International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A prospective randomized controlled study to compare two supraglottic airway devices LMA-Protector™ and LMA-ProSeal™ in anaesthetized patients

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Received: 03-03-2026
Accepted: 20-3-2026
Available online: 05-04-2026

ABSTRACT

Background: Laryngeal mask airway (LMA)-ProSeal™ has been in use for a long time and has stood the test of time. LMA Protector™ is a composite of various supraglottic devices, and like LMA ProSeal, it promises high oropharyngeal leak pressures and gastric access. It has a preformed curved shaft like LMA Fastrack™, LMA Supreme™ and LMA Auragain™, and it is a single-use device like LMA Supreme™ and LMA unique™. Besides, LMA Protector™ has two unique features: a dual gastric port and an in-built intracuff pressure monitor.
We found sparse literature on LMA Protector, and only a few research papers compare LMA Protector with LMA ProSeal. We aimed to compare the device's clinical performance regarding oropharyngeal leak pressure (OLP) and LMA insertion time, the ease of orogastric tube insertion, and the severity of sore throat.
Results: OLP was significantly higher in the LMA Protector group compared to the LMA ProSeal group (34.8±3.5cmH20 vs 31.7±4.5 cmH20, p = 0.001). LMA insertion time was considerably longer with LMA Protector (25.7±5.2 sec vs 23.4±5.3 sec; p = 0.047). The ease of LMA insertion was comparable. Gastric tube insertion was grade 1 in the majority of patients. Incidence and severity of postoperative sore throat at 2 and 24 hours were similar in both groups.
Conclusion: Compared to LMA ProSeal™, LMA Protector™ achieved a better oropharyngeal seal by attaining higher oropharyngeal leak pressures. LMA Protector's observed 7.5% initial insertion failure rate though statistically insignificant as a key clinical consideration when first-attempt success is critical. Insertion characters of both the devices were similar.

Keywords: *Laryngeal Mask Airway; Airway Management; Supraglottic Airway Devices; Anesthesia, General; Airway Resistance; Oropharyngeal Leak Pressure.*

INTRODUCTION

The 21st century witnessed a tremendous increase in the armamentarium of airway devices with the introduction of supraglottic airway devices (SAD) and video laryngoscopes. The endotracheal tube remains the gold standard for securing the airway. However, laryngoscopy and endotracheal intubation may be associated with considerable morbidities such as sore throat, stimulation of the sympathetic nervous system and failure to secure the airway. Supraglottic airway devices have collectively enjoyed an unparalleled safety record and are very popular devices in everyday practice [1] with broadening indications, such as including difficult airway algorithms in adults and children. They offer distinct advantages such as prompt and easy placement, difficult airway securing, hemodynamic stability, and lower incidence of postoperative sore throat and hoarseness. The second-generation SAD provides an improved pharyngeal seal and allows aspiration of gastric contents to reduce the risk of aspiration, making them more efficient in their performance. [2,3]

LMA-ProSeal™ has been in use for a long time and has stood the test of time. However, rare instances of airway obstruction after insertion have been reported by compressing the supraglottic and glottic structures or by cuff in-folding.[4] The same manufacturer, Teleflex™, has recently introduced another second-generation SAD, the LMAProtector™ with improvised features. This device is a composite of various SADs and, like LMA ProSeal™, promises high oropharyngeal leak pressures and gastric access. It has a preformed curved shaft like LMA Fastrach™, LMA Supreme™ and Ambu AuraGain™, and it is a single-use device like LMA Supreme™ and LMA Unique™. Besides, LMA Protector™ has two unique features: a dual gastric port and an in-built intracuff pressure monitor.

Considering an increasing number of airway management devices being introduced into clinical practice, with some having little previous evidence of their clinical efficacy or safety, the Airway Device Evaluation Project Team formed by the Difficult Airway Society proposed that products with documented proof of effectiveness and safety should be preferred to those whose evidence is lacking.[1] We found sparse literature on LMA Protector™ (PubMed search reveals 38 meagre results with LMA Protector since 2017, compared to 345 with LMA ProSeal™ since 2000). In addition, to the best of our knowledge, only a few research papers compare LMA Protector™ with its similar cousin, LMA ProSeal™ [5,6,7], and their results are contrary to oropharyngeal leak pressures.

Hence, we undertook this study with the primary aim of determining and comparing the oropharyngeal leak pressures of LMA ProSeal™ and LMA Protector™ and the secondary objective of resolving the ease of LMA insertion, its successful 1st attempt, number of insertion attempts, LMA insertion time, ease of gastric tube insertion, incidence of postoperative sore throat, dysphagia and hoarseness of voice (HOV) in the postoperative period

MATERIALS AND METHODS

After approval from the institutional ethical committee, this prospective randomized study was conducted from December 2022 to October 2023 at a tertiary care hospital. It was registered with the Clinical Trial Registry of India (CTRI/2022/10/046532). All participants gave their written informed consent for the use of their data for research and teaching. The research was carried out in compliance with the Consolidated Standards of Reporting Trials (CONSORT) standards and the 2013 Helsinki Declaration. The study included 80 patients of either gender with body weight more than 30 kg belonging to American Society of Anesthesiologists Physical Status (ASA-PS) class I and II undergoing elective surgeries under general anaesthesia using SAD for securing the airway as the primary device and requiring neutral head position. Patients with anatomical or pathological upper airway abnormality, moderate to severe bronchial asthma/ COPD, BMI≥ 35, and head and neck surgeries were excluded from the study. After a thorough pre-anaesthetic evaluation, written and informed consent was sought from the eligible patients. After arrival in the operating room, standard monitoring was initiated. Patients were randomized into Group ProSeal (n=40) and Group Protector (n=40), using a previously computer-generated random number and a sequentially numbered sealed opaque envelope technique, and allocated to either group. The anesthesiologist recording the oropharyngeal leak pressure was blinded, as the device was draped after the insertion time was recorded. However, blinding was not possible for assessing the ease of LMA insertion, first-attempt success, number of insertion attempts, LMA insertion time, and ease of gastric tube insertion. The patient was unaware of the allocated group The patient received premedication with fentanyl 2 µg/kg. General anaesthesia was induced with propofol 1.5–2 mg/kg, followed by muscle relaxation with rocuronium 0.6 mg/kg. After confirming the absence of a motor response to the jaw thrust, either of the LMA devices was inserted. The size of each device was selected based on the manufacturer's instructions, using body weight criteria. All insertions were performed by an investigator experienced with more than 20 prior insertions of each LMA device. Both devices were lubricated on the dorsal surface of the mask.

In the sniffing position, the LMA Protector™ was held by the shaft, introduced into the mouth, and advanced in a curved motion along the hard palate until resistance was felt in the hypopharynx. The LMA ProSeal™ was inserted similarly, using an introducer tool. During device insertion, the following manipulations were permitted: jaw thrust, head extension, head flexion, and adjustment of insertion depth.Ease of LMA insertion was assessed based on the number of airway manoeuvres required:1 = Easy, no manoeuvre required,2 = Mild difficulty, one type of manoeuvre required,

3 = Moderate difficulty, more than one type of manoeuvre required,4 = Failure of device placement after two attempts.After successful insertion of either LMA device, the cuff was inflated with air to achieve and maintain an intracuff pressure of 60 cmH2O (approximately 44 mmHg). For the LMA Protector™, this was facilitated by its integrated intracuff pressure monitor, which provided real-time feedback. For the LMA ProSeal™, an external manometric device (Teleflex Medical) was connected to the pilot balloon to accurately measure and adjust the cuff pressure.

Insertion time was measured from the moment the LMA was picked up to the appearance of the first capnography upstroke, indicating successful placement. Insertion was considered successful if there was bilateral and equal chest rise, equal breath sounds on auscultation, no audible leak, no gastric insufflation, and a square wave capnography pattern.

The first-attempt success rate was noted. In cases where LMA insertion failed (e.g., inability to negotiate the oropharynx, significant audible or auscultatory leak, inadequate ventilation, or ETCO2 > 45 mmHg), endotracheal intubation was performed after three unsuccessful attempts.

Following successful insertion, a lubricated, appropriately sized gastric tube was introduced via the gastric channel of the supraglottic airway device, and the ease of insertion was recorded as follows:

1 = First attempt, 2 = Second attempt, 3 = Failure to insert. The correct placement of the gastric tube was confirmed through the injected air by auscultation of the epigastrium and aspiration of gastric content. After proper fixing, the LMA was connected to a circle absorber system with a breathing circuit. Oropharyngeal leak pressure was measured supine with the head in the neutral position. After that, ventilation was briefly suspended, fresh gas flow was adjusted to 3 L/min, and the expiratory valve was closed, causing the airway pressure to rise gradually. The point at which the airway pressure became stabilized (digital value of airway pressure on the monitor) was considered airway leak pressure. However, if airway pressure exceeded 40 cmH2O during this measurement, the expiratory valve was released to prevent barotrauma. Gastric insufflation was monitored by auscultation over the epigastrium during the OLP test.

After the OLP test, mechanical ventilation of the lung was initiated with appropriate ventilator settings to maintain EtCO2 of 30-35 mm of Hg. Anesthesia was maintained with sevoflurane in N2O with FiO2 0.4 to maintain a minimum alveolar concentration (MAC) of 1. At the end of the surgery, the residual neuromuscular block was reversed with an injection of neostigmine 50 µg/kg injection and glycopyrrolate 10 µg/kg. After confirming full recovery of the spontaneous ventilation, LMAs were removed. The patient was shifted to a postoperative room and an investigator unaware of the patient group recorded the incidence and severity of postoperative sore throat (0- no sore throat, 1- mild sore throat, 2- moderate sore throat, 3- severe sore throat), dysphagia (0- no dysphagia, 1- mild dysphagia, 2- moderate dysphagia, 3- severe dysphagia) and hoarseness of voice (severity: 0- no hoarseness of voice, 1- minimal hoarseness of voice, 2- moderate hoarseness of voice, 3- severe hoarseness of voice) 2 and 24 hours later.

Demographic parameters such as age, gender, weight, type, and duration of surgery were recorded. The primary outcome was oropharyngeal leak pressure in a neutral head position. Secondary outcomes were ease of LMA insertion, successful 1st attempt, number of insertion attempts, LMA insertion time, ease of gastric tube insertion, incidence of postoperative sore throat, dysphagia and hoarseness of voice (HOV) were recorded in the postoperative period at 2 hours and 24 hours.

Sample size calculation was based on the primary outcome variable, OLP, from two previous study [8] The mean (standard deviation) OLP was 30.7 (6.2) cm of H2O and 26.8 (4.1) cm of H_2O for two LMA's. With a type I error of 0.05 and a power of 80%, a sample size of 38 patients in each group was calculated. Considering some dropouts due to failure to place the device or inability to measure OLP, 40 patients in each group were enrolled for the study.

Statistical Analysis

Data was entered in M.S. excel and analysis done using SPSS 21.0 version. Categorical variables were displayed in number and percentage (%) and continuous variables are represented as mean ± standard deviation (S.D.). Unpaired t test or Mann Whitney U test was applied to compare mean or median between the two groups. Chi square or Fisher exact test was applied to find out association between categorical variables. A *P* value of less than 0.05 was taken as significant at 95% confidence level.

RESULTS

A total of 40 patients were randomized to each group, However, 3 patients randomized to the LMA Protector™ group experienced failed insertion and were subsequently excluded from the primary outcome analysis, leading to n=37 for the LMA Protector™ group for outcome measures (Figure 1), whereas there were no failures with LMA ProSeal™ (p = 0.241). The results were statistically similar in the two groups in terms of demography, duration of surgery and ASA-PS (Table 1).

Table 1: Table comparing demographic data, intubation time and LMA insertion time

	Proseal Mean ±SD	Protector Mean± SD	P value
Age (years)	12.7±2.2	13.4±4.0	0.370
Weight (kg)	36.6±6.2	35.5±6.8	0.430
Duration of Surgery (hours)	1.22±0.46	1.31±0.46	0.402

Abbreviations: SD-Standard deviation

LMA size 3 was most commonly used in both groups (97.5% patients in the ProSeal group and 89.2 % patients in the Protector group, p = 0.189), and OLP was significantly higher in the LMA Protector group compared to the LMA ProSeal group (34.8±3.5cmH20 vs 31.7±4.5 cmH20, p = 0.001).

Table 2: Table comparing gender, ASA-PS and comorbidities among the two groups

		Proseal n (%)	Protector n(%)	P value
Gender	Male	21(52.5)	23(57.5)	0.653
	Female	19(47.5)	17(42.5)	
ASA-PS	ASA-PS 1	33(82.5)	34(85.0)	0.762
	ASA-PS 2	7(17.5)	6(15.0)	
Comorbidities	None	34(85.0)	34(85.0)	0.501
	Anemia	0(0.0)	2(5.0)	
	Cerebral Palsy	1(2.5)	0(0.0)	
	Hypertension	0(0.0)	1(2.5)	
	Seizure disorder	1(2.5)	1(2.5)	
	Systemic Lupus Erythematous	1(2.5)	0(0.0)	
	Thrombocytopenia	0(0.0)	1(2.5)	

Abbreviations: ASA-PS (American Society of Anaesthesia-Physical status)

The ease of insertion of LMA was comparable in both groups (p = 0.532). First-attempt success was achieved in most patients in both groups (p = 0.130). LMA insertion time was significantly longer with LMA Protector™(25.7±5.2 sec vs 23.4±5.3 sec p = 0.047); the 2 sec difference is clinically insignificant. Gastric tube insertion was grade 1 in most patients (p = 0.571) (Table 3). Incidence and severity of postoperative sore throat at 2 and 24 hours were similar in both groups (p = 0.731, P = 1.000). Dysphagia and hoarseness of voice were not recorded in either of the patients in the groups.

Table 3: Table comparing LMA Size, ease of insertion, first attempt success, ease of gastric tube insertion(n%)

		Proseal n=40	Protector n=37	P value
Size LMA	3	39(97.5%)	33(89.2%)	0.189
	4	1(2.5%)	4(10.8%)	
LMA Insertion ease	1	31(77.50%)	25(67.6%)	0.532
	2	7(17.5%)	8(21.6%)	
	3	2(5.0%)	4(10.8%)	
First attempt success	Yes	36(90.0%)	31(83.8%)	0.507
	No	4(10.0%)	6(16.2%)	
Ease of gastric tube insertion	1	36(90.0%)	32(86.5%)	0.571
	2	4(10.0%)	4(10.8%)	
	3	0(0.0)	1(2.7%)	
OLP cmH2O (mean±SD)		**31.7±4.5**	**34.8±3.5**	**0.001**
LMA Insertion time in sec (mean±SD)		**23.4±5.3**	**25.8±5.2**	**0.047**

Abbreviations: OLP- Oropharyngeal leak pressure, sec-Seconds

Table 4: Table comparing complications in the postoperative period at two and 24 hours

		Proseal n=40	Protector n=37	P value
Sore throat 2 hrs	0	36(90.0%)	32(86.5%)	0.731
	1	4(10%)	5(13.5%)	
	2	0(0)	0(0)	
	3	0(0)	0(0)	
Sore throat 24 hrs	0	38(95.0%)	35(94.6%)	1.000
	1	2(5.0%)	2(5.4%)	
	2	0(0)	0(0)	
	3	0(0)	0(0)	

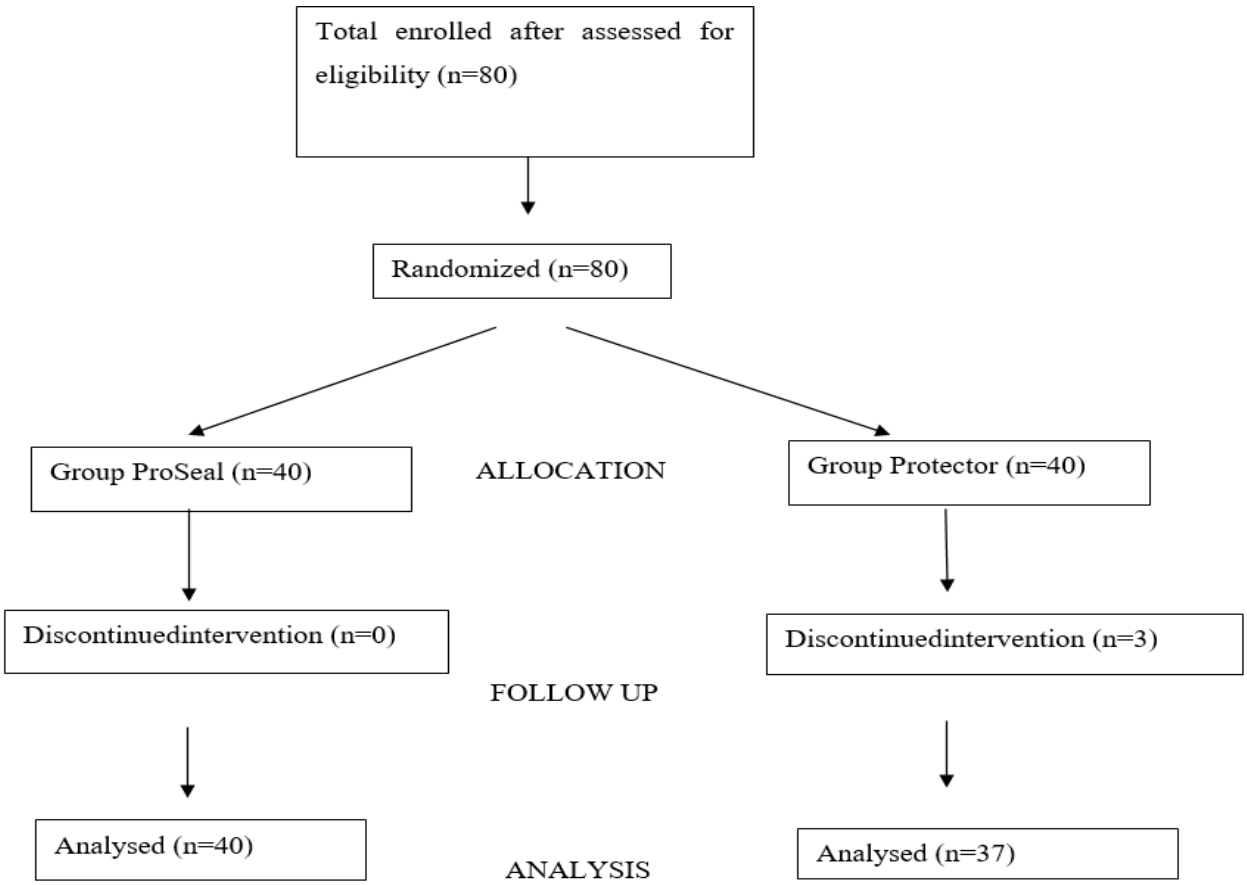

Figure 1. Flow Diagram of patient recruitment

Figure 2. Comparing the angulation of cuff tip of size 3 LMA ProtectorTM (blue in colour) and LMA ProSealTM each inflated with 20ml air.

Figure 3. Comparison of cuff length between size 3 LMA ProtectorTM (blue in colour) and LMA ProSealTM each inflated with 20ml air

DISCUSSION

Our study found that the oropharyngeal leak pressure (OLP) was significantly higher in the LMA Protector group compared to the LMA ProSeal group (34.8 ± 3.5 cmH2O vs. 31.7 ± 4.5 cmH2O, p = 0.001). This difference is likely attributable to the improved pharyngeal seal achieved by the LMA Protector. Variations in cuff design, including length and tip curvature, may contribute to a better fit and seal, facilitating adequate ventilation and preventing aspiration, consistent with previous studies.[7-11]

Although the results are statistically significant, they may not be clinically relevant, as the OLP values for both devices fall within the normal range. The OLP values of the LMA ProSeal™ in our study align with those reported in earlier research.[10] In a preliminary evaluation of the LMA Protector™ in non-paralyzed patients, Snget al.[2] reported a lower OLP of 25.5 cmH2O in patients aged 21–70 years. This difference may partly be attributed to patient age and the absence of muscle paralysis in their study. However, the impact of muscle paralysis on OLP remains inconclusive.[10]

Estimating the oropharyngeal leak pressure is one way to assess the seal between the LMA cuff and the pharyngeal mucosa. An effective seal ensures leak-proof ventilation and protects against aspiration, similar to the role of the endotracheal tube cuff. A higher OLP indicates closer contact between the cuff and pharyngeal tissues, which is more likely when the cuff shape conforms to the pharyngeal space and remains consistently positioned.

Mamta et al. suggested that the higher oropharyngeal leak pressure (OLP) observed with the LMA Protector™ could be attributed to the 10° slant of the distal cuff tip, which better conforms to the contours of the patient's hypopharynx.[6] However, we did not observe any visible difference in the curvature of the cuff tip (Fig. 2).

Kerai et al. reported statistically comparable OLP values between the LMA Protector™ and LMA ProSeal™ in a neutral position (32.24 ± 7.02 cmH2O vs. 29.74 ± 5.57 cmH2O, respectively) and attributed this similarity to the comparable cuff design and similar material used for both devices.[5] The cuff of the LMA Protector™ is marginally longer (Fig. 3) than that of the LMA ProSeal™. Additionally, they suggested that the slightly larger anteroposterior diameter of the LMA Protector™ cuff could result in a better seal.

According to the manufacturer, both devices are made of silicone. However, the LMA ProSeal™ is a reusable device made of durable silicone, whereas the LMA Protector™ is a single-use device with a stiffer cuff, which may enhance the seal. Furthermore, the LMA Protector™ features a preformed shaft, enabling a better fit in the pharynx compared to the flexible shaft of the LMA ProSeal™. During in vitro testing, when both devices' cuffs were inflated with 20 ml of air, we observed that the dorsal cuff of the LMA ProSeal™ bulged outward, while the LMA Protector™ maintained a flat contour. The additional dorsal cuff of the ProSeal™ is designed to enhance the seal, yet the higher OLP achieved with the LMA Protector™ in our

study suggests that other factors, such as shaft design and material properties, play a crucial role in the performance characteristics of supraglottic devices.

In our study, the ease of insertion and the first-attempt success rate were comparable between the two groups. However, the insertion time was statistically longer with the LMA Protector™, although the difference was not clinically significant. We encountered difficulty in positioning the LMA Protector™ in three patients, consistent with the failure rate reported by Kerai et al.[5] Although this difference is not statistically significant, the 7.5% failure rate with the LMA Protector™ holds clinical importance, especially since the LMA ProSeal™ had a 100% success rate, aligning with previous studies.[11-13] It remains unclear whether the anatomically curved shaft of the LMA Protector™ contributed to the placement failures, as previous studies with other preformed supraglottic devices, such as the LMA Supreme™ and LMA AuraGain™, reported success rates ranging from 94% to 100%.[13]

The LMA Protector™ is the only supraglottic airway device equipped with dual gastric ports. These ports open at the distal cuff tip and emerge as separate channels proximally: one port facilitates the insertion of a gastric tube for direct suction of gastroesophageal contents, while the other collects secretions near the upper esophageal sphincter into a pharyngeal chamber on the dorsal side of the cuff, diverting them away from the larynx. We used a 12 Fr nasogastric tube for size 3 and a 14 Fr tube for size 4 of both devices. The gastric tube was successfully inserted with minimal difficulty in all patients, consistent with previous studies.[2] However, some earlier researchers have reported challenges in inserting the gastric tube.[7,9,14] Chang et al. documented a failure rate of 16% in inserting a gastric tube through the LMA Protector™ and a lower (49%) success rate on the first attempt, attributing these issues to the absence of a dedicated passage and the less favorable inner material of the common pharyngeal chamber for smooth passage.[14]

The overall incidence of sore throat was very low in our study. No patients reported dysphagia or hoarseness in either group, consistent with previous studies.[2,6,15] Sore throat following airway management can cause significant discomfort and dissatisfaction, particularly after ambulatory anesthesia. As patient safety continues to gain emphasis, reducing iatrogenic injuries from patient care remains a priority. High intracuff pressure in the LMA can compromise pharyngeal mucosal perfusion, leading to postoperative discomfort.[16] In rare cases, excessive intracuff pressure may cause cranial nerve injuries due to pressure neuropraxia.[17] Previous studies have recommended limiting the LMA intracuff pressure to less than 44 mmHg to minimize the risk of postoperative pharyngolaryngeal complications.[18] Currently, routine use of manometry to monitor and regulate intracuff pressure after LMA insertion is uncommon. Notably, the LMA Protector™ is equipped with integrated cuff pressure monitoring technology to help prevent overinflation.

Young Uk Kim et al. reported increased intracuff pressure during N2O anesthesia but did not find a higher incidence of postoperative sore throat despite the pressure rise.[15] In our extensive experience with various supraglottic devices in both adults and children, postoperative throat irritation is infrequent, suggesting that this parameter may be less relevant when evaluating the functional characteristics of emerging supraglottic devices.

There are numerous second-generation supraglottic devices available for airway management, each with unique attributes such as cuff and shaft shape, material, inflation technique, and ability to separate the airway from the gastric tract. Selecting the most suitable device depends on the individual patient's anatomy and clinical context.

Strength and limitation

Strengths of our study is robust design with adequate sample size, minimizing type II error. Randomization and comparable baseline characteristics reduced selection bias. The use of standardized protocols for device insertion and outcome assessment ensured consistency.Furthermore, a key strength of our study was the active monitoring and management of intracuff pressure for both devices, allowing for a more standardized comparison and reducing potential confounding factors related to mucosal ischemia and postoperative complications."While there are few limitations like being a single-center study it limits generalizability. Lack of blinding may introduce observer bias. Additionally, the clinical significance of statistically significant differences remains uncertain.

CONCLUSION

LMA Protector™ and LMA ProSeal™ demonstrated comparable efficacy in ease of insertion, first-attempt success, and postoperative complications. Although the LMA Protector™ showed higher oropharyngeal leak pressure and longer insertion time, these differences were clinically insignificant.However, clinicians should be aware of the 7.5% initial insertion failure rate with the LMA Protector. This rate is not statistically significant, but it is clinically important and could affect the choice of device, especially in cases where a guaranteed first-attempt success is very important. Both devices otherwise are safe and effective for airway management, allowing clinician preference to guide choice.

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