Original Article

Comparison of oropharyngeal leak pressure of LMA Protector and LMA ProSeal in anaesthetised paralysed patients – A randomised controlled trial

Address for correspondence:
Dr. Mamta Bhardwaj,
40/9J, Medical Campus,
Rohtak, Haryana - 124 001,
India.
E-mail: drbmamta@gmail.com

Submitted: 05-May-2023
Revised: 10-Oct-2023
Accepted: 14-Oct-2023
Published: 21-Nov-2023

Access this article online

Website: https://journals.lww.com/ijaweb

DOI: 10.4103/ija.ija_403_23

Quick response code

Mamta Bhardwaj, Sunny Dhania, Kiranpreet Kaur, Jatin Lal, Priya[1], Suresh K. Singhal

Department of Anaesthesiology and Critical Care, Pt. BD Sharma University of Health Sciences, Rohtak, Haryana, [1]Department of Anaesthesia, ABVIMS and Dr. RML Hospital, Delhi, India

ABSTRACT

Background and Aims: In the present study, we hypothesised that the laryngeal mask airway (LMA) Protector would provide higher oropharyngeal leak pressure (OLP) than LMA ProSeal. Thus, we planned this study to compare the clinical performance of LMA Protector and LMA ProSeal in terms of OLP as a primary objective and insertion characteristics as secondary objectives. **Methods:** Ninety patients of either gender, aged 18–70 years, were randomised into groups PS (LMA ProSeal) and *P* (LMA Protector). Following anaesthetic induction, the device was inserted as per group allocation. OLP of both devices was taken as a primary objective. Secondary objectives such as insertion time, ease of insertion, number of attempts required, fibre-optic view grading, amount of air (mL) required to get a cuff pressure (CP) of 60 cm H2O, and CP adjustment required and complications, if any, were also noted. Data were analysed using coGuide statistics software, Version 1 (BDSS Corp. Bangalore, Karnataka, India). **Results:** The median (interquartile range) OLP was significantly higher with LMA protector than with LMA ProSeal [33.00 (27.0, 36.0) versus [29.50 (26.0, 32.0) ($P = 0.009$)]. First-attempt success rate was 95.4% (42/44) in group PS and 93% (40/43) in group P. Insertion time, ease of insertion, and fibre-optic view grading were not different between the groups. Gastric tube placement failed in one patient in group PS and in three patients in group P ($P = 0.606$). The median amount of air (mL) required to get a CP of 60 cm H_2O was 26.5 (20, 28) in group PS and 12 (8,13) in group P (95% confidence interval [CI] =10.808–14.575) ($P < 0.001$). At all time points, CP was significantly higher, and more CP adjustments were needed in group PS than in group P ($P < 0.001$). Incidence of blood staining and post-operative sore throat at 1 and 24 h were not different between the groups. **Conclusion:** LMA Protector provided a significantly higher OLP and less requirement of CP adjustments but comparable first-attempt success rate, mean insertion time, fibre-optic view, and gastric tube insertion as compared to LMA ProSeal.

Keywords: Airway, anaesthesia, laryngeal mask airway, LMA ProSeal, LMA Protector, oropharyngeal leak pressure, supraglottic airway devices

INTRODUCTION

Second-generation supraglottic airway devices (SADs) with gastric access are recommended for daily clinical practice. Laryngeal mask airway (LMA) ProSeal, a benchmark of second-generation SAD, has a double cuff to improve the seal. Its advantages, such as easier insertion, minimal trauma, and sufficient oropharyngeal seal pressure, are well-identified in clinical practice.

How to cite this article: Bhardwaj M, Dhania S, Kaur K, Lal J, Priya, Singhal SK. Comparison of oropharyngeal leak pressure of LMA Protector and LMA ProSeal in anaesthetised paralysed patients – A randomised controlled trial. Indian J Anaesth 2023;67:S245-50.

LMA Protector is also a second-generation but single-use SAD; it contains two drain channels that emerge proximally as separate ports (male and female) and distally enter a common pharyngeal chamber located behind the cuff bowl. The chamber further narrows into an orifice located at the end of the cuff to communicate distally with the upper oesophageal sphincter. An integrated cuff pressure (CP) indicator in the inflation line for the pilot balloon provides continuous monitoring and easy adjustment of intracuff pressure (Cuff Pilot™ Technology).

Recent clinical trials on LMA Protector have shown that it is easy to insert and provides a higher oropharyngeal leak pressure (OLP) than other commonly used SADs.[1,2] We hypothesised that LMA Protector would provide higher OLP than LMA ProSeal because of the different cuff material and design. However, results from previous studies in adults are contradictory to this assumption. Thus, we planned the present study to compare the clinical performance of LMA Protector and LMA ProSeal in terms of OLP (primary objective) and insertion characteristics (secondary objective).

METHODS

The present randomised and single-blind study was conducted in a tertiary care institute from February 2022 to November 2022 after approval from the institutional Biomedical Research Ethics Committee (vide approval number BREC/Th/2021/Pharma/08 dated 02/04/21) and registering with the Clinical Trials Registry-India (vide registration number CTRI/2022/02/040280, www. ctri. nic.in). Written informed consent was obtained from all the participants to use their data for research and educational purposes. The study was conducted in accordance with the declaration of Helsinki, 2013 and adherence to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Ninety patients of either gender, age 18–70 years, belonging to the American Society of Anesthesiologists (ASA) physical status I–III, undergoing surgery of 1–3-h duration under general anaesthesia were included. Patients with known difficult airway, edentulous, body mass index (BMI) >30 kg/m^2, upper airway pathology, mouth opening <3.2 cm, gastroesophageal reflux, increased risk of aspiration, recent upper respiratory tract infection, and lack of consent to participate were excluded from the study.

The study participants were randomised into group PS (LMA ProSeal) and group P (LMA Protector) by using a computer-generated random number sequence. The allocation was done by a serially numbered opaque envelope method. The envelope was opened and revealed to the investigator after subject recruitment. A standard general anaesthetic induction technique comprising intravenous (IV) propofol 2–2.5 mg/kg, fentanyl 2 μg/kg, and vecuronium 0.01 mg/kg was used. After 3 min of mask ventilation with sevoflurane (1.5%–2.5%) in 100% oxygen, an LMA Protector or LMA ProSeal was inserted as per the manufacturer's instructions, depending upon the group allocation. An anaesthesiologist with experience of more than 25 LMA Protector or LMA ProSeal insertions with standard technique inserted the device. The size of both devices was chosen as per the manufacturer's recommendations (size 3 for patients ≤50 kg, size 4 for patients 51–70 kg). During insertion, the following manipulations were allowed: jaw thrust, adjusting insertion depth or head extension, and flexion beyond the sniffing position. If required, any manoeuvre among the three was opted as per the choice of the anaesthesiologist. A maximum of three attempts was allowed. If not successful after three attempts, insertion was considered a failure and an alternative technique was used for airway management. The appropriate placement was confirmed by proper chest expansion, auscultation, and square waveform on the capnograph. Insertion time was defined as the time from the picking up of the device to the appearance of the first waveform of the end-tidal carbon dioxide. It was calculated by adding the time taken for each attempt, but the time between the two attempts was not added. Ease of insertion was assessed according to the above-mentioned manoeuvres during insertion as follows: easy for no manoeuvre, fair for one type of manoeuvre, and difficult for more than one type of manoeuvre. The LMA Protector cuff was inflated till the end of the green zone, and CP was noted. The amount of air required to inflate the cuff, up to 60 cm H_2O, was noted for both SADs. CP was recorded every 30 min by using a handheld aneroid manometer. If the CP was >60 cm H_2O, then it was adjusted by removal of air. The number of these adjustments was noted. OLP was recorded with the adjustable pressure limiting valve fully closed and oxygen flow maintained at 3 L/min. The pressure at which an audible leak occurred or up to a maximum pressure of 40 cm H_2O was noted as OLP. The anatomic position of devices was evaluated using a fibre-optic bronchoscope and graded on a scale of 1–4 as follows[3]: 1:Vocal cords fully

visible; 2: Vocal cords partially visible or arytenoids cartilages visible; 3: Epiglottis visible; 4: No laryngeal structures visible. A well-lubricated gastric tube was passed through the female port into the gastric access channel of LMA Protector (16 F- sizes 3 and 4) and a drain tube of LMA ProSeal (16 F for size 3/4). Ease of gastric tube placement was graded as follows: 1. (easy: one attempt); 2. (difficult: >1 attempt); 3. (impossible). The suprasternal notch (SSN) test was performed by applying a bolus of gel on the male port (drain) and occluding the female drain port. In contrast, other investigators applied the SSN pressure. If there was a slight movement of the gel, then the test was said to be positive. In the case of LMA ProSeal, the gel was placed on the drain tube. Haemodynamic parameters (heart rate and systolic and diastolic blood pressure) were recorded before induction (baseline) of anaesthesia, after induction, immediately, and 5 min after the insertion of SAD. At the end of the surgery, residual neuromuscular blockade was reversed, SAD was removed, and the presence of any blood staining was noted. Patients were enquired about complaints of sore throat, dysphagia, and hoarseness of voice at 1 and 24 h after the removal of the device.

The sample size was calculated assuming the OLP with LMA ProSeal as 31 with a similar standard deviation (SD) of 6 as per the previous study.[4] To be able to detect a minimum clinically significant difference of 4 cm H_2O between the two groups (as in a study by Moser *et al*.[2] and considering 80% power of research and 5% alpha error, the required sample size came out to be 40 in each group. To account for a non-participation rate of about 10%, 45 subjects were taken in each group.

Data were analysed using coGuide statistics software, Version 1 (BDSS Corp. Bangalore, Karnataka, India). Categorical variables, such as gender, ASA physical status, type of surgery, Mallampati grading, size of SAD, number of insertion attempts, ease of insertion, fibre-optic grading, and ease of gastric tube placement, were compared between study groups by using the Chi-square test. Normally distributed quantitative parameters, such as age, height, and weight, were presented as mean and compared using an independent sample *t*-test. Non-normally distributed quantitative parameters, including insertion time, OLP, CP, and amount of air required to get a CP of 60 cm H_2O, were presented as the median and interquartile range (IQR) and analysed using the Mann–Whitney U test. A *P*-value of <0.05 was considered statistically significant.

RESULTS

Ninety patients were enroled, and there was no dropout in the study [Figure 1]. There were one and two failures of insertion in LMA ProSeal and LMA Protector, respectively, but it was statistically insignificant. An alternative airway management technique was used in these patients and were excluded from the analysis. Demographic characteristics were comparable between the groups [Table 1]. Data regarding the performance of LMA ProSeal and LMA Protector are depicted in Table 2. OLP was significantly higher with LMA protector than with LMA ProSeal ($P = 0.009$) [Table 2]. Other study parameters are summarised in Table 2. The overall success rate was 97.7% and 95.5% in groups PS and P, respectively ($P = 0.672$). Insertion time, ease of insertion, and fibre-optic view grading were not different between the groups. Gastric tube placement failed in one patient in group PS and in three patients in group P ($P = 0.606$). The median of the amount of air (mL) required to get a CP of 60 cm H_2O was 26.5 (IQR: 20–28) versus 12 (IQR: 8–13) in the PS group and *P* group, respectively ($P < 0.001$). At all time points, the CP was significantly higher, and more CP adjustments were needed in LMA ProSeal than in LMA Protector ($P < 0.001$) [Table 2]. The incidence of blood staining on the device and post-operative sore throat at 1 and 24 h was not different between the study groups.

DISCUSSION

The present study showed that LMA Protector provides a significantly higher OLP than LMA ProSeal. The insertion time, success rate, ease of insertion, fibre-optic view grading, and number of manoeuvres required were comparable between the two groups.

Our results are consistent with previous studies showing significantly higher OLP of LMA Protector than other second-generation SADs.[5,6] Higher OLP with LMA Protector can be due to the fact that it is made up of medical-grade silicone with an anatomically shaped airway tube and a 10° slant of the tip of the distal part of the cuff, thus providing individualised fit in the pharynx and hypopharynx. In contrast to the present study, Kerai *et al*.[7] reported comparable OLP between LMA Protector and ProSeal. In their study, the authors inflated the cuff of LMA Protector till the middle of the green zone and did not measure the CP, whereas, in the present study, we inflated the cuff till

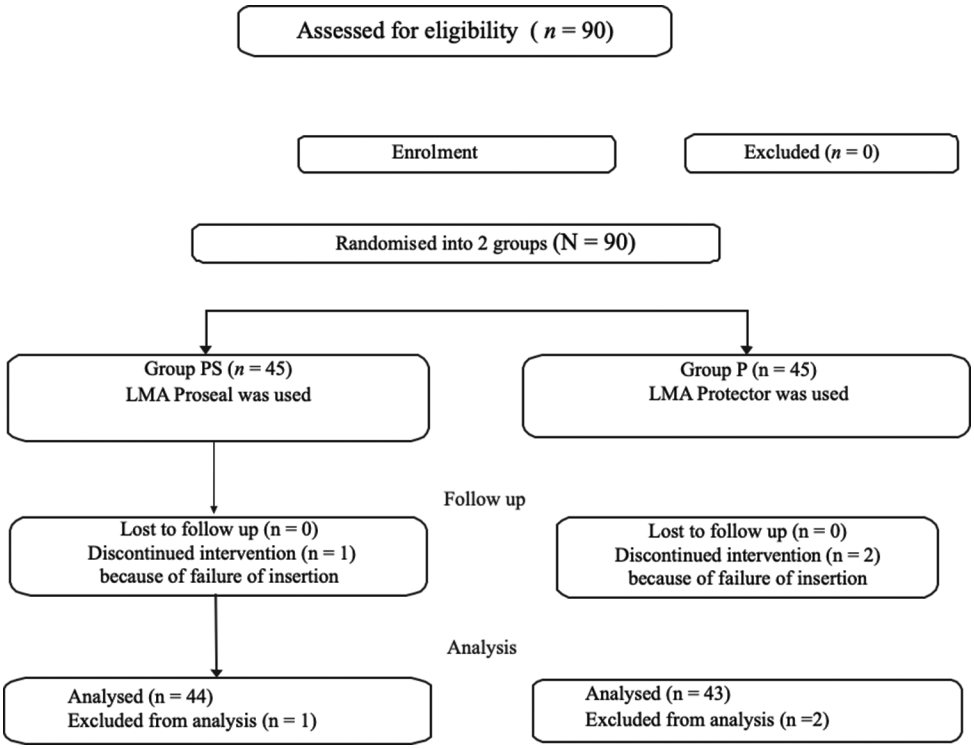

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) chart for flow of study participants

Table 1: Demographic characteristics

Parameters	PS group (*n*=45)	P group (*n*=45)
Age (years)	41.40 (13.86)	39.62 (13.05)
Gender - Male/Female	8/37	12/33
Weight (kg)	62.24 (9.45)	62.87 (10.25)
Height (cm)	157.03 (7.70)	158.14 (8.29)
Body mass index (kg/m^2)	25.12 (2.98)	25.11 (3.32)
American Society of Anesthesiologists- Physical status – I/II	32/13	37/8
Mallampati grading – I/II/III	8/27/10	10/23/12
Size of device – 3/4	28/17	27/18
Duration of Anaesthesia (min)	92.50 (90.0, 110.0)	90.00 (90.0, 110.0)

Data are presented as mean (standard deviation), median (interquartile range) or numbers. *n*=Numbers

the end of the green zone to get a CP of 60 cm H_2O. Sng *et al*.[8] also observed lower OLP with LMA Protector. This difference can be attributed to the lack of use of muscle relaxants and the use of only size 3 in their study. Although the effect on OLP with the help of muscle relaxants is inconclusive, it has been found to expand the pharyngeal space and enable higher OLP and lower leak in a recent study.[9]

Contrary to our results, Kerai *et al*.[7] found longer insertion time, significantly less ease of placement, lower first-attempt success rate, and worse fibre-optic view with LMA Protector compared to LMA ProSeal. Similar results were obtained by Chang *et al*.[6], who reported that the insertion time of LMA Protector was longer compared to i-gel™. Still, ease of insertion, first-attempt success rate, and fibre-optic view grading were similar between the two groups. This finding can be due to different definitions of insertion time, relative unfamiliarity with the new device, and lack of use of neuromuscular blocking agents. Shariffuddin *et al*.[9] also recorded longer insertion times and lower first-attempt success rates because they conducted a study in moderately obese patients.

We failed to insert the gastric tube in three patients (7%) through LMA Protector and in one patient through LMA ProSeal. Zaballos *et al*.[10] found a similar rate of failure of gastric tube placement as in the present study. In contrast to our findings, Sng *et al*.[8] reported a lower failure rate, whereas Moser *et al*.[2] reported a higher rate of insertion failure of gastric tube in their study. Similar to our findings, Zundert *et al*.[11] reported significantly less intracuff pressure adjustment with

Table 2: Performance characteristics between LMA ProSeal and Protector

Parameter	PS group (*n*=44)	P group (*n*=43)	*P*
Oropharyngeal leak pressure (cm H_2O)	29.50 (26, 32)	33 (27, 36)	0.009
Time of device insertion (s)	14 (11, 18)	15 (12, 18)	0.450
No. of insertion attempts – 1/2/3	42/2/0	40/3/0	0.672
Ease of insertion – Easy/Fair/Difficult	34/10/0	33/10/0	0.953
Fibre-optic view grading – 1/2/3	15/26/3	15/25/3	0.995
Suprasternal notch test – Positive/Negative	38/6	34/9	0.367
Ease of gastric tube placement – Easy/Difficult/Impossible	37/6/1	33/7/3	0.606
Post-operative complications			0.437
Blood on device	3	6	
POST - 1 h	1	2	
POST - 24 h	2	3	
Device Cuff pressure (cm H_2O) at different time intervals			
0 min	60.00 (60.0, 60.0)	60.00 (60.0, 60.0)	0.064
30 min	66.00 (65.0, 71.25)	60.00 (60.0, 66.0)	<0.001
60 min	67.00 (62.75, 70.0)	65.00 (60.0, 65.0)	0.004
90 min	66.50 (64.75, 70.0)	60.00 (60.0, 62.75)	<0.001
120 min	67.50 (63.5, 72.5)	60.00 (60.0, 67.0)	0.032
150 min	66.00 (64.0, 68.0)	60.00 (60.0, 65.0)	0.155

Data are presented as median (interquartile range) or number. POST=Post-operative sore throat, *n*=Numbers

the LMA Protector as compared to the LMA Supreme group.

In the present study, blood staining of the device and sore throat were similar between the two SADs. Our results are contrary to various previous studies.[9,12,13] These reported higher incidence of blood staining of the device and sore throat in the range of 19%–25%. This can be due to the fact that these studies were conducted in anaesthetised, non-paralysed patients and moderately obese patients.

This study had a few limitations. Firstly, the anaesthesiologists who inserted the SAD could not be blinded to the group assignment due to the nature of the study. All patients and investigators who evaluated postoperative sore throat were blinded to the group allocation. Secondly, investigators who inserted the SAD had more experience with LMA ProSeal than with LMA Protector. Less experience with a newer device may be a possible source of bias. Thirdly, this study was performed in anaesthetised and paralysed patients with normal airways. Thus, our results cannot be generalised to non-paralysed patients and patients with difficult airways. In addition, this study was conducted in patients with a mean BMI of 24 kg/m^2, not in obese patients; as such, our results may not be applicable to obese patients.

Although higher OLP with LMA Protector was statistically significant, it may not be clinically relevant to all patients. Although it may be helpful to subsets of populations such as obese, laparoscopic surgery, and poor lung compliance patients, its safety cannot be ascertained from the present study as they were not studied.

CONCLUSION

LMA Protector provided a significantly higher OLP and less requirement for CP adjustments. However, comparable first-attempt success rate, mean insertion time, fibre-optic view, and gastric tube insertion as compared to LMA ProSeal were noted.

Study data availability

De-identified data may be requested with reasonable justification from the authors (e-mail to the corresponding author) and shall be shared upon request.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Acknowledgements

The authors thank Mr. Dinesh Kumar (operation theatre technician) for his help in conducting the study.

ORCID:

Mamta Bhardwaj: https://orcid.org/0000-0002-3942-3268

Sunny Dhania: https://orcid.org/0009-0007-3541-0658

Kiranpreet Kaur: https://orcid.org/0000-0003-3592-0061

Jatin Lal: https://orcid.org/0000-0002-0937-1065
Priya: https://orcid.org/0009-0008-3829-8515
Suresh Kumar Singhal: https://orcid.org/0000-0002-8993-9924

REFERENCES

1. Mendonca C, Tourville CC, Jefferson H, Nowicka A, Patteril M, Athanassoglou V. Fibreoptic-guided tracheal intubation through i-gel® and LMA® Protector™ supraglottic airway devices-A randomised comparison. Anaesthesia 2019;74:203-10.
2. Moser B, Audigé L, Keller C, Brimacombe J, Gasteiger L, Bruppacher HR. A prospective, randomised trial of the Ambu AuraGain™ laryngeal mask versus the LMA® protector airway in paralyzed, anaesthetised adult men. Minerva Anestesiol 2018;84:684-92.
3. Kleine Brueggeney M, Theiler L, Urwyler N, Vogt A, Greif R. Randomized trial comparing the i-gel™ and Magill tracheal tube with the single-use ILMA™ and ILMA™ tracheal tube for fibreoptic-guided intubation in anaesthetized patients with a predicted difficult airway. Br J Anaesth 2011;107:251-7.
4. Maitra S, Khanna P, Baidya DK. Comparison of laryngeal mask airway Supreme and laryngeal mask airway Pro-Seal for controlled ventilation during general anaesthesia in adult patients: Systematic review with meta-analysis. Eur J Anaesthesiol 2014;31:266-73.
5. Moser B, Keller C, Audige L, Bruppacher HR. Oropharyngeal leak pressure of the LMA Protector vs the LMA Supreme; A prospective, randomized, controlled clinical trial. Acta Anaesthesiol Scand 2019;63:322-8.
6. Chang JE, Hyerim Kim H, Jung-Man Lee JM, Min SW, Won D, Jun K, *et al*. A prospective, randomized comparison of the LMA-Protector™ and i-gel™ in paralyzed, anesthetized patients. BMC Anesthesiol 2019;19:118.
7. Kerai S, Bhatt G, Saxena KN, Gaba P, Wadhwa B. Comparison of oropharyngeal leak pressure of LMA Protector and LMA-ProSeal in different head and neck positions in anaesthetized and paralyzed patients; A prospective randomized study. Indian J Anaesth 2023;67:201-6.
8. Sng BL, Ithnin FB, Mathur D, Lew E, Han NR, Sia AT. A preliminary assessment of the LMA protector in non-paralysed patients. BMC Anesthesiol 2017;17:26.
9. Shariffuddin II, Chaw SH, Ng LW, Lim CH, Zainal Abidin MF, Wan Zakaria WA, *et al*. Clinical performance of the LMA Protector™ airway in moderately obese patients. BMC Anesthesiol 2020;20:184.
10. Zaballos M, Zaballos J, Lopez S, Fernandez-Dıez AI, Lluch-Oltra A, Mexedo C, *et al*. The LMA® Protector™ in anaesthetised, non-paralysed patients: A multicentre prospective observational study. Anaesthesia 2019;74:333-9.
11. van Zundert AAJ, Wyssusek KH, Pelecanos A, Roets M, Kumar CM. A prospective randomized comparison of airway seal using the novel vision-guided insertion of LMA-Supreme and LMA-Protector. J Clin Monit Comput 2020;34:285-294.
12. Chan W, Liu C. Clinical performance comparison of LMA Protector™ Cuff Pilot™ and LMA Supreme™ when used in anesthetised, non-paralyzed patients. Cureus 2022;14:e23176.
13. Liu Y, Song Y, Wang M, Yang M, Shen H, Wang Z, *et al*. LMA® Protector™ in patients undergoing laparoscopic surgeries: A multicenter prospective observational study. BMC Anesthesiol 2021;21:318.