



Baska mask vs ProSeal Laryngeal mask on airway seal pressure in cases undergoing general anesthesia by mechanical ventilation: A randomized controlled trial

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ABSTRACT

Background: Supraglottic Airway Devices (SGAs) are designed to counteract the drawbacks of endotracheal intubation. They have proven to be easy to use, robust, versatile, and usable in many difficult situations. This work aims to investigate the use of the Baska Mask (BM) airway and ProSeal™ Laryngeal Mask Airway (PLMA) as SGAs for ventilation.

Methods: This randomized controlled trial was carried out on 74 cases aged 21–65 years old for elective surgery of a planned duration of up to 2 h during general anaesthesia with intermittent positive pressure ventilation. Cases were divided into two equal groups. Ventilation was done either by BM® Airway (group BM) or PLMA (group PLMA).

Results: BM had a shorter insertion time and lower leak fraction versus PLMA, while seal pressure elevated significantly with BM versus PLMA ($P < 0.001$). PLMA had significantly more cases than the BM mask group complaining of a sore throat at 2 h ($P = 0.042$). Complication after gastric tube insertion was parallel between both groups.

Conclusions: BM can be used successfully during anesthesia as it displays a shorter insertion time, lower leak fraction, higher seal pressure, and lower incidence of sore throat and gastric tube insertion complications than PLMA.

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1. Introduction

The last decades have shown the development of many supraglottic airway (SGA) strategies, all of which purpose to provide a less invasive option to endotracheal intubation [1]. SGA apparatus are used to ventilate cases by supplying anaesthetic gases/oxygen above the vocal cords to prevent teeth, vocal cords, laryngeal, and tracheal injury, overstated hemodynamic response, and the more invasive nature of endotracheal intubation [2,3].

Some of the benefits of using SGA are avoiding laryngoscopy, being less invasive for the respiratory system, better tolerance and stability of blood pressure, simpler insertion by novice personnel, and decreasing the severity of sore throat and cough [3].

When intubation difficulties arise in cases with a challenging airway, particularly when it has become impossible to intubate, the American Society of Anesthesiologists (ASA) recommends using SGA devices (such as Laryngeal Mask Airway (LMA)). In unexpectedly challenging tracheal intubation, the

European Difficult Airway Society recommends utilizing an LMA or an intubating LMA [4].

There have been several modifications to the LMA over the years: addition of venting ports, intubation aids, camera attachments, ability to use as an endotracheal intubation conduit and so on, and SGAs have proven to be easy to use, robust, versatile, and usable in many difficult situations where direct laryngoscope is difficult or unnecessary [5].

This work aims to investigate the use of Baska mask (BM) airway and ProSeal™ Laryngeal Mask (PLMA) airway on seal pressure for ventilation.

2. Materials and methods

This randomized controlled trial included 74 adults aged from 21 to 65 years old, ASA class I-II with body mass index (BMI) $< 30 \text{ kg/m}^2$, for elective surgery of planned duration up to 2 h under general anesthesia with intermittent positive pressure ventilation, from December 2018 to February 2019.

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The actual work was done at Kasr Al-Ainy Hospital, Cairo, Egypt.

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After receiving approval from the research ethics committee and registering with clinicaltrials.gov (ID: NCT03812081), the study was conducted at Kasr Al-Ainy Teaching Hospital, Cairo, Egypt. Informed written consent was obtained from each participant.

Exclusion criteria included a history of difficult intubation, nausea and vomiting susceptibility, a hiatal hernia, gastroesophageal reflux disease, or prior operations on the upper digestive system.

Cases were divided into two equal groups. Ventilation was done either by BM® Airway (group BM) or PLMA (group PLMA).

Dentition, cervical mobility, and common predictive parameters (body mass index, thyromental distance, Mallampati grade, interincisor distance) were assessed preoperatively for cases with a history of intubation difficulties.

All cases were given an intravenous (IV) anti-emetic (ondansetron 4 mg) and an antacid (ranitidine 50 mg) 1 h before surgery.

Basic monitoring was performed using a pulse oximeter, electrocardiogram, temperature probe, capnogram, and non-invasive blood pressure.

Heart rate, oxygen saturation, and blood pressure were recorded preinduction, after insertion, and after removal of SGA.

An hour before general anesthesia, all cases were given midazolam at a dose of 0.1 mg/kg orally.

Induction of anesthesia was performed by administering propofol 2–2.5 mg/kg, fentanyl 1–1.5 g/kg, cisatracurium 0.1 mg/kg, and sevoflurane 1–2% in a combination of 60% air and oxygen to maintain anesthesia while the case was supine with their head in a neutral posture. After enough relaxation as measured by a peripheral nerve monitor, a properly lubricated (PLM or BM # 3, 4, 5, as directed by the manufacturer) was inserted. The PLM cuff was distended with air to a pressure of 60 cmH₂O intra-cuff.

Different ventilator parameters were tested for proper positioning to assess the adequacy of ventilation as judged by inspection of chest inflation, bilateral chest auscultation, neck auscultation for abnormal respiratory sounds and absence of any leak sounds from the mask, and capnography readings of six successive waves.

Jaw thrust was done, and the device was moved down and up in the event of inadequate positioning of the device, as determined by fractional loss of >20% of set tidal volume and/or poor capnographic curve. Manipulation (including flexion of the head, extension of the neck, increasing depth of insertion or anesthesia, or re-adjusting the cuff volume of PLM) may be needed.

PLM was inserted using the index finger in a comparable procedure recommended by the manufacturer to the classic LMA or insertion with an introducer similar to an intubating LMA. The appropriate

size of PLMA was chosen in accordance with the cases' weight. The PLMA cuff was adjusted to a pressure of 60 cmH₂O and kept for the duration of the anesthesia using a calibrated aneroid manometer. If the mask still did not seal, it was taken out and reinserted, and each time it was tried, it was counted. In case of failure (three attempts), either a classic LMA or endotracheal tube was inserted. Every case was given 1 g of acetaminophen intravenously.

2.1. Primary outcome

Airway sealing pressure was at 5-min post placement in cmH₂O. Leak pressure was computed as the plateau airway pressure attained with the introduction of fresh gas 6 L/min, and the pressure control valve was fixed at 70 cmH₂O, keeping the patient apneic and recording the airway pressure at which balance was achieved. An air leak can be detected by hearing an audible noise from the mouth or by putting a stethoscope lateral to the thyroid cartilage [6].

2.2. Secondary outcomes

2.2.1. The success of insertion

A number of attempts were required to place the SAD correctly. Grading of "ease of device insertion" was grade 1: (Very easy)-No manipulation, grade 2: (Easy)-Only one manipulation or grade 3: (Difficult)-More than one manipulation [7].

2.2.2. Insertion time

Insertion time required for positioning the SAD was documented for each device, beginning with the removal of mask ventilation and insertion of the mask, cuff inflation, and connection to capnography with appearance of capnography waves.

2.2.3. Leak fraction

Leak fraction was computed as follows: $(V_{insp} - V_{exp}) / V_{insp} \times 100$. The leakage volume was calculated as the variation between the inspired and the expired tidal volumes; these volumes were recorded 3 min after the insertion of the masks using the integral spirometer in the anesthetic machine (Datex-Ohmeda Inc., Madison, Wisconsin, USA).

2.2.4. Laryngeal view grade (Brimacombe & Berry)

After device insertion and confirmation of position, the patient was disconnected from the ventilator circuit, and the anatomic position was determined by passing a fiberoptic bronchoscope to a position just proximal to the end of the airway. Grade I: complete visibility of vocal cords; grade II: visibility of the rear tip of the epiglottis; grade III: no visibility of the epiglottis at all. The anterior epiglottis tip is visible in grade III; in grade IV, the anterior epiglottis surface is visible and obscures

the view of the vocal cords by at least half or more. No view was seen (grade V) because the epiglottis fully blocked the aperture of the instrument [8].

2.2.5. Ease of gastric tube insertion

Once the patient is connected to the ventilator circuit, a lubricated gastric tube will be passed through the integrated drainage channel present in each device. The insertion success rate was recorded, ease of its passage through the specific channel and confirmed placement by aspiration of gastric contents or by auscultation over the stomach as air was injected into the tube. The number of attempts made to enter it was counted. Failure to advance the orogastric tube was considered a failed effort; a maximum of two tries were permitted. The orogastric tube was eliminated immediately post insertion. The ease of gastric tube insertion was graded as grade 1: an easy-insertion on the first attempt, grade 2: difficult-insertion on the second attempt or grade 3: failure – unable to pass (inability to pass the gastric tube even with two attempts).

After the operation was completed, the case's anesthetic gas was switched to 100% oxygen to speed up the recovery process, and any neuromuscular weakness was treated with a combination of neostigmine and glycopyrrolate when the tissue oxygen fraction (TOF) ratio reached 0.9. Once the case was breathing normally and responding to vocal commands by opening their eyes, the PLM or BM was taken away.

2.3. Postoperative complication

The case was checked for coughing; lip, tongue, and teeth trauma; hoarseness; regurgitation; or pulmonary aspiration postoperative airway morbidities like sore throat or hoarseness, dysphasia, heartburn, nausea, and vomiting. Nausea and vomiting onset has been divided into acute (within first 24 h) or delayed (2–5 days).

After taking off the mask, we double examined to make sure it was in good condition and free of any mucous or gastric fluids, blood stains, or evidence of stomach fluid in the trachea. A rating was assigned to the mask's simplicity of removal (very easy, easy, difficult, and very difficult) [9].

Cases' follow-up was performed in the postoperative recovery at arrival, 2, 4, and 24 h after release from the recovery on the initial postoperative day.

2.4. Postoperative assessment

The cases met extubation criteria if they regained consciousness, were able to protect their airway, began breathing on their own, maintained a respiratory rate of less than 30 breaths per minute, had an adequate tidal volume of more than 5 ml/kg, maintained stable hemodynamic and metabolic status, and had

a satisfactory reversal of residual neuromuscular block on clinical tests.

2.5. Sample size calculation

The calculation of sample size was determined by G*Power 3.1.9.2 (Universitat Kiel, Germany). According to a research done by Al-Rawahi [10], the mean seal pressure was 29.98 ± 8.51 with BM and 24.50 ± 6.19 with PLM. With $\alpha = 0.05$ and $\beta = 0.2$, the sample size required (per group) was 34. With 10% of the dropout divided between the two groups, the total sample size was 74.

2.6. Statistical analysis

We utilized SPSS v18 for statistical analysis. The expression of variables was done by mean and standard deviations for parametric quantitative data, median (IQR) for nonparametric quantitative data, and numbers and percentages for qualitative data. The variables were compared using unpaired T-test for parametric quantitative data, Mann-Whitney for nonparametric quantitative data, and Chi-square or Fisher exact tests for qualitative data. A two-tailed *P* value is significant at ≤ 0.05 level.

3. Results

The two groups had no significant differences regarding cases, airway, and surgery characteristics data (Table 1).

The BM group had a shorter insertion time, lower leak fraction, and smaller mask size versus the PLMA group, while seal pressure was higher in the BM group versus the PLMA group ($P \leq 0.05$). The success of insertion, overall success rate, the need for additional maneuvers, and ease of device insertion were similar between both groups. (Table 2)

Laryngeal view grading, ease of gastric tube insertion, and attempts at gastric tube insertion were insignificantly different between groups (Table 3).

There was a significant relationship between laryngeal view grading and seal pressure in BM ($P < 0.001$). No significant relationship existed between laryngeal view grading and seal pressure in PLMA. There was a significant relationship between laryngeal view grading and gastric tube insertion ($P < 0.001$) (Table 4).

Insignificant differences were noticed between both groups regarding the heart rate, blood pressure, or oxygen saturation before induction, after insertion, and after device removal (Figure 1).

The PLMA group had significantly more cases than the BM group complaining of sore throat at 2 h ($P = 0.042$). No significant differences were found between both groups in gastric tube insertion regarding postoperative complications at 2 h (blood stain mucous, dysphasia, and hoarseness), 4 h, and 24 h (Table 5).

Table 1. Cases' airway and surgery characteristics, and type and duration of surgery of cases enrolled in the research.

		BM N = 37	PLMA N = 37	P value
Age		30.41 ± 5.41	31.05 ± 5.30	0.604
Sex	Males	19 (51.4%)	22 (59.5%)	0.483
	Females	18 (48.6%)	15 (40.5%)	
Weight		65.70 ± 6.0	68.51 ± 7.58	0.082
Height		164.11 ± 4.75	165.73 ± 6.69	0.234
BMI		24.39 ± 2.10	24.85 ± 2.22	0.363
ASA physical status		1.0 (1.0–2.0)	1.0 (1.0–2.0)	0.186
Airway measurements	Thyromental distance; cm	7.76 ± 0.21	7.84 ± 0.23	0.101
	Inter-incisor distance; cm	4.79 ± 0.21	4.83 ± 0.22	0.359
Mallampati classification	1	21 (56.8%)	19 (51.4%)	0.641
	2	16 (43.2%)	18 (48.6%)	
Type of surgery	Eye	3 (8.1%)	4 (10.8%)	0.910
	Gynecological	12 (32.4)	10 (27.0%)	
	Orthopedic	5 (13.5%)	7 (18.9%)	
	General Surgery	10 (27.0%)	11 (29.7%)	
	Urology	7 (18.9%)	5 (13.5%)	
Duration of surgery (minutes)		57.08 ± 14.38	64.32 ± 14.41	0.034

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, ASA: American Society of Anesthesiologists, BM: Baska mask, PLMA: ProSeal™ Laryngeal Mask.

Table 2. Data regarding insertion of BM and PLMA masks.

		BM N = 37	PLMA N = 37	P value
Success of insertion	First time	32 (86.5%)	30 (81.1%)	0.775
	Second time	4 (10.8%)	5 (13.5%)	
	Third time	1 (2.7%)	2 (5.4%)	
Overall success rate		36 (97.3%)	35 (94.6%)	0.556
Additional maneuver		8 (21.6%)	14 (37.8%)	0.127
Ease of device insertion	Very easy	29 (78.4%)	23 (62.2%)	0.226
	Easy	6 (16.2%)	8 (21.6%)	
	Difficult	2 (5.4%)	6 (16.2%)	
Insertion time (seconds)		19.86 ± 1.18	23.51 ± 1.42	<0.001*
Seal pressure		35.92 ± 2.1	26.38 ± 2.00	<0.001*
Leak fraction		7.12 ± 1.22	9.22 ± 1.15	<0.001*
Size of mask		4 (4–4)	4 (4–5)	0.002*

Data are presented as mean ± SD, frequency (%), or median (IQR), * significant as *P* value ≤ 0.05. BM: Baska mask, PLMA: ProSeal™ Laryngeal Mask.

Table 3. Comparison between BM and PLMA regarding laryngeal view grading and ease of gastric tube insertion.

		BM N = 37	PLMA N = 37	P-value
Laryngeal view grading	1	19 (51.4%)	11 (29.7%)	0.293
	2	12 (32.4%)	16 (43.2%)	
	3	4 (10.8%)	7 (18.9%)	
	4	2 (5.4%)	3 (8.1%)	
Ease of gastric tube insertion	Easy	32 (86.4%)	29 (78.4%)	0.359
	Difficult	5 (13.5%)	8 (21.6%)	
	Impossible	0 (0.0%)	0 (0.0%)	
Attempts at gastric tube insertion	1	34 (91.9%)	32 (86.5%)	0.454
	2	3 (8.1%)	5 (13.5%)	

Data are presented as frequency (%). BM: Baska mask, PLMA: ProSeal™ Laryngeal Mask.

4. Discussion

The ideal SAD would be easily placed with adequate sealing to protect against aspiration. Oropharyngeal seal pressure (OSP) prevents regurgitation and sustains adequate breathing. One of the recently released devices is BM that has the potential to shorten insertion time, improve seal quality, and reduce the risk of aspiration because of its superior conformance to the oropharyngeal structure [11].

Our results revealed that seal pressure was significantly higher in BM versus PLMA. Also, BM had

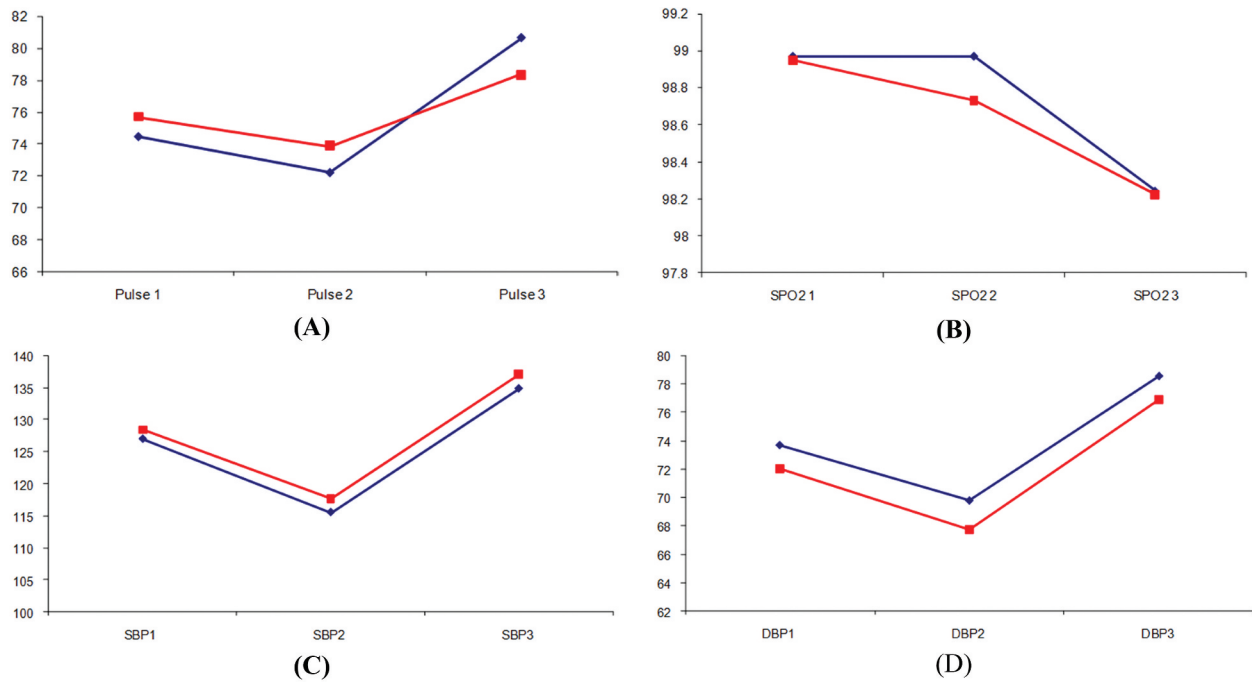
a significantly shorter insertion time, lower leak fraction, and smaller mask size versus PLMA. The success of insertion, overall success rate, additional maneuver, and ease of device insertion were matched between both groups. BM insertion can be accomplished quickly with relatively little previous experience as BM has no cuff membrane, and the fact that the second oropharyngeal curve can be easily modified by dragging the tab of the BM, which improves its distal curvature relative to the PLM [12].

BM's thermolability of the membranous cuff, which adapts to the laryngopharyngeal morphology, may

Table 4. Comparison between BM and PLMA regarding seal pressure and between gastric tube insertion regarding laryngeal view grading.

		Laryngeal view grading				P-value
		1	2	3	4	
Seal pressure	BM	36.47 ± 1.74	33.58 ± 2.31	34.50 ± 1.00	38 ± 0.00	0.001*
	PLMA	27.10 ± 2.56	25.24 ± 1.99	25.00 ± 2.31	25.33 ± 2.08	0.160
Gastric tube insertion	Easy	30 (49.2%)	28 (45.9%)	2 (3.3%)	1 (1.6%)	<0.001*
	Difficult	0 (0.0%)	0 (0.0%)	9 (69.2%)	4 (30.8%)	

Data are presented as mean ± SD or frequency (%), * significant as P value ≤ 0.05. BM: Baska mask, PLMA: ProSeal™ Laryngeal Mask.

**Figure 1.** Comparison between Baska mask (blue line) and ProSeal™ Laryngeal mask (red line) regarding: A: heart rate, B: oxygen saturation, C: systolic blood pressure, D: diastolic blood pressure before induction, after insertion and after removal of device.

account for its superior seal pressure compared to PLM [11].

Brimacombe and coworkers [13] postulated that the larger cuff would impede digital positioning and pharynx propulsion and the absence of a backplate would increase the likelihood of the cuff folding over at the back of the mouth. Therefore, accurate tip positioning would be required to prevent air leakage up the drainage tube.

Our findings agreed with Agrawal et al. [9] who reported that the mean seal pressure was significantly higher in BM versus PLMA at 5 min (37.6 ± 2.43 cm H₂O vs 30.82 ± 3.96 cm H₂O; $P < 0.001$) and at 30 min post-device insertion (38.83 ± 1.72 cm H₂O vs 30.82 ± 3.96 cm H₂O; $P < 0.001$). Also, they observed that the time required to reach an open airway was significantly decreased in BM than PLMA (12.58 ± 1.81 sec vs 17.92 ± 2.45 sec, $P < 0.001$).

Table 5. Comparison between BM and PLMA regarding postoperative complications.

		BM N = 37	PLMA N = 37	P value
At 2 hours	Blood stain mucous	3 (8.1%)	7 (18.9%)	0.173
	Sore throat	4 (10.8%)	11(29.7%)	0.042*
	Dysphasia	2 (5.4%)	5 (13.5%)	0.233
	Hoarseness	3 (8.1%)	4(10.8%)	0.691
At 4 hours	Sore throat	2 (5.4%)	6(16.2%)	0.134
	Dysphagia	1 (2.7%)	2 (5.4%)	0.555
	Hoarseness	2 (5.4%)	3(8.1%)	0.644
At 24 hours	Sore throat	0 (0%)	1 (2.8%)	0.313
	Dysphagia	0 (0%)	0 (0%)	1.0
	Hoarseness	1 (2.8%)	0 (0%)	0.313

Data are presented as frequency (%), * significant as P value ≤ 0.05. BM: Baska mask, PLMA: ProSeal™ Laryngeal Mask.

However, Agrawal et al. [9] reported leak percent at 5 min that was comparable between both groups.

Also, Kachakayala et al. [14] observed that oropharyngeal leak pressure (cmH₂O) was significantly higher in BM versus PLMA (31.2 ± 4.8 vs. 25.8 ± 3.3; $P < 0.001$) and a significantly shorter insertion time for BM (16 s) versus PLMA (20.9 s) ($P < 0.001$).

Moreover, Hussain et al. [15] documented that the mean OSP at five and 30 min was significantly higher in BM (31.55 ± 2.23 cm H₂O, and 35.86 ± 3.70 respectively) versus PLMA (24.17 ± 3.74 cm H₂O and 25.97 ± 3.79 cm H₂O respectively) ($p < 0.001$). However, they reported that the mean value for the leak fraction was insignificantly different between BM and PLMA. Lower sample size in their research may be an appropriate explanation for this variation.

According to our results, success of insertion, overall success rate, additional maneuver, and ease of device insertion were insignificantly different between both groups. Supporting our results, Kachakayala et al. [14] highlighted that there was insignificant variation in the ease of insertion and the number of attempts for both the BM and PLMA.

In our research, laryngeal view grading, ease of gastric tube insertion, and attempts at gastric tube insertion were insignificantly different between groups. However, Agrawal et al. [9] reported that anatomical alignment of SGD with glottis was significantly beneficial in group B (34/40) versus group P (25/40) ($P = 0.009$). Different sample sizes may explain this variation.

In our research, no significant variation was found between both groups regarding the vitals of cases. PLMA had significantly more cases than BM complaining of sore throat at 2 h ($P = 0.042$). Insignificant variation was noticed between both groups in gastric tube insertion regarding postoperative complication at 2 h (blood stain mucous, dysphasia, and hoarseness), 4 h, and 24 h.

Similarly, Kachakayala et al. [14] noted that blood staining of device was similar in BM and PLMA. Postoperative complication did not occur in both BM and PLMAs.

Also, Singh et al. [11] documented that the rate of dysphagia and hoarseness of voice documented at 1 h and 5 h postoperatively was statistically insignificant between BM and PLMAs. However, in contrast to our findings, they reported that sore throat was also similar between both groups. PLMA insertion requires experience and learning curve, and this differs from one anesthesiologist to another, which explains variations of incidence of complications between studies.

In our research, the incidence of additional maneuvers to achieve an open airway was insignificantly different between both groups. This was similar to Agrawal et al. [9] research who found no significant

variation between BM and PLMA in incidence for manipulation done for effective ventilation.

Limitations: The research included only ASA class I and II cases with controlled ventilation in a short procedure that did not include spontaneous breathing case or emergency procedure. Our research did not include obese or difficult airway cases.

5. Conclusions

BM can be used successfully during anesthesia as it displays a shorter insertion time, lower leak fraction, higher seal pressure, and lower incidence of sore throat and gastric tube insertion complications than PLMA.

Disclosure statement

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