Journal of Advanced Medical and Dental Sciences Research

@Society of Scientific Research and Studies ***NLM ID:*** *101716117*

Journal home page: www.jamdsr.com doi: 10.21276/jamdsr Index Copernicus value = 85.10

(e) ISSN Online: 2321-9599; (p) ISSN Print: 2348-6805

Original Research

Baska Supraglottic Airway Device as an Alternative to Conventional Endotracheal Intubation in Patients Undergoing Laparoscopic Surgery

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ABSTRACT:
Background: Laparoscopic surgeries namely cholecystectomies, appendicectomies hernia repairs, urologic and minor gynaecological procedures like diagnostic hysterolaparoscopy (DHL) are common in routine medical practice. Tracheal intubation is considered ideal for airway management in laparoscopic surgeries as it provides safe glottic seal, adequate ventilation and protects against pulmonary aspiration even in the presence of raised airway pressures due to pneumo-peritoneum. Supraglottic airway devices (SGAs) are gaining popularity as alternative to endotracheal tubes (ETT) as a tool for airway management due to their positioning outside of the larynx making them less invasive as compared to ETT. **Material & Methods:** We used a newer Supraglottic device - Baska mask for airway maintenance in 114 patients undergoing laparoscopic surgeries and compared it with conventional ETT in a randomised, controlled clinical trial. **Results:** Median seal pressures were comparable with the two devices. The first time success rate for insertion and ease of insertion was higher with the Baska mask than that seen with the ETT (90% vs 70%) respectively, $p < 0.001$). There was a significant variation in heart rate and mean arterial pressure between the two groups at the time of insertion and removal of devices with ETT group showing a significant rise in both parameters at insertion and removal ($p < 0.05$). The Baska mask proved easier and quicker to insert as compared to ETT. The mean insertion time for Baska mask being 12.2 ± 2.1sec and for ETT 19.4 ± 2.6 sec. Compared to ETT there were less complication rates with Baska mask such as laryngospasm or throat discomfort during post-op period. **Conclusion:** Baska mask is a useful and safe alternative to ETT in patients undergoing short (<1 hr) laparoscopic procedures and surgeries. As compared to ETT, Baska mask has advantages of ease of insertion and lesser complications.
Key words: Baka mask, Airway, Laparoscopic procedures.

Received: 14 May, 2020 Accepted: 28 May, 2020

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This article may be cited as: Singhal R, Deshwal V, Chaudhary V. Baska Supraglottic Airway Device as an Alternative to Conventional Endotracheal Intubation in Patients Undergoing Laparoscopic Surgery. J Adv Med Dent Scie Res 2020;8(6):5-10.

INTRODUCTION

Laparoscopic surgeries namely, cholecystectomies, appendectomies, hernia repairs, urologic and minor gynaecological procedures are common in routine surgical practice.

Laparoscopic surgery has been shown to adversely impact intra-operative pulmonary mechanics, thus providing the most severe test of the efficacy of an airway device.[1] Pneumoperitoneum causes a fall in pulmonary compliance and increased airway resistance leading to high airway pressures.[2] The problems associated with maintenance of a patent airway and adequate ventilation are due to carbon dioxide insufflation in the peritoneal cavity, raised intra-abdominal pressure(IAP) and potential danger of regurgitation and pulmonary aspiration.

Supraglottic airway devices (SGAs) are gaining popularity as tools for airway management in anaesthesia and also in certain situations outside the operating room. These devices offer several advantages over the endotracheal tube (ETT) with regard to ease of insertion, haemodynamic stability, favourable

respiratory mechanics and decreased airway morbidity,[3-5] due to their positioning outside of the larynx they are less invasive as compared to ETT. SGAs have been used as an alternative to ETT in open surgeries under general anaesthesia but their use in laparoscopic surgeries has been very limited. The Baska Mask (PROACT Medical Systems, Frenchs Forest NSW, Australia), designed by Australian anaesthesiologists Kanag and Meena Baska**,** is a new supraglottic airway device, provided in single use and multi-use versions.

This study was conducted to compare the use of Baska mask and endotracheal tube (ETT) in patients undergoing short laparoscopic procedures/surgeries (<1 hr) under general anaesthesia using controlled ventilation. We compared time of insertion, hemodynamic changes during insertion and removal, efficacy of ventilation, and complications with use of Baska mask and ETT in laparoscopic surgeries.

Tracheal intubation is considered ideal for airway management in laparoscopic surgery as it provides safe glottic seal, adequate ventilation and protects against pulmonary aspiration even in the presence of raised airway pressures due to pneumo-peritoneum. However, the device is not fool proof against aspiration and endo-bronchial intubation is also not uncommon during laparoscopic procedures,[6] this definitive airway may fail in a difficult airway scenario.

MATERIALS AND METHODS

This prospective, comparative, randomised study was conducted after being reviewed and approved by institutional ethical committee in a tertiary care hospital. A total of 114 patients were enrolled in the study. The patients having presence of any significant acute or chronic lung disease, pathology of the neck or upper respiratory tract, potential difficult intubations, mouth opening <2.5 cm, cervical spine disease, increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux disease, full stomach pregnant women), patients with body mass index (BMI) >35 kg/m^2 and all emergency surgeries were excluded from the study. 14 patients out of 114 had to be excluded from the study as per the exclusion criteria. After obtaining written informed consent of patients, 100 adult patients of American Society of Anaesthesiologists physical status (ASA- PS) I or II undergoing elective laparoscopic surgeries were randomly allocated to one of the two groups of 50 patients each. In Group-B (Baska mask) appropriate sized Baska mask was inserted, and in Group-T (ETT), patients airway was secured with laryngoscopy guided endotracheal intubation. After securing intravenous (IV) line, all standard monitors like electrocardiogram (ECG), non- invasive blood pressure and pulse oximeter were applied and patient's baseline parameters, pulse rate (PR), mean blood pressure (MAP) and peripheral oxygen saturation (SpO_2) were recorded. Patients were premedicated with inj Glycopyrrolate 0.2 mg IV, Inj Ondansetron 50 µg/kg and inj Fentanyl 1.5 µg/kg IV. After 15 min of premedication all the patients were induced with inj Propofol 2-2.5 mg/kg IV and inj Atracurium 0.5 mg/Kg to facilitate the endotracheal intubation/ Baska mask placement. Airway devices (Baska mask and ETT) of appropriate size were then inserted. Position of the airway devices and efficacy of positive-pressure ventilation were assessed by observing adequate chest rise on manual ventilation, bilateral equal air entry on auscultation, normal capnograph tracing, absence of audible leak and normal SpO_2 (>95%). After fixing the airway device, appropriate sized gastric tube was inserted. Ease of insertion of Baska mask / ETT was assessed as a) Easy: No resistance to insertion in the pharynx in a single manoeuvre; b) Difficult: Resistance to insertion or more than one manoeuvre was required for the correct placement of the device; c) Impossible: Unable to insert Baska mask/ETT. We also recorded the number of attempts and time required for insertion of airway device. The time for insertion was recorded as time from cessation of face mask ventilation to the first capnograph trace. The ease of placement and the number of attempts required to place the device and gastric tube were noted. Anaesthesia was maintained with O_2 air, and inhalation agents and intermittent doses of inj atracurium. Controlled ventilation was provided with tidal volume of 8-10 ml/kg and respiratory rate set to obtain an end tidal carbon dioxide (Et CO_2) between 30 and 40 mmHg. At the end of surgery, neuromuscular blockade was reversed with Inj glycopyrrolate 10µg/kg and inj neostigmine 50µg/kg. Removal of Baska mask/ ETT was done after recovery of adequate spontaneous respiration and muscle strength. Monitoring of HR, NIBP, SpO_2, $EtCO_2$, and ECG was done throughout the peri-operative period. Haemodynamic and ventilatory parameters were recorded before induction (baseline), just after intubation, then at 3 and 5 min after Baska mask insertion/intubation, after pneumo- peritoneum, beforebefore removal of device and after Baska mask removal/extubation. Common complications such as coughing, laryngospasm, gastric distension, regurgitation, aspiration, blood on device, injuries (to lip, teeth, and gum) were recorded during the intraop period. Sore throat and dysphagia were recorded in postoperative period.

A total of 114 patients were enrolled and 14 patients were excluded as per exclusion criteria, and a balance sample size of 100 was studied (50 in each group) and calculated at 85% power and type-1(A) error of 0.05 using airway seal pressures, hemodynamics (HR and MAP) as primary outcome measures. Patients were randomly allocated to one of the two groups based on a

computer-generated code. The data was tabulated in Microsoft Excel data sheet; SPSS software (version 21.0; SPSS Inc, Chicago, IL) was used for the analysis. The independent t-test was used to compare the patient demographic profile. All the data obtained from the observations were compiled and subjected to relevant tests like Chi square, Fischer exact test, Pearson correlation, linear regression as required for statistical analysis. P value < 0.05 was considered significant.

OBSERVATIONS AND RESULTS

Participants of this study were recruited from routine laparoscopic surgery list and there were no dropouts. Demographic profile of the subjects is shown in Table-1, the parameters were comparable in both groups. No significant differences in terms of age, weight, height, BMI and duration of surgery were noted.

In all the patients the size of airway recommended by the manufacturer as per the age, weight and sex of patient was inserted. The type of laparoscopic surgery our patients in the study were subjected to are as per Table 2. The data regarding the size of Baska mask/ETT, attempts and ease of insertion of device and attempts for insertion of gastric tube, time taken for insertion of device and their sealing pressures are shown in Table 3. The mean time for insertion of the airway device was significantly less in group B (12.2 ± 2.1s) when compared with group T (19.4 ± 2.6 s). Baska mask was placed in 1st attempt in 45/50 (90%) cases and rest 5/50 (10%) cases required two attempts. ETT was placed in 1st attempt in 35/50 (70%) cases, 12/50 (24%) cases required two attempts and rest 3/50 (6%) required additional manoeuvres and attempt. Results for gastric tube insertion were comparable in both groups, Group B (1st attempt 92%, 2nd attempt 8%) and group T (1st attempt 88%, 2nd attempt 12%). There was no significant difference in the HR (P = 0.18) and MAP (P = 0.292) before insertion of airway device between the two groups. The variation in heart rate and MAP noted at different time intervals during the study is shown in table- 4 and table -5 respectively. Following insertion of airway device in group –T there was significant rise in HR from baseline just after intubation (24%, P = 0.01), 3 min after intubation (16%, P = 0.02) and 5 mins after intubation (11%, p = 0.02) . The figures for group B showed an increase in 5.2%, 2.5 % and – 2.5% respectively the p value was > 0.05. The rise in MAP in group – T followed the same trend as HR, a significant rise was noted just after intubation (22% P = 0.01), 3 min after intubation (15% P = 0.03), 5 min after intubation (10%, P = 0.03). In group-B patients the corresponding rise was 9%, 7.5% and 4.5% and were statistically not significant. However, after 5 min of securing the airway till the removal of airway device the changes in HR and MAP were statistically not significant in either groups. After removal of the airway devices there was again a significant rise in both the HR and MAP noted in group T. The rise in heart rate was 11% from the preceding value (p = 0.03) and the rise in MAP was 12% (p=0.04) from the preceding value. The corresponding rise in mean HR and MAP in group B were 5.4% and 5% respectively and statistically not significant.

SpO_2 and $EtCO_2$ between the two groups were comparable at all times. SpO_2 remained >95% and $EtCO_2$ remained between 30 and 40 mmHg, throughout the procedure in all patients.

There were no significant differences in complications associated with the use of either airway devices. On removal, visible blood indicative of mucosal injury was noticed in 2/50 (4%) patients of group - B. Injury to lips/gums/teeth was observed in 3/50 (6%) patients in group – T. Post-operative mild sore throat was observed in 2 /50 (4%) patients in group T and none in group B.

No incidence of coughing, bronchospasm, laryngospasm, regurgitation, aspiration or gastric insufflation was noted in group B however 2/50 (4%) patients in group- T had transient bronchospasm.

Table -1 Demographic Profile of the Patients

Demographic Parameters	Group B (Baska Mask)	Group T (ETT)	P - Value
Age (Years)	32 ± 4.7	34 ± 3.8	0.32
Weight (Kg)	55 ± 4.2	52 ± 4.8	0.28
Height (cm)	160 ± 8.6	162 ± 7.4	0.20
BMI (Kg/m^2)	22.2 ± 1.8	22.45 ± 2.1	0.44
Sex (M/F)	28 / 22	32/18	0.22
Surgery duration (Min)	46 ± 4.6	48 ±5.4	0.18

Table 2 Type of Surgeries in the study

	B Group	T Group
Lap Cholecystectomy	25	24
Gynaecological procedures	18	16
Herniorrhaphy	06	07
Urological Procedures	01	03

Table 3 - Size, ease of insertion and time to placement of the devices and sealing pressures

	Group - B	Group - T
Number of patients (size)	38 (3) 12 (4)	24 (7 mm ID) 20 (8 mm ID) 06 (8.5mm ID)
Ease of insertion (Easy/Difficult/Failed)	45/5/0	35/15/0
No. of attempts at insertion (1/2/3)	45/5/0	35/12/3
No. of attempts at gastric tube insertion (1/2/3)	46/4/0	44/6/0
Time taken for insertion (Sec)	12.2 ± 2.1	19.4 ± 2.6
Mean Sealing Pressure (cm H_2O)	33.05 ± 2.21	28.06 ± 6.2

Table – 4 Variations in HR between the two groups

Time Interval	Mean Heart Rate (beats/min) (SD)		P- Value
	Group B	Group T	
Before Induction (Baseline)	76.8 (10.20)	78.2 (11.6)	0.18
Immediately after placement of device (Baska/ETT)	80.7 (10.8)	96.9 (10.2)	0.01*
After 3 mins	78.8 (9.8)	90.7 (10.8)	0.02*
After 5 mins	74.9 (8.6)	86.8 (9.7)	0.02*
After Pneumoperitoneum	78.2 (11.2)	80.6 (11.4)	0.15
Prior to Device removal /extubation	77.9 (9.6)	76.8 (7.8)	0.40
Just after device removal/extubation	82.1 (10.2)	89.1 (9.4)	0.04*

SD – Standard Deviation
P value < 0.05 – significant *

Table – 5 Variations in MAP between the two groups

Time Interval	MAP (mm Hg) (SD)		P- Value
	Group B	Group T	
Before Induction (Baseline)	89.9 (9.1)	92.8 (8.6)	0.29
Immediately after placement of device (Baska/ETT)	97.9 (8.8)	113.2 (11.2)	0.01*
After 3 mins	96.0 (8.2)	106.7 (8.2)	0.03*
After 5 mins	93.9 (10.1)	101 (9.6)	0.03*
After Pneumoperitoneum	93.2 (10.6)	95.4 (10.6)	0.15
Prior to Device removal /extubation	90.8 (7.8)	90.8 (7.8)	0.40
Just after device removal/extubation	95.3 (8.6)	101.7 (9.2)	0.04*

MAP – Mean Arterial Pressure
SD – Standard Deviation
P value < 0.05 – significant *

Table: 6 Complications during placement / device removal

	Group B n = 50 (%)	Group T n = 50 (%)	P Value
Cough	0	0	
Bronchospasm	0	2 (4)	0.12
Evidence of regurgitation	0	0	
Evidence of aspiration	0	0	
Oral/Tracheal trauma	0	3 (6)	0.08
Blood stains on the device	2 (4)	3 (6)	0.2
Dysphagia	0	0	
Sore throat	0	2 (4)	0.08

DISCUSSION

Baska mask is a relatively newer supraglottic device with features for better patient safety in terms of better sealing pressure, it gives higher sealing pressure compared to other supraglottic devices.[7] Its safety profile is comparable to Endotracheal tube which is considered as gold standard for definitive airway management. Conventional laryngoscopy and placement of ETT have adverse hemodynamic consequences in the form of tachycardia and hypertensive response due to sympatho-adrenal response. Placement of supraglottic device with good

sealing pressure can be an alternative to ETT eliminating the pressor response to laryngoscopy and intubation.

In our study we observed a rise in heart rate in group T compared to group B immediately, at 3 mins and 5 mins after intubation / Baska mask placement. The rise was 24%, 16%, 11% from baseline immediately after intubation, at 3 minutes & 5 minutes after intubation respectively in group T ($p < 0.05$), for group B the corresponding figures were 5.2%, 2.5%, and – 2.5% respectively ($p > 0.05$). The HR did not show any significant variation at different time intervals till extubation / device removal in either group. At the time of device removal/extubation HR showed a rise in both the groups; 5.4% for the B group and 11% for the T group from the previous readings. The pattern of rise in MAP followed the same trend as HR in both the groups at different time intervals. The rise of MAP in group T was statistically significant immediately after ETT placement, at 3 mins and 5 mins intervals, it showed a rise by 22%, 15% and 10% respectively. The corresponding figures for group B were 9%, 7.5% and 4.5 % and were not statistically significant. The MAP did not rise significantly till the device removal or extubation and showed a rise after the device removal which was 12% and 5 % for group T and group B respectively. Similar to the HR, the rise in MAP was statistically significant in group T. Similar results were found in study conducted by Khetarpal et al in which they compared Baska mask and ETT in adult patients undergoing open surgeries under general anaesthesia.[8] Study by Lamba et al on victims of military trauma managed with Baska mask and ETT also concurred with our findings of significantly exaggerated pressor response to ETT placement compared to Baska mask.[9]

Baska mask forms an effective seal around the glottis allowing adequate oxygenation and controlled ventilation as good as ETT. Oxygenation and ventilation were optimal in all our patients throughout the surgery as well as in post-operative period. The oxygenation and ventilation measured by ETCO2 readings, capnography trace and pulse oximetery showed no adverse pattern in any of our patients in our study. The average SPO2 in our study was 97.6% in group B and 98.2 % in group T. The $ETCO_2$ readings remained between 30-40 mm Hg in all patients in both the groups. The mean seal pressure of Baska mask in Group B was found to be 33.05 ± 2.21cm of H2O. The cuff pressure of ETT in Group T was 28.3 ± 6.3 cm of H_2O. The high sealing pressure in B group which increases with IPPV and forms an effective laryngeal seal preventing aspiration and leak around the laryngeal opening is an inherent advantage of Baska mask. The mean sealing pressures of Baska mask recorded in a study by Khetarpal et al was 37.03 ± 2.28 cm of H_2O.[8] Study by Kumar et al found that the mean seal pressure of Baska mask was 42.46 ± 19.11 cm of H2O which is higher than our study.[10]

The firmness of the tube section of Baska mask and its natural oropharyngeal curve allows the device to be easily and rapidly inserted by grasping the proximal part, which helps to glide the leading edge against the hard palate into pharynx. There is a tab which can be pulled to increase the curvature of Baska mask for easy insertion and thereby increasing the success rate with first attempt even with inexperienced anaesthesiologists. In our study Baska mask was successfully placed in 1st attempt in 45/50 (90%) cases and rest 5/50 (10%) cases required 2nd attempt. The mean times from insertion of airway device to the first capnograph trace was significantly less for Baska mask (12.2 ± 2sec) when compared with ETT (19.4 ± 2.1sec). Endotracheal intubation involves laryngoscopy for visualisation of larynx and adds to time taken for securing the airway. Study by Mahajan SM, showed the mean insertion time for Baska mask as 11.02 ± 2.11s.[11] Studies by Lamba et al[9] and Khetarpal et al[8] recorded Baska mask insertion time of 10 ± 2 s and 12.8 ± 1.36s and for ETT placement 16 ± 2s and 15.93 ± 1.51s respectively. The difference in time for insertion of Baska mask and ETT was statistically significant in all the studies. Results for gastric tube insertion were comparable in both Baska mask (1st attempt 92%, 2nd attempt 8%) and ETT (1st attempt 88%, 2nd attempt 12%) groups.

There were no significant differences in complications associated with the use of either airway devices. On removal, visible blood indicative of mucosal injury was noticed in 2/50 (4%) patients in group - B. Minor injury to lips/gums/teeth and post-operative mild sore throat was observed in 3/50 (6%) patients in group – T.

No incidence of coughing, bronchospasm, laryngospasm, regurgitation, aspiration or gastric insufflation was noted in group B however 2/50 (4%) patients in group- T had transient bronchospasm which settled with the inhalation of bronchodilators.

CONCLUSION

We concluded that Baska mask requires less time for insertion with minimal hemodynamic changes when compared to ETT. Baska mask also provides adequate positive-pressure ventilation, comparable with ETT. In addition, the gastric channel in Baska mask provides protection against aspiration. Hence, Baska mask can be a safe and suitable alternative to ETT for laparoscopic surgeries of less than one hour duration.

ACKNOWLEDGMENT

We are thankful to Department of Surgery and Obstetrics & Gynaecology for allowing us to do study.

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