

Comparative study of Baska mask with proseal LMA in adult patients undergoing elective surgery under general anesthesia with controlled ventilation

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Abstract

Background and Aims: Several supraglottic airway devices (SGD) are available nowadays. But none has been found to be better than Proseal laryngeal mask (PLMA) in terms of oropharyngeal leak pressure (OLP). We aimed to compare OLP of newly introduced Baska® Mask with PLMA in patients undergoing elective surgical procedures under general anesthesia.

Material and Methods: Totally, 80 consecutive adult patients of either sex requiring general anesthesia were randomized into two groups Group B (Baska mask, $n = 40$) or Group P (PLMA, $n = 40$). After standardized induction with propofol 2 – 2.5 mg/kg⁻¹ and fentanyl 2 µg/kg⁻¹, and muscle relaxation with vecuronium 0.1 mg/kg⁻¹ one of the two devices was placed. OLP (primary outcome) was measured 5 minutes and 30 minutes post induction. The time needed to achieve effective airway, anatomical alignment of the device, number of attempts, leak fraction, and postoperative laryngopharyngeal morbidity were noted.

Results: Both the devices could be inserted in first attempt in all the patients, but the time needed to achieve effective airway was significantly less in Group B (12.58 ± 1.81 sec vs 17.92 ± 2.45 sec, $P < 0.001$). The mean OLP was better in Group B at 5 min (37.6 ± 2.43 cm H₂O vs 30.82 ± 3.96 cm H₂O) and at 30 min (38.83 ± 1.72 cm H₂O vs 30.82 ± 3.96 cm H₂O; $P < 0.001$). Anatomical alignment of SGD with glottis (FOB grade 3 or 4 view) was significantly better in group B (34/40) as compared to group P (25/40) ($p = 0.009$). There was no difference in laryngopharyngeal morbidity in the two groups.

Conclusion: Baska mask provided higher OLP, better alignment to the glottis and faster placement time as compared to PLMA.

Keywords: Anesthesia, Baska mask, elective surgical procedures, general, laryngeal masks, oropharyngeal leak pressure

Introduction

The supraglottic airway devices (SGD) have drastically changed the face of airway management in patients undergoing anesthesia and have become a key component of airway manager's armamentarium.^[1] Recently, a number of second generation SGDs have been developed that integrate protective bite blocks, gastric drainage tubes and improved airway seal, thereby, enhancing patient safety.^[2,3]

Proseal LMA (PLMA, Teleflex corporation Ltd, USA) is a reusable device with an additional inflatable dorsal cuff, integrated bite block, and a gastric drain tube that acts as bypass channel for regurgitated gastric contents.^[2] It has been touted as the “gold standard” SGD against which the performance of other devices is compared. PLMA has been found to be a suitable alternative to endotracheal tube (ETT) for airway management in laparoscopic surgeries.^[4,5] Despite introduction of new SGDs, none of them has fared better than

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PLMA in terms of oropharyngeal seal pressures (OLP).^[6-9] However, PLMA has certain limitations like over inflation of its cuff can displace it and diffusion of nitrous oxide into the cuff during anesthesia can increase the intracuff pressure that may increase laryngo-pharyngeal morbidity.^[10]

The Baska Mask (Baska Versatile Laryngeal Mask (BVLM) Pvt Ltd, Strathfield NSW, Australia), is a novel SGD made of silicone. It has a self-sealing membranous recoiling cuff that inflates and deflates proportionally with each positive pressure breath. An increase in airway pressure during positive pressure ventilation (PPV), increases the OLP whereas in PLMA it merely increases the leak.^[11] Baska mask has an inbuilt “tab” to that facilitate its insertion and a gastric reflux high-flow suction system for the clearance of gastric fluids and pharyngeal secretions.

The Baska mask has been evaluated in a handful of studies with a limited number of patients.^[11-13] These studies reported an overall successful insertion rate of between 96 and 100%, and an OLP >35 mmHg. However, its efficacy has not been conclusively proven against well-established devices like PLMA. We designed this study to compare the clinical performance and OLP of Baska Mask with that of PLMA in adult patients undergoing elective surgery under general anesthesia with controlled ventilation.

Material and Methods

The study was conducted in 80 adult patients of 18–60 years of age, of either gender weighing 30 – 70 kg, American Society of Anaesthesiologists (ASA) physical status I and II and undergoing elective surgery under general anesthesia with controlled ventilation in supine position. They were recruited for the study after hospital ethics committee approval and written informed consent. Patient with obesity (BMI >30 kg/m²) anticipated difficult airway (Mallampatti grade 3/4, mouth opening <3 cm, thyromental distance <6 cm, positive upper lip bite test), cervical spine pathology, operation time greater than 4 hours, high risk of aspiration and pregnancy were excluded.

A previous study^[13] observed that the mean OLP was significantly higher in the Baska Mask group as compared to LMA Proseal group (29.98 ± 8.51 vs. 24.50 ± 6.19 cm H₂O) ($p = 0.013$). Taking these values as reference, the minimum required sample size with 80% power of study and 5% level of significance was 29 patients in each study group. A total of 80 (40 patients per group) were chosen to account for failures and dropouts. Block randomization in series of blocks of 10 was done to allocate 80 patients into two equal

groups using sealed envelope technique: Group B- Baska mask was inserted ($n = 40$) and Group P- LMA Proseal was inserted ($n = 40$).

After preanesthetic check-up all, the patients were made to fast overnight and received tablet alprazolam 0.25 mg, tablet ranitidine 150 mg, and tablet metoclopramide 10 mg orally night before surgery and 2 h prior to surgery. On the operation table, the standard monitors [non-invasive blood pressure (BP), electrocardiography, and pulse oximetry (SpO₂)] were attached and baseline readings were noted. After preoxygenation for 3 min with 100% oxygen, anesthesia was induced with intravenous (IV) fentanyl 2 µg/kg⁻¹ and propofol 2–2.5 mg/kg⁻¹. Vecuronium bromide 0.1 mg/kg⁻¹ was administered IV to achieve neuromuscular blockade and after 3 min of PPV appropriate-sized lubricated airway device (according to the weight of the patient as per manufacturer’s recommendation) with preloaded gastric tube was inserted with the patient’s head in sniffing position. The operator who inserted the devices had an experience of successful placement of each of the device in at least 30 patients before starting the study.

In group B, the proximal, firmer part of the mask was compressed between thumb and two fingers and the mask was pushed past the front teeth towards the hard palate, avoiding the tongue. The mask was then advanced until resistance is encountered. In group P, a lubricated PLMA of appropriate size was inserted in sniffing position using introducer technique. After placement of PLMA, introducer was removed, and its cuff was inflated to 60 cmH₂O using cuff pressure gauge.

Effective airway was said to be achieved if there was bilateral chest expansion, square wave capnograph, lack of gastric insufflation, and no audible leak at peak airway pressure (PAP) of 20 cm of water during manual ventilation.

Airway manipulations such as jaw thrust, neck flexion or extension, chin lift, and change in the depth of device needed for achieving effective airway were noted. Time for achieving effective airway (time when SGD was held at the teeth for insertion till appearance of first square wave capnograph) was noted using a stopwatch by an independent assessor. After securing the airway, the gastric catheter was passed into the stomach. The correct placement of the gastric tube will be confirmed by the detection of injected air on epigastric auscultation. Achieving both an effective airway and a successful insertion of gastric tube was considered as a successful insertion of the device.

To assess and grade the anatomical alignment of the SGD to the glottis, a fiberoptic bronchoscope (FOB) was passed

into the airway tube, with its tip kept just inside the distal end. [Table 1].^[14]

Ease of insertion of device was graded by the anesthetist inserting the device [Table 1].

In the event of failure to insert the device, or if effective airway was not achieved, or if the gastric catheter could not be passed into the stomach, the device was removed, and it was counted as a failed attempt. After three failed attempts, airway was secured with endotracheal intubation. If there was a fall in SpO₂ to less than 95% any time during insertion of device, the attempt was terminated, and the patient was mask ventilated with 100% oxygen.

Our primary outcome was OLP which was measured within 5 and at 30 min after device insertion by closing the circle system's expiratory valve at fixed gas flow of 3 Lmin⁻¹, at bag mode of ventilation and noting the airway pressure (maximum 40 cmH₂O allowed) at which equilibrium was reached.^[15] Secondary outcomes included number of attempts of insertion, time for achieving effective airway, ease of insertion score, anatomical alignment of the supraglottic device, leak percent, difference in OLP and PAP and hemodynamic parameters. The patient was ventilated on volume-controlled mode of ventilation maintaining EtCO₂ of 30–35 mm Hg. Anaesthesia was maintained with (N₂O 67%, O₂ 33%) with isoflurane (0.6–0.8%).

Ventilatory parameters like inspiratory tidal volume (ITV), expiratory tidal volume (ETV), EtCO₂, peak airway pressure (PAP) were noted at 1, 5, 15, 30 min after connecting the patient on to the ventilator. Leak percent = $\frac{ITV-ETV}{ITV} \times 100$ was calculated at 5 min post device insertion. Difference in OLP and PAP was calculated at 5- and at 30-min post-device insertion. Hemodynamic parameters and SpO₂ were noted just before device insertion, 1, 3, 5, 15, and 30 min after device insertion and then monitored throughout the surgery.

At the end of surgery, residual neuromuscular blockade was reversed with IV neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Gastric catheter was removed after applying suction

through it. The device was removed when patient was awake with return of full reflexes. Any visible trauma to lip, tongue, teeth, and oral tissues and any staining of device with blood was noted postoperatively. An independent observer (who was not the part of investigating team) evaluated adverse events such as desaturation (SpO₂ < 92%), aspiration, or regurgitation (gastric fluid in airway port or in hypopharynx), need to change the device, airway obstruction, bronchospasm, and laryngospasm. Postoperative laryngo-pharyngeal morbidity (sore throat, dysphagia hoarseness of voice) was also recorded at 1 and 4 hrs.

Statistical analysis

The data were entered in MS EXCEL spreadsheet and Statistical analysis was performed using SPSS software version 20 for Windows (IBM Inc. Chicago, IL, USA). Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups. Qualitative variable were compared using Chi-Square test/Fisher's exact test. A *P* value of < 0.05 was considered statistically significant.

Results

A total of 100 adult patients were screened for eligibility as per inclusion criteria. Twenty patients were excluded and a total of 80 were randomly allocated into two groups of 40 each. [Figure 1] The demographic characteristics, airway assessment parameters, and duration of anesthesia were comparable in both the groups [Table 2]. The first attempt success rate of insertion for both the devices was 100%. However, the time for achieving effective airway was significantly less in Group B (12.58 ± 1.81 sec vs 17.92 ± 2.45 sec). (*p* < 0.001) [Table 3].

The mean OLP was higher in Group B as compared to group P at 5 min (37.6 ± 2.43 cm H₂O vs 30.82 ± 3.96 cm H₂O) and at 30 min post device insertion (38.83 ± 1.72 cm H₂O vs 30.82 ± 3.96 cm H₂O; *P* < 0.001) [Table 3, Figure 2]. In Group-B, 52.5% (21/40) patients had OLP of ≥ 40 cm H₂O at 30 min, as compared to none in Group-P. [Table 3, Figure 3].

Table 1: Score regarding anatomical alignment and ease of insertion of device

Score	Ease of insertion	Fibreoptic View
Score 1	Easy-insertion successful at first attempt without any tactile resistance	Vocal cords not visible
Score 2	Slightly difficult- insertion successful at first attempt with tactile resistance	Part of vocal cords and anterior surface of epiglottis seen
Score 3	Difficult- insertion successful at second attempt	Part of vocal cords and posterior surface of epiglottis seen
Score 4	Very difficult-insertion successful at third attempt	Full view of vocal cords
Score 5	Impossible- insertion failed at third attempt	

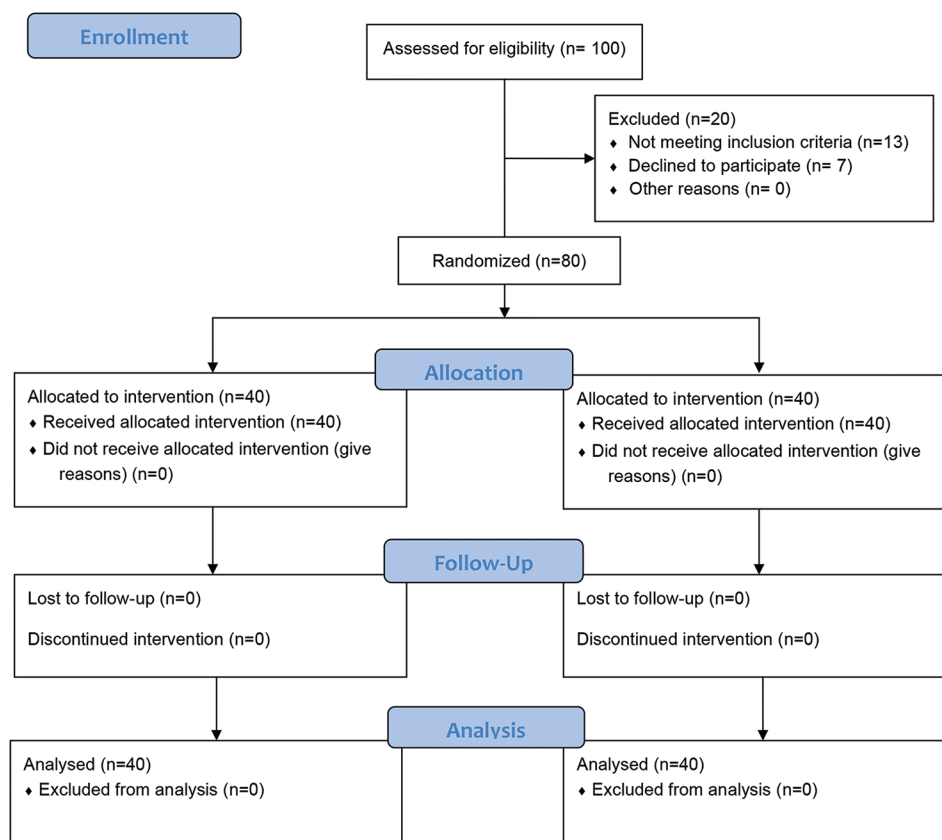


Figure 1: Consort flow diagram

Insertion of device was easy (score 1) in 100% patients in Group B and in 90% patients in Group P. ($p = 0.12$). No manipulations were required to insert the device in Group B while jaw thrust was required in 4 patients in Group P. ($p = 0.116$).

Anatomical alignment of supraglottic device with glottis (FOB grade 3 or 4 view) was significantly better in group B (34/40) as compared to group P (25/40). ($p = 0.009$) [Table 3].

The difference between OLP and PAP (OLP-PAP) was also significantly better in Group B at 5 min (21.98 ± 3.78 cm H₂O vs 14.02 ± 4 cm H₂O) and at 30 min post device insertion (23.02 ± 3.8 cm H₂O vs 15.4 ± 4.21 cm H₂O). [Table 2] ($P < 0.001$). The leak percent at 5 min was similar in the two groups (4.28 ± 3.65 cm H₂O in Group B vs 3.72 ± 3.04 cm H₂O in Group P). [Table 3] ($p = 0.365$). No intraoperative and postoperative adverse events such as desaturation ($SpO_2 < 92\%$), aspiration or regurgitation and airway obstruction were noted in any of the groups. No patient had visible trauma to lip, tongue, teeth, and oral tissues in both the groups. The hemodynamic parameters (mean heart rate and mean blood pressure), EtCO₂ and SpO₂ were comparable in the two groups.

There was no incidence of dysphagia or hoarseness in the two groups. Sore throat was observed in 6 (15%) patients in Group B and in 7 (17.5%) patients in Group P ($p = 0.89$). However, it resolved in all patients within 4 hours. Difficulty in swallowing was observed in 1 (2.50%) Group B and in 3 (7.50%) in Group P ($p = 0.168$).

Discussion

In this prospective comparative interventional randomized study, it was found that the Baska Mask provided significantly greater OLP, shorter insertion times and better anatomical alignment with glottis as compared to LMA Proseal in adult patients undergoing elective surgery.

First generation SGDs were introduced in 1980 and found widespread applications.^[16] Further advancement led to introduction of devices like PLMA and the novel Baska mask. The Baska Mask has a self-sealing membranous, non-inflatable, recoiling cuff. During PPV, as airway pressure increases, its membranous seal apposes to the glottis incrementally to increase OLP.

The mean OLP (cm H₂O) within 5 min (37.6 ± 2.43 vs 30.82 ± 3.96 ; $P < 0.001$) and at 30 min post device

Table 2: Comparison of age, weight, height, BMI, duration of surgery, and airway assessment parameters

Variable	Group B	Group P	P
Age (Years)	(36.98±13.4)	33.92±10.92	0.381
Sex (M/F), n (%)	19/21 (52.50/47.50/)	22/18 (45.00/55.00)	0.502
Weight (Kgs)	54.28±8.14	55.45±7.05	0.831
Height (cms)	163.57±9.51	165.75±8.8	0.292
BMI (kg/m ²)	20.64±2.72	22.1±2.88	0.658
ASA (I/II), n (%)	40/0 (100.00/0.00)	36/4 (90.00/10.00)	0.116
Thyromental Distance (cm)	8.13±1.29	8.03±0.89	0.892
Mallampati Class (I/II), n (%)	29/11 (72.5/27.5)	23/17 (57/43)	0.162
Interincisor gap (cm)	4.67±0.47	4.55±0.54	0.410
Duration of Surgery (h)	1.6±0.46	1.78±0.45	0.069

Table 3: Device insertion attempts, insertion time, sealing pressure, duration of anesthesia, ease of gastric tube insertion

Variable	Group B	Group P	P
Size of Device (3/4), n (%)	16/24 (40.00/60.00)	13/27 (32.50/67.50)	0.485
OLP within 5 min	37.6±2.43	30.82±3.96	<0.001
OLP at 30 min	38.83±1.72	30.82±3.96	<0.001
(OLP-PAP) AT 5 min	21.98±3.78	14.02±4	<0.001
(OLP-PAP) AT 30 min	23.02±3.8	15.4±4.21	<0.001
FOB score (4/3/2/1)	18/16/6/0	5/20/15/0	0.009
Total time for achieving effective ventilation (secs)	12.58±1.81 sec	17.92±2.45 sec	<0.001
Ease of insertion of device (1/2/3/4/5)	40/0/0/0/0	36/4/0/0/0	0.116
Manipulation done for effective ventilation (Y/N)	0/40	4/36	0.116
Leak percent at 5 minutes	(4.28±3.65)	(3.72±3.04)	0.365
Pharyngolaryngeal morbidity at 1 h			
Sore throat	6	7	0.89
Difficulty in swallowing	1	3	0.168
Pharyngolaryngeal morbidity at 4 h			
Sore throat	0	0	
Difficulty in swallowing	0	0	

OLP=oropharyngeal leak pressure, PAP=peak airway pressure, FOB=fiberoptic bronchoscope

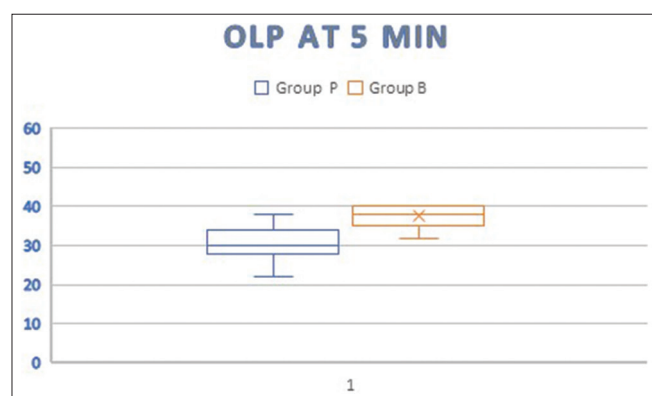


Figure 2: Box-and-whisker plots illustrating OLP at 5 minutes (in cm H₂O) with PLAM and Baska mask. The inner horizontal line within the box represents the median time for the glottic view, and the outer horizontal lines of the box represent the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals

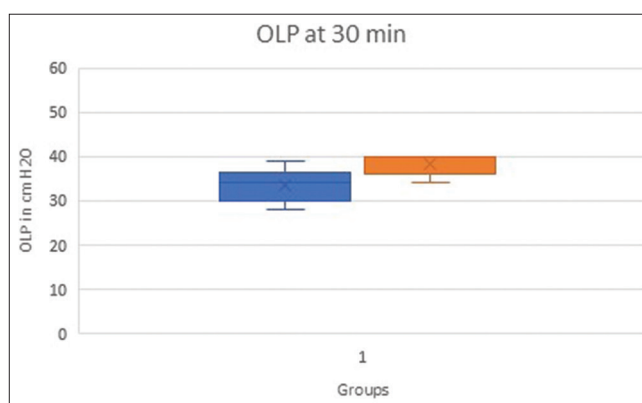


Figure 3: Box-and-whisker plots illustrating OLP at 30 minutes (in cm H₂O) with PLAM and Baska mask. The inner horizontal line within the box represents the median time for the glottic view, and the outer horizontal lines of the box represent the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals

insertion (38.83 ± 1.72 vs 30.82 ± 3.96 ; $P < 0.001$) was significantly higher in group-B. The mean OLP in fact increased at 30 min after device insertion in group-B while it remained constant in group-P. This difference in mean OLP of 8.01 cm H₂O (at 30 min) can be of importance while

ventilating patients with poor lung compliance or for surgeries requiring higher ventilation pressures.

Al-Rawahi *et al.*^[13] found a similarly higher OLP with Baska mask (29.98 ± 8.15 vs 24.50 ± 6.19 ; P value = 0.13) as

compared with PLMA in 52 adult patients and concluded that mean difference of 5.48 cm H₂O in OLP between the two devices may be of clinical importance in patients with decreased thoracic compliance.

Zundert TV *et al.*^[11] in their study on Baska mask observed that the OLP was above 30 cm H₂O in all patients and it reached the maximum value of 40 cm H₂O at the time of insertion of the Baska mask in 76% of the patients and at 30 min following insertion in 82% of the patients. However, any increase in OLP at 30 min following insertion, cannot be commented upon as its measurement was aborted once airway pressure reached 40 cm of water due to risk of barotrauma. Sachidananda R *et al.*^[17] reported that the OLP was significantly higher with Baska mask as compared to that of i-gel (28.9 ± 3.5 vs 25.9 ± 2.5 cm of water), (*p* = 0.001). Kumar MRA *et al.*^[18] in their observational study in 100 adult anesthetized patients reported OLP of 42.46 ± 19.12 cm of water with Baska mask which is in agreement with our study.

The difference between OLP and PAP was significantly higher in Group-B as compared to Group-P at both times of comparison. Also, the maximum OLP value of 40 was achieved in 52.5% patients of Group-B as compared to none in Group-P. This implies that although both devices will provide satisfactory oropharyngeal seal and effective ventilation, higher OLP-PAP of Baska mask will make it superior to PLMA especially in patients with decreased thoracic compliance or those who need to be ventilated at high PAP.

The mean leak percent at 5 min of Group B was comparable in both the groups. Similar low percentage leak with Baska mask was found in studies by Al-Rawahi *et al.*^[13] and Kumar MRA *et al.*^[18] suggesting an adequate oropharyngeal seal and effective ventilation.

First attempt success rate of insertion and overall success rate of insertion was 100% with both the devices. Similarly, Kumar MRA *et al.*^[18] in their observational study on Baska mask in 100 adult patients found a first attempt success rate to be 97% and overall success rate of 100%. Al-Rawahi *et al.*^[13] also found no significant difference in the mean number of attempts required for either Baska mask or PLMA placement (1.20 ± 0.41 vs 1.18 ± 0.39; *P* = 0.873).

However, Zundert TV *et al.*^[11] and Aziz ARAR *et al.*^[19] observed a lower first attempt success rate with Baska mask (88% and 90%). This could possibly be due to the lack of use of muscle relaxant for device insertion in Zundert's study and due to anatomically different airway in obese patients in the latter study.

Time taken for achieving effective airway was significantly higher with LMA Proseal as compared to that with Baska mask as additional time was required for removal of the introducer, cuff inflation and adjusting its pressure to 60 cm H₂O with a hand-held manometer. In contrast, the Baska mask has a non-inflatable self-sealing membranous cuff. Al-Rawahi *et al.*^[13] similar to our study found that the mean insertion time was significantly shorter with the Baska mask as compared to that with PLMA (16.43 ± 4.54 sec vs 21.45 ± 6.13 sec; *P* = 0.001). They attributed faster insertion with Baska mask to presence of a tab which when pulled overcame any difficulty in negotiation of the oropharyngeal curve and a noninflatable cuff. Similar insertion times have been reported in the studies by Zundert TV *et al.*^[11] and Kumar MRA *et al.*^[18]

Ease of insertion of the device was comparable in the two groups (easy in 100% in Group-B vs 90% in Group-P; *P* = 0.116). No manipulations were needed for inserting the Baska mask while 4 patients required jaw thrust to facilitate insertion of PLMA when tactile resistance was felt during insertion. Zundert TV *et al.*^[11] and Kumar MRA *et al.*^[18] similarly observed that the Baska mask insertion was very easy or easy in 98% patients.

A superior anatomical alignment to the glottis (grade 4 view—full vocal cords) was attained with Baska mask (45% patients) as compared to PLMA (12.5% patients). Furthermore, none of the devices revealed the worst grade-1 view. Better anatomic alignment of Baska mask with glottis may lead to higher intubation success rate through it and higher OLP with better ventilation. The observations in the present study closely approximate the findings of Zundert TV *et al.*^[11] who reported a near perfect view with Baska mask (75–100% of glottic aperture visible) in 54% of the patients while none of the patients showed an absent vocal cords/epiglottis view.

Gastric tube was preloaded in this study as it was observed to come out of the sump cavity of the Baska mask into the pharynx during insertion in pilot cases. None of the patients in either of the groups, required a second attempt for gastric tube insertion suggesting a correct alignment of drain tube with esophagus. Zundert TV *et al.*^[11] in their study found that it was easy to insert a gastric tube through one of the gastric drain tubes like our study.

There was no significant difference in the intraoperative hemodynamic parameters, SpO₂, and peak airway pressures between the two groups, Alexiev *et al.*^[20]

No adverse events such as aspiration, regurgitation, blood staining of the SGD after removal visible airway trauma, and airway obstruction were noted in any the patients. Zundert

TV *et al.*^[11] in his study found blood staining of Baska mask in 8% patients and trauma to lip in 2% patient. Chauhan G *et al.*^[21] found blood staining of PLMA in 16% patients. Absence of any trauma or blood staining of device in our study could be attributed to gentle insertion of the airway device by experienced operators without using any undue force and exclusion of factors predicting difficult airway.

Postoperative pharyngo-laryngeal morbidity was comparable and minimal in both groups. Al-Rawahi *et al.*^[13] reported a higher overall incidence of sore throat than our study in both Baska and Proseal groups (43.3% and 45.5%, respectively).

The reported incidence of sore throat in observational study by Kumar MRA (15%) coincided with our study.^[18] The minimal incidence of postoperative pharyngolaryngeal morbidity (sore throat, difficulty in swallowing, or hoarseness) in our study could be attributed to the fact that water soluble jelly was used for lubrication and cuff pressure of PLMA was maintained at 60 cmH₂O throughout the surgery.

Limitations

Our study has a few limitations. First, operator blinding was not possible due to the nature of the study and different shape of the study devices and may be a source of potential bias. However, majority of the outcome parameters were recorded by an independent assessor not further involved in the study. The results may not be applicable to patients with difficult airway as this study was conducted in patients with normal airway.

Conclusions

The present study concludes that the Baska mask provides higher oropharyngeal leak pressure, better anatomical alignment with glottis, and faster time to achieve effective airway as compared to LMA Proseal without increasing the airway morbidity. Baska mask is superior to PLMA for ventilation and especially in patients who require high intrathoracic airway pressure or have poor lung compliance.

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Conflicts of interest

There are no conflicts of interest.

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