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Comparison of Baska mask and I-gel with endotracheal tube in laparoscopic cholecystectomy: A randomized controlled study

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ABSTRACT

Background: Supraglottic airway devices are frequently used instead of endotracheal intubation in laparoscopic surgeries. Two such devices, I-gel (IG) and Baska mask (BM), have been compared with respect to their sealing properties and leak fraction (LF) in comparison to the endotracheal tube. **Aims and Objectives:** The aim of the present study is to compare the performance of IG and BM with endotracheal tube in patients undergoing laparoscopic cholecystectomy under general anesthesia. **Materials and Methods:** In this randomized trial, 84 patients scheduled for laparoscopic cholecystectomy under general anesthesia were randomized to group (endotracheal tube [ETT], n = 28), group BM (BM, n = 28), or group IG (IG, n = 28). All the patients received standard general anesthesia and the airway was maintained with either of three devices. The primary outcomes were the difference in the LF and airway sealing pressure (ASP) at different time points before and after pneumoperitoneum. Secondary outcomes were insertion-time, number of insertion attempts, and gastric insufflations. Heart rate and blood pressure were recorded. Complications such as sore throat, coughing, laryngospasm, blood staining of the device, and aspiration were noted. **Results:** P-values of LF of the three groups at time points T- after insertion (Ti), T-after pneumoperitoneum (Tp), and T- after peritoneal deflation (Tr) were 0.000 each and P-values of ASP at those time points were 0.000 each, respectively. Insertion time was significantly less for IG than ET ($P < 0.001$). Heart rate and blood pressure showed P-values at Ti and Tp ($P = 0.004$ and 0.000). **Conclusion:** It was concluded that IG or BM can maintain an airway with adequate seal and were not associated with any incidence of aspiration or laryngospasm. IG placement was found to be easier whereas the ease of ventilation was noted with BM.

Key words: Baska mask; I-gel; Airway sealing pressure; Leak fraction; Laparoscopic surgeries

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INTRODUCTION

Introduction of first- and second-generation supraglottic airway devices (SAD/supraglottic airway [SGA], Cook's classification[1]) for airway management in clinical practice, to aid mechanical ventilation and delivery of anesthetic gases has provided viable alternatives to tracheal intubation.[1,2] Till date, the cuffed endotracheal tube (ETT) has been the gold standard for providing a safe glottic seal for thoracic and abdominal surgeries (especially laparoscopic) under general anesthesia.[3,4] Laryngeal mask airway (LMA) is routinely used in clinical practice[5] during anesthesia for

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spontaneously breathing patients[6] in short procedures and also used for positive pressure ventilation (PPV) and is less invasive than an ETT.

I-gel (IG) is a second-generation SAD with a soft gel-like non-inflatable cuff designed to provide an anatomical fit into the perilaryngeal framework with effective seal withstanding high airway pressure during PPV. Recent studies support its successful use during surgery for spontaneously breathing anesthetized patients[7,8] and PPV patients with few complications. The Baska mask (BM) is a SAD with non-inflatable cuff that is continuous with the airway channel and, thus, gets inflated with PPV improving cuff seal.[9] The advantages of SGAs include the ease of placement, improved hemodynamic stability, reduced anesthetic requirements, and less complications of tracheal intubation.[10,11] SGAs provide lower airway sealing pressure (ASP) than ETTs.[12] Higher inspiratory pressures in laparoscopic surgeries may exceed the ASP increasing the leak fraction (LF) and chances of aspiration. Second-generation SADs which provide higher seal pressure and separate channels for alimentary and respiratory tracts are, therefore, desirable for laparoscopic surgery.[13]

The aim of the present study is to compare the performance of IG and BM with endotracheal tube in patients undergoing laparoscopic cholecystectomy under general anesthesia.

Aims and objectives

1. The primary objectives of this study were to compare the leak fraction and the airway sealing pressure of the three devices.
2. The time taken for insertion of the three devices, number of insertion attempts, the hemodynamic parameters at various time points and any other adverse effects were also noted.

MATERIALS AND METHODS

After Ethics Committee approval from IPGME&R, SSKM Hospital, and obtaining a written informed consent from all the patients eligible for the study, the randomized clinical trial was conducted in the main surgical OT complex.

Patient allocation

Eighty-four patients were randomized to group (endotracheal tube [ET], n=28) or group BM (BM, n=28), or group IG (IG, n=28). Randomization was done by a computer-generated random number table. Standard technique of general anesthesia was followed in every patient and the insertion of all airway devices was done by the same anesthesiologist.

Inclusion and exclusion criteria

Patients aged between 18 and 65 years weighing 30–80 kg with ASA physical Status I–II scheduled for laparoscopic cholecystectomy under general anesthesia were included in the study. Patients with a difficult airway, body mass index >30 kg/m^2, high risk of aspiration, and other systemic diseases were excluded from the study.

Anesthesia and device performance

The patients were fasted for 8 h preoperatively. In the OT standard monitoring devices, that is, non-invasive blood-pressure measurement, pulse-oximetry, temperature-probe, end-tidal carbon-dioxide sensor, and electrocardiogram were attached and baseline vitals recorded. Anesthetic machine, drugs for general anesthesia, airway device, and resuscitation measures were checked and kept ready. Patients were pre-oxygenated with 100% oxygen for 3 min. Injection glycopyrrolate (0.1 mg/kg), fentanyl (2 mcg/kg), and standard anti-aspiration measures were given as premedication 5 min before induction. Patients were induced by thiopentone sodium (5 mg/kg). After checking adequate mask ventilation, injection atracurium (0.5 mg/kg) administered and the patients were ventilated with 100% oxygen for 3 min.

In group ET, trachea was intubated with internal diameter of 7.0 mm and 8.0 mm for women and men, respectively, in the standard "sniffing the morning air" position. ETT cuff pressure was maintained at 20–30 cm H_2O.

The size of IG to be used was determined by the weight as well as height: Size 3 for 30–50 kg (up to 60 kg, if patient's height was <160 cm), size 4 for 60–90 kg (down to 50 kg, if patient's height was >160 cm). BM size 3 was used for 30–60 kg, size 4 for >60 kg, and size 5 for average adult males. The BM and IG were lubricated on the external side and inserted along the hard palate strictly as per recommended insertion technique of the manufacturer. Mouth opening was aided with the right hand thumb and index finger and with the left hand the device was inserted along the hard palate until resistance was met. There was additional hand control to aid the flexion of the BM for easy passage. Effective ventilation was ascertained with bilateral air entry on auscultation of the chest with no audible leak, chest movement, and capnography. Thereafter, device was taped over the chin and connected to anesthesia machine.

Proper placement of a nasogastric or gastric tube was done and placement confirmed. Anesthesia was maintained with oxygen at 40%, nitrous oxide at 60%, isoflurane at 1% with fresh gas flow adjusted at 5 L/min, fixed tidal volume of 8 mL/kg, and inspiratory to expiratory ratio 1:2 without positive end-expiratory pressure. Respiratory rate was adjusted to maintain 35–45 mmHg end-tidal

carbon dioxide ($EtCO_{2)}$. Intra-abdominal pressure was maintained around 12–14 mm of Hg throughout surgery with goals to maintain SpO_2 >95% and $EtCO_2$ <45 mmHg. Hypercarbia was managed with increasing respiratory rate and tidal volume.

All attempts were made by the same anesthesiologist who had experience of at least 25 device insertions prior. Insertion time was measured from the time of withdrawal of facemask until successful ventilation of the chest. Gentle pushing, pulling, head extension, jaw thrust, or neck flexion manipulations were tried before considering failed attempt that is when the device was removed from the mouth after initial placement. Three attempts were allowed. In case of failure, the device was removed and endotracheal intubation done and the patient excluded from the study. In the case of difficult intubation, the difficult airway protocol was followed.

Oropharyngeal leak pressure (OLP)/ASP (OLP/ASP in cm H_2O) was then measured using a fresh gas flow rate 5 L/min, by closing the adjustable pressure limiting valve of the anesthetic circuit and recording airway pressure (not allowed to be more than 40 cm H_2O) at which equilibrium was achieved noted by:

1) Plateau on pressure-time curve/digitally displayed pressure gauge
2) Pressure at which audible gas leak was heard by auscultation at the lateral aspect of thyroid cartilage.

The LF was calculated as leak volume (Inspiratory tidal volume [ITV] – expiratory tidal volumes [ETV] [ml]) divided by ITV.

The primary outcomes of the study were the difference in the LF and ASP between three airway devices under investigation at different time points before and after pneumoperitoneum (intra-abdominal pressure 12–14 mm/Hg). Secondary outcomes were time taken for insertion, number of insertion attempts, and presence of gastric insufflations. Heart rate and blood pressure were recorded at the following time points:

- To/B – Before insertion
- Ti – After insertion
- Tp – After pneumoperitoneum
- Tr – After peritoneal deflation
- Te – After extubation
- $EtCO_2$ – at T-insertion (Ti), Tp and Tr.

15 min before completion of the surgery, all patients received ondansetron (4 mg), the gastric drainage tube suctioned. Residual neuromuscular blockade reversed with neostigmine 0.05 mg/kg IV and glycopyrrolate 0.01 mg/kg IV and the devices were removed after fulfilling the criteria of adequate reversal.

Complications such as sore throat, coughing, laryngospasm, blood staining of the device, gastric distension, and aspiration were noted. The data were collected by an observer and analyzed using standard statistical methods.

Statistical analysis

The sample size for this study was based on LF and ASP, which is the primary outcome measured. It is estimated that 28 subjects will be required per group to detect the difference of 20% in LF in a study with 80% power and 5% probability of Type 1 error. This calculation assumes standard deviation of LF to be 0.02 and two-sided testing. Sample size calculation was done using nMaster 2.0 (Department of Biostatistics, Christian Medical College, Vellore) software.

Data were summarized as mean and standard deviation for numerical variables that are normally distributed, the median and interquartile range for skewed numerical variables, and count and percentages for categorical variables. Numerical variables were compared between groups by one-way analysis of variance (ANOVA), if normally distributed, or by Kruskal–Wallis H test, if otherwise; analysis was two-tailed and statistical significance level was set at $P<0.05$ for all comparisons (Figure 1).

RESULTS

The mean age and sex distribution in all the three groups were comparable. The mean age of group ET, group BM, and group IG were 42.61, 40.25, and 40.93 years, respectively.

ANOVA determined P-values of LF of the three groups at time points Ti, Tp, and Tr to be 0.000, 0.000, and 0.000, respectively, which were statistically significant (Table 1 and Figure 2).

Table 1: Leak fraction of the three devices at Ti, Tp, and Tr

Time point	Group	Mean	Median	Standard deviation	P-value
Leak fraction Ti	Group ET	0.02	0.03	0.016	0.000
	Group BM	0.06	0.06	0.026	
	Group IG	0.07	0.07	0.026	
Leak fraction Tp	Group ET	0.04	0.04	0.023	0.000
	Group BM	0.07	0.07	0.025	
	Group IG	0.06	0.06	0.023	
Leak fraction Tr	Group ET	0.03	0.03	0.021	0.000
	Group BM	0.06	0.06	0.027	
	Group IG	0.04	0.04	0.028	

BM: Baska mask, IG: I-gel, Ti: After insertion, Tp: After pneumoperitoneum, Tr: After peritoneal deflation

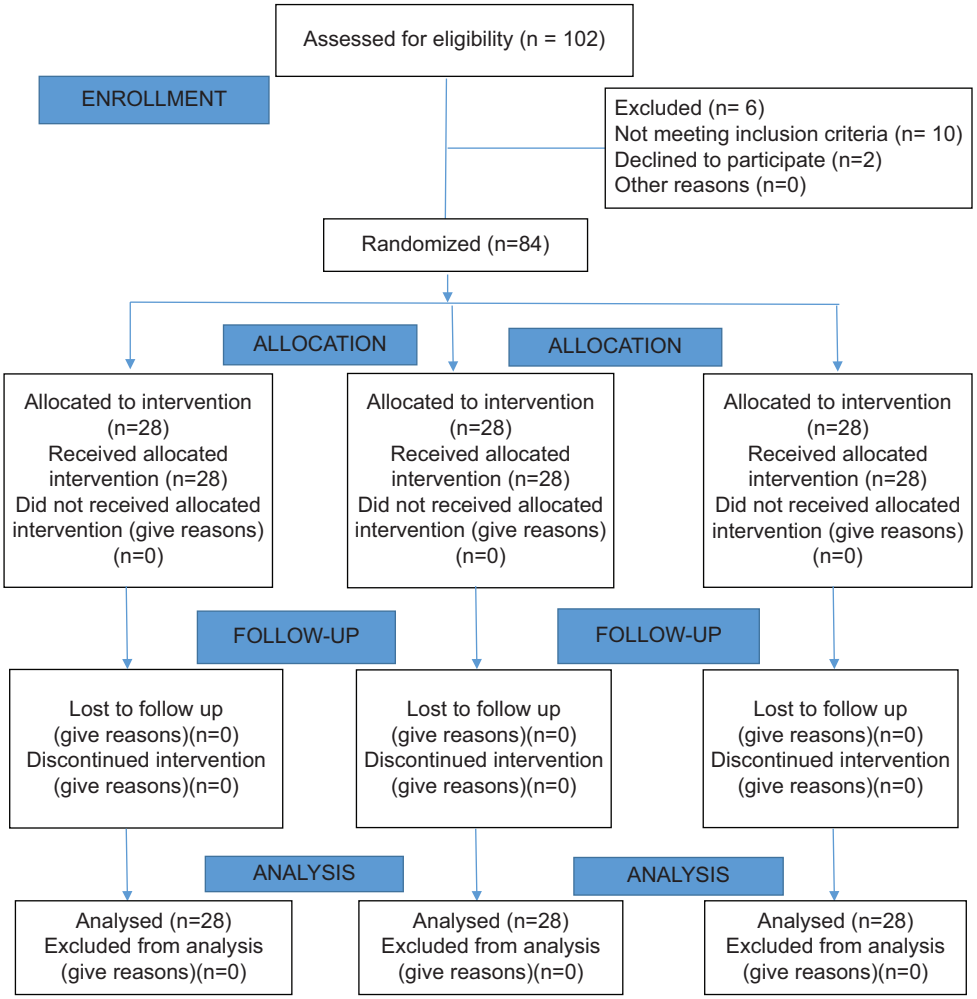

Figure 1: CONSORT 2010 flow diagram

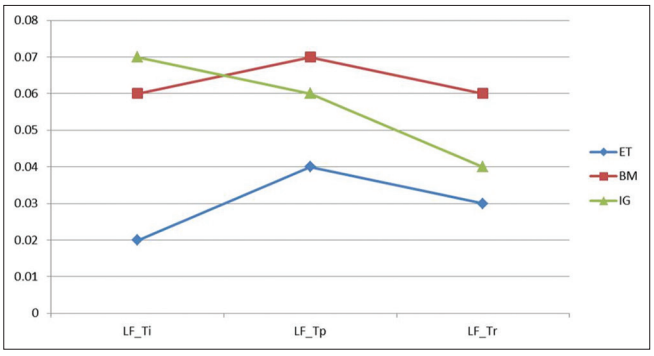

Figure 2: Comparison between leak fraction of the three devices at 3 time points

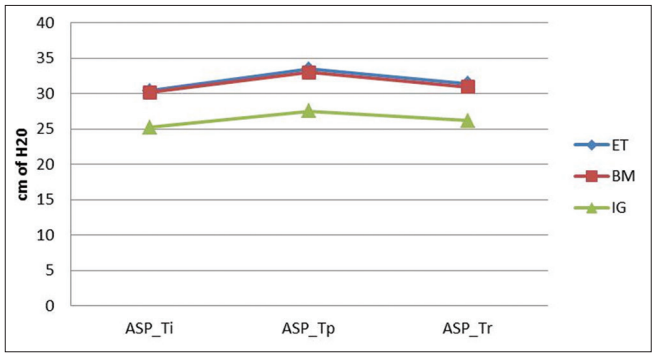

Figure 3: Line diagram showing airway sealing pressure of the three groups at Ti, Tp, and Tr

ANOVA determined P-values of ASP at time points Ti, Tp, and Tr to be 0.000, 0.000, and 0.000, respectively, which was also statistically significant (Table 2 and Figure 3).

Patients inserted in the first attempt were 96.42% in group ET, 78.57% in group BM, and 85.71% o in group IG. There was no failure of insertion of the device in any of the three groups. Kruskal–Wallis ANOVA determined P-value to be 0.140 which was statistically non-significant.

Comparison of insertion time of the three devices (in s) showed the mean insertion time of group ET, group BM, and group IG were, respectively, 17.07, 16.21, and 14.36 s. Kruskal–Wallis ANOVA determined P<0.001 which was statistically significant.

Baseline hemodynamic parameters in group ET, group BM, and group IG were comparable in all the groups.

Table 2: Airway sealing pressure (cm of H_2O) of the three devices at Ti, Tp, and Tr

Time point	Group	Mean	Median	Standard deviation	P-value
Airway sealing pressure Ti	Group ET	30.39	30.00	1.707	0.000
	Group BM	30.14	30.00	1.580	
	Group IG	25.21	25.00	1.287	
Airway sealing pressure Tp	Group ET	33.46	34.00	1.774	0.000
	Group BM	33.00	33.00	1.886	
	Group IG	27.54	27.00	1.621	
Airway sealing pressure Tr	Group ET	31.39	32.00	1.524	0.000
	Group BM	30.93	31.00	1.438	
	Group IG	26.14	26.00	1.208	

BM: Baska mask, IG: I-gel, Ti: After insertion, Tp: After pneumoperitoneum, Tr: After peritoneal deflation

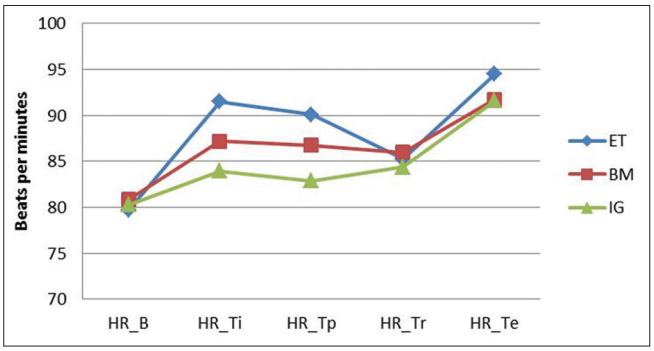

Figure 4: Comparison of heart rates (beats/min) at the four different time points

Heart rate showed statistically significant P-values at Ti and Tp (P=0.004 and 0.000, respectively, vide Figure 4).

There was no statistically significant difference in the systolic blood pressure (SBP) at any time point (P>0.05) except at Tp – After pneumoperitoneum time point (P=0.001). There was no statistically significant difference in the diastolic blood pressure (DBP) at any time point (P>0.05) except at Tp time point (P=0.000) and Te time point (P=0.01).

Laryngospasm and aspiration did not occur in any patient of any group. Four out of 28 patients of ET group had gastric distension and three had post-extubation cough which did not require any treatment. Two patients of group IG had sore throat and one patient had cough. In group BM, one patient each had sore throat and post-extubation cough. Blood staining was found in 10.71%, 3.57%, and 7.14% of patients belonging to group ET, group BM, and group IG, respectively.

DISCUSSION

Laparoscopic procedures lead to an increase in airway pressure in excess of 20 cm H_2O, increased risk of aspiration,[14-16] and increased minute ventilation to compensate the hypercarbia. Airway devices with high ASP are needed to counter the adverse effects of increased airway pressure.[17] The cuffed ETT was the gold standard for providing definitive glottic seal. However, Archie brain used the LMA prototype for PPV for 16 cases of gynecological laparoscopy in 1983. BM and the IG form a more effective seal than the earlier classic LMA and have a drainage protecting against regurgitation[7] providing alternatives to endotracheal intubation yet with an effective seal. The LF and ASP between BM and IG and the ETT were therefore the primary parameters measured in the present study.

A lower LF is an indication of an effective laryngeal seal. LF was found to be significantly higher in group IG than group BM and group ET (P=0.000) after insertion (Ti). However, after pneumoperitoneum (Tp) and release of pneumoperitoneum (Tr), there was a statistically significant difference (P=0.000) in the LF of the three devices but LF of Group IG had reduced to lesser values than group BM but higher than group ET.

Similarly, Gabbott and Beringer[18] observed in their study that IG provides a better seal improving over time probably due to the thermoplastic properties of gel cuff forming a better laryngeal seal after warming to body temperature. Ibrahim et al.,[19] compared IG with ETT in 60 patients undergoing elective cholecystectomy and found that there was a significant difference of LF at 8 mL/kg and at 10 mL/kg tidal volume before and after pneumoperitoneum.

In our study, ASP of group ET, group BM, and group IG at time points Ti, Tp, and Tr was statistically significant (P=0.000 each). *Post hoc* Tukey's test revealed that ASP of group ET and group BM at time point Ti, Tp, and Tr was not statistically significant but ASP of group IG was lower than that of group ET and group BM in all the time points.

In 2017, Aziz and Osman[20] conducted a study comparing IG with BM for controlled ventilation in obese patients undergoing ambulatory surgeries. ASP was significantly higher following BM insertion than IG group. They concluded that both devices were suitable for PPV in

anesthetized paralyzed patients; however, BM gave a better laryngeal seal when compared to IG especially when used in obese patients.

In 2018, Chaudhary et al.,[18] similarly observed that BM provided a higher ASP compared to IG providing greater airway protection during laparoscopic surgery (29.9 cm H_2O at insertion, 33.54±1.16 cm H_2O at 30 min in BM; 23.16±3.07cm H_2O and 25.97±2.25cm H_2O with IG) in patients undergoing laparoscopic cholecystectomy in 100 adult patients.

Hemodynamic parameters were also compared in the present study at five different time points. Heart rate showed significant P-values at time points Ti and Tp (P=0.004 and P=0.000 respectively). *Post hoc* Tukey's test showed that at Ti and Tp, there was a significant difference between group ET and group IG but not between the other groups. Significant differences in SBP, DBP, and mean arterial pressure (MAP) were noted between all groups at time point Tp (P=0.001, 0.000, and 0.000, respectively) and DBP at time point Te (P=0.019). Hemodynamic changes due to placement of SAD and inflation of cuff cause pharyngeal wall receptor stimulation and a reflex sympathetic stimulation. IG and BM have a cuff not requiring inflation and no laryngoscopy required causing less hemodynamic changes.

Similar findings were observed in the study done by Badheka et al.,[7] with IG and endotracheal tube in laparoscopic surgeries in 60 patients. There was a significant rise in pulse rate and MAP during insertion of ETT than IG (P=0.0013 and P=0.011 immediately after intubation and 3 and 5 min after intubation, respectively). They concluded that IG required less time for insertion with minimal hemodynamic changes in the first 5 min following insertion when compared to ETT.

Biswas et al.,[21] in 2015, compared the hemodynamic stress response between endotracheal intubation and IG usage in 64 patients. There was a significant increase in heart rate at the 1st and 45th min (P=0.02 and 0.034), respectively, and an increase in MAP at the 15th and 30th min (P=0.034 and 0.026), respectively, in the ETT group compared to IG group.

Other parameters included in the study were insertion time of the three devices. Analysis of the number of insertion attempts revealed that 96.42% of patients of group ET, 78.57% in group BM, and 85.71% in group IG were inserted in the first attempt (P=0.140).

Similar findings were reported by Jadhav et al.[22] and Chaudhary et al.[18] [BM (58%) and IG (76%)]. Shin et al.,[23] found that the success rate of the first attempt was lower for the IG (78%) than for the PLMA and LMA classic (89 and 84%, respectively); however, these differences were not statistically significant and were attributed to the lack of experience of the anesthesiologists with IG.

Insertion time analysis revealed mean insertion time for group ET, group BM, and group IG were 17.07, 16.21, and 14.36 s, respectively (P-value of insertion time to be <0.001 which was statistically significant). The firmness of the tube section of IG and its natural oropharyngeal structures allows the faster insertion time.

Chaudhary et al.,[28] found that time for insertion of the device was significantly lesser in IG with the greater ease of insertion. IG is less bulky as compared to BM making it a handier device to insert. In 2015, Badheka et al.,[7] also observed that IG required less time for insertion.

In 2017, Aziz and Osman[20] in their study comparing IG with BM for PPV in obese patients undergoing ambulatory surgeries found that insertion time was significantly shorter in IG group.

Badheka et al.[7] and Mukadder et al.,[24] found SpO_2, $EtCO_2$ comparable, and ventilator parameters as in other studies.

In the present study, no episode of laryngospasm or aspiration was noted. Similar findings were noted by Saraswat et al.

Tang et al.,[25] found that following extubation, mild choking cough occurred in 40% of ETT group compared to 10% of patients with mild choking cough in IG group. In 2016, Park et al.,[26] conducted a meta-analysis comparing between SAD and ETT in 1433 patients from 17 studies. They found that the incidence of laryngospasm, cough, and sore throat were higher in the ETT group than in the SGA group.

In 2017, Lai et al.,[27] compared IG and ETT in 40 patients undergoing gynecological laparoscopic surgeries and observed that post-operative sore throat was significantly lower in the IG group.

In the present study, group ET had higher incidence of sore throat (P=0.03) and cough on extubation. It was less in group IG and least in group BM. Blood staining of the cuff was found in similar order being least in group BM.

Gastric distension was found in 14.29% of patients in group ET and 7.14% of patients in both group BM and group IG. It was found to be non-significant (P=0.575).

Limitations of the study

Certain group of patients were excluded from the study:

1. Obese patients
2. Patients with a high risk of aspiration
3. Patients with reduced thoracic compliance
4. Patients requiring higher airway pressures for effective positive pressure ventilation.

Inclusion of these patients in future studies can be conducted to assess the device efficacy.

CONCLUSION

Endotracheal intubation is the gold standard for airway management in laparoscopic surgery as it provides adequate ventilation and protects against pulmonary aspiration in the presence of raised airway pressures due to pneumoperitoneum. However, from the present study, it may be concluded that properly placed IG or BM can maintain effective oxygenation and ventilation in selected patients undergoing laparoscopic cholecystectomy with adequate seal of the airway and were not associated with any incidence of aspiration or laryngospasm. BM provided a better seal with a higher airway-sealing pressure and lower LF and provided better airway protection than IG. Future directions might include studies on obese patients with SAD with higher sealing pressures.

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IPGME&R, Kolkata, West Bengal, India.

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AG- Literature survey, prepared first drift of manuscript, implementation of study protocol, data collection, data analysis, manuscript revision; **SM**- Definition of intellectual content, concept, design, clinical protocol, manuscript preparation, editing and manuscript revision; **SG**- Design of study, statistical analysis and interpretation; **SS**- Definition of intellectual content, design of study, review manuscript, literature survey and preparation of figures, coordination and manuscript revision; **USM-** Statistical analysis and interpretation, manuscript preparation and editing**; AC-** Design of study, statistical analysis and interpretation review manuscript.

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