ORIGINAL RESEARCH

Comparison of Baska® mask with Proseal™ laryngeal mask airway in nonparalyzed adult patients under general anaesthesia for day care surgery

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ABSTRACT

Background: The adoption of supraglottic airways has been growing rapidly and especially popular for airway management in ambulatory surgical procedures. Baska® mask is a new entrant in supraglottic airway devices. **Aims and Objective**: The purpose of this study was to compare the efficacy and utility of thethe Baska®mask andProseal™ laryngeal mask airway during ambulatory procedures performed under general anesthesia without the use of a muscle relaxant. **Materials and Methods:**Eighty American Society of Anesthesiologists grade I–II patients, aged 21–55 years, scheduled for elective ambulatory procedures under general anesthesia were randomly assigned to Group B or Group P in this randomized prospective trial using Baska® mask and Proseal™ LMA, respectively.The effective airway time was the most significant finding. Secondary outcomes included insertion ease, number of tries, oropharyngeal leak pressure, hemodynamic parameters, and pharyngolaryngeal adverse events. **Statistical analysis:** All statistical computations were performed using SPSS (Statistical Package for the Social Science). Fisher's test and Chi-square test were used for categorical variables. The study groups' continuous variables were compared using the unpaired t-test. **Results:** Group B had a statistically significant shorter effective airway time in comparison to group P, (14.50 1.66 vs. 17.95 1.81 s, respectively) (P= 0.000). The oropharyngeal leak pressure in group B was significantly higher than that in group P (30.10 2.90 vs. 26.552.06 cm H2O, respectively) (P= 0.000). **Conclusion:**The Baska® mask requires less time to insert and has a higher oropharyngeal leak pressure as compared to Proseal™ LMA. It has better suitability for both controlled and spontaneous ventilation in ambulatory surgery.

Key words: Supraglottic airway, Baska mask, Laryngeal mask airway Proseal, Time for insertion, Oropharyngeal leakpressure, Ambulatory procedure

INTRODUCTION

The introduction of day care surgery into the present clinical setting has made safe airway management a top priority. The correct choice of an anesthetic airwayis crucially needed for successful conduction of ambulatory procedures. When faced with a "cannot intubate, cannot ventilate situation,''supraglottic airways devices can be utilized for airway rescue.[1]

The advantages of stable hemodynamics and reduced airway morbidity make supraglottic airways devices (SADs) a common use in day care procedures.[2] SADs can be used to aidblind or fiber optic bronchoscope guided intubation. [3-5]

The upgraded SADs, Baska mask® and Proseal™ laryngeal mask airway, have specific features that enhance positive pressure breathing and lower the aspiration risk.The third-generation SAD Baska mask® was developed by Australian anaesthetists Kanag and Meena Baska. It has a non-inflatable, self-sealing membranous, variable pressure recoiling cuff, and dual drainage tube system that provides continuous stomach content suctioning.

It has several benefits including easy insertion without the need for repeated attempts and minimal risk of compression trauma, which can happen with inflatable SADs like Proseal™ laryngeal mask airway. In other words, Baska mask® represents yet another journey towards the perfect supraglottic airway.

In view of a few studies that produced inconsistent results, the current study was designed to assess the clinical utility and efficacy of the Baska® mask versus the Proseal™ laryngeal mask airway in nonparalyzed adult patientsduring ambulatory surgeries, with a focus on measuring insertion time, oropharyngeal seal pressure, insertion attempts, haemodynamic parameters, and postoperative complications.

MATERIALS AND METHODS

This prospective, randomized, clinical study was conducted from March 2018 to August 2019 in human subjects and in accordance with the principles of the Declaration of Helsinki (2013). After receiving Institutional Ethical Committee clearance and registering the trial with the Clinical Trials Registry India (no. CTRI/2018/07/014842), this study was conducted on 80adultspatients with American Society of Anesthesiologists (ASA) Grade I & II, agebetween 20to55years,with body mass index <30kg/m2, who were scheduled for elective day care surgeries of not more than an hour duration under general anaesthesia.

Written informed consents were obtained from all patients. Patient with known or predicted difficult airway, mouth opening of <2.5 cm, any history of gastroesophageal reflux disease, pathology of upper respiratory tract, acute and chronic lung disease were excluded from the study. Patients were informed about the study's objective, benefits, and detail of the entire research protocol.

The night before surgery, patients were given 150 mg of ranitidine and 0.25 mg of alprazolam orally. Patients were fasted for 6 hours before surgery. In the operation theatre, heart rate, invasive blood pressure (NIBP), electrocardiography (ECG), pulse oximetry, and end-tidal carbon dioxide (ETCO2) were all routinely monitored.

Group B (Baska® mask) and Group P (Proseal™LMA) were randomly assigned to patients using a computer-generated random numbers table (http://www.randomiser.org). Before induction of anesthesia, the sealed opaque envelopes containing the allocation were unsealed. The placement of devices was done by an anesthesiologist who had experienced of using the Baska® mask and Proseal™ LMA; they were not involved in the data collection for this study. The group allocation was hidden from both the participants and the investigators who were observing the patients in perioperative period.

Initially, preoxygenate for three minutes with 100% oxygen. Following preoxygenation, an intravenous dose of morphine (0.1 mg/kg), injection of ondansetron (0.1 mg/kg), and injection of glycopyrrolate (10 mcg/kg) were administered. Propofol 2-2.5 mg/kg was used to induce anesthesia until vocal communication was lost. To attain anadequate depth of anesthesia before inserting the device, anadditional dose of propofol was administered. The measurement of minimal isoflurane alveolar concentration at 1 and loss of vocal contact was used to determine the depth of anesthesia. Since nitrous oxide may affect intracuff pressure, it was avoided.

Patient was kept in sniffing position prior to device insertion. We followed weight-based algorithm as per the manufacturer's recommendations i.e., size 3 for weighing <50 kg and size 4 for weighing 50-70 kg. 2% lidocaine jelly was used as a lubricant and put on tip and posterior surface of the device.

Supraglottic airway device was inserted based on group allocation.After securing the device, oxygen, nitrous oxide 70% volume, and 1% isoflurane were used to maintain spontaneous ventilation and anesthesia. The anatomically placement of the device was assessed clinically and was confirmed with end tidal CO_2 waveform and maintained normocapnia ($EtCO_2$:35–45 mmH).

At the end of surgery, all anesthetics were tapered off and the supraglottic airway device was removed after the patient regains consciousness and responds to verbal command. Presence of visible blood stains over the device was noted.

A three-point scale was used to qualitatively evaluate the ease of insertion. If device was inserted without any manipulation, it was classified as extremely easy, if only one manipulation needed to insert the device, it was categorized as easy; difficult if there was any difficulty beyond that.

The number of times the supraglottic device was put into and taken out of the mouth was counted to calculate the number of insertion attempts. The patient was intubated and removed from the research if three attempts were unsuccessful.

During the insertion of the device, the insertion time (timed between picking up the prepared supraglottic airway device and successful placement) and the effective airway time (the time it took to take up the prepared supraglottic airway device and get the first normal capnograph) was measured.Any complication during device insertion like hypoxia (SpO_2<95%), laryngospasm, bronchospasm, coughing/hiccupping were also noted.

After ten minutes of inducing anesthesia,the oropharyngeal leak pressure (OLP) was measured by closing the expiratory valve of the circular system at a fixed gas flow rate of 3L/min and recording the airway pressure (maximum allowed was 40 cmH2O) at which equilibrium was attained. The precision and interobserver reliability of this measuring method have already been demonstrated. [6]

All the patients were interviewed for postoperative sore throat (constant pain in the throat, independent of swallowing),dysphagia (difficulty or pain with swallowing) and dysphonia (difficulty or pain with

speaking) in the recovery room at immediate and 3rd postoperative hours.

Statistical analysis

The Statistical Package for the Social Science System (SPSS) version 19.0 was used for statistical analysis. Continuous data were shown as mean standard deviation (SD), while categorical variables were shown as absolute numbers and percentages. The student's t-test was used to compare normally distributed continuous variables between groups. The Chi-square test or Fisher's test were used to compare nominal categorical data between the groups. P<0.05 was regarded as statistically significant, whereas P<0.001 was regarded as extremely significant.

RESULTS

A total 80 adult patients were randomly allocated and completed the study. The demographic characteristics, duration of surgery and anaesthesia and airway assessment parameters were comparable in both the groups. [Table 1].

Insertion of device was easy (sore 1) in 95% patients in Group B and in 97.5% patients in Group P, (P=0.603)though difference was statistically insignificant. Removal of device was easy in both the Groups.

single attempt of device insertion was required in 92.5 % of patients in Group B and 85 % of patients in Group P. Two attempts were required in 7.5 % of patients in Group B and 15% in group P. (P=0.288) [Table 2] butdifference was statistically insignificant.

The mean insertion time was less in Group B(6.00±1.48sec) as compared to Group P (7.88 ±1.41, P<0.001).[Table 2]and difference was statistically significant.

The mean effective airway time, was less in group B (14.50 ±1.66 sec) as compared to group P, (17.95±1.81, P<0.001).[Table 2] [Figure 1]and difference was statistically significant.

Themean oropharyngeal leak pressure (OLP)was higher in Group B (30.10±2.90 cm H_20) as compared to Group P (26.55±2.06 cm H_20, P<0.001)and difference was statistically significant.[Table 2]

The haemodynamic parameters mean heart rate, mean blood pressure,$EtCO_2$, SpO_2 were comparable in the two groups.

The blood-stained device after removal and postoperative complication rate was slightly higher in theGroup P as compared to Group B, but it was statistically insignificant [Table 2].

Table 1: Demographic Data

Variables	Group B (n=40)	Group P (n=40)	P Value
Age (years)	33.50±9.22	37.73±10.2	0.056
Weight (Kg)	54.66±6.78	53.18±8.17	0.788
BMI(Kg/m^2)	24.080±1.21	24.011±0.95	0.778
Sex(F/M)	24/16	22/18	0.651
ASA (I/II)	25/15	32/8	0.084
Size of LMA (3/4)	4.11±5.31	4.23±6.11	0.765

BMI: Body mass index, F/M: female/male, ASA: American society of Anaesthesiology, Group B=Baska airway, Group P=Proseal airway, Statistically significant, P<0.05

Table 2: Characteristics of Baska Mask and PLMA

	Baska Mask (n=40)	PLMA (n=40)	P value
Number of attempts (1/2/3), N	37/3/0	34/6/0	0.288
Ease of insertion (very easy/easy/difficult)	1/38/1	0/39/1	0.603
Mean insertion time (secs), mean±SD	6.00±1.48	7.88±1.41	<0.001**
Oropharyngeal Leak Pressure (cm H_20)mean±SD	30.10±2.90	26.55±2.06	<0.001**
Ease of removal (Very easy/easy/difficult), N	0/40/0	0/40/0	1.000
Complications			
Sore throat	2	4	0.396
Dysphagia	0	1	0.314
Dysphonia	0	0	NA
Blood stained on removal Yes/No	4/36	6/34	0.457

Group B=Baska airway, Group P=Proseal airway, Statistically significant, P<0.05

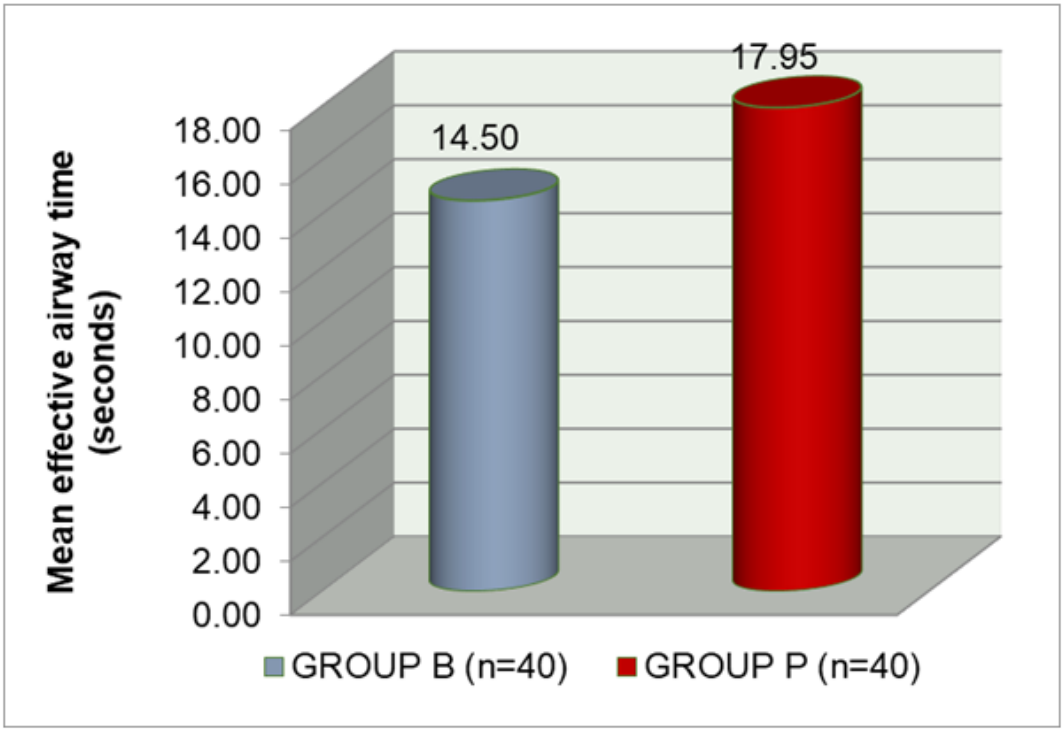

Figure 1: Comparison of mean effective airway time

Group B=Baska airway, Group P=Proseal airway

DISCUSSION

The findings of our study demonstrated that the mean effective airway time of the Baska® Mask (14.50± 1.66 s) was significantly shorter than the Proseal™LMA (17.95 ±1.81). It could be due to larger bulk of the Proseal™ LMA tip and time required for cuff inflation of PLMA after its insertion.

Our findings are consistent with Singh B et al. that the effective airway time was shorter in the Baska® mask group, with a mean effective airway time of 14.25±3.82 sec.[7]Rawahi et al. and Kini G et al. made similar observations and discoveredeffective airway time in the Baska® mask group.[8,9]In contrast to present study, Verma et al. andBrimacombe et al. discovered that the Proseal™LMA group had a shorter effective airway time.[6,10] The possible explanation could be use of introducer tool to direct the device around the oropharyngeal inlet in their study.

Device insertion was reported to be very easy in 2.5 percent of patients and easy in 95 percent of patients in the Baska® mask group, compared to easy in 97.5 percent of patients in the Proseal™ LMA group. Each group had 2.5 % of patients who had difficulty in inserting LMA. The ease with which both LMAs were inserted was not statistically significant (P=0.603). The findings were similar with the study done by of Aziz RA et al. [11] The presence of tab for manually curving the Baska® mask facilitates insertion of device. We used digital method to insert Proseal™ LMA and found that the insertion would have been easy if introducer or bougie were used.

The pressure at which a gas leaks around the airway is known as oropharyngeal leak pressure (OPL), and it is a significant indicator of LMA performance and safety in terms of positive pressure breathing success and airway protection. Our study demonstrated that OPL of the Baska® mask group were higher (30.10 ±2.90 cm H20) than that of the Proseal™ LMA (26.55±2.06 cm H20), revealing Baska® mask to create laryngeal seal more effectively than Proseal™ LMA. Similar observations were made by Alexiev V et al. [12] However, Shin H et al., and Sood S et al. found that higher OLP in Proseal™ LMA group compared to I-gel and Supreme LMA respectively in two different studies. [13,14] No specific reason could be attributed to this difference.

The number of attempts made during LMA insertion revealed that LMAs were inserted in a single attempt in 92.5 % of patients in the Baska® mask group and 85 % of patients in the Proseal™ LMA group. Two attempts were required in 7.5 % of patients in Baska® mask group and 15% in Proseal™ LMA group. So, Baska® mask was inserted mostly in first attempt. There was no statistically significant difference in the number of attempts in the insertion of both the LMAs. A similar observation was made by Kumar E et al. where they could not find any difference in the number of insertions attempts of the two LMAs. [15]However, Gupta R et al. discovered a significant difference in the number of insertion attempts, finding that the Proseal group had a higher success rate of first attempt insertion than the Air-Q blocker (AQB) group in patients undergoing elective laparoscopic cholecystectomy.[16]

Perioperative haemodynamic variables like systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, end tidal carbon dioxide and oxygen saturation were comparable in both the groups at various time interval. Both the LMAs lead to lesser haemodynamic variation during insertion.

In the Baska® mask and Proseal™ LMA groups, sore throat was noted in 5% and 10% of patients, respectively. At 3 hours after surgery, 2.5 percent of patients in the Proseal™ LMA group (one patient) had dysphasia. 4 patients in the Baska® mask group and 6 patients in the Proseal™ LMA group had blood staining of the LMA following removal. With Baska® mask, Zundert TV et al. found sore throat in 5 patients and dysphasia in 1 patient.[17]

Sore throat was the major complication seen more with Proseal™ LMA as the inflatable cuff can absorb anaesthetic gases leading to increased mucosal pressure where as non-inflatable cuff of Baska® mask provides soft seal. Despite the fact that the Proseal™ LMA group had greater issues, the difference was statistically insignificant. There was no difficulty in removing LMAs in any group of patients.

The limitations of our study included firstly, to determine the benefits of LMAs, a higher number of studies with a larger sample size are required. Secondly, observer who measured the effective airway time and oropharyngeal leak pressure was not blinded to the type of device.

CONCLUSION

We concluded that Baska® mask provides more safety in terms of shorter insertion time and higher sealing pressure so can be used as an alternative to Proseal™ LMA in nonparalyzed ambulatory surgery.

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