

Comparison of I-Gel™ and LMA ProSeal™ as Airway Device for Laparoscopic Hernioplasty

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Abstract

Background and Aims: Supraglottic device can provide adequate ventilation for laparoscopic surgeries. This study was aimed to compare Proseal Laryngeal Mask Airway and I-Gel as airway device in laparoscopic hernioplasty. **Methods:** This was a prospective randomised study, conducted on 60 American Society of Anaesthesiology I-II adult patients posted for laparoscopic hernioplasty. Anaesthesia was induced with propofol and rocuronium. PLMA or I-Gel were introduced and fixed and Ryle's tube was inserted. The attempts, ease of insertion, quality of airway sealing, haemodynamic changes, oxygenation, ventilation, respiratory mechanics and postoperative adverse event were noted. Statistical analysis was done with EPI 2000 software and ease of insertion was the primary outcome variable. **Results:** Success rate of I-Gel insertion was 100% and that of PLMA was 96.67%. I-Gel was inserted at first attempt in 96.67% patients but for PLMA it was possible in 73.34% patients. Ease of insertion was more with I-Gel (score 3-93.33%) as compared to PLMA (score 3-70%). Difference between two device was statistically not significant in quality of airway sealing, haemodynamic parameters, attempts of Ryle's tube insertion, oxygenation and ventilation ($p>0.05$). After capnoperitoneum, the peak airway pressure was 19 ± 3.47 cmH₂O, 21.03 ± 3.77 cmH₂O in I-Gel and PLMA group respectively. Insignificant adverse event were noted in both groups. **Conclusion:** Both I-Gel and PLMA can be used as airway device in laparoscopic hernioplasty. Insertion of PLMA is more difficult than I-Gel but it provides effective ventilation similar to I-Gel, with minimum increase in peak airway pressure as compared to I-Gel.

Keywords: I-Gel; PLMA; Capnoperitoneum.

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Introduction

Any development in surgical and anaesthesia technique aims to reduce morbidity, mortality and hospital stay with consequent reduction in health care cost. Minimally invasive surgery and ambulatory surgery are the two most important concepts and practices in this perspective. Inguinal hernia repair is one of the most common procedures performed in any surgical unit. The recent trend of laparoscopic

hernia repair has advantages like reduced pain and discomfort, shorter hospital stay and early resumption of daily activities [1].

General anaesthesia remains the technique of choice for laparoscopic hernia repair, with assured patient as well as surgical comfort. The major concern of the anaesthesiologist is to maintain adequate gas exchange while ensuring minimal airway morbidity. Endotracheal intubation is the gold standard for securing the airway. The supraglottic devices due to

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their property of minimal haemodynamic effects, effective positive pressure ventilation, minimal sore throat [2], less vocal cord morbidity and reduced anaesthetic requirement are highly recommended for day care surgeries. The concern with the use of supraglottic devices is that the insufflation of gas during laparoscopic procedure can result in inadequate oropharyngeal seal leading to inadequate ventilation and increased risk of aspiration [3]. The second generation supraglottic airway devices like I-Gel and Proseal Laryngeal Mask Airway with better oropharyngeal seal pressure and additional drain tube appear promising in this situation. Literature review came up with limited studies on the use of second generation supraglottic devices for laparoscopic hernia surgeries. Most of the studies were either in laparoscopic cholecystectomy or elective short surgeries.

So, this study is an effort to compare the two second generation supraglottic devices, that is, I-Gel and PLMA for ease and effectiveness of insertion and respiratory mechanics during positive pressure ventilation in laparoscopic hernioplasty.

Materials and Methods

After approval from the ethics committee a prospective randomised study was conducted in a teaching hospital. Study is registered in clinical trial registry with registration number CTRI/2016/10/007374.

Sixty patients classified as American Society of Anaesthesiology I and II, with body weight 40-75 kilograms of either sex posted for elective laparoscopic hernioplasty were included in the study. Obese patients, patients with anticipated difficult airway like, mouth opening < 2.5 fingers, patients with known cervical spine disease, or patients prone to aspiration like patients with gastro-oesophageal reflux disease, hiatus hernia and emergency surgeries were not included in the study. Also patients who did not want to be part of the study were excluded.

After informed written consent, patients were randomly allotted into two groups – group I-Gel and group PLMA by computer generated open labelled random numbers. All patients were preloaded with ringer lactate 15ml/kg through a wide bore intravenous cannula and were premedicated with injection glycopyrrolate 0.2 mg intramuscular and inj. pentazocine 0.6 mg/kg i.m. After taking the patient in the operation theatre inj. midazolam 1 mg iv was given. Monitors were attached and baseline hemodynamic readings of heart rate, systolic and

diastolic blood pressure, oxygen saturation were noted. After adequate preoxygenation patients were induced with inj propofol 3 mg/kg i.v and inj rocuronium 0.9 mg/kg.

After adequate mask ventilation, appropriate airway device as per the allotted group was inserted after adequate lubrication with water soluble jelly by an experienced anaesthesiologist. Proseal LMA was inserted using the introducer, after confirming the proper positioning introducer was removed, cuff was inflated and proseal LMA was fixed. Number of attempts of insertion and ease of insertion were noted and accordingly insertion device score (Table 1). More than two attempts were considered as failure and patient was intubated conventionally. Device was fixed adequately and ryle's tube was introduced through gastric channel. The number of attempts of insertion of ryle's tube were noted. Effective ventilation by device was defined by bilateral equal air entry on auscultation and capnography tracing. All patients were ventilated with either Aestiva 5 or Fabius – plus work-station having facility to monitor airway pressure, expired tidal volume, and minute volume. Difference in the inhaled and exhaled volume was noted as leak volume. The quality of airway sealing was scored according to the leak volume calculated (Table 2).

Capnograph and haemodynamic readings were noted at 1, 3, 5, 7, 10, 15 minutes after insertion of device. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane and intermittent positive pressure ventilation to maintain end tidal carbon-dioxide between 30-45 mm Hg. Peak airway pressure, exhaled tidal volume, leak volume, minute volume and EtCO₂ were recorded 10 minutes after Carbon dioxide insufflation and 10 minutes after release of CO₂. After surgery was completed patients were reversed with inj neostigmine 0.05 mg/kg iv and inj glycopyrrolate 0.008 mg/kg iv. The airway device was removed after proper oral suctioning when patients were fully conscious and following verbal command, and then patients were shifted to post-operative recovery room. Complications related to airway device such as blood on airway device, incidence of cough, laryngospasm, lip and dental trauma were noted and patients were questioned twelve hours after surgery regarding sore throat, dysphagia, dysphonia, numbness over tongue or oropharynx.

Assuming the first attempt success rate (ease of insertion) minimum of 50% and to detect 35% difference keeping the power of study at 80 and confidence interval 95% minimum calculated sample size was 29 for one tail test. The data was entered into

Table 1: Ease of insertion of Supraglottic device

Score	Description
3	insertion at first attempt without any tactile resistance
2	insertion at first attempt with tactile resistance
1	insertion successful at second attempt
0	insertion failed at second attempt

Table 2: Quality of airway sealing

Score	Description
3	Minor leak (<20%)
2	Moderate leak of tidal volume (20% to 30%)
1	Insufficient seal (>30% loss)

Microsoft excel worksheet. Mean and standard deviation were calculated using Microsoft excel. The data was analysed using paired T test and chi square test in open epi 2000 software.

Results

The demographic profile was comparable in both the groups (Table 3). If the airway device was placed effectively within two attempts, it was considered a successful placement. In only one patient airway could not be secured with a supraglottic device, that in PLMA group who required tracheal intubation (Table 4). The success of insertion was comparable in I-Gel and PLMA group ($p > 0.05$). It was seen that I-Gel was placed at first attempt in 96.67% patients and only 3.33% patients required second attempt. In 73.34% patients, PLMA was placed at first attempt and in 23.33% patients it was placed at second attempt. When attempts of insertion between I-Gel and PLMA were compared the difference was statistically significant ($p < 0.05$). Table 4 shows ease of insertion score with both devices.

Quality of airway sealing was graded according to leak volume. No or minimum leak volumes indicated good airway sealing and indirectly suggested the ability to provide adequate ventilation.

In I-Gel group, quality of airway sealing score was 3 in 28 patients and score 2 in 2 patients. In PLMA group all 29 patients had quality of airway sealing score grade 3 (leak < 20% of Tidal Volume). The I-Gel and PLMA groups were compared for quality of airway sealing score and the difference was statistically not significant ($p > 0.05$).

Ryle's tube was placed in 100% patients with PLMA and in 93.33% of patients in I-Gel group.

Table 3: Success rate of supraglottic device insertion

Outcome	I-Gel (n=30)		PLMA (n=30)		P value
Successful	30	100%	29	96.67%	$P > 0.05$
Failed	0	0	1	3.33%	

Table 4: Ease of insertion score

Score	I-Gel (n = 30)	PLMA (n = 30)
3	28 (93.33%)	21 (70%)
2	1 (3.33%)	1 (3.33%)
1	1 (3.34%)	7 (23.34%)
0	0	1 (3.33%)

Success of Ryle's tube insertion in I-Gel and PLMA group was compared and the difference was statistically not significant ($p > 0.05$). Pulse rate, systolic and diastolic blood pressure were monitored at 1, 3, 5, 7, 10, 15 minutes after device insertion. The haemodynamic parameters were comparable between two groups. EtCO₂ remained in normal range during and after capnoperitoneum in both I-Gel and PLMA group. Oxygen saturation was maintained throughout the study period and it remained between 98% to 100% in both groups.

Peak airway pressure ranged from 13-21 cm of H₂O in both the groups. In both group there was significant rise in peak airway pressure after capnoperitoneum. Peak airway pressure was significantly more in PLMA group than I-Gel group after capnoperitoneum and even after release of capnoperitoneum ($p < 0.05$) (Table 5).

After removal of the airway device, patients were observed for presence of blood on device, post extubation cough, nausea, laryngospasm, and trauma to lip and teeth. Blood was present in 2 out of 30 cases in I-Gel group, while it was present in 6 cases out of 29 cases in PLMA group ($p > 0.05$). Nausea and cough was present in one patient each in I-Gel and PLMA group respectively. Patients were visited in postoperative ward, for any delayed complications such as dysphonia, numbness over tongue, sore throat, and dysphagia. Dysphonia was present in 1 case out of 30 in I-Gel group. No other delayed complications were noted in either group.

Discussion

Laparoscopic hernia surgery is a common surgical procedure carried out in any operation theatre. The

Table 5: Peak airway pressure

Interval	I-Gel (n = 30) cm of H ₂ O	PLMA (n=29) cm of H ₂ O	P Value
10 mins after insertion of device	13.10±2.37	14.44±3.29	P > 0.05
10 mins after CO ₂ insufflation	19.00±3.47*	21.03±3.77*	P < 0.05
10 mins after CO ₂ release	14.03±2.68	16.31±3.39*	P < 0.05

*indicates P<0.05 when each value was compared with baseline (10mins after device insertion)

CO₂ insufflation, which may be intraperitoneal or extraperitoneal, causes an increase in intra-abdominal pressure which predisposes these patients to regurgitation and aspiration. Both I-Gel and PLMA, the second generation supraglottic device compared in this study, have an inbuilt gastric tube through which both air or fluid can be vented out, thereby, preventing regurgitation in oropharynx which may be a risk for patient.

The primary objective of the study was to compare the I-Gel with PLMA for success rate in securing airway during laparoscopic hernia surgery. From 30 patients, successful insertion was possible in all 30 patients in I-Gel group and in 29 patients of PLMA group. The success rate was excellent and comparable in both I-Gel and PLMA group (p>0.05). More number 23.33% patients in PLMA group than 3.33% patients in I-Gel group required second attempt for insertion (p<0.05). It was observed that insertion of I-Gel was easier than PLMA. In the study by Singh et al. [4] it was observed that the ease of insertion was better with I-Gel than PLMA. The difference was statistically significant (p< 0.05). The number of attempts required to secure airway were comparable (p >0.05). I-Gel insertion is easier than PLMA with more success rate [5].

PLMA can be inserted with the finger technique or with an introducer. Success rate of PLMA insertion was more with introducer technique than finger technique as observed by Brimacombe et al. [6].

The larger cuff and the deflated edge of mask can catch the edge of epiglottis causing it to downfold. The semi-rigid tip of PLMA, as compared to softer tip of I-Gel makes placement of PLMA difficult [4] Softer, pliable, thermoelastomer material of I-Gel, leads to a better anatomic fit over framework [5]. Also, pliable, flexo-metallic tube of PLMA makes it more prone to malrotation and dislocation. In the institute where this study was carried out, most of the anaesthetists were well versed with the use of I-Gel, as it is used

more commonly for securing airway. Although, reasonable expertise was established with the use of proSeal LMA before commencing the study, it may be one of the factors which lead to the observations described above. Ryle's tube was inserted through drain tube in 100% cases in PLMA and 93.33% cases in I-Gel. Ryle's tube insertion through drain tube is also indirect indication of proper placement of supraglottic airway device. I-Gel having smaller drain channel than PLMA [7] may create some resistance to insertion which may have been a reason of failure in two cases in this study.

Along with maintaining the patency of the airway, adequacy of the ventilation is another important prerequisite for any airway device. Adequacy of ventilation was checked by connecting patient to anaesthesia machine and measuring difference between inspired and expired tidal volume. When difference in inspired and expired tidal volume that is leak is less than 20% indicates good airway sealing leading to adequate ventilation. The quality of airway sealing or adequacy of ventilation was scored and it was found to be good and comparable between I-Gel and PLMA.

The following studies also compared leak in these two supraglottic devices and the result obtained were similar to this study. One of the study with PLMA in laparoscopic surgeries found leak in only 1.5% cases [8] while in other study it was observed that both I-Gel and PLMA were comparable in sealing the airway [4].

PLMA has a larger ventral cuff which fills the gaps in pharynx and the dorsal cuff when inflated pushes ventral cuff further anterior to create seal around the larynx [6]. The I-Gel is made up of thermoplastic elastomer material which changes the contour according to the shape of airway of the patient after insertion at body temperature. I-Gel is soft and shape is so that it creates an effective seal around the perilaryngeal structures [4,9].

Adequacy of ventilation is very important in laparoscopic surgeries due to changes in ventilation,

occurring due to creation of pneumoperitoneum. The airway device needs to provide excellent quality of ventilation when used for laparoscopic surgeries. Both I-Gel and PLMA provide adequate ventilation with negligible leak. It was also confirmed by normal EtCO₂ and saturation throughout the surgery in both the group.

The haemodynamic parameters were comparable after insertion of both I-Gel and PLMA. Laryngoscopy leads to stimulation of receptors present in upper respiratory tract, causing tachycardia and hypertension. Endotracheal intubation further increases plasma catecholamines level, aggravating the rise in pulse and blood pressure. With the insertion of a supraglottic device, laryngoscopy is totally avoided and so is the haemodynamic stress response to it. Endotracheal intubation is the strongest stimulus causing catecholamine surge. Supraglottic device is situated in perilaryngeal area so there is no stimulation of the larynx and trachea and minimum haemodynamic response [10]. If depth of anaesthesia is adequate, the response is minimal. In this study both I-Gel and PLMA were inserted after induction with propofol and muscle relaxation with rocuronium. In both the groups patients were adequately anaesthetised and relaxed.

Peak Airway pressure (PAP) was noted down 10 minutes after device insertion, 10 minutes after inflation of CO₂ and 10 minutes after release of CO₂. Peak airway pressure after release of capnoperitoneum was comparable to baseline in I-Gel group but significantly more in PLMA group. When peak airway pressure of I-Gel and PLMA group were compared it was significantly more in PLMA group than I-Gel group ($p < 0.05$).

Another study noted the significant rise in PAP with both devices after creation of pneumoperitoneum in laparoscopic cholecystectomy [11] but PAP in both I-Gel and PLMA group was comparable before and after pneumoperitoneum ($p < 0.001$). In another study PAP was higher for PLMA group than I-Gel, though not statistically significant [3].

An exhaustive literature search concluded that there was a rise in PAP after capnoperitoneum. In this study also it was observed that PAP increases after capnoperitoneum. Two studies compared PLMA, ETT, I-Gel in their respective studies and noted that the rise in PAP after capnoperitoneum was comparable to that with ETT insertion [10,12]. This suggests that PLMA, I-Gel can provide comparable respiratory mechanics in context of airway pressure to the gold standard which remains to be endotracheal tube.

In this study the PAP was significantly higher in PLMA group than I-Gel group after capnoperitoneum and even after release of capnoperitoneum. This may be due to the displacement of supraglottic device after creation of pneumoperitoneum. The diaphragm gets pushed up after CO₂ insufflation which further displaces mediastinum along with trachea and larynx leading to malposition of supraglottic devices. The PLMA being a cuffed device is more prone for malposition [7] than I-Gel. Slight malposition is usually overlooked as it does not hamper ventilation much, but it may be a reason contributing to the rise in PAP even after release of CO₂. Such malpositions can be confirmed only by fiberoptic visualization. In this study the fiberoptic confirmation of position of supraglottic device was not done. Though the value of PAP in PLMA group was not very much increased, when compared to that of I-Gel group ($19.00 \pm 3.47 \times 21.03 \pm 3.37$ and $14.03 \pm 2.68 \times 19.31 \pm 3.39$),

The airway tube of PLMA is long, narrow and wire-reinforced like that of flexible LMA, so higher resistance is offered by it as compared to wide bore airway tube of I-Gel. This may also be a reason of higher PAP seen in PLMA group in this study [3].

Two patients in I-Gel group had blood on airway device, while six patients in PLMA group had blood on airway device but the difference was not statistically significant. The complications found with PLMA group might be due to its larger inflatable cuff as compared to I-Gel. Also, the PLMA has been found to be more difficult to place as compared to I-Gel and thus increasing the number of attempts [9].

Conclusion

Thus it is concluded from the study that both I-Gel and PLMA can successfully be used as airway device for laparoscopic hernioplasty. Insertion of PLMA appears to be more difficult than I-Gel insertion but it provides effective ventilation similar to I-Gel at the cost of minimum increase in peak airway pressure compared to I-Gel.

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