Original Article

Efficacy of Baska mask as an alternative airway device to endotracheal tube in patients undergoing laparoscopic surgeries under controlled ventilation

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Abstract

Background and Aims: Newer supraglottic devices with an additional gastric channel offer greater protection from aspiration and avoidance of laryngoscopy for their insertion would result in attenuated hemodynamic responses.The primary objective was to assess hemodynamic responses to insertion of Baska mask as compared to tracheal intubation. The time and attempts taken to secure airway and evidence of regurgitation and pulmonary aspiration of gastric contents were also assessed.

Material and Methods: This prospective, randomized study was conducted in 80 patients undergoing laparoscopic cholecystectomy. All patients received standardized anaesthesia protocol. Baska mask was used to secure airway in Group B, while tracheal intubation was done in group T. Methylene blue was injected through Ryle's tube into stomach in both groups. At end of surgery, fibreoptic bronchoscopy was performed to detect bluish staining of trachea and/or main bronchi as evidence of aspiration of gastric contents and bluish staining in oropharynx as evidence of regurgitation. Chi-square test and Independent sample t-test were applied.

Results: The time taken to secure airway was significantly longer in Group B as compared to Group T (45.3 ± 12.6 vs. 24.3 ± 9.1 sec) Percentage of patients who had oropharyngeal blue stain was comparable in both groups. No patient in both groups had tracheal blue stain. Group T had significantly higher HR and MAP after intubation till 10 min later.

Conclusion: Baska mask insertion was associated with attenuated hemodynamic responses, though more time and attempts were required for securing the airway. It could be considered as an alternative to tracheal intubation during laparoscopic surgeries.

Keywords: Aspiration, hemodynamic, intubation, laparoscopic, mask

Introduction

Tracheal intubation with a cuffed tube has remained as a standard practice for providing general anaesthesia during laparoscopic surgeries for long. However, the accelerated hemodynamic stress responses associated with tracheal intubation could be dangerous in high risk patients, especially in those with compromised cerebral or cardiovascular system.[1,2] Supraglottic airway devices (SADs), which evoke lesser hemodynamic responses on insertion, are now commonly being used for providing general anaesthesia.[3] With the introduction of newer SADs like Baska mask, it is generally assumed that airway will be better protected than with older devices.[4,5]

However due to concerns over increased risk of aspiration, difficulties encountered when trying to maintain effective gas transfer while delivering the higher airway pressures required

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during pneumoperitoneum and dislodgement of SADs due to patient positioning during laparoscopic surgeries,[6] many anaesthesiologists still prefer tracheal intubation in such cases. With the introduction of second generation SADs, which provide higher sealing pressure, thus reducing the risk of aspiration and facilitating effective ventilation at higher pressures, there has been an increase in its use during laparoscopic surgery. Though usefulness of various SADs[7,8] during laparoscopic surgeries has been extensively investigated, a direct comparison of Baska mask insertion to tracheal intubation remains less explored.

The primary objective of the present study was to assess the hemodynamic stress response to insertion of Baska mask as compared to tracheal intubation in patients undergoing laparoscopic surgeries. The secondary objectives were assessment of time and attempts taken to secure airway and evidence of pulmonary aspiration of gastric contents at end of surgery in these patients.

Material and Methods

This prospective, randomized, single blinded study was conducted after obtaining Institutional Ethical Committee clearance (AIIMS/Pat/IEC/2018/305 dated 26.10.2018) and consent of patients and was registered in Clinical Trial Registry of India (CTRI/2019/03/017921). Eighty patients undergoing elective laparoscopic cholecystectomy under general anesthesia, aged 18-60 years of American Society of Anesthesiologists (ASA) physical status 1-2 were included in the study. Those with anticipated difficult airway, renal dysfunction, hiatus hernia, obesity, pregnancy and those on rate controlling medications, steroids, opioids, regular antacids, were excluded.

As there were no similar studies published so far, the present study was initiated as a pilot study in 20 patients with 10 patients in each group comparing the heart rates at 1 min following securing the airway as the primary objective with use of Baska mask versus tracheal intubation. It was seen that Baska mask group had lower heart rate at the specified time point (100.1 ± 11.9 vs. 109.4 ± 13.3).Based on this result, with 90% power and 95% confidence interval, a sample size of 78 was calculated. Hence, we recruited a total of 80 patients in the subsequent study with 40 patients in each group. The data of the patients of pilot study were not utilized in the final study.

Following a thorough pre-anesthetic evaluation and after performing relevant investigations pertaining to associated medical conditions and proposed surgery, patients were accepted for surgery under general anesthesia. All patients were kept fasting, 6 hours for solids and 2 hours for clear fluids, before surgery. Patients after recruitment into the study were randomly allocated to two equal groups (B and T) using computer generated random sequence of numbers. Sequentially numbered opaque sealed envelopes were used for allocation concealment. Patients in both groups received general anesthesia following a standardized protocol. In the operation theatre, a large bore (18G) intravenous cannula was introduced and all patients were given glycopyrrolate 0.2mg, midazolam 1 mg and fentanyl 2μg/kg body weight intravenously (IV). They were induced with propofol 1.5 to 2.0 mg/kg IV and mask ventilated with isoflurane 1% in oxygen. Following vecuronium 0.1mg/kg IV, 3 minutes later laryngoscopy was performed using traditional Macintosh laryngoscope in group T ($n = 40$) and patients were intubated using a low pressure, high volume cuffed endotracheal tube with 8mm ID in males and 7mm in females. Correct tube placement was confirmed with auscultation and appearance of end tidal capnography. Intraoperatively nitrous oxide was avoided and cuff pressures were maintained at 20-22 cm of H_2O.

In group B ($n = 40$), airway was secured with appropriate sized Baska Mask [Figure 1] according to body weight. Either Baska mask size 3 or size 4 was used as per body weight and was fixed maxilla to maxilla. Correct placement was confirmed with auscultation and end tidal capnography. Time taken to secure the airway in both groups was noted i.e., time from beginning of laryngoscopy to appearance of endtidal CO_2 waveform in group T and from insertion of Baska mask into oral cavity to appearance of endtidal CO_2 waveform in group B.

Baska mask was inserted by experienced anesthesiologists who had performed at least 15 successful placements previously. Any difficulty during insertion was overcome with gentle jaw

Figure 1: Different views of Baska mask

thrust to aid proper placement. Number of attempts at securing airway was noted and those who required more than three attempts were intubated and excluded from the study. Heart rate and mean arterial pressures were noted before induction, 1, 3, 5 and 10 min after tracheal intubation.

After tracheal intubation, a nasogastric tube was passed into the stomach and gastric contents were aspirated in Group T. Whereas in Group B, after successful placement of Baska mask, a well lubricated 12 F Ryle's tube was inserted through the drainage channel to facilitate gastric drainage. In both groups following emptying of gastric contents, 5ml of commercially available methylene blue for medical use was injected through Ryle's tube followed by 10ml saline.

Oropharyngeal seal pressure was measured after five minutes of placement of Baska mask using a fresh gas flow of 5L/min with the adjustable pressure limiting (APL) valve closed at 40cm H_2O. An initial rise in pressure followed by a plateau, the pressure at which gas starts to escape at the laryngeal inlet, was looked for. The pressure at which pressure had plateaued was documented as the seal pressure. Anaesthesia was maintained with oxygen and air (1:1) with isoflurane 1.5-2%. Vecuronium 1 mg was repeated every 30 min IV intraoperatively. Patients were mechanically ventilated with a tidal volume of 6-8ml/kg body weight, respiratory rate of 12-16/min aiming to maintain end tidal carbon dioxide of 40-45mmHg.

At end of surgery residual muscle paralysis was reversed along with prior administration of ondansetron as antiemetic. Nasogastric/Ryle's tube was suctioned and removed before extubation. In both groups fibreoptic bronchoscopy was then performed through the respective airway device and any bluish staining of trachea and main bronchi was looked for as evidence of aspiration of gastric contents. Direct laryngoscopy was then performed in both groups to look for bluish staining or secretions in oropharynx as evidence of regurgitation. Patients were extubated once awake with return of protective airway reflexes.

Chi-square test was used to compare the categorical variables of Group B and T. Independent sample t-test was used to compare the continuous variable in Group B and T. Statistical analyses were conducted using SPSS Version 20.0 for Windows (IBM Corporation ARMONK, NY, USA).

Results

A total of 80 patients were recruited in the study [Table 1]. Comparison of mean age, weight, duration of surgery as well as distribution of gender and ASA physical status were comparable in both Group B and T. But time take to secure airway was significantly longer in Group B as compared to Group T (45.3 ± 12.6 vs. 24.3 ± 9.1 sec) [Tables 2 and 3]. Though more patients in Group B required 2 attempts to secure airway as compared to Group T (22.5 vs. 7.5%), the difference was not statistically significant. The percentage of patients who had oropharyngeal blue stain did not show any statistically significant difference between both groups. No patient in both groups had tracheal blue stain as well. The mean sealing pressure in Group B was 36.6 ± 2.1 cm of H_2O.

Baseline HR and MAP were comparable in both groups. But comparison of changes in haemodynamics showed that Group T had higher HR immediately after tracheal intubation, as well as at 1,3,5 and 10 min later. This difference was statistically significant at all time points except at 10 min. Mean MAP was significantly higher in Group T at all time points after tracheal intubation as compared to Group B [Tables 4 and 5].

Discussion

Though the time taken to secure the airway was significantly longer in Group B, the number of attempts required was comparable in both groups. Patients in Group T had an exaggerated hemodynamic response following tracheal intubation which was significant. The incidence of oropharyngeal blue stain, indicating regurgitation of gastric contents, was similar in both groups. But no patient in either group had signs of pulmonary aspiration as evidenced by absence of tracheal blue stain. The mean sealing pressure of Baska mask was 36.6 ± 2.1 cm of H_2O in our study.

The hemodynamic stress responses resulting from laryngoscopy and tracheal intubation may not cause a significant problem for most normal patients. However, secondary to resultant tachycardia and hypertension those with cardiovascular or cerebral disease may be at increased risk of morbidity and mortality.[2] Avoiding laryngoscopy for tracheal intubation, by using intubating laryngeal mask airway Fastrach and Trachlight lightwand, had shown to attenuate hemodynamic responses in hypertensive patients, but not in normotensive, anesthetized, paralyzed patients.[1] Avoidance of laryngoscopy and tracheal stimulation with use of a supraglottic device results in reduced hemodynamic stress response while securing the airway as compared to tracheal intubation[9] and hence is advantageous in high risk patients.

However, the risk of aspiration remains as a major concern with use of SADs. Whether the newer supraglottic devices with an

Table 1: CONSORT flow diagram

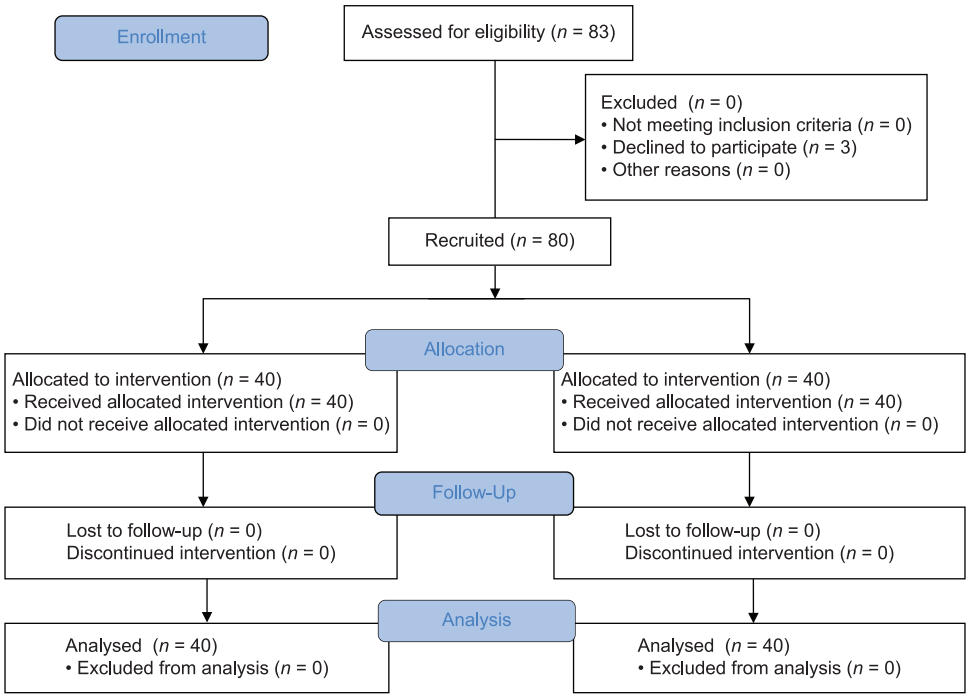

Table 2: Comparison of age, weight, duration of surgery and time taken to secure airway

Variable	Group B		Group T		*P*
	Mean	SD	Mean	SD	
Age in years	46.2	9.0	46.9	6.5	0.659
Weight in kg	80.9	13.9	76.5	11.8	0.127
Duration of surgery in min	55.4	12.9	60.9	10.0	0.057
Time taken to secure airway in seconds	45.3	12.6	24.3	9.1	<0.001

additional gastric channel offer greater protection against aspiration of gastric contents is being investigated lately and has shown promising results.[10]However the risk of device displacement during positioning and subsequent loss of airway with use of SADs during laparoscopic surgeries remain as unresolved concerns.

The seal pressure of first generation supraglottic devices is 16-20 cm H_2O, whereas it is 25-28 cm H_2O in second-generation devices. Second generation devices are considered more suitable during laparoscopic surgeries as intra-abdominal pressures are high due to pneumoperitoneum,[11] with subsequent risks of regurgitation and aspiration. After the introduction of SADs with drainage system, the risk of aspiration is considered greatly diminished.[12] Higher seal pressures will aid in ventilating at high airway pressures which is frequently required after creation of pneumoperitoneum.

Baska mask is a relatively new, self-sealing, membrane cuff, extraglottic airway device in which cuff seal is provided by a thin, pliable, conformable diaphragm which virtually adheres, at each breath, to the laryngeal introitus. As the air during positive pressure ventilation inflates the cuff and seals the airway, it results in improvement in the seal reducing leak and ventilation becomes more efficient.[13] It can be inserted blindly and is associated with a reduced risk of aspiration.

The functional analysis of I- gel with Baska mask during laparoscopic surgeries with controlled ventilation was compared by Ramaiah R *et al.*[7] and Chaudhary.[8] It was found that both airways devices were suitable for laparoscopic surgeries, but I-gel was quicker and easier to insert, while Baska mask gave good oropharyngeal airway seal. Baska® mask was found to offer a superior airway seal pressure with minimum complications in comparison to an I-Gel® device.[14-16]In another study it was found that though first attempt insertion success rate with Baska mask was 88% additional manoeuvres were necessary in 44% of the cases. Baska mask size 3 needed significantly less adjustments, and achieved a higher seal pressure than larger sizes. They found it to provide effective ventilation along with quick access to gastric contents for drainage.[15] The mean sealing pressure in our study in the Baska mask groupwas 36.6 ± 2.1 cm of H_2O. In previous studies it varied between 33 ± 7 cm H_2O to 35.7 ± 13.3 cm H_2O.[15,17] The study by Jadhav PA *et al.* had revealed that the mean airway sealing pressure of I-gel was 20.07 ± 02.94 cm of H_2O whereas that of Proseal was 25.73 ± 02.21 cm of H_2O.[18]

Table 3: Comparison of ASA physical status, gender, number of attempts taken to secure airway, presence or absence of blue stain in oropharynx and trachea

Variable	Group B		Group T		*P*
	n	%	*n*	%	
Gender					
Male	15	37.5	19	47.5	0.366
Female	25	62.5	21	52.5	
ASA 1	20	50	25	62.5	0.260
ASA 2	20	50	15	37.5	
Number of attempts					
1	31	77.5	37	92.5	0.115
2	9	22.5	3	7.5	
Oral blue stain					
Yes	35	87.5	36	90.0	1.000
No	5	12.5	4	10.0	
Blue tracheal stain					
Yes	0	0	0	0	NA
No	40	100.0	40	100.0	

Table 4: Comparison of changes in heart rate

Time	Group B		Group T		*P*
	Mean HR	SD	Mean HR	SD	
Baseline	75.8	6.9	75.4	7.1	0.798
Immed intubation	80.2	5.4	92.1	11.1	<0.001
1 min	79.7	4.9	95.9	14.2	<0.001
3 min	75.1	5.6	86.8	11.7	<0.001
5 min	77.9	6.4	82.5	12.8	0.044
10 min	76.5	6.6	79.1	5.6	0.053

Table 5: Comparison of mean arterial pressure

Time	Group B		Group T		*P*
	Mean MAP	SD	Mean MAP	SD	
Baseline	93.8	20.3	91.9	19.2	0.656
Immed intubation	94.0	9.0	105.7	10.9	<0.001
1 min	98.4	10.5	111.0	8.8	<0.001
3 min	97.6	9.0	105.6	7.2	<0.001
5 min	95.3	19.3	102.4	8.0	0.035
10 min	89.0	15.6	97.7	9.7	0.004

When usefulness of Baska mask was compared with single-use laryngeal mask airway in low-risk female patients undergoing ambulatory surgery, it was again noted that orolaryngeal seal pressure (OSP) was significantly higher with Baska mask. Though overall device insertion success rate was same with both devices, the first time success rate for insertion of the Baska mask was lower than cLMA. These authors also found Baska mask to be more difficult to insert, requiring more insertion attempts, requiring longer time for proper placement. They were of the opinion that in clinical situations where adequate glottic aperture seal takes priority over ease of insertion, the Baska mask was superior to cLMA.[4] In another study, it was shown that Baska FESS mask provided higher mean OSP in different head and neck positions, but was inferior to LMA Supreme, in terms of ease and speed of insertion.[19] Repeated attempts were required in our study for proper placement of the device which consumed significantly more time than intubation. Despite this hemodynamic response was found to be less in that group showing advantage of use of Baska mask in this regard especially in high risk patients.

Contrary to these observations, in the clinical trial by Fotedar S *et al.*,[20] in the first attempt, Baska mask insertion was found to be quick and easy, however additional manoeuvres whether applied or not and the experience of proceduralist were not mentioned. Though it has been postulated that learning curve of Baska mask insertion is short and prior placement of 15 Baska mask may be sufficient to learn the correct technique, in our study many required repeated attempts. Al-Rawahi SAS *et al.*[21] also were of opinion that Baska mask takes significantly shorter placement time and provides a better seal as compared to Proseal laryngeal mask. They observed that it took a mean 16.48 sec to place the Baska mask in correct position, but we took 45.3 ± 12.6 sec for it. The difference could be because in many previous studies a single investigator had performed all the mask insertions, whereas in our study different people inserted Baska mask. Though all had experience of more than 15 insertions of the mask, varying level of skill among them might have influenced the time taken for correct placement.

Though study by Ng CC[22] has shown that Baska mask can be used as an alternative to endotracheal intubation during laparoscopic cholecystectomy, with shorter insertion times, fewer perioperative complications and better hemodynamic responses, they have not looked into risks of aspiration in an evidence based way. The strength of our study was that we tried to identify evidence of regurgitation of gastric contents and pulmonary aspiration using introduction of methylene blue to the stomach which yielded very reliable and accurate results. Limitations of our study were that it was an open label study and securing the airway in all the cases was not performed by the same anaesthesiologist. Though we did not observe any aspiration in either group, the study was not powered to look at safety of Baska mask in protecting against risk of aspiration. Future studies with larger sample size may be required to confirm the safety of Baska mask in this regard. The proper placement and position of the Baska mask was not assessed using bronchoscope after insertion. We did not assess postoperative complications like sore throat, which might have been less with use of Baska mask.

Conclusion

The Baska mask insertion was associated with attenuated hemodynamic responses as compared to tracheal intubation, though more time and attempts were required for securing the airway. The Baska mask may be considered as an alternative airway device to endotracheal tube in patients undergoing laparoscopic surgeries under controlled mechanical ventilation.

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Conflicts of interest
There are no conflicts of interest.

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