

Evaluation of Baska Mask Performance in Laparoscopic Cholecystectomy

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Abstract:

Aims: Laparoscopic cholecystectomy is a commonly performed surgical procedure. Pneumoperitoneum during laparoscopic cholecystectomy may be associated with decrease respiratory compliance and increase airway resistance. Baska mask is a newly introduced membranous cuffed supraglottic device. These improved devices could be used safely during anaesthesia for procedures associated with high peak pressure of airway like laparoscopic cholecystectomy. We conducted airway management of 85 patients undergoing laparoscopic cholecystectomy with Baska mask to evaluate its performance and efficacy.

Settings and Design: A prospective, open label study was planned in the department of Anaesthesia, after the approval from Institutional Ethics committee.

Methods and Material: Total 85 patients undergoing elective laparoscopic cholecystectomy were included in the study. We evaluated the demographic data, insertion success rates, insertion time, airway leak pressure, airway leak fraction. Following extubation, the patient was assessed for coughing, blood staining, trauma and sump clearance. Postoperative airway morbidity in the form of sore throat, dysphagia, dysphonia were evaluated at the end of surgery. Demographic details were compared using the Chi-square and t-tests. Student's t-test for independent variables was used to compare means of data obtained.

Results: The airway was secured with Baska mask in all the patients with the first attempt rate of 80% and second attempt rate of 100%. The average insertion time was 12 ± 1.64 seconds. The oropharyngeal leak pressure was 23.55 ± 3.33 cmH₂O after insertion and 32.6 ± 2.82 cmH₂O after 30 min. of insertion and leak fraction was $3.8548 \pm 3.8\%$. There was no airway morbidity in the form of dysphagia or dysphonia. There was mild sore throat in three patients which resolved in 2 hours

Conclusions: Baska mask is a good alternative to the endotracheal tube in laparoscopic cholecystectomy with minimal leak fraction and adequate airway leak pressure.

Key-words: Cholecystectomy, Laparoscopic, Intermittent Positive-Pressure Ventilation, Masks, Baska mask

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I. Introduction

Trends in airway management has recently been progressed from using an endotracheal tube (ETT) to a supraglottic airway device (SAD) because of quick and ease of placement of the airway device itself, a lesser requirement for neuromuscular blockade, as well as a lower incidence of postoperative adverse events such as sore throat, dysphagia and dysphonia^{1,2,3}. However, the use of SADs in laparoscopic surgery remains controversial because of the increased risk of insufficient ventilation and pulmonary aspiration^{4,5}. The third generation supraglottic airway devices have been introduced to overcome these disadvantages to a large extent. The Baska mask (PROACT Medical Systems, Frenchs Forest NSW, Australia) is a newly introduced third generation supraglottic airway device with high volume suction clearance. It features non-inflatable cuff that may facilitate a better airway seal, seal increases with intermittent positive pressure ventilation (IPPV) without gastric inflation, novel pharyngeal drainage system that may reduce the risk of lung aspiration and integrated bite block. There are limited studies available for its use in laparoscopic surgeries. Hence, we planned a study to evaluate the performance and efficacy of Baska mask in patients undergoing laparoscopic cholecystectomy surgery.

II. Aim And Objective

The primary aim of the study was to evaluate OLP of the Baska mask at insertion and after 30 minutes. Secondary outcome was to measure the ease of insertion and removal of the device, time taken for device insertion, number of attempts, leak fraction, coughing, blood staining on the device, or trauma to lips, tongue,

and teeth, the sump clearance and postoperative laryngopharyngeal morbidity in the form of dysphagia, dysphonia and sore throat. We hypothesized that the Baska mask, being the third generation supraglottic airway device will prove an effective alternative to endotracheal intubation in patients undergoing laparoscopic surgery.

III. Subjects And Methods

A prospective, open label study was planned in the department of Anaesthesia, after the approval from Institutional Ethics committee. Total 85 American Society of Anesthesiologists (ASA) physical status score I or II patients, aged 20 years to 70 years of either sex were included in the study who were to undergo elective laparoscopic cholecystectomy under general anaesthesia. The patients with a known or predicted difficult airway, with mouth opening of <2.5 cm, with increased risk of aspiration of gastric contents, any pathology of neck or upper respiratory tract and the patients with obesity, BMI (body mass index) > 30 kg/m² were excluded from study. Written informed consent was obtained from all the patients before taking them into the operation theatre.

The pre-anaesthetic visit of the patient was performed by an anaesthetist not involved in this study, screening the patients for difficult intubation. The common predictive indices for difficult intubation (BMI, thyromental distance, Mallampati grade, interincisor distance), their dentition and neck movement were evaluated. After removal from its sterile packet, the integrity and function of the Baska mask was 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. 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.

Size selection was based on the manufacturer's recommendation of weight-based estimate by only two experienced anaesthetists, who had used the Baska mask prior to this clinical study in 10 "pilot" patients

A standard anaesthesia sequence was followed. On arrival in operation theatre, the patient was connected to standard monitoring device. Induction of anaesthesia was achieved using intravenous injection of fentanyl - 2µg/kg, propofol 1.5-2 mg/kg and atracurium 0.5 mg/kg. Anaesthesia was considered adequate for device insertion when the patient had lost the response to verbal command had adequate muscle relaxation and did not respond to anterior jaw thrust. During insertion, the mask was pushed past the front teeth towards the hard palate, avoiding the tongue. If necessary, when the mask was fully within the mouth, the tab, a unique feature of the Baska mask, was used to help negotiate the palato-pharyngeal curve. The mask was then advanced until resistance was encountered, at which point the tip of the mask was engaged into the upper end of the esophagus. An initial assessment of airway patency and the ability to ventilate the lungs was made by gently squeezing the reservoir bag, whilst "fine tune" adjusting the device and observing the amplitude of end-tidal carbon dioxide waveforms and the presence of chest movement. Anaesthesia was maintained using isoflurane 1-2.5% in oxygen 40% in nitrous oxide to achieve a MAC (minimum alveolar concentration) of 1.3. A clear airway was defined as SpO₂ (peripheral capillary saturation of oxygen) >95%, ETCO₂ (end tidal carbon dioxide) <50 mmHg and tidal volumes >6 ml/kg. One of the clearance channels was connected to the suction apparatus via the suction elbow (supplied in the packaging) and suction was applied either continuously or intermittently as required. The 14 Fr suction catheter was negotiated through the other port to deflate the stomach prior to start of surgery. At the end of surgery, residual neuromuscular blockade was antagonized by intravenous injection neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg. Injection ondansetron 4 mg was given as prophylactic measure for postoperative nausea and vomiting. Injection diclofenac 75 mg and injection paracetamol 15mg/kg were given for postoperative pain. Baska mask was removed when response to verbal commands, adequate spontaneous breathing and an adequate neuromuscular reversal was achieved.

The following assessments were made:

The success of insertion was assessed by the number of insertion attempts (counted as an attempt when the Baska is taken in and out of the mouth). The ease of insertion was considered as very easy, easy, difficult or very difficult. The insertion time was taken as the time between touching the teeth with the prepared mask and obtaining the first capnograph. The anatomical position of the Baska mask in situ was assessed clinically by observing that the midline of the device remained in the anatomical midline. Airway leak test was performed while the patient was apneic. The airway leak pressure was defined as the plateau airway pressure reached with fresh gas flow 6 l/min, and pressure adjustment valve set to 70cm H₂O.

The device stability was evaluated by monitoring the leak fraction. Leak fraction was defined as tidal volume inspired - tidal volume expired / tidal volume inspired (V_{insp} - V_{exp}) / V_{insp} x 100. Ease of removal of the device was defined as very easy, easy, difficult, very difficult.

Following extubation, the patient was assessed for coughing, blood staining on the device, or trauma to lips, tongue, and teeth. The sump was observed for adequate clearance. Postoperative laryngopharyngeal morbidity in the form of sore throat, dysphagia, dysphonia was graded as none, mild, moderate, or severe

measured on VAS scale (Visual Analogue score). The laryngopharyngeal morbidity was assessed immediately after removal of Baska mask and at 2 h in the postoperative recovery room by a trained assistant, not involved in the study.

Intra-operative complication as well as any intervention required to correct the use of the Baska mask were also recorded. At the time of removal of the mask, its shape and integrity was checked thoroughly. The failure to insertion was defined as the failure to ventilate with Baska mask in three attempts. In case of failure, the patients were intubated with the standard endotracheal tube and the surgery was performed. Data was collected and entered in MS Excel 2010. Statistical analysis was performed using SPSS software 20 (SPSS, Inc., Chicago, IL). The data was presented as mean \pm SD). The One-Sample Kolmogorov-Smirnov Test was employed to determine whether data sets differed from a normal distribution

IV. Results

Total 88 ASA grade 1 and 2 patients were recruited in the prospective, open label study. There was failure to ventilate with Baska mask in three patients with a large leak, of which two patients were edentulous and one patient had mouth opening of 2.5 cm but there was difficulty during insertion of mask. The airway was secured with endotracheal tube in these cases and surgery was completed uneventfully. The success rate of Baska mask placement was 96.59%. These three cases were excluded and more cases were recruited to complete the number to 85. The characteristics of the patients enrolled in the study are given in (table 1).

Table 1— Demographic data of the patients

Variable	Outcome
Age (yrs)	42.81 \pm 12.45
Sex., F:M(n) /%	73: 12 (85.88 : 14.12)
Height (cm)	159.176 \pm 4.284
Weight (kg)	56.64 \pm 6.56
Surgery time (sec.)	51.18 \pm 9.65
ASA I / II (n)	75/10

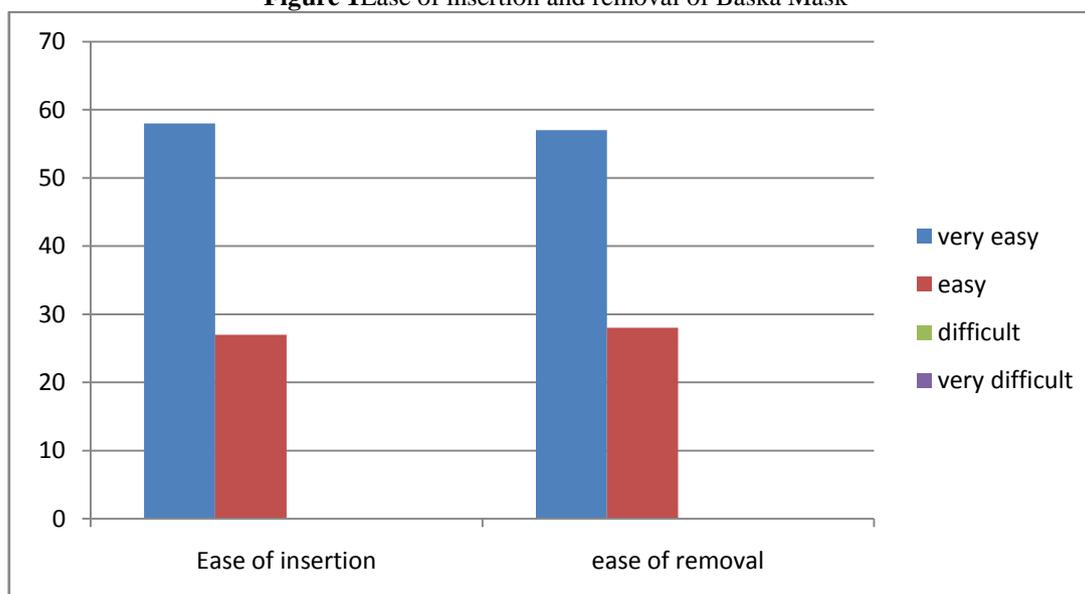
The rate of insertion in first attempt was 88.23% and the rate of insertion in second attempt was 100% (table 2).

Table 2— Baska mask placement parameters

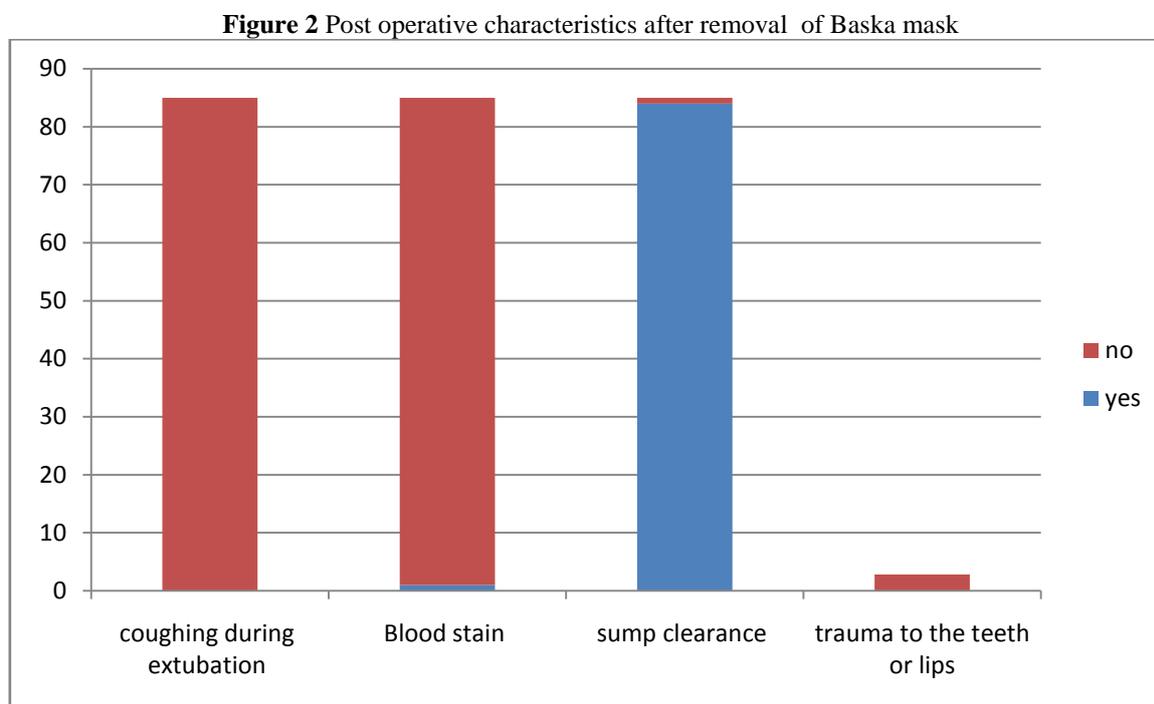
Variable		Outcome
Successful insertion (n = 85)	1:2:3 (no. of attempts)	75/ 10/ 0
Insertion time,(seconds)		11.02 \pm 2.11
Oropharyngeal leak pressure (cm H20)	At insertion	29.25 \pm 1.42
	30 min.	33.47 \pm 1.34
Oropharyngeal leak fraction(%)		2.75 \pm 3.06

Average time of insertion was 11.02 \pm 2.11 seconds. The Baska mask is a very user friendly device with very easy insertion in 68.24% patients and easy in 31.76 % patients (figure 1).

Figure 1 Ease of insertion and removal of Baska Mask



None of the anaesthetists found the insertion to be difficult or very difficult. Similarly the removal was found easy in 32.94% patients and very easy in 67.05% patients. The oropharyngeal leak pressure was 29.25 ± 1.42 cmH₂O after insertion and 33.47 ± 1.34 cm H₂O after 30 minutes of insertion. There was no coughing during extubation (figure 2).



Blood stain was present on the cuff in just one case and bile was present in the sump in one case. In rest of the patients there was no blood stain and the sump clearance was adequate. There was no trauma to the teeth or lips in any of the cases during insertion or removal. Three of the cases complained of mild sore throat just after removal which was resolved in 2 hours (table 3).

Table 3—Laryngopharyngeal morbidity parameters

Complications	After extubation	After 2 hrs
Sore throat (none, mild, moderate, or severe)	82/3/0/0	85/0/0/0
Dysphagia (none, mild, moderate, or severe)	85/0/0/0	85/0/0/0
Dysphonia (none, mild, moderate or severe)	85/0/0/0	85/0/0/0

There was no history of sore throat 2 hours after surgery in any patient. There was no laryngopharyngeal morbidity in the form of dysphagia or dysphonia in immediate postoperative period or after two hours.

V. Discussion

The Baska mask is a new supraglottic airway device, featuring non-inflatable cuff that may facilitate a better airway seal, seal increases with IPPV without gastric inflation. It has novel pharyngeal drainage system that may reduce the risk of lung aspiration. Limited studies are available for its use in laparoscopic surgeries⁶.

laparoscopic cholecystectomy is a commonly done surgical procedure associated with increased abdominal pressure with increased risk of aspiration. We planned a study to analyze its function in the laparoscopic cholecystectomy surgery. The Baska mask was used to secure the airway in 85 patients undergoing laparoscopic surgery and was found to be an effective airway device for carrying out the surgery. We had a 88.23% first attempt rate of insertion with insertion time of 11.02 ± 2.11 seconds whereas Zundert et al⁷ observed the insertion time of 16 ± 6 seconds. The cuffless mask and the tab for insertion had attributed to the less time required for securing the airway. We were able to ventilate all the patients with adequate tidal volume and minimum leak with a mean value of 2.75 ± 3.06 % which was within the permissible limits of 5% to 20% in accordance with similar study⁸. There was no leak in four of the patients. We observed airway leak pressures of

was 29.25 ± 1.42 cmH₂O in most of the patients at insertion which increased to 33.47 ± 1.34 cmH₂O after 30 minutes. As the pressure increases, the cuff inflates itself with positive pressure ventilation, which may improve the seal, thereby reducing leak and making ventilation more efficient as observed by Alexiev et al⁶. The orogastric tube was inserted through one of the port and the stomach was emptied adequately before creation of pneumoperitoneum in all cases. Baska mask has novel pharyngeal drainage system that may reduce the risk of lung aspiration. We observed adequate sump clearance in 98.82% cases. Bile staining was present in only one case.

In postoperative period none of the patients complained of dysphagia or dysphonia and only three patients complained of mild sore throat which resolved completely within 2 hours. Zundert et al⁷ and Alexiev et al⁶ observed similar findings with low incidence of postoperative dysphonia, dysphagia and sore throat. Since there is no need of inflation of the cuff of Baska mask during insertion and cuff inflate with positive pressure ventilation, it leads to less tissue trauma and nerve damage⁷. It leads to decreased post operative morbidity and increased patient satisfaction.

VI. Conclusion

We found that Baska mask is a very good alternative to the endotracheal tube in laparoscopic cholecystectomy with minimal leak fraction and adequate airway leak pressure. It has adequate sump clearance and decreased incidence of postoperative sore throat, dysphagia and dysphonia. Further clinical studies are needed to determine its role in high risk patients undergoing laparoscopic cholecystectomy.

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