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RESEARCH ARTICLE
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"SAFETY AND EFFICACY OF BLOCKBUSTER LARYNGEAL MASK AIRWAY VS BASKA MASK FOR DAYCARE SURGERY UNDER GENERAL ANAESTHESIA: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: On the day after surgery, patients can return home and recuperate in a familiar setting thanks to the more individualized and aimed care they receive in day-care surgical units. This led to a major innovation in Laryngeal-mask airway in 1981 by Dr. Archie Brain. In such cases LMA have become a modality which will help patient in early recovery and less postoperative complications which were seen during endotracheal intubation. Blockbuster LMA has undergone fewer studies than other devices. The Baska mask and Blockbuster LMA are some of SGA useful in daycare modality. Therefore, this study was done to compare the safety and efficacy between Baska Mask and Blockbuster LMA.

Methods: This prospective randomized, control study was conducted among patients undergoing day care surgery under General Anaesthesia in Rohilkhand Medical College Hospital, Bareilly. Hundred patients were included in the study with 50 patients for each group. Group A: Blockbuster LMA was used to secure the airway and Group B: Baska mask was used to secure the airway. Premedication with I.V. Butorphanol 0.02 mg/kg and Midazolam 0.02 mg/kg. Preoxygenation was done for 3 minutes, after which I.V. Propofol 2 mg/kg was used to induce anaesthesia. After confirming adequate mask ventilation, Succinylcholine 1 mg/kg was administered for neuromuscular blockade. After 60 seconds, either of the devices was inserted using a midline insertion technique with the neck in a neutral posture. The primary measure was the time taken for insertion, ease of insertion, OLP and Number of attempts Secondary outcome measures included laryngopharyngeal morbidity (blood staining, and sore throat) immediately and 2, 4 and 6 hours postoperatively. Data analysis was done using SPSS version 17.

Results: Mean time of Insertion was more in Group A (11.62 ± 4.0) as compared to Group B (8.62 ± 3.49) and there was significant difference in mean time of Insertion in between Group A and Group B (P=0.000). **T**here was no measurable difference between the Baska mask and Blockbuster LMA in

terms of ease of insertion, OLP, sore throat and fewer maneuvers were needed. Blood stain on Device was absent in 31 cases and present in 19 cases in Group A and Blood stain on Device was absent in 39 of cases and present in 11 of cases in Group B. There was significant difference in Blood stain on Device in between Group A and Group B (P=0.013).

Conclusion: In this study Baska mask was superior in terms of time taken for insertion in seconds in comparison to Blockbuster LMA, Ease of insertion, Oropharyngeal leak pressure, Number of attempts for insertion were found to be non-significant. Blood stain on device was marked increased in Blockbuster LMA group with no significant difference seen in terms of sore throat at different intervals.

Keywords: Supraglottic airway device, Baska Mask, Blockbuster LMA.

INTRODUCTION:

Supraglottic airways allow us to ventilate, oxygenate, and deliver anaesthetic gases without the necessity for endotracheal intubation once they are introduced into the pharynx. SGA can provide unobstructed ventilation. SGA aids during advanced cardiac life support, as used by primary responders during cardiac arrest. This is particularly crucial for patients at the very end of the age range. This led to a major innovation in Laryngeal-mask airway in 1981 by Dr. Archie Brain. In such cases LMA have become a modality which will help patient in early recovery and less postoperative complications which were seen during endotracheal intubation.

Baska mask is an advanced supraglottic airway device, with a cuffless dynamic self-inflating membranous bowl and a dual drainage tube element for drainage of gastric content. Baska mask is present in four different sizes- 3,4,5& 6.[1] Baska Mask provides protective mechanisms toward tissue or nerve damage due to non-inflating cuff and no intra cuff pressure monitoring is required.

Blockbuster-laryngeal mask airway was invented by Prof. Ming Tian. The Blockbuster Intubating Laryngeal Mask Airway is a relatively new device that was designed in 2012 in China. Because it improves the quality and safety of anesthetics, its popularity is growing. Improved ventilation and a wider intubation route are among the advantages. It was recently added to second generation LMA as a tolerable airway conduit with tracheal intubation function. It offers long-term breathing, a solid seal, and a higher success rate for blind tracheal intubation using an intubation channel.[2] It is made up of silicon material- flexible and biocompatible.

Blockbuster LMA has undergone fewer studies than other devices. The comparison of these two SGA regarding safety and efficacy are studied minimum in numbers. Therefore, this study was done to compare the safety and efficacy between Baska Mask and Blockbuster LMA. The effectiveness and safety of these devices in short-term surgery have not been compared in any research. Therefore, this study was done to find beneficial effects and failure of these devices.

MATERIAL AND METHODS:

The study was conducted at the Department of Anesthesiology, Rohilkhand medical college and hospital, Bareilly on 100 patients admitted for elective surgeries under general anesthesia lasting less than one hours. After approval by the Institutional Ethical Committee patients who were between the ages of 18-60 years of both sexes, undergoing elective surgeries. American Society of Anesthesiologist (ASA) grades I and II, and body mass index (BMI) < 30 kg/m^2 were included in the study with Mallampati grading 1 and 2. Patients who refused to participate in the study, had restricted mouth opening, Patient with neck pathology, Anticipated difficult airway, History of gastro-oesophageal reflux or increased risk of gastric aspiration, Lesion in oral cavity, Mouth opening less than 2 cm. The patients were randomly divided by a computer-generated random number table into two equal groups of 50 each: Group A (Blockbuster LMA) and Group B (Baska Mask).

The sizes of the Blockbuster and Baska mask devices was as per the manufacturer's recommendation and it was based on the patients' body weight, i.e., size 3 for 30-50 kg, size 4 for 50-70 kg for Blockbuster; and size 3 for weight 30–50 kg, size 4 for 50–70 kg for the Baska mask.

Patients were taken in pre-operative room, 18-gauge cannula was secured and IV fluid attached, and vitals were monitored. After shifting patient to operation theatre, multiparameter monitors was attached and recorded – pulse rate, non-invasive measurements of SBP, DBP, continues ECG monitoring, and oxygen saturation. Premedication with I.V. Butorphanol 0.02 mg/kg and Midazolam 0.02 mg/kg. Preoxygenation was done for 3 minutes, after which I.V. Propofol 2 mg/kg was used to induce anaesthesia. After confirming adequate mask ventilation, Succinylcholine 1 mg/kg was administered for neuromuscular blockade. After 60 seconds, either of the devices was inserted using a midline insertion technique with the neck in a neutral posture.[3] The appropriate size of Supraglottic airway was selected according to body weight. During the insertion of SGA in both groups, airway manipulations, such as jaw thrust, insertion depth adjustment, were performed at the discretion of the attending anesthesiologist. Three attempts were allowed for placement of successful SGA in both groups.

Following insertion, the Smiths cuff pressure manometer was used to inflate the LMA cuff with oxygen until the recommended pressure of 60 cm H2O.[4] The SGA was connected to the breathing circuit. Successful placement was confirmed with the ability to achieve tidal volume of at least 6 ml/kg with a square wave capnogram.[5] Correct positioning of SGA was confirmed by capnography, unobstructed inspiratory and expiratory flow, passage of nasogastric tube, and suprasternal notch test (Place a nontoxic gel solution across the proximal end of the drain tube. Gently tap the suprasternal notch or cricoid cartilage. Observe the gel membrane for pulsation. A positive test result means the LMA tip is in the correct position. A negative result could indicate that the LMA is malposition). Time required for insertion' of SGA device was defined from removal of facemask to the time where adequate ventilation was established through SGA with normal square wave capnogram.[6] The number of Attempts to insert the SGA device were recorded.[3] Ease of Insertion of SGA devices was evaluated according to required manoeuvres during insertion; easy for no manoeuvre, fair for one type of manoeuvre, difficult for more than one type of manoeuvre.[7] The Oropharyngeal Leak Pressure was measured with expiratory-valve closed and fresh gas flow of 3L/m until equilibrium was seen on the pressure gauge (not allowed to exceed 40cm H_2O).[3] The patients, mean arterial pressure (MAP), heart rate (HR) and SpO_2 were recorded for 25 minutes. SpO_2<95 was considered as oxygen desaturation. Occurrence of intraoperative laryngospasm, bronchospasm, gastric distension, cough and hiccups were observed. Nitrous oxide 50 percent in oxygen and isoflurane was used to maintain anaesthesia. The mechanical ventilation of the patient's lungs was minutely regulated to maintain normocapnia (EtCO2 between 35 and 40mm Hg). Isoflurane was discontinued at the end of surgery. Following surgery, the device was removed when the patient was awake and responsive. The integrity of the device and the presence of blood stains was noted. The patient was inspected for any injury to the lips, tongue and teeth. Cough, indications of reflux, and aspiration were noted after the device is removed. All patients were followed up for 6 hours for sore throat. The sore throat was described as discomfort, scratchiness, or irritation of the throat. A 4-point scale was used to evaluate the situation: 1- No sore throat, 2- Mild (sore throat complaints only on questioning), 3- Moderate (sore throat complaints without inquiry), and 4- Severe (sore throat with soreness and associated with pain in throat). The sore throat was assessed at frequent time intervals like immediate postoperative, after 30 minute, 2 hours then at 6 hours.[8]

All statistical analysis was performed using SPSS 22.0 software package (SPSS Inc., Chicago, IL, USA). *T*- test for independent samples was used to compare two groups for data with a normal distribution. Yates's continuity correction test (Chi-square test) and Fisher's exact test were used for comparison of qualitative data. All data were summarized as Mean± standard deviation for continuous variables/numbers and as percentages for categorical variables. $P < 0.05$ was considered statistically significant.

RESULTS:

The demographic profiles of the patients regarding age, Weight, height, Mouth Opening and Mallampati Grading were comparable in both groups but statistically insignificant (Table 1).

Table 1. Comparison of Group A and Group B based on demographic data

VARIABLE	GROUP A	GROUP B	P-VALUE
AGE (IN YEARS)	38.42 ± 10.98	42.48 ± 12.67	**0.090#**
WEIGHT (KG)	56.84 ± 5.32	58.6 ± 9.23	**0.246#**
HEIGHT (CM)	163.74 ± 4.25	163.22 ± 4.82	**0.569#**
MOUTH OPENING	3 ± 0	3 ± 0	**-**
MALLAMPATI GRADING	1.50 ± 0.51	1.66 ± 0.48	**0.107#**

***Statistically significant #Statistically not significant.**

Baska mask was inserted in less time and with greater ease when compared to Blockbuster LMA, which was statistically significant (Table 2). Blockbuster LMA and Baska mask were also noted to provide a higher OLP with non-significant result. (Table 2), conferring the advantage of withstanding higher positive airway pressures. Ease of insertion and number of attempts were non-significant in both the groups. (Table 2)

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.

VARIABLE	GROUP A	GROUP B	p-VALUE
NUMBER OF ATTEMPTS mean±SD	1.52 ± 0.54	1.42 ± 0.57	**0.374#**
TIME TAKEN FOR INSERTION (SECONDS) mean±SD	11.62 ± 4.0	8.62 ± 3.49	**0.000***
OROPHARYNGEAL LEAK PRESSURE (cmH20) mean±SD	27.36 ± 4.13	27.76 ± 3.47	**0.601#**
EASE OF INSERTION (Difficult/Fair/ Easy)	2/18/30	5/18/27	**0.486#**

***Statistically significant #Statistically not significant.**

A higher incidence of complications like blood staining, and sore throat was seen in patients in Blockbuster LMA but sore throat was found not significant (Table 3 & 4).

Table 3. Incidence of Blood stain on device in Group A and Group B.

BLOOD STAIN ON DEVICE	GROUP A		GROUP B		P-VALUE
	NUMBER	%	NUMBER	%	
ABSENT	31	62	39	78	**0.013***
PRESENT	19	38	11	22	
Total	**50**	**100**	**50**	**100**	

***Statistically significant.**

Table 4. incidence of sore throat on device in Group A and Group B.

	GROUP A		GROUP B		
Immediately after Extubation	**NUMBER**	**%**	**NUMBER**	**%**	**P-VALUE**
No Sore Throat	19	38	16	32	
Mild Sore Throat	19	38	22	44	
Moderate Sore Throat	12	24	10	20	
Severe Sore Throat	0	0	2	4	**0.447#**
Total	50	100	50	100	

#Statistically not significant.

DISCUSSION:

Demographic profile regarding age, Weight, height, mouth opening, Mallampati grading were comparable in both groups, which was not statistically significant ($p>0.05$). Both groups' hemodynamic parameters like mean arterial pressure, heart rate, and oxygen saturation were comparable and statistically insignificant ($p >0.05$).

SGAs are frequently employed in general anesthesia to control airways. More obese or high risk patients are now being secured with SGAs, which are also utilized like those in a conduit for intubation and for airway management outside of the operating room, in pre-hospital emergency care or during resuscitation or cardiac arrest, where they may provide better ventilation success rates than orotracheal intubation, especially in cases when the clinicians are not properly educated to do intubation.

SADs are classified into two types based on two critical distinctions. The first is whether or not an inflatable cuff is present. Cuffless devices reduce the risk of cuff-related morbidity but may increase the risk of leaks and failure. First-generation devices are simple airway tubes with no particular design features aimed at reducing the risk of aspiration of gastric contents into the lungs. Second-generation SADs have additional modifications that help improve positive pressure ventilation (PPV) and lower the risk of aspiration into the lung.

The main observation of our study was that less time of insertion was taken by Baska mask as compared to Blockbuster LMA which was found statistically significant (p-value 0.000). **Das PP** study showed that mean time of insertion of device was lesser in Group I-Gel (13.50 ± 2.62 seconds) than that of Group Blockbuster LMA (14.09 ± 2.01 seconds). However, it was determined that this difference was not statistically significant.[9] Similarly, our study found that Baska Mask insertional time was lower than Blockbuster LMA. In studies were cuffless devices were compared, such as the study conducted by **Kara D,** where the Baska mask was compared with the I-gel; the mean insertion time of the Baska mask was significantly greater than I-gel in which they observed that it took a mean of 14-seconds to place the Baska mask and 7-seconds for I-gel.[10] The morphology of the device and the particular skill required to insert it may be the cause of the lower success rates attained with the Baska mask. I-gel required longer time for placemen.

The ease of insertion, number of attempts and OLP were superior in both the groups with non-significant result. In our study, mean number of attempts to insert the Baska mask and Blockbuster LMA were 1.52 and 1.42 respectively with p value of 0.374 which are statistically non-significant. This study is comparable with the result finding by **Sharma P *et al*** who had no notable variation in the number of attempts. Most of the devices were used on the first try in each group. Additionally, there was no discernible difference in the quantity of effort between Baska Maska and I gel.[11]

The non-significant numbers of attempts between two groups can be attributed to two factors. First, by pulling the tab of the Baska mask, which increases its distal curvature, any challenges in navigating the oropharyngeal curve might be resolved. Secondly, there is no inflatable cuff in Baska mask, so time to inflate the cuff and volume adjustment requires multiple attempts.

Number of attempts were also found non-significant with Baska mask and I-gel in the study done by **Jain P *et al*,** showing the data regarding characteristics of insertion of both Baska Mask and I-gel groups.[12] Airway could be secured in 35 patients in the Baska Mask group and 38 patients in the I-gel group in first attempt. For successful insertion, two patients in the I-gel group and three patients in the Baska Mask group needed a second
try.

The study done by **Khare A** where Blockbuster LMA was compared to I-gel showed a significant increased number of attempts in Blockbuster LMA group.[3] Lower success rate may be attributed to the morphology of the devices and unique expertise needed to insert the device.

Dsouza R discovered that there was a marginal advantage of Blockbuster LMA over Igel, but no statistically significant difference in the number of insertions tries needed between the two groups, as indicated by the p-value of 0.51 obtained from the comparison of insertion attempts between the two groups.[6]

In our study Ease of Insertion in Group A was difficult in 02 of cases, Easy in 18 of cases and Fair in 30 of cases and Ease of Insertion was difficult in 05 of cases, Easy in 18 of cases and Fair in 27 cases in Group B. Groups 1 and 2 did not significantly differ in terms of Ease of Insertion (P=0.486).
Jain P who did study revealed that Ease of insertion(I/II/III/IV) in Baska Mask was 30/8/0/2 attempts, and 34/6/0/0 for I-Gel which was statically non- significant 0.281 (NS) the reason behind failed device ease could be attributed to bigger cuff size of Baska Mask.[12]
Selvin CC *et al* study showed the ease of insertion in parameters of (easy/very easy/difficult). In the I-gel group they found 68/2/0 value and in Baska-mask group they found values such as 68/2/0, which was statistically non-significant and was correlating to our study.[7]
Khare A who did comparative study between blockbuster LMA and I-gel found that ease of insertion was significantly higher in Blockbuster LMA group, the ease of insertion was graded as very easy in 46 patients in Group Blockbuster LMA and 26 patients in Group I-Gel.[3]
In our study, the mean oropharyngeal leak pressure with Baska mask was found to be 27.76 ± 3.47 and that with Blockbuster LMA was 27.36 ± 4.13 with p value of 0.601**,** which is statically non-significant. Because Blockbuster LMA has an extra dorsal cuff that enhances seal ability and lowers aspiration risk, it showed higher seal pressures. As the airway pressure rises during inspiration, the Baska mask cuff could self-inflate and adhere tightly to the surrounding surface.
Agrawal N et al in their study, the difference between OLP and PAP (OLP-PAP) was also significantly better in Group Baska Mask at 5 min (21.98 ± 3.78 cm H_2O vs 14.02 ± 4 cm H_2O) and at 30 min post device insertion (23.02 ± 3.8 cm H_2O vs 15.4 ± 4.21 cm H2O).[13]
In study by **Al-Rawahi *et al***. found a similarly higher OLP with Baska mask (29.98 ± 8.15 vs 24.50 ± 6.19; *P* value = 0.13) as compared with Proseal LMA in 52 adult patients and concluded that mean difference of 5.48 cm H_2O in OLP between the two devices may be of clinical importance in patients with decreased thoracic compliance.[14]
Because the Baska mask's cuff is a re-coilable membrane that expands and contracts in response to the respiratory cycle, it maintains sealing pressure better. As a result, several studies have found that using a Baska mask improves oropharyngeal leak pressure.

Studies done in Blockbuster LMA and Proseal LMA with regards to OLP had differential results such as in study done by **Premkumar KG** study found that there between these three groups, there is no statistically significant variation in airway sealing pressure. Both Proseal LMA and Blockbuster LMA have a dorsal cuff, but Proseal has better sealing pressure than Blockbuster LMA.[15]

In our study, nineteen patients in Group Blockbuster LMA had blood staining of device while in Group Baska mask group eleven patients had blood staining of device, and this difference was found statistically significant (*P* = 0.013). Due to cuff inflating nature of Blockbuster LMA, there are increased chances of damage to the surrounding mucosa and tissue whereas Baska mask gets adjusted by self-inflation method and gets adjusted near surrounding structures and causing them less damage.
Study done by **A Khare *et al*** where in their study fifteen patients in Group I-gel had blood staining of device while in Group Blockbuster LMA, six patients had blood staining of device, and this difference was found statistically significant.[3]
Dsouza R Who conducted the I-Gel vs. Blockbuster Laryngel Mask Airway comparison among patients having surgery for day care According to their research, the two groups' blood-tinged removal did not differ statistically significantly (p = 0.397).[6] In particular, this problem occurred in 2.4% of patients in the Blockbuster LMA group and 4.9% of patients in the I-gel group.

In our study there is no statistically significant result found in respect to sore throat at different time intervals and in modality of level of sore throat between Baska mask and Blockbuster LMA. The lower incidence of sore throat in our study could be due to short duration of surgery, thereby resulting in less tissue damage.

Study done by **Al-Rawahi**[14] where Baska mask and Proseal LMA were compared and study done by **Premkumar KG**[15] where Blockbuster LMA and Proseal LMA was

compared, both studied found that there was no statistically significant difference in respect to sore-throat. In study by **Al- Rawahi et al** where they found that the Baska mask had 8 (26.7%) incidence and Proseal LMA had 9 (40.9%) incidences with p-value of 0.279 which is non-significant.

Comparative Study Between LMA BlockBuster and LMA ProSeal in Patients Undergoing Operative Procedures Under General Anaesthesia done by **Saxena A** found non-significant result in incidence of sore throat which was like our study finding.[8]

Limitations

This study had some limitations. The study was done in a single center with limited patients. ASA grade III and IV patients and patients with difficult airways were excluded. Second, the patients involved in this study were single-centered and there was heterogeneity in the surgery performed. As a result, more research may be required to complete the validation analysis based on the findings of this investigation.

CONCLUSION:

The observations made in this study are that Baska mask was superior in terms of time taken for insertion in seconds in comparison to Blockbuster LMA, Ease of insertion, Oropharyngeal leak pressure, Number of attempts for insertion were found to be non-significant. Blood stain on device was marked increased in Blockbuster LMA group with no significant difference seen in terms of sore throat at different intervals. There is role of both Blockbuster LMA and Baska Mask in terms of safety and efficacy in Day care surgery and in management of maintaining adequate airway.

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