Section: Anaesthesia

Original Research Article

EVALUATION OF EASE OF INSERTION BETWEEN BASKA MASK AND LMA-SUPREME IN LAPAROSCOPIC SURGERIES - A PROSPECTIVE RANDOMIZED STUDY

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Abstract

Background: For laparoscopic procedures, the supraglottic airway device (SAD) has shown to be a suitable substitute for endotracheal intubation because of its many benefits, including less airway manipulation and steady hemodynamics. The way these devices suit the architecture of the airway, where they seal, how well they ventilate, and how safe they are all vary. **Aim:** The current study was carried out to compare the effectiveness and safety of the Baska mask and LMA Supreme in elective laparoscopic surgeries under general anaesthesia. **Material & Methods:** This one-year (2019-2020) prospective randomised controlled study was conducted at Coimbatore Medical College and Hospital on 50 patients who had come for elective laparoscopic cholecystectomy surgery equally divided into two groups receiving Baska mask and LMA Supreme devices. The insertion time ,number of attempts and changes in the peak airway pressure, heart rate, mean arterial pressure and airway complications were also determined and compared within the groups. **Results:** Baska mask and LMA Supreme have equal insertion time and are equally efficient regarding haemodynamic variations. Baska mask has a higher Oropharyngeal Leak Pressure and less airway pressure changes when compared with the LMA Supreme. Complications such as postoperative sore throat and hoarseness of voice are similar in both the groups compared, and it is not statistically significant. **Conclusion:** Compared to LMA Supreme, the Baska mask has a larger OLP, indicating a stronger sealing pressure. The Baska mask and the LMA Supreme groups had lower rates of postoperative problems, such as sore throats and voice hoarseness.

INTRODUCTION

Supraglottic airway devices (SADs) are non-invasive alternatives that patients of all ages undergoing various surgical procedures can use to preserve a clean upper airway under general anaesthesia.[1] SADs are crucial in anaesthetic management, providing an alternative airway rescue without muscle relaxants or laryngoscopy, causing less haemodynamics disturbances and agitation.[2] Supraglottic airways provide a clear airway and ventilate patients by delivering anaesthetic gases and volatiles above vocal cords, eliminating the disadvantages of routine endotracheal intubation.[3] Advantages of supraglottic airway devices over endotracheal tubes are less invasive, avoidance of laryngoscopy-induced stress response, ease of insertion, improved hemodynamic stability, smoother awakening and fewer airway-related complications.[4] They form a niche between the face mask and the endotracheal tube. Nowadays, more than 40% of general anaesthesia is successfully managed with supraglottic airway devices.[5]

Supraglottic airway devices offer advantages over endotracheal intubation, including reduced hemodynamic stress response, reduced anaesthetic requirements, improved airway tolerance, and fewer pharyngolaryngeal complications.[6] Laparoscopic surgeries utilise Supraglottic airway devices due to improved oropharyngeal seal and airway protection against aspiration.[7] SADs vary in airway architecture, sealing site, breathing performance, and safety and seal pressure.[8] The Laryngeal Mask Airway Supreme (LMA S) is a sterile, single-use

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second generation SAD with additional gastric lumen providing functional separation of the digestive and respiratory systems.[9]

The Baska mask (BM) is a third-generation self-sealing supraglottic airway device that combines features of second-generation SADs. It features a non-inflatable cuff and improved sealing pressure, offering more effective ventilation and mitigating drawbacks like pulmonary aspiration. Its self-recoiling cuff maintains a semi-dilated seal during resting conditions.[10] With a wide distal aperture at the upper oesophagus that exits into the inbuilt sump chamber, it also has a gastric reflux drainage system. The patency of the seal against stomach overflow is provided by the soft, oval airway opening located at the distal end.[11]

Using a Baska mask during laparoscopic surgeries significantly reduces postoperative pharyngolaryngeal complications like sore throat and hoarseness of voice in 120 patients.[12] SADs are superior to Endotracheal intubation because of their ease and quick insertion, smoother awakening, lesser requirement of anaesthetic drugs, reduced risk of bronchospasm, reduced risk of barotrauma and also lesser post-op complications such as sore throat, dysphonia and postoperative nausea and vomiting.[13] So, in this study, we compared the Baska mask & Supreme Laryngeal Mask Airway in terms of insertion time, number of attempts, Oropharyngeal leak pressure, peak inspiratory pressure, blood pressure, heart rate, oxygen saturation & End tidal CO2 and complications.

Aim

The study aimed to compare the insertion time of the Baska mask airway and Supreme Laryngeal Mask Airway in adult patients undergoing elective laparoscopic cholecystectomy under general anaesthesia.

MATERIALS AND METHODS

This prospective randomised controlled study was conducted after getting approval from the ethical committee of Coimbatore Medical College and Hospital on 50 patients who had come for elective laparoscopic cholecystectomy surgery for one year (2019-2020).

Inclusion Criteria

ASA I & II (Elective Cases only) patients of both genders aged 18-60, with BMI < 30, Anticipated duration of less than 3 hours and a mouth opening >2.5 cm were included in the study.

Exclusion Criteria

Patients who did not consent to the study and those out of the age group 18-60 with a BMI <30, patients with restricted mouth opening < 2.5cm, difficult airway, K/c/o GERD and those who belonged to ASA III, IV & V along with pregnant women and emergency cases were also excluded from this study.

Methods

The patients were divided equally into groups: A - Bask Mask Airway - 25 Subjects and B - Supreme LMA - 25 Subjects. After getting consent from each patient who belonged to the criteria mentioned earlier, they were shifted to the operation theatre. Monitors used are NIBP, PR, SPO2, ECG, and ETCO2. Baseline parameters were noted. Afterwards, the patient's head was placed in the sniffing position and premedicated with Inj Glycopyrrolate 0.1mg/kg. They were preoxygenated with 100% oxygen for three minutes. Induction with Inj Fentanyl 2µg/kg, Inj Propofol 2mg/kg and neuromuscular paralysis facilitated with Inj Atracurium 0.5mg/kg. The size of the mask was chosen according to the patient body weight.

Patients in Group A received a Baska mask, and Group B received an LMA Supreme. After 3 minutes of neuromuscular blockade, the lubricated supraglottic airway device was pushed against the hard palate till definitive resistance was obtained. Any difficulty during insertion was overcome with gentle jaw thrust to facilitate adequate placement. After insertion of LMA, the cuff was inflated with 15-30 ml of air using a syringe in case of Supreme LMA. Then, it was connected to the breathing circuit and checked for bilateral air entry. If air entry was decreased, the LMA was removed, reinserted, and checked for air entry. Even after two attempts or more than 60 seconds, if air entry was not adequate with LMA, then the surgery proceeds with endotracheal intubation.

The successful placement of an LMA was confirmed through auscultation and end-tidal carbon dioxide on the capnogram. The number of attempts required, and the insertion time were recorded. A pre-mounted 14F orogastric tube was advanced through the gastric drainage aperture of the LMA, and suction was performed at the beginning and end of the surgery. Anesthesia was maintained with 1.5 to 2.0% Sevoflurane and 50% Nitrous oxide with Oxygen, Inj Atracurium 0.1mg/kg. The tidal volume was set at 6 to 8 ml/kg, and the respiratory rate was maintained to maintain an end-tidal carbon dioxide concentration of 30 to 40 mmHg. The carbon dioxide insufflation pressure was kept below 12mmHg during pneumoperitoneum.

The oropharyngeal leak pressure was recorded by closing the adjustable pressure-limiting valve and transiently stopping ventilation in manual mode and insufflating the closed breathing system with 3L/min of fresh gas flow and the peak airway pressure was recorded when the leak occur. Upon completion, inhalation was cut off and when spontaneous bag movement noted, neuromuscular blockade was reversed and the orogastric tube was suctioned and removed. Once the patient becomes conscious and obeys commands, LMA was removed and inspected for blood. The incidence of sore throat and hoarseness of voice were assessed before discharge from the post-anesthesia care unit.

Based on the estimates of insertion time by Shanmugavelu et al. (20.1 ± 8.1) among Baska masks and by Sharma et al. (14.2 ± 5.5) among Supreme LMA, the number of laparoscopic surgeries needed,

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to study an absolute difference of 6 seconds between the two devices, with 80% power at 5% level of significance was calculated to be 24 subjects per study group.[14]

Two groups were compared in terms of insertion time, number of attempts, heart rate, blood pressure (systolic BP, diastolic BP, mean arterial pressure), oxygen saturation, end-tidal carbon dioxide, oropharyngeal leak pressure, peak inspiratory pressure at Before and After induction, After LMA insertion, Before and 10 minutes after pneumoperitoneum, at one and after 2 hours.

Statistical Analysis

The collected data was analysed using IBM.SPSS (Statistical Package for Social Sciences) statistics software 23.0 Version. The difference between the means of duration of insertion attempts till success, airway insertion time, oropharyngeal leak pressure, peak airway pressure before and after pneumoperitoneum, intra-operative haemodynamic changes and other continuous demographic data was analysed using an independent t-test after checking for normality of data (Kolmogorov Smirnov test). A non-parametric test was used where relevant. A chi-square test for association was employed to test for associations between categorical variables. A p-value of ≤ 0.05 was considered to be significant.

RESULTS

Among 50 patients enrolled in the study, the mean age was 31.1 (BASKA) and 34.6 (Supreme) in groups A and B, respectively, with corresponding mean BMI of 26.2 and 27.2 (Table 1). The two groups had no significant difference in the age and BMI distribution. The BASKA group had a higher frequency of male patients (44%) than the Supreme group (36%). Female patients were higher in the Supreme group (64%) than in the BASKA group (56%). [Table 1]

The difference in proportions was not statistically significant (p=0.564). This indicates sex distribution is equal in both groups. 52% of the subjects in the BASKA Mask group were with ASA 1, whereas in the Supreme Mask group, it was 40%. The difference in proportions is not statistically significant (p=0.395). This indicates ASA distribution is equal in both groups.

The median insertion time in the BASKA and Supreme masks were 20 secs and 23 secs, respectively. The difference in the insertion time distribution is insignificant at a 5% significance level, as the p-value is 0.069. So, the two groups have no significant difference regarding insertion time (Table 2). There is no significant association between the number of attempts and the group. The median duration in both BASKA and Supreme Mask was 120 minutes. The p-value of 0.230 indicates no significant difference in the duration between the two groups. [Table 2]

Repeated measures mixed model was used to estimate the least square means and the difference of the means of change from the baseline of haematological parameters between the two groups. The model was fitted with the factors Group, Visit (Repeated Factor), Baseline Heart Rate, blood pressure, Group Visit Interaction and ASA status. The adjusted mean difference in change from baseline heart rate is not statistically significant at any point at a 5% significance level. The two groups have no significant change in heart rate. [Figure 1]

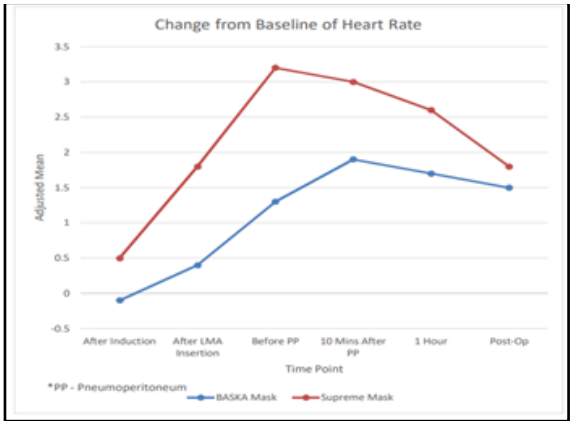

Figure 1: Change from baseline of heart rate

The adjusted mean change difference from baseline between BASKA Mask and Supreme Mask was statistically significant after induction, after LMA insertion, before Pneumoperitoneum and 10 mins after Pneumoperitoneum at a 5% significance level. So, compared to the Baska mask, there was a significant increase in systolic blood pressure (SBP) in Supreme LMA groups (Figure 2).

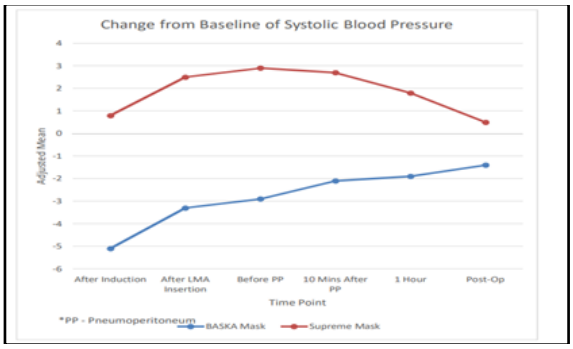

Figure 2: Change from baseline of SBP

The adjusted mean difference of change from baseline of diastolic blood pressure after induction, after LMA insertion, before pneumoperitoneum, 10 minutes after pneumoperitoneum and 1 hour were statistically significant at a 5% significance level. It indicates that at these time points, there is a significant increase in BP in Supreme LMA compared to BASKA Mask (Figure 3). The adjusted mean difference of change from the baseline of MAP was statistically significant at all the tie points at a 5% significance level. Therefore, it indicates that at all times, there is a significant increase in the MAP in Supreme LMA compared to Baska Mask (Figure 4).

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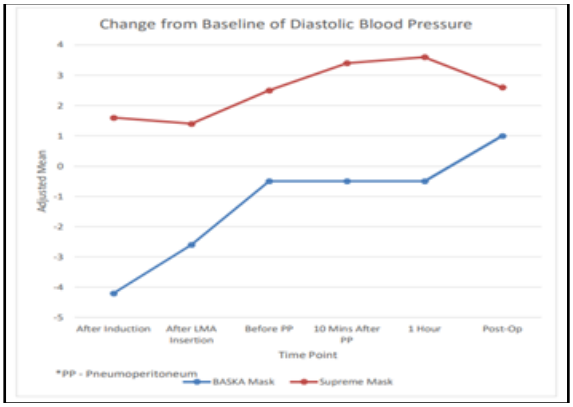

Figure 3: Change from baseline of DBP

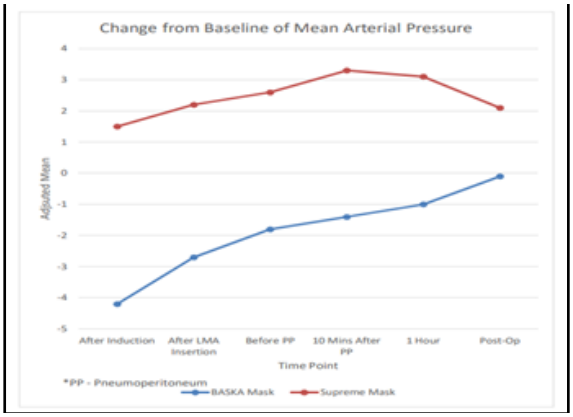

Figure 4: Change from baseline of MAP

There is no significant difference in change from baseline of either heart rate, systolic blood pressure, diastolic blood pressure, or mean blood pressure at 2 hours. [Table 3]

At all the measured intra-operative time points, ETCO2 values were statistically significant between the two groups after adjusting for ASA status. This indicates that the mean ETCO2 levels were significantly lower in the BASKA Mask group (Figure 5).

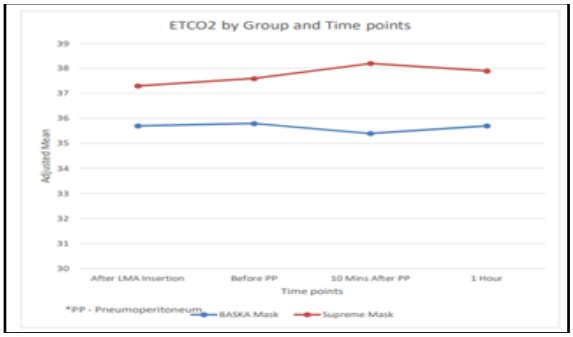

Figure 5: ETCO2 by Group and Time points

At all the measured intra-operative time points, PIP(Peak Inspiratory Pressure) values significantly differed between the two groups after adjusting for ASA status at a 5% significance level. This indicates that the mean PIP levels were significantly lower in the BASKA Mask group (Figure 6). There is a significant mean difference in the OLP between the two groups. This indicates that BASKA MASK has a greater sealing pressure than LMA SUPREME (Table 4). The chi-square test was used to test if there was a significant difference in the complications between the two groups. The calculated p-value for the difference in the percentage of sore throat between the two groups (p=0.185). It could be concluded that there is no significant difference in the incidence of sore throat between the two groups. Similarly, the p-value of 0.157 for the difference in the incidence of hoarseness between the two groups indicates no significant difference. [Table 4]

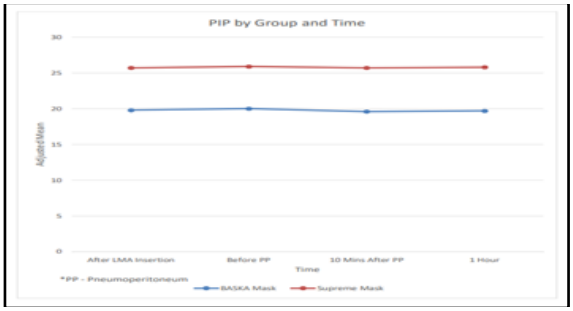

Figure 6: PIP by Group and Time

Table 1: Demographic data

Criteria	BASKA Mask (n = 25)	Supreme Mask (n = 25)	P-value
Age	31.1 ± 12.83	34.6 ± 12.16	0.336
BMI	26.2 ± 2.92	27.2 ± 2.12	0.190
Sex			
Male	11 (44%)	9 (36%)	0.564
Female	14 (56%)	16 (64%)	
ASA			
ASA I	13 (52%)	10 (40%)	0.395
ASA II	12 (48%)	15 (60%)	

Table 2: Insertion parameters

Insertion time Median (Q1, Q3) *	20 (19.5, 23.5)	23 (20.5, 28.0)	0.069*
Number of ATT			
I	21 (84)	20 (80)	0.713†
II	4 (16)	5 (20)	
Duration of procedure Median (Q1, Q3) *	120 (60, 120)	120 (90, 120)	0.230*

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Table 3: Change of haematological parameters from baseline at 2 hours

Change from Baseline	BASKA Mask (n = 13) Mean ± SD	Supreme Mask (n=18) Mean ± SD	P-value
HR	-0.3 ± 6.47	2.2 ± 6.02	0.272
SBP	0.3 ± 11.1	2.4 ± 12.05	0.619
DBP	0.5 ± 6.74	5.3 ± 7.23	0.067
MAP	-0.5 ± 7.49	4.3 ± 8.27	0.109

Table 4: OLP and occurrence of complications

	BASKA Mask (n = 25) Mean ± SD	Supreme Mask (n=25) Mean ± SD	P-value
OLP	32.2 ± 1.26	28.4 ± 1.12	<0.001
Complications			
Sore throat	4 (16)	8 (32)	0.185
Hoarseness	1 (4)	4 (16)	0.157

DISCUSSION

When managing the airway under anaesthesia, supraglottic airway devices are very helpful, particularly when there is a problematic airway or in an emergency. Today's LMAs and laryngeal tubes have various designs that offer superior aspiration prevention and airway control. In this study, 50 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia with intermittent positive pressure ventilation were compared between the clinical effectiveness and safety of the Baska mask and the Supreme Laryngeal Mask Airway by dividing them equally into two groups. The two groups were compared in terms of Insertion time, number of attempts, Heart rate, Systolic blood pressure, Diastolic blood pressure, mean arterial pressure, Oxygen saturation, End-tidal carbon dioxide, Oropharyngeal leak pressure, Peak inspiratory pressure and postoperative complications like sore throat and hoarseness of voice.

Our study's mean age of patients was less than that of many other studies. Mean age and gender had no significant association with grouping.[12-16]

Our study found that both groups' insertion time and number of attempts were statistically insignificant. So, there is no significant difference in both Laryngeal Mask Airways regarding insertion time. A study by Kachakayala et al. found no significant difference in ease of insertion and number of attempts. This was in contrast with the results published earlier, which reported that LMA Supreme is inserted quickly and easily compared to the Baska mask.[17,18] Another study also reported that the first attempt success rate during the insertion of the Baska mask was greatly reduced when compared with classic LMA.[10]

In our study, it is found that there is no significant difference in heart rate changes in both groups. A significant difference in both groups after pneumoperitoneum. However, in both groups, the parameters differed after pneumoperitoneum and were statistically significant, and at the end of the surgery, there was not much difference in either group. LMA Supreme group has higher systolic blood pressure after pneumoperitoneum than the Baska mask group at the beginning of surgery and soon after pneumoperitoneum. However, at the end of the surgery, there are no significant changes in both groups. So, the Baska mask and LMA Supreme are equally efficient regarding changes in haemodynamic parameters. A study comparing the Baska mask with the single-use Classic laryngeal mask airway in low-risk female patients posted for ambulatory surgery conducted in 150 female patients concluded no haemodynamic significance between the two groups pre and post-insertion.[10] However, in a study conducted by Kachakayala et al., the Baska mask was compared with Proseal LMA in a short gynaecological procedure, and it was reported that Proseal LMA and the haemodynamic changes are significantly less in the Baska mask.[17]

Our study found that the Baska mask has a greater oropharyngeal leak pressure and lower peak inspiratory pressure than Supreme LMA. So, the Baska mask has a greater sealing pressure, is superior to LMA Supreme regarding airway pressure changes, and is statistically significant. This was following the results published by Jeyalekshmi et al.15 Other similar studies also concluded that Baska mask achieves a higher oropharyngeal seal pressure, thereby creating a higher airway seal than LMA Supreme.[18,19]

In our study, there was no significant difference in the incidence of sore throat and hoarseness of voice between the two groups. So, the Baska mask and LMA Supreme are equally good in reducing postoperative complications. A study conducted by Jeyalekshmi et al. comparing the efficacy of the Baska mask and LMA Supreme during positive pressure ventilation in 60 patients concluded that the incidence of postoperative complications is equal in both groups.[15] Tosh et al. also reported that the Baska mask greatly decreases pharyngo-laryngeal complications compared to endotracheal intubation.[12] A similar study also reported the incidence and severity of post-op sore throat, hoarseness of voice and cough following the use of I-Gel and Baska mask, which showed no significant differences.[20]

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CONCLUSION

Supraglottic airway devices are less invasive, have lesser haemodynamic variations, and lesser pharyngolaryngeal trauma than endotracheal tubes. This study compared two such devices, the Baska mask and LMA Supreme, in elective laparoscopic surgeries under general anaesthesia with intermittent positive pressure ventilation regarding haemodynamic variation and airway pressure changes. Our primary outcome variable is insertion time. Our study concludes that the Baska mask and LMA Supreme are equally efficient regarding haemodynamic changes since both insertion times are more or less equal and statistically insignificant (P-value < 0.05). However, the Baska mask has a higher OLP when compared with the LMA Supreme, which shows that the Baska mask has a greater sealing pressure. Postoperative complications such as sore throat and hoarseness of voice are lesser in both the Baska mask and LMA Supreme groups.

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