Randomized Controlled Trial to Compare Baska® Mask versus ProSeal Laryngeal Mask Airway for General Anesthesia with Intermittent Positive Pressure Ventilation

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Abstract

Introduction: A myriad of supraglottic airway devices (SADs) are developed over time to search the device that conforms to the anatomy of the human respiratory tract noninvasively, but these devices are associated with the risk of aspiration. Baska® mask (BM) is the latest addition to the family of SADs to circumvent the incidence of aspiration. Aims of Study: The aim of the study was to compare the sealing pressure and rapidity of the insertion of BM with ProSeal laryngeal mask (PLM) airway and the incidence of laryngopharyngeal morbidity between two devices. Materials and Methods: A randomized prospective open-label study was done on sixty adult patients of the age group of 18–60 years after approval from the institutional ethical committee and registration of trial in the Clinical Trials Registry. The patients were randomly divided into two groups: Group I (BM) where BM was inserted after the induction of general anesthesia and Group II (PLM) where PLM was inserted after induction. The airway sealing pressure in BM was calculated. The mean time of insertion of respective SAD and the number of successful attempts were also recorded in both groups. For analysis of continuous variables, independent sample Student’s t-test was applied, and for categorical variables, Chi-square test was used. P < 0.05 was considered statistically significant. Results: The rate of successful attempts of insertion was comparable in both the groups. The mean insertion time was 14.25 ± 3.82 s in BM group and 22.01 ± 2.64 s in PLM group, which was statistically significant. The airway sealing pressure was 30.25 ± 3.34 cmH₂O in BM group and 23.50 ± 4.05 cmH₂O in PLM group, which was also statistically significant. Conclusion: BM has better ease of insertion with adequate sealing pressure as compared to PLM airway, thus reducing the chances of aspiration and offering its potential application in securing airway in emergency situations.

Keywords: Airway sealing pressure, Baska® mask, ProSeal laryngeal mask

INTRODUCTION

Archie Brain in 1981 changed the focus of airway management with supraglottic devices for oxygenation and ventilation.[1] Varieties of supraglottic airway devices (SADs) are developed from time to time to properly fit the anatomy of the human airway. Laryngeal mask airway (LMA) has its own benefits such as lesser invasive technique for securing the airway, better patient tolerance, and easier to insert but with the associated risk of aspiration.[2]

The Baska® mask (BM) is the latest entry in the realm of SADs for airway management. It is currently available in four sizes: 3, 4, 5, and 6 for patients having weight between 30 and 100 kg. It is made of medical grade silicone. It has four distinctive features, which result its supremacy over ProSeal LMA.

It has a cuffless membranous bowl which inflates and deflates with each positive pressure inspiration and expiration during intermittent positive pressure ventilation. An inbuilt “tab” that results in increasing its angulation for easier accommodation of the oropharyngeal curve during placement, a binary drainage system for pharyngeal contents; and a bite block.[3] Earlier studies with BM have proved that it is ideal for maintaining the airway of patients having surgery <2 h duration.
when there is no need of endotracheal intubation. However, due to paucity of studies demonstrating the superiority of BM over ProSeal LMA in terms of rapidity of securing of the airway with lesser number of attempts as well as reduced incidence of laryngopharyngeal morbidity, we have taken up this scientific study for further exploration.

We hypothesized that due to cuffless membranous bowl and inbuilt tab, BM may withstand higher inflation pressure, faster and easier insertion, and less postoperative laryngopharyngeal morbidity due to diffusion of nitrous oxide as compared to ProSeal laryngeal mask (PLM) airway in patients undergoing elective surgical procedures of 2 h or less duration.\cite{3,4}

**Aims and objectives**

- Primary aim: To compare the sealing pressure of BM with PLM airway in patients undergoing general anesthesia for a variety of elective surgical procedures of 2 h or less duration.
- Secondary aim: To compare the incidence of laryngopharyngeal morbidity in each group.

**Materials and Methods**

After approval from the institutional ethical committee, we had registered the trial in the Clinical Trials Registry vide no. CTRI/2019/02/017675. We enrolled sixty American Society of Anesthesiologists I and II, nonobese (body mass index <30) adult patients ranging from 18 to 60 years of age, belonging to either sex, undergoing elective surgical procedure in the supine position with SAD placement for 2 h or less duration. An informed consent was obtained from all patients participated in the study. Patients excluded from the study included patients with mouth opening <2.5 cm, any history of cardiac or renal insufficiency, and risk of aspiration of gastric contents. Patients included in the study were randomized into two groups: Group I (n = 30) where BM was inserted after induction of general anesthesia and Group II (n = 30) where PLM was inserted after induction of general anesthesia. Randomization was performed using computer-generated random numbers.

All patients were premedicated with oral 0.1 mg.kg$^{-1}$ diazepam about an hour prior to induction of anesthesia. After shifting to the operation theater, 20G intravenous (i.v.) cannula was inserted under local anesthesia. Injection glycopyrrolate 0.01 mg.kg$^{-1}$ i.v. along with injection ondansetron 0.08 mg.kg$^{-1}$ was given. Anesthesia was induced in the supine position with the patient’s head in the neutral position using propofol 2–2.5 mg.kg$^{-1}$, butorphanol 0.04 mg.kg$^{-1}$, and injection vecuronium 0.1 mg.kg$^{-1}$.

Following adequate relaxation, a well-lubricated ProSeal or Baska LMA 3, 4, or 5 was digitally placed by an anesthesiologist. The cuff of the ProSeal LMA was inflated with air to an intracuff pressure of 60 cmH$_2$O. Accurate placement of device was assessed by good rectangular capnographic tracing and delivery of adequate tidal volume. In case of failure of delivery of adequate tidal volume, jaw thrust was performed. If still leak persists, then the LMA device was removed and reinserted for a maximum of two attempts. Repeated failure was managed by inserting an endotracheal tube of appropriate size, and the patient was excluded from the study. Anesthesia was maintained with isoflurane 1.0%–2.0% in a mixture of 60% nitrous oxide and oxygen and intermittent doses of injection vecuronium. Standard monitoring was performed throughout the procedure, including noninvasive arterial blood pressure, electrocardiogram (three leads), pulse oximetry, and capnography.

Intraoperatively, 1 g in 100 ml paracetamol i.v. was administered for analgesia. Postoperatively, pain was treated as per the institutional protocol with injection diclofenac 75 mg as i.v. infusion over 20 min.

At the conclusion of surgery, residual neuromuscular paralysis was reversed using a mixture of neostigmine (0.05 mg.kg$^{-1}$) and glycopyrrolate (0.01 mg.kg$^{-1}$). ProSeal or BM was removed after establishing adequate respiration and patient’s eye opening response on verbal command. The assessment of laryngopharyngeal morbidity was done by asking about the complaints of sore throat, dysphagia, and hoarseness of voice at the end of surgery and after 5 h.

The following parameters were recorded:

Airway sealing pressure was noted in cm of H$_2$O at 5 minutes after placement of SADs. The airway sealing pressure is the pressure at which leak starts. This leak pressure is calculated as the plateau airway pressure reached with a fresh gas flow 8 L/min and pressure adjustment valve set at 60 cmH$_2$O. The cuff pressure obtained in ProSeal LMA was measured using a handheld manometer.

- Insertion time needed for the placement of the SADs 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 recorded.
- Number of attempts needed to correctly insert the SAD.
- Incidence of sore throat, dysphagia, and hoarseness of voice at 1 h and 5 h postoperatively.

**Statistical analysis**

For analysis of continuous variables, independent sample Student’s $t$-test was applied, and for categorical variables, Chi-square test was used. $P < 0.05$ was considered statistically significant.

**Results**

Table 1 shows that there was no significant difference in demographic variables between the two groups ($P > 0.05$).

Table 2 shows that there was a significant difference in the mean insertion time and mean airway sealing pressure between the two groups ($P < 0.05$), however the number of attempts, anesthesia duration, and size of mask variables are statistically nonsignificant ($P > 0.05$).
Table 3 shows that the incidence of sore throat, dysphagia, and hoarseness of voice recorded at 1 h postoperatively was statistically nonsignificant between the two groups ($P > 0.05$).

Table 4 shows that the incidence of sore throat, dysphagia, and hoarseness of voice recorded at 5 h postoperatively was also statistically nonsignificant between the two groups ($P > 0.05$).

**DISCUSSION**

As anesthesiologist, we are still searching for an ideal SAD which is easy to insert, provides a better seal, and prevents aspiration. BM is one of the newly introduced devices with promise of rapidity of insertion, better seal, and prevention of aspiration as it conforms to the anatomy of the oropharynx in a better way.$^{[5]}$  

Regarding age, sex, duration of anesthesia, and size of the mask, data were comparable between the two groups.

In our study, the number of attempts needed to insert BM was 1.40 ± 0.31 as compared to 1.51 ± 0.25 in the PLM group, which was statistically nonsignificant ($P > 0.05$), and similarly, a study conducted by Al-Rawahi et al.$^{[6]}$ in 2013 demonstrated that there was no statistically significant difference between the number of attempts needed for correct placement of BM and PLM (BM – 1.20 ± 0.41 vs. PLM – 1.18 ± 0.39).

For checking the rapidity of securing the airway, we compared the mean insertion time of BM and PLM, which came out to be statistically significant in our study (BM – 14.25 ± 3.82 s vs. PLM – 22.01 ± 2.64 s). Similar findings were demonstrated in the study conducted by Al-Rawahi et al.$^{[6]}$ in 2013 (BM – 16.43 ± 4.54 vs. PLM – 21.45 ± 6.13). This may be due to the short learning curve of BM needed for its correct placement and cuffless membrane, and other factors that make it easier are cuffless membrane of BM and second oropharyngeal curve that can be easily negotiated by pulling the tab of the BM, which increases its distal curvature as compared to PLM, which results in swift insertion of BM.$^{[3]}$

Previous studies$^{[7]}$ demonstrated that the use of PLM is associated with improved airway seal by 50%, which is attributed to the posterior second cuff. Although BM is without inflatable cuff, it offers improved sealing pressure as compared to PLM due to its thermoliability of membranous cuff, which conforms to laryngopharyngeal anatomy, so we have also compared the sealing pressure of PLM with BM to support our hypothesis. The mean airway sealing pressure in our study for BM was 30.25 ± 3.34 cmH$_2$O and for PLM, it was 23.50 ± 4.05 cmH$_2$O, which was statistically significant. Similar statistically significant findings were recorded by Al-Rawahi et al. in 2013 (BM – 29.98 ± 8.51 vs. PLM – 24.05 ± 6.19)$^{[9]}$.

As our secondary objectives of the study, we also noted the laryngopharyngeal morbidity in terms of incidence of sore throat, dysphagia, and hoarseness of voice in both the groups. These findings were statistically nonsignificant between the two groups. Similar results were observed by Al-Rawahi et al.$^{[6]}$ in 2013 as well as in a study conducted on laryngopharyngeal complaints with associated LMAs by Jaensson et al.$^{[4]}$ comparing gender differences in sore throat and hoarseness following endotracheal tube or LMA. It may be because BM membrane seal pressure on surrounding tissues never exceeds the peak airway pressure, resulting in comparable laryngopharyngeal morbidity as demonstrated in other studies$^{[8-10]}$ conducted on LMAs.

We suggest that BM may offer the advantage of rapid airway securing with efficient seal, making it a suitable alternative for securing in emergency situations as well as for difficult airway management, but needs further studies for its potential application.
This study has limitations of not including patients younger than 18 years as well as obese patients due to the dearth of suitable sizes of BM.

**Conclusion**

The findings of this study support our hypothesis that BM takes significantly shorter placement time and provides a better seal as compared to PLM airway but without a significant difference in laryngopharyngeal morbidity. Hence, our study favors limited studies available on BM, suggesting it as the latest favorable addition to the family of SADs.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Alexiev V, Salim A, Kevin LG, Laffey JG. An observation study of Baska mask: A novel supraglottic airway. Anaesthesia 2012;67:640-5.
2. Anil Kumar MR, Shetty SM, Marulasidappa M, Parmar P, Vyshnavi S. Baska mask®-A third generation supraglottic airway device in clinical practice: A prospective observational study. Indian J Clin Anaesth 2018;5:576-81.
3. Zundert TV,Gatt S. The Baska Mask®-A new concept in Self-sealing membrane cuff extraglottic airway devices, using a sump and two gastric drains: A critical evaluation. J Obstet Anaesth Crit Care 2012;2:23-30.
4. Jaensson M, Gupta A, Nilsson U. Gender differences in sore throat and hoarseness following endotracheal tube or laryngeal mask airway: A prospective study. BMC Anesthesiol 2014;14:56.
5. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: A randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. Anesthesiology 2000;93:104-9.
6. Al-Rawahi SA, Aziz H, Malik AM, Khan RM, Kaul N. A Comparative analysis of the Baska Mask vs. ProSeal laryngeal mask for general anesthesia with IPPV. Anaesth Pain Intensive Care 2013;17:233-36.
7. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: A review of the literature. Can J Anaesth 2005;52:739-60.
8. Burgard G, Möllhoff T, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. J Clin Anesth 1996;8:198-201.
9. Wong JG, Heaney M, Chambers NA, Erb TO, von Ungern-Sternberg BS. Impact of laryngeal mask airway cuff pressures on the incidence of sore throat in children. Paediatr Anaesth 2009;19:464-9.
10. Figueredo E, Vivar-Diago M, Munoz-Blanco F. Laryngo-pharyngeal complaints after use of the laryngeal mask airway. Can J Anaesth. 1990;46:220-5.