

Original Research Article

A comparative evaluation of I-gel and laryngeal mask airway supreme in laparoscopic surgeries: a randomized comparative study

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ABSTRACT

Background: Supraglottic airway device results in less hemodynamic responses during laparoscopic surgery but supraglottic airway device to be used should have higher oropharyngeal seal pressure than peak pressure for effective ventilation as laparoscopic surgery also leads to higher airway pressure. In this study the efficiency of the I-gel with SLMA is compared in patients undergoing laparoscopic cholecystectomy surgeries.

Methods: Sixty patients were randomized in to two groups, group A where I-gel was considered for airway management and group B where LMA Supreme was the device chosen for airway management.

Results: Oropharyngeal seal pressure was significantly lower in group A than group B, 5 minutes after insertion of airway device it was 24.90 ± 3.03 cm H₂O and 27.30 ± 3.41 cm H₂O in group A and group B, respectively and 5 minutes after creation of pneumoperitoneum it was 25.53 ± 3.17 cm H₂O and 27.57 ± 3.36 cm H₂O in group A and group B, respectively. There was significant difference in the difference between inspiratory and expiratory tidal volume between the groups at all the time periods being higher in group A than group B. Hemodynamics were comparable between the two groups. Time taken to insert the airway device and Ryle's tube insertion was significantly lesser in group B in comparison to group A. The percentage of complications was higher in group A than group B with no significant ($p > 0.05$) association.

Conclusions: Both the I-gel and SLMA devices can be used safely in laparoscopic cholecystectomy in non-obese patients. But in SLMA group oropharyngeal seal pressure was higher with lesser leak volume in comparison to I-gel group.

Keywords: Cholecystectomy, I-gel, Laparoscopic surgery, Laryngeal mask airway supreme

INTRODUCTION

Laparoscopic surgery is usually performed under general anaesthesia with tracheal intubation. But both tracheal intubation as well as extubation lead to increase in hemodynamic responses that may be undesirable in certain group of population like hypertensive patients and coronary artery disease patients. Insertion of supraglottic airway device results in lower hemodynamics responses

in comparison to laryngoscopy and endotracheal intubation.^{1,2} Use of supraglottic airways also result in less increase in stress response during surgery in comparison to endotracheal tube.^{3,4}

I-gel is a second generation, supraglottic airway device with an integrated gastric channel. It is made up of thermoplastic elastomers and has a soft gel like non-inflatable mask, which is designed in such a way that it

conforms the anatomical shape of larynx and provides an airtight seal.⁵ The Laryngeal Mask Airway Supreme (SLMA) is a second-generation airway made up of PVC with features of the PLMA and ILMA. It is curved like the LMA Fastrach that helps in ease of insertion and its cuff shape and area provides a better anatomic fit in the pharynx than the classic LMA.⁶

Various studies have been done to study the clinical performance of SLMA and I-Gel in various situations and it has been observed that both provide adequate positive pressure ventilation.⁷⁻¹¹ But there are very few studies which have compared these devices in laparoscopic surgeries.¹²⁻¹⁴ So this study was undertaken to compare the efficiency of the I-Gel with SLMA in patients undergoing laparoscopic cholecystectomy surgeries under general anesthesia with neuromuscular blockage. The primary objective of the study was to compare oropharyngeal seal pressure between I-gel and SLMA. The secondary objectives of the study were to compare difference between inspiratory and expiratory tidal volumes, peak airway pressure, number of attempts and time taken for airway device insertion, nasogastric tube insertion time, hemodynamic responses (BP, HR, RR, SPO₂, EtCO₂) and incidence of complications between the two groups.

METHODS

This randomized comparative study was taken place on admitted patients of Gandhi Memorial and associated hospitals, KG medical university, Lucknow undergoing laparoscopic cholecystectomy surgery under General Anesthesia. After obtaining approval from Institutional Ethical Committee, KG medical university, Lucknow, Patients scheduled for elective surgeries from August 2016 to July 2017 were enrolled in the study. The written and informed consent was obtained.

Inclusion criteria

- ASA I-II patients aged between 18-60 years having Body Mass Index (BMI) between 20-30 kg/m².

Exclusion criteria

- Patients having anticipated difficult airway, upper respiratory tract infections, history of previous thoracic, abdominal and neurosurgery operations, history of obstructive sleep apnea, history of allergy to one or more drugs and latex, duration of surgery >2 hrs., increased risk of aspiration (GERD, hiatus hernia), pregnant patient, device placements had failed after three attempts were excluded from the study.

Patients were randomly divided in two groups using computer generated randomization number list. Two groups of 30 patients in each were formed, group A where I-gel (size 3 for patient weight 30-60 kg, size 4 for

patient weight 50-90 kg) was considered for airway management and group B where LMA Supreme (size 3 for patient weight 30-50 kg, size 4 for patient weight 50-70 kg) was the device chosen for airway management of the patients. The dragger primus workstation was used in all the patients. The fresh gas control worked precisely, and the leakage rate of rebreathing system did not exceed 50 ml/min. After arrival in the operation theatre, standard monitors were attached which included pulse oximeter (SPO₂), electrocardiograph, non-invasive blood pressure monitor and capnography. All these parameters were recorded, and monitoring was continued throughout intraoperatively. For premedication injections of glycopyrrolate 0.005 mg/kg, midazolam 0.02 mg/kg, fentanyl 1-1.5 µg/kg were administered intravenously. After preoxygenation with 100% oxygen for 3 to 5 minutes, propofol 2-2.5 mg/kg was administered slowly over a period of 30 seconds until loss of consciousness was obtained with adequate facemask ventilation followed by administration of Inj. Vecuronium 0.1 mg/kg to facilitate device placement. Size 3 and 4 LMA Supreme's cuff was inflated with 30 and 40-ml air, respectively. The time from which airway device was picked up to the time it was correctly placed with two effective end-tidal capnography waveforms was noted. Successful ventilation was defined as visible chest movement on manual ventilation, square wave capnograph, stable arterial oxygen saturation above 95% and the ability to achieve an expired tidal volume of 7 ml/kg⁻¹. A well-lubricated gastric tube was passed (12FrG) via the gastric channel in both groups. Correct placement was confirmed by air injection and epigastric stethoscope. Anesthesia was maintained with oxygen 50%, nitrous oxide 50%, isoflurane and vecuronium bromide with flow rate 5 liter/min initially for 5 minutes and then flow rate decreased to 2 liter/min. Additional relaxant doses of vecuronium were given at the discretion of the anesthetist. There was a continuous display of intraabdominal pressure and the volume of CO₂ insufflated on the monitor of the insufflators. Intraabdominal pressure was kept below 12 cm of water and minute ventilation was adjusted to keep the EtCO₂ between 35-40 mmHg. At the end of surgery anesthetic agents were discontinued and neuromuscular block was antagonized with neostigmine and glycopyrrolate. The device was removed after the patient regained consciousness and responded to verbal command to open the eyes. The parameters measured were as follows: Hemodynamic responses (heart rate and mean arterial blood pressure), Pulse Oximetry (SPO₂) and End Tidal Carbon Dioxide (EtCO₂) were recorded preoperatively, Pre induction; 1 and 3 min after insertion of device respectively; before pneumoperitoneum; and 5, 15, 30, 45 min after pneumoperitoneum and 5 min after pneumoperitoneum abolished. Oropharyngeal Leak pressure was measured 5 minutes after insertion of device and 5 minutes after creation of pneumoperitoneum. It was measured after closing the expiratory valve of the system with a fresh gas flow of 3 liter/minute, recording the airway pressure when there is an audible leak from throat.

Number of insertions attempts, and time taken for insertion of the airway device were noted. Time taken for insertion of the airway device was the time from which airway device was picked up to the time it was correctly placed with two effective end-tidal capnography waveforms. Time taken from device insertion to successful securing a ryle's tube was also observed. Peak Airway Pressure (PAP), ventilator rate, inspired tidal volume, expired tidal volume was recorded from the ventilator monitor 3 min after insertion of device; before pneumoperitoneum; and 5, 15, 30, 45 min after pneumoperitoneum and 5 min after pneumoperitoneum abolished.

The incidence of any complications like gastric distension, regurgitation, aspiration, any throat discomfort or pain, change of voice, difficulty in swallowing, post-extubation cough, breath holding or laryngospasm, presence of blood on airway device, lip and dental injury and any other complication were noted.

Statistical analysis

The results are presented in frequencies, percentages and mean±SD. The Chi-square test was used to compare the categorical variables between the groups. Unpaired t-test was used to compare the continuous variables between the groups. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

Sample Size

Thus, primary outcome of the study was to compare the difference between oropharyngeal seal pressure in both groups. If a difference of 5 cm H₂O is considered significant between two groups and standard deviation taken from a previous study 12 and power of 90% and a significance level of 0.05. Sample size was calculated to 30 cases in each group.

$$n = \frac{2(a + b) Z^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

a= conventional multiplier of alpha 0.05
b= conventional multiplier of power 0.90.

RESULTS

The present study was conducted with the aim to compare I-gel (group A) and SLMA (group B) in laparoscopic cholecystectomy surgeries. A total of 30 patients were included in each group. Demographic characters between the two groups and they were comparable between the two groups (Table 1).

Oropharyngeal seal pressure and it was significantly lower in group A in comparison group B (Table 2).

There was significant (p=0.0001) difference in the difference between inspiratory and expiratory tidal volume between the groups at all the time periods being higher in group A than group B (Table 3).

Table 1: Demographic profiles.

Variables	Group A (n=30)	Group B (n=30)	p value
Age	38.47±7.41	37.87±6.16	0.73 [#]
Sex ratio	14:16	11:19	0.43 [#]
Male: female			
ASA grading I:II	27:3	27:3	1 [#]
Height in cms	151.73±5.80	153.27±6.86	0.35 [#]
Weight in kgs	56.00±4.68	54.73±3.88	0.25 [#]
BMI in kg/mtr ²	24.31±1.43	23.34±1.63	0.06 [#]
Duration of surgery (in hrs.)	67.33±4.38	67.87±4.33	0.63 [#]

*Significant, #Non-significant

Table 2: Oropharyngeal seal pressure (cm H₂O).

Time periods	Group A (n=30)	Group B (n=30)	p value
5 minutes after insertion of airway device	24.90±3.03	27.30±3.41	0.01*
5 minutes after creation of pneumoperitoneum	25.53±3.17	27.57±3.36	0.02*

*Significant, #Non-significant

Table 3: Comparison of difference between inspiratory and expiratory tidal volume (in ml) between the groups across the time periods.

Time periods	Group A (n=30)	Group A (n=30)	p-value
3 minutes after insertion	28.87±1.14	18.87±1.38	0.0001*
Before p	28.80±1.54	17.70±1.34	0.0001*
5 minutes	28.03±2.22	20.07±1.72	0.0001*
15 minutes	28.23±1.91	20.87±1.04	0.0001*
30 minutes	28.13±2.50	19.20±1.16	0.0001*
45 minutes	29.13±1.25	19.43±1.57	0.0001*
5 minutes after p ceases	28.23±1.56	20.20±1.66	0.0001*

Unpaired t-test, *Significant, #Non-significant

Before pneumoperitoneum peak airway pressure were 21.07±1.11 cm H₂O and 18.63±1.10 cm H₂O in group A and group B, respectively and after creating pneumoperitoneum peak airway pressure rises in both groups and after pneumoperitoneum ceases it decreased to pre pneumoperitoneum values (Table 4).

The comparison of ventilator rate required to maintain ETCO₂ between the groups across the time periods.

Ventilator rate was found to be almost similar at all the time periods between the groups. (Table 5)

Table 4: Comparison of peak inspiratory pressure (cm H₂O) between the groups across the time periods.

Time periods	Group A (n=30)	Group B (n=30)	p value
3 minutes after insertion	20.72±1.14	19.23±1.41	0.001*
Before pneumoperitoneum	21.07±1.11	18.63±1.10	0.001*
5 minutes	25.03±1.94	23.47±0.68	0.001*
15 minutes	24.73±2.16	24.10±.66	0.001*
30 minutes	24.37±1.50	24.37±0.96	0.001*
45 minutes	27.47±1.25	24.80±1.16	0.001*
5 minutes after pneumoperitoneum ceases	21.20±1.16	19.46±1.26	0.001*

*Significant, #Non-significant

Table 5: Comparison of ventilator rate (per minute) between the groups across the time periods.

Time periods	Group A (n=30)	Group B (n=30)	p value
3 minutes after insertion	12.00±0.00	12.00±0.00	-
Before pneumoperitoneum	12.00±0.00	12.00±0.00	-
5 minutes	14.97±0.18	15.00±0.00	-
15 minutes	14.00±0.00	14.00±0.00	-
30 minutes	14.00±0.00	14.00±0.00	-
45 minutes	12.00±0.00	12.00±0.00	-
5 minutes after pneumoperitoneum ceases	12.00±0.00	12.00±0.00	-

*Significant, #Non-significant

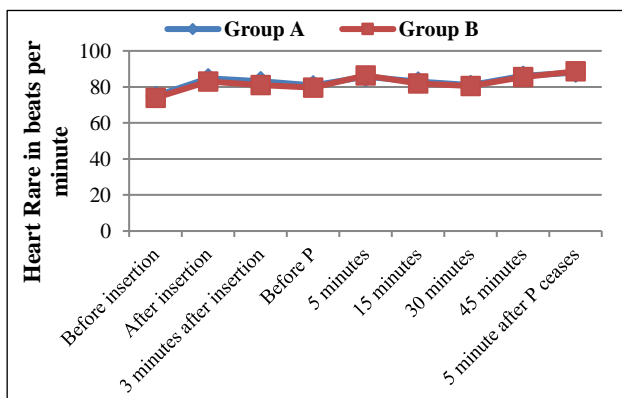


Figure 1: Comparison of HR between the groups across the time periods.

Figure 1, 2 and 3 show the comparison of HR, SBP and DBP respectively between the groups across the time periods. There was no significant (p>0.05) difference in

all these parameters between the groups at all the time periods.

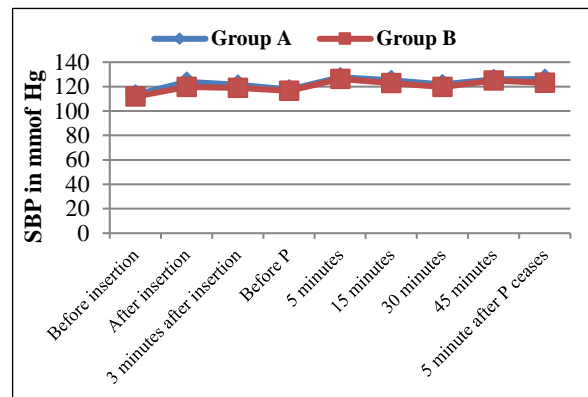


Figure 2: Comparison of SBP between the groups across the time periods.

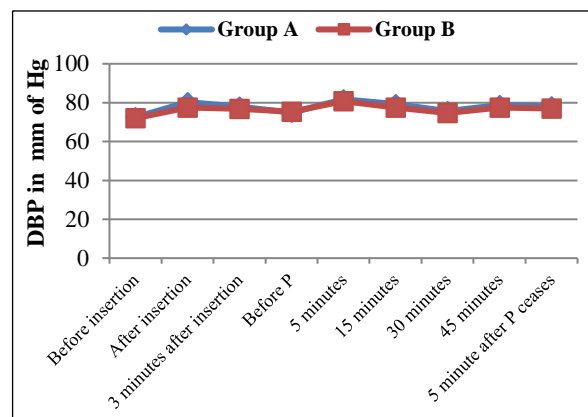


Figure 3: Comparison of DBP between the groups across the time periods.

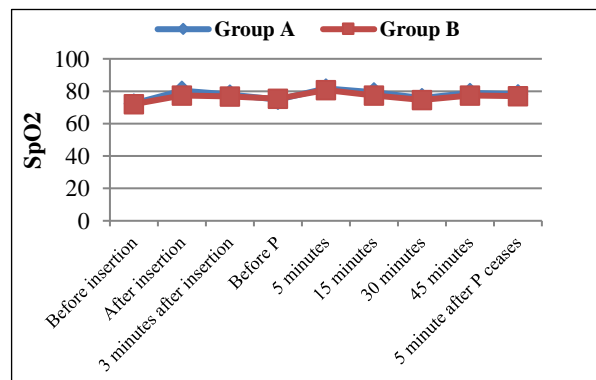


Figure 4: Comparison of SPO₂ between the groups across the time periods.

The comparison of SPO₂ between the groups across the time periods. SPO₂ was similar in both the groups at all the time periods (Figure 4).

Parameters of airway devices and complications. Regarding insertion attempts for airway device there was

no significant ($p>0.05$) difference of number attempts between the groups. One attempt was in majority of patients in both groups i.e. in group A it was 80% and group B it was 93.3% (Table 6). The time taken to insert airway device was significantly higher in group A than

group B. Time taken to insert RT was also significantly higher in group A than group B. The percentage of complications was higher in group A than group B with no significant ($p>0.05$) association. (Table 6)

Table 6: Airway devices parameters and complications.

Parameters		Group A (n=30)	Group B (n=30)	p value
Device insertion attempts	One	24(80%)	28(93.3%)	0.27 [#]
	Two	5(16%)	2(6.7%)	
	Three	1(4%)	0	
Time taken to insert device(sec)		27.97±6.3	13.80±2.85	0.0001*
Time taken to insert RT (sec)		21.73±4.01	15.43±2.32	0.0001*
Complications	Blood on device	4(13.3%)	2(6.7%)	0.21 [#]
	Sore throat	8(26.7%)	2(6.7%)	
	Others	6(20%)	4(13.3%)	

*Significant, #Non-significant

DISCUSSION

In this study, author have compared the safety and efficacy of the I-gel and LMA Supreme (SLMA) in laparoscopic cholecystectomy surgeries. Author have observed that both devices can be safely used in laparoscopic cholecystectomy surgeries.

Laparoscopic surgery is associated with rise in abdominal pressure and peak airway pressure so the airway device to be used must achieve higher oropharyngeal seal pressure than peak airway pressure for effective ventilation and to reduce gastric insufflation. Primary objective of the study was to compare oropharyngeal seal pressure between the I-Gel and SLMA in laparoscopic cholecystectomy surgeries and author have measured oropharyngeal seal pressure 5 minutes after insertion of airway device and 5 minutes after creation of pneumoperitoneum and author observed that oropharyngeal seal pressure was significantly higher in LMA supreme than I-gel at both times but there was no difference in their ability to provide adequate ventilation and oxygenation during surgery. Similarly Ragazzi R et al, and Chew EFF et al, also found that oropharyngeal seal pressure was significantly higher in LMA supreme than I-gel.^{9,15} But Teoh WH et al, and Park SY et al, observed that oropharyngeal seal pressure was almost similar between SLMA and I-gel.^{12,13} Mukkader S et al, observed in their study in which they compared I-gel, SLMA and Proseal LMA during laparoscopic gynecologic surgery that initially oropharyngeal seal pressure was lower in I-gel group but after 30 min and 60 min it was more than that of SLMA and Proseal LMA.¹⁴ In this study author have observed that oropharyngeal pressure after creating pneumoperitoneum was increased in both groups but SLMA oropharyngeal seal pressure remained higher than that of I-gel.

Peak airway pressure before pneumoperitoneum were 21.07±1.11 cmH₂O and 18.63 cmH₂O in I-Gel and SLMA group ($p=0.001$) respectively, and after insufflations of carbon dioxide they were 25.03±1.94 cmH₂O and 23.47±0.68 cmH₂O respectively in I-gel and SLMA groups. Teoh WHL et al, Park SY et al, and Mukkader S et al, also demonstrated that peak pressures were higher after creating pneumoperitoneum.¹²⁻¹⁴ Teoh WHL et al, have observed that peak airway pressures were 16.5±4.1 cmH₂O and 15.8±3.5 cmH₂O before pneumoperitoneum and after creating pneumoperitoneum they were 23.8±5 cmH₂O and 22.4±4.7 cmH₂O in SLMA and I-gel group, respectively.¹² Park SY et al, and Mukkader S et al, observed that peak airway pressures were similar in both SLMA and I-gel group.^{13,14}

The difference between inspiratory and expiratory tidal volume between the two groups was less than 30 ml in both groups throughout duration of surgery and author observed this difference was higher in I-gel group. It was 28.48±0.42 ml in I-gel group and for SLMA it was 19.48±1.03 ml and this difference was statistically significant. The value of ITV and ETV difference found in this study is similar to those in previous studies. Previously done studies by Teoh WHL et al, found it to be 31.2±23.5 ml for I-gel and 21.5±15.2 for SLMA and Lai CJ et al, found it to be 31.99±14.54 ml for I-gel.^{12,16}

In this study it was observed that SLMA has higher success rate of airway device insertion in first attempt in comparison to I-gel. It was 80% for I-gel and 93% for SLMA. Fernandez et al, and Ragazzi R et al, also found that higher first attempt placement rates for SLMA in comparison to I-gel which is similar to this study.^{8,9} But Radhika S et al, Theiler LG et al, and Teoh WHL et al, observed that first attempt insertion success rate was similar for both devices.^{10,12,17} Radhika S et al, observed

first attempt insertion success rate was 76% for I-gel in 71% for SLMA which is lesser than this study.¹⁰ Teoh WHL et al, observed first attempt insertion success rate was 96% for I-gel and 94% for SLMA. Liew GHC et al, found that the success rates of the first insertion attempt was higher for I-gel (90%) in comparison to SLMA (82%) which is in contrast to this study.^{12,18}

The mean device insertion time was longer with I-Gel (27.97±6.30 seconds) than with SLMA (13.80±2.85 seconds) (p=0.0001). Zundert V et al, and Fernandez et al, have also showed in their study that the SLMA was easier to insert and had a shorter effective airway time than the I-gel.^{8,19} But Radhika KS et al, and Park SY et al, have observed that insertion time was same for two devices.^{10,13}

The successful passage of the gastric tube may serve as indirect confirmation of proper functional positioning in the LMA Supreme and I-gel. Author were able to place the nasogastric tube in all the patients. The mean time taken to secure a nasogastric tube after device insertion in the I-gel group was 21.73±4.01 sec which is more than SLMA group where it was 15.43±2.32 sec (p<0.0001) respectively. The success rate of first-time insertion of gastric tube was 83.3% with the I-gel and 93% with SLMA. Teoh WHL et al, and Liew GHC et al, also found that longer time was required to insert the gastric tube in the I-gel group as compared to SLMA.^{12,18} Park SY et al, also found longer insertion time for gastric tube in I-gel than SLMA but every gastric tube was successfully inserted on the first attempt in both groups in their study.¹³

Regarding hemodynamics author have observed that there was less hemodynamic stress response with SLMA when compared with I gel, but difference was not statistically significant. I-Gel and SLMA being a supraglottic device does not require laryngoscopy, hence they do not evoke a significant laryngoscopy response. Park SY et al, also found that there was no significant difference between I-gel and LMA Supreme group on hemodynamics.¹³

Incidence of blood on device after removal and postoperative throat discomfort were higher in I-gel group but it was not statistically significant. In the I-gel group, complication encountered was throat discomfort blood on device, altered taste. Throat discomfort occurred in 8(26%) patients whereas blood on device occurred in 4(13%) patients. However, in the SLMA group, throat discomfort was reported in 2(6.6%) patients and blood on device was in 2(6.6%) patients. The virtual absence or decrease in occurrence of post-operative laryngopharyngeal comorbidities with I-gel and SLMA is consistently the finding of almost all the studies conducted so far. Similar to this study Park SY et al, and Ragazzi R et al, also demonstrated less incidence of blood-stained device and postoperative sore throat with SLMA in comparison to I-gel.^{9,13}

This study has a few limitations. Firstly, only those patients were studied who were not obese. Author cannot extrapolate from these data to performance in other groups. Secondly, fiberoptic bronchoscopy cannot be used to assess the anatomical position of I-gel and SLMA in relation to the vocal cords.

CONCLUSION

Both the I-gel and SLMA devices can be used safely in laparoscopic cholecystectomy in non-obese patients. Ventilation was not compromised in any patient, with delivery of adequate tidal volumes and anesthetic agents for the duration of surgery. But in SLMA group oropharyngeal seal pressure was higher with lesser leak volume in comparison to I-gel group.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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