMA was judged by observation of adequate chest wall excursion, $SpO_2 > 97\%$ and a square-wave capnograph trace. Three attempts were allowed before insertion is considered a failure and a rescue device was used. The total number of attempts were noted and recorded. Between attempts, the patient's lungs were ventilated using the face mask with sevoflurane 2-4% in oxygen. Once insertion is successful, using the digital manometer, the intra cuff pressure was set at 60 cmH_2O based on the recommended upper limit recommended in the study by Schloss et al.[7] Anesthesia was maintained with 2-4% sevoflurane in 50% oxygen and 50% air and patient was allowed to breathe spontaneously.

At the end of the procedure, the anesthetic agent was discontinued and patient was given 100% oxygen and during this period the patient was not disturbed. Oropharyngeal suction was done carefully to minimize trauma. The LMA was removed when patient was fully awake. Following removal of LMA, supplementary oxygen was given via a regular face mask.

Patients and their parents were interviewed in recovery room 6 hours after surgery and before discharge. An independent observer asked patients about self assessment for the presence of sore throat (constant pain, independent of swallowing). A four-point categorical pain scale used in the investigation was explained to patients and parents. Grading of severity is as follow: sore throat is rated as 0 = none, 1= mild, 2 = moderate and 3 = severe. Any adverse events such as evidence of trauma to oropharyngeal structure, stridor, hiccup, laryngospasm and biting of the LMA during removal and drop of SpO_2 were recorded.

We are planning a study of independent cases and controls with 1 control(s) per case. Prior data indicate that the incidence of sore throat among controls is 0.42. If the true incidence for experimental subjects is 0.21 (50% less), we will need to study 85 experimental subjects and 85 control subjects to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use a continuity-corrected chi-squared statistic or Fisher's exact test to evaluate this null hypothesis[8].

Demographic data were analyzed using the Student t test while the Chi-square test was used to analyze the incidence of sore throat between PLMA and cLMA. A p value of < 0.05 was considered statistically significant.

Results

The demographic data of the patients are shown in Table I. There were no significant differences between the two groups in terms of age, sex, weight, and ethnic group but there was a statistically significant longer duration of surgery in PLMA group compared to cLMA ($p < 0.001$).

Table I
Demographic data of patients in both groups.
Data are mean ± standard deviation (SD)

Data are mean ± standard deviation (SD)

	Classic LMA™ (n = 100)	Proseal LMA™ (n = 100)
Age (year)	9.2 ± 2.0	9.1 ± 2.0
Weight (kg	33.2 ± 8.2	30.6 ± 8.0
Gender :		
Male	51	46
Female	49	54
Ethnic group :		
Malay	57	58
Chinese	28	25
Indian	13	15
Others	2	2
Duration of surgery (min)	34.5 ± 11.9	46.4 ± 19.58

Fig. 1
Pain scores in the immediate postoperative period in recovery room and 6 hours later

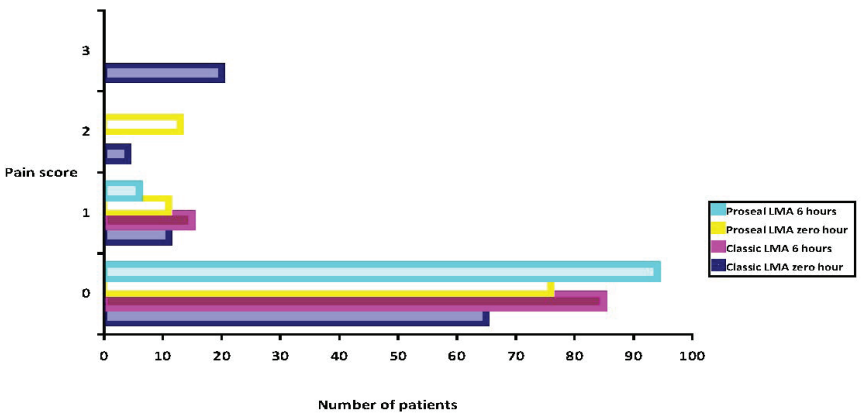

Figure 1 shows the pain scores between the two groups at immediate postoperative period in recovery room and 6 hours later. Table II shows the incidence of sore throat in recovery room and 6 hours postoperatively. Classic LMA™ and Proseal LMA™ had no statistically significant difference in the incidence of sore throat in immediate postoperative period (P=0.09). However at 6 hours later, the incidence of sorethroat was lower in the Proseal LMA group (p<0.001). None of the patient had dysphonia and dysphagia.

Table III shows the numbers of attempt taken for insertion of the device and the difference sizes of airway used among the two groups. There was no statistically significant difference in the number of attempts (P=0.471) when using Classic LMA™ and Proseal LMA™. Regarding the size of airway used, 61% of patients used size 2.5 Proseal LMA™ as compared to 58% of patients used size 3 Classic cLMA™.

Table II
Incidence of sore throat

	Classic LMA™	Proseal LMA™
Incidence of sore throat (%)	(n=100)	(n=100)
Recovery room	35	24
6 hours postoperative	15	6

Table III
Number of attempts of insertion of the device and airway sizes used

	Classic LMA™	Proseal LMA™
Number of attempt	(n=100)	(n=100)
1	79	83
2	20	16
3	1	1
Airway size		
2.5	32	51
3.0	68	49

Discussion

In this study the incidence of sore throat was lower in the Proseal LMA group at 6 hours postoperatively. Of interest was the lower incidence of sore throat observed after PLMA insertion in children and this could be attributed to the differences in laryngopharyngeal anatomy and physiology between children and adults. Under-reporting by children and/or parents may also have contributed to the lower reported incidence of sore throat.

In the case of the pediatric PLMA, the lack of a dorsal cuff may be significant as it results in lesser fold over as the cuff is pushed into the mouth, and this may facilitate insertion of the device. However, we did not find any difference in terms of the number of attempts required to achieve successful insertion.

This study demonstrated that the use of a slightly larger LMA^T was not associated with a higher incidence of sore throat compared to a smaller size airway used in the PLMA group. Grady et al found a fourfold increased risk of developing sore throat when a larger LMA was used in adult patients[9,10,11,12]. Originally, the manufacturer of the LMA recommended insertion of a size 3 LMA in children and small adults weighing more than 30 kg, a size 4 LMA in normal adults and a size 5 LMA in large adults. More recently, Brain and other investigators have recommended the routine use of a larger LMA. Many of these studies reported lower oropharyngeal leak pressure during positive pressure ventilation associated with the use of a larger LMA. However, a smaller LMA may be equally effective in spontaneously breathing patients, in whom a very good seal around the laryngeal inlet is less critical to achieve effective functioning of the LMA[10].

Postoperative sore throat ranges 22.7% vs. 41.8% of patients with LMS use[8]. In adults, the incidence of postoperative sore throat is similar in anaesthetized, non-paralyzed compared to intubated patients, probably both are equally affected by a combination of trauma on insertion and pressure exerted by the cuff against the pharyngeal mucosa[6,9,10].

Grady et al. identified longer surgical procedure as being a factor predictive of higher incidence of sorethroat[11]. The longer duration of operation in the PLMA group that can theoretically result in higher incidence of sore throat was not reflected in this study.

Williams el al studied 400 children and found that, thirteen children (3.3%) developed sore throat after LMA. Using a laryngeal mask airways with a polyvinyl chloride (PVC), material was associated with a higher risk for sore throat compared with an LMA with a silicone material (P = 0.0002). They concluded that, with controlled low cuff pressures, the incidence of sore throat was low and the use of an introducer device did not affect the rate of sore throat[12].

This study had several limitations. First, multiple operators with different length of experience were involved in using the devices. All the devices were inserted by personnel with relatively short period of experience of use of these airway devices and the data obtained in this study may not be applicable to those which involved very experienced personnel. Secondly, this study did not use a standard questionnaire to evaluate the severity of sore throat, there were differences among individual assessor and patient in the definition of sore throat. It has been shown for example that direct questioning results in a significantly higher incidence of sore throat than indirect questioning[13,14].

In conclusion the incidence of sore throat was lower in children ventilated using the Proseal LMA compared to the Classic LMA group at 6 hours postoperatively.

References

1. Splinter WM, Smallman B, Rhine EJ, Komocar L: Postoperative sore throat in children and the laryngeal mask airway. *Can J Anaesth;* 1994, Nov, 41(11):1081-3.
2. Reier CE: Bleeding, Dysphagia, Dysphonia, Dysarthria, Severe Sore Throat and possible recurrent laryngeal, hypoglossal and lingual nerve injury associated with routine laryngeal mask airway management: Where is the vigilance? *Anesthesiology;* 2004, 101:1241-42.
3. Bhavesh Patel, Robert Bingham: Laryngeal mask airway and other supraglottic airway devices in paediatric practice. *Oxford J Anaesth;* 2009, 9:6-9.
4. FE McHardy and F Chung: Postoperative sore throat: cause, prevention and treatment. *Anaesthesia;* 1999, 54:444-453.
5. M Lopez-Gil, J Brimacombe: The Proseal Laryngeal Mask Airway in children. *Paediatric Anaesthesia;* 2005, 15:229-234.
6. J Brimacombe: *Laryngeal Mask Anesthesia;* Second edition, 2005, 357-382 (United Kingdom Saunders).
7. Schloss B, Rice J, Tobias JD: The laryngeal mask in infants and children: what is the cuff pressure? *J Pediatr Otorhinolaryngol*; 2012, Feb, 76(2):284-6.
8. Spiro M, Gross J, Boomers O: The influence of laryngeal mask airway (LMA) cuff pressure on postoperative sore throat: 19AP3–1. *European Journal of Anaesthesiology*; June 2010, volume 27, Issue 47, p. 250.
9. J Brimacombe: A Multicenter Study Comparing the PLMA and Classic™ Laryngeal Mask Airway in Anesthetized, nonparalyzed patients. *Anesthesiology;* 2002, 96:289-95.
10. Brain AIJ, Verghese C, Strube PJ: The LMA Proseal: A laryngeal mask with an oesophageal vent. *Br J Anaesth;* 2000, 84:650-4.
11. Grady Deirdre, McHardy Fiona: Pharyngolaryngeal morbidity with the laryngeal mask airway in spontaneously breathing patients: Does size Matter? *Anesthesiology;* 2001, 94:760-766.
12. William A, Chambers NA, Erb TO, von Ungern-Sternberg BS: Incidence of sore throat in children following use of flexible laryngeal mask airways-impact of an introducer device. *Paediatr Anaesth;* 2010 Sep, 20(9):839-43.
13. Brimacombe J, Keller C: Laryngeal mask airway size selection in males and females: Ease of insertion, oropharyngeal leak pressure, pharyngeal mucosal pressures and anatomical position. *Br J Anaesth;* 1999, 82:703-7.
14. Rieger B, Brunne I Hass: Laryngo-pharyngeal complaints following laryngeal mask airway and endotracheal intubation. *Clin. Anesth J*; 1997, 9:42-47.