Original Article

I-Gel versus Proseal Laryngeal Mask Airway: A Comparison between Two Supraglottic Airway Devices in Elective Laparoscopic Cholecystectomy Patients

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Abstract

Introduction: Although tracheal intubation is considered ideal for airway management in laparoscopic surgeries, as it provides adequate ventilation and protects against pulmonary aspiration even in the presence of raised airway pressure due to carboperitoneum, supraglottic airway devices are beginning to be used more commonly in the same scenario in the right subset of patients. **Materials and Methods:** Eighty American Society of Anesthesiologists I and II patients coming for laparoscopic cholecystectomy surgeries were divided into two groups of I-gel and proseal laryngeal mask airway (PLMA) each. Ease of device insertion, time of device insertion, number of insertion attempts, airway leak pressure, and ease of insertion of gastric tube was observed. Patient was inspected for any "injury" of the lips, teeth or tongue, and the device for blood stain. 18–24 h after surgery, patients were interviewed for any "postoperative complications" such as sore throat, dysphagia, and hoarseness. **Results:** Both I-gel and PLMA can be used safely for laparoscopic cholecystectomy; ProSeal provides better sealing pressure while I-gel is easier to use practically and has less hemodynamic variations.

Keywords: Airway control, laparoscopic cholecystectomy, post operative complications, supraglottic airway devices

Introduction

Airway management devices and strategies have been subjects of discussion and study for many years. Laparoscopic surgery has been shown to adversely affect intraoperative pulmonary mechanics, thus providing the most severe test of the efficacy of an airway device.Tracheal intubation is considered ideal for airway management in laparoscopic surgeries, as it provides adequate ventilation and protects against pulmonary aspiration even in the presence of raised airway pressure due to carboperitoneum. Endobronchial intubation is also not uncommon during laparoscopic procedures, and in difficult airway situations, this may fail. I-gel and other supraglottic airway devices (SAD's) may overcome some of these problems, even in obese patients and in those who require high airway pressure for adequate ventilation. The anesthesiologist must ensure a patent airway and adequate ventilation. SAD's such as proseal laryngeal mask airway (PLMA) and the I-gel forms a more effective seal than the LMA and has a drainage tube that facilitates the passage of a gastric tube. It provides protection against regurgitation and prevents gastric insufflation when correctly placed. I-gel can be a safe and suitable alternative to endotracheal tube (ETT) for laparoscopic surgeries. Very few studies have been found in the literature comparing these two SADs in laparoscopic cholecystectomy patients; hence, this study was undertaken in Indira Gandhi Medical College and Associated Hospitals, Shimla, to compare these two SADs in anesthetized adult patients posted for laparoscopic cholecystectomy under general anesthesia.

Materials and Methods

A study entitled "I-gel versus PLMA: A comparison between two SADs in elective laparoscopic cholecystectomy patients" was undertaken in Indira Gandhi Medical College and Hospital, Shimla.

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A total of 80 patients, scheduled for elective laparoscopic cholecystectomy under general anesthesia belonging to the American Society of Anesthesiologists (ASA) Class I and II, were included in the study in the period of 2016–2017.

Inclusion criteria for the study

1. Adult normotensive patients of ASA I and II, aged between 18 and 60 years, of either sex having body weight between 50 and 70 kg
2. Patients having Mallampati Grade I and II
3. Duration of surgery <60 min.

Exclusion criteria

The following patients will be excluded from the study.

1. Age <18 years and >60 years having body weight <50 and >70 kg
2. ASA Class III and above
3. Patients having abnormal airway anatomy, tonsillar hypertrophy, hematoma, and/or abscess
4. History of any condition which increase the risk of regurgitation of gastric contents.
   a. Full stomach (<8 h fasting), uncertainty about intake of food or drink
   b. Trauma
   c. Intra-abdominal pathology such as intestinal obstruction, peritonitis, and/or gastric paresis
   d. Diabetes (gastroparesis diabeticorum)
   e. Uremia (uremic enteropathy)
   f. Esophageal disease such as symptomatic reflux motility disorder
   g. Pregnancy.

The study population was randomly divided into two groups with 40 patients in each group.

- Group 1: I-gel (size 4) was used
- Group 2: PLMA (size 4) was used.

All patients included in the study were given premedication with tablet alprazolam 0.5 mg at bedtime before day of surgery. Patients were kept nil orally for solids 10 pm onward on the previous night and for clear fluids up to 2 h before induction.

Patients were given injection ranitidine 150 mg slow intravenous (IV) and injection metoclopramide 10 mg slow IV 1 h before the time of surgery.

On arrival of the patient in the operating room, an 18G IV cannula was inserted and an infusion of ringer lactate was started. Patient was connected to Datex patient monitor and ''Baseline'' blood pressure (systolic/diastolic/mean), heart rate, electrocardiogram, and oxygen saturation was recorded.

Every patient was premedicated with injection midazolam 1 mg IV slow and injection fentanyl 2 mcg/kg IV slow as an analgesic. After preoxygenation with 100% oxygen for 3 min, anesthesia was induced with injection propofol 2.0 mg/kg intravenously slow followed by injection rocuronium 0.6 mg/kg intravenously. Patients were ventilated with the mask with 100% oxygen, and at the end of 90 s injection propofol, 0.5 mg/kg was given in addition to the bolus dose.

"Predevice insertion" parameters were recorded and airway was secured with the device as per the group after 120 s of preoxygenation. I-gel supraglottic airway (size 4), in Group 1 and PLMA device (size 4) in Group 2, was inserted after performing standard preuse tests for both devices. Again "Postdevice Insertion" parameters were recorded, ''Time Taken for Device Insertion," and "Airway Leak Pressure" was noted. Thereafter, all the parameters were recorded at 1, 3, and 5 min intervals.

Anesthesia was maintained using 66% nitrous oxide and 33% of oxygen with 0.6% isoflurane. At the end of the procedure, the patient was reversed with neostigmine 0.05 mg/kg body weight and glycopyrrolate 0.01 mg/kg body weight. The patient remained in the supine position and the device removed after the patient was fully awake and met all the reliable signs of recovery from neuro muscular blockade.

Patient was inspected for any "injury" of the lips, teeth, or tongue and the device for blood stain. 18–24 h after surgery, patients were interviewed for any "Postoperative Complications" such as sore throat, dysphagia, and hoarseness.

Parameters studied during the procedure

Ease of device insertion

If after device insertion, the placement of device was found to be inadequate, manipulations were done in the following sequence-gentle pulling and pushing of the device, head flexion and extension, jaw thrust, chin lift, and deep rotation and any manipulation was recorded. A maximum of three attempts were tried for adequate placement, after which insertion was recorded as a failure, and the airway was secured with an appropriate-sized ETT.

Grading of "ease of device insertion:"

- Grade 1: (Very easy)-No manipulation
- Grade 2: (Easy)-Only one manipulation
- Grade 3: (Difficult)-More than one manipulation.

Time of device insertion

Cumulative time taken from picking up the device upto the time of confirmation of effective ventilation (by bilateral symmetrical chest movement and square waveforms on capnograph with normal range end-tidal CO_2).

Number of insertion attempts

Number of attempts required for the insertion of each device was noted. If after three attempts ventilation was not found to be adequate, considering it a failure, airway was secured with an appropriate-sized ETT and case was excluded from the study.

Airway leak pressure

Airway pressure at which leak occurs was noted using closed circuit with mechanical ventilation. Keeping the flow rate of 3 L/min and maximum pressure limit of 40 cm H_2O, the airway

pressure was gradually increased. The pressure at which an audible noise was detected using a stethoscope placed just over the mouth opening (over the lips) was taken as the airway leak pressure.

Ease of insertion of gastric tube

The ease of insertion of the gastric tube was graded as follows:

- Grade 1: (Easy)-Insertion on the first attempt
- Grade 2: (Difficult)-Insertion on second attempt
- Grade 3: (Failure) -Unable to pass (inability to pass the gastric tube even with 2 attempts).

The correct position of the gastric tube was confirmed by the injection of air and by auscultation over the epigastrium.

Injuries

The patient was inspected for any injury of the lips, teeth or tongue, and the device for blood stain after its removal at the end of the surgery.

Postoperative complications

Patients were interviewed for any postoperative complications such as sore throat, dysphagia, hoarseness, and difficulty in phonation till 24 h after the device removal.

Statistical analysis

Data were entered in Excel sheet and imported to Statistical Package for Social Sciences software version 20.0 (softronics). Quantitative variables have been expressed as mean and standard deviation. Qualitative variables have been expressed as percentages. Student's *t*-test was applied to establish difference between quantitative variables in two groups. Chi-square test was applied to see the association of qualitative variables with two procedures. $P < 0.05$ was considered significant at 95% confidence intervals.

Results

Results of the study are shown in Tables 1-7.

Table 1: Comparison of number of attempts of device insertion

Insertion attempts	Group 1 (I-gel), *n* (%)	Group 2 (PLMA), *n* (%)
First attempt	34 (85)	30 (75.)
Second attempt	6 (15)	10 (25)
Total	40 (100)	40 (100)
P	0.263 (NS)	

NS: Not Significant, P-LMA: ProSeal laryngeal mask airway

Table 2: Comparison of "ease of insertion"

Ease of device insertion	Group 1 (I-gel)	Group 2 (P-LMA)
Grade-1 (very easy)	35 (87.5)	32 (80)
Grade-2 (easy)	4 (10)	7 (17.5)
Grade-3 (difficult)	1 (2.5)	1 (2.5)
Total	40 (100)	40 (100)
P	0.621 (NS)	

NS: Not Significant, P-LMA: ProSeal laryngeal mask airway

Table 3: The mean duration for insertion

	Mean duration of insertion (s)
Group 1	14.85±1.001
Group 2	20.1±1.646
P	<0.001 (HS)

HS: Highly significant

Table 4: The mean airway leak pressures

	Mean airway leak pressure (cmH_2O)
Group 1	24.58±1.41
Group 2	29.10±0.871
P	<0.001 (HS)

HS: Highly significant

Table 5: The intergroup comparison of oxygen saturation (%) SpO_2 changes in response to insertion of I-gel in Group 1 and ProSeal laryngeal mask airway in Group 2 patients

Time	Group 1 (I-gel)	Group 2 (P-LMA)	*P*
Basal	96.30±1.363	96.25±1.532+	0.878 (NS)
Before device insertion	100.0±0.000	99.95±0.316	0.320 (NS)
Just after device insertion	99.30±0.853	99.40±0.871	0.605 (NS)
1 min - AI	98.80±0.911	98.98±0.947	0.402 (NS)
3 min - AI	98.80±0.911	99.00±0.934	0.335 (NS)
5 min - AI	98.90±0.928	99.00±0.961	0.637 (NS)

P-LMA: ProSeal laryngeal mask airway, HS: Highly significant, S: Significant, NS: Not significant, AI: After insertion

Discussion

Both the groups were comparable, and there was no statistically significant difference with regard to mean age, weight, sex, and duration of surgery.

Ease of device insertion

One of the primary objectives was to compare the "*Ease of Device Insertion"* between the two devices. The grading of insertion was done similar to the study conducted by Sanket *et al.*[1] where the ease of device insertion was recorded as; very easy (no manipulations), easy (1 manipulation), or difficult (>1 manipulation).

In our study, the "*Ease of Insertion"* of I-gel was very easy (Grade 1) in 35 (87.5%) patients, easy (Grade 2) in 4 patients (10%), and difficult in 1 patient (2.5%). In Group 2, insertion of PLMA was very easy (Grade 1) in 32 patients (80%), easy (Grade 2) in 7 patients (17.5%), and difficult (Grade 3) in 1 patient (2.5%). There was no statistically significant difference between the two groups with respect to ease of insertion ($P > 0.05$). The insertion of I-gel was found comparatively easier and required less skill as compared to PLMA; however, the results were not statistically

Table 6: The intergroup comparison of ease of gastric tube insertion in Group 1 and in Group 2 patients

	Group 1 (I-gel), *n* (%)	Group 2 (P-LMA), *n* (%)
Easy	35 (87.5)	32 (80)
Difficult	5 (12.5)	8 (20)
P	0.363 (NS)	

NS: Not Significant, P-LMA: ProSeal laryngeal mask airway

Table 7: The occurrence of "injuries and postoperative complications"

Injuries and postoperative Complications	Group 1 (I-gel), *n* (%)	Group 2 (PLMA), *n* (%)
Tongue/lip/tooth injury	1 (2.5)	6 (15)
Blood on device	1 (2.5)	6 (15)
Sore throat	1 (2.5)	3 (7.5)
Postoperative dysphagia	-	1 (2.5)
Postoperative hoarseness	-	2 (5.0)
P	<0.000 (HS)	

HS: Highly significant

significant. The I-gel having a noninflatable cuff and firm in consistency is much easier for insertion as compared to PLMA. Our study regarding the "*Ease of Insertion"* of the devices was similar to the study conducted for classic LMA by Siddiqui *et al.*[2] and Janakiram *et al.,*[3] who also did not find any statistically significant difference. The result of our study is supported by the study done by Sanket *et al.*[1] where very similar statistically comparable ($P > 0.025$) results were obtained regarding the ease of device insertion comparing I-gel and P-LMA. In addition, the result of our study is supported by the study done by Chauhan *et al.*[4] where the I-gel device insertion was inserted in first attempt in 80% of the patients. Insertion of PLMA in our study were in conformity with the earlier reported studies conducted by Brain *et al.*[5] and Brimacombe.[6]

Time of insertion

Time of device insertion was considered according to the study conducted by Helmy *et al.*[7] from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end-tidal CO_2, and stable arterial SpO_2 (>95%). In our study, the "*Time for Insertion"* of I-gel (14.85 s) was shorter compared to PLMA (20.1 s) which was highly significant statistically ($P = 0.000$). The results of our study regarding the time of insertion of I-gel was supported by the study conducted by Chauhan *et al.*[4] where the median time for the insertion of I-gel was found to be 11.2 s whereas in our study, the median time for insertion of I-gel was 14.85 s. In our study, the median insertion time for P-LMA was found to be 20.1 s which is supported by the study conducted by Chauhan *et al.*[4] where the insertion time for PLMA was 15.13 s which was longer than the insertion time for I-gel. The I-gel SAD is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence, is easier and requires less time for successful insertion as compared to PLMA which has a cuff to be inflated after its insertion.

Number of attempts

In this study, the device insertion in Group 1 (I-gel group) was successful in the first attempt in 85% patients as compared to 80% 1st time insertion with P-LMA in Group 2. Very similar results for the I-gel insertion attempts were found in studies conducted by Helmy *et al.*,[7] Uppal *et al.,*[8] and Siddiqui *et al.*[2] Similar result for P-LMA insertion attempts was found in studies conducted by Sanket *et al.*[1] and Kini *et al.*[9]

Airway leak pressure

In our study, the mean airway sealing pressure in the Group 2 patients (29.1 cm H_2O) was found to be significantly higher than that observed in Group 1 patients (24.58 cm H_2O) with a $P < 0.0001$. The airway leak pressure detection in our study was performed in a manner similar as done by Uppal *et al.*[8] in their study where the fresh gas flow was adjusted to 3 L/min and the adjustable pressure limiting valve of the circle system was completely closed. Airway pressures were not allowed to exceed 40 cm H_2O. The oropharyngeal sealing pressure (OSP) for I-gel has been reported to be = 30 cm H_2O.[4,8] The mean OSP was higher for PLMA signifying better protection against aspiration and better suitability in patients with low compliance or higher airway resistance. The higher seal pressure for the PLMA is most likely due to the deeper bowl, a bigger cuff with its dorsal and ventral components, the proximal wedge shape of the cuff, the corresponding larger surface area in comparison to I-gel and also due to the inflatable nature of the cuff in comparison to the cuffless I-gel.

The average airway sealing pressure was reported as 25.27 cm H_2O with I-gel and 29.6 cm H_2O with PLMA by Singh *et al.*[10] The seal pressure appears to improve over time in a number of patients due to the thermoplastic properties of the gel cuff, which may form a more efficient seal around the larynx after warming to body temperature.[11]

Airway leak pressure of I-gel in our study was comparable with Uppal *et al.*[8] and Helmy *et al.*[7] studies and of PLMA with Chauhan *et al.*[4]

The efficacy of the oropharyngeal seal of the SAD depends on the fit between the structures surrounding the glottis and the distal mask of the SAD. With PLMA, to obtain a good seal, the distal cuff has to be inflated. The I-gel made of thermoplastic elastomer is designed anatomically to fit the perilaryngeal and the hypopharyngeal structures without the use of an inflatable cuff. The airway seal of PLMA is higher than that of I-gel.

Ease of gastric tube insertion

In our study, the insertion of gastric tube in Group 1 patients (I-gel) was successful in 35 (87.5%) patients in 1st attempt and in Group 2, it was successful in 32 patients (80%), whereas gastric tube insertion was successfully inserted in 2nd attempt in Group 1 (I-gel) in 5 (12.5%) patients and in 8 (20%) patients. There was no statistically significant difference

between the two groups with respect to ease of gastric tube insertion ($P > 0.05$). Assessment of success rate of gastric tube insertion with I-gel was found to be 87.5%. This is consistent with what has been reported by Richez *et al*.[12] as the gastric tube was inserted in 100% of cases. Assessment of success rate of gastric tube insertion with P-LMA was found to be 80%. This is consistent with the study done by Chauhan *et al*.[4] where the gastric tube insertion was successful in 1st attempt in the P-LMA group in 72.5% patients.

Injuries and postoperative complications

Injuries

The inflatable SADs**,** during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to downfold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression, and nerve injury. In our study, the patients were inspected for any injury of the lips, teeth or tongue, and the device for blood stain after its removal at the end of the surgery similar to study done by Siddiqui *et al*.[2] Lip injury was noted in 1 patient (2.5%) in Group 1 (I-gel) out of 40 and in 6 patients out of 40 (15%) in Group 2 (PLMA). The incidence was found to be statistically significant ($P < 0.05$). the higher incidence of lip injury seen in Group 2 patients is a deviation from the study done by Chauhan *et al*.[4] and Singh *et al*.[10] In our study, only 1 case in Group 1 (I gel) had blood stain on the device, but blood stain on the device was noted in 6 patients in Group 2 (PLMA), and it was found to be statistically significant ($P < 0.05$). The higher incidence of blood staining of the device in Group 2 patients in our study is supported by the results of the study done by Chauhan *et al*.[4] which demonstrated a higher incidence of some complications such as blood staining of the device in the PLMA group when compared with the I-gel group.

Postoperative complications

18–24 h after surgery, patients were interviewed for any postoperative complications such as sore throat, dysphagia, and hoarseness. Only 1 patient (2.5%) in Group 1 had developed sore throat postoperatively compared to 3 patients (7.5%) in Group 2. The incidence was not statistically different ($P = 0.305$) when compared between the two groups. The sore throat in all the 4 cases was mild requiring no treatment. None of the patients in both the groups developed postoperative hoarseness or dysphagia. Our results were consistent with the studies done by Siddiqui *et al*.[2] Helmy *et al*.[7] where the difference between LMA and I-gel regarding postoperative complications was not statistically significant. In addition, the results of our study for postoperative complications were supported by the results of the study done by Singh *et al*.[10] and Chauhan *et al*.[4]

Hence, from our study, we conclude both the SADs PLMA and I-gel can be used safely and effectively during general anesthesia with positive pressure ventilation in selected patients. Both devices are easy to insert. The PLMA provides a better airway sealing pressure compared to I-gel. The I-gel is a cheap and effective SAD which is easier to insert with shorter device insertion time and lesser number of insertion attempts (statistically significant as compared to LMA-ProSeal). It has other potential advantages such as effective airway sealing pressure, easier gastric tube placement, less hemodynamic variations, and lesser rate of postoperative complications. The I-gel SAD has low pharyngolaryngeal morbidity rate as compared to PLMA. Although the sample size of the present study is relatively small, it clearly elucidates that the I-gel appears to be efficacious in insertion characteristics. In our opinion, the I-gel is a useful SAD for using in elective laproscopic cholecystectomy in ASA I and II patients.

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Conflicts of interest

There are no conflicts of interest.

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