A Randomised Clinical Trial to Compare the Effectiveness of Baska Mask Versus i-gel in Patients Undergoing Laparoscopic Surgeries in a Tertiary Centre

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ABSTRACT

BACKGROUND

A wide array of supraglottic airway devices (SAD) are available for the present day anaesthetic practice, each having its own unique features. Laparoscopic surgeries demand meticulous airway maintenance due to the impact of pneumoperitoneum on cardiorespiratory physiology. It thus becomes imperative to have knowledge about the most optimal SAD that can be used for laparoscopic surgeries to provide good quality anaesthesia. The objective of this randomised trial was to compare the airway sealing pressure (ASP) of Baska mask and i-gel and overall success rate in patients undergoing laparoscopic surgeries under general anaesthesia and controlled ventilation.

METHODS

One hundred and forty patients undergoing laparoscopic surgeries were randomly assigned to either Baska group (Group B) or i-gel group (Group I). Anaesthesia was induced with propofol 2 - 2.5 milligram per kilogram (mg / kg) and relaxation achieved with vecuronium 0.1 mg / kg and SAD was inserted. The primary outcome was airway sealing pressure (ASP) noted after insertion of the device. The secondary outcome measures included the number of attempts and time taken for successful insertion, ASP after gas insufflation of abdomen, Brimacombe grading, hemodynamic changes, airway morbidity (blood on the SAD upon removal, post-operative sore throat, dysphagia and dysphonia) and any other adverse events associated with the use of the devices.

RESULTS

There were no significant differences in demographic and hemodynamic data. ASP after insertion of the device was significantly higher ($p < 0.0001$) with Baska than i-gel (41.45 $\pm$ 4.72 versus 30.29 $\pm$ 5.76 cm H_2O respectively). Brimacombe scoring of grade four was seen in 75.3 % of Baska compared to 18 % in i-gel group. Time taken to insert Baska was significantly more than with i-gel (14.84 versus 11.25 seconds respectively, $P < 0.001$). However, first time success was more with Baska than with i-gel (147 versus 140 respectively).

CONCLUSIONS

Both Baska and i-gel can be used safely and effectively in laparoscopic surgeries. Baska provides a better ASP and Brimacombe view than i-gel. However, i-gel offers the advantage of easier insertion in shorter time.

KEYWORDS

Supraglottic Airway Device, Baska Mask, i-gel, Airway Sealing Pressure

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BACKGROUND

Supraglottic airway devices (SAD) are routinely used to secure the airway in a variety of clinical settings. With the introduction of Dr Archie Brain's laryngeal mask airway-classic (cLMA) into clinical practice in 1988, endotracheal intubation and face mask ventilation were replaced by the use of SAD in > 40 % of cases requiring general anaesthesia.[1] The scope of its use widened dramatically, with the development of newer and better devices with improved structure like integrated bite blocks and separate gastric channels. They also provide stable haemodynamics, and have a lower incidence of emergence cough and postoperative sore throat. However, some concerns with these devices remain, such as failure to provide adequate ventilation and increased likelihood of pulmonary aspiration of gastric contents.[1] Hence it becomes obvious to study and compare the SADs in various clinical settings and patient populations to establish its safety and efficacy. In this study we attempted to compare the ASP of Baska mask with i-gel, another commonly used 2nd generation SAD in elective laparoscopic surgeries requiring general anaesthesia and controlled ventilation.

i-gel is a second-generation SAD which is anatomically designed with non-inflatable soft gel like material.[2] It is made up of medical grade thermoplastic elastomer called styrene ethylene butadiene styrene. The soft non inflatable cuff fits snugly onto the peri laryngeal framework and when properly placed, the tip lies in the proximal opening of the oesophagus. This tip incorporates the distal end of an integrated drainage tube, termed as 'gastric channel' by the manufacturers. The device also has a buccal cavity stabiliser which adapts its shape to the oropharyngeal curvature of the patient and houses the airway tubing and the gastric channel.[3,4]

Baska mask is a newly introduced third generation SAD. It's structure incorporates the features of LMA Proseal, LMA supreme, i-gel and SLIPA.[5] It has a medical grade silicon cuff which is non inflatable, self-sealing, membranous, of variable pressure, and designed in such a way that during IPPV, the seal opposes to the glottis incrementally to augment seal pressure with increasing airway pressure. Baska mask also has an esophageal drainage inlet and side channels for aspiration of gastric contents and an integrated bite block. The dorsal surface of the cuff is moulded to direct any oropharyngeal contents away from the glottis and towards the side channels to which suction can be attached. Another unique feature of Baska mask is the presence of an extended hand tab attached to the cuff that permits the operator to control the degree of flexion of the device during insertion. The device comes in four sizes ranging from paediatric to adult.[5,6,7]

METHODS

This was a randomized open labelled clinical trial conducted from January 2017 to December 2018 at a tertiary health care medical college in South India. All patients undergoing elective laparoscopic surgical procedures (laparoscopic cholecystectomy, appendicectomy, total laparoscopic hysterectomy) under general anaesthesia were assessed for eligibility for inclusion in this study. The inclusion criteria were patients aged between 18 to 60 years, of both gender, belonging to American Society of Anaesthesiologist Physical Status (ASA-PS) I - II, with no relevant allergies (silicon) and with Body mass index (BMI) of 20 - 30 kilogram per square meter. Patients with neck pathology, previous / anticipated problems with the upper airway or upper GI tract (reflux, hiatus hernia, oropharyngeal tumour, upper respiratory tract infection in preceding ten days), predicted or previously documented difficult airway, and pregnant patients were excluded from the study.

Randomization was done using computer generated random numbers which was kept in sealed opaque envelop. A detailed pre-anaesthetic evaluation was done 24 hours prior to surgery and after confirming eligibility for inclusion, an informed consent for enrolment in the study was obtained. Allocation was after the consent at the end of the pre anaesthetic evaluation.

All patients received a standardised general anaesthetic care. Standard monitoring included electrocardiogram, non-invasive blood pressure, pulse oximetry (SpO2) and end-tidal carbon dioxide (EtCO2) monitoring. All patients were premedicated with 0.02 mg / kg midazolam, ondansetron 4 mg intravenously prior to induction of anaesthesia. Anaesthesia was induced in the supine position with the patient's head in neutral position using propofol 2 – 2.5 mg / kg, fentanyl 1.0 microgram (mcg) / kg, and vecuronium 0.1 mg / kg. Following adequate relaxation, a well lubricated Baska mask size 3 or 4 or i-gel mask (according to the manufacturers' recommendations of weight based estimate plus clinical judgement) was placed.

After lubricating the i-gel, it was held firmly with its cuff outlet facing the chin. Then it was gently pressed down into the mouth in a direction towards the hard palate until a definitive resistance was felt. In the cases where Baska mask was used, the proximal part of the mask was compressed between the fingers and the mask was inserted in the mouth avoiding the tongue. It was pushed against the hard palate until resistance was encountered, denoting that the tip of the mask was at the upper end of the oesophagus.

A clear airway was defined as SpO2 > 95 %, EtCO2 between 35 - 45 millimeter mercury (mm Hg), bilaterally equal chest rise and end-tidal waveform traces with plateau. Suction apparatus was attached to gastric channel via the suction elbow either continuously or intermittently as required. The other channel was left open to atmosphere in Baska. Anaesthesia was maintained with isoflurane 0.8 % to 1.5 % in a mixture of 60 % nitrous oxide and oxygen. If the device placement was considered inadequate, as judged by poor capnographic curve and/or delivery of inadequate tidal volumes (fractional loss of > 20 % of set tidal volume); it was remedied by jaw thrust and adjusting the depth of insertion; removal and re-insertion for a maximum of two attempts or changing the size. Continued ineffectiveness was treated as failure and the patient's airway was managed by performing endotracheal intubation.

First pass success was defined as a smooth and easy insertion in first attempt with no further need for manipulations, adjustments or reinsertions to ensure effective ventilation and correct placement of the device. ASP was measured approximately five minutes after SAD insertion and again at five minutes, after creation of pneumoperitoneum by setting the pressure of the adjustable pressure limiting valve at 70 cm H2O, placing the bell of the stethoscope on the patient's trachea and noting the peak airway pressure at which a leak was audible over the trachea. The Brimacombe grading was assessed by passing the fibre optic scope through the SAD and visualising the glottic structures. A nasogastric tube of appropriate size was then passed through the gastric channel of the respective SAD after creation of pneumoperitoneum.

Heart rate and systolic blood pressure were measured before and soon after insertion of SADs. At the conclusion of surgery, SAD was removed after establishing adequate respiration and reversal from neuromuscular blockade with injection neostigmine 0.05 mg / kg and injection glycopyrolate 0.01 mg / kg. Upon removal of the SAD, Laryngopharyngeal morbidity (LPM) in terms of blood on the SAD was noted and post-operative sore throat, dysphagia and dysphonia were noted two hours later.

Airway sealing pressure noted soon after insertion of SAD was the primary outcome. The secondary outcomes included following parameters: ASP after abdominal gas insufflation, device insertion time, number of attempts, ease of insertion, fibreoptic laryngeal view, hemodynamic changes with insertion and LPM. Insertion time needed for placement of the device was defined as time in seconds from device touching the teeth to the first recorded near rectangular capnogram curve.

Only the successful attempt time was counted. Number of attempts needed to correctly place the device was counted as an attempt when the mask was taken in and out of the mouth. Insertion was defined as easy if there was no resistance to the passage of the SAD through the oropharynx.

Fibreoptic laryngeal view was assessed using Brimacombe grading scale which is as follows: four = only vocal cords seen; three = vocal cords plus posterior epiglottis seen; two = vocal cords plus anterior epiglottis seen; one = vocal cords not seen, but function adequate; zero = failure to function, where vocal cords are not seen fibreoptically. Intraoperative oxygen desaturation (SpO2 < 90 %) and regurgitation/aspiration and any other adverse events were noted. This trial was approved by institutional ethics committee [JSS / MC / PG / 4623 / 2018 - 19] and informed consent of the patients was taken prior to enrolment in the trial.

Statistical Analysis

Based on prior trials, we expected a difference of 10 cmH_2O in sealing pressure between Baska mask and i-gel mask.[3,5] With 80 % power and a significance level of 5 %, a minimum of 63 subjects were required in each group for the study. Assuming failure in SAD insertion in some cases we enrolled 70 cases in each group. All data were entered in Microsoft excel sheet and statistical calculations were performed using SPSS version 19 software. All continuous variables were analyzed using independent sample t test and all categorical variables were analyzed using chi square test or Fisher's exact test.

RESULTS

The baseline parameters of enrolled patients are given in table 1. All the baseline parameters were comparable between two groups. The outcome data is provided in table 2. Baska mask provides a significantly better airway sealing pressure than i-gel – both after insertion and after creating pneumoperitoneum. Fibreoptic visualization of glottis is better with Baska mask. However, i-gel demonstrated easier insertion in a shorter time.

A statistically significant marginal increase in both pulse rate [mean (SD) of 7.71 (5.08) vs 5.94 (5.82) $p < 0.05$] and systolic blood pressure [mean (SD) of 6.05 (5.37) vs 4.77 (7.11) $p < 0.001$] was noted with Baska mask insertion.

Post-operative sore throat was significantly higher in Baska mask group compared to i-gel group (56.7 % vs 23.3 %). In two cases blood stains were noted on Baska mask upon removal, while none in i-gel group had such findings.

Variable	Group B	Group I	P Value
Age (years) Mean (SD)	37.65 (12.5)	36.91 (13.4)	0.6
Female n (%)	35 (50.0)	36 (51.4)	0.7
Type of surgery			
Lap. Appendicectomy	18 (23.7 %)	17 (24.2 %)	0.96
Lap. Cholecystectomy	40 (57.1 %)	38 (54.2 %)	
Lap. Hysterectomy	12 (17.1 %)	15 (21.4 %)	

Tables 1. Comparison of Baseline Variables between Baska Mask and i-gel Group

Group B= Baska mask, Group I= i-gel; Lap= laparoscopic

Variable	Baska Mask	i-gel	P Value
ASP after insertion (mm of Hg)*	41.45 (4.72)	30.29 (5.76)	< 0.0001*
ASP after pneumoperitoneum (mm of Hg)*	44.25 (3.78)	30.82 (5.54)	< 0.0001*
Time for insertion (second) $	14.84 (1.85)	11.25 (1.76)	< 0.0001*
Successful insertion in first attempt#	69 (98.5)	65 (92.8)	0.04*
Brimacombe grading#			
I/II	5/0 (7.1 %)	5 / 25 (42.8 %)	< 0.0001*
III	12 (17.1 %)	27 (38.5 %)	
IV	53 (75.7 %)	13 (18.5 %)	
Ease of insertion#			
Yes	59 (84.2 %)	70 (100 %)	0.0006*
No	11 (15.8 %)	0	

Table 2. Comparison of Outcome Variables between Study Groups

* in mean (SD), # in n (%)

$ indicates statistical significance at $P < 0.05$

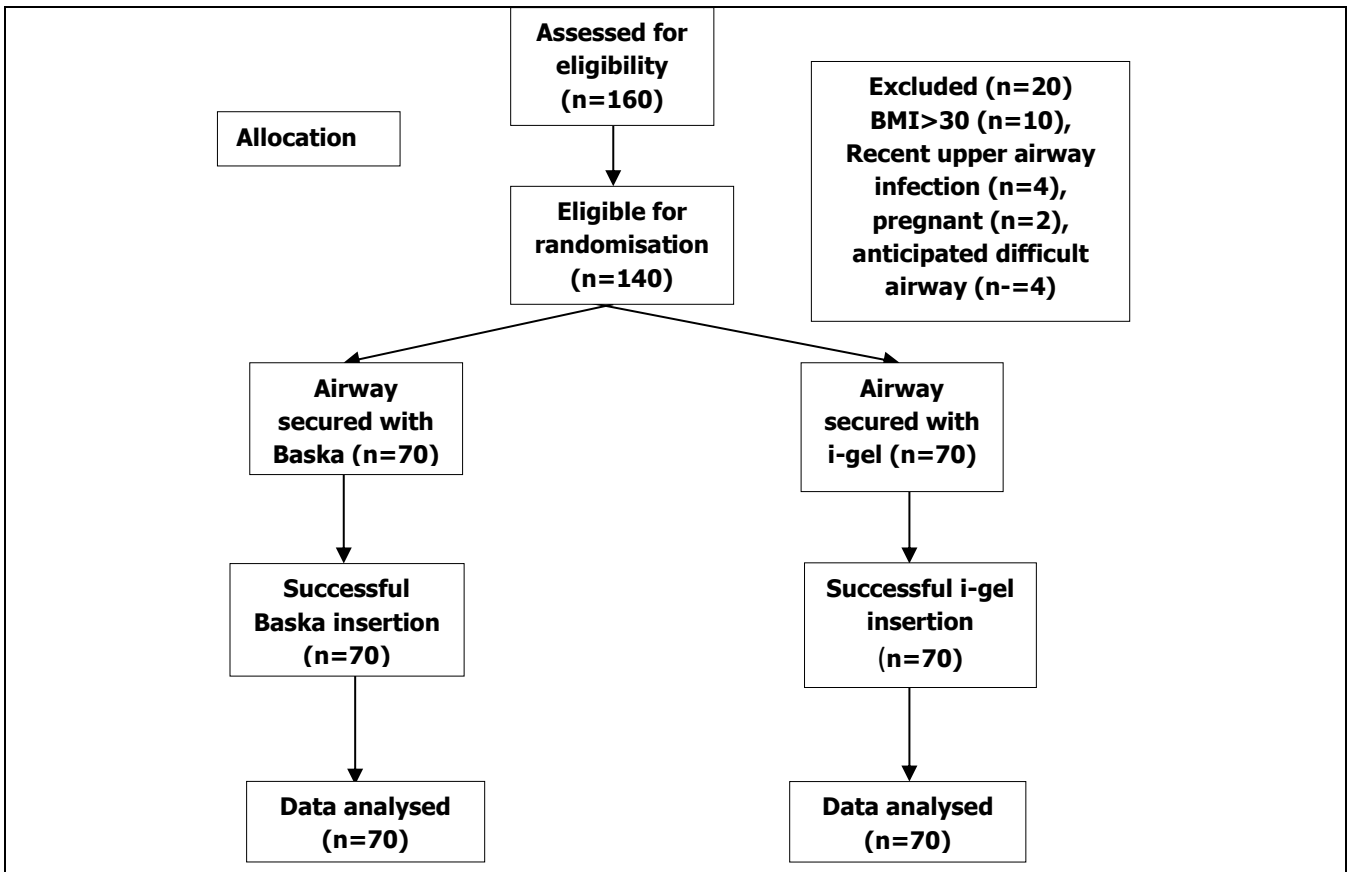

Figure 1. Consort Flow Chart

DISCUSSION

Baska mask is a recently introduced third generation SAD. It is slightly bulkier than commonly used second generation SAD like i-gel. It is supposed to give better airway sealing pressure than i-gel. This higher ASP is helpful in reducing the incidence of aspiration. Laparoscopic surgeries pose a different challenge while using SAD. Maintaining a reliable airway seal becomes important to maintain effective ventilation and prevent aspiration in these cases. Creation of pneumoperitoneum alters the physiology of the adjacent respiratory system due to upward displacement of diaphragm causing changes in compliance and resistance. The higher ASP provided by Baska mask may be useful in these cases. But, there is paucity of evidence on higher ASP in laparoscopic surgeries. Hence we looked into this data in our study.

We observed that Baska mask provided a better airway sealing pressure of 40.4 cm of H2O compared to 30.3 cm of H2 O with i-gel after insertion. This is in concordance with several other studies.[6,8] The ASP after creating pneumoperitoneum increased in Baska mask group and this was not seen in i-gel group. The elevated ASP post pneumoperitoneum was statistically significant. The relatively more increase in ASP of Baska mask can be explained by the fact that it gets "inflated" with the increasing pressure of positive pressure ventilation after creation of pneumoperitoneum, thereby bettering its seal with the glottic aperture. This reduces the leak, and increases the efficiency of ventilation.[7] It has been found by Gabbott et al in their study that the thermoelastic gel cuff of i-gel warms up to the body temperature upon placement and provides a good airway seal which improves over time.[9] Though the ASP is found to be lesser than that of Baska, several studies comparing i-gel with other SADs have provided conclusive evidence that i-gel can be used safely for positive pressure ventilation without the risk of aspiration as the sealing pressures of i-gel is almost similar to LMA-Proseal and more than that of Classic LMA and LMA-Unique.[10,11,12] In our study too, though the ASP was less with i-gel, there were no cases of failure or air leak noted.

The mean time of insertion of i-gel was 11.25 seconds compared with 14.84 seconds for Baska mask placement. A similar finding of shorter insertion time for i-gel placement has been reported in other studies as well.[6,13,14] However, in our study, we noticed a greater first time success rate for Baska (147 / 150) than for i-gel (140 / 150). This discrepancy between ease of insertion and first pass success rate can be explained by the fact that though i-gel is easier to insert, the correct positioning as assessed by adequate bilateral chest rise, bilateral equal air entry upon auscultation and a satisfactory capnogram was better with Baska mask with first time insertion itself as compared to i-gel, which required other manoeuvres for a satisfactory placement.

The exact position of the cuff was confirmed fibre optically and scored by means of Brimacombe grading in our study. Studies comparing this particular parameter are sparse and hence we took it up to add to the existing body of information about the SADs and their precise placements. We noted that Baska mask provided a grade four anatomical

positioning in 113 patients as compared to only 27 patients in i-gel group. This was statistically significant.

There was a statistically significant increase in heart rate and systolic blood pressure soon after insertion in the Baska mask group, though it was not significant clinically. This can probably be explained by the bulkier structure of Baska mask and more time taken for its insertion compared to i-gel. We had no case of aspiration in both groups. The study was not powered enough to prove reduced incidence of aspiration. There was also no failure in device insertion needing endotracheal intubation.

The main strength of our study is in higher sample size. However the study was carried out in cases with no anticipated difficult airway. Given the nature of intervention, blinding was not possible.

CONCLUSIONS

Baska mask provides a better and well sustained airway sealing pressure in cases of laparoscopic surgeries. However, it takes longer time to insert and a marginally higher incidence of minor airway trauma was noted with Baska mask compared to i-gel. The hemodynamic changes, laryngopharyngeal morbidity were not significant clinically. We conclude that both Baska and i-gel can be safely used in laparoscopic surgeries though Baska may have a slight clinical advantage by providing a better oropharyngeal seal, favourable Brimacombe scoring, and hence an improved safety profile.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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