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COMPARISON OF BASKA MASK VERSUS PROSEAL LARYNGEAL MASK AIRWAY IN ELECTIVE SURGERIES UNDER GENERAL ANAESTHESIA: A RANDOMIZED CLINICAL TRIAL

Anaesthesiology

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ABSTRACT

Background: The Baska Mask (BM), a third-generation supraglottic airway device with a self-inflating cuff, was compared to the ProSeal laryngeal mask airway (PLMA) in terms of insertion time, ease of insertion, and oropharyngeal seal pressure (OSP) during elective surgeries under general anaesthesia lasting less than two hours. **Methods:** This double-blind study involved 60 patients divided into PLMA (Group A) and BM (Group B) groups. Exclusions included BMI over 30 and pharyngeal pathology. Following induction with propofol, fentanyl, and atracurium, either BM or PLMA was inserted. Primary outcomes were insertion time and ease; secondary outcomes included attempts, OSP, and laryngopharyngeal morbidity immediately and 24 hours postoperatively. **Results:** BM had a significantly shorter insertion time (24±1.136s) and higher OSP (31.34±1.638 cmH2O) than PLMA. Complications were more frequent with PLMA but statistically insignificant. BM had a higher first-attempt success rate. **Conclusion:** BM showed better insertion time, OSP, and first-attempt success compared to PLMA.

KEYWORDS

INTRODUCTION

Supraglottic airway devices (SADs) are increasingly preferred over tracheal intubation for patients with low aspiration risk and those not requiring high airway pressure. They offer quicker insertion and fewer complications. Since the Laryngeal Mask Airway (LMA®) Classic™ was introduced in 1988, many innovative extra glottic airway devices (EADs) have been developed. SADs, used for short surgical procedures, facilitate breathing, oxygenation, and anaesthetic gas administration.

The ProSeal™ LMA (PLMA), a second-generation SAD, features two cuffs, an integrated bite block, and an oesophageal drainage tube to reduce gastric insufflation and aspiration risk. However, it can experience issues like cuff overinflation and increased intracuff pressure due to nitrous oxide diffusion.

The third-generation Baska Mask (BM) includes a non-inflatable silicone cuff, color-coded sizes, and an improved design to minimize tissue damage and leakage. Its dorsal surface deflects oropharyngeal content away from the glottis, enhancing safety and efficacy.

AIMS & OBJECTIVES

The primary objective of this study was to compare the time taken for insertion and ease of insertion to determine the first-pass success rate. Secondary objectives were oropharyngeal seal pressure (OSP), and complications such as trauma to the lip, sore throat, and dysphagia between the two groups.

MATERIALS AND METHODS

The study at Navodaya Medical College & Research Centre Raichur involved 60 patients undergoing elective surgeries under general anaesthesia for less than two hours. After ethical approval, patients were randomly assigned to two groups: Group A (PLMA) and Group B (BM).

Patients fasted for eight hours for solids and two hours for clear liquids, and took 150 mg ranitidine the night before. On surgery day, baseline measurements were recorded, an IV line was established with a 20G cannula, and patients were premedicated with IV ondansetron (0.15 mg/kg), glycopyrrolate (0.2 mg), and midazolam (0.01 mg/kg). They were pre-oxygenated with 100% oxygen for three minutes. LMA size was selected based on body weight, and induction used IV propofol (2-3 mg/kg), fentanyl (2 mcg/kg), and atracurium (0.5 mg/kg).

The principal investigator, trained in both devices, selected sizes according to manufacturer guidelines. Data collection and analysis were performed by a blinded anaesthesiologist. Midline insertion was confirmed by bilateral chest movements, equal air entry, six square waveforms on EtCO2, and no leak at 20 cmH2O.

A maximum of three attempts were allowed; if unsuccessful, intubation was performed. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane, and atracurium. Insertion time, attempts, and ease were recorded. Oropharyngeal seal pressure (OSP) was measured five minutes post-insertion with a fresh gas flow at 6 L/min and APL valve closed at 40 cmH2O.

Post-extubation, patients were monitored for laryngospasm and treated with 100% oxygen, IV corticosteroids, or succinylcholine as needed. Persistent cases required reintubation. Pharyngolaryngeal morbidity was assessed by inspecting for trauma and correlating with postoperative sore throat and hoarseness.

STUDY DURATION: 18 months
STUDY DESIGN: A randomised clinical trail
SAMPLE SIZE: 60 patients

A. INCLUSION CRITERIA:

1. Patients belonging to ASA I and II
2. Age: Adult more than 18-60 years of either sex
3. Patients undergoing elective surgeries for general anaesthesia < 2hours duration
4. BMI < 30 kg/m2

B. EXCLUSION CRITERIA:

1. Patient refusal
2. Had restricted mouth opening,
3. Neck burns or swellings
4. Prior neck surgeries
5. High aspiration risk

SAMPLE SIZE

Sample size calculation was based on the study by Kumar et al. [8]. The required minimum sample size was 30 per group (i.e., a total sample size of 60, assuming equal group sizes) for achieving a power of 99% and a significance level of 2% (two-sided) for detecting an actual difference in means between two groups.

Patients were explained the procedure during the preoperative visit and written informed consent was taken.

STATISTICAL ANALYSIS

Data were analyzed using IBM SPSS Statistics, Version 20.0. Categorical variables were depicted using counts and percentages;

continuous variables used Mean ±SD. P value <0.05 was considered significant.

RESULTS

TABLE 1: Comparison of Group A and Group B based on demographic data

Group A: ProSeal laryngeal mask airway; Group B: Baska mask

Demographic variables	Group A	Group B (Mean + SD)	p-value
Age (years), mean±SD	34.19±11.544	30.84±10.568	0.183
BMI (kg/m^2), mean±SD	22.2±1.65	21.59±1.47	0.125
Duration of surgery (minutes), mean±SD	59.38±28.65	53.13±25.708	0.334

The demographic profiles of the patients regarding age, BMI, ASA grade, and duration of surgery were comparable in both groups but statistically insignificant (Table 1).

*Statistically significant, $p < 0.05$

TABLE 2: Comparison of Group A and Group B based on time taken for insertion, number of attempts, ease of insertion, and oropharyngeal seal pressure.

Group A: ProSeal laryngeal mask airway; Group B: Baska mask

	Group A	Group B	p-value
Time taken for insertion (seconds), mean±SD	28.59±1.682	24.00±1.136	0.001*
Number of attempts, N (%)			
1	20 (66.66%)	27 (90%)	0.0296*
2	10 (33.34%)	3 (10%)	
Ease of insertion, N (%)			
I	19 (63.34%)	25 (83.33%)	0.007*
II	8 (26.66%)	5 (16.66%)	
III	3 (10%)	0 (0%)	
Oropharyngeal seal pressure (cmH2O), mean±SD	24.81±1.469	31.34±1.638	0.001*

BM was inserted in less time and with greater ease when compared to PLMA, which was statistically significant (Table 2). BM was also noted to provide a higher OSP than PLMA (Table 2), conferring the advantage of withstanding higher positive airway pressures.

TABLE 3: Incidence of complications in Group A and Group B

Group A: ProSeal laryngeal mask airway; Group B: Baska mask

Trauma to lip	Group A	Group B	p-value
	N (%)	N (%)	
NO	25 (83.33)	29 (96.66)	0.08
YES	5 (16.66)	1 (3.33)	
Blood staining			
NO	25 (83.33)	28 (93.33)	0.2296
YES	5 (16.66)	2 (6.66)	
Sore throat			
NO	27 (90)	29 (96.66)	0.3017
YES	3 (10)	1 (3.33)	

A higher incidence of complications like trauma to the lip, blood staining, and sore throat was seen in patients where PLMA was used (Table 3). However, this was statistically insignificant.

DISCUSSION

The demographic profile—including age, gender, BMI, ASA grade, and surgery duration—was comparable between the two groups with no statistical significance ($p > 0.05$). Similarly, hemodynamic parameters such as mean arterial pressure, heart rate, and oxygen saturation showed no significant differences ($p > 0.05$). The primary finding was a shorter insertion time for the Baska Mask (BM) (24±1.136 seconds) compared to the ProSeal™ LMA (PLMA) (28.59±1.682 seconds), which was statistically significant ($p < 0.001$). The BM also had a higher first-attempt success rate (90% vs. 64%) and a greater proportion of grade I insertions (84.4% vs. 62.5%) than the PLMA.

The BM's cuffless design and adjustable curvature contribute to its quicker and more efficient insertion. Supporting studies show similar results: Balwinderjit et al. reported a mean insertion time of 14.25±3.82 seconds for BM and 22.01±2.64 seconds for PLMA, with similar findings from van Zundert and Gatt, and Kumar et al. Supraglottic airway devices (SADs) are classified based on their cuff design and aspiration risk prevention features.

First-generation devices lack specific modifications, while second-generation devices like the PLMA offer better positive pressure ventilation (PPV) and reduced aspiration risk with features like bite blocks and gastric ports. The BM, a third-generation device, incorporates features from the PLMA, LMA Supreme, i-gel, and SLIPA, enhancing oropharyngeal seal pressure and reducing aspiration risk with its recoiling cuff and design.

Our study showed a significantly higher oropharyngeal seal pressure (OSP) for BM (31.34±1.638 cmH2O) compared to PLMA (24.81±1.469 cmH2O) ($p < 0.001$). Similar results were found by Al-Rawahi et al. and Agrawal et al. Complications like insertion trauma, blood staining, and sore throat were more common in the PLMA group (15.6%, 15.6%, and 9.4%, respectively) than in the BM group (6.3%, 3.1%, and 3.1%, respectively), though these differences were statistically insignificant ($p > 0.05$). No cases of dysphagia, hoarseness, or gastric content aspiration were observed post-LMA removal.

LIMITATIONS

This single-center study had limited patients and excluded ASA grade III and IV patients and those with difficult airways. Additionally, the heterogeneity of surgeries necessitates further research to validate these findings across diverse settings and patient populations.

CONCLUSION

BM placement offers quicker, easier insertion, and a higher first-attempt success rate than PLMA. It provides better OSP, protects against aspiration, and has fewer complications. Our study supports the clinical advantages of using BM over PLMA.

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