Comparison of Safety and Efficacy of Endotracheal Tube, Laryngeal Mask Airway Supreme and I Gel in Laparoscopic Surgeries

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ABSTRACT

BACKGROUND

Present study was undertaken to assess the feasibility of laryngeal mask airway (LMA) supreme and I gel, the second generation supraglottic airway devices in laparoscopic surgeries.

METHODS

120 patients with American Society of Anaesthesiologists (ASA) I and II (20 - 50 years) of either sex who underwent laparoscopic surgery under general anaesthesia were randomly divided into three groups. Airway was secured with endotracheal tube (ETT) in group E (N = 40), with LMA supreme in Group S (N = 40) and with I-gel in group I (N = 40). Insertion characteristics of airway device, ease of gastric tube insertion, haemodynamic response and perioperative laryngopharyngeal morbidities were assessed.

RESULTS

I-gel was easier to insert with higher first attempt success rate (95 %) than LMA Supreme (85 %) and ETT (90 %) but it was statistically insignificant. Heart rate (HR) and mean arterial pressure (MAP) was significantly higher in ETT group at the time of intubation, continued till 5 minutes and also at the time of extubation but statistically significant increase in HR and MAP were noted in group S and I only at the time of device insertion. Gastric tube was easier to insert in group S with shortest insertion time which was statistically significant. Incidence of coughing, dysphonia, dysphagia and sore throat was significantly more in group E.

CONCLUSIONS

I-gel and LMA Supreme can be used as an alternative to ETT for airway management in adult patients undergoing elective laparoscopic surgeries.

KEYWORDS

Endotracheal Tube, I-gel, LMA Supreme, Supraglottic Airway Device

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BACKGROUND

Traditional open surgeries are progressing to minimally invasive laparoscopic surgeries. Simultaneously, airway management of patients has also progressed from endotracheal tube to lesser invasive supraglottic airway devices (SAD) because of the advantages that such devices confers.[1] Gold standard in airway management in surgeries requiring laparoscopic pneumoperitoneum is tracheal intubation. However, the use of SADs in surgeries requiring laparoscopic pneumoperitoneum remains controversial due to the risk of pulmonary aspiration and ineffective ventilation.[2,3]

The newer second generation SADs have additional safety features that enhance the oesophageal and pharyngeal seal, the risk of aspiration is decreased with the introduction of the gastric channel, which enables gastric suctioning, venting and passage of nasogastric tube. Commonly used second generation SADs are laryngeal mask airway Supreme and I-gel. LMA Supreme is a single use SAD made of polyvinyl chloride. LMA Supreme consists of first seal ™ with the oropharynx (oropharyngeal seal) and second seal ™ with the upper oesophageal sphincter (oesophageal seal).[4] It is elliptical and anatomically shaped which facilitates its easy insertion without introducer or putting finger into patients mouth. It has a gastric access using a lubricated gastric tube up to size 16 F.[5,6] The I-gel is a latex free SAD made of a medical-grade thermoplastic elastomer gel and thus, does not require inflation with air.[7] I-gel takes the shape and contours accurately with the perilaryngeal anatomy to create the perfect fit. The design creates a more intimate interface for interacting with supraglottic tissues.[8] I-gel provides effective seal during anaesthesia for both spontaneous and controlled ventilation.[9,10]

Present study was undertaken to compare I-Gel and LMA Supreme with standard ETT for the attempts taken for insertion, hemodynamic variables, perioperative laryngopharyngeal morbidity during general anaesthesia (GA) in healthy adult patients undergoing elective laparoscopic surgeries.

METHODS

The present randomised single blind comparative study was conducted over a period of one and half year (December 2018 to June 2020) in the Department of Anaesthesiology, Government Medical College Jammu and Kathua. After hospital ethical committee approval and informed written consent, 120 patients of either sex, 20 - 50 years of age belonging to ASA Class I and II scheduled for elective laparoscopic surgeries under GA were selected. Patients were randomised into three groups of 40 patients each using computer generated random numbers

Group E - used ETT as airway device
Group S - used LMA Supreme as airway device
Group I - used I-gel as airway device.

Exclusion Criteria

- Patients with anticipated difficult airway
- Patients with body mass index (BMI) > 35 kg m^{-2}
- Pathology of neck or upper respiratory tract
- Cardiopulmonary comorbidity
- Cervical spine fracture or instability
- Known risk factors of aspiration (gastroesophageal reflux disease, hiatus hernia, pregnant patients)
- Mouth opening < 2.5 cm

Using G*Power software version 3.0.10 (Heinrich Heine University Dusseldorf, Germany), it was estimated that the least number of patients required in each group with 80 % power, effect size of 0.29 and 5 % significance level was 40. Since, we had to compare three groups in our study, a total of 120 patients were included in our study.

Patients were kept fasting overnight and premedicated with injection rabeprazole 20 mg intravenous (IV). Standard monitoring including heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), end tidal carbon dioxide ($EtCO_2$) and electrocardiography (ECG) were instituted. Patient was administered injection midazolam 0.02 mg kg^{-1}, glycopyrrolate 0.005 mg kg^{-1}, 1 - 2 minutes before induction. After preoxygenation induction was done with injection propofol 1.5 - 2.5 mg kg^{-1} till the loss of verbal commands. Neuromuscular blockade was achieved with injection rocuronium 0.6 mg kg^{-1} body weight. Following induction and adequate paralysis, the corresponding airway device was inserted in each group. The size of the SAD was selected based on the patient's weight, as per the manufacturers' size recommendations. For the Supreme group, sizes 3, 4 and 5 were used for weights of 30 – 50 kg, 50 – 70 kg and > 70 kg, respectively. For the I-gel group, sizes 3, 4 and 5 was used for weights of 30 – 60 kg, 50 – 90 kg and > 90 kg, respectively. However, there was overlap at the weights of 50 – 60 kg for I-gel sizes 3 and 4, so the weight limits were modified to size 3 for 30 – 54.9 kg and size 4 for 55 – 90 kg to avoid confusion. ETT size was 7.5 mm for females and 8.5 mm for males. SADs were lubricated with water-soluble gel, and all insertions were performed as per the manufacturers' instructions by anaesthesiologists familiar with both devices. Correct placement of the device was confirmed by symmetrical chest wall movement and capnograph. Anaesthesia was maintained with oxygen and nitrous oxide mixture, isoflurane and rocuronium. For intraoperative analgesia, injection tramadol 2 mg kg^{-1} and injection paracetamol 20 mg kg^{-1} was administered intravenously.

The rate of successful SAD insertion at the first attempt was the primary outcome. If not effective, the SAD was completely removed and reinserted. After two failed attempts, a third attempt was made with a different size of the same SAD device. Failed third attempt was defined as a failed insertion of the SAD, and the attending anaesthesiologist managed the airway according to his or her discretion. Insertion time was defined as the time from picking up the device to be inserted until the appearance of the first wave on the capnograph. Following SAD insertion, a lubricated gastric tube was inserted though the gastric

channel (size 12 FG for i-gel, and size 14 FG for LMA supreme and ETT). Ease of gastric tube insertion was graded on a three-point scale (1 = first attempt, 2 = second attempt and 3 = impossible).

SpO_2 and $EtCO_2$ was recorded. The aim was to maintain target SpO_2 (> 95 %) and $EtCO_2$ (< 45 mm Hg) by adjusting the fraction of inspired oxygen (FiO_2), respiratory rate and tidal volume. When SpO2 was 90 - 94 % the oxygenation was graded as suboptimal and failed if it was < 90 %.

The outcomes measured were as follows:

- Insertion time and attempts of insertion of device
- Insertion time and ease of gastric tube insertion
- HR, MAP, SpO_2 and $EtCO_2$ were recorded at baseline, before induction, at the time of insertion; 1, 2, 3 and 5 min after insertion of device; after achieving pneumoperitoneum, and after removal of devices.
- Incidences of air leak, laryngospasm, regurgitation, aspiration, coughing, blood staining of device, gastric content staining, trauma to lip, teeth, tongue and postoperative hoarseness, dysphonia, dysphagia and sore throat were recorded.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS version 20.0 (SPSS Inc., Chicago, Illinois, USA). Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Continuous variables were expressed as Mean ± SD and categorical variables were summarised as percentages. Analysis of variance (ANOVA) was employed for inter group analysis of data. Chi-square test or Fisher's exact test, whichever appropriate, was used for comparison of categorical variables. A P-value of less than 0.05 was considered statistically significant. All P-values were two tailed. Statistical software SPSS (version 16.0) was used to carry out the statistical analysis of data. Data was analysed by means of descriptive statistics viz. means, standard deviations and percentages. Chi-square test was used for qualitative data.

RESULTS

There was no statistically significant difference in the demographic data among the study groups (Table 1). In this study, it was observed that ETT, LMA Supreme and I gel were successfully inserted in all patients and there was no failed case of insertion in any of the three groups. Insertion success rate at first attempt was 90 % (36 patients) for ETT, 85 % (34 patients) for LMA Supreme and 95 % (38 patients) for I gel which was statistically insignificant (Table 2). Second attempt for device insertion was done in 4 patients (10 %) in group E, 4 patients (10 %) in group S and 2 patients (5 %) in group I (Table 2). A third attempt was required only for 2 patients (5 %) in group S (Table 2). There was no case of failed insertion in any of the study group (Table 2). Attempts of insertion were comparable in all the groups. The average insertion time was shortest in group I (23.6 ± 4.78 s) compared to group E (27.2 ± 6.19 s) and group S (25.1 ± 7.25 s) and was statistically significant (P < 0.05) (Table 2). Ease of device insertion was highest in I-gel group but was statistically insignificant (Table 2).

Insertion time of gastric tube was shortest in group S (16.4 ± 1.9 s) compared to group E (21.3 ± 2.3 s) and group I (20.6 ± 2.7 s) which was statistically significant (P < 0.05) (Table 2). Ease of gastric tube insertion on first attempt was highest in group S and was statistically significant (P < 0.05) (Table 2).

	Parameter	Group E (N = 40)	Group S (N = 40)	Group I (N = 40)	P-Value
Gender	Age (Years) (mean ± SD)	44.7 ± 7.54	45.3 ± 6.89	43.9±7.18	0.685
	Male (n) (%)	28 (70 %)	29 (72.5 %)	26 (65 %)	0.761
	Female (n) (%)	12 (30 %)	11 (27.5 %)	14 (35 %)	
	Weight (Kg) (mean ± SD)	73.8 ± 8.61	75.3±7.93	73.4±7.26	0.532
Type of surgery	Cholecystectomy (n) (%)	27 (67.5 %)	25 (62.5 %)	24 (60 %)	0.989
	Appendicectomy (n) (%)	6 (15 %)	7 (17.5 %)	8 (20 %)	
	Mesh hernioplasty (n) (%)	5 (12.5 %)	6 (15 %)	5 (12.5 %)	
	Diagnostic (n) (%)	2 (5 %)	2 (5 %)	3 (7.5 %)	
	Duration of surgery (Minutes) (mean ± SD)	57.4 ± 7.92	60.5 ± 10.17	58.7 ± 8.14	0.291
	Duration of anaesthesia (minutes) (mean ± SD)	72.6 ± 9.52	71.4 ± 8.62	71.9 ± 8.17	0.829

Table 1. Comparison of Demographic Characteristics of Patients between the Study Groups (N = 120)

SD = Standard deviation

	Parameter	Group E (N = 40)	Group S (N = 40)	Group I (N = 40)	P Value
Attempts of insertion	First (n) (%)	36 (90 %)	34 (85 %)	38 (95 %)	0.519
	Second (n) (%)	4 (10 %)	4 (10 %)	2 (5 %)	
	Third (n) (%)	0 (0 %)	2 (5 %)	0 (0 %)	
Insertion time (seconds)	Average insertion time (mean ± SD)	27.2 ± 6.19	25.1 ± 7.25	23.6 ± 4.78	0.035*
	Insertion time ≤ 30 s	31 (77.5 %)	34 (85 %)	36 (90 %)	0.305
	Insertion time > 30 s	9 (22.5 %)	6 (15 %)	4 (10 %)	
Ease of insertion	Easy (n) (%)	35 (87.5 %)	35 (87.5 %)	38 (95 %)	0.164
	Fair (n) (%)	4 (10 %)	5 (12.5 %)	2 (5 %)	
	Difficult (n) (%)	1 (2.5 %)	0 (0 %)	0 (0 %)	
Ease of gastric tube insertion	1st attempt (n) (%)	33 (82.5 %)	40 (100 %)	34 (85 %)	0.025*
	2nd attempt (n) (%)	7 (17.5 %)	0 (0 %)	6 (15 %)	
	Impossible (n) (%)	0 (0 %)	0 (0 %)	0 (0 %)	
	Insertion time of gastric tube (s) (mean ± SD)	21.3 ± 2.3	16.4 ± 1.9	20.6 ± 2.7	< 0.001**

Table 2. Comparison of Insertion Characteristics of ETT, LMA-Supreme and I-Gel between the Study Groups (N = 120)

*P < 0.05 is statistically significant, **P < 0.001 is highly statistically significant, SD = Standard deviation

Parameter		Group E (N = 40)		Group S (N = 40)		Group I (N = 40)		P-Value
		No.	% Age	No.	% Age	No.	% Age	
At insertion of device	Air leak	0	0.0	1	2.5	3	7.5	0.232
	Laryngospasm	3	7.5	1	2.5	0	0.0	0.164
	Trauma to lip teeth and tongue	3	7.5	2	5.0	1	2.5	0.591
At removal of device	Coughing	12	30.0	4	10.0	3	7.5	< 0.001**
	Blood staining of device	3	7.5	4	10.0	1	2.5	0.392
	Gastric content staining	0	0.0	1	2.5	1	2.5	0.601
Postoperative	Hoarseness	15	37.5	4	10.0	1	2.5	0.003*
	Dysphonia	10	25.0	3	7.5	2	5.0	0.013*
	Sore throat	12	30.0	4	10.0	3	7.5	0.010*
	Dysphagia	13	32.5	5	12.5	3	7.5	0.008*

Table 3. Comparison of Laryngopharyngeal Morbidity between the Study Groups (N = 120)

*P < 0.05 is statistically significant, **P < 0.001 is highly statistically significant

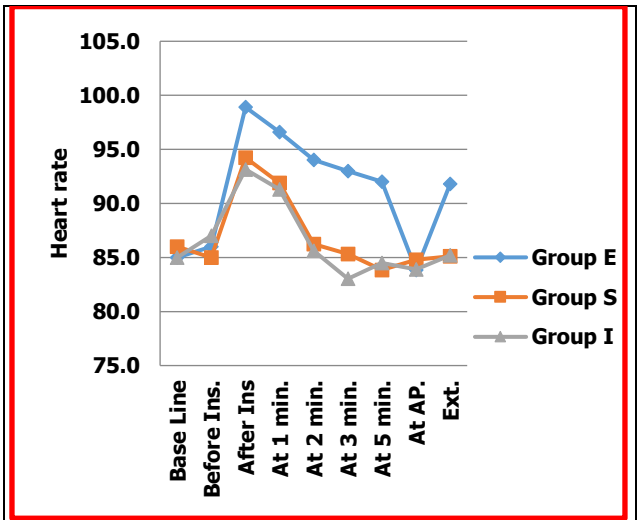

Figure 1. Graphical Representation of Heart Rate (in Beats / min) at Different Time Intervals in Group E, Group S and Group I

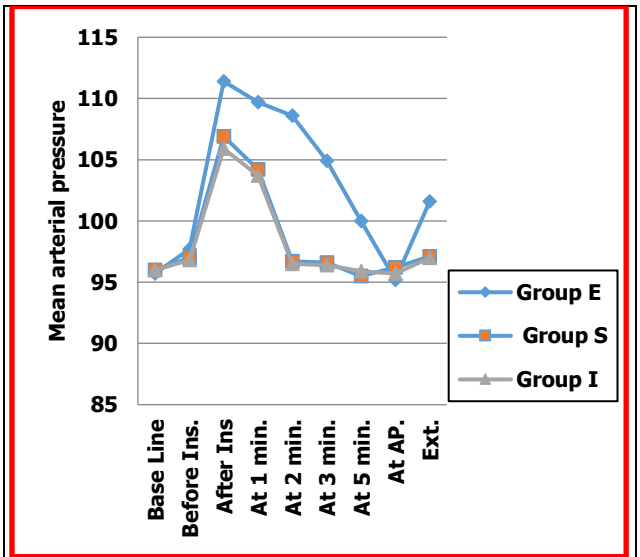

Figure 2. Graphical Representation of Mean Arterial Pressure (in mm Hg) at Different Time Intervals in Group E, Group S and Group I

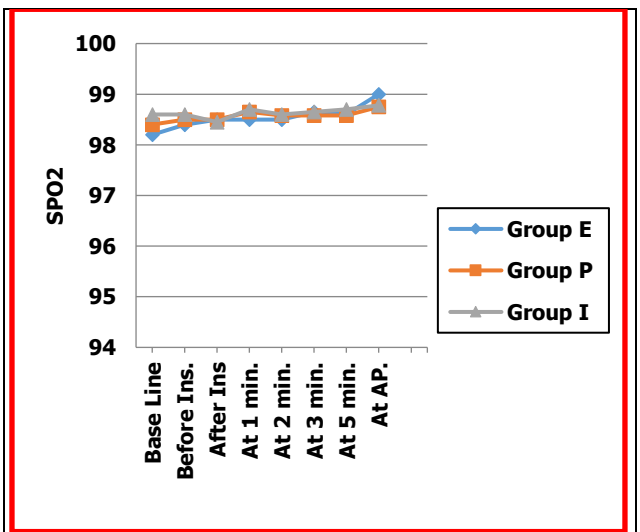

Figure 3. Graphical Representation of SpO_2 (Partial Pressure of Oxygen Saturation in %) at Different Time Intervals in Group E, Group S and Group I

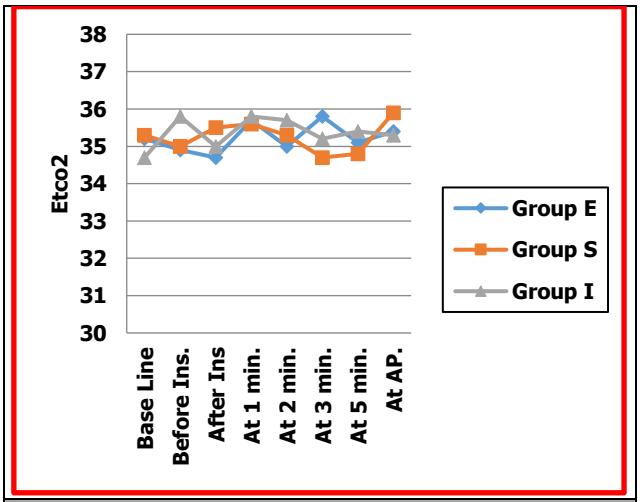

Figure 4. Graphical Representation of $EtCO_2$ (End Tidal Carbon dioxide in mm hg) at Different Time Intervals in Group E, Group S and Group I

HR and MAP increased significantly after intubation, continued up to 5 minutes and at the time of extubation also in group E ($P < 0.05$) (Fig. 1 and 2). Whereas in group S and group I statistically significant increase in HR and MAP was observed only after insertion of device ($P < 0.05$) (Fig. 1 and 2). There were no statistically significant differences in SpO2 and EtCO2 among the three groups before or during pneumoperitoneum (Fig. 3 and 4). Air leak immediately after insertion of device was noted in 3 patients (7.5 %) in group I and in 1 patient (2.5 %) in group S, which was statistically insignificant (Table 3).

There was no incidence of aspiration or regurgitation in any group. Incidence of coughing, hoarseness, dysphonia, dysphagia and sore throat was more in group E than group S and group I which was statistically significant ($P < 0.05$) (Table 3). Incidence of trauma to lip, teeth and tongue, blood staining of devices and gastric content staining of device were comparable among groups (Table 3).

DISCUSSION

The recent advent of newer designs in SADs provides a possible alternative to the traditional use of ETT during laparoscopic surgeries. The advantages of SADs are related to the fact that they may be inserted easily using a blind technique, and they allow for effective positive pressure ventilation.[11] In this study, we found that ETT, LMA Supreme and I gel were successfully inserted in all patients and there was no case of failed insertion. Although I-gel was easier to insert with higher success rate in first attempt (95 %) than ETT (90 %) and LMA Supreme (85 %) it was statistically insignificant.[12,13,14] I-gel was easier and faster to insert because of its cuff less nature, unique gel like material, shape and contour, buccal stabiliser and epiglottis blocker that prevents epiglottis downfolding.[15]

Every gastric tube was successfully inserted in first attempt in group S with shortest insertion time compared to group I and group E which was statistically significant. However, it was more difficult to insert gastric tubes in patients of I-gel group because of the smaller aperture of

gastric access port, resulting in longer insertion time as noted by Sang et al. and Chen et al.[16,14] Our results are in contrast to the study conducted by Mukadder et al. and Teoh et al. who demonstrated no difference in the success rate of gastric tube insertion among these devices.[12,13]

On comparing the hemodynamic variables, the significant increase in HR and MAP in group ETT, immediately after intubation which continued till 5 minutes and at the time of extubation also, attributed to sympathetic stimulation during laryngoscopy and the passage of the ETT through the vocal cords. Whereas LMA Supreme and I gel being supraglottic devices do not require laryngoscopy and probably do not evoke a significant sympathetic response. Our findings are similar to the results of previous studies, which observed hemodynamic perturbations, maximum with tracheal intubation and moderate with laryngeal mask airway while stable with I-gel.[17,18] Qiuping Ye et al. also showed that after creation of pneumoperitoneum in laparoscopic surgery both LMA supreme and I gel were effective for controlled ventilation with stable haemodynamics and lower incidence of sore throat and hoarseness as compared to ETT.[19]

"None of the patients in I-gel had blood staining of the device but in group S there was blood staining of the airway device at removal, indicating airway mucosal trauma as noted by Mukadder et al.[12] Since I-gel has a non-inflatable cuff that was designed to provide an anatomical fit over the perilaryngeal structures, minimised the risk of compression of perilaryngeal neurovascular structures. Hence, reducing the incidence of airway complications.[20,21]

In our study, coughing, hoarseness, dysphonia, sore throat and dysphagia were significantly found in group E as compared to other two groups. Similar results were seen in study by Jindal et al. and other colleagues, who noticed coughing during emergence from anaesthesia in patients whose airway was secured with ETT compared to I-gel and Proseal LMA.[21,22,23] The virtual absence of sore throat in group S and group I could be due to the fact that mucosal pressures achieved are usually below pharyngeal perfusion pressure.[13,23]

In our study there was no case of aspiration similar to the findings of the study conducted by Chi-Jun Lai et al.[24] Initial air leak noted in both the SAD groups in our study is similar to the findings of Mukadder et al.[12] Limitation of our study is that anaesthesiologist was aware of the air way device used and hence, possible source of bias was present. To remove this bias, the postoperative observer and patients were not aware of the device used. Study included only ASA I and II patients so further research is needed in patients with morbid obesity and those with gastroesophageal reflux.

CONCLUSIONS

I-Gel and LMA supreme are better than ETT in terms of hemodynamic stability with less incidence of perioperative complications. However, gastric tube was easy to insert with shortest insertion time in LMA Supreme. Hence, we conclude that I-gel and LMA Supreme can be used as alternatives to ETT for airway management in patients undergoing laparoscopic surgeries.

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