Original Article

Comparison Between Proseal Laryngeal Mask Airway and Supreme Laryngeal Mask Airway in Laparoscopic Cholecystectomy: A Randomized Controled Trial

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Abstract

Background: Supraglottic airway devices (SADs) offer an alternative airway with improved airway seal, enabling higher airway pressures during positive pressure ventilation (PPV). We compared the safety and efficacy of laryngeal mask airway (LMA) Proseal and LMA Supreme in laparoscopic cholecystectomy.

Materials and Methods: Eighty patients, 18-60 years, ASA grade 1 and 2 were randomly allocated into two groups of 40 each. After induction of anesthesia, LMA Supreme or LMA Proseal of appropriate size was then inserted randomly. Parameters like the ease of LMA insertion, OGT insertion; oropharyngeal leak pressure (OLP); hemodynamics, adequacy of ventilation were recorded. Complications, if any, were also recorded.

Results: LMA Supreme was easier to insert than LMA Proseal. Gastric tube insertion was comparatively easier in LMA Supreme than LMA Proseal. The mean oropharyngeal leak pressure was higher with LMA Proseal (31.98 \pm 2.49cmH2O) than with LMA Supreme (30.23 \pm 3.65 cmH2O). Peak airway pressures were comparable for the two groups. There was comparatively more airway trauma (mucosal injury, sore throat) in LMA Proseal than LMA Supreme.

Conclusion: A higher oropharyngeal leak pressure makes LMA Proseal a better choice than LMA Supreme in procedures with raised intragastric pressure.

Keywords: Laryngeal Mask Airway, Proseal, Supreme, Oropharyngeal leak pressure

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Introduction

Supraglottic airway devices offer an alternative airway to traditional tracheal intubation or a face mask. Supraglottic airway devices (SADs) have been classified as – First-generation SADs whose ventral cuff forms a low-pressure laryngeal seal and lack drainage access e.g. laryngeal mask airway (LMA) classic. Use of positive pressure ventilation (PPV) above 20 cmH₂O leads to the risk of leakage of gases and aspiration of gastric contents especially in obesity, gastro-oesophageal reflux, and laparoscopic surgery. Second-generation SADs have an additional drainage tube to provide access to the gastrointestinal tract and

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Corresponding Author: Heena Gupta, Department of Anesthesiology and Critical Care, Government Medical College, Jammu, India. **Email:** heenaguptadr@gmail.com improved airway seal, enabling the use of higher airway pressures during PPV (25–28 cmH₂O). Secondgeneration devices include the Proseal Laryngeal Mask Airway, I-gel, the Supreme Laryngeal Mask Airway, the Laryngeal Suction Mark II (LTS II), the streamlined liner of the pharynx airway (SLIPA), and the Baska Mask (1).

The Proseal Laryngeal Mask Airway (PLMA) (Laryngeal Mask Company, Henley Thames, UK) is a reusable device that has an additional dorsal cuff that improves the seal (2). These reusable devices pose a potential risk of cross-infection, particularly with prion diseases such as variant Creutzfeldt-Jakob disease (3). LMA Supreme (Intravent Orthofix, Maidenhead, Berkshire, UK) is a disposable supraglottic device introduced in 2007 that presents combined features of LMA Proseal, Fastrach and Unique. It combines flexibility, curved structure, single-use features, and a different cuff structure to ease its insertion (4). It is made up of polyvinyl chloride. Features unique to it are that it has a semirigid elliptical airway tube-shaped at 90° angles to facilitate insertion; a drain tube running along the posterior midline through the airway tube to facilitate the passage of a gastric tube; the strengthened inner cuff to prevent airway obstruction from epiglottic infolding and epiglottic fins have been added to prevent epiglottic downfolding (5). The more elongated cuff ends in a reinforced tip to prevent it from folding over during insertion.

Although studies have been conducted comparing LMA Proseal and LMA Supreme but have not yet achieved a consensus regarding their oropharyngeal leak pressure. (6-10). Also, there is very little information on the efficacy of these two devices in laparoscopic cholecystectomy. The primary outcome of the present study was to compare the safety and efficacy of laryngeal mask airway (LMA) Proseal and LMA Supreme concerning oropharyngeal seal. The secondary outcome was to compare ease of LMA insertion, OGT insertion, and complications related to these devices in laparoscopic cholecystectomy.

Methods

After approval from the Institutional Ethical Committee (Government Medical College, Jammu IEC/2015/195, dated 21/05/2015), this clinically oriented, prospective, randomized, controlled, comparative study was carried out in 80 patients of American Society of Anesthesiologists Grade 1 and 2 scheduled for elective laparoscopic cholecystectomy under general anesthesia after obtaining written consent from them. Patients who had known or suspected difficult airway, Body Mass Index > 35kg/m², cervical spine pathology, increased risk of aspiration, and respiratory tract pathology were excluded from the study.

Patients were randomly assigned into two groups (Group P and Group S) of 40, each using a computer-generated random number table. Allocation concealment was done using sequentially numbered, and sealed envelopes. Patients were coded. premedicated with Tab Alprazolam 0.25 mg and Tab Ranitidine 150 mg orally the night before surgery. Patients then received an injection of Diclofenac 75 mg I/V in 100 ml of normal saline. All baseline parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation was recorded. Patients then received injection Palanosetron 0.075 mg I/V and injection Tramadol 1 mg/kg I/V. The size of the airway device was chosen according to the patient's body weight and manufacturer's instructions i.e. Size 3 for 30-50 kg, Size 4 for 50-70 kg, Size 5 for > 70 kg. Preoxygenation with 100% oxygen was done for 3 minutes. Anesthesia was induced with Propofol 2-2.5 mg/kg I/V injection until the loss of verbal contact and Inj. Atracurium 0.5 mg/ kg I/V was administered. Patients were ventilated manually for 3 minutes with 50% N₂O, 50 % 0₂, and 0.5-1% halothane (to achieve MAC 1). LMA Supreme (SLMA) or LMA Proseal (PLMA) of appropriate size was then inserted randomly, with the patient's head in the 'sniffing position. Cuff was inflated with an adequate volume of air to achieve an intracuff pressure of 60 cmH₂O using a cuff pressure manometer (Rusch Endotest, Cuff Pressure Gauge). Ease of LMA insertion was graded using a Four-point scoring system; 3- no tactile resistance, 2- with tactile resistance, 1- insertion at the second or third attempt, 0- failed three attempts. After LMA insertion, a 14 French orogastric tube was inserted into the LMA, and ease of OGT insertion was graded as Score 1, 2, 3 for 'Easy', 'Difficult', and 'Impossible' insertion, respectively.

Anesthesia was maintained with 33% O₂, 66% N₂O, and 0.5-1% halothane (to achieve MAC 1). Relaxation was maintained with incremental doses of injection Atracurim 0.1 mg/kg. The patient was then put on volume control ventilation (Datex Ohmeda, Aestiva 5) with a tidal volume of 8 ml/kg, inspiratory: expiratory ratio of 1:2, respiratory rate of 12-15/min to achieve ETCO₂ of 30-45 cm H₂O. Pneumoperitoneum was established by insufflation of carbon dioxide to a pressure of ≤ 12 mmHg. Oropharyngeal leak pressure (OLP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 5 L/ min (maximum peak pressure allowed = $40 \text{ cm H}_2\text{O}$) and recording the pressure from the manometer in the circuit at which audible leak heard during auscultation over the trachea. Peak airway pressure was recorded from Drager Vista 120 monitor.

At the end of the procedure, neuromuscular blockade was antagonized by injection of neostigmine 50 micrograms/kg and injection of glycopyrrolate 10 micrograms/ kg. 100% oxygen was given before emergence. Before removal of the LMA, the stomach was emptied and OGT removed. Removal of the device was done when the patient was awake and able to open the mouth on verbal commands

Failed LMA Insertion was defined by >3 unsuccessful attempts, failed passage into the pharynx, malposition, ineffective ventilation (maximum expired volume < 6 ml/kg), end-tidal CO₂ > 45 mm Hg. After removing the device, any traces of visible gastric fluid or blood staining on the LMAs were noted. Patients were asked about postoperative complications like sore throat, dysphagia, dysphonia & hoarseness at 30

minutes, 2 hours, and 24 hours after removing the device.

Statistical Analysis: Our primary comparison parameter was oropharyngeal leak pressure. To detect a difference of 10%, power analysis at 80% power and the 0.05 level of significance showed that a sample size of 31 patients would be required. We recruited 40 patients for each group keeping in mind the possibility of failed SAD insertion. All statistical tests were twosided and were performed at a significance level of α =0.05. The two groups were compared using the student t-test. Proportions were compared using the Chi-square test or Fisher's exact test, whichever test was applicable. A value of P<0.005 was considered significant.

Results

Demographic data such as age, sex, weight, and body mass index (BMI) were comparable in both groups (Table 1). OLP was lower in the LMA Supreme group ($30.23 \pm 3.65 \text{ cmH}_2\text{O}$) than in the LMA Proseal group ($31.98 \pm 2.49 \text{ cmH}_2\text{O}$) and the difference was significant statistically (p<0.05) (Table 2). The difference in the ease of LMA insertion was significant statistically (p=0.010) with easier insertion in the SLMA group (Table 3). In Group P, 36 patients (90%) had LMA insertion in the first attempt with no tactile resistance and were scored 3 while the remaining (10%) had mild resistance to LMA insertion. In group S, 39 patients (97.50%) were scored 3. Ease of OGT insertion was easier in LMA Supreme (SLMA 100% vs PLMA 95%; p=0.0001) (Table 3).

Table 1: Demographic characteristics of study groups.

Variable	LMA Proseal (Group P)	LMA Supreme (Group S)	P-value
Age (years)	42.50 ± 11.82	38.18 ± 10.30	0.085
Sex(M/F)	12.5%/87.5%	20%/80%	0.153
Weight (kg)	54.33 ± 3.92	54.95 ± 4.23	0.495
Height (cm)	149.53 ± 7.62	151.38 ± 8.97	0.274
BMI (kg/m ²)	24.52± 3.31	24.15 ± 3.37	0.627

Table 2: Group con	mparison for	Oropharyngeal	Leak Pressure.
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Time interval	Mean ± Standar	p-value	
	Group P	Group S	p-value
After LMA insertion	30.03 + 3.03	27.88 + 3.47	0.004
(Before pneumoperitoneum	50.05 ± 5.05	27.00 ± 3.47	0.004
Immediately after pneumoperitoneum	32.30 ± 2.77	30.90 ± 3.56	0.048
At 20 minutes	32.75 ± 2.20	31.05 ± 3.14	0.011
At 40 minutes	32.86 ± 1.97	31.10 ± 4.46	0.026
Mean	31.98 ± 2.49	30.23 ± 3.65	0.022

 Table 3: Ease of LMA insertion and OGT insertion.

	LMA Proseal (N=40)	LMA Supreme (N=40)	P value	
The score of ease of LMA	0/0/4/36	0/0/1/39	0.010	
insertion (0/1/2/3)				
Score of ease of OGT insertion	38(95%)/2(5%)	40(100%)/0(0%)	0.0001	
(1/2)				

No significant differences existed between the two groups concerning hemodynamic (Heart rate, mean arterial pressure) and ventilation parameters (peak airway pressure) (Table 4, 5) and incidence of postoperative complications (Table 6). On statistical analysis, the difference in SpO₂ values, ETCO₂, inspiratory and expiratory tidal volumes, delivered by both the devices, were comparable. The difference in Peak airway pressures was statistically significant at various time intervals, with high airway pressure values obtained for group P (16.27 \pm 1.93 vs 15.52 \pm 1.23 cmH₂O). However, the mean values for airway pressures during the operative period were comparable.

On inspection of the device after removal, a bloodstain was found in 7 patients (17.50%) in group P and 2 patients (5%) in Group S, which was statistically insignificant. No gastric fluid was noted on either of the devices. No trauma was noted on lips, tongue, or mouth in any group. Postoperatively, the incidence of sore throat was statistically significant at 30 minutes (p= 0.013) and 2 hours (p= 0.021), with a

higher value for Group P but insignificant at 24 hours.

Discussion

Control and protection of the airway are fundamental considerations in anesthesia. The search for an ideal airway for use in modern anesthesia led to the development of the Laryngeal mask airway by Dr. Archie Brain in 1981. The advent of supraglottic airway devices, especially those with a second lumen, i.e. drain tube, may circumvent many disadvantages of tracheal intubation, such as exaggerated pressure response, even in patients who require high airway pressures for adequate pulmonary ventilation in laparoscopic surgery. Using a supraglottic airway device under conditions of elevated intra-abdominal pressure requires an excellent airway seal to divide the respiratory and alimentary tract reliably, due to the potential risk of regurgitation.

The present study demonstrated that both PLMA and SLMA provided each patient with an effective airway with a low rate of complications. OLP

Time interval	Group P	Group S	P-value
Heart rate (beats/min)			
Baseline	88.13±11.08	$86.35{\pm}8.97$	0.433
After LMA insertion	87.1±3 8.58	84.90± 8.25	0.238
1 min after pneumo	92.90± 8.50	90.40 ± 8.58	0.194
5 min after pneumo	90.48± 8.33	90.78 ±9.29	0.880
15 min after pneumo	86.98± 6.56	87.38± 9.98	0.833
20 min after pneumo	83.23 ±6.69	83.13±9.13	0.956
40 min after pneumo	81.95 ±7.59	80.58 ±8.61	0.451
Mean Arterial Pressure (MAP)			
Baseline	93.43 ± 9.46	95.00 ± 10.13	0.474
After LMA insertion	93.58 ± 10.29	89.15 ± 9.72	0.058
1 min after pneumo	99.40 ± 13.60	101.80 ± 10.66	0.382
5 min after pneumo	98.45 ± 11.67	100.83 ± 12.16	0.376
15 min after pneumo	93.55 ± 10.05	96.68 ± 9.80	0.163
20 min after pneumo	89.70 ± 9.67	92.00 ± 9.92	0.297
40 min after pneumo	89.78 ± 10.30	90.70 ± 8.58	0.664

Table 4: Group comparison for Hemodynamic Variables.

or airway sealing pressure is a commonly used parameter to indicate the degree of airway protection, the feasibility of positive pressure ventilation, and the success of the supraglottic airway device placement (11, 12). It quantifies the seal of LMA around the airway. It is the pressure at which gas leaks around the airway, which is a key marker of efficacy and safety of its use; a higher leak pressure suggests a better seal between the artificial airway and patient's airway and denotes the successful placement of the device. Inadequate placement will increase the leak and the purpose of use.

In our study, the mean oropharyngeal leak pressure for the LMA Proseal was higher than LMA Supreme (p=0.023), suggesting that LMA Proseal is a more effective ventilatory device. Our results were

0.002 0.011 0.531
0.531
0.424
0.327
0.021
0.192
0.192

 Table 5: Group comparison for Peak airway pressures.

similar to the oropharyngeal leak pressure of 32 cmH₂O reported for the PLMA in a retrospective series of 245 patients by Brimacombe et al (13). A similar result was found in a study by Eschertzhuber et al who observed that the OLP was lower in Group S by 4-8 cm H2O than in Group P in a crossover trial in 93 female patients undergoing surgery with a size 4 S-LMA (14). Our results were also comparable with the study conducted by Belena et al., who compared oropharyngeal leak pressure in LMA Proseal and LMA Supreme in 120 patients undergoing elective laparoscopic cholecystectomy (15). The mean OLP in LMA Proseal was significantly higher than in the LMA Supreme group $(30.7 \pm 6.2 \text{ versus } 26.8 \pm 4.1 \text{ cmH}_2\text{O};$ p=0.01). They concluded that PLMA had a higher OLP and achieved a higher maximum tidal volume compared to the SLMA. They stated that higher OLP for the PLMA was mainly related to the dorsal cuff and the silicone rubber double cuff design compared to the polyvinylchloride single cuff of the SLMA. They also suggested that the lower OLP observed in SLMA could be explained due to the movement of the semirigid curved airway tube, something which did not seem to happen with the elastic tube of the PLMA. In another study conducted by them in 180 patients undergoing laparoscopic cholecystectomy under general anesthesia, they found significantly high oropharyngeal leak pressure for LMA Proseal (PLMA 30.87; I-gel 29.28; SLMA 29.02 cmH₂O) (16).

Many clinical studies found lower OLP in LMA Supreme than Proseal (17-19). Some studies found no difference in OLP between LMA Supreme and LMA Proseal (20). To date, no study reported higher OLP of LMA Supreme than LMA Proseal.

The mean margin of safety of oropharyngeal leak pressure (difference between oropharyngeal leak pressure and peak airway pressure) for the PLMA group was 16.57 ± 2.93 cmH₂O for the SLMA group was 15.72 ± 3.69 cmH₂O (p = 0.283).

In addition, LMA Supreme was easier to insert with easier gastric tube insertion than LMA Proseal in this study, we found that both PLMA and SLMA were successfully inserted in all the patients and there was no case of failed insertion in any of the two groups. Ease of device insertion was graded using a four-point scoring system. In the PLMA group, 90% had a score of 3, while 97.5% had a score of 3 in the SLMA group. Our findings were comparable to the other studies that found LMA Supreme comparatively easier to insert than LMA Proseal (16,17,20,21). They contributed this to several refinements in the design of LMA Supreme such as its anatomical shape and more rigidity in the airway tube.

No difference in hemodynamic parameters was statistically significant with both the device use. In the present study, ventilatory parameters were measured and there was no statistical difference between the two groups. The difference in Peak airway pressures was

Postoperative complications	Group P (n=40)	Group S(n=40)	P value
Blood stain	7(17.5%)	2(5%)	0.011
Gastric stain	0(0%)	0(%)	0
Trauma(lip, mouth, mucosal injury)	0(0%)	0(0%)	0
Sore throat			
• 30 minutes	11(27.5%)	5(12.5%)	0.013
• 2 hours	9(22.5%)	4(10%)	0.021
• 24 hours	0(0%)	0(0%)	0.184
Dysphagia	0(0%)	0(0%)	0
Dysphonia	0(0%)	0(0%)	0
Hoarseness	0(0%)	0(0%)	0

statistically significant at various time intervals, with high airway pressure values obtained for the Group P (PLMA). However, the mean values for airway pressures during the operative period were comparable. Mean Peak airway pressure was $16.27 \pm 1.93 \text{ cmH}_2\text{O}$ for Group P and $15.52 \pm 1.23 \text{ cmH}_2\text{O}$ for Group S.

In our study, blood staining was seen with both the devices with lower incidence in LMA Supreme. This could be attributed to the flat and soft fixed curved tube of LMA Supreme, which has less likelihood of exerting high pressures against the pharyngeal mucosa. Similar findings were found in different studies with variable incidence (14, 17, 20). On the contrary, only one study reported a higher incidence of blood staining in LMA Supreme (6).

In disagreement with our study where no upper airway trauma was observed with either of the two devices, Timmermann A et al. (21) reported upper airway trauma in 9% of cases.

After removing the LMA, patients were enquired about postoperative complications like sore throat, dysphagia, dysphonia, and hoarseness of voice at 30 minutes, 2 hours, and 24 hours after removing the device. The sore throat was significantly higher in LMA Proseal. Unlike our observation, other studies found no difference between PLMA and SLMA concerning the incidence of postoperative sore throat (6, 15). Only one study noted hoarseness of voice in one patient in the PLMA group, whereas no such incidence was reported in our study (6, 18).

There was no blinding in the data collection, which is a possible source of bias. Oropharyngeal leak pressure can vary according to the method of measurement (e.g. palpable vs audible leak). Reverse Trendelenburg position can lessen the effects of pneumoperitoneum on the LMA cuff and yield different results than those demonstrated in the present study.

Conclusion

Both LMA Proseal and LMA Supreme show similar efficacy in maintaining ventilation and oxygenation during laparoscopic cholecystectomy. LMA Supreme is easier to insert and provides easier gastric tube insertion than LMA Proseal. However, LMA Proseal provides a more efficient oropharyngeal seal than LMA Supreme. A higher oropharyngeal leak pressure makes LMA Proseal a more obvious choice for airway management in procedures with raised intragastric pressure.

Acknowledgment

None.

Conflicts of Interest

The authors declare that they have no conflict of interest.

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