Original Article

Comparison of gum elastic bougie-guided insertion of LMA Protector™ versus the conventional method in achieving oesophagal patency - A randomised comparative study

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ABSTRACT

Background and Aims: The passage of a Ryle's tube through the drain port on the laryngeal mask airway (LMA) Protector™ has been reported to be arduous despite the larger gastric channel. There are no studies on the evaluation of the guided insertion of LMA Protector™ to achieve adequate gastrointestinal drainage function. **Methods:** This randomised study included 132 patients who underwent surgery under general anaesthesia. The gum elastic bougie (GEB)-guided insertion of LMA Protector™ (group I) was compared with the conventional method (group II), and the alignment of the tip of the drain tube with the oesophagus was assessed. The insertion characteristics of the device, accuracy of LMA Protector™ placement, haemodynamic parameters, and post-operative airway morbidity following the insertion of the device were also compared between the two groups. **Results:** The first-attempt success rate for the placement of LMA Protector™ and the patency of oesophagus was higher in group I patients than in group II (100% vs 84.8%; $P < 0.001$). However, the time taken for device insertion and associated haemodynamic changes were significantly longer in group I. The patients in group I had better visualisation of laryngeal structures. The GEB-assisted insertion of LMA Protector™ resulted in less incidence of blood staining at the cuff of the device. **Conclusion:** GEB-guided insertion of LMA Protector™ achieved better oesophageal patency than the conventional insertion method. This method also had higher first-attempt success at the placement of the device and was observed to be less traumatic.

Keywords: Gum elastic bougie, laryngeal masks, LMA Protector™, oesophagal patency, supraglottic devices

INTRODUCTION

Second-generation supraglottic devices (SGDs) have become integral to airway management during anaesthesia care. Compared with first-generation SGDs, they have been designed to improve the pharyngeal seal and decrease the risk of aspiration.[1] When a second-generation SGD is correctly placed, the distal opening of the drain tube is wedged against the upper oesophageal sphincter (UES), thus facilitating gastroesophageal drainage and preventing the escape of gases.[2] The ease of passage of a Ryle's tube into the stomach via the drain tube has been shown to correlate with the optimal positioning of SGDs over the larynx.[3,4]

Laryngeal Mask Airway (LMA) Protector™ is a new addition to the armamentarium of second-generation SGDs that provides dual gastric access through two proximal ports.[5] Studies have reported failure of Ryle's tube passage through LMA Protector™ in 7%–31% of

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cases.[6-8] As the failure of passage of the gastric tube through the drain port raises uncertainties in the ability of second-generation SGDs to protect against the risk of gastric insufflation and aspiration, it is imperative to resolve this predicament with LMA Protector™. El Beheiry *et al*.[9] previously showed that insertion of ProSeal LMA by using a gum elastic bougie (GEB) achieved proper alignment of the drain tube and the upper oesophageal opening more frequently than the insertion with a metallic introducer.

We hypothesised that accurate alignment of the tip of the drain tube with the UES will be achieved in adult patients when LMA Protector™ is inserted by guiding it over a GEB inserted into the oesophagus compared to the conventional method recommended by the manufacturer. The study's primary objective was to compare the success rate of LMA Protector™ insertion using a GEB with the conventional method in achieving alignment of the distal tip to the UES. Secondary objectives included comparing GEB-guided LMA Protector™ insertion and the conventional method in terms of first-attempt success rate, time taken, ease of placement, fibreoptic grading for optimal placement, haemodynamic changes following device insertion, and post-operative airway morbidity.

METHODS

This randomised comparative study was conducted in a tertiary care teaching hospital from September 2022 to March 2023. Before the commencement of the study, ethical committee approval (vide approval number F.I/IEC/MAMC/91/03/2022/154 dated 10th August 2022) and trial registration under the Clinical Trials Registry-India (CTRI/2022/09/045899, www.ctri.nic.in) was done.

Patients aged 18–75 years with American Society of Anesthesiologists (ASA) physical status I and II and anticipated duration of surgery of less than two hours were included in the study. The exclusion criteria were patients with body mass index (BMI) ≥35 kg/m^2, anticipated difficult airway, risk of aspiration, and surgery requiring the patient to be positioned in prone or lateral decubitus. The patients scheduled for elective surgery were screened for eligibility during the pre-anaesthetic evaluation. Those fulfilling the eligibility criteria for study participation were enroled. Written informed consent was obtained from patients to participate in the study and to allow the use of patient data for research and educational purposes. The study procedures followed the guidelines in the World Medical Association Declaration of Helsinki ethical principles for medical research involving human subjects.

Based on the technique used to insert LMA Protector™, patients were randomly assigned to either group I or group II. In group I, the device was inserted with the help of a GEB, whereas in group II, it was inserted as recommended by the manufacturer (conventional method). Randomisation was achieved using a computer-generated random table in the allocation ratio of 1:1. The group allocation was concealed in sequentially numbered opaque, sealed envelopes. The envelope was opened on the day of surgery just before shifting the patient to the operation room by an assistant not involved in the study.

On the day of surgery, the patient was shifted to the operation theatre, and standard anaesthesia monitoring was instituted. After noting the baseline values of vitals, intravenous (IV) access was secured on the dorsum of the non-dominant hand. General anaesthesia was induced with IV fentanyl 1–2 μg/kg, propofol 2–2.5 mg/kg, and vecuronium 0.1 mg/kg. After three minutes of intermittent positive pressure ventilation with a gaseous mixture of oxygen and nitrous oxide (50:50) in isoflurane titrated to achieve a minimum alveolar concentration (MAC) of 1.2, SGD was inserted as per group allocation.

The manufacturer's recommendation was followed for selecting the size of LMA Protector™ in the patients. The airway device was prepared for insertion by completely deflating the cuff, and a water-soluble lubricant jelly was applied to the posterior cuff and airway tube. The insertion of LMA Protector™ in both study groups was performed by experienced anaesthesiologists who had previously used the device in at least 20 patients using both techniques.

Group I: The insertion of LMA Protector™ by GEB-guided technique followed the steps described by Brimacombe *et al*.[10] The drain tube of LMA Protector™ is primed with a well-lubricated bougie with its straight end protruding through its distal end, leaving 5 cm of bent portion protruding from the proximal end. An assistant held the proximal end of the GEB while the anaesthesiologist manipulated the distal part of the GEB. Using a laryngoscope, the patient's tongue was depressed and displaced towards the left

side of the oral cavity. When the laryngoscope tip reached the vallecula, the aryepiglottic fold was lifted, thus exposing the laryngeal inlet and oesophagus opening posteriorly. The distal portion of the GEB was placed into the oesophagus by gently sliding the GEB onto the posterior pharyngeal wall. The laryngoscope was removed, and the anaesthesiologist inserted LMA Protector™ over the GEB. Finally, the GEB was removed while the LMA Protector™ was left in position.

Group II: Under direct vision, the distal tip of the device was pressed flat against the hard palate. The device was inserted inwards using a slightly diagonal approach. Keeping the airway tube close to the chin, the device was rotated inwards in a circular motion to follow the curvature behind the tongue until definite resistance was felt.[11]

The cuff of LMA Protector™ was inflated with air so that the cuff pressure indicator reached the middle of the green zone of the cuff pilot. The anaesthesia breathing circuit was connected to the airway channel, and the success of ventilation through LMA Protector™ was ascertained by the appearance of a square wave capnograph and ease of ingress and egress of the anaesthesia gas mixture through it. With successful ventilation, optimal placement of LMA Protector™ was confirmed by advancing a paediatric fibreoptic bronchoscope through the drain and airway tubes. The ability to visualise oesophageal mucosa through the drain tube and to pass the fibrescope more than 35 cm without resistance was evaluated. The glottic structures were visualised using the fibrescope inserted through the airway channel and assessed using the Brimacombe grading scale.[12]

Following this, a short column (2 cm) of water-soluble jelly was injected into the drain tube of the device, and a Ryle's tube of size 14 Fr was inserted through it. Successful placement of LMA Protector™ was defined as the appearance of six consecutive square wave capnography on ventilation and the ability to pass the cable of a paediatric fibrescope more than 35 cm through the drain channel without resistance. Three attempts were permitted for the successful placement of LMA Protector™. Manoeuvres for facilitating successful placement of devices such as jaw thrust, adjusting insertion depth, change in head position, or necessity for change in the device's size were left at the discretion of attending anaesthesiologists. The operator's ease of insertion of the device was subjectively graded as easy, fair, or difficult. In cases where it was impossible to pass a fibreoptic bronchoscope into the oesophagus despite adequate lubrication, LMA Protector™ was not taken out, and the patient's airway was managed by inserting an endotracheal tube of suitable size. No attempt to pass Ryle's tube was made in these cases.

The total time taken for successful insertion of LMA Protector™ was noted, defined as the time elapsed when the anaesthesiologist introduced the device through the mouth of the patient until the appearance of the six consecutive square wave capnograph on the anaesthesia monitor. After successfully inserting the device, the patient's heart rate and blood pressure were monitored every minute for the next five minutes. The oropharyngeal leak pressure of LMA Protector™ was measured using a manometer stability test after five minutes of device insertion.

Intra-operatively, anaesthesia was maintained using isoflurane in an oxygen and nitrous oxide gas mixture, which was titrated to achieve a minimum MAC of 1.2. Intermittent boluses of one-fifth of the intubating dose vecuronium were administered as guided by the train of four monitoring for neuromuscular blockade. After surgery, the residual neuromuscular block was reversed by IV glycopyrrolate and neostigmine, and on the full awakening of the patient, LMA Protector™ was taken out. The presence of a blood stain at the dorsal cuff was noted. Post-operatively, the presence of sore throat in the patients was evaluated at 2, 4, 6, and 24 hours after surgery.

The sample size for the study was calculated based on 80% power and 5% significance level. In a previous study, the ability to pass paediatric fibreoptic to the oesophagus through the drain channel of ProSeal LMA was more successful when GEB-assisted insertion was used compared to the conventional method (97% versus 81% of subjects, respectively).[9] If we consider 95% accuracy and the true relative error for experimental subjects as 0.10 along with 0.8 effect size, at least 60 subjects are needed in each group. Considering the 10% dropout rate, 132 patients were enroled for participation in the present study.

The Statistical Package for Social Studies (SPSS) software version 24.0 (SPSS version 24.0 Chicago, Illinois) was used to analyse study data. Categorical variables were presented in number and percentage, and continuous variables as mean ± standard deviation (SD). The normality of the data was checked using the Kolmogorov–Smirnov test. Pearson

Chi-square or Fisher exact test was used for comparing nominal data, wherever appropriate. An unpaired *t* test was applied to see the difference in continuous variables. $P < 0.05$ was considered significant at a 95% confidence level.

RESULTS

A total of 132 patients were enroled for participation. All patients received the intended intervention and completed the study protocol [Figure 1]. The age of patients in group I was significantly higher than that in group II ($P = 0.03$). The rest of the demographic variables were comparable between the two groups. The groups were similar in terms of the ASA physical status of patients and the size of LMA Protector™ used [Table 1].

The first-attempt success rate for device placement was higher for group I compared to group II (100% versus 57.5%; $P < 0.001$); however, the time taken for successful insertion was significantly longer [Table 2]. The ease of placement of the device, which the operator rated, was similar in both groups. Patients in group I were found to attain a better fibreoptic bronchoscopic view of the laryngeal inlet, with 37.8% (25/66) of patients showing a grade-4 view as opposed to 22.7% (15/66) in group II. The alignment of the tip of LMA Protector™ with the oesophageal inlet, as assessed by the ability of the fibrescope to visualise oesophageal mucosa, was obtained in all the patients in group I. In contrast, only 84.8% (56/66) of LMA Protector™ in group-II patients achieved alignment with the oesophageal inlet. The ability to pass the paediatric bronchoscope through the drain channel

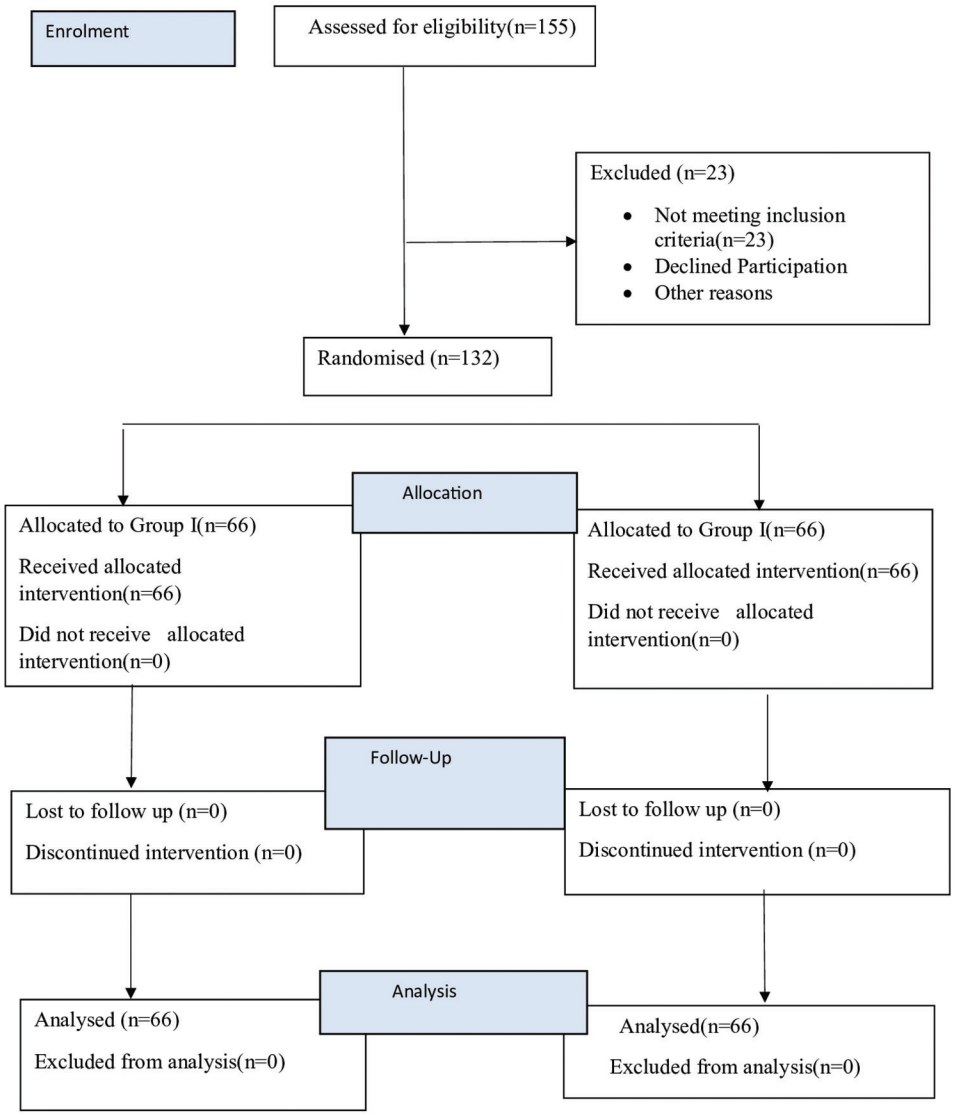

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) Diagram

was not possible in 10 patients in group II; thus, the placement of LMA Protector™ was considered unsuccessful. The subjective grading of Ryle's tube placement was similar in both study groups [Table 2]. The oropharyngeal leak pressure was comparable between the two groups.

Table 1: Comparison of baseline parameters

Demographic variable	Group I (*n*=66)	Group II (*n*=66)
Age (years)	40.09 (12.91)	35.61 (10.88)
Weight (kg)	60.46 (10.97)	58.55 (11.99)
Body Mass Index (kg/m^2)	23.8 (2.6)	22.2 (3.6)
Gender - Male: Female (*n*)	22:44	18:49
American Society of Anesthesiologists Physical Status - I:II (*n*)	56:10	58:08
Size of the device - 3:4:5 (*n*)	24:40:2	30:35:1

Data expressed as mean (standard deviation) or *n* (number)

In both study groups, the heart rate, systolic, and diastolic blood pressure increased from baseline after device insertion [Figure 2]. However, in group I, five minutes after the insertion of LMA Protector™, the changes in haemodynamic parameters remained statistically significant as opposed to group II [Table 3]. The blood stain at the dorsum of the cuff at the end of

Table 2: Comparison of device insertion characteristics

Study Parameter	Group I (n=66)	Group II (n=66)	Difference in mean (95%CI)	*P*
Time taken for device insertion (in seconds)	36.98 (6.66)	28.42 (6.67)	−8.55 (−10.95 to −6.15)	<0.001
OLP (in cm of H_2O)	30.93 (5.09)	31.25 (5.85)	0.31 (−1.67 to 2.27)	0.750
Number of attempts for LMA insertion - 1/2/3 *n* (%)	66 (100)/0 (0)/0 (0)	38 (57.5)/15 (22.7)/3 (4.5)	-	<0.001
Ease of LMA Placement - Easy/Fair/ Difficult *n* (%)	61 (92.4)/5 (7.5)/0 (0)	49/66 (74.2)/15/66 (22.7)/2/66 (3.0)	-	0.062
Oesophageal Patency Yes No/- *n* (%)	66/(100)/0 (0)	56 (84.8)/10 (15.2)	-	<0.001
Ease of insertion of Ryle's tube - Easy/Mild difficulty/Moderate difficulty/ Extreme difficulty *n* (%)	60 (90.9)/4 (6)/2 (2)/0/(0)	46 (82.1)/4 (7.1)/6 (10.7)/0/(0)	-	0.120
FOB® view grade - I/II/III/IV *n* (%)	0 (0)/1 (1.5)/40 (60.6)/25 (37.8)	4 (6)/19 (28.7)/28 (42.4)/15 (22.7)	-	0.007
Bloodstain at dorsal cuff *n* (%)	0	11 (19.6%)	-	<0.001
Postoperative sore throat at 2/4/6 h *n* (%)	8 (12.1)/2 (3)/0 (0)	10 (17.8)/3 (5.3)/1 (1.7)	-	

Data is expressed as mean (standard deviation) or number (percentages). LMA=Laryngeal Mask Airway, OLP=Oropharyngeal Leak Pressure, FOB=Fibreoptic bronchoscope, *n*=number

Table 3: Comparison of haemodynamic parameters following insertion of LMA Protector in groups I and II*

Haemodynamic variables	Group I (*n*=66)	Group II (*n*=66)	Difference in mean (95% CI)	*P*
Heart Rate (in beats/min)				
Baseline	70.68 (11.89)	74.98 (12.87)	4.30 (−0.14 to 8.73)	0.050
1 min	73.28 (10.96)	75.69 (11.69)	2.40 (−1.65 to 6.47)	0.240
2 min	73.89 (11.09)	75.17 (11.47)	1.28 (−1.68 to 6.50)	0.530
3 min	74.12 (10.97)	75.75 (12.26)	1.62 (−2.55 to 5.81)	0.440
4 min	74.34 (12.40)	75.05 (12.19)	0.70 (−3.72 to5.13)	0.750
5 min	73.83 (11.68)	73.73 (0.8)	−0.10 (−4.16 to 3.96)	0.960
Systolic Blood Pressure (in mm Hg)				
Baseline	100.81 (12.28)	103.60 (15.55)	2.78 (−2.23 to 7.81)	0.270
1 min	104.59 (13.40)	109.10 (17.05)	2.76 (−0.94 to 9.98)	0.100
2 min	109.39 (19.67)	108.44 (18.72)	−0.94 (−7.87 to 5.97)	0.780
3 min	106.40 (14.81)	104.85 (14.47)	−1.55 (−6.82 to 3.72)	0.560
4 min	108.57 (16.04)	104.37 (15.87)	−4.20 (−9.94 to 1.54)	0.150
5 min	109.04 (17.21)	106.12 (16.39)	−2.92 (−8.97 to 3.13)	0.340
Diastolic Blood Pressure (in mm Hg)				
Baseline	63. 57 (11.31)	68.16 (12.89)	4.58 (0.24 to 8.92)	0.030
1 min	64.90 (11.24)	70.62 (11.98)	5.71 (1.54 to 9.88)	0.008
2 min	67.59 (12.23)	68.51 (12.35)	0.92 (−3.49 to 5.34)	0.670
3 min	67.68 (12.70)	68.37 (10.64)	0.69 (−3.55 to 4.93)	0.740
4 min	68.09 (12.90)	67.76 (11.48)	0.32 (−4.73 to 4.09)	0.880
5 min	69.25 (13.41)	67.57 (11.75)	−1.68 (−6.24 to 2.87)	0.460

Data expressed as mean (standard deviation). CI=Confidence Interval

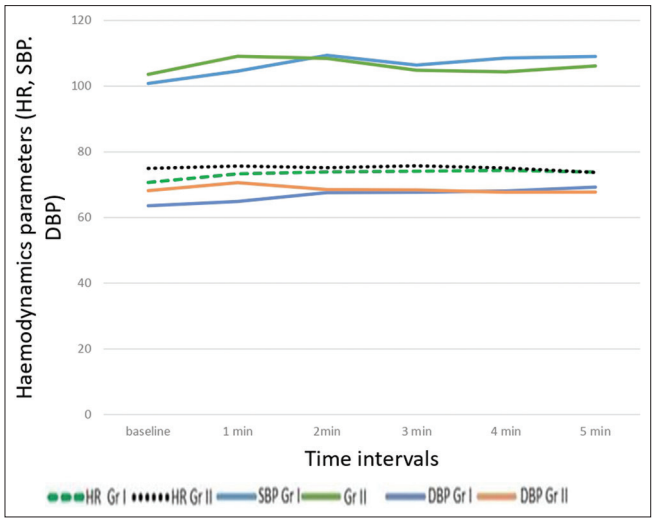

Figure 2: Comparison of haemodynamic variables in the study groups. HR=Heart Rate, SBP=Systolic Blood Pressure, DBP=Diastolic Blood Pressure, Gr=Group

surgery was noted in a greater proportion of patients in group II compared to group I. There was no difference in the incidence of postoperative sore throat at 2, 4, and 6 hours following surgery.

DISCUSSION

Our study found that the GEB-guided insertion of LMA Protector™ resulted in oesophageal alignment in 100% of patients. In contrast, the introduction of LMA Protector™ using the conventional method failed to achieve oesophageal alignment in 15% of patients.

Previous studies on LMA Protector™ have shown that the passage of Ryle's tube through the drainage channel is difficult.[6-8,13] The failure rate of Ryle's tube passage through other commonly used SGDs is reported to be lesser and generally indicates malpositioning of the device.[14] When a SGD is correctly placed, the distal tip lies behind the arytenoids and cricoid cartilages; thus, the Ryle's tube emerging from it enters the oesophagus. Backward folding of the tip of SGD occludes the drain channel and resists the passage of Ryle's tube. Overinflation of the cuff can also present trouble in introducing Ryle's tube as it leads to the bulge of the backplate and compression of the drain channel from behind. Inadequate lubrication of Ryle's tube, selection of larger size LMA, coiled Ryle's tube, and inappropriate method of sterilisation are other causes leading to difficulty in passage of Ryle's tube through an SGD.[15,16] LMA Protector™ has a soft silicone tip, unlike other SGDs such as i-gel and ProSeal LMA. When inserted using the conventional method, the distal tip folds against the posterior pharyngeal wall before passing into the hypopharynx. GEB-guided insertion prevents the tip from folding, directs it toward the hypopharynx, and achieves accurate alignment with the oesophagus.

In agreement with previous studies, the GEB-guided method resulted in a higher first-attempt success rate for insertion. The conventional insertion method required more than one attempt for successful insertion in 42.5% of patients. LMA Protector™ has acute angled preformed curvature and a large inflatable cuff, which may have led to more mucosal injury during insertion in group II. We found that the time taken for insertion of the device is longer in the GEB-guided method compared to the conventional method. This finding is congruous with the fact that GEB-guided insertion involves additional steps of performing pharyngoscopy, introducing GEB to the oesophageal inlet, and railroading LMA Protector ™ to the pharynx.

This study observed that the GEB-guided method resulted in greater haemodynamic perturbations than the conventional LMA Protector™ insertion method. However, although the haemodynamic changes five minutes after device insertion were statistically significant, the degree of changes observed was less than 15% from baseline. Hence, the haemodynamic alterations associated with GEB-assisted insertion are unlikely to have clinical significance in normal patients.

Previous studies have shown that the GEB-guided method is associated with a higher incidence of minor oropharyngeal trauma.[9,17] In contrast, we found that GEB-guided insertion of LMA Protector™ resulted in less oropharyngeal trauma, as evident by less incidence of blood-stained cuff. The incidence of post-operative sore throat, however, was observed to be comparable in both groups.

Our study has the limitation that it was single-blinded as it was not possible to conceal the intervention method from the investigator and the assistant collecting data. The study was not adequately powered to assess the post-operative airway morbidity between the two groups. We found that the GEB-guided method resulted in less blood staining of the cuff on device removal. Previous studies on GEB-guided insertion of other SGDs have shown that it is associated with a greater incidence of minor oropharyngeal trauma.[7] As the physical characteristics of LMA Protector™ differ

from other SGDs, further studies are needed to ascertain this finding.

CONCLUSION

GEB-guided insertion of LMA Protector™ is superior to the conventional method of insertion of the device in terms of accurate alignment of the distal tip to the UES.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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