

A Randomized Prospective Study to Compare Use of I-GEL™ and LMA Proseal™ in Patients undergoing Laparoscopic Cholecystectomy

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Abstract

Introduction: With the availability of supraglottic devices in providing effective seal even in conditions of raised airway pressures, use of these devices in laparoscopic surgeries has become popular. Of the various supraglottic devices being used in laparoscopic surgery LMA ProSeal™ and i-gel™ airway are commonly used with efficacy. The aim of this study was to compare the use of i-gel™ and LMA ProSeal™ in patients undergoing Laparoscopic cholecystectomy.

Methodology: This was a prospective randomized, hospital based study conducted at a tertiary care hospital. Adult inpatients of either gender posted for elective laparoscopic surgery were recruited in the study. A total of 100 patients were included out of which 50 each were randomly allocated to either i-gel™ group (Group I) or LMA ProSeal™ group (Group P). After randomization, the chosen supraglottic airway device (i-gel/Proseal LMA) was inserted. Airway insertion attempts, time to successful ventilation, Gastric tube placement, Airway sealing quality, Numbers of attempts required for correct placement and complications were recorded and the data was assessed.

Results: Demographic data were comparable in the two groups. The Ventilation time was found to be significantly faster with PLMA as compared to i-gel. I-gel and Proseal showed no significant differences in the airway and gastric tube insertion attempts, ventilation success rate, airway sealing pressures, SpO₂, EtCO₂, airway sealing quality score and intra abdominal pressures.

Conclusion: Both i-gel and Proseal both provide adequate ventilation in laparoscopic cholecystectomy surgeries. Complications such as airway injury and bleeding with Proseal LMA are significantly more as compared to i-gel.

Keywords: Laryngeal Masks; Cholecystectomy; Laparoscopic.

Introduction

The intraoperative requirements of laparoscopic surgeries produce significant physiological changes. These changes are mainly the result of patient position, introduction of exogenous insufflating gas CO₂, pneumoperitoneum and

increased intra abdominal pressure. General anaesthesia is the preferred anaesthetic technique of choice for laparoscopic surgeries. Endotracheal intubation was considered the gold standard for airway management for laparoscopic procedures.¹ However with the availability of supraglottic devices which provide effective seal even in

conditions of raised airway pressures, use of these devices in laparoscopic surgeries has become popular.

Of the various supraglottic devices being used in laparoscopic surgery LMA Proseal™ (The Laryngeal Mask Company Limited, Le Rocher, Victoria, Mahe, Seychelles) is widely used. It has a unique double cuff and a two tube arrangement. This design allows an oropharyngeal seal of >30cm H₂O without increase in directly measured mucosal pressures. The drainage tube is effective in preventing gastroesophageal insufflation and allows regurgitation liquid to escape via the drainage tube and thereby preventing aspiration.²

i-gel™ airway (Intersurgical Ltd., Crane House, Molly Millars Lane, Workingham, Berkshire, RG412RZ, U.K) is a novel supraglottic device made of a thermoplastic elastomer (SEBS, styrene ethylene butadiene styrene) with a soft gel like feel. The mask of the i-gel™ is designed anatomically to fit the perilaryngeal and hypopharyngeal structures without the use of inflatable cuff. The shape of the outer cuff ensures adequate blood flow to the laryngeal and perilaryngeal framework and hence chances of neurovascular compression trauma are minimized.^{3,4}

Various studies have assessed hemodynamic changes and ease of insertion of different supraglottic airway devices such as PLMA, SLIPA™ (Steamlined Liner of the Pharynx Airway) and i-gel™ along with their efficiency in providing reasonable alternative to tracheal tube during pressure control ventilation with moderate airway pressures.⁵⁻⁷

Similarly Uppal et al compared i-gel and cuffed tracheal tube using leak volume (Inspired tidal volume - Expired tidal volume) and leak fraction (Leak volume divided by Inspiratory tidal volume) by in 25 patients and found i-gel to be an effective alternative.⁸

The aim of this study was to compare the use of i-gel™ and LMA Proseal™ in patients undergoing Laparoscopic cholecystectomy. The primary objective was to assess the time taken for successful placement of supraglottic airway device. The secondary objective was to compare the number of attempts for insertion of airway device and nasogastric tube, the airway sealing pressure and the intraoperative ventilation parameters (airway sealing quality score, SpO₂, inspiratory, tidal volume, expiratory tidal volume, peak airway pressure and EtCO₂) and Oropharyngeal and laryngeal morbidity among the two groups.

Methodology

This was a prospective randomized, hospital based study conducted at a tertiary care hospital. Adult inpatients of either gender posted for elective laparoscopic surgery were recruited in the study. A total of 100 patients were included out of which 50 each were randomly allocated to either i-gel™ group (Group I) or LMA Proseal™ group (Group P). Approval was obtained from the Institutional Ethical Committee.

Randomization was done by using randomizing software from <http://www.randomizer.org>. Insertion time was taken as a primary outcome variable. The power of study was taken as 0.80, with 5% as level of significance. Based on a study by Chauhan et al the sample size to detect a difference of 2 minutes in insertion time with SD =3 (assuming to be true for both groups) worked out to be 42 for each group.⁹ Sample size for this study was then taken as 50 expecting 10% possible dropouts and non compliance.

The study was conducted from January 2014 to January 2015. Adult patients of either gender belonging to ASA I and II admitted for elective laparoscopic cholecystectomy were included in the study. Cases of difficult airway, Cervical spine disease, Body Weight <30kg, BMI >35 kg/m², History of gastroesophageal reflux disease (GERD), previous gastric surgery were excluded from the study.

Preoperative evaluation of the patients was done by taking detailed history, physical examination, airway assessment and investigations. The investigations carried out were blood haemoglobin, total leucocyte count, differential leucocyte count, platelet count, coagulation profile, liver function tests, blood sugar (fasting and post prandial), blood urea, serum creatinine, serum electrolytes, chest radiograph and electrocardiogram. Informed consent was taken. The patients were asked to fast overnight for at least 8 hours.

On the morning of surgery, intravenous access was secured. Inj. Ranitidine 50mg and Inj. Metoclopramide 10mg was given to the patient 2 hours before the surgery. Patients were shifted to the operation theater and randomization was done by using randomizing software, Research Randomizer from <http://www.randomizer.org>. Depending on the randomization and body weight, the appropriate sized airway device was prepared. Monitoring included ECG, HR, pulse oximetry for SpO₂ and PR and NIBP.

Patients were pre-oxygenated with 100% oxygen for 3 min and given fentanyl 12µg/.kg, glycopyrrolate 0.004mg/kg and midazolam 0.02mg/kg. Induction of anaesthesia was done with propofol 2.0–2.5 mg/kg. Facemask ventilation was done with 67% nitrous oxide and 33% oxygen and is of lurane. PLMA (Proseal™ laryngeal mask airway) or i-gel™ was checked and lubricated with water soluble jelly. After induction of anaesthesia was achieved, vecuronium bromide 0.1mg/kg was given for muscle relaxation and facemask ventilation was done for 3 minutes. After 3 minutes the placement of supraglottic device was attempted. Depending on the randomization, the chosen supraglottic airway device (i-gel™/Proseal™ LMA) was inserted. After two attempts, if the device failed to be inserted or did not provide proper ventilation, the airway was secured with endotracheal tube and the patient was excluded from the study. Correct placement of the airway device was ascertained by auscultation of chest for bilateral air entry, appearance of square waveform on capnography and adequate expiratory tidal volume. Ryle's tube was inserted through the gastric channel and correct placement was confirmed by syringe test or aspiration. In case of failure of gastric tube insertion in 2 attempts, alternative airway like endotracheal tube was inserted and the patient was excluded from the study. The airway device was fixed with adhesive tape and connected to anaesthesia machine Datex Ohmeda 7100 (GE Healthcare, Datex-Ohmeda, Inc., 3030 Ohmeda Drive, Po Box 7550, Madison, WI, 53707, USA) and ventilated with IPPV mode via the circle absorber breathing system with tidal volume 7–8ml/kg. Anaesthesia was maintained with 67% nitrous oxide and 33% oxygen and isoflurane (0.2%–2.0%) with intermittent vecuronium bromide for muscle relaxation. Airway sealing pressure was measured by closing the expiratory valve of the circle system. At a fixed gas flow rate of 3L/min, the stethoscope was placed lateral to thyroid cartilage to detect the gas leakage. The airway pressure at which leak was detected was noted from the analog pressure gauge on the anaesthesia machine.⁹ Hemodynamic and respiratory function monitoring was done using Datex Ohmeda monitor 7100 for inspiratory tidal volume, expiratory tidal volume and peak airway pressure and Philips Gas Monitor G5-M1019A for SpO₂ and EtCO₂. The lungs were ventilated at a respiratory rate of 12–16 breaths/min to maintain tidal volume of 6–8 ml/kg, inspiratory and expiratory ratio of 1:2 and fresh gas flow of 3 L/min (nitrous oxide and oxygen) to maintain cardiovascular parameters within 20% of baseline values, SpO₂>95% and EtCO₂

35–45 mmHg. Carbon dioxide was insufflated by the surgeon into the peritoneal cavity at 2L/min to create pneumoperitoneum. Intraabdominal pressure was maintained between 12–14 mmHg throughout laparoscopic procedure. At the end of surgery, patient was manually ventilated with 100% oxygen till the return of spontaneous respiration. Inj. Neostigmine 0.05mg/kg and Inj. Glycopyrrolate 0.008mg/kg i.v was given for the reversal of neuromuscular blockade. The supraglottic device was removed when the patient awakened and attained regular spontaneous respiration. The device was checked for any blood stain and any injury to the lips, teeth and tongue was noted. Any other device related complications were recorded too.

Only two attempts were made to insert the chosen airway device. On failed insertion with 2 attempts, endotracheal intubation was done. Time to successful ventilation was taken as the time from insertion of device to establishment of square wave capnography after insertion of supraglottic device. The gastric tube placement was confirmed by aspiration of gastric fluid or epigastric auscultation after injecting 10 ml of air. Numbers of attempts required for correct placement were recorded. Failure was defined as inability to advance gastric tube into the stomach within 2 attempts. In case of failure of gastric tube placement, alternative airway device was used and the patient excluded from the study.

Airway sealing quality was measured using the Airway Sealing Quality Score:¹⁰

1: No leak detected

2: Minor leak of tidal volume (V_t loss less than or equal to 20%)

3: Moderate leak of tidal volume (V_t loss between 20%–40%)

4: Insufficient seal (V_T loss >40%)

Airway sealing pressure was measured as pressure at which leakage was heard with stethoscope as described in the methodology above. The following parameters were monitored- Inspiratory tidal volume, Expiratory tidal volume, End tidal CO₂, SpO₂, Peak airway pressure and Intra abdominal pressure. Monitoring of these parameters was done using Datex Ohmeda 7100 every 5min, for initial 15 mins and then every 15mins till the end of surgery.

Complications such as oropharyngeal trauma were checked for by observing the blood staining of device after removal or any injury to the lips, teeth

or tongue. After the removal of supraglottic device post surgery, any trauma caused due to the device and device related complications were noted. The patient was monitored in the PACU during the postoperative period for at least one hour.

Data was presented as mean±SD for Age, BMI, MPS, ASA, ventilation time (time from insertion of airway device to attainment of ventilation), ASP, SpO₂, EtCO₂, peak airway pressure and intra abdominal pressure. Gender and ventilation success rates were compared using fisher's exact value test. MPS, ASA, ventilation time, airway attempts, gastric tube attempts, ASP, SpO₂, EtCO₂, peak airway pressure and intra abdominal pressure were compared using one way ANOVA test. Qualitative data like ASQ score, airway sizes used and traumatic complications were compared using Chi square test.

Results

The mean age of the subjects in Group I in whom i-gel™ was inserted was 42.78±13.32 years and that in Group P in whom LMA Proseal™ was inserted was 47±12.72 years. Thus the mean age between the two groups was comparable and there was no statistical significance. (p=0.091)

There were 63 females and 37 males in the study. There was no statistical difference between the groups in terms of gender (p=0.5). The mean BMI of the subjects in Group I was 25.3±2.60kg/m² and in Group P was 26.1±3.13kg/m² with no statistical significance (p=0.749). The most commonly used airway I-Gel and Proseal LMA was size 3 for both (29% and 27% respectively). Chi square test showed a p-value 0.585 (p>0.05) indicating that airway size distribution used in both groups was statistically insignificant. 46(92%) patients were ventilated successfully with i-gel and 47(94%) patients with Proseal. Unsuccessful ventilation with Proseal and i-gel were 4 patients (8%) and 3 patients (6%) patients respectively. Fisher's exact value test showed a p-value 0.500 (p>0.05) indicating that this difference is statistically insignificant as shown in Table 1.

Mean Ventilation Time

The mean ventilation time for i-gel was 17.8 second for Proseal was 13.8 sec. The F-value is 28.759 and is p value is 0.000 hence the result is statistically significant at p < 0.05 as shown in Table 2.

Airway Sealing Pressure (ASP)

Average 'Airway sealing pressure' for i-gel was 37.55 cm H₂O with SD of 11.2 and for LMA Proseal was 36.04 cm H₂O with SD of 10.19. The p-Value is 0.997 with no statistical significance as seen in Table 3.

Airway Insertion Attempts

In Group I, i-gel™ insertion was successful at first attempt in 38/50 patients, second attempt in 8/50 patients and failed in 4/50 patients. In Group P, LMA Proseal insertion was successful at first attempt in 37/50 patients, second attempt in 10/50 patients and failed in 3/50 patients. The F-value is 0.221 and p-value is 0.640 with no statistical significance at p > .05 as shown in Table 4.

Gastric Tube Insertion

In Group I there was one failed gastric tube insertion. 40 gastric tubes were inserted at 1st attempt and 5 at 2nd attempt. In Group P there was no failed gastric tube insertion. 45 gastric tubes were inserted at 1st attempt and 2 at 2nd attempt. The F value is 0.551 and p-value is 0.460. Hence the result is statistically not significant at p > 0.05. (Fig. 1)

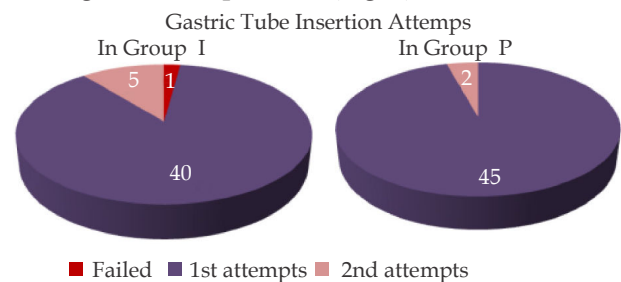


Fig. 1: Gastric tube insertion attempts among the two groups.

Airway sealing pressure (ASP) Group I had Airway sealing quality score of 2.02 with SD of 14.506. Group P had Airway sealing quality score of 2 with SD of 10.193. The p-value is 0.997, hence the result is not statistically significant at p > 0.05 as shown in Table 5.

Average End Tidal CO₂ (ETCO₂)

Average End Tidal CO₂ in Group I was 34.87 and 34.55 Group P and was comparable throughout the surgery with p values >0.05 indicating no statistical significance.

Table 1: Comparison of ventilation-success rate among Group I and Group P.

Variables	Group I	Group P	Fisher's exact-value	p-value
Yes	46 (92%)	47 (94%)	0.154	0.500
No	4 (8%)	3 (6%)		

Table 2: Relation between mean ventilation times among Group I and Group P (One-Way ANOVA test).

Variables		N	Mean	S.D.	F value	p- Value	Significance
Ventilation Time	Group I	50	17.8	4.354	28.759	0.000	Significant
	Group P	50	13.8	2.642			

Table 3: Airway Sealing Pressure (ASP) among the 2 groups.

Variables		N	Mean	S.D.	F value	p- Value	Significance
ASP (cm)	Group I	50	37.5	14.506	0.000	0.997	Non Significant
	Group P	50	36.04	10.193			

Table 4: Relation between Airway Attempt variables among Group I and Group P (One-Way ANOVA test).

Variables		N	Mean	S.D.	F value	p- Value	Significance
Airway Attempts	Group I	50	1.17	0.383	0.221	0.640	Non Significant
	Group P	50	1.21	0.413			

Table 5: Relation between ASP variables among Group I and Group P (One-Way ANOVA test).

Variables		N	Mean	S.D.	F value	p- Value	Significance
ASP (cm)	Group I	50	37.5	14.506	0.000	0.997	Non Significant
	Group P	50	37.6	10.193			

Table 6: Relation between Peak Airway Pressure in Group I and Group P (One-Way ANOVA test).

Time Interval (mins)	Group	N	Mean	S.D.	F value	p- Value	Significance
0	I	46	15.6	4.24	0.567	0.453	Non Significant
	P	47	16.1	2.81			
5	I	46	20.1	5.6	0.061	0.806	Non Significant
	P	47	20.4	4.11			
10	I	46	21.06	5.66	1.933	0.168	Non Significant
	P	47	22.4	4.69			
15	I	46	20.8	4.83	4.677	0.033	Significant
	P	47	22.7	3.42			
30	I	46	20.04	6.2	5.108	0.026	Significant
	P	47	22.6	4.68			
45	I	46	15.2	9.69	0.912	0.342	Non Significant
	P	47	17.2	10.2			

Table 7: Relation between Intra Abdominal Pressure and Group I and Group P (One-Way ANOVA test).

Time Interval (mins)	Group	N	Mean	S.D.	F value	p- Value	Significance
0	I	46	0.17	1.17	1.022	0.315	Non Significant
	P	47	0.00	0.00			
5	I	46	8.02	5.84	0.249	0.619	Non Significant
	P	47	7.44	5.25			
10	I	46	10.8	3.3	0.107	0.744	Non Significant
	P	47	11.02	2.38			
15	I	46	10.5	3.24	2.283	0.134	Non Significant
	P	47	11.3	1.79			
30	I	46	10.2	3.61	0.281	0.598	Non Significant
	P	47	10.6	4.39			
45	I	46	7.1	5.64	0.078	0.781	Non Significant
	P	47	7.44	6.01			

Table 8: Comparison of Traumatic Complications in Group I and Group P.

Variables	Group I	Group P	Chi square-value	p-value
Blood staining	1(2%)	6 (11%)	6.271	0.043
Gum Bleeding	1(2%)	0(0%)		
Airway Trauma	0(0%)	1(2%)		

Peak Airway Pressure (PAP)

The result is statistically not significant with $p > 0.05$ at interval 0, 5, 10 and 45 minutes. At interval of 15 mins. and 30 mins, both groups had PAP >20 cm H₂O with p value <0.05 and were statistically significant as depicted in Table 6.

Intra Abdominal Pressure (IAP)

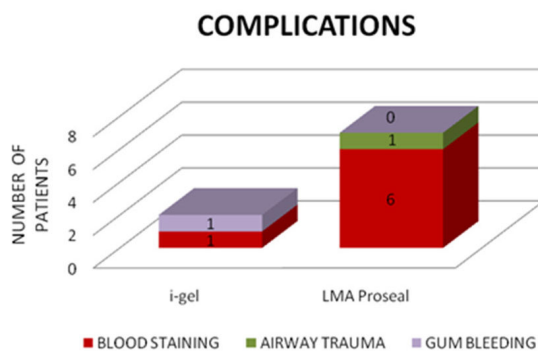
The Group I surgeries recorded an average intra abdominal pressure of 8.25 mmHg with SD of 2.17 while Group P recorded an average intra abdominal pressure of 8.31 mmHg with SD of 1.52. One way ANOVA test shows that the two groups had IAPs which were statistically not significant at $p > 0.05$ as shown in Table 7.

Complications

Group I had 1 patient with blood staining and 1 with gum bleeding. Blood staining was seen in 2% cases. Gum bleeding was seen in 2% cases. There were no complications in 96% cases of Group I.

Group P had 6 patients with blood staining and 1 patient with airway trauma. Blood staining was seen in 11% cases. Airway trauma was seen in 2% cases. There were no complications in 87% cases of Group P.

The Chi square-value is 6.271 and p -value is 0.043. Thus the result is statistically not significant at $p > .05$ as seen in Table 8 and Fig. 2.

**Fig. 2:** Complications among the two groups.

Discussion

In our study, we compared i-gel with PLMA during laparoscopic cholecystectomy. The primary outcome measured was the ventilation time (The time taken from insertion of airway device to attainment of ventilation) while the secondary outcomes were the airway and gastric tube insertion attempts, respiratory parameters- airway sealing pressure, peak airway pressure, SpO₂, EtCO₂ and inspired and expired tidal volumes (for adequacy of ventilation) and oropharyngeal and laryngeal morbidity. The demographic parameters were comparable in both groups showed no significant differences in Group I and Group P.

Ventilation success rates of both groups were not significantly different. Singh I et al compared clinical performance of i-gel and LMA Proseal in elective surgeries and found that in all patients both devices were inserted successfully within three attempts. There were no failures and the results were statistically insignificant.¹¹

Group P showed significantly shorter ventilation time as compared to Group I with p value <0.05 . In Chauhan et al's study mean insertion time for the i-gel (11.12 ± 1.814 sec) was found to be significantly lower than the mean insertion time for PLMA. A statistically significant difference was found between the i-gel (grade 3 = 32/40) and PLMA (grade 3 = 25/40) groups with regard to ease of insertion.⁹ Similarly a study by Saran et al in pediatric patients showed that the insertion times were comparable in i-gel and Proseal.¹²

The number of attempts for airway device insertion and gastric tube insertion showed no significant difference between i-gel and LMA Proseal which was similar to the findings of a study by Jeon W.J et al.¹³ A similar comparative study done by Chauhan et al showed success rate of first time insertion of gastric tube was 100% with the I-gel than with the PLMA.⁹ Singh et al however concluded that success rate of device insertion was better in i-gel (100%) than Proseal (93.3%) but showed no statistical difference.¹¹

In our study, Airway sealing pressures in both groups were not significantly different. In a study by Sharma B et al it was concluded that PLMA

had a better seal than i-gel™.¹⁴ On the contrary, Jadhav et al compared i-gel and Proseal LMA in short surgical procedures and found that i-gel had acceptable airway sealing pressure.¹⁵ In Chauhan et al's study the mean airway sealing pressure in the PLMA group was found to be significantly higher than that observed in the i-gel™ group which was unlike the findings of our study.

SpO₂, end tidal CO₂, airway sealing quality score and intra abdominal pressure were comparable in both groups with no statistically significant differences. Peak airway pressures showed significant differences only at 15 and 30 mins of laparoscopic cholecystectomy surgery in Group I (mean 20.8 and 20.04 cm H₂O respectively) and Proseal (mean 22.7 and 22.24 cm H₂O respectively). Despite these statistically significant differences in both groups, both i-gel and Proseal have maintained satisfactory ventilation with an airway pressure above 20 cm of H₂O. As such this difference in mean airway pressure is unlikely to have any bearing in their clinical use.

Jeon W.J et al showed that leak airway pressures 10 min after insertion were similar between PLMA and the I-gel™. Further, leak pressure did not vary significantly between or within groups 15 min after CO₂ insufflation. In addition, leak volumes and leak fractions of these devices before and after CO₂ insufflation were not statistically significantly different. The similarities in airway leak pressures, leak volumes and leak fractions demonstrated that both devices sealed equivalently and protected airway effectively. A study by Sharma Bimla et al however showed that the end tidal CO₂ though within normal limits in both the groups, was found to be higher at carboperitoneum in the PLMA Group.¹⁵

Proseal showed significantly more post operative complications (blood staining and airway trauma) than i-gel. This was similar to independent studies by Jadhav et al and Singh et al where they compared i-gel and proseal in short surgical procedures and found i-gel™ to be lesser traumatic than LMA Proseal™.^{11,15}

Conclusion

The following inferences were drawn from this study:

The Ventilation time (The time taken from insertion of airway device to attainment of ventilation) is significantly faster with PLMA as compared to i-gel™.

I-gel™ and Proseal have shown no significant differences in the airway and gastric tube insertion attempts, ventilation success rate, airway sealing pressures, SpO₂, EtCO₂, airway sealing quality score and intra abdominal pressures.

Both i-gel™ and Proseal both provide adequate ventilation in laparoscopic cholecystectomy surgeries.

Complications such as airway injury and bleeding with Proseal LMA are significantly more as compared to i-gel™.

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Conflicts of interest: None

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