

Effectiveness of Proseal laryngeal mask airway and laryngeal tube suction in elective non-laparoscopic surgeries of up to ninety minutes duration: A prospective, randomized study

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Abstract

Background and Aims: Proseal laryngeal mask airway (LMA) and laryngeal tube suction (LTS) are both supraglottic devices with an esophageal suction port. In the present prospective, randomized study, the effectiveness of airway seal, hemodynamic variables, ability to pass orogastric tube, and postoperative complications with the two devices were evaluated.

Material and Methods: This was a prospective, randomized, single-blind study conducted in a hospital-based setting. Sixty patients (American Society of Anesthesiologists Grade I and II) undergoing elective general surgery were randomly allocated to Group A (Proseal LMA) or Group B (LTS), and airway seal pressure (primary outcome), peak pressure, hemodynamic parameters (blood pressure, pulse rate and pulse oximetry) during and 5 min after insertion, insertion time, ease of insertion, and postoperative complications (sore throat and hoarseness of voice for a period of 24 hours) (secondary outcomes) were noted. The quantitative data was summarized as mean and standard deviation, and analyzed using Student's *t*-test. All the qualitative data were summarized as proportions and analyzed using Chi-square test. The levels of significance and α -error were kept 95% and 5%, respectively, for all statistical analyses. $P \leq 0.05$ was considered significant (S).

Results: Proseal LMA had shorter insertion time (16.4 ± 5.6 vs. 20.0 ± 3.9 s), higher seal pressure (27.6 ± 4.6 vs. 24.1 ± 5.6 cm of H₂O), lesser peak pressure (16.3 ± 2.3 vs. 18.5 ± 3.9 cm of H₂O), higher success rate of orogastric tube passage (86.7 vs. 76.7%), and lesser postoperative sore throat (3.3 vs. 10%).

Conclusions: Both Proseal LMA and LTS were acceptable alternatives for airway management in elective surgeries with controlled ventilation, but the quality of ventilation was found to be significantly better with Proseal LMA (in terms of higher seal pressure, lesser peak pressure, lesser insertion time, and lesser complications).

Keywords: Airway seal pressure, laryngeal tube suction, Proseal laryngeal mask airway, supraglottic device

Introduction

Supraglottic airway devices have been described as a missing link between facemask and endotracheal intubation.^[1] They have become the standard of care in day-care surgeries. Laryngeal mask airway (LMA) Proseal is the modification of

LMA classic and has been extensively studied.^[1,2] Laryngeal tube suction (LTS) is a newer version of the laryngeal tube that was introduced mainly for prehospital emergencies.^[3,4] It shares certain features of Proseal LMA, i.e., esophageal suction port for gastric decompression.^[4] Although having established role in emergency situations, its effectiveness in the maintenance of anesthesia for elective surgeries is yet to be explored.

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Access this article online	
Quick Response Code:	Website: www.joacp.org
	DOI: 10.4103/joacp.JOACP_101_16

How to cite this article: Verma S, Sharma SP. Effectiveness of Proseal laryngeal mask airway and laryngeal tube suction in elective non-laparoscopic surgeries of up to ninety minutes duration: A prospective, randomized study. J Anaesthesiol Clin Pharmacol 2018;34:58-61.

In this study, we compared the effectiveness of airway seal, i.e., seal pressure, of LMA Proseal and LTS as the primary outcome. We also studied secondary outcomes viz. the time taken and ease of insertion, peak airway pressure, hemodynamic variables, ease of orogastric tube passage, and postoperative complications following device insertion in paralyzed patients undergoing elective surgery under general anesthesia.

Material and Methods

The study was a prospective, randomized, single-blind study conducted after approval of the Institutional Ethical Committee and Review Board, and written informed consent from all patients. Sixty patients of either sex, with weight ranging between 40 and 60 kg and height ranging between 150 and 180 cm, American Society of Anesthesiologists Grade I or II undergoing elective general surgical procedures lasting up to 90 min duration. They were randomly allocated to one of the two groups (randomization by chit in the box method, each of which contained either of the two letters, A or B), one of which was opened by the author after induction of anesthesia. Group A received LMA Proseal and Group B received LTS as the airway device.

Patients with increased risk of pulmonary aspiration (gastroesophageal reflux disease, hiatus hernia, or pregnant patients) and those with upper respiratory tract/alimentary tract pathology were excluded from the study.

After securing peripheral venous access, the standard multipara monitor was attached, and baseline pulse, blood pressure, and pulse oximetry were recorded.

Patients were premedicated with injection glycopyrrolate 0.005 mg/kg, midazolam 0.02 mg/kg, and fentanyl 1.5 mcg/kg. After preoxygenation with 100% oxygen for 5 min, induction dose of propofol was given (2 mg/kg) till the loss of verbal commands. Neuromuscular blockade to facilitate placement of device was achieved by succinylcholine 1.5 mg/kg. Following induction and adequate paralysis, the corresponding airway device was inserted in each patient by one of the authors (with experience of more than 200 device insertions). In Group A, size 3 or 4 Proseal LMA (according to weight)^[5,6] was used. For the purpose of standardization, the introducer was used for insertion of Proseal for all cases. The cuff was fully deflated, and posterior surface was lubricated with water-based jelly before insertion. The patient's head was maintained in the sniffing position. In Group B, LTS size 4 (according to height)^[7] was inserted following standard blind insertion technique and then connected to the breathing circuit.

The cuff was inflated with the volume of air that prevented leak around the cuff^[6,8] (no leak on auscultation over suprasternal notch and observation of square waveform on capnography). Airway seal pressure was noted at this volume at a flow of 4l/min with expiratory valve fully closed, through aneroid manometer, i.e., observing the dial as the airway pressure increased and noting the pressure at which the dial reached equilibrium.

Correct placement of the device was confirmed by bilateral equal chest rise, square wave capnography, observation of tidal volume of 8 ml/kg, and auscultation of good air entry in all lung fields. If proper seal was not obtained (audible leak on auscultation present or "suboptimal" ventilation), manipulations were done in the form of chin lift and jaw thrust. No other manipulations were used. Three attempts were allowed before the device could be considered failure in which case the airway was secured by conventional endotracheal intubation. Patients were connected to the ventilator with volume control mode, tidal volume set to 8 ml/kg (ideal body weight). The respiratory rate of 12/min was required to maintain end-tidal carbon dioxide between 30 and 38 mmHg. Orogastric tube number 14 was inserted through the drain tube.

Anesthesia was maintained with oxygen, nitrous oxide, and isoflurane along with injection atracurium 0.5 mg/kg loading and 0.1 mg/kg for repeated dose.

At the end of surgery, inhalational anesthetic agents were discontinued and patients were kept on 100% oxygen, and intravenous (i.v.) glycopyrrolate 0.01 mg/kg followed by i.v. neostigmine 0.05 mg/kg was given for reversal of residual neuromuscular blockade. After full deflation of cuff, the device was removed in a spontaneously breathing patient. The patients were followed up for 24 h to watch for complications such as sore throat and hoarseness of voice.

The quantitative data was summarized as mean and standard deviation and analyzed using Student's *t*-test. All the qualitative data were summarized in the form of proportions and analyzed using Chi-square test. The levels of significance and α -error were kept 95% and 5%, respectively, for all statistical analyses.

$P < 0.05$ was considered statistically significant. Sample size was calculated at 80% study power and alpha error of 0.05, assuming standard deviation of 5 cm H₂O as found in a study of Cook *et al.*^[4] For minimum detectable mean difference in airway pressure of 4 cm H₂O, 25 patients in each group were required which were enhanced and rounded off to thirty patients in each group expecting 20% attrition.

Results

Thirty patients were included in each group. Demographic data of age, sex, height and weight were comparable between the two groups [Table 1]. The surgical procedures included lower limb amputation, appendicectomy, breast surgery, ileostomy closure, lumbar sympathectomy, fistulectomy, and sebaceous cyst excision. Hemodynamic variables and oxygen saturation were comparable between the two groups before and 5 minutes after insertion of device [Tables 2-3]. The insertion time was significantly less for Proseal LMA than LTS [Table 4]. Higher seal pressure was obtained with Proseal LMA compared to LTS [Table 4]. Peak pressure was lesser with Proseal LMA than LTS (16.3 ± 2.3 vs. 18.5 ± 3.9 cm of H_2O ; $P = 0.013$) and it took lesser number of manipulations than LTS (6.7% vs. 3.3%). Gastric tube insertion was successful in 86.7% of Proseal LMA cases in the first attempt and 76.7% cases in LTS. The second attempt for gastric tube insertion was required in 13.3% of Proseal and 23.3% of LTS group patients. Sore throat was seen in 3.3% of Proseal group versus 10% cases of LTS group. Optimal ventilation (i.e., adequate chest movement, stable oxygenation, and square wave capnography) was achieved in all cases of Proseal LMA (100%) while in only 90% with LTS.

Table 1: Comparison of demographic profile of patients in two groups

Variables	Group A (PLMA)	Group B (LTS)	P
Age (years)	38.6 \pm 13.5	38.8 \pm 14.4	0.941
Sex (male:female)	16:14	14:16	0.606
Weight (kg)	58.8 \pm 10.4	58.4 \pm 7.5	0.882
Height (cm)	161.8 \pm 10.5	162.1 \pm 8.7	0.915

Data was expressed as mean \pm Standard deviation or proportion. Student's *t* test or Chi-square test was used for analysis. $P < 0.05$ was considered significant. PLMA=Proseal laryngeal mask airway, LTS=Laryngeal tube suction

Discussion

In the present study, both Proseal LMA and LTS were found to be acceptable alternatives for airway management in elective surgeries with controlled ventilation, but Proseal provided better seal pressure, lesser peak pressure, and lesser complications.

The device insertion time for Proseal LMA was significantly lesser than that of LTS. The introducer tool was used for Proseal for the purpose of standardization. This finding is comparable with the findings of Cook *et al.*^[4] who reported that although success rate of insertion between both was similar, LTS took longer time to insert. Brimacombe *et al.*^[9] also found that effective airway time was shorter in Proseal, possibly because the insertion is easier with the introducer as it occupies lesser volume due to flat configuration, directs the cuff around the oropharyngeal inlet, and facilitates a full depth of insertion.

The seal pressure obtained with Proseal laryngeal mask was higher than that with LTS. Similar finding was reported by Cook *et al.*^[4] Other studies^[10,11] have reported the difference as statistically insignificant. The relative inexperience with LTS could be one explanation for this.

The peak airway pressures produced by Proseal were lower compared to LTS. Kikuchi *et al.*^[12] found similar results while comparing the two devices. One of the explanations for the higher peak airway pressures could be the higher resistance to airflow because of the smaller ventilation outlets of the LTS.^[13]

Gastric tube no. 14 could be successfully passed through the esophageal port in 86.7% of Proseal LMA cases while 76.7% of LTS cases. The difference was insignificant. This finding was seconded by the study of Gaitini *et al.*^[14] who studied 150 patients and found that the success rate of passing gastric tube through Proseal LMA and LTS is the same.

Table 2: Comparison of mean pulse rate (beats/min) before and 5 minutes after device insertion between two groups

Time	Group A (PLMA)		Group B (LTS)		P value between groups
	Mean \pm SD	P	Mean \pm SD	P	
Before device insertion	88.2 \pm 16.7		92.6 \pm 17.8		0.627
5 min after device insertion	90.4 \pm 18.1	0.204	98.1 \pm 19.5	0.063	0.068

PLMA=Proseal laryngeal mask airway, LTS=Laryngeal tube suction, SD=Standard deviation

Table 3: Comparison of Mean arterial pressure (mm Hg) before and 5 minutes after device insertion between two groups

Time	Group A (PLMA)		Group B (LTS)		P value between groups
	Mean \pm SD	P	Mean \pm SD	P	
Before device insertion	100.1 \pm 8.9		99.4 \pm 12.9		0.796
5 min after device insertion	92.3 \pm 9.9	0.001	90.1 \pm 10.0	0.001	0.398

PLMA=Proseal laryngeal mask airway, LTS=Laryngeal tube suction, SD=Standard deviation

Table 4: Comparison of device insertion time and seal pressure between the two groups

Device characteristics	Group A (PLMA)	Group B (LTS)	P
Insertion time (s)	16.4±5.6	20.0±3.9	0.005
Seal pressure (cm of H ₂ O)	27.6±4.6	24.1±5.6	0.011

PLMA=Proseal laryngeal mask airway, LTS=Laryngeal tube suction, SD=Standard deviation

Optimal ventilation (i.e., adequate chest movement, stable oxygenation, and square wave capnography) was obtained in all cases of Proseal whereas “suboptimal ventilation was seen in 10% cases with LTS” although no rescue device was required. Dahaba and Rehak *et al.*^[15] obtained similar result while comparing postoperative complications of these two devices with an intubating LMA. In another study, hypoxemia and suboptimal ventilation with LTS were attributed to axial rotation of the device relative to the larynx.^[16]

Postoperative sore throat was more with LTS than with Proseal LMA (10% vs. 3.3%). The result was in concordance with those found by Dahaba and Rehak^[15] Higher cuff pressure of cuff of the laryngeal tube was speculated to be the probable reason for this in another study, due to which Proseal LMA may be more suited for prolonged use.^[17]

Based on the results of the present study, it can be interpreted that Proseal LMA is distinctively better (lesser insertion time, lesser peak pressure, and higher seal pressure) than LTS in nonlaparoscopic elective surgeries under general anesthesia. Easy passage of orogastric tube for gastric decompression through both Proseal LMA as well as LTS further reduced the risk of passive regurgitation with both devices. Fiberoptic scope for glottic visualization grading could not be used as the equipment was not readily available for all the cases at the time of the study.

Conclusion

We infer that both Proseal LMA and LTS were found acceptable for airway management in elective surgery under general anesthesia, however Proseal LMA was superior to LTS in terms of higher seal pressure, lesser insertion time, lesser peak pressure and lesser complications.

Financial support and sponsorship
Nil.

Conflicts of interest

There are no conflicts of interest.

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