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Original Research Article

Comparision Of Efficacy And Complications Between Baska Mask And Classical Lma In Anaesthetised Spontaneously Breathing Patients-A Randomised Controlled Trial.

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ABSTRACT

Objectives: Extraglottic airway devices (EGD) like the laryngeal mask airway (LMA) and the Baska mask are commonly used for minor surgical procedures under general anaesthesia. These devices are intended to be used as an alternative to traditional endotracheal intubation, which can be difficult and time-consuming, as well as risky, such as airway trauma, bleeding, and infection. EGDs have the advantage of being relatively easy to insert and requiring less training than traditional intubation techniques. As a result, they may be useful for less experienced anaesthetists or in emergency situations. The LMA is a well-known EGD that has been in use for more than 20 years. It consists of a mask-like device that sits over the larynx and is sealed by an inflatable cuff.

Methods: One forty patients with American society of anesthesiology class 1 and 2 undergoing minor surgeries were randomized to either have their airway maintained with baska mask or cLMA. Ease of device insertion, number to attempts, time taken to insert the device, airway leak pressure hemodynamic responses and post op complications if any were evaluated. The statistical analysis was done using student t test and chi-square test.
A p value <0.05 was considered to be statistically significant.

Results: Compared to classical LMA, baska mask required a longer time for insertion (48.0±18.03), (74.26±22.17) p value-0. 0001.Baska mask required a greater number of attempts to be placed and its first attempt success rate was only 30%whereas classical LMA is 61% p value -0.002.the airway leak pressure was higher in baska mask (33.40±1.57) when compared to classical LMA (19.47±2.28). hemodynamic parameters were stable in both the groups. post operative complications was higher with baska mask.

Conclusion: The baska mask provides a better oropharyngeal leak pressure than cLMA, but it is inferior to cLMA in terms of first pass success rate, number of attempts, duration, and ease of insertion.

Keywords: anesthesia, airway, extra glottic device, baska mask, seal pressure

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INTRODUCTION

Extraglottic airway devices (EGD) such as the laryngeal mask airway (LMA) and the Baska mask are widely used for minor surgical procedures under general anesthesia. These devices are designed to provide an alternative to traditional endotracheal intubation, which can be difficult and time-consuming, and carry risks such as airway trauma, bleeding, and infection. One of the main advantages of EGDs is that they are relatively easy to insert and require less training than traditional intubation techniques. This can make them a useful option for less experienced anaesthetists or in emergency situations[1-3].

The LMA is a well-established EGD that has been in use for over 20 years. It consists of a mask-like device that sits over the larynx, with an inflatable cuff that seals the airway. The LMA is available in several different versions, including the classic laryngeal mask airway (cLMA) and the ProSeal LMA, which incorporates a second seal to reduce the risk of air leaks.

The Baska mask is a newer EGD that was first introduced in 2002. It is similar in design to the LMA, but features a more curved shape to better fit the contours of the upper airway. The Baska mask also has a second aperture behind the main mask, which allows for the use of a continuous positive airway pressure (CPAP) circuit[4-6].

The objectives of this study were to compare two different generation SAD in relation to number of attempts, time of insertion, airway leak pressure, ease of intubation, hemodynamic changes intraoperative and post operative complications in anaesthetized spontaneously breathing patients posted for elective minor surgeries.

METHODS

Study primer:-This prospective randomized controlled study was approved by the institutional human ethics committee and followed the principles laid down in the declaration of Helsinki.Patients scheduled for elective minor surgeries formed the study population.

Inclusion and Exclusion criteria:-From the study population patients between 18 and 60 years of age, body mass index (BMI) less than 35 kg/m2, American Society of Anaesthesiologists physical status I and II who gave written and informed consent were included.

Patients with anatomically difficult airway, reactive airway diseases, pregnant patients, patients with laryngeal and pharyngeal pathologies were excluded.

Randomization:-The patients were randomly categorised into two groups of 70each (group I: baska mask group B: cLMA) by computer-generated random numbers that were enclosed in a sealed envelope opened only at the time of induction. The size of the SAD chosen were based on the patient's body weight, in line with the manufacture's recommendation (Size 3 for weight 30-50 kg, size 4 for 50-70 kg, size 5 for 70-100kgs).

Data collection:-All the patients were kept nil per oral for 6 hours . A 18 g venflon was secured and they received intravenous Injection(Inj). midazolam 1 mg, Inj.glycopyrollate 0.2 mg and Inj ondansetron 4mg half an hour before the surgery in the pre-anesthetic room. On arrival in the operating room, after the placement of standard monitoring devices (pulse oximetry, ECG and NIBP) patients were preoxygenated for three minutes with 100 % oxygen. Anaesthesia was induced with Inj Propofol 1%, 2.5mg/kg IV and fentanyl 2µg/kg IV. Patients were ventilated with oxygen for one minute by bag and mask. Anaesthesia was considered adequate for device insertion when the patient was unresponsive with no spontaneous respiration, jaw relaxed and had lost eyelash reflex. Corresponding device, of appropriate size (according to the weight of the patient) was lubricated and inserted, bilateral(B/L) air entry was checked and the device was secured with tape. For successful device insertion following factors were considered b/l chest raise and a satisfactory ETCO2 value. Anaesthesia was maintained with nitrous oxide and oxygen along with sevoflurane and patient was maintained in spontaneous ventilation. If an effective airway could not be achieved the SAD was removed and reinserted in the same technique. A total of 3 attempts were permitted

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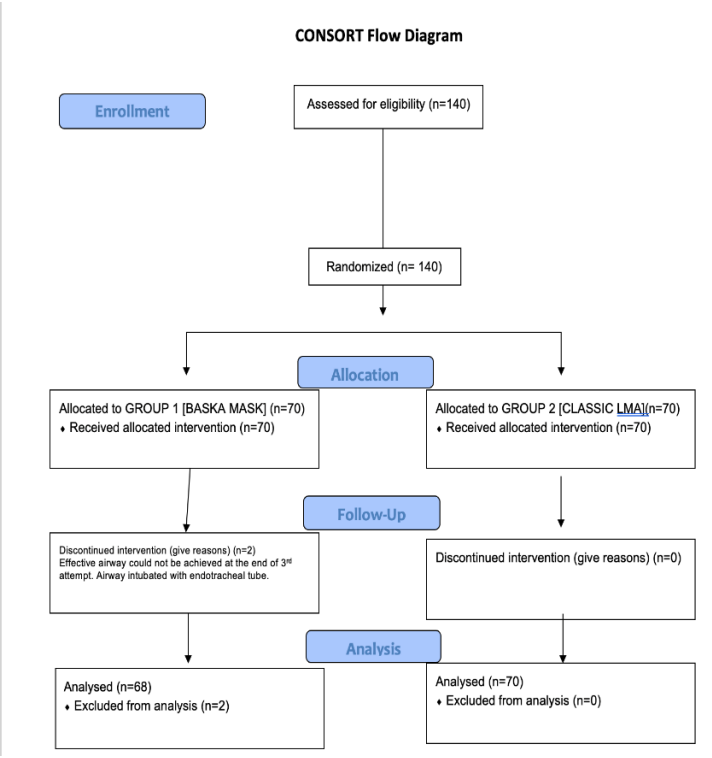
before it was interrupted as failure and airway was managed with endotracheal intubation and will be excluded from the study.

Outcome measures:-The primary outcome of the study was to compare Number of attempts, time for insertion, Airway leak pressure, Ease of insertion. The secondary outcomes were Hemodynamic Responses and Complications such as Sore throat, Post Removal Cough, Dysphagia, Dysphonia

Variables:-Insertion time was calculated from the time taken from picking up the airway in the hand to the successful placement of airway as confirmed by auscultation of bilateral equal air entry over the chest. In the event of desaturation (SPO_2 <95%) during the three attempts, rescue ventilation was planned with bag and mask and that time period was also be included in the total insertion time. Number of insertion attempts was recorded. Ease of insertion is defined as no resistance to insertion in the pharynx in the single maneuver [10]. Its graded as easy when no airway manipulation is required. Satisfactory when less than two maneuvers are required and when more than two maneuvers are required its graded as difficult. Maneuvers were neck extension, jaw thrust, chin lift, flexion, gentle pushing or pulling of the device. Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and recording the oropharyngeal leak pressure by detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage. The corresponding airway pressure displayed in the monitor was recorded. Heart rate in beats per minute, blood pressure in mm/hg and saturation in percentage were monitored prior to insertion at 0 and every minute until 10 minute and then every 5 minutes until 30 minutes after securing the airway.

Following surgery, the device was removed when the patient was awake and responsive. On removal of the device, cough, signs of regurgitation and aspiration were looked for. All patients were followed up for 24 hours for any dysphagia, dysphonia and sore throat. With the hypothesis testing for single proportion, and a population proportion of 0.73, Alpha error of 5 and a power of 80, a sample size of 140 was derived. The parametric data were tested with student t test and the non-parametric ranking with chi square tests and a p value of < 00.05 was considered significant.



RESULTS

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From all the one forty patients of the study, in two patients of baska mask group, effective airway was not achieved at the end of 3rd attempt, hence they were intubated with endotracheal tube and were excluded from the study. One thirty-eight patients completed the study.

The two study groups were comparable for age, sex, weight, ASA physical status and mallampatti class. Compared to cLMA, baska mask look longer time to insert with mean value of 74.26±22.71, whereas the mean value of cLMA was 48.04±18.03 with significant p value (0.0001). The ease of insertion was better and first attempt success rate was higher in cLMA (61.4%) when compared to baska mask (30.9%) p value (0.0002). Baska mask has a greater oro-pharyngeal leak pressure (33.40±1.57)than cLMA(19.17±2.28).(Tables 1 &2) The incidence of postoperative sore throat was significantly lower in C LMA group. (Table 3)

Hemodynamic stability was comparable in both the groups. Post operative complications were statically not significant.

Table 1 - DEMOGRAPHIC DATA

	Group 1 baska mask	Group 2 classic lma
Age (years)	35.19±10.12	38.01±11.80
Sex	28:40	23:47
Weight	60.93±10.73	58.10±7.47
Asa (1:2)	56:12	56:14
MPC (1:2)	41:27	43:27

Table 2 outcome variables and statistical significance

	GROUP 1 Baska mask	**GROUP 2** cLMA	p value
Insertion time	74.26±22.71	48.04±18.03	**0.0001**
Number of attempts 1 2 3	n (%) 21(30.9) 29(42.6) 18(26.5)	n (%) 43(61.4) 16(22.9) 11(15.7)	0.0002
Oro-pharyngeal leak pressure	33.40±1.57	19.17±2.28	**0.0001**
Ease of insertion Easy Satisfactory Difficult	n (%) 21(30.9) 32(47.1) 15(22)	n (%) 41(58.6) 20(47.1) 9(12.9)	**0.0001**

Table 3 with post operative complications;

	GROUP 1 Baska mask	**GROUP 2** cLMA
Sore throat	**16**	**5 (p< 0.05)**
Post removal cough	4	3
Dysphagia	0	0
Dysphonia	0	0

DISCUSSION

Our results showed that baska mask provided a better seal when compared with cLMA. However, baska mask is more difficult to insert than cLMA with lower first pass success rate and longer insertion time. There was also an increased rate of post operative sore throat in baska mask group.

In our study the first attempt success rate in cLMA was 61% whereas in baska mask was only 30 %. Among the study population effective airway was not achieved in 2 patients even at the end of third attempt, hence they were intubated with endotracheal tube and according to our study protocol they were excluded from the study. We attribute this to the size of baska mask used. We followed the manufactures recommended size of the baska mask depending on the weight of the patient. In both the patients baska mask used was larger to the patient, hence the unsuccessful insertion. Others studies have also found similar results where the first attempt success rate was higher in cLMA than baska mask [7-9].

In our study, baska mask required a longer time to insert which was 74.26±22.71seconds than cLMA which was 48.04±18.03seconds. Alexiev et al(7)in their randomized control trial observed that Baska Mask requires a Longer time to insert when compared to cLMA and it was statistically significant. Similarly bindal et al(8) reported a longer insertion time for baska mask which was 12.04 when compared with cLMA is 5.78seconds . Other studies have also found longer insertion time for baska mask with median insertion time as 14 seconds (9).

In our study insertion of baska mask was easy in 21 patients whereas in cLMA it was easy is 41 patients. Alexvier et all in their study concluded that Baska Mask proved more difficult to insert and had higher median insertion difficult scores (1.6(0.8-2.2) (0.1 – 5.6)) vs 0.5(0.3-1.4(0.1-4.0)) respectively $P < 0.001$. similarly in our study 32 patients in baska mask required minimum of two maneuverers and 15 patients required more than two maneuverers for insertion. But in cLMA group only 20 and 9 patients required minimum of two and more than two maneuverers for insertion respectively. Other literature study reported that 44%of the patients required additional maneuverers for insertion of baska mask and also a higher need for manipulation for insertion of the baska mask device [9].

In our study, Baska Mask has a higher oropharyngeal leak pressure (33.40 ±1.57) cm H_2O than Classic LMA (19.17 ±2.28) cm H_2O, which is statistically significant. literature studies also shows the similar results [7,9]. This means that baska mask has a higher sealing pressure and provides adequate ventilation than cLMA.

With respect to hemodynamic there is no statistical significance between the two SAD devices. Other investigators also found no significant changes in hemodynamic monitoring.

In our study population Post removal cough was noted in 4 patients in Baska mask group and 3 patients in cLMA group. But this report was statistically insignificant. On the contrary bindalal et al. reported a greater number of post removal cough in cLMA than baska mask. In our study sore throat was seen in 16 patients in Baska Mask group and 5 patients in cLMA group. No incidence of dysphagia and dysphonia were noted in both the group. One more study suggested that the use of the GEB method for inserting the PLMA in patients with simulated restricted neck mobility may be more effective than the IT method in terms of positioning and ETCO2 values, despite taking longer[10-12]. However, it is also important to note that the study had a small sample size and that there are other factors to consider when selecting the method of insertion, such as the expertise and comfort of the clinician performing the procedure.

LIMITATIONS

As the study involved SAD, the person performing could not be blinded to the study. The operators who inserted the SAD had more experience with cLMA. However, all the operator received prior training with baska mask to eliminate this bias. As it is not double blinded there could be investigator bias, especially with user reported difficult scores.

CONCLUSION

This study compared the use of two different supraglottic airway devices, the Baska mask and the classical laryngeal mask airway (cLMA), in 140 patients undergoing minor surgeries under general anesthesia. The results showed that the Baska mask had a longer insertion time and a higher number of insertion attempts compared to the cLMA, with a lower first-pass success rate. The Baska mask

also had a higher oropharyngeal leak pressure and a higher rate of postoperative complications compared to the cLMA. The hemodynamic parameters, or measures of heart function, were stable in both groups. Overall, the cLMA was found to be superior to the Baska mask in terms of ease of insertion, success rate, and number of attempts, as well as postoperative complications.

Conflict of interest- NIL
Financial aid -NIL
Concept, data collection- PN, design and data- BG, manuscript and communication- SPS
Ethical issues – Yes- IEC/SRM/1108/2017

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