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Original Article

Comparison of Baska Laryngeal Mask Airway and Endotracheal Tube in Adult Patients Undergoing Surgery under General Anesthesia: A Prospective Randomized Study

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Abstract

Background: Airway management is considered as an integral part of general anesthesia. Use of Baska mask, since a supraglottic airway device, could result in the low incidence of hemodynamic alterations and post-operative pharyngolaryngeal complications. We conducted this study to compare the hemodynamic parameters, i.e., systolic blood pressure (SBP), diastolic blood pressure, mean arterial pressure (MAP), heart rate (HR), ease of insertion, time of insertion, and post-operative pharyngolaryngeal complications during Baska mask and endotracheal tube (ETT) insertion.

Materials and Methods: It was a prospective randomized study which was conducted on 80 adult patients admitted for elective surgery under general anesthesia (GA) of 60–90 min duration. A total of 80 patients were randomly allocated into two groups, i.e., Group B and Group E of 40 each. Group B patients underwent Baska mask insertion and Group E patients underwent ETT insertion. The statistical analysis was done by Student's *t*-test and Chi-square test. $P < 0.05$ was considered statistically significant.

Results: There was a statistically significant rise in SBP, diastolic blood pressure, MAP, and HR during ETT insertion as compared to Baska mask insertion. The mean time of insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. Insertion of Baska mask was easy in 85% whereas insertion of ETT was easy in 65%.

Conclusion: Baska mask can be used as an alternative to ETT in adult patients undergoing surgeries under GA of 60–90 min duration with minimal hemodynamic alterations and post-operative pharyngolaryngeal complications.

Key words: Baska, Insertion, Intubation, Post-operative, Sore throat

INTRODUCTION

Airway management is an integral part of general anesthesia (GA). Endotracheal intubation has been considered as a conventional gold standard method for securing the airway during GA. The disadvantages of tracheal intubation are concomitant hemodynamic responses such as tachycardia, hypertension, and arrhythmias which can lead to myocardial ischemia; damage to oropharyngeal structures during insertion of endotracheal tube (ETT) itself or during laryngoscopy and post-operative sore throat. Baska mask is the latest third generation supraglottic airway device[1] designed by Australian anesthesiologists Kanag and Meena Baska with gastric sump channels that offer protection against aspiration.[2] As we do not require laryngoscopy during Baska mask insertion leading to a lower incidence of post-operative pharyngolaryngeal complications.

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MATERIALS AND METHODS

Ethics

After approval from the Institutional Ethics Committee, Government Medical College, Amritsar, and after taking written informed consent, the prospective randomized study was conducted on 80 healthy patients. The patients

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were of either sex belonging to the American Society of Anesthesiologists Grades I or II, aged 20–50 years and bodyweight 40–76 kg undergone surgeries of 1–1.5 h duration under GA. Patients with inadequate mouth opening, body mass index >26 kg/m^2, anticipated difficult airway, the patient having increased risk of aspiration, oropharyngeal pathology, and severe respiratory disease were excluded from the study.

Patients were randomized for airway management with Baska mask and ETT by opening an opaque envelope inside the operation theatre containing the computer generated random assignment into two groups of 40 each.

- Group B – Undergone Baska mask insertion
- Group E - Undergone endotracheal intubation.

Each patient was examined in the preanesthesia room and was explained about the questionnaire related to sore throat and hoarseness of voice. The sore throat was defined as constant pain or discomfort in the throat independent of swallowing.

The severity of post-operative sore throat was graded as:

- Grade 0 – No sore throat at any time since the operation
- Grade 1 – Patient answered in the affirmative when asked about sore throat (minimal)
- Grade 2 – Patient complained of sore throat on his/her own (moderate)
- Grade 3 – Patient is in obvious distress (severe).

Hoarseness is defined as an abnormal change in voice and often experienced in conjunction with a dry or scratchy throat.

The patient was kept nil per orally after 12 midnight and tablet alprazolam (Alprax) 0.5 mg was given at 6 am in the morning before surgery with a sip of water which acts as anxiolytics. In the operation theatre, standard monitors were attached and baseline parameters were recorded. The monitoring equipment and anesthetic drugs used during general anesthesia were kept on the work station on the head side of the operating table.

After removal from its sterile packet, the integrity and function of the Baska mask were checked by occluding the airway opening of the proximal connector end with one thumb, holding the mask head with the other hand and placing the other thumb over the airway opening of the mask to seal. The pressure was applied for 5 s using a reservoir bag squeeze to confirm the absence of leak in the device. The entire body of the mask was then lubricated with a water-based lidocaine (lignocaine) gel.

The insertion time of Baska mask was measured in seconds as the time between picking up of the Baska mask to the appearance of the first capnograph trace. However, in the case of ETT, insertion time was measured from the direct laryngoscopy to the appearance of the first capnograph trace.

After attaining the intravenous access, injections of midazolam 0.02 mg/kg, glycopyrrolate 0.005 mg/kg, and butorphanol 1–2 mcg/kg were given. General anesthesia was induced by injection propofol 1.5–2.5 mg/kg. Neuromuscular blockade to facilitate placement of device was achieved by injection vecuronium 0.08–0.1 mg/kg. Following induction and adequate paralysis, the corresponding airway was inserted in each group. In Group B, size 3 Baska mask was used for females and size 4 Baska mask was used for males according to their weight. In Group E, endotracheal intubation (7–7.5 females and 8–8.5 in males) was performed in a standard manner. After Baska mask insertion and intubation in the respective group of patients, the anesthesia was maintained with oxygen, nitrous oxide, isoflurane, and vecuronium. The seal pressure was calculated as the plateau pressure with fresh gas flow at 6 liters by closing the adjustable pressure limiting valve at 70 cm H_2O and was measured in cm of H_2O at 10 min post placement of Baska mask. The cuff pressure of ETT was measured 10 min of post-intubation using an aneroid manometer. The aneroid manometer was connected to the pilot balloon of the ETT cuff through a three-way stopcock and ETT cuff pressure was measured and recorded. The correct placement of the devices was confirmed by adequate chest movement on manual ventilation, auscultation, square wave capnography, expired tidal volume of more than 8 ml/kg, and no audible leak.

Hemodynamic responses include mean arterial pressure (MAP), SpO_2, electrocardiogram (heart rate [HR]), and $ETCO_2$. All these parameters were recorded before induction; after induction/before laryngoscopy; after laryngoscopy; during intubation/Baska mask insertion; at 1, 3, 5, 10, and 15 min after insertion of device, then every 10 min until the end of surgery; and even after removal of the airway devices. Ease of insertion was also noted during insertion of Baska mask and ETT. Insertion of baska mask is categorised as - Insertion at first attempt with no resistance (easy); difficult insertion or at second attempt or insertion with manipulation of tab (fair); failed insertion or insertion not possible (difficult).

At the end of surgery, injection Myo Pyrrolate (neostigmine + glycopyrrolate) 0.04–0.06 mg/kg was given as reversal. When the patient was awake and following commands, Baska mask and ETT were removed. Parameters such as the presence of bloodstain on the cuff, incidence of bronchospasm, laryngospasm, regurgitation, and aspiration were noted. The patient was then shifted to the post-

anesthesia care unit. After surgery, pharyngolaryngeal complications, consisting of a sore throat, coughing, and hoarseness of voice, were assessed at 1, 2, 4, 8, 12, and 24 h postoperatively. The predetermined definitions of pharyngolaryngeal complications were used for the assessment.

Statistics

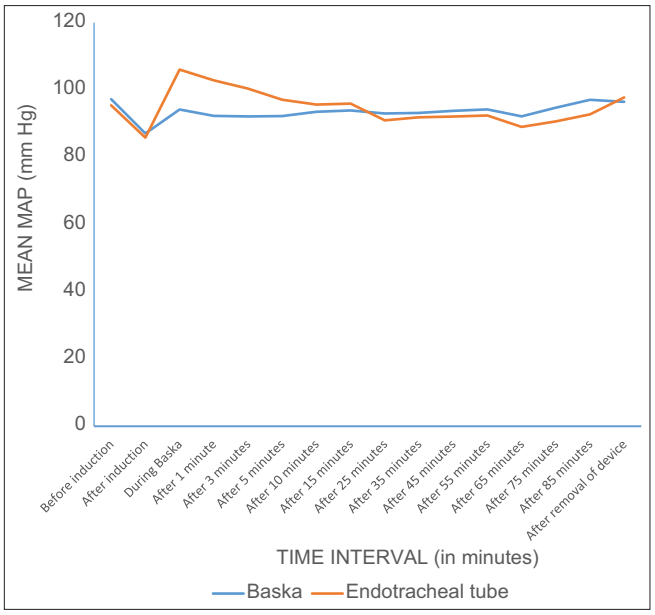
The sample size was calculated keeping in view at most 5% risk, with minimum 85% power and 5% significance level (significant at 95% confidence interval) ($\alpha = 0.5$, $\beta = 0.5$) for comparison of quantitative and continuous data, a minimum of 40 patients in each group with a total minimum of 80 patients either male or female were included in the study. Raw data were recorded in a Microsoft Excel spreadsheet and analyzed using Statistical Package for Social Sciences version 23.00 (IBM Corporation ARMONK, NY, USA). The continuous variables were presented as mean with standard deviation (SD) (mean ± SD). Normally continuous variables were analyzed using Student's *t*-test. The categorical variables were analyzed using Chi-square test. *P*-value of 0.01–0.05 was considered statistically significant and $P < 0.001$ was considered highly statistically significant.

RESULTS

With respect to the demographic parameters, the patients in the two groups were analogous as is evident from Table 1. Themean duration of surgery was 69.02 ± 9.55 min in Group B and 70.35 ± 9.74 min in Group E. The difference was statistically non-significant ($P > 0.05$).

Coming to the hemodynamic parameters, when the MAP was compared during insertion of Baska mask and ETT, statistically highly significant difference was found ($P < 0.001$) with MAP 94.18 ± 5.80 mmHg in Group B and 106.05 ± 4.34 mmHg in Group E. The rise in MAP during insertion of airway device was 8% and 24% in Group B and Group E, respectively, when compared with their post-induction values. Even at 1 min, 3 min, and 5 min post-insertion statistically significant difference was found in mean MAP between Group B and Group E ($P > 0.05$). The MAP was then measured at 10 and 15 min, every 10 min interval until the end of surgery, and even after removal of airway device, statistically insignificant difference was observed between Group B and Group E ($P > 0.05$) [Graph 1 and Table 2].

The mean HR during insertion of Baska mask and ETT shows statistically highly significant difference ($P < 0.001$) with mean HR 102.13 ± 10.67 beats/min (bpm) in Group B and 113.55 ± 9.57 bpm in Group E. The rise in HR was 7% and 16% in Group B and Group E, respectively when compared with their baseline values. Even at 1 min, 3 min, and 5 min of surgery statistically significant difference was found in mean HR between Group B and Group E ($P > 0.05$). When the comparison of HR at 1 min was done with their respective baseline values, 5% and 14% rise was observed in Group B and Group E, respectively. At 10 min, 15 min, and at every 10 min interval until the removal of the airway device, no statistically significant difference was observed in mean HR between the two groups [Graph 2 and Table 3].



Graph 1: Variations in mean arterial pressure at different time interval in both groups

Table 1: Demographic characteristics of patients

Demographic data	Group B (Baska)	Group E (endotracheal tube)	*P*-value
Mean age (in years)	36.12±9.51	38.10±10.36	0.377 (NS)
Mean body weight (in kg)	60.58±8.30	62.90±7.27	0.09 (NS)
Duration of surgery (in minutes)	69.02±9.55	70.35±9.74	0.16 (NS)

NS: Non-significant

The mean $ETCO_2$ and SpO_2 in both Group B and Group E from the pre-induction phase until the removal of the device remained statistically non-significant ($P > 0.05$).

When we compared the ease of insertion of Baska mask with ETT, we observed that the insertion was easy in 85% of patients and fair in 15% of patients whereas insertion of ETT was easy in 65% patients and fair in 35% of patients and the difference came out to be statistically significant ($P < 0.05$). None of the patient in any of the group had difficult insertion of device [Graph 3 and Table 4].

The mean duration of insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. The difference in

Table 2: Variations in MAP in Group B and Group E

Time interval	Group B		Group E		*t*-value	*P*-value	Statistical significance
	MAP (mmHg)	SD	MAP (mmHg)	SD			
Before induction	97.26	7.24	95.44	7.21	0.91	0.13	NS
After induction	87.08	3.04	85.82	4.84	1.16	0.09	NS
During insertion	94.18	5.80	106.05	4.34	−10.17	0.00	HS
After 1 min	92.29	5.20	102.86	4.63	−7.62	0.02	S
After 3 min	92.13	6.04	100.42	3.57	−6.59	0.03	S
After 5 min	92.23	5.66	97.10	4.52	−3.79	0.04	S
After 10 min	93.52	5.32	95.65	5.23	−1.85	0.06	NS
After 15 min	93.91	4.75	95.94	5.14	−1.67	0.06	NS
After 25 min	93.01	3.90	90.97	5.94	1.51	0.07	NS
After 35 min	93.18	4.11	91.87	5.12	1.22	0.10	NS
After 45 min	93.81	4.59	92.11	5.67	1.45	0.07	NS
After 55 min	94.21	5.79	92.40	4.69	1.32	0.06	NS
After 65 min	92.17	8.70	89.02	11.22	−3.93	0.13	NS
After 75 min	94.73	3.08	90.65	9.98	−5.22	0.19	NS
After 85 min	97.07	4.23	92.75	5.80	−3.52	0.07	NS
After removal of device	96.49	5.20	97.78	8.22	−0.69	0.20	NS

NS: Non-significant; *P*>0.05, HS: Highly significant; *P*<0.001, S: Significant; *P*<0.05. MAP: Mean arterial pressure, SD: Standard deviation

Table 3: Comparison of variation of heart rate (heart rate in beats per minute) in Group B and Group E

Time interval	Group B		Group E		*t*-value	*P*-value	Statistical significance
	Mean	SD	Mean	SD			
Before induction	89.98	14.80	90.63	11.55	−0.20	0.41	NS
After induction	94.70	15.71	97.38	8.56	−0.97	0.17	NS
During insertion	102.13	10.67	113.55	9.57	−4.91	0.00	HS
After 1 min	99.13	18.84	103.18	9.38	−1.99	0.02	S
After 3 min	92.68	11.08	99.80	9.47	−2.59	0.01	S
After 5 min	89.25	10.35	93.73	8.01	−1.96	0.02	S
After 10 min	90.05	10.63	92.43	8.00	−1.18	0.13	NS
After 15 min	87.28	9.95	90.10	8.13	−1.22	0.08	NS
After 25 min	86.18	7.61	86.70	8.30	−0.28	0.38	NS
After 35 min	84.88	6.62	86.23	7.20	−0.74	0.19	NS
After 45 min	85.35	6.25	87.25	5.62	−1.56	0.08	NS
After 55 min	86.23	8.74	86.98	5.04	−0.47	0.32	NS
After 65 min	84.80	7.06	87.36	5.79	−4.73	0.07	NS
After 75 min	86.40	8.17	86.35	7.91	−7.17	0.50	NS
After 85 min	89.40	6.07	85.88	13.11	−3.46	0.29	NS
After removal of device	89.70	10.69	90.80	12.57	1.72	0.34	NS

NS: Non-significant, *P*>0.05, HS: Highly significant, *P*<0.001, S: Significant, *P*<0.05. SD: Standard deviation

the duration of insertion between Group B and Group E was found to be statistically highly significant ($P < 0.05$) [Graph 4 and Table 5].

Post-operative pharyngolaryngeal complications such as sore throat, hoarseness, and coughing were observed. Increase in incidence of post-operative sore throat at 1, 2, 4, 8, 12, and 24 hour of post operative period in Group E as compared to Group B. Patients who underwent Baska mask insertion developed Grade 1 sore throat whereas in patients who underwent endotracheal intubation developed Grade 2 sore throat.

Similarly incidence of post-operative coughing at 1, 2, 4, 8, and 12 h is statistically significant in Group E as compared

Table 4: The ease of insertion

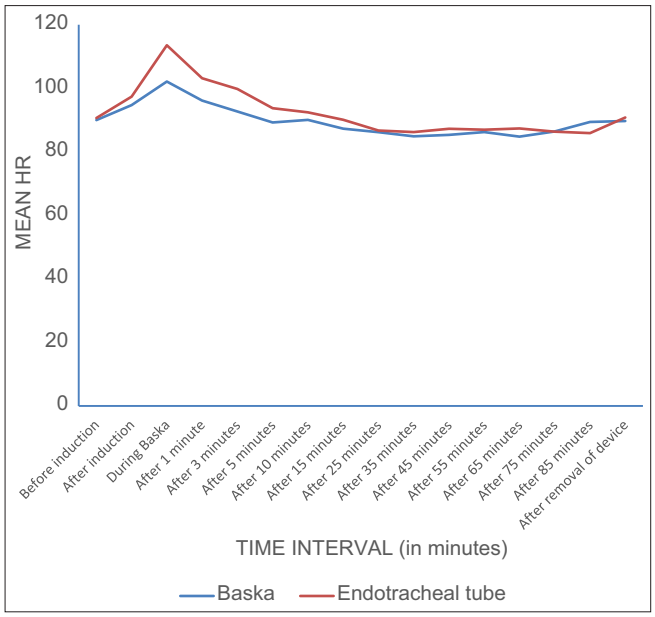
Ease of insertion	Group B		Group E		*P*-value
	Number of patients	Percentage	Number of patients	Percentage	
Easy	34	85.00	26	65.00	0.03 (S)
Fair	6	15.00	14	35.00	0.03 (S)
Difficult	0	0.00	0	0.00	
Total	40	100.00	40	100.00	

S: Significant; *P*<0.05

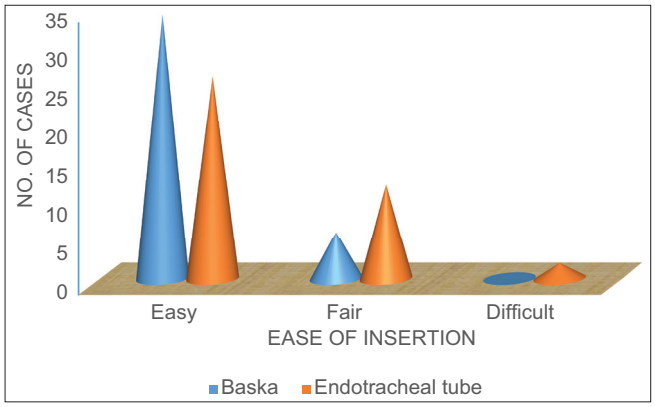
Table 5: Mean duration of insertion (in seconds)

Group	Mean	Standard deviation	*t*-value	*P*-value
B	12.80	1.36	−8.34	0.001 (HS)
E	15.93	1.51		

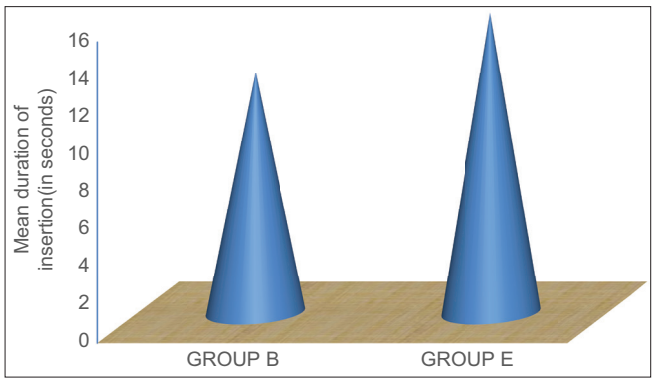
HS: Highly significant, *P*<0.001



Graph 2: Variations in mean heart rate at different time intervals in both groups



Graph 3: Ease of insertion



Graph 4: Mean duration of insertion

to Group B whereas the difference in post-operative cough was statistically insignificant at 24 h. Hoarseness of voice was observed to be more in Group E than Group B at 1, 2, and 4 h of post-operative period.

Regurgitation and aspiration was not observed in any of patient in both groups. Laryngospasm was observed in 1 patient in Group E and managed by switching to 100% oxygen, deepening the plane of anesthesia with intravenous propofol (0.5 mg/kg) and by giving manual positive pressure ventilation.

None of the patient in Group B suffered from trauma to the lip and tongue whereas in Group E, 2 patients (5%) suffered from trauma to lip and tongue during laryngoscopy. In Group B, blood staining of Baska mask during removal was observed in 2 patients (5%) whereas in Group E it was observed in 4 patients (10%).

The mean seal pressure of Baska mask in Group B was found to be 37.03 ± 2.28 cm of H_2O. The cuff pressure of ETT was measured 10 min of post-intubation using an aneroid manometer and was found to be 26.3 ± 8.2 cm of H_2O.

DISCUSSION

The deleterious hemodynamic consequence in the form of an increase in HR and hypertension following laryngoscopy and endotracheal intubation is a matter of concern. The use of laryngeal mask airway (LMA) in place of ETT has been shown to attenuate these hemodynamic responses and provides a promising alternative to ETT.

Baska mask is one of the newly introduced devices to fit in the anatomy of the oropharynx that provides several advantages over the existing supraglottic airway devices. It has non-inflatable self-sealing membranous cuff that facilitates better airway seal, seal increases with intermittent positive pressure ventilation without gastric insufflation. It incorporates a tab to help negotiate the palatopharyngeal curve. It has two large tubes entering the sump area for high suction clearance of the sump.

There was a statistically significant rise in MAP at the time of insertion of ETT and also at 1, 3, and 5 min following the insertion in Group E when compared to Group B ($P < 0.05$). The percentage rise in MAP in Group E was 24% whereas it was only 8% in Group B during the insertion of the device. Similarly, at 10 and 15 min, when MAP was compared between Group B and E , statistically insignificant difference was observed. Thereafter, MAP was monitored at every 10 min interval until the end of surgery and even after removal of the device, no statistically significant difference was observed between two groups ($P > 0.05$).

At the time of insertion of endotracheal intubation requires laryngoscopy that causes an increase in sympathoadrenal

activity. Major sources of the stimuli responsible for the adrenergic response are the distortion of supraglottic structures during laryngoscopy. However, no laryngoscopy is required in insertion of the supraglottic airway devices; thus, they have been shown to have attenuated hemodynamic responses.[3]

There was a statistically significant rise in HR during insertion of device and also at 1, 3, and 5 min following insertion in Group E when compared to Group B. Then, at 10 and 15 min post-insertion, minor variations in HR were observed between Group E and Group B but the difference was statistically insignificant ($P < 0.05$). The HR was then monitored at every 10 min interval until the end of surgery and even after the removal of the device and no statistically significant difference was observed between two groups.

Our study results are consistent with the study conducted by Lamba *et al.*[4] in which they compared Baska mask with ETT and concluded that statistically significant increase in mean blood pressure was seen just after intubation, at 3 and 5 min following intubation when compared to Baska mask insertion.

Similar results were observed by a study conducted by Akhondzade[5] in which the hemodynamic changes after insertion of ETT group, LMA group, and I gel group were assessed and it was concluded that there was significant increase in systolic blood pressure and HR during ETT insertion and at 1, 2, and 5 min after insertion of ETT when compared to other groups. Similar results were also reported by another study conducted by Dadmehr *et al.*[6]

Insertion of Baska mask was found easy in 34 patients (85%) and fair in 6 patients (15%) whereas insertion of ETT was easy in 26 patients (65%) and fair in 14 patients (35%). The major advantage in our study was the 100% success rate of insertion of Baska mask. The physical characteristic that aids in easy insertion of Baska mask is that the extended hand tab that can be attached to the cuff permits the operator to control the degree of flexion of the device, thus, aids in easier insertion.

Concordant results were found by Kumar *et al.*[7] in which they concluded that the insertion of Baska mask was very easy, i.e. no manipulation needed in 88% of cases, easy (hand tab manipulation required) in 10% of cases, difficult in 1% cases (needed jaw thrust for Baska insertion), and very difficult (repositioning of Baska mask needed after insertion) in 1% of the patients.

Almost similar results were reported by Lamba *et al.*,[8] the insertion of Baska mask was easy in 90% of cases whereas in 10% of cases require the second attempt for insertion. However, ETT was placed in the first attempt in 70% of cases and 24% of cases required the second attempt.

Similar results were also obtained by a study conducted by Mahajan[9] in which they evaluated the performance of Baska mask in laparoscopic cholecystectomy. The rate of insertion in the first attempt was 88.23% and the rate of insertion in the second attempt was100%.

The mean duration of the insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. This difference comes out to be statistically highly significant ($P < 0.001$).

As we know that the insertion of endotracheal intubation requires laryngoscopy and cuff inflation, thus increases the average duration for insertion of ETT. The contributing factors that make the insertion of Baska mask easier are first the membranous cuff of the Baska mask that inflates and deflates with the positive pressure ventilation, and second, the oropharyngeal curve that can be easily negotiated by pulling the tab of the Baska mask and thus aids in easy and insertion.

These results are comparable to the study conducted by Mahajan[9] in which they concluded that the meantime of insertion of Baska mask was 11.02 ± 2.11 s which were almost similar to the results obtained in our study.

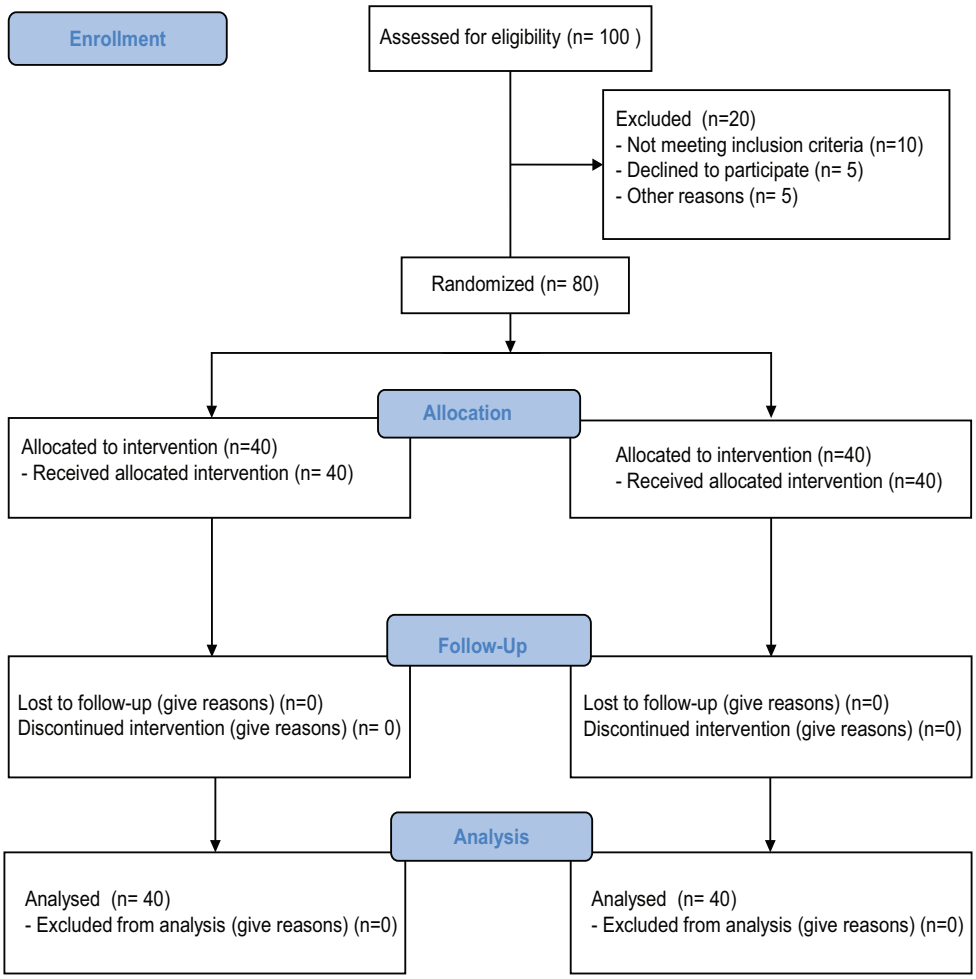
Similar results are obtained by a study conducted by Lamba *et al.*[8] in which the meantime of Baska mask insertion was 10 ± 2 s and of ETT was 16 ± 2 s. Comparable results were found by Sachidananda *et al.*[10] in which the mean insertion time of the Baska mask was 14.9 ± 6.2 s.

The mean seal pressure of Baska mask in Group B was found to be 37.03 ± 2.28 cm of H_2O. It was observed in our study that due to the thermolability of the membranous cuff of the Baska mask it get easily fit over the patient's laryngopharynx and inflated during each breath; thus, there is a gradual improvement in seal of the mask over first 2–3 min.[11]

On measuring the cuff pressure of ETT in Group E, it was found to be 26.3 ± 8.2 cm of H_2O. It came out to be in the safe recommended range, i.e., in between 20 and 30 cm of H_2O which was unlikely to impair tracheal capillary mucosal perfusion.[12]

Our results were also similar to the study conducted by Kumar *et al.*[7] and found that the mean seal pressure of Baska mask was 42.46 ± 19.11 cm of H_2O.

Post-operative sore throat and cough are one of the most common complaints following intubation and LMA



Flow Chart: Consort Flow Diagram

insertion. It usually results from an inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy and tracheal mucosa due to ETT cuff. Trauma during laryngoscopy and intubation is another major contributing factor.

In the post-operative period at 1, 2, 4, 8, 12, and 24 h, there was a significantly higher incidence of sore throat and coughing in Group E as compared to Group B. Hoarseness of voice at 1, 2, and 4 h postoperatively was observed more in Group E than in Group B. These observations were comparable with the study conducted by Tosh *et al.*[8]

As in our study, none of the patient developed post-operative aspiration and regurgitation. There was no incidence of laryngospasm in Group B and only in 1 patient in Group E. There were only 2 patients in Group E who developed trauma to the lip and tongue whereas in none of the patient in Group B. Blood staining of the device on removal was observed in 2 patients in Group B and in 4 patients in Group E.

Strengths of Study

The unique distinction of our study is that we have also taken into account the potential known confounders for pharyngolaryngeal complications that are the ease of insertion, number of attempts of insertion, incidence of laryngospasm, and presence of blood staining after removal. Furthermore, the anesthetic technique used for all the cases was similar thus ensuring homogeneity in the procedure. None of the patients were excluded from our study; this also adds an additional advantage to our study.

Limitations of Study

The limitation of our study includes small sample size. As the data had been derived from a single center, thus it may have a referral bias. This study was conducted on healthy, normotensive patients with normal airways. It is, therefore, not known how the changes would have been in hypertensive patients. Baska mask cannot be inserted in patients with body weight <30 kg and in pediatric patients as pediatric size of Baska mask is not available. Another drawback of our study was that all the intubations and Baska mask insertions were not performed by a single anesthesiologist.

CONCLUSION

From our study, we concluded that a significant hemodynamic response consisting of an increase in HR and MAP was seen after the insertion of ETT as compared to Baska mask. The duration of insertion of Baska mask was significantly shorter and insertion of Baska mask was easier. Baska mask provides adequate positive pressure ventilation that is comparable with ETT. Post-operative complications such as sore throat, cough, and hoarseness of voice are significantly less with Baska mask as compared to ETT.

In conclusion, we can say that during routine elective surgeries of 60–90 min duration, the Baska mask provides a satisfactory airway for positive pressure ventilation and therefore is a suitable alternative to endotracheal intubation for adult patients.

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