Original Research Article

Comparison of Baska mask and classical laryngeal mask airway in anaesthetised non-paralysed adult patients

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Abstract

Background: To compare the Baska mask with classical Laryngeal mask airway (cLMA) with respect to seal pressure, rate of first time successful insertion and overall success rate, attempts at insertion, hemodynamic profile and complications. **Methods** The study was conducted on 60 patients of ASA grade I and II posted for elective surgeries under General Anaesthesia at Guru Nanak Dev hospital Amritsar attached with Govt. Medical College Amritsar. Patients were allotted into 2 groups of 30 each: Group B (Baska mask) and Group L (classic Laryngeal mask airway). **Results:** Baska mask provides a higher seal pressure (36.83 cm H_2O) compared to classic LMA (17.80 cm H_2O) at insertion. No statistically significant difference was reported between the two groups, regarding hemodynamic changes and complications like trauma and blood staining etc. **Conclusion:** Baska mask is another step forward in the search for an unsurpassed supraglottic airway device and can serve as desirable, auxiliary airway device for short surgical procedure with minimum complications

Keywords: Airway sealing pressure, Baska mask peak airway pressure, Supraglottic airway device.

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INTRODUCTION

Airway management is one of the most important skills to master during the delivery of anaesthesia and to ensure adequate oxygenation and ventilation to the patient. There has been a lot of consideration regarding the airway and affliction faced during its management and this led to the evolution of array of devices which can result in better anticipation and decision making.[1] Endotracheal intubation has been considered as gold standard technique during general anaesthesia. However some unpleasant complications are associated with it for example, trauma to lips, teeth, tongue, epiglottis, larynx and even trachea, hemodynamic instability, sore throat as it requires laryngoscopy and manipulation of vocal cords; supraglottic airway devices (SGA) have evolved as alternative to endotracheal intubation. SGA insertion requires comparatively low anaesthetic depth, result in less haemodynamic stir and a lower frequency of airway complications such as coughing and sore throat from anaesthesia as compared to endotracheal intubation.[2] The laryngeal mask airway (LMA) is a useful addition in the airway management, filling a niche between facemask and endotracheal tube. It has been considered as a good alternative to bag-valve-mask ventilation which helps in freeing the hands of the anaesthesia provider with the benefit of more haemodynamic stability, lesser gastric distension and airway related morbidity.[3] Baska mask is the latest addition to an array of supraglottic airway devices in clinical use. It has been designed by Australian anaesthetists Kanag and Meena Baska. It is available in single and multi-use versions and made of hypoallergenic silicone latex polymer with adequate shore hardness except

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for the 15 mm connector, which fits into the proximal ends of the main (ventilation/breathing) airway tube and clearance tubes and an interchangeable (left or right) swivel suction elbow, attached to either of the suction/air inflow ports. The Baska mask also has a bite block throughout the entire length of the airway tube which makes the airway patent at all times. The oval-shaped airway tube matches the shape of the mouth and reduces rotation within the pharynx. The mask can be easily inserted in the neutral position. It is currently available in four sizes: 3, 4, 5 and 6 for patients weight ranging between 30 to >100 kg.[4] In short, it brings together the features of LMA Proseal (high seal pressure, gastric access port and bite block which facilitate ventilation, provide airway protection and minimise airway obstruction), LMA supreme (oval shaped, anatomically curved airway tube which incorporates a gastric drain tube), I-gel (gel like cuff instead of inflatable balloon) and SLIPA (cuffless, anatomically pre-shaped sealer with sump reservoir). However, Baska mask has been included in second generation supraglottic airway devices by many authors and its classification as a third generation device is controversial.[5] Since baska mask is a newly introduced device in India, not much literature is available regarding its use alone and comparison with other available supraglottic airway devices. Moreover no such study has been conducted in our set up so we have done this study.

MATERIAL AND METHODS

After obtaining approval from the Institutional Ethics Committee, along with written and informed consent, a total of 60 patients of either sex belonging to ASA (American society of Anaesthesiologist) grade I-II aged 18-60 years scheduled to undergo general anaesthesia were enrolled in a prospective, randomised, comparative study. The patients were selected through computer generated randomization list software. The patients were further divided into two groups of 30 each and posted for surgery under general anaesthesia. Patients with inadequate mouth opening, BMI > 35 kg/m2, anticipated difficult airway, patient having high risk of aspiration like gastro esophageal reflux disease, hiatus hernia, oropharyngeal pathology, ASA grading III, neck pathology and pregnancy were excluded from the study. To maintain the blinding, the investigator was not involved in opening the envelope. The other anaesthesiologist not involved in the study was asked to open the envelope just before the administration of general anaesthesia. The same anaesthesiologist was not involved in the management and taking observations. Pre-anaesthetic check-up including a detailed history and thorough general examination of the patient was carried out a day before surgery and was recorded. All patients included in the study were kept nil orally for 12 hours preoperatively. On arrival to operation theatre, baseline vital parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, SpO_2, $EtCO_2$ were recorded. An intravenous line was secured with 20G cannula and 10ml/kg/hr ringer lactate infusion was started. Anaesthesia was induced in the supine position with the patient's head in the neutral position, resting on a pillow about 8 cm in height and was pre-medicated with fentanyl 2 microgram/kilogram (µg/kg) body weight and injection glycopyrrolate 0.2 milligram (mg) intravenously. After recording baseline parameters and administering 100 % oxygen, preservative free lignocaine 2 % (1-2 milligram /kg) was given to attenuate the pain from propofol injection. Patient was given injection propofol 2-4 mg /kg intravenously. Anaesthesia was considered adequate for device insertion when the patient became unresponsive; not responding to anterior jaw thrust and eyelash reflex was abolished. Following propofol, patient was manually ventilated with sevoflurane, O_2 and N_2O (50:50). Predetermined appropriate sized supraglottic airway device was then introduced into the oral cavity of the patient and secured after checking successful placement which was defined as the presence of bilateral chest expansion, satisfactory end tidal carbon dioxide (CO_2) tracing with plateau and a leak fraction less than 1/3 third of the inspired tidal volume. After successful placement of supraglottic airway device, general anaesthesia was maintained with O_2: N_2O (50:50), sevoflurane and intermittent positive pressure ventilation. Analgesia was provided using fentanyl intravenously in intermittent doses. At the end of surgery, anaesthetic gas mixture was replaced with 100 % O_2 and Baska mask /cLMA was removed when protective reflexes returned to normal. We also observed that Baska mask cuff can easily be decreased in size by compressing between thumb and fingers, making insertion easier. Further, presence of hand tab helped us to control the degree of flexion of device aiding in easier insertion. Time of insertion was measured in seconds from the time the device was picked up by the operator until attaching it to the breathing circuit.Ease of insertion for Baska mask was categorised as very easy / easy / difficult /very difficult on the basis of resistance to insertion, number of attempts and additional manoeuvres needed. Very easy - very easy insertion at first attempt with no resistance; Easy - use of hand tab required; Difficult - use of additional manoeuvres- like jaw thrust, head extension; very difficult - more than one attempt needed. Ease of Insertion of classic Laryngeal mask airway was graded as follows: Very easy - very easy insertion at first attempt with no resistance; Easy - some resistance to insertion during first attempt; Difficult- impossible to insert without manipulations, additional manoeuvres required; Very

difficult- more than one attempt needed. Airway sealing pressure was the pressure at which leak starts (the point where minimum leak was heard), this leak pressure was calculated as the plateau airway pressure reached with fresh gas flow 5-6 litres/min, and pressure adjustment valve set at 70 cm H_2O. It is measured at insertion and then after 30 minutes post placement respectively. At the time of removal of the mask, its shape and blood staining of any of the device was checked thoroughly. Patient was monitored for any complications following the removal of device and then shifted to post anaesthesia care unit. After surgery, pharyngolaryngeal complications such as sore throat, dysphonia, and dysphagia were assessed at 2, 4, 6, 8, 12 and 24 hours postoperatively. The postoperative sore throat pain was treated by intravenous fentanyl 1-1.5µg/kg in titrated doses according to patient's comfort. Sample size was calculated keeping in view at most 5% risk, with minimum 85% power and 5% significance level (significant at 95% confidence interval). Raw data was recorded in a Microsoft excel spread sheet and analysed using IBM SPSS (Windows ver.23.0, IBM SPSS, Armonk, 2015, New York). Continuous variables such as age, height, weight, device insertion time, sealing pressure were compared between two groups using unpaired t-test and they were presented as mean with standard deviation (mean ± SD). Categorical variables such as device insertion attempts, ease of insertion, and complications were compared using Chi –square test. The p value was determined finally to evaluate the levels of significance. The p value of >0.05 was considered non-significant, p value of 0.01 to 0.05 was considered significant and p value <0.001 was considered highly significant. The results were then analysed and compared to previous studies.

OBSERVATIONS AND RESULTS

With respect to the demographic parameters, the patients in the two groups were analogous as is evident from Table 1. The mean duration of surgery was 48.33 ±9.03 min in group B and 45.50±9.40 min in group L and the difference was statistically nonsignificant (p>0.05). Haemodynamic parameters were also found to be insignificant (p>0.05) in both the groups. The difference in number of attempts and ease of insertion between two groups was comparable and statistically insignificant. Though the first time success rate in Baska mask is less but overall successful rate was comparable between both the groups as shown in table 2. In our study, the time taken for insertion of group B was 14.30 seconds and for group L was 19.53 seconds and it was found to be statistically significant (p<0.05) as shown in table 2. Additional manoeuvers were required in 4 patients (13.30%) of Group B and 2 patients (6.70 %) patients of Group L as shown in figure 1. It was found to be statistically non- significant (p >0.05) We have seen that Baska mask provides a higher seal pressure (36.83 cm HO) compared to cLMA (17.80 cm H_2O) at insertion as shown in figure 1. Seal pressure increases to 41.53±2.96 in group B and 21.33±2.85 in group L as the duration of anaesthesia increases as shown in figure 2. With Baska mask, neither cuff inflation nor deflation is required. The seal depends on its flexible membrane. Since cLMA depends upon an inflated cuff to make a seal, it poses potential hazards of cuff pressure. Over inflation may cause airway trauma and under inflation may lead to leak and aspiration. In group B and L mean peak airway pressure was 15.87$\pm$ 2.37cm H_2O and 14.40$\pm$2.54 cm H_2O respectively and the difference in the mean peak airway pressure was statistically significant (p= 0.02) as shown in figure 3. Complications during insertion like laryngospasm, trauma and blood staining were found to be insignificant in both the groups as shown in table 3. Sore throat and dysphagia were seen in patients of group L and its incidence was maximum at 4 and 6 hours postoperatively which was statistically significant (p<0.05) as shown in table 3. Dysphonia was not seen in any patient in either group.

DISCUSSION

Baska mask is a supraglottic airway device with non-inflatable cuff for better airway seal which increases with each positive pressure ventilation. It has a hand tab, oesophageal drainage inlet, high volume suction clearance for suctioning of gastric contents and integrated bite block.[6] In Group B, device size 3 was used in 80 % of patients and size 4 was used in 20 % of patients whereas in Group L size 3 classic LMA was used in 73.30 % of patients and size 4 classic LMA was used in 26.70% of patients and the distribution of size between two groups was comparable (p value >0.05). The size selection of Baska mask and classic LMA was based on patient's ideal body weight and manufacturer's instructions for each device. Size 3 and 4 were selected for the patient with weight 30-50 kg and 50- 70 kg, respectively.

In Group B, first attempt success rate was 86.7% and second attempt success rate was 13.3%, whereas, in classic LMA first time success rate was 93.3%. Though, the first time success rate of group B was lower than group L but overall success rate was not statistically significantly (p >0.005). Our results were in accordance with study by Zundert Tv *et al.* [4] where first time success rate of Baska mask was 88 % and overall success rate was 92 % and took 16 seconds for insertion. Our results are also supported by a similar study conducted by V Alexiev *et al.* in 30 female patients where first time success rate was 76.7% while the overall success rate of Baska mask insertion was 96.7%.[7] The number of attempts was noted and it was considered a failure, if the insertion was not successful in three attempts.

Thereafter, a different size of the same device was tried. Only the successful attempt time was counted. In our study, we noted that number of attempts needed to place the device correctly was almost comparable in both the groups. In group B and L, the mean time for device insertion was 14.30±1.64 seconds and19.53±3.04 seconds respectively. Our study findings were supported by Sachinanda *et al.*[8] and Tom Van *et al..*[4], where Baska mask took 14.9 seconds and 16 seconds for insertion respectively. Our results were also supported by Zundert V *et al..* [9] observed that mean time required to place the classic LMA was 19.20 seconds. This is attributable to the fact that cuff inflation and volume adjustment was required in classic LMA so time required to achieve effective airway is longer.[10] The difference in mean insertion time between two groups can be attributed to two factors. First, any difficulty in negotiation of the oropharyngeal curve could be overcome by pulling the tab of Baska mask which increases its distal curvature. Secondly, there is no inflatable cuff in Baska mask, so time to inflate the cuff and volume adjustment as required in classic LMA was not required in Baska mask. Duration of each attempt was measured from the time of picking up the device until attaching it to the breathing system. Insertion of Baska mask was to be very easy in 10 patients (33.3%), easy in 12 patients (40%), difficult in 4 patients (13.3 %) and very difficult in 4 patients (13.3%).Our results were supported by Zundert Tv [4] where ease of insertion was very easy, easy, difficult, very difficult in 36%, 26%, 2%, 0% respectively. Anil kumar MR *et al.*[6] evaluated ease of insertion of Baska mask in 100 patients and concluded that ease of insertion was very easy, easy, difficult, and very easy in 88%, 10%, 1%, and 1% respectively. Insertion of LMA classic was found to be very easy in 12 patients (40 %), easy in 14 patients (46.7%), difficult in 2 patients (6.70%) and very difficult in 2 patients (6.7%) and the difference in the ease of insertion between the two groups was statistically non-significant (p>0.05). Additional manoeuvers were required in 4 patients (13.30%) of Group B and 2 patients (6.70 %) of Group L. This difference between the groups was found to be statistically non-significant (p >0.05) Following manipulations were performed in case the device did not function properly. We adjusted the depth of insertion by pushing the device in 2 patients of Baska mask. In 1 patient of classic LMA we had to withdraw the device slightly in order to achieve better seal. In Baska group, 2 patients required jaw thrust and only 1 patient in classic LMA group needed jaw thrust for device insertion. In our study, we discussed that Baska mask provides a higher seal pressure (36.83 cm H_2O) compared to cLMA (17.80 cm H_2O) after insertion. Our findings were supported by Alexiev V *et al..* [11] compared the Baska mask with the single-use classic laryngeal mask airway (cLMA) and concluded that the Baska mask had a higher airway seal pressure (40 cm H_2O) when compared to classic LMA (22 cm of H_2O) indicating a better seal. The airway seal pressure was measured again after 30 minutes of surgery and we found that seal pressure increased to 41.53 ±2.96 cm H_2O in Baska mask compared to 21.33±2.85 cm H_2O in classic LMA and thereby providing greater airway protection and the mean difference in seal pressure at insertion and 30 minutes in our study was not comparable and was statistically significant ($p < 0.05$). Our results are comparable to mean seal pressure of 42.46 ± 19.12 cm H_2O obtained by Baska mask in a study conducted by Anil Kumar MR *et al.*[6] Our findings were also in accordance with Zundert TV *et al..* study, who found that the oropharyngeal leak pressure of Baska mask was above 30 cm of H_2O in all patients and maximum leak pressure of 40 cm of H_2O was noted in 82 % of patients with the passage of time.[4] The above results could be attributed to the fact that continuous positive pressure ventilation gradually increases the cuff seal around the larynx; hence airway sealing pressure is known to improve over time following insertion of the mask. Therefore it requires 10 -20 breaths to achieve complete seal of the airway. Peak airway pressure is the pressure when there is airflow in the circuit, i.e. during inspiration. It is the airway resistance in the lungs which determine peak airway pressure. So whenever there is problem with the airways the peak pressure will rise. In group B and L mean peak airway pressure was 15.87± 2.37cm H_2O and 14.40±2.54 cm H_2O respectively and the mean peak airway pressure was not comparable in both the groups and was statistically significant (p= 0.02). Our study findings were also supported by Alexiv V *et al..*,[11] where peak airway pressure of Baska mask was higher compared to classic LMA (15.9 cm H_2O versus 14.7 cm H_2O). In our study we observed that there were no significant intraoperative differences between the groups with respect to hemodynamic parameters. Laryngospasm is an uncontrolled or involuntary muscle contraction (spasm) of the vocal folds. Direct laryngeal stimulation can produce laryngospasm in light planes of anaesthesia. There are number of risk factors that can lead to laryngospasm like – insufficient depth of anaesthesia, airway irritation, mucus or blood etc.In our study, laryngospasm was not encountered in any of the patient of group B whereas It was observed in 2 patients of group L but the difference between the two groups was statistically non-significant (p>0.05). Trauma to lips, tongue and teeth was seen in 3 patients (10%) with Baska mask and in 2 patients (6.70%) using classic LMA. The difference in trauma in both the groups was found to be statistically insignificant (p>0.05). Sore throat (constant pain in the throat independent of swallowing) is one of the most common postoperative complaints, which follows tracheal intubation, use of

laryngeal mask airway, oral airway insertion, and even mask ventilation. In our study, sore throat was seen in 1 patient (3.3%) of group B and 5 patients (16.7%) of group L at 2 hour postoperatively. Our study results were supported by Basarigabad A and Panchgar V,[12] who observed that incidence of postoperative sore throat was more with classic LMA as compared to I-gel. The lower incidence of sore throat compared to classic LMA in our study could be because of two reasons. Firstly due to short duration of surgery and second due to non- inflatable soft cuff of Baska mask compared to classic LMA. Since there is no need of inflation of cuff of Baska mask which inflates with positive pressure ventilation, it leads to less tissue trauma, less nerve damage, decreased post- operative morbidity and increased patient satisfaction. In our study, there was no incidence of dysphagia in patients of group B, but was seen in 2 patients (6.7%) of group L. It was more pronounced at 4 hours postoperatively in patient with classic LMA. Neither of the patients in any group presented with dysphonia. Similarly, Alexiv V *et al.* demonstrated that with the use of Baska mask, the incidence of dysphagia and dysphonia was found to be low.[13] The unique distinction of our study is that we have not used any kind of muscle relaxant during insertion of device or during maintenance. The other Strength of our study is minimum postoperative morbidity in the form of sore throat, dysphagia and dysphonia. The main limitation of our study is small sample size. We studied only low risk patients (ASA I and II) who had normal airways. Our data being derived from a single centre may have referral bias and also not double blinded. Lastly, all the Baska mask insertions were not performed by single anaesthesiologist. Although all insertions were done by anaesthesiologist with more than 5 years of experience, varying individual skills might have influence the outcome of our study.

CONCLUSION

We concluded that the Baska mask provides a superior seal compared with cLMA which improved with time and at 30 minutes it was found to be significantly higher compared to our initial readings. This is because of continuous positive pressure ventilation, which gradually increased the cuff seal around the larynx. Also Baska mask took lesser time for insertion compared to classic LMA which can be attributed to presence of tab and non-inflatable cuff in the Baska mask. Incidence of post-operative pharyngolaryngeal morbidity in the form of a sore throat, dysphagia and dysphonia was least with the use of Baska mask. Thus Baska mask is another step forward in the search for an unsurpassed supraglottic airway device which amalgamates an airway tube, a tab to help negotiate the palato-pharyngeal curve, two large tubes entering the sump area, a large sump reservoir, a bite block, and anatomically curved airway tube and can serve as desirable, auxiliary airway device for short surgical procedure with minimum complications. Further studies to compare and assess the clinical efficacy of Baska mask with other advanced supraglottic airway devices are needed to determine the exact place of Baska mask for routine use in anaesthesia. Further evaluation needs to be done in the pregnant and obese adult population and children.

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