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Comparative study of safety of Baska mask and Proseal LMA with respect to the oropharyngeal seal in a tertiary centre

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Abstract

Background: Traditionally, endotracheal intubation has been the standard practice for administering general anaesthesia for most of the surgeries. Now a number of supraglottic airway devices (SAD) have been introduced in the clinical practice offering a simple and effective alternative to the endotracheal intubation, avoiding the use of laryngoscope to put the ETT (endotracheal tube) which is associated with exaggerated hemodynamic response.

Method: The present prospective comparative study was conducted in the Department of anaesthesiology and Intensive Care, Government Medical College, Jammu. After attaining approval of the Ethical committee of the Institute, present study included 90 patients of either gender ranging from 18 – 70 years, belonging to ASA grade I and II scheduled for elective surgery of less than 2 hours duration under general anaesthesia. Patients were randomly allocated into Group P (PLMA) & Group B (Baska mask) of 45 patients in each group.

Result: Mean oropharyngeal leak pressure for Group P and Group B was almost equal (30.1 ± 3.08 cm H₂O vs 30.7 ± 2.59 cm H₂O after 5 minutes and 30.4 ± 3.09 cm H₂O vs 31.6 ± 2.55 cm H₂O after 30 minutes of device placement respectively).

Conclusion: Oropharyngeal seal provided by the Baska mask is comparable with that of Proseal LMA with no difference in postoperative oropharyngeal morbidity.

Keywords: Comparative study, Baska mask, Proseal LMA, Oropharyngeal leak pressure

Introduction

Traditionally, endotracheal intubation has been the standard practice for administering general anaesthesia for most of the surgeries.

Now a number of supraglottic airway devices (SAD) have been introduced in the clinical practice offering a simple and effective alternative to the endotracheal intubation, avoiding the use of laryngoscope to put the ETT (endotracheal tube) which is associated with exaggerated hemodynamic response (Forbes AM *et al.*, 1970; Shribman *et al.*, 1987; Wood *et al.*, 1994) ^[19, 20, 21], increase in intraocular pressure and barotrauma (Brimacombe J *et al.*, 1994) ^[22] and for use in cases with failed endotracheal intubation. These devices have extended an anaesthesiologist's arsenal for airway management. SAD offer an alternative airway to traditional tracheal intubation or a face mask. These devices comprise a family of medical devices that facilitate oxygenation and ventilation without endotracheal intubation (White C *et al.*, 2009) ^[23].

Classification

Based on Generation (COOK TM *et al.*, 2011) ^[11]

SADs are classified as follows.

First-generation SADs

These are SADs which fit the description 'simple airway device'. They include the CLMA, flexible LMA, and all LMAs Second-generation SADs

- SADs that have been designed for safety and which have design features to reduce the risk of aspiration. In several cases, the efficacy of that design is unproven. Efficacy for ventilation is often a by-product of design for safety. These include:

- PLMA
- I-gel
- Supreme LMA (SLMA)
- Laryngeal tube suction II (LTS-II) (and disposable version LTS-D)
- Streamlined liner of the pharynx airway
- Baska Mask

Proseal LMA

The Proseal Laryngeal Mask Airway –PLMA (Laryngeal Mask Company, Henley on Thames, UK) overcomes most of the drawbacks of Classic Laryngeal Mask Airway (CLMA) associated with positive pressure ventilation. The uses and indication are ever increasing with reports of pressure control and pressure support ventilation being effectively done with the Proseal. It became commercially available in 2000. PLMA besides providing all the inherent qualities of CLMA, offers several advantages over CLMA (Brimacombe *et al.*, 2000) [24].

Baska Mask

Baska mask is a second generation supraglottic airway device, designed by Kanag and Meenakshi Baska. It is a new SAD, provided in single use and multi –use versions. The Baska brings together features of LMA Proseal i.e. high seal pressure, gastric access port and bite block, which facilitate ventilation, provide airway protection and minimize airway obstruction, respectively. It also has the advantages of the LMA-Supreme i.e. oval shaped, anatomically curved airway tube which incorporates a gastric drain tube.

Since Baska mask is a recently designed supraglottic device, there are limited number of studies comparing Proseal LMA and Baska mask. In this study, we plan to compare the use of Proseal LMA and Baska mask with respect to their safety profile in anaesthetized patients undergoing elective surgery under general anaesthesia.

Aim of study

1. To study and compare the safety of Baska mask and Proseal LMA with respect to the oropharyngeal seal.

Material and Methods

The present prospective comparative study was conducted in the Department of anaesthesiology and Intensive Care, Government Medical College, Jammu. After attaining approval of the Ethical committee of the Institute, present study included 90 patients of either gender ranging from 18 – 70 years, belonging to ASA grade I and II scheduled for elective surgery of less than 2 hours duration under general anaesthesia. Pre-anaesthetic check-up was done one day prior to the surgery and included a detailed history, thorough physical and systemic examination along with routine and relevant investigations. Informed written consent was taken from each patient enrolled in the study. Preoperatively, airway was assessed using Mallampati Grade, Thyromental distance and neck mobility.

Exclusion criteria

- Patients with known or predicted difficult airway.
- Patients with cervical spine pathology.
- Patients allergic to any drug used in the protocol.
- Patients with any respiratory tract pathology.
- Patients with BMI > 40.
- Patients with increased risk of aspiration.

Patient groups

Patients were randomly allocated into 2 groups and each group consisted of 45 patients.

Group P: Proseal LMA Group

Group B: Baska mask Group

An informed written consent was taken from each patient. The patients were prepared by overnight fasting and were premedicated with tablet alprazolam 0.25mg and tablet pantoprazole 40 mg orally night before surgery.

On the morning of surgery, intravenous line was secured. Patients then received injection pantoprazole 40 mg intravenous and injection diclofenac 75 mg intravenous in 100ml of normal saline 30 minutes before surgery. In operation theatre ringer lactate infusion was started. Monitors like ECG, Pulseoximeter and Non-invasive blood Pressure were attached to the patient. All baseline parameters like heart rate, systolic, diastolic, mean blood pressure and oxygen saturation were recorded.

Patients received injection tramadol 1mg/kg intravenous and were preoxygenated with 100% oxygen for 3 minutes. Anaesthesia was induced with injection propofol 2-2.5 mg /kg intravenous till the loss of verbal contact with the patient. Neuromuscular blockade was achieved with injection succinylcholine 1.5mg/kg. Patient was ventilated manually for 1 minute with 100% oxygen after which the supraglottic device of appropriate size was inserted into the pharynx.

In group P, the cuff of Proseal LMA was thoroughly deflated and water soluble lubricant was applied on the dorsal surface of the Proseal LMA. The device was preloaded with a gastric tube of an appropriate size and LMA Proseal of appropriate size was inserted into the pharynx. The cuff was inflated with air and the intracuff pressure was adjusted to 60 cm of H₂O using a hand held cuff pressure manometer (Rusch Endotest, Cuff Pressure Gauge).

In group B the entire Baska mask was lubricated before insertion into the mouth. A lubricated orogastric tube of appropriate size was preloaded via one of the gastric channels and mask was pushed past the front teeth towards the hard palate avoiding tongue. If necessary when mask was fully within the mouth, the Tab was used to help negotiate the palato-pharyngeal curve and device was inserted into the pharynx.

After placement the device was connected to the anaesthesia machine and correct placement of the device was judged by:

- Auscultation over both the lungs and adequate chest expansion on manual ventilation.
- Easy passage of gastric tube into the stomach via drain tube and by absence of gurgling sounds on auscultation of epigastrium.
- A square wave capnography and end tidal CO₂ between 35-45 mmHg.

After placement, device was fixed by taping it over the chin. Anaesthesia was maintained with 33% O₂, 66% N₂O and 0.5 – 1% isoflurane (to achieve MAC 1). Relaxation was maintained with loading dose of atracurium 0.5 mg/kg followed by incremental doses of injection atracurium 0.1mg/kg. Patient was put on volume controlled ventilation with tidal volume 6-8 ml/kg, inspiratory: expiratory ratio of

1:2, respiratory rate 12-14/minute to maintain ETCO₂ of 35-45mmHg. Ondansetron 0.1 mg/kg was administered towards the end of the procedure.

At the end of procedure, neuromuscular blockade was antagonized by injection neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg. 100% oxygen was given before emergence. Before removal of SAD, stomach was emptied by suctioning of drain tube. Removal of the device was done when patient was awake and able to open mouth on verbal commands.

Following parameters will be noted
Oropharyngeal Leak Pressure (OLP)

After device placement and confirmation of adequate ventilation, the airway seal pressure was tested with the patients head and neck in the neutral position by closing the expiratory valve and setting the fresh gas flow to 3litres/minute and observing the rise of ventilators airway pressure. A puffing sound was heard near the patients mouth

(release of pressure) indicating the airway seal pressure which was taken as the pressure at which the needle of the manometer attached to the anaesthesia circuit reached equilibration associated with an audible air leak from the oropharynx up to maximum pressure of 40 cm H₂O.

OLP was measured

After 5 minutes of insertion of the supraglottic device.
 After 30 minutes of the device placement.

Statistical Analysis

Using alpha of .01 and a desired power of 0.9, we estimated that 39 patients would be required to demonstrate a significant difference in leak pressure between two devices. To adjust for non-compliance and exclusions, a sample size of 45 would be taken in each group.

At the end of study, data was compiled and analyzed using appropriate test.

Results

Table 1: Age distribution of study patients

Age (years)	Group P		Group B		P-value
	No.	%age	No.	%age	
≤ 30	10	22.2	10	22.2	0.755
31-40	22	48.9	21	46.7	
41-50	8	17.8	8	17.8	
51-60	5	11.1	6	13.3	
Total	45	100	45	100	
Mean ± SD	38.7±10.32		38.0±9.85		

NS- not significant

The mean age in Group P was 38.7±10.32 years.
 The mean age in Group B was 38.0±9.85 years.
 Both the groups were comparable in terms of age

distribution and the difference was not statistically significant.

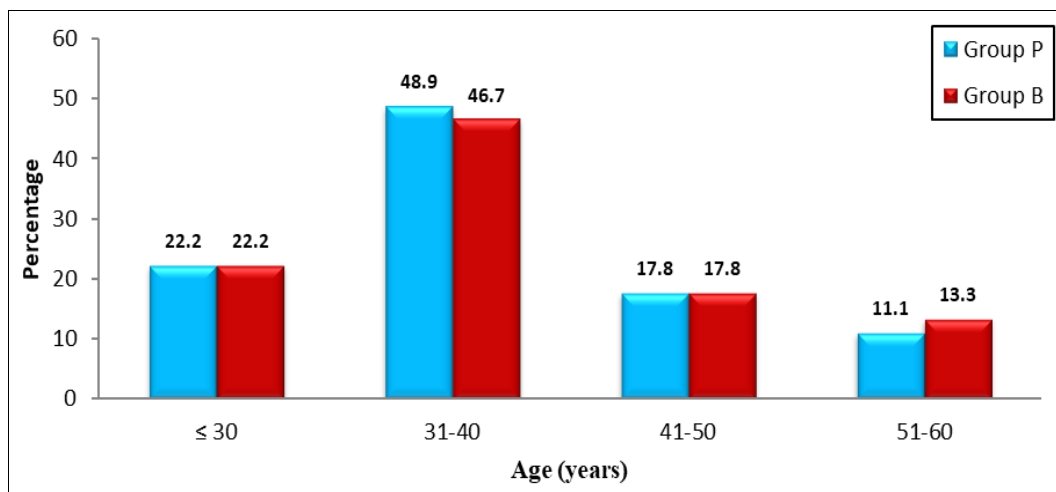


Fig 1: Age distribution of study patients in two groups

Table 2: Gender distribution of study patients

Gender	Group P		Group B		P-value
	No.	%age	No.	%age	
Male	9	20.0	9	20.0	1.000
Female	36	80.0	36	80.0	
Total	45	100	45	100	

NS-not significant

All values are expressed as numbers with percentage in brackets.

In both Group P and Group B 9 patients (20%) were males and 36 patients (80%) were females.

Both groups were comparable in terms of sex distribution and the difference was not statistically significant.

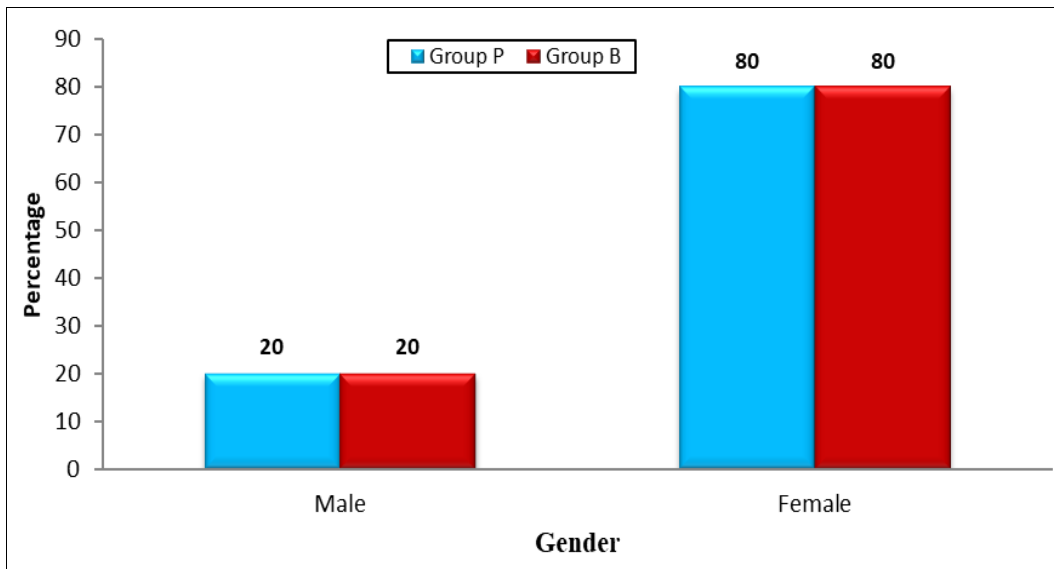


Fig 2: Gender distribution of study patients in two groups

Table 3: Showing mean weight (Kg) of study patients in two groups

Weight (Kg)	N	Mean	SD	P-value
Group P	45	56.6	5.33	0.784
Group B	45	57.0	5.42	

NS –not significant

The mean weight in Group P was 56.6± 5.33 kgs
 The mean weight in Group B was 57 ±5.42 kgs.
 Both the groups were comparable in terms of weight

distribution and the difference was not statistically significant.

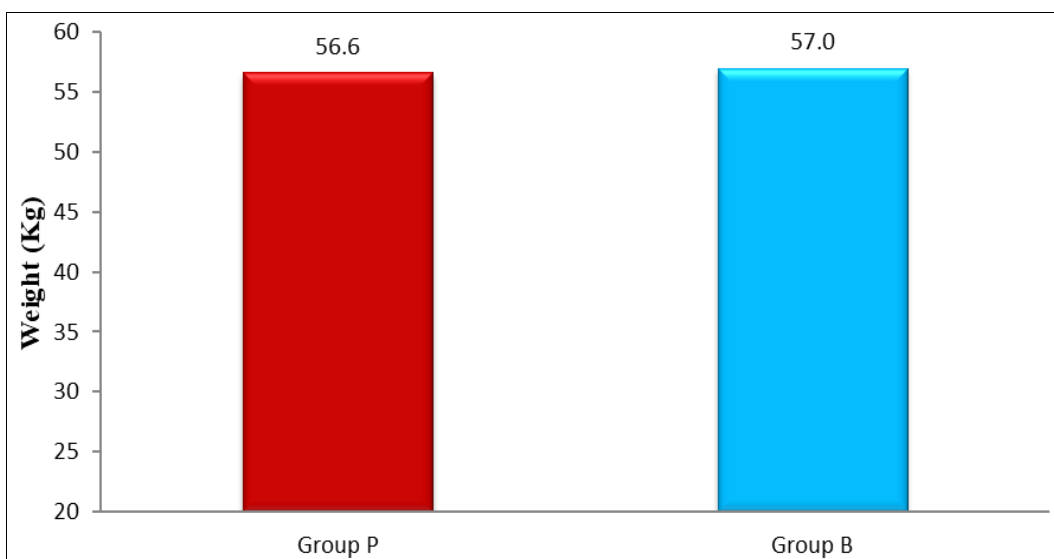


Fig 3: Showing mean weight (Kg) of study patients in two groups

Table 4: Showing mean height (cm) of study patients in two groups

Height (cm)	N	Mean	SD	P-value
Group P	45	154.3	6.86	0.765
Group B	45	154.7	6.52	

NS- not significant

The mean height in Group P was 154.3 ± 6.86 cms.
 The mean height in Group B was 154.7 ± 6.52 cms.
 Both the groups were comparable in terms of height

distribution and the difference was not statistically significant.

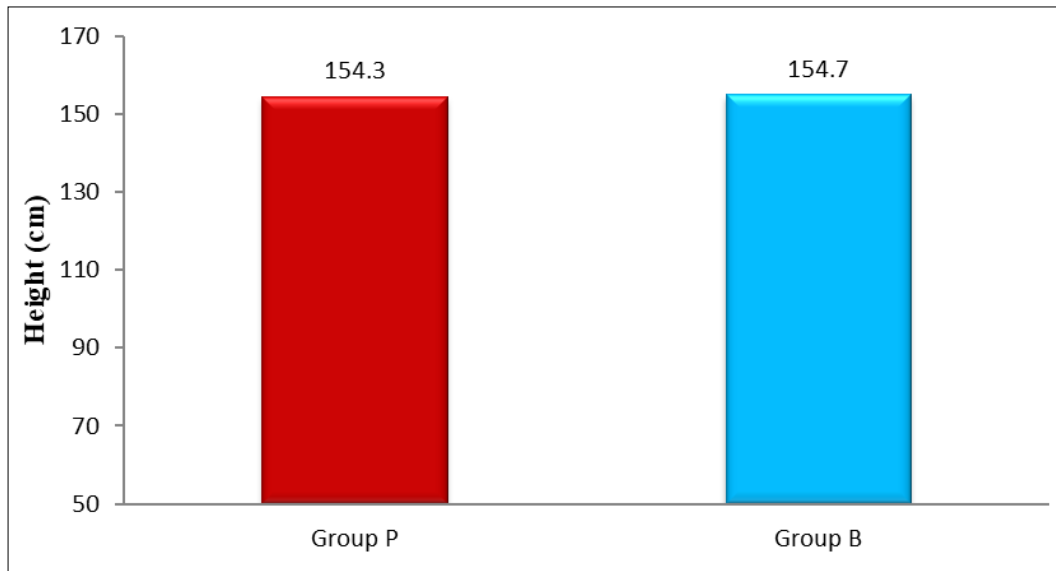


Fig 4: Showing mean height (cm) of study patients in two groups

Table 5: Showing mean BMI of study patients in two groups

BMI	N	Mean	SD	P-value
Group P	45	23.6	2.17	0.765
Group B	45	23.8	2.24	

NS- not significant

The mean BMI in Group P was $23.6 \pm 2.17 \text{ kg/m}^2$. The mean BMI in Group B was $23.8 \pm 2.24 \text{ kg/m}^2$. Both the groups were comparable in terms of BMI values and the difference was not statistically significant.

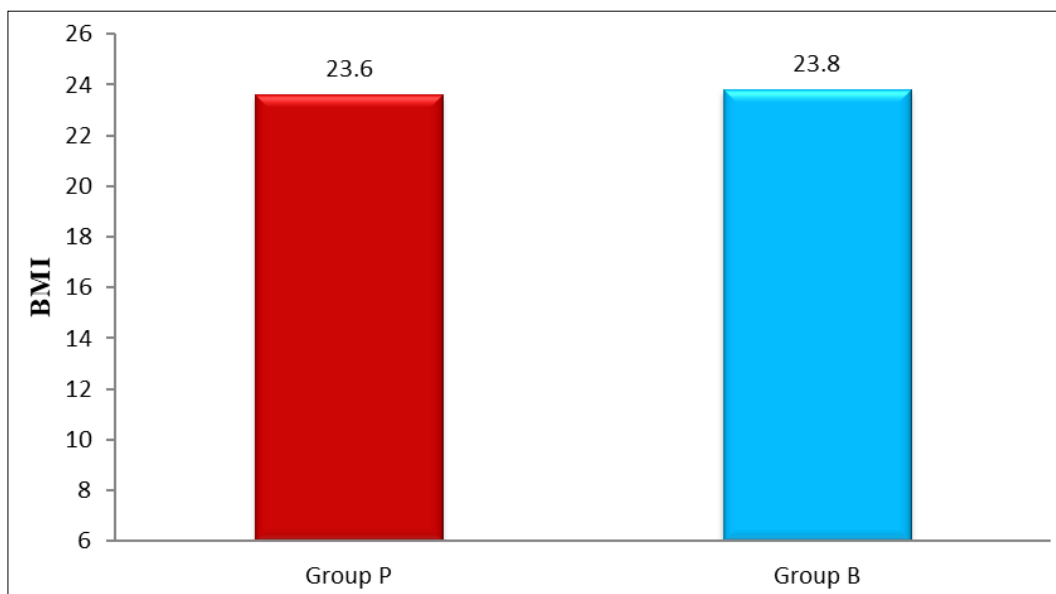


Fig 5: Showing mean BMI of study patients in two groups

Table 6: Showing Oropharyngeal leak pressure in two groups

Oropharyngeal leak pressure	Group P		Group B		P-value
	Mean	SD	Mean	SD	
After 5 minutes of insertion	30.1	3.08	30.4	3.09	0.609
After 30 minutes of insertion	30.7	2.59	31.6	2.55	0.082

NS –not significant

Mean oropharyngeal seal pressure for Group P at 5minutes and 30 minutes after device insertion was $30.1 \pm 3.08 \text{ cm H}_2\text{O}$ and $30.75 \pm 2.59 \text{ cm H}_2\text{O}$ respectively. Mean oropharyngeal seal pressure for GroupB at 5minutes

and 30 minutes after device insertion was $30.4 \pm 3.09 \text{ cm H}_2\text{O}$ and $31.6 \pm 2.55 \text{ cm H}_2\text{O}$ respectively. The difference in the oropharyngeal leak pressure was not significant statistically.

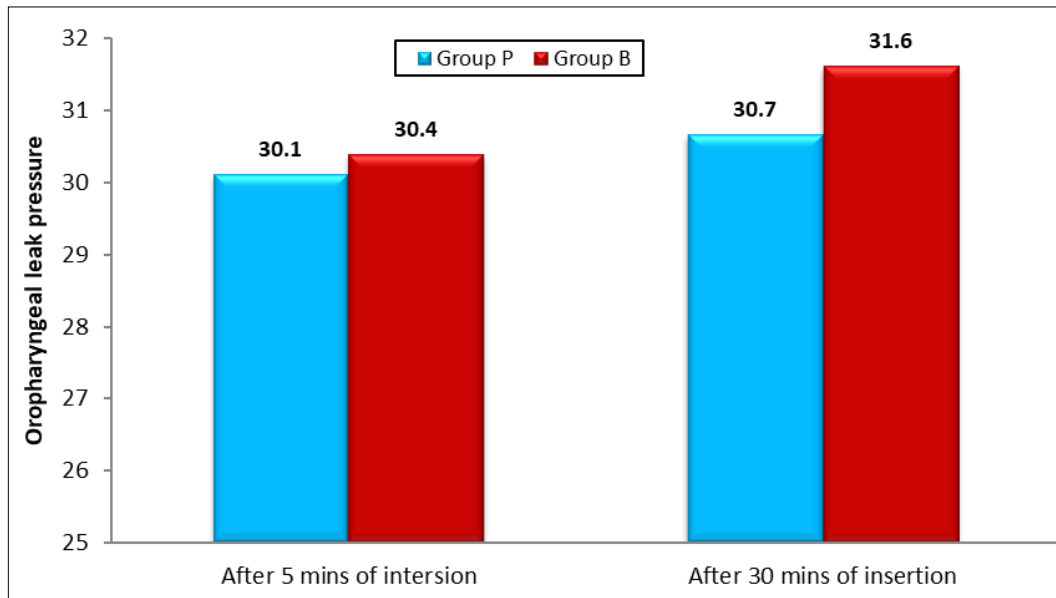


Fig 6: Showing Oropharyngeal leak pressure in two groups

Discussion

Many second generation SADs now outperform the first generation LMAs in all these domains being with higher oropharyngeal seal pressures and with design features that are intended to reduce the risk of aspiration.

Mean oropharyngeal leak pressure for Group P and Group B was almost equal (30.1 ± 3.08 cm H₂O vs 30.7 ± 2.59 cm H₂O after 5 minutes and 30.4 ± 3.09 cm H₂O vs 31.6 ± 2.55 cm H₂O after 30 minutes of device placement respectively). Our results collaborated clinically to the study conducted by Van Zundert and Gatt S (2012) [17] in which mean oropharyngeal leak pressure for Baska mask was above 30 cm H₂O in all patients. Alexiev V *et al.* (2012) [1] in their report found that mean (SD) airway leak pressure with the BM was $35.7(13.3)$ cm H₂O. Alexiev V *et al.* (2013) [25] found that median seal pressure was higher with the Baska mask compared to cLMA (40 vs 22cm H₂O) respectively. Lopez A.M. *et al.*, (2015) [26] found mean airway sealing pressure for Baska mask was 33 ± 7 cm H₂O. In 65% of patients pressure of over 30cm H₂O was noted.

In the study conducted by Galgon *et al.*, (2011) [27] it was observed that mean \pm SD oropharyngeal seal pressures for Air-Q and PLMA were 30 ± 7 cm H₂O and 30 ± 6 cm H₂O respectively similar to the values obtained in our study. Maltby JR *et al.*, (2002) [28] compared PLMA with endotracheal tube with respect to pulmonary ventilation and gastric distension during laproscopic cholecystectomy and found that the median (range) airway pressure at which oropharyngeal leak occurred with LMA Proseal was 34(18-45) cm H₂O.

Belena JM *et al.*, (2015) [29] randomized 140 patients undergoing elective laproscopic cholecystectomy and observed that PLMA had higher leak pressure (30.9 ± 2.6 cm H₂O) as compared to I-gel (28.3 ± 3.3 cm H₂O).

Summary

The present study titled A comparative evaluation of LMA Proseal and Baska mask in patients undergoing elective surgery under general anaesthesia was conducted in the department of Anaesthesiology and Intensive care, GMC Jammu, on 90 patients of either sex aged 18-70 years and belonging to ASA I&II. Our aim was to study and compare

the safety, efficacy of Baska mask and PLMA with respect to oropharyngeal seal. Patients were randomly allocated into Group P (PLMA) & Group B (Baska mask) of 45 patients in each group. The following key observations were made in this study:

1. In the present study, the patients were comparable with respect to age, sex, weight and height distribution.
2. The mean oropharyngeal seal pressure was almost equal for Baska mask and Proseal LMA and the results were not statistically significant.

Conclusion

The Baska mask is another step forward in the search for an ideal supraglottic airway device, which incorporates an airway tube, a tab to help negotiate the palate-pharyngeal curve, two large tubes entering the sump area for high suction clearance of the sump, a large sump reservoir to collect any fluid entering the pharynx, a bite block over full length of the airway tube, an oval, anatomically –curved airway tube and a non –inflatable silicone mask (which adjusts to the contours of the mouth and pharynx, bringing the aperture of the mask towards the glottic entrance). Oropharyngeal seal provided by the Baska mask is comparable with that of Proseal LMA with no difference in postoperative oropharyngeal morbidity.

Conflict of Interest

Not available

Financial Support

Not available

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