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Original Research Article

A Comparison of I-Gel and Proseal LMA's Effects on Hemodynamics in Adult Patients Undergoing Laparoscopic Cholecystectomies under General Anesthesia

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Abstract

Introduction: Proseal (LMA)™ has an inflatable cuff while i-gel™ has a noninflatable cuff made of thermoplastic elastomer.

Objectives: To compare and evaluate the hemodynamic response and during device insertion and during maintenance of general anesthesia in patient undergoing lapcholecystectomy.

Methods: This study was conducted as randomized observational study in a teaching hospital. One hundred American Society of Anesthesiologists I and II, patients posted for lapcholycystectomy under general anesthesia were divided in two groups of fifty each. LMA Proseal™ and i-gel™. Hemodynamic response, hemodynamic data, at 1, 3, 5, 10, 15, 20, 25 and 30 min of insertion. Descriptive analyses were expressed as a mean ± standard deviation. Independent *t*-test used for parametric data, Chi-square test for nonparametric data and hemodynamic data were analyzed using repeated measures ANOVA to find statistical difference within the groups.

Results and Conclusions: Our study conclude that both devices I-gel and PLMA are equally good for maintenance of airway in Lapcholecystectomy under GA and can be effectively used for maintenance of general anaesthesia without any significant hemodynamic changes.

Keywords: Diastolic blood pressure, heart rate, i-gel™, systolic blood pressure.

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Introduction

The major responsibility of anaesthesiologist is to provide adequate ventilation to patient. Tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia. [1]

Laparoscopic surgery is an evolving subspecialty of surgery and is not only limited to minor gynaecologic surgery or cholecystectomy but has extended to procedures such as appendicectomy, hernia repairs (inguinal, epigastric and incisional), advanced gastrointestinal, urologic and gynaecologic procedures. The problems common to all such procedures are, a) hypercarbia, b) raised abdominal pressure and, c) potential danger of regurgitation and pulmonary aspiration. The anaesthesiologist must ensure a patent airway and adequate ventilation. [2,3] Till date the cuffed tracheal tube was considered as ideal for providing a safe

glottis seal especially for laparoscopic procedures under general anaesthesia. The proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 2000. [4,5] The I-gel is the most recent development in supraglottic airway devices. The I-gel is truly anatomical device. Different studies have shown that I-gel and proseal LMA can be used safely during position pressure ventilation with stable haemodynamics and normal oxygenation and ventilation. [6] The purpose of this study is to compare two supraglottic airway devices I-GEL and Proseal LMA in adult patients undergoing elective laproscopic cholecystectomy under general anaesthesia Evaluation of hemodynamic change at the time of insertion of I-Gel and proseal LMA and to compare hemodynamic changes between I-GEL and proseal LMA

Material and Methods

After approval from hospital ethical committee and written informed consent from patient, this randomized prospective study was performed on 60 ASA Grade I & II patients of either sex (30 patients in each group) admitted in CSS hospital undergoing elective laproscopic cholecystectomy under general anaesthesia.

Inclusion Criteria

- Patients undergoing elective laproscopic cholecystectomy under general anaesthesia
- Surgery time < 2 hrs
- Age between18 to 58 years.

Exclusion Criteria

- Patient refusal
- ASA III and IV
- Pre op sore throat
- Inter incisor gap < 2cm
- Mp grad III and IV
- Difficult airway
- BMI >30K g/m^2
- Surgery duration> 2 hrs
- Patients with high risk of aspiration (hiatus hernia, GERD and full stomach)
- Pregnancy

Randomization of Patients

Two groups were formed.

GROUP I: I- GEL (Intersurgical ltd. Workingham, Berkshire (UK) used for insertion. (B=30)

GROUP P: Proseal LMA (intavent venner's medical (Singapore) used for insertion. (N=30)

A total of 60 cards (30 in each group) was prepared by another person who was blinded about the study, after recruitment every patient was allowed to draw one card, and grouped accordingly.

Anaesthetic Technique

Pre-anaesthetic evaluation of the patients was done by an anesthesiologist a day before surgery. Detailed clinical history, careful evaluation of airway and written informed consent was taken and patients were advised pre operative fasting as per ASA Guidelines.

On arrival of the patient in operation room the anesthetic technique was standardized as follows:

Patients received standard monitoring (GE cardiocap-5) including HR, NIBP, SpO_2, $EtCo_2$, spirometery, ECG (5 lead). 18G i.v. canula was secured & ringer lactate solution at 100 ml/hr. was started.

Patients were premedicated with IV inj. Glycopyrrolate (0.005 mg/kg), inj. Midazolam (0.05 mg/kg), inj., fentanyl (2µgm/kg). Anaesthesia was induced with Inj. Propofol 1% (2 mg/kg) followed by vecuronium 0.1 mg/kg). I-GEL or PLMA was inserted when no response was obtained in train of four stimulation. successful placement was confirmed by bilateral chest movement, auscultation and normal EtCo2 tracing and value[11]. In accordance with manufacture manual sizes of I-GEL is dependent on patients weight.

Size 3 was used for patients less than 50 kg and size 4 for those between 50 and 90 kg. similarly size of PLMA was selected depending on patient's weight. Anaesthesia was maintained with Isoflurane, nitrous oxide and oxygen. The insertion technique include neck flexion, head extension and then airway device is inserted. Cuff pressure is measured by (pressure manometer VBM Germany) of the PLMA not exceeded more than 60 cm of H_2O. Gastric tube was passed into the stomach and its position was assessed by suction of gastric fluid if needed.

Following parameters were recorded:

Hemodynamic parameters:

(HR, SBP, DBP, MAP) SPO_2, and $EtCo_2$ were recorded before induction, after induction, at the time of insertion of device, then every 1 min interval till 5 mins after insertion and then every 5 min till 30 min.

Statistical Analysis:

Descriptive analyses were expressed as a mean ± standard deviation. Independent *t*-test used for parametric data, Chi-square test for nonparametric data and hemodynamic data were analyzed using repeated measures ANOVA to find statistical difference within the groups.

Results

Table 1: Demographic and Hemodynamic data between both groups.

Demographic Data		Groups				P Value
		Group I		Group P		
Age (Year)		N	Mean ±SD	N	Mean±SD	
		30	40.30 ± 6.7	30	41.43± 10.7	0.624
Weight (kg)		30	59.40 ± 4.7	30	61.33± 4.7	0.159
Gender	Male		8 (26.7%)		7 (23.3%)	
	Female		22 (73.3%)		23 (76.7%)	.0235
ASA grade	I		30 (100%)		27 (90%)	
	II		0 (0%)		3 (10%)	0.237
MP grade	I		2 (6.7%)		6 (20%)	
	II		28 (93.3%)		24 (80%)	0.2524
HR (bpm) Before induction		30	84.50± 7.3	30	88.75± 9.4	0.055
SBP (mmHg) Before Induction		30	128.80± 8.9	30	127.20± 9.3	0.498
DBP (mmHg) Before Induction		30	81.07±3.0	30	76.60±12.7	0.065
MAP (mmHg) Before Induction		30	102.40±7.5	30	98.71±11.70.151	

Table 1 shows the demographic and hemodynamic data of patients. No demographic and hemodynamic data are statistically significant. ($p>0.05$) which suggest that they all are comparable in terms of ASA grade, MP grade, HR, SBP, DBP, MAP.

Table 2: Heart rate between both groups.

HR	Groups				P Value
	Group I		Group P		
	N	Mean±SD	N	Mean±SD	
Before Induction	30	84.50±7.3	30	85.5±9.4	0.821
After Induction But just before insertion	30	81.90±16.1	30	83.2±11.8	0.732
At Insertion	30	81.63±30.3	30	81.54±27.5	0.831
1 min	27	86.00±14.3	28	87.2±6.2	0.849
2 min	27	83.33±8.7	28	85.2±6.7	0.799
3 min	27	76.44±11.1	28	78.29±6.3	0.801
4 min	27	75.44±10.3	28	74.07±7.3	0.829

5 min	27	77.07±12.3	28	78.04±7.4	0.820
10 min	27	82.26±14.8	28	81.68±5.8	0.743
15 min	27	83.26±15.9	28	84.43±3.9	0.645
20 min	27	81.70±17.2	28	82.75±5.2	0.544
25 min	27	83.04±16.9	28	85.25±7.8	0.659
30 min	27	82.37±16.8	28	84.68±6.9	0.797

As per table 2 shows heart rate from the time of Induction data of patients which shows no significant data. (p>0.05).

Table 3: Systolic blood pressure between both groups.

SBP	Groups				P Value
	Group I		Group P		
	N	Mean±SD	N	Mean±SD	
Before Induction	30	128.8 ± 8.9	30	127.20±9.3	0.498
After Induction But just before insertion	30	98.30±12.7	30	104.17±10.5	0.056
At Insertion	30	94.50±32.8	30	106.33±30.9	0.156
1 min	27	110.56±8.7	28	109.54±6.9	0.631
2 min	30	95.47±33.2	30	99.37±28.1	0.626
3 min	30	97.10±33.3	30	100.10±28.1	0.708
4 min	27	107.41±10.5	28	110.39±5.7	0.195
5 min	27	111.56±11.9	28	123.18±11.9	0.201
10 min	27	121.96±11.4	28	125.15±11.9	0.293
15 min	27	124.07±5.2	28	127.79±11.9	0.122
20 min	27	121.11±5.6	28	123.14±6.9	0.215
25 min	27	121.63±3.9	28	124.10±7.4	0.111
30 min	27	119.78±6.5	28	121.75±8.3	0.333

As per table 3 shows systolic blood pressure from the time of Induction data of patients which shows no significant data. (p>0.05).

Table 4: Diastolic blood pressures between both groups.

DBP	Groups				P Value
	Group I		Group P		
	N	Mean±SD	N	Mean±SD	
Before Induction	30	81.07±3.0	30	76.60±12.7	0.065
After Induction But just before insertion	30	60.87±10.7	30	65.13±11.3	0.137
At Insertion	27	65.74±5.3	28	67.89±7.1	0.209
1 min	27	70.15±7.3	28	66.32±8.1	0.059
2 min	27	66.30±8.4	28	62.25±8.9	0.075
3 min	27	64.48±2.9	28	63.07±10.2	0.492
4 min	27	65.89±5.7	28	65.11±8.3	0.688
5 min	27	71.22±11.2	28	76.00±13.4	0.157
10 min	27	76.56±5.7	28	80.86±12.9	0.100
15 min	27	78.74±6.2	28	81.32±13.2	0.361
20 min	27	74.52±4.7	28	78.54±9.6	0.055
25 min	27	75.41±6.2	28	77.93±9.6	0.253
30 min	27	7281±6.9	28	71.93±10.3	0.710

As per table 4 shows Diastolic blood pressure from the time of Induction data of patients which shows no significant data. (p>0.05).

Discussion

This randomized prospective study was carried out in MLB Medical College. Total 60 subjects of either sex (30 patients in each groups) of ASA I & II, of age 15-58 years undergoing laparoscopic cholecystectomy under general anaesthesia with positive pressure ventilation. Patients were divided in two groups I (I-gel) and P (PLMA-Proseal LMA). Both the groups were compared for demographic profile like age, gender, ASA grade and MP grade. Both the groups were also compared for hemodynamic parameters (HR, SBP, DBP, MAP).

Regarding the hemodynamic stability and effect of each of the supraglottic devices, no statistically significant difference was reported when comparing heart rate, systolic and diastolic arterial blood pressure throughout the surgery. Jindal et al. [7] reported hemodynamic stability with both LMA and I-gel devices, with no statistically significant difference between both devices, which is consistent with our findings. Richez et al. [8] carried out one of the earliest studies to evaluate the I-gel. They found that insertion success rate was 97%. Insertion was easy and was performed at the first attempt in every patient. I-gel is easily and rapidly inserted, providing a reliable airway in over 90% of cases. Acott, [9] assessed the use of I-gel as an airway device during general anesthesia. In accordance with our results, they reported that a single insertion attempt was required in the majority of patients and all the insertion times recorded were less than 10 seconds. The I-gel has potential advantages over other supraglottic airways for use by non-anesthetists during cardiopulmonary resuscitation. It has no cuff to inflate, making it simple to use. Its drain tube allows access to the gastrointestinal tract and it is designed to reduce the risk of gastric inflation and regurgitation. Simple airway maneuvers were required to assist in the placement but all devices were placed within two attempts. [10] These findings are consistent with our results. One of the most important parameters to be compared between both supraglottic devices was postoperative complications. [11]

Conclusions

We conclude that both the devices can be effectively used in laparoscopic surgeries though their frequent use and safety needs further evaluation. Demographic profile like age, gender, ASA grade and MP grade were comparable between groups. ($p>0.05$). According to our study we conclude that both I-gel and PLMA are comparable in maintaining a patent airway during controlled ventilation. Both PLMA and I-gel are emerging as an effective alternative for tracheal intubation. We also concluded that both PLMA and I-gel do not cause any significant alteration in the hemodynamics (HR, SBP, DBP, MAP).

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