

Baska mask®-A third generation supraglottic airway device in clinical practice- A prospective observational study

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Abstract

Introduction and Aim: Supraglottic airway devices are safer alternatives to endotracheal intubation during general anaesthesia. The recently introduced Baska mask is a third generation supraglottic airway device available now in India. As there are no studies about Baska mask published in India, this study was undertaken to evaluate the efficacy and safety of using the Baska mask in patients with no predictors of difficult airway.

Materials and Methods: Hundred patients belonging to American society of Anesthesiologists physical status class I and II with no predictors of difficult airway undergoing elective surgery under general anaesthesia were included for the study. The patients were classified as normal and overweight depending on the body mass index (<25 kg/m² – normal and >25 kg/m² - overweight). The ease of successfully securing the airway with the device was evaluated using the time, the number of attempts and ease of insertion. The correct placement was confirmed by fibre-optic assessment using the Brimacombe scoring system. The airway sealing pressure and leak fraction were estimated. Complications like airway trauma, sore throat, dysphagia and dysphonia were noted after removal. Statistical analysis was done using SPSS software version 22 and assessed by t-test and chi square test.

Results: Mean time of insertion was 9.7±1.9sec. In 97% (n=97) of patients the mask was placed successfully in the first attempt. Airway sealing pressure was 42.46±19.11 cmH₂O and the leak fraction was 8.81±0.03%. Effective ventilation was present in all grades of Brimacombe scoring. Minimal postoperative airway trauma and sore throat were noticed.

Conclusions: Baska® mask is an effective supraglottic airway device which is easy to insert, provides good ventilation and has minimal complications.

Keywords: Supraglottic airway device, Baska mask, Airway sealing pressure, Leak fraction, Brimacombe scoring.

Introduction

Dr Archibald Ian Jeremy Brain is responsible for the development of the first supraglottic airway device (SAD) which he named as the laryngeal mask airway (LMA) in 1983.¹ The Baska Mask® (Logikal Health Products PTY Ltd., Morisset, NSW, Australia) is the first commercially available third generation novel SAD designed by Australian anaesthesiologists Kanag and Meena Baska. The characteristic feature of this mask is that the airway pressure is transmitted intermittently to the flexible element of the cuff so that it inflates and deflates with each positive pressure inspiration and expiration respectively thus forming a perfect seal, reducing leaks and making intermittent positive pressure ventilation (IPPV) very efficient.² It is made of medical grade silicone and is available in four sizes- #3, 4, 5 and 6. The airway tube of the mask has a distal laryngeal aperture in the cuff portion for ventilation and a proximal 15 mm connector for breathing circuit. The cuff is a soft, non-inflatable; self-sealing, pliable membranous structure rendering it non-traumatic during insertion as well as after positioning.³ The oesophageal aperture opens into a sump cavity which is drained by two suction channels present on either side. Thus the virtual separation of the respiratory and gastric tract makes it a superior SAD not only as a ventilatory device but also to prevent aspiration. An

extended hand tab is attached to the proximal portion of the cuff which helps in angulation during insertion of the device.⁴

There are no published studies with the use of Baska mask in India, hence this prospective observational study was undertaken to assess the efficacy and safety of Baska mask as a supraglottic airway device in patients for elective surgery under general anaesthesia (GA) with no predictors of difficult airway.

Materials and Methods

After obtaining ethics committee approval, 100 patients were enrolled in this prospective observational study. The American society of Anesthesiologists physical status (ASA-PS) I and II patients, between 18-60 years of age, of either sex, weighing 30-70 kg and BMI of 20-30 kg/m² undergoing elective surgical procedures of duration 1-1½ h under GA including laparoscopic surgeries were selected for this study. Exclusion criteria included any predictors or history of difficult airway, surgeries in non-supine position, head and neck surgeries, pregnancy, any past allergic reactions to silicone and increased risk for regurgitation and aspiration. A thorough pre-anaesthetic evaluation was done 24-48 h prior to the surgery, height and weight were recorded, BMI was calculated and ASA-

PS was graded. The patients were classified as normal if $BMI < 25 \text{ kg/m}^2$ and overweight if $BMI > 25 \text{ kg/m}^2$. Adequacy of neck movements, thyromental distance, interincisor distance and Mallampatti grading were recorded. Informed written consent was obtained from all patients.

The anaesthesiologists involved had the experience of inserting a minimum of 50 supraglottic airway devices prior to this study. During the pilot study of 20 cases with the Baska mask it was noted that #3 size mask was suitable for patients up to 70 kg and difficulty in insertion of #4 size mask was observed as against the manufacturers recommendation of #4 size for 50-70 kg. Hence it was decided that #3 size Baska mask would be used for all the patients included in the study irrespective of their weight from 30-70 kg.

Standard GA protocol was followed for all patients on the day of the surgery. Preoperative basal monitoring of electrocardiogram (ECG), heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SPO₂) and end tidal carbon dioxide (EtCO₂) were noted. The face mask with side stream EtCO₂ probe was held and the approximate preoperative EtCO₂ reading during spontaneous respiration was noted. This basal parameter was used to know if there is any significant increase in the EtCO₂ values after insertion of the mask. Premedication was with intravenous (iv) injection (inj.) of midazolam 0.02mg/kg, inj. fentanyl 1µg/kg and iv fluid infusion with Ringer's lactate was initiated. Preoxygenation was done with 100% oxygen (O₂) using Drager Fabius Plus anaesthesia workstation. Anaesthesia was induced with inj. propofol 2mg/kg and after confirming adequacy of ventilation inj. vecuronium bromide 0.1mg/kg for muscle relaxation was administered. Patients were ventilated with 100% oxygen for 3 min and after adequate relaxation, a well lubricated #3 size Baska mask was inserted into the oral cavity with the neck in neutral position. The proximal firmer part of the mask was held between the thumb and two fingers, negotiating along the hard palate the mask was pushed towards the pharynx. The hand tab was used only if angulation of the mask was required to curve along the palatopharyngeal part of the airway. The mask was advanced until resistance was encountered and the circuit was connected to the airway tube to check for adequacy of ventilation as indicated by bilateral chest rise and confirmed by capnography.

The insertion time was noted, defined by the time in seconds from the device touching the teeth during insertion to the first view of a near rectangular capnographic curve. If the device placement was found to be unsatisfactory as judged by poor capnographic curve and delivery of inadequate tidal volumes (fractional loss of >20% of set tidal volumes), jaw thrust was performed and the device was moved up and down to achieve an ideal position. If this manipulation in the first attempt was ineffective, the mask was

removed and reinserted attributing it to be a second attempt, failure of which the procedure was abandoned and endotracheal intubation was done using the conventional laryngoscope. Ease of insertion was classified as very easy, easy, difficult and very difficult.⁴ (Very easy – no manipulation, easy – use of hand tab, difficult – use of jaw thrust, very difficult – repositioning of the device after insertion).

A good placement of the device was said to be achieved when SPO₂ >95%, EtCO₂ <45mmHg and bilateral equal chest rise was present. The correct internal placement was confirmed and noted after 5 minutes with Brimacombe scoring system (Table 3) using Fibreoptic bronchoscope (Karl Storz).⁵ Intermittent suction was applied to one of the side suction ports and the other port was left open. Airway sealing pressure in centimetres of water (cmH₂O) at 5 minutes (min) post placement was calculated as the plateau airway pressure with 100% O₂ of 5 litres/min and pressure adjustment valve set at 70 cmH₂O. Leak fraction percentage was calculated using inspiratory tidal volume (V_{insp}) and expired tidal volume (V_{exp}) with the formula $(V_{insp} - V_{exp}) / V_{insp} \times 100$.⁴ Anaesthesia was maintained with intermittent positive pressure ventilation with isoflurane 0.8- 1.5% in a mixture of nitrous oxide and oxygen. Intraoperative monitoring included HR, NIBP, ECG, SPO₂ and EtCO₂. During laparoscopic surgeries the operating laparoscopic surgeon was advised to look for any gastric inflation during the insertion of the port, in between the surgery and at the end of surgery. At the conclusion of surgery neuromuscular blockade was reversed and on meeting all the criteria of reversal the Baska mask was removed making note of any trauma to the oropharyngeal structures as evidenced by blood stains on the mask. The ease of removal was also graded as very easy, easy, difficult and very difficult. Postoperatively, patients were asked about any complaints of hoarseness, sore throat and dysphagia immediately after removing the mask and at 2 h and 12 h postoperatively. Sore throat was graded as none, mild, moderate and severe by the patient.

Sample size was calculated based on the results of previous study⁴ with the mean sealing pressure at 30cmH₂O, Standard Deviation (SD) of 9, relative precision of 10%, and Alpha error of 5%, sample size of 75 was required. However, considering drop outs the sample size was fixed at 100.

The data obtained were analysed using SPSS software version 22 and interpreted as descriptive statistics in the form of percentages or as mean \pm standard deviation (SD). For analysis of continuous variables independent samples t-test was applied and for categorical variables chi-square test was used. Value of $p < 0.05$ was considered significant in this study.

Results

The various demographic and general physical parameters observed in the preanaesthetic evaluation like age, sex, BMI, ASA-PS grading of 100 patients included in this study were recorded and tabulated as in table 1.

Airway characteristics of all the 100 patients included in this study are as shown in table 2.

Adequacy of neck movements was present in all 100 (100%) patients.

Ease of insertion was very easy in 88% (n=88), easy-10% (n=10), difficult-1% (n=1) and very difficult in 1% (n=1) of the patients.

The Brimacombe grading obtained after insertion of Fiber-optic scope through the mask is depicted in table 3.

Securing the airway and adequacy of ventilation using the Baska mask were studied using the parameters as shown in table 4 and the same was compared between normal and overweight population. For comparison of mean time of insertion between normal and overweight individuals t-test was used and numbers of attempts across BMI categories were assessed using chi square test.

Gastric inflation was noticed only in 2/41 laparoscopic cases at the time of insertion of the port

Total duration of surgery was 94.59±43.17 minutes and the duration of anaesthesia was 105.58±43.27 minutes. Ease of removal of the mask at the end of surgery was classified as very easy in 97% (n=97) and easy in 3% (n=3) of patients.

Complications during or after removal of the mask were minimal, taking into account blood staining of the mask which was nil in 95% (n=95) of patients and mild staining in 5% (n=5) of patients. None of the patients had dysphagia or dysphonia at any given time. The incidence of sore throat after removal of the mask is as shown in table 5.

The haemodynamic changes were not significant when compared with the preoperative values and at 30 min following the insertion of the mask are shown in table 6.

There was no episode of desaturation and oxygen saturation was maintained above 95%, and EtCO₂ was maintained between 35-45 mmHg in all the study patients throughout the procedure as shown in the graph 1.

Table 1: Demographic Profile

Parameters		Mean±SD	variables n(percentage)	
Age(years)		40.08±13.1		
Weight(kg)		61.14±7.55		
BMI (kg/m ²)*		23.03±2.4	< 25 (normal)	78(78%)
			>25 (overweight)	22(22%)
ASA	I		24(24%)	
	II		76(76%)	
Sex	Male		33(33%)	
	Female		67(67%)	

n- number of patients, SD-standard deviation, ASA-American Society of Anesthesiologist, BMI- Body Mass Index, *-World Health Organisation Classification

Table 2: Airway characteristics

Airway parameters	mean±SD	n(Percentage)
Thyromental distance(cm)	7.18±0.47	
Inter-incisor distance(cm)	4.15±0.46	
Dentition-		
a)buck teeth		1(1%)
b)intact teeth		95(95%)
c)loose teeth		4(4%)
Mallampatti class		
a)I		85(85%)
b)II		15(15%)

N-number of patients, SD- Standard deviation

Table 3: Anatomical position of the baska mask as per brimacombe grading

Grade (anterior-posterior- rima glottidis distance)	n (Percentage)
I (75-100%)	78(78%)
II (50-75%)	10(10%)
III (25-50%)	04(04%)
IV (00-25%)	03(03%)
V (no vocal cords, only epiglottis visible)	05 (05%)
VI (no vocal cords/epiglottis visible)	0(00%)

N- number of patients

Table 4: Comparison of normal and overweight patients with securing the airway and effective ventilation parameters

Variables	All patients	Normal	Overweight	p value
Insertion time(seconds)	9.7±1.9sec	9.5±1.89sec	10.25±2.15sec	1.85
Attempts	1st attempt	n=97(97%)	n=77(98.71%)	0.051
	2nd attempt	n=3(3%)	n=1(1.29%)	
Airway sealing pressure (cm H2O)	42.46±19.12	42.63±4.1	41.87±5.05	0.472
Leak fraction (%)	8.81±0.03	7.02±2.2	8.3±2.4	0.02

p value<0.05-significant, n-number of patients

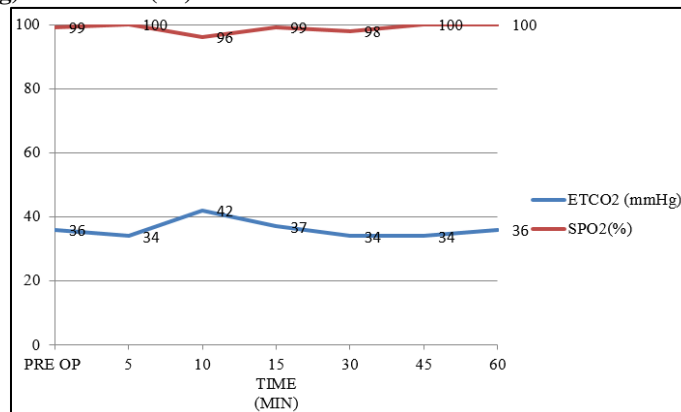
Table 5: Incidence of sore throat

Time	Severity of sore throat	n (percentage)
Immediate post-removal of SAD	None	83(83%)
	Mild	15(15%)
	moderate	02(02%)
	Severe	0(00%)
2 h	None	91(91%)
	Mild	09(09%)
	Moderate	0(00%)
	Severe	0(00%)
12 h	None	91(91%)
	Mild	09(9%)
	Moderate	0(00%)
	severe	0(00%)

N-number of patients,

Table 6: Haemodynamic changes:

	Pre op	15 Min	30 Min	P value
MBP (mm Hg)	86.14±5.237	88.43±5.728	88.47±9.712	0.987
SBP (mm Hg)	122.18±8.912	123.23±9.449	124.23±16.498	0.775
DBP (mm Hg)	70.124±7.142	71.70±7.359	71.17±8.682	0.798
HR (per minute)	72.12±11.236	76.47±12.428	77.73±12.163	0.691

Graph 1: EtCO₂ (mm Hg) and SPO₂ (%) values before and after the insertion of the Baska mask

Discussion

This was an observational study done to evaluate the safety and efficacy of the Baska mask in adult

patients undergoing general anaesthesia for elective surgeries. As this was a novice study, patients with any

predictors of difficult airway and risk of aspiration were excluded from the study.

Successful insertion of the mask was obtained in the first attempt in 97% with ease of insertion being very easy in 88% of patients. In a similar study, "first attempt" success rate of 88% and overall "easy to very easy" insertion rate of 92% in adult patients was obtained in patients undergoing surgical interventions.⁴ The Baska mask cuff can easily be decreased in size by compressing the proximal, firmer part of the mask between thumb and fingers, making insertion easier. The extended hand tab attached to the cuff permits the operator to control the degree of flexion of the device aiding in easier insertion. In our study when the insertion of the mask in the first attempt was very difficult in 1% due to the presence of buck teeth, the hand tab was used to angulate the mask which enabled the operator to place the mask in the appropriate position in the second attempt.

The mean insertion time required to successfully place the mask was 9.7 ± 1.9 sec in our study. Mean insertion time of 23.9 sec was obtained in a similar study when the Baska mask was used in 30 low risk female patients.⁶ The duration progressively decreased over time as the investigator became more adept with the device, with a mean time of just over 10 sec in the last five patients. The time required to insert the mask depends on the expertise of the user and the ease of insertion which is largely contributed by patient factors. It was noted that patients with BMI $>25\text{kg/m}^2$ had a longer duration of insertion when compared with patients of BMI $<25\text{kg/m}^2$, but it was not clinically or statistically significant. This proves that the Baska mask can be placed easily even in overweight patients. However, our study was restricted to patients of BMI $<30\text{kg/m}^2$. Hence further studies are required to know the ease of insertion in overweight or obese patients. Number of attempts required for the successful placement of Baska mask in normal and overweight individuals was not statistically significant (p value-0.051).

Airway sealing pressure was obtained at a mean of 42.46 ± 19.12 cmH₂O with an average leak fraction of $8.8 \pm 0.03\%$ in our study. The high sealing pressure obtained by the shape and surrounding structures of the laryngopharynx with an intermittently inflated cuff is useful in providing effective ventilation during positive pressure ventilation with a minimum leak. This superior seal is a potential advantage in laparoscopic surgeries where gastric distension can be avoided. In our study during laparoscopic procedures (41 cases) gastric inflation was noticed in only 2/41 cases at the time of insertion of the laparoscope for which Ryle's tube was inserted through the side channel of the mask and deflated. Comparative study was undertaken between the Baska mask and single use classic laryngeal mask airway (cLMA) in 150 females undergoing ambulatory surgery in which 21(30%) were subjected to

gynaecological laparoscopic surgeries. This study concluded that in clinical conditions where the seal with the glottic aperture takes priority over ease of insertion, the Baska mask may provide a useful alternative to cLMA.⁷

The leak fraction was significant (p value -0.02) between normal ($7.02 \pm 2.2\%$) and overweight patient groups ($8.3 \pm 2.4\%$) This observation was probably because #3 size mask was used for all the patients in our study irrespective of the weight from 30-70kgs. Therefore the size of the mask used in normal and overweight individuals to assess the leak fraction further needs to be evaluated. The non-inflatable cuff requires 10-20 breaths to achieve complete seal of the airway which warrants that the leak fraction has to be measured 5 min after the placement of the mask. Hence it is advisable not to manoeuvre the mask immediately after placement if a leak is observed.

In a similar study, clinical performance of the Baska mask was evaluated in 80 patients and it was concluded that it achieves a high seal pressure, effective ventilation and a quick access to drain gastric contents.⁸ As there is no inflatable cuff in the mask, neither should it cause tissue or nerve damage nor should the intra-cuff pressure need monitoring. Adjustments of the depth of insertion may be required to minimize leaks. An advantage of the dual gastric drain is that one drain tube can be used to apply low pressure suction intermittently. The other gastric drain tube serves as free vent and/or as a guide for a Ryle's tube, which can be used to empty the stomach. If regurgitation is anticipated, suction should be connected to the suction port of the device and left running continuously intraoperatively and during removal of the device at the end of the procedure. Maintaining high pressure suction continuously throughout the procedure is not advisable as it could predispose to post-operative sore throat due to the drying action of the airflow.²

Fibreoptic visualization of the anatomic position of the Baska mask in situ and its grading as described by Brimacombe⁵ revealed grade 1 in 78% of our patients. However, adequate ventilation and oxygenation was not compromised even in grade II and more. Occasionally, the soft, membranous part of the cuff may get wrinkled around the epiglottis obstructing the airway patency and obscuring the glottic view. Ease of removal of the mask at the end of the surgery and after complete reversal was noted to be very easy in 97% of the patients. This is a very important indicator of a well-tolerated airway device during emergence. Slight manipulation of the mask was required in one patient during removal as she had buck teeth.

Complications like injury to the oral structures as noted by blood stain on the device after its removal was noted only in 5% patients. This could be attributed either to the second attempt of insertion of the mask or difficult insertion. Postoperative complications like severity of throat discomfort, dysphagia and dysphonia

were evaluated in a similar study and the incidence was found to be very low.⁶ In our study mild sore throat was observed in the immediate postoperative period in 15% patients which settled at the end of 2h, this was noted in the initial part of the study when generous and specified areas of lubrication was not given enough priority. However, none of the patients had complaints of dysphagia or dysphonia. This is an important advantage over most of the other inflatable cuffed SAD where the continuously inflated cuff exerts excess pressure and injures the surrounding tissue or can cause nerve damage resulting in dysphonia. Endotracheal intubation which was considered as the gold standard for airway maintenance for majority of the surgeries under GA has the major disadvantage of causing sore throat and dysphagia, which can be totally prevented with the use of this SAD with added benefits.

The properties of an ideal SAD includes easy insertion in neutral position, high insertion success rate even by inexperienced users, stability of the device after positioning, protection against aspiration of gastric contents, sufficient sealing quality to apply intermittent positive pressure ventilation and low incidence of postoperative complications such as sore throat, hoarseness, cough or dysphagia.¹ The ability to secure an airway successfully as early as possible is the top priority of an anaesthesiologist. The major concern being safety of the patient during anaesthesia, prevention of aspiration and effective ventilation does warrant equal importance. The minimal postoperative airway morbidity with the Baska mask ensures patient comfort and easy compliance.

The pitfalls in this study are that the hemodynamic changes associated with the insertion of the Baska mask have not been studied at frequent intervals. However they have been monitored at induction, 15 minutes and 30 minutes following insertion of Baska mask. The future scope of this study includes evaluation of its usage in patients with anticipated and unanticipated difficult airway. Further the use of Baska mask in patients undergoing laparoscopic surgeries can be separately evaluated. The major limitation for the routine use of Baska mask is the cost factor. However, the introduction of reusable masks can bring down the expenses drastically thus making it cost effective.

Conclusion

Baska mask is very easy to insert, provides efficient ventilation and causes least intraoperative and postoperative complications, thus avoiding the disadvantages and complications associated with laryngoscopy and endotracheal intubation. Hence Baska mask can be considered as an almost ideal supraglottic airway device which is both safe and efficient for its use in adults with normal airway undergoing general anaesthesia.

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Conflicts of Interest: None.

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