

ORIGINAL ARTICLE

A comparative analysis of the Baska® Mask vs. Proseal® laryngeal mask for general anesthesia with IPPV

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ABSTRACT

Objective: To compare the sealing pressure of the Baska® Mask (BM) with Proseal® laryngeal mask (PLM) in patients undergoing general anesthesia for a variety of elective non-head and neck surgical procedures.

Design: Prospective, randomized, ethical issues committee approved interventional study.

Setting: Operating rooms of Khoula Hospital, Muscat (Oman).

Methodology: 52 consecutive adult patients of either sex requiring general anesthesia were included in the study. Patients with BMI >30, having known tendency to nausea/vomiting or pharyngeal pathology were excluded from the study. Following uniform induction with propofol 2-2.5 mg/kg, fentanyl 1.0-1.5 µg/kg, and relaxation with cisatracurium 0.1 mg/kg, either BM (n= 30) or PLM (n= 22) was placed. Primary outcome measure was airway seal pressure while secondary outcome measures included device insertion time, number of attempts, leak fraction, duration of use, and laryngopharyngeal morbidity (sore throat, dysphagia, and dysphonia) at 1 hour and 4 hours postoperatively. Data collection was done by a staff member not involved with the study.

Results: The mean insertion time was significantly shorter in the BM group as compared to the PLM group (16.43 ± 4.54 vs. 21.45 ± 6.13) ($P=0.001$). Mean sealing pressure was significantly higher in the BM group (29.98 ± 8.51 vs. 24.50 ± 6.19) ($p= 0.013$). The leak fraction showed no difference between the devices and it ranged from 5.5-20% and 5-20% in the BM and PLM group respectively. All other studied parameters showed insignificant differences between the two devices.

Conclusion: BM takes significantly shorter placement time and provides a better seal as compared to PLM.

Key words: Baska® mask; Proseal® laryngeal mask; Supraglottic airway device; Sealing pressure; Morbidity

Trial Registration: Nederland's Trial Registry No: NTR3931

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INTRODUCTION

The Baska® Mask (Proact Medical Ltd, Northants, UK) is the latest addition to an array of supraglottic airway devices in clinical use (Figure 1). It is currently available in four sizes: #3, 4, 5 and 6 for patients ranging between 30 to >100 kg. It is made of medical grade silicone. It differs in several ways from the conventional laryngeal mask airway (LMA), including; a cuffless membranous bowl which inflates and deflates with each positive pressure inspiration and expiration

respectively, an inbuilt “tab” that permits to increase its angulation for easy negotiation of the oropharyngeal curve during placement, a dual drainage system for pharyngeal contents; and a bite block (1, 2). Initial experience with Baska® Mask (BM) has demonstrated it to be a suitable airway device for procedures less than 2 hours or when endotracheal intubation is not required.^{3,4} Till date, no randomized study has been undertaken to judge its sealing pressure as compared to Proseal® laryngeal mask (PLM) which is considered to be the gold standard 2nd generation

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supraglottic airway device (SAD) for surgical procedures. We hypothesized that with its cuffless membranous bowl; the BM would withstand higher inflation pressures, have a faster placement time, and have no problem with diffusion of nitrous oxide despite longer duration of use that would lead to less postoperative laryngopharyngeal morbidity as compared to PLM in patients undergoing elective surgical procedures of 2 hours or less duration.

METHODOLOGY

Following approval from Ethical Issues Committee and an informed patient consent, we enrolled 52 ASA I and II, non-obese (BMI<30) adult patients ranging from 18-45 yr of age, belonging to either sex for this interventional trial over a three month period. Patients underwent a variety of elective surgical procedures in the supine position with SAD placement of ≤ 2 hours duration. Patients were excluded from the study if their mouth opening was less than 2.5 cm or were at risk of aspiration of gastric contents. Patients were then randomized into two groups; PLM Group (n=22) and BM Group (n=30) according to the use of SAD. Randomization was done using computer generated random numbers. Sealed opaque envelopes were used for allocation concealment.

All patients were uniformly premedicated with oral 0.1 mg/kg midazolam about an hour prior to induction of anesthesia. Anesthesia was induced in the supine position with the patient's head in neutral position using propofol 2-2.5 mg/kg, fentanyl 1.0-1.5 μ g/kg, and cisatracurium 0.1 mg/kg. Anesthesia was maintained with sevoflurane 1.0% to 2.0% in a mixture of 60% nitrous oxide and oxygen. Following adequate relaxation as judged by a peripheral nerve stimulator, a well lubricated PLM or BM # 3, 4 or 5 (according to the manufacturers' recommendations)² was digitally placed by an anesthesiologist with at least 15 BM placements previously. Cuff of the PLM was inflated with air to an intra-cuff pressure of 60 cmH₂O. If the device placement was considered inadequate, as judged by poor capnographic curve and/or delivery of inadequate tidal volumes (fractional loss of >20% of set tidal volume); jaw thrust was performed and the device moved up and down. In case of PLM, cuff volume was also re-adjusted. If the device failed to work effectively despite this maneuver, it was removed and re-inserted for a maximum of two attempts for correct placement. Continued ineffectiveness was treated as failure and the patient's airway managed by performing endotracheal intubation. SAD cross over was not permitted by ethical issues committee.

At the conclusion of surgery, residual neuromuscular paralysis was reversed using a mixture of neostigmine and glycopyrrolate. PLM or BM was removed after establishing

adequate respiration and patient's eye opening response on verbal command. Intraoperatively, all patients received one gram of paracetamol as intravenous infusion. Post operative pain was treated as per protocol.

Data were collected by an individual who was not part of the study. Postoperative scoring of LPM was done by a nursing staff member who was unaware of the grouping.

The following parameters were recorded as primary (airway sealing pressure) or secondary outcome measures;

1. Airway Sealing Pressure in cmH₂O at 5 mins post-placement. The airway sealing pressure was the pressure at which leak starts. This leak pressure was calculated as the plateau airway pressure reached with fresh gas flow 6 l/min, and pressure adjustment valve set at 70 cmH₂O.
2. Insertion time needed for placement of the SAD was defined as time in seconds from SAD touching the teeth to the first recorded near rectangular capnogram curve. Only the successful attempt time was counted.
3. Number of attempts needed to correctly place the SAD.
4. The leak fraction was calculated as: $(V_{insp} - V_{exp}) / V_{insp} \times 100$.
5. Duration for which the device remained in the oropharynx in minutes.
6. LPM Score = Sum of sore throat, dysphagia and hoarseness scores as shown in Table 1.

Table 1: Laryngopharyngeal morbidity parameter with scores

Scores	0	1	2	3
Sore throat	none	minimal	moderate	Severe; never an SAD again
Dysphagia	none	minimal	moderate	Severe; cannot eat
Hoarseness	none	minimal	moderate	Severe; cannot speak

SAD: Supraglottic airway device

Statistical Analysis: For analysis of continuous variables independent samples t-test was applied and for categorical variables chi-square test was used. Value of $p < 0.05$ was considered significant in this study. In an earlier pilot study, we found mean sealing pressures of 21.88 ± 5.817 in PLM group (n=8) and 27.72 ± 8.729 in BM group (n=9). To detect similar difference in the means with 80% power, a sample size of 52 was calculated using the OpenEpi: Open Source Epidemiologic Statistics for Public Health, Version 2.3.19.

RESULTS

Both of the groups were comparable with respect to sex

distribution, SAD size used and the duration of anesthesia. However, patients in BM group were significantly younger as compared to PLM group ($p= 0.029$) (Table 2).

Table 2: Comparison of possible confounding factors

Parameter	BM(n=30)	PLM(n=22)	p-Value
Sex (male): Number (%)	21 (70.0)	18 (81.8)	0.331
Age (yr): Mean \pm SD	29.50 \pm 9.27	36.09 \pm 11.86	0.029
SAD Size: Mean \pm SD	4.23 \pm 0.57	4.09 \pm 0.53	0.362
Duration of Anesthesia (min): Mean \pm SD	71.50 \pm 26.75	59.77 \pm 21.07	0.095

BM= Baska® mask, PLM= Proseal laryngeal mask, SAD= Supraglottic airway device, SD= Standard deviation

There was no significant difference in the mean number of attempts required for SAD placement in either group. However, the mean insertion time was significantly shorter in the BM group as compared to the PLM group by a mean of 5.02 s. Mean sealing pressure was significantly higher in the BM group ($p= 0.013$). The seal pressure ranged from 15-40 cmH₂O and 14-32 cmH₂O in the BM and PLM group respectively. No significant difference was found in leak fraction between the two groups. The leak fraction ranged from 5.5-20% and 5-20% in the BM and PLM group respectively. This was recorded with the head resting over a 6 cm head ring (Table 3).

Table 3: Comparison of SAD placement parameters in both treatment groups

Parameter	BM (n=30)	PLM (n=22)	p-Value
Number of Attempts: Mean \pm SD	1.20 \pm 0.41	1.18 \pm 0.39	0.873
Insertion time (s): Mean \pm SD	16.43 \pm 4.54	21.45 \pm 6.13	0.001
Sealing Pressure (cmH ₂ O): Mean \pm SD	29.98 \pm 8.51	24.50 \pm 6.19	0.013
Leak Fraction (%): Mean \pm SD	14.44 \pm 9.18	12.68 \pm 5.34	0.422

BM= Baska® mask, PLM= Proseal laryngeal mask, SAD= Supraglottic airway device, SD= Standard deviation

There was no significant difference in the mean LPM score at 1 and 4 hour as well in individual component scores (Table 4 & 5). We noted a higher incidence of sore throat as compared to dysphagia and hoarseness of voice in both the groups at 1 and 4 hr. Hoarseness of voice had completely disappeared by 4th hr in either group. Unfortunately, the 4 hr data of three patients in the PLM group could not be collected as an oversight. Other than this, there were no drop outs as a result of continued failure of device placement in either of the two groups.

Table 4: Laryngopharyngeal morbidity parameters at 1 hour postoperatively

Parameter	BM (n=30)	PLM (n=22)	p-Value
LMPs: Mean \pm SD	0.83 \pm 1.02	0.73 \pm 0.71	0.677
Sore throat: Number of patient (%)	13 (43.3%)	9 (45.5%)	0.879
Dysphagia: Number of patient (%)	6 (20.0%)	5 (22.7%)	0.812
Hoarseness: Number of patient (%)	6 (20.0%)	1 (4.5%)	0.107

LMPs= Laryngopharyngeal morbidity score, BM= Baska® mask, PLM= Proseal laryngeal mask, SD= Standard deviation

Table 5: Laryngopharyngeal Morbidity parameters at 4 hour postoperatively

Parameter	BM (n=30)	PLM (n=19)	P-Value
LMPs: Mean \pm SD	0.30 \pm 0.54	0.55 \pm 0.74	0.170
Sore throat: Number of patient (%)	8 (26.7%)	9 (40.9%)	0.279
Dysphagia: Number of patient (%)	1 (3.3%)	3 (15.8%)	0.168

LMPs= Laryngopharyngeal morbidity score, BM= Baska® mask, PLM= Proseal laryngeal mask, SD= Standard deviation

DISCUSSION

In this trial, most of the confounding factors which could influence the results e.g sex distribution, mask size, duration of anesthesia and to some extent age, were similar in both groups. This enabled us to analyze the performance parameters of the two devices with greater authority.

We noted that the number of attempts needed to place the device correctly, were similar in both of the groups. This demonstrates that the short learning curve of 15 BM placements is sufficient for its correct placement. In addition, it was observed in this study that it took a mean of 16.48 sec to place the BM which is identical to that observed by van Zundert and Gatt.⁴ Our finding suggests that BM placement time was significantly shorter as compared to PLM. This may be attributed to two factors. First, any difficulty in negotiation of the oropharyngeal curve could be easily overcome by pulling the tab of the BM which increases its distal curvature. Second, being devoid of an inflatable cuff, time to inflate the cuff and volume adjustment as required in PLM, is not needed. However, it may be argued that a short placement time of the BM by 5 sec as compared to PLM may not be of much clinical significance.

Both PLM and BM are essentially dual channel supralaryngeal airway devices with the provision for separation of airway from gastric tract. It has been observed

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in earlier studies that the airway seal is improved by 50% while using PLM⁵. This is attributed to a second posterior cuff fitted to improve the seal.⁶ Although BM is devoid of an inflatable cuff, we noted that the sealing pressure was significantly higher with BM as compared to PLM. This mean difference of 5.48 cmH₂O (95% confidence interval = 1.18-9.78) seal pressure between the two devices may be of clinical importance in patients with decreased thoracic compliance. The BM sealing pressure recorded in this study is in agreement to that noted by other workers.^{3,4} We concur with Laffey et al³ that there is a gradual improvement in BM seal against the glottis over first 2-3 minutes. This may be due to thermolability of the membranous mask which makes it more adaptable to the shape of laryngeal outlet over time and hence a better seal.

The mean leak fraction observed in the BM group of our study (14.44%) was nearly identical to median of 9.8% observed by Laffey et al without a pillow.³ The slight difference could be due to the difference in reporting the leak fraction. Ours is a mean value where as Laffey et al reported it as median value.³

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