

A prospective randomised comparative study of proseal LMA, I-gel and endotracheal tube in laparoscopic cholecystectomy

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Abstract

Introduction: The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient because airway related problems are still the most common cause of anaesthesia related morbidity and mortality. The use of I-gel has been reported in laparoscopic surgeries and was found equally effective ventilatory device as PLMA. Therefore, we planned this study to compare I-gel and PLMA with ET tube in patients undergoing laparoscopic cholecystectomy.

Materials and Methods: This prospective study was conducted on 90 patients of both sex, 18-60 years age, ASA grade I-II, scheduled for elective laparoscopic surgery under general anaesthesia. All patients were randomised into three groups of 30 patients each; Group I (I-gel), Group P (PLMA), Group E (ET Tube). Attempts of insertion of devices, effective airway time and easiness of gastric tube; hemodynamic parameters (HR, MAP, SpO₂ and EtCO₂) were recorded.

Results: There was significantly less 2nd attempt required in I-gel group (10%) as compared with ET tube (36.7%) and PLMA (13.3%), (p=0.019). Laryngopharyngeal morbidity were significantly more in Group E as compared to Group P and I (p<0.05). Hemodynamic changes were significantly higher in Group E immediately after intubation which persisted for 3 minutes and immediately after extubation (p= 0.00).

Conclusion: Supraglottic Airway Devices (PLMA and I-gel) were as effective as ET tube in establishing airway and the haemodynamic stability is better than ET tube in laparoscopic cholecystectomy.

Keywords: Endotracheal tube, Proseal LMA, I-gel, Laparoscopic cholecystectomy, Supraglottic Airway Devices.

Introduction

Common cause of anaesthesia related morbidity and mortality are still the airway related problems¹ and it is the anaesthesiologists responsibility to provide & maintain adequate ventilation.² Gynecologic and general surgery procedure and now-a-days bariatric surgery are done by laparoscopic technique.³ The laparoscopic surgery had some common problems, which are a) Intra-peritoneal or extra-peritoneal CO₂ insufflation; b) Raised intra-abdominal pressure. Increased risk of pulmonary aspiration.

So the anaesthesiologist have to ensure a patent airway along with adequate ventilation at high airway pressures. Archie Brain developed the Pro-Seal LMA (PLMA) in the late 1990's with improved ventilatory characteristics.⁴ In patients who require PPV and for operative procedures in which intra-operative gastric drainage or decompression is desirable (laparoscopy),⁵ PLMA may be more suitable than the classical LMA. The limitations of PLMA are demand for careful handling to prevent cuff damage, relative difficulty of insertion and it is costly.⁶ The Intersurgical Ltd. (Wokingham, UK) has a supraglottic airway device 'I-gel' which is cheap, cuffless and can be used as a reasonable alternative to endotracheal tube during pressure controlled ventilation (moderate airway pressure).^{7,8} Various studies reported that I-gel is found equally effective device as Proseal LMA to provide positive pressure ventilation in laparoscopic surgeries

but has less seal pressure as compared to PLMA.⁹ However, there are very few studies with limited data that compare I-gel and PLMA with Endotracheal tube to assess their performance in anaesthetized and artificially ventilated patients scheduled for lap surgery (cholecystectomy).

Therefore, this study was planned to compare I-gel and PLMA with standard endotracheal tube regarding (a) Efficacy in controlling airway for oxygenation and ventilation; (b) Ease of insertion; (c) Hemodynamic changes and complications in patients posted for laparoscopic cholecystectomies.

Materials and Methods

After institutional ethics committee (IEC) approval, this prospective, randomized, controlled study was done from January 2016 to December 2016, at M.B. Government Hospital, attached to RNT Medical College, Udaipur, Rajasthan. 90 patients of 18-60 years of age, both sex, ASA I – II grade, scheduled for elective laparoscopic cholecystectomy under general anaesthesia were included and informed written consent was taken from each patients. All these patients were subjected to pre-anesthetic evaluation and were enquired about the history of past prolonged illness and drug therapy; and routine investigations like hemogram, complete blood count, blood urea, creatinine, blood sugar (fasting), liver function tests, chest X-ray, and

electrocardiography tests were carried out during this evaluation.

Exclusion criteria: The exclusion criteria were patients with known case of hypertension, cervical spine disease, anticipated difficult airway, cardiovascular pathology, history of sore throat within the previous 10 days, history of gastro-esophageal disease, those with severe asthma, restrictive lung disease, at risk of pulmonary aspiration, BMI >35 kg/m², and had any contraindication to Supraglottic airway device.

The primary outcome measure was the establishment of the airway with the supraglottic airway devices (SAD). The secondary outcome measure was time taken to establishment of the airway, hemodynamic alterations and the leak pressures. Based on the pilot study difficult establishment of airway device was 60 % less in I-gel as compared to Proseal LMA. When taking a power of 80% and alpha error of <0.05 in two tailed test, the number of patients required were 22 in each group. To compensate for drop outs we decided to include 30 patients in each group.

For randomisation and group allocation a total of 92 patients were assessed for eligibility and 2 patients were excluded because of not meeting the inclusion criteria. Using sealed envelope technique 90 patients were randomized in 3 groups according to use of devices as follows; Group I (n=30): I-gel, Group P (n=30): Proseal LMA, Group E (n=30): ET Tube.

After overnight fasting, patient was taken in O.T. and monitoring was done using pulse oximetry, ECG and non-invasive blood pressure measurement. Intravenous line was secured with 20/18 G cannula. Ringer lactate infusion was started. As per institutional protocol patient was premedicated. After pre-oxygenation, anaesthesia was induced with intravenous propofol 2 mg kg⁻¹ and vecuronium 0.1 mg kg⁻¹ intravenously. I-gel and PLMA was lubricated with a water soluble jelly. Once adequate depth of anaesthesia was achieved, I-gel, PLMA or endotracheal tube was inserted by experienced anaesthesiologist as per group allocation. Proseal LMA was inserted by finger guidance technique. Correct insertion and establishment of an effective airway was confirmed by capnography trace, normal thoracoabdominal movement, lack of gastric insufflation (by epigastric auscultation) and absence of gas leak. If an effective airway with I-gel and PLMA was not achieved, the device was removed and re-inserted. Two attempts of I-gel and PLMA insertion was performed before the attempt was labeled as failure and endotracheal tube intubation was then done to secure the airway. After fixing the I-gel or PLMA, gastric tube (Ryle's tube) was inserted through gastric channel in group-I, drainage tube in group-P and nasally in group E. Anaesthesia was maintained with propofol infusion (50-200 µg/kg/min). Intermittent atracurium was used to maintain muscle relaxation if required. The oropharyngeal leak or seal pressure was determined by closing the APL (adjustable pressure

limiting) valve and allowing a fresh gas flow of 3 L/min. Airway pressure at equilibrium or when there was audible leak from throat was noted. The maximum pressure that was allowed was 40 cm of H₂O. For standardization intra-abdominal pressure was maintained at 8-12 mm of Hg. Patient was reversed with inj. neostigmine 0.06 mg/kg plus inj. glycopyrrolate 0.004 mg/kg i.e. at end of surgery and the devices were removed. The data were recorded (by second anaesthesiologists) as follows: 1. The number of attempts of insertion of airway device were recorded; 2. Ease of insertion of device was defined as "Easy": no resistance to insertion in pharynx in a 1st attempt, "Difficult": if resistance was encountered during placement, or requires >1 attempt. "failure": if could not be inserted in three attempts; 3. The effective airway time was recorded and defined as 'time between picking up the airway device and obtaining first effective ventilation, for a maximum of two attempts for the same patient'. As achievement of first successful ventilation assessed by chest expansion and EtCO₂ monitor was defined as end point; 4. Oropharyngeal leak was assessed clinically by the audible leak at mouth or by the audible noise using a stethoscope placed just lateral to the thyroid cartilage; 5. The ease of insertion of gastric tube No.12 (Ryle's tube) through the SAD was recorded as Easy: as in first attempt; Difficult: if not inserted in 2 attempts. Correct placement was ascertain by aspiration of gastric contents or epigastric auscultation with injection of air; 6. Mean Airway Leak or Seal pressure; 7. Vitals Parameters: Intraoperative heart rate, Non-invasive blood pressure (Mean Arterial Pressure, MAP), Peripheral oxygen saturation (SpO₂) and end-tidal carbon dioxide (EtCO₂) were recorded before induction, at the time of insertion of airway device, at 1, 3 and 5 minutes after insertion of device, after achieving carboperitoneum, then after every 15 minutes till the end of surgery and during removal of devices. Adequate ventilation and oxygenation was maintained by keeping SpO₂ >95% and EtCO₂ < 45 mmHg. If ventilation and oxygenation could not be maintained intraoperatively in PLMA and I-gel group, they were replaced with endotracheal tube. 8. Following removal of device, coughing, blood staining of device, trauma to the lips, tongue or teeth was recorded. 9. Any intraoperative respiratory and cardiac complications (desaturation, bronchospasm, laryngospasm, hypertension, hypotension, arrhythmias, ischemic event etc.) were noted and their management was recorded. 10. After 24 hours of surgery 2nd anaesthesiologist who was not aware of groups interviewed the all patients regarding the presence or absence of sore throat and hoarseness of voice.

For statistical analysis evidence of one qualitative character on groups was tested using Chi square test and difference between means of different quantitative data among groups was tested by F test using one-way

ANOVA. The analysis was considered as statistically significant if $p < 0.05$ [using IBM Statistical Package for the Social Sciences (SPSS) version 2016].

Results

Group P, I and E were statistically comparable regarding mean age, weight, height, body mass index (BMI) and sex distribution. (Table 1)

For insertion of airway device second attempt was required in 10.0% cases in I-gel group which was found to be significantly less as compared to insertion of ET tube (36.7%) and Proseal LMA (13.3%) cases, ($p = 0.019$). However, none of the patient in all three groups had failed insertion. (Table 2) Gastric tube (Ryle's tube) was inserted in 1st attempt in 28 patients of Group P, 25 patients of Group I and only 16 patients of Group E (statistically significant, $p = 0.001$). Mean time of insertion of airway device was significantly longer in Group E as compared to Group I and Group P, ($p = 0.000$), I and P group were not significant. Mean

Airway Leak Pressure (MALP) was achieved significantly higher in Group P than Group I, ($p = 0.000$).

Laryngopharyngeal morbidity with regards to coughing, blood staining of device and sore throat were significantly more common in Group E as compared to Group P and Group I ($p < 0.05$). Incidence of trauma to lip /tongue and hoarseness of voice were statistically comparable among the three groups.

Hemodynamic changes (Heart rate & MAP) were significantly higher in Group E immediately after intubation ($p = 0.002$) and persisted for 3 minutes thereafter ($p = 0.00$) and immediately after extubation ($p = 0.00$); while in Groups P and I, the HR and MAP increased just after insertion of the devices and remained comparable in two groups at all other time intervals. [Figure 1 & Fig. 2]

The oxygen saturation (SpO₂) and end tidal carbon dioxide (EtCO₂) before or during carboperitoneum were statistically comparable in the three groups.

Table 1: Demographic characteristics

Variance	Group P(n=30)	Group I(n=30)	Group E(n=30)	P value
Age (yrs)	41.87±9.8	40.67±8.9	40.53±7.7	0.81
Weight (kg)	55.00±2.8	54.63±5.6	54.67±4.9	0.9
Height (cm)	155.8±3.8	156.93±4.79	155.73±3.85	0.4
Sex (M/F)	5/25	6/24	11/19	0.155
BMI (kg/m ²)	22.83±1.23	21.97±1.54	22.37±1.62	0.08

Table 2: Laryngopharyngeal morbidity among various groups

Variance		Group P (n=30)	Group I (n=30)	Group E (n=30)	P value
Insertion of airway device	1 attempt	26 (86.7%)	27 (90%)	19 (63.3%)	0.019
	2 attempts	4 (13.3%)	3 (10%)	11 (36.7%)	
	3 attempts	0 (0%)	0 (0%)	0 (0%)	
	Failed	0 (0%)	0 (0%)	0 (0%)	
Gastric tube (Ryle's tube) insertion	1 attempt	28 (93.3%)	25 (83.3%)	16 (53.3%)	0.001
	2 attempts	2 (6.7%)	5 (16.7%)	14 (46.7%)	
Insertion time of airway device (seconds)		28.43±5.51	17.33±5.52	34.10±5.10	0.000
Mean Airway Leak Pressure (MALP) (cm of water)		32.00±1.41	22.90±2.35	-	0.00
Morbidity at removal of device					
Coughing		2 (6.7%)	1 (3.3%)	8 (26.7%)	0.01
Blood stain on airway devices		3 (10%)	2 (6.7%)	10 (33.3%)	0.01
Tongue or lip trauma		3 (10%)	1 (3.3%)	3 (10%)	0.53
Post-operative morbidity (24 hrs after surgery)					
Sore throat		3 (10%)	1 (3.3%)	9 (30%)	0.009
Hoarseness of voice		2 (6.7%)	1 (3.3%)	3 (10%)	0.58

Flow Chart of Study Patients

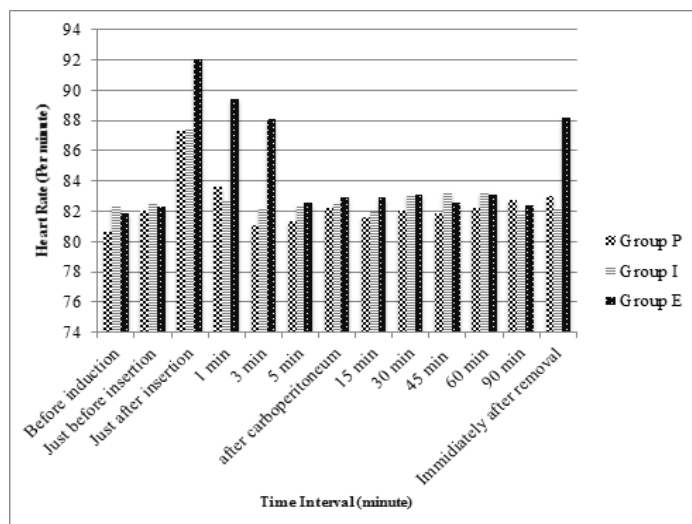
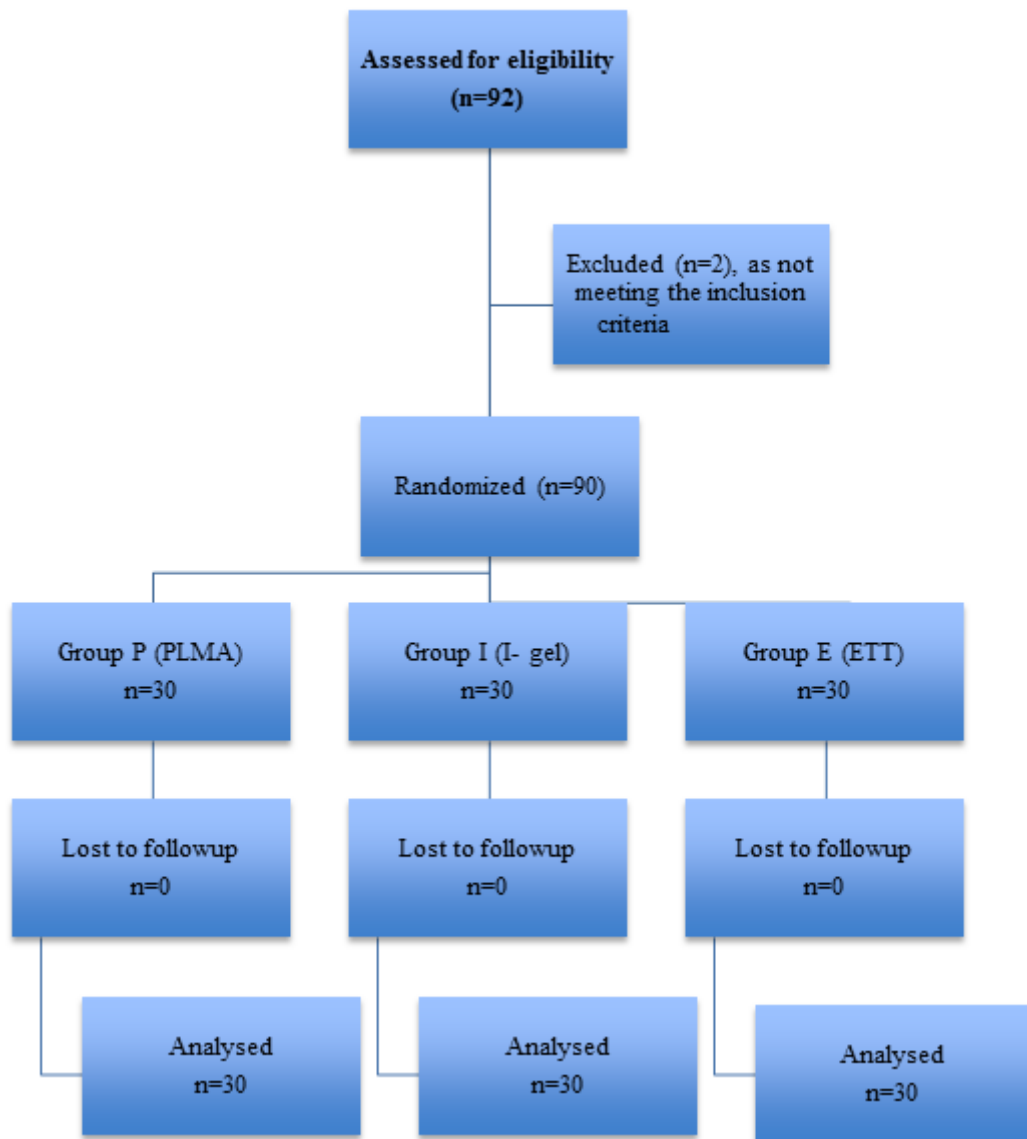


Fig. 1: Comparison of heart rate in three groups at different time intervals

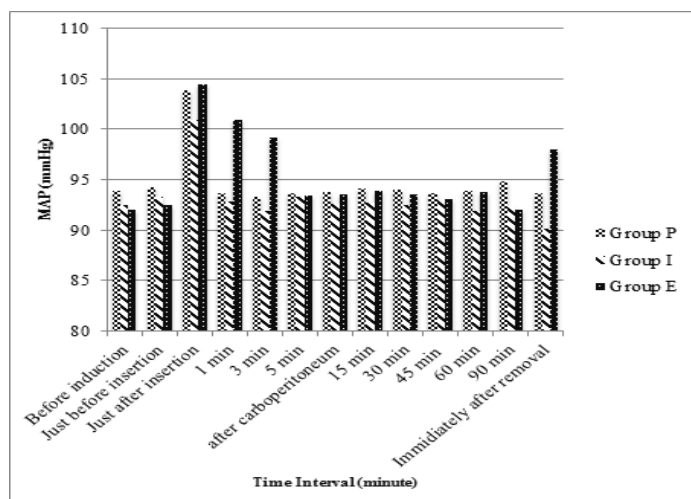


Fig. 2: Comparison of mean arterial pressure in three groups at different time intervals

Discussion

SAD's have several well-established advantages in comparison to endotracheal tube including: easy insertion,⁹ less hemodynamic upset during anaesthesia,¹⁰ lower incidence of sore throat.¹¹ Hence there has been a growing trend towards substituting an SAD for endotracheal tube for controlled ventilation in patients with minimal risk of aspiration. Laparoscopic surgery has been shown to adversely affect intraoperative pulmonary mechanics, thus providing the most effective way to test the efficacy of an airway device; as here the pulmonary compliance is decreased and the resistance is increased leading to high airway pressures.¹² SAD like proseal LMA provide higher oropharyngeal seal pressure and it had separate esophageal and laryngeal passage are desirable for laparoscopic surgery, as the seal pressure serve as an index of airway/respiratory mechanics.¹³

1. Ease of insertion of airway device: We assessed that I-gel was inserted with more ease in first attempt in (90%) patients as compared to endotracheal tube where only (63.3%) patients were intubated in 1st attempt (statistically significant, $p=0.019$). However PLMA was inserted with similar ease as I-gel, (86.7%). Second attempt was required in 4(13.3%), 3(10.0%) and 11(36.7%) patients respectively in group P, I and E. None of the patient required third attempt/ failed device insertion in any groups. Thus insertion of I-gel was significantly easier as compared to endotracheal tube ($p=0.019$) but similar to PLMA.

Najeeb et al¹⁴ stated that I-gel was easier to insert with higher success rate in 1st attempt (92.5%) than Proseal LMA (85%) and endotracheal tube (82.5%) but it was not statistically significant, and all devices were inserted successfully in all patients. Singh I et al¹⁵ found that the ease of insertion was more (96.6%) with I-gel. These studies including present show that the I-gel had easier insertion than endotracheal tube because of

the design which was inspired by physiology of the perilaryngeal framework itself. The shape, softness and contour accurately mirror image the perilaryngeal anatomy to create the perfect seal and no cuff inflation is required:

- 2. Mean insertion time of airway device:** In our study, mean insertion time was significantly longer in Group E (34.10 ± 5.10 sec), as compared to Group I (17.33 ± 5.52 sec) and Group P (28.43 ± 5.51 sec) ($p=0.000$). Badheka et al¹⁶ compared I-gel with ETT and found that the mean insertion time was significantly less in I-gel insertion (11.28 ± 2.91 seconds) when compared with ETT (14.33 ± 1.56 sec). Helmy A et al¹⁷ found that the mean insertion time was 15.6 ± 4.9 sec in I-gel group. The difference in insertion times between I-gel, PLMA and ETT may be due to the fact that the I-gel is easily inserted and does not have a cuff that needs to be inflated before the first breath, which was our end-point for the insertion time. This leads to shorter insertion time in I-gel. However PLMA took longer time than I-gel due to time taken in inflating the cuff and due to relatively larger size.
- 3. Ease of ryle's tube-insertion:** We observed that ryle's tube was inserted in 93.3% patients in 1st attempt of Group -P, 83.3% patients of Group-I and 53.3% patients of Group-E (statistically significant, $p= 0.001$). Singh I. et al¹⁵ found that the ease of insertion of ryle's tube was 100% with I-gel. Saraswat N. et al¹⁸ reported that the success rate of NG tube insertion in 1st attempt was 66.67% via nasal route in intubated patients. These studies show that the SAD's (PLMA and I-gel) have significantly higher success rate for gastric tube insertion than conventional placement via nasal route, which required in patient with endotracheal tube. This can be explained by the fact that the SAD's have a separate port for gastric tube insertion through which gastric

tube can be easily inserted without disturbing airway / coiling in airway tract.

- 4. Oropharyngeal leak and mean airway leak pressure:** There were 2 (6.7%) cases in I-gel group who had oropharyngeal leak which disappeared after 5 minutes because I-gel comprises a soft gel like non-inflatable cuff made of thermoplastic elastomer which swell after some time and provide adequate seal. None of the patients in both groups of present study had oropharyngeal leak after pneumoperitoneum throughout surgery. It has been reported that the seal of the I-gel seems to improve over time due to the thermoplastic cuff warming to the body temperature.¹³ In present study, Oropharyngeal leak was assessed clinically by palpation (with hand placed over laryngeal area) or presence of audible leak during positive pressure ventilation (PPV), as we did not have device to measure leak or leak pressure. In present study the MALP was achieved significantly higher in Group P (32.00±1.41 cm of H₂O) than Group I (22.90±2.35 cm of H₂O); statistically significant (p=0.000) may be because PLMA has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressures without leak.¹⁴ Uppal V et al⁸ found MALP for the I-gel was 28 [20–35.5] cm H₂O using the auscultation method and 28 [20.5–36] cm H₂O using the manometer stabilization method, (Statistically not significant, p=0.068). Airway leak pressures for all the participants when intubated consistently reached 40 cm H₂O. Badheka et al¹⁶ compared I gel with ETT and found MALP of 25.27 cm of H₂O. Saraswat et al¹⁸ reported that in PLMA group, MALP of 35 cm of H₂O. Incidence of leak was 0% in all the groups in our study because we measured it as if audible throat sound is present. This would be present only if major leak was present. Moreover we studied patients who had normal airway; present study results could be different if obese patients or difficult airway patients were included. However the method which we used for measuring MALP was similar to Saraswat et al¹⁸ and was effective.
- 5. Hemodynamic changes (Heart rate & mean arterial pressure):** In present study we found significant changes in HR and MAP immediately after insertion, persisted till 3 minutes after intubation and during extubation in ET tube. Increase in the HR and MAP in PLMA and I-gel group were only after insertion of device. It is attributed to

sympathetic stimulation during laryngoscopy and the passage of the ET through the vocal cords.¹⁹ The Proseal LMA and I-gel being supraglottic devices do not require laryngoscopy and probably do not evoke a significant sympathetic response. Attenuation of this response may be due to diminished catecholamine release. Our result correlates with the other studies.^{14,18} In which they observed hemodynamic perturbations, were more with tracheal intubation and stable hemodynamic observed with PLMA and I-gel.

- 6. Laryngopharyngeal morbidity:** In our study laryngopharyngeal morbidity (coughing, blood staining of device and sore throat) were found more in group E as compared to groups P and I (p= 0.01; statistically significant). The trauma to lip/ tongue and hoarseness of voice were more common in endotracheal group but statistically not significant (p=0.58). Similar results were seen in other studies.^{14,15,17,18} As with I-gel and PLMA mucosal pressures achieved are usually below pharyngeal perfusion pressure.²⁰

Limitation of our study were: a). We did not have facility to measure leak pressure, we assessed Oropharyngeal leak clinically by palpation with hand placed over laryngeal area or presence of audible leak over laryngeal area; b). The sample size of our study was small i.e. 30 patients in each PLMA, I-gel and ETT group so that our data cannot be generalized and need further study with large study group; c). The study was conducted in elective surgeries in controlled setting, so we could not find I-gel efficacy in emergency resuscitation / surgeries.

Conclusion

We conclude that to establish airway the Supraglottic Airway Devices (PLMA and I-gel) are equally effective as ET tube. These supraglottic airway device are easy to insert and maintain hemodynamic parameter with lesser post-operative complications as compared to ET tube in laparoscopic cholecystectomy surgery under general anaesthesia with controlled ventilation.

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