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Comparison of Ventilation and Haemodynamic Parameters between I-Gel and Proseal LMA in Adult Patients undergoing Laparoscopic Cholecystectomy under General Anaesthesia

R. Nisarga*, D. A. Bhavana, D. Devika Rani and S. S. Nethra

Department of Anaesthesiology, BMCRI, Bangalore, Karnataka, India; rs.nisarga@gmail.com

Abstract

Background: The Proseal Laryngeal Mask Airway (PLMA) has been used as a safe alternative to endotracheal tube for many laparoscopic procedures while the I-Gel is still being evaluated for its use in anaesthesia with positive pressure ventilation in laparoscopic surgeries. Our aim was to compare ventilation and hemodynamic parameters between I-Gel and PLMA. **Methods:** 50 patients were randomly assigned to one of two groups, namely, the group-A (Proseal, n = 25) and the group-B (I-Gel, n = 25). Premedication and anaesthesia technique was standardized in both groups. Airway device was inserted as per group allocation after induction of anaesthesia. Oropharyngeal Seal Pressure (OSP) was recorded. Airway pressures, compliance and resistance, tidal volumes were recorded after insertion of SGA device at 5 min intervals before pneumoperitoneum, 10 minute intervals during pneumoperitoneum and at 5 min intervals after release of pneumoperitoneum till removal of device. Heart rate, systolic, diastolic and mean blood pressure were recorded after insertion of the device, 1 min and every 5 min throughout the surger. **Results:** Demographic parameters were comparable. OSP was higher with group B (32.16 + 2.61 cmH2O, P<0.001). Peak and mean airway pressures increased in both groups during pneumoperitoneum, but Ppeak increased more in group-A (8.62 ± 1.59 cmH2O, P< 0.001) and Pmean increased more in group B (4.19 ± 1.00 cmH2O, P<0.001). Compliance decreased to greater extent in group B (19 ± 3.7 ml/cmH2O). PaCO2 was higher in group A during pneumoperitoneum.(35.52 ± 1.89, p = 0.004). There was greater increase in heart rate, SBP, DBP, MAP following PLMA insertion. Adverse events were comparable in both groups. **Conclusion:** I-Gel is associated with lower peak airway pressures, EtCO2, PaCO2 and higher mean airway pressures during pneumoperitoneum compared to PLMA and hence may provide better ventilation. I-Gel provides better haemodynamic stability.

Keywords: I-Gel, Oropharyngeal Seal Pressure, Pneumoperitoneum, Proseal LMA

1. Introduction

Laparoscopic cholecystectomy is one of the most commonly performed general surgical procedures. General anesthesia with endotracheal intubation is the standard practice in management of patients during laparoscopic surgeries[1]. Supraglottic Airway devices (SGA) devices have become a standard fixture in airway management, filling a niche between the face mask and tracheal tube in terms of both anatomical position and degree of invasiveness.

SGA devices are suggested as alternatives to endotracheal intubation in patients undergoing laparoscopic surgeries under general anaesthesia to avoid potential complications of intubation such as increased sympathetic stimulation resulting in

*Author for correspondence

increased blood pressure, increased heart rate and arrhythmias[2]. These devices offer several advantages over the Endotracheal Tube (ETT) with regard to ease of insertion, haemodynamic stability, favourable respiratory mechanics and decreased airway morbidity[3].

The ProSeal laryngeal Mask Airway (PLMA) (Intavent Orthofix, Maidenhead, UK) and the I-Gel airway (Intersurgical Ltd, Wokingham, Berkshire, UK) are two second generation supraglottic devices which provide higher Oropharyngeal Seal Pressure (OSP) than the classic LMA, have an additional drain tube and have been designed for use with spontaneous as well as Positive Pressure Ventilation (PPV)[4].

PLMA has a dorsal cuff, in addition to the peripheral cuff of classic LMA, ensures good seal and facilitates use of higher airway pressures, but studies in adults have shown that higher pressures in LMA cuffs are generally associated with increased morbidity, such as sore throat, hoarseness, and nerve palsies[5,6].

I-Gel has a single use non-inflatable device is made up of a thermoplastic elastomer that is soft, gel-like, transparent and structured to fit to the perilaryngeal and hypopharyngeal structure, so that it does not require an inflatable cuff[7]. The buccal cavity stabilizer and integral bite block, along with epiglottic rest with a protective ridge provide added benefit of better alignment and seal with minimal pressure[8].

Many studies have compared PLMA with ETT for ease of insertion, haemodynamic changes and postoperative airway complications[9–11], while the I-Gel is still being evaluated for its use in anaesthesia with positive pressure ventilation in laparoscopic surgeries[12]. Several studies in the literature has been reported comparing the efficacy of I-Gel with the PLMA in airway management and haemodynamic parameters[13,14]. There is limited evidence comparing I-Gel with PLMA in airway pressures, compliance, resistance and tidal volumes under controlled ventilation during laparoscopic surgeries. Hence the present study was designed to compare the haemodynamic and ventilation parameters using I-Gel and PLMA in adults undergoing laparoscopic cholecystectomy under general anaesthesia.

Our aim was to compare ventilation and haemodynamic parameters between I-Gel and PLMA in adult patients undergoing laparoscopic cholecystectomy under general anaesthesia. The primary objective of the study was to compare effect on compliance between I-Gel with PLMA before, during and after carboperitoneum, whereas effect on airway pressures, oropharyngeal seal pressure, airway resistance and hemodynamic parameters were secondary objectives.

2. Materials and Methods

After approval from institutional ethics committee, this prospective randomized comparative study was conducted from November 2016 to May 2018 in patients undergoing laparoscopic cholecystectomy under general anaesthesia. Those patients who gave written informed consent of either sex in the age group of 20-60 years with ASA physical status I and II were included in the study. Patients with mouth opening less than 2.5 cm, Body mass index of more than 35 kg/m^2 with restricted neck and chest wall movements, distorted airway anatomy, cardiac and respiratory problems and those with risk of aspiration were excluded from the study.

The patients were randomly assigned to one of the two groups with 25 patients each to either PLMA (Group A) or I-gel (Group B). The randomization sequence was entered in a piece of paper and kept in a sequentially numbered opaque sealed envelope, which was opened just before intervention. The anaesthesia technique was standardised for both groups. All patients were assessed by pre-anesthetic examination on previous day and relevant investigations were done. Height, weight and body mass index was calculated for each patient. On arrival to the operation theater, monitors including pulse oximeter, noninvasive arterial blood pressure, electro cardio graph were connected to the patient and baseline vitals recorded. An appropriate cannula was used for IV access. All patients were pre-medicated with Midazolam 0.03 mg/kg, Fentanyl 2 mcg/kg intravenouslyand pre-oxygenated with 100% oxygen for 3 min. Anaesthesia was induced with Propofol 2 mg/kg, Vecuronium 0.1 mg/kg was administered for muscle relaxation, after confirming mask ventilation.

A single anaesthesiologist who had performed more than 25 insertions of both PLMA and I-gel inserted the appropriate sized PLMA or I-Gel devices in patients included in the study after mask ventilation for three minutes. Proper placement of LMA was confirmed by absence of audible leak in oral cavity at peak airway

pressure of 25 cm H_2O, appearance of square waves in capnography. Three insertion attempts were allowed before a failure of insertion was recorded. After successful insertion of the device, it was connected to the breathing system and OSP was recorded by setting a fresh gas flow of 2 lts/min and closing the Adjustable Pressure Limiting (APL) valve and observing the point at which Ppeak stops rising. Airway pressure was allowed to increase upto a maximum limit of 40 cm of H_2O.

Following placement of device, patient was mechanically ventilated with VT of 7 ml/Kg, respiratory rate of 12–14 breaths/min, PEEP of 5 cm H_2O, Inspiratory:Expiratory ratio 1:2. Ventilation was considered optimum when bilateral chest movement was adequate, SpO_2>95% and $EtCO_2$ in the range of 35 to 45 mm Hg. Patient was maintained on oxygen:airmixture (40% FiO_2), Isoflurane (0.2-1.2%) and vecuronium (0.02 mg/kg) top ups. Anaesthesia depth was monitored using entropy and maintained between 50–60. Muscle relaxation was monitored using Train of four test and count maintained below 2 intraoperatively. Tidal volume was adjusted by 2 ml/kg increments or decrements, as required, to maintain $EtCO_2$ between 35 to 45 mm Hg. At the end of surgery, Isoflurane was discontinued, muscle relaxant effect was reversed with Inj. Neostigimine 0.05 mg/kg and Inj. Glycopyrrolate 0.01 mg/kg and SGA device was removed after adequate recovery of patient. Adverse events if any were noted.

Ventilation parameters like dynamic compliance (ml/cm H_2O), Inspired and expired Tidal volume (ml/min), Resistance (cm H_2O/l/sec), Mean airway pressure (cm H_2O), Peak airway pressure (cm H_2O), $EtCO_2$ (mm Hg), EtO_2 (%) were recorded after insertion of device, carboperitoneum start, 10 min after carboperitoneum and after release of carboperitoneum from the values displayed on ventilator of anaesthesia workstation. Intra abdominal pressure was recorded during carboperitoneum and maintained below 14 cm of H_2O. Haemodynamic parameters such as Heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Peripheral Oxygen Saturation (SpO_2) were measured at baseline, after premedication and induction, 5 min after insertion of device and immediate post-operative period.

Sample size was calculated based on dynamic compliance as primary outcome measure, with values based on previous study[19]. Keeping power at 80% and alpha error at 0.05, we hypothesized that I-Gel was associated with higher compliance compared to PLMA. A minimum of 21 patients would be required in each group to detect a 15% difference in dynamic compliance between 2 groups. We included 25 patients in each group to compensate for drop outs.

Descriptive statistics done for all data and suitable statistical tests of comparison were applied. All the nominal values are expressed in numbers and percentages and parametric values as mean ± Standard Deviation (SD). Categorical data presented in tabular format. Quantitative data were also analysed for normality of distribution using Shapiro Wilk test and then statistically tested using Student t-test/Mann Whitney U test. Intragroup comparison was done using paired t test. Categorical data analyzed using Chi-square test and Fischer exact test. A p value <0.05 is considered as statistically significant.

3. Results

All the patients included in the study received the assigned intervention and were followed up till the end of study. There were no exclusions or drop outs. Patient demographic characteristics were comparable in both groups (age, gender, BMI). Number of patients belonging to ASA class I and II were uniformly distributed between both the groups. Mean OSP was 28.64 + 3.32 cm of H_2O in group A and 32.16 + 2.61 cm of H_2O in group B which was stastistically significant. The mean intra abdominal pressure was comparable between the groups (Table 1).

Compliance was greater in group B than group A (P<0.001) at pre-pneumoperitoneum. Compliance during and post-pneumoperitoneum were comparable in both the groups. The average decrease in compliance following pneumoperitoneum was 16.15 ± 2.98 ml/cmH_2O in group A and 19 ± 3.7 ml/cmH_2O in group B compared to pre-pneumoperitoneum values which was statistically significant. Resistance before, during and after pneumoperitoneum were comparable in both the groups. The increase in resistance following pneumoperitoneum was also comparable in both the groups. Ppeak before pneumoperitoneum were comparable in both the groups. However, following pneumoperitoneum, Ppeak was greater in group A compared to group B (p<0.001). Post pneumoperitoneum Ppeak was comparable in both

Table 1. Demographic parameters and OSP* - opening seal pressure

Parameters		Group A	Group B	P value
Age (years)		39.88 ± 10.67	38.88 ± 13.45	0.78
Sex	Female	16	9	0.047
	Male	9	16	
BMI (kg/m^2)		22.64 ± 2.93	22.66 + 2.81	0.99
ASA	Grade I	14	15	0.082
	Grade II	11	10	
OSP*(cmof H_2O)		28.64 ± 3.32	32.16 ± 2.61	<0.001
Intra abdominal pressure		13.57 ± 1.12	13.84 ± 1.1	0.394

Table 2. Ventilator Parameters I

Parameters		Group A	Group B	P value
Compliance (ml/cm H_2O)	Pre pneumoperitoneum	36.7 ± 2.95	39.8 ± 2.89	< 0.001
	Pneumoperitoneum	20.54 ± 1.21	20.79 ± 2.04	0.6
	Post pneumoperitoneum	36.05 ± 3.5	36.78 ± 3.09	0.4
Resistance (cm H_2O/l/sec)	Pre pneumoperitoneum	7.68 ± 0.62	7.9 ± 0.92	0.32
	Pneumoperitoneum	10.37 ± 0.75	9.97 ± 2.58	0.46
	Post pneumoperitoneum	8 ± 0.57	7.42 ± 0.62	0.001
Ppeak (cm H_2O)	Pre pneumoperitoneum	13.16 ± 1.17	13.4 ± 0.96	0.43
	Pneumoperitoneum	21.78 ± 1.26	19.47 ± 1.95	<0.001
	Post pneumoperitoneum	13.34 ± 1.17	13.8 ± 1.95	0.31
Pmean(cm H_2O)	Pre pneumoperitoneum	5.86 ± 1.24	5.88 ± 0.79	0.94
	Pneumoperitoneum	8.69 ± 1.10	10.77 ± 0.95	<0.001
	Post pneumoperitoneum	6.6 ± 0.69	7.54 ± 0.69	<0.001

the groups. The average increase in Ppeak following pneumoperitoneum was higher in group A when compared to group B (p<0.001) which was clinically and statistically significant. Ppeak never exceeded 35 mm of Hg in any of the patient in either groups at any point of study. P mean before pneumoperitoneum were comparable in both the groups. Following pneumoperitoneum Pmean was higher in group B compared to group A (P<0.001) and continued to be higher in group B after release of pneumoperitoneum. The increase in Pmean following pneumoperitoneum was higher in group B when compared to group A which was statistically significant (Table 2).

Inspired tidal volume before and during pneumoperitoneum were comparable in both the groups. Post pneumoperitoneum inspired tidal volume was

Table 3. Ventilator Parameters II

Parameters		Group A	Group B	P value
Inspired TV (ml/min)	Pre pneumoperitoneum	422.28 ± 5.43	425.42 ± 5.22	0.042
	pneumoperitoneum	424.32 ± 4.69	427.19 ± 3.4	0.016
	Post pneumoperitoneum	426 ± 7.25	430.5 ± 4.05	0.010
Expired TV (ml/min)	Pre pneumoperitoneum	408.68 ± 5.71	410.02 ± 4.39	0.35
	pneumoperitoneum	413.46 ± 12.79	417.58 ± 4.47	0.13
	Post pneumoperitoneum	427 ± 9.56	429.02 ± 5.67	0.36
$ETCO_2$ (mm Hg)	Pre pneumoperitoneum	31.66 ± 1.35	30.96 ± 1.49	0.089
	pneumoperitoneum	38.42 ± 1.54	34.83 ± 1.23	<0.001
	Post pneumoperitoneum	36.38 ± 1.96	29.54 ± 1.32	<0.001

Table 4. Haemodynamic parameters

Parameters		Group A	Group B	P value
HR (b/m)	Baseline	78.08 ± 7.01	78.80 ± 11.35	0.788
	1 min after insertion	102.32 ± 8.68	83.44 ± 11.59	< 0.001
	5 min after insertion	103.60 ± 8.22	80.32 ± 10.55	< 0.001
	5 min after pneumoperitoneum	102.44 ± 10.15	83.04 ± 11.10	< 0.001
SBP (mm Hg)	Baseline	112.92 ± 10.78	121.00 ± 11.72	0.014
	1 min after insertion	131.08 ± 11.14	121.36 ± 12.13	0.005
	5 min after insertion	133.00 ± 6.71	115.88 ± 10.78	< 0.001
	5 min after pneumoperitoneum	136.28 ± 7.20	125.40 ± 10.76	< 0.001
DBP (mm Hg)	Baseline	70.00 ± 7.19	78.68 ± 7.51	< 0.001
	1 min after insertion	77.88 ± 9.54	76.60 ± 8.28	0.615
	5 min after insertion	81.52 ± 4.85	75.44 ± 7.86	0.002
	5 min after pneumoperitoneum	81.76 ± 6.26	78.52 ± 7.95	0.116
MAP (mm Hg)	Baseline	84.31 ± 7.21	92.79 ± 8.56	< 0.001
	1 min after insertion	95.61 ± 8.60	91.52 ± 9.07	0.108
	5 min after insertion	97.88 ± 6.18	88.92 ± 8.30	< 0.001
	5 min after pneumoperitoneum	99.93 ± 5.18	94.15 ± 8.40	0.005
SPO_2 (%)	Baseline	100.00	100.00	
	1 min after insertion	99.92 ± 0.28	99.92 ± 0.28	1
	5 min after insertion	99.92 ± 0.28	99.92 ± 0.28	1
	5min after pneumoperitoneum	100.00	100.00	

greater in group B compared with group A (P <0.001). The average change in the inspired tidal volume following pneumoperitoneum were comparable in both the groups. Expired tidal volume was marginally higher in group B before and during pneumoperitoneum, but was not clinically or statistically significant. The average change in the expired tidal volume following pneumoperitoneum was comparable in both the groups. $EtCO_2$ 5 min after insertion of the device was lower with group B than group A (P<0.001). During pneumoperitoneum and post pneumoperitoneum $EtCO_2$ was lower with group B (P<0.001). The average increase in $EtCO_2$ following pneumoperitoneum was higher with group A 6.76 ± 1.62 mmHg than group B 3.87 ± 1.25 mmHg. In none of the patients $EtCO_2$ crossed 45 mmHg at any time during intraoperative period (Table 3).

Percentage of oxygen saturation before, during and post pneumoperitoneum were comparable in both the groups. No evidence of desaturation noted in both the groups. The basal heart rate was comparable in both the groups. Heart rate after insertion of SGA device, during pneumoperitoneum were higher in group A. The average increase in heart rate after insertion of the device from base line was higher in group A which was clinically and statistically significant. The maximum magnitude of change in intraoperative heart rate from baseline was 28 (24-34) beats/min in group A, compared to 7 (4-11) beats/min in group B which was statistically significant. Basal SBP was comparable in both the groups. After insertion of SGA device and during pneumoperitoneum SBP increased in group A compared to group B. Though the basal DBP was significantly different in both the groups, post induction and after insertion of device, Diastolic Blood Pressure significantly increased in group A. MAP was higher in group A than in group B after insertion of device. The maximum magnitude of change in intraoperative MAP from baseline was 18 (12.66, 23.66) mm Hg in group A, compared to 5 (0, 7.33) mm Hg in group B which was clinically and statistically significant (Table 4). Adverse events such as blood staining (3 in group A, 1 in group B), sore throat (2 in group A, 1 in group B) were comparable between the two groups, no other adverse events such as nausea, vomiting, hoarseness, desaturation, laryngospasm and bronchospasm were noted in either groups.

4. Discussion

In the present study comparing PLMA and IGelin adults patients undergoing laparoscopic cholecystectomy under general anaesthesia and found that the OSP was higher with I-Gel. Compliance and Pmean were also higher in I-Gel, whereas Ppeak and $EtCO_2$ was lower, probably suggestive of better ventilation with I-Gel compared to PLMA. There was greater increase in heart rate, SBP, DBP, MAP following PLMA insertion than I-Gel. The postoperative adverse events like blood staining of the device and sorethroat were comparable in both the groups.

Changes in respiratory mechanics following carboperitoneum may result in increased airway pressures that may exceed the oropharyngeal seal pressure of the used device, leading to inadequate ventilation, gastric insufflation and increased risk of regurgitation and subsequent pulmonary aspiration. Pulmonary compliance is decreased and the resistance is increased leading to high airway pressures[15]. Therefore, higher inspiratory pressures are required to provide adequate tidal volume and minute ventilation. Intra-abdominal pressure of 15-20 mm Hg is associated with increase in the peak airway pressure, decrease in lung compliance and an increase in $PaCO_2$[16,17].

In a study conducted in 2014, comparing PLMA, I-Gel airway and SLIPA during general anesthesia observed that I-Gel was associated with quicker insertion and less leak fraction compared to PLMA. Haemodynamic parameters were comparable with all the three devices[18]. Studies comparing I-Gel with PLMA in children scheduled for surgery under general anaesthesia observed that OSP in the I-Gel group was higher compared to PLMA, where as pulmonary machanics like Ppeak, Pmean, resistance and compliance were similar in both the groups[19,20]. Even in our study OSP was higher with I-Gel. But in our study Ppeak was higher with PLMA probably because of higher resistance offered by narrow tube when compared to wide bore tube of I-Gel and Pmean and compliance were higher with I-Gel.

In a study conducted in 2017, on patients undergoing laparoscopic cholecystectomy with I-Gel or PLMA, it was found that PLMA provided better sealing pressure while I-Gel was easier to use practically and with less hemodynamic variations[21,22], contrary to observations in our study, which may be attributed to method of measuring OSP. We used much more objective method of

measurement of OSP and noted that I-Gel had higher OSP than PLMA. The malleable nature of I-Gel on exposure to body temperature may result in better conturing around the perilaryngeal structures and hence may provide better seal. Ppeak and resistance was higher with PLMA where as Pmean, compliance was higher with I-Gel which augurs with our observations. However, resistance was comparable between the two groups in the present study.

This study has few limitations. This study was done in non obese patients undergoing laparoscopic cholecystectomy; the results cannot be extrapolated to obese patients. Use of Trendelenberg position may have effects on oral seal pressure and position of airway device, hence observations might differ when Trendelenberg position is used. We did not measure the oral seal pressure after creation of pneumoperitoneum and hence could not comment upon the influence of position and pneumoperitoneum on airway seal and ventilatory parameters. Lastly, blinding could not be followed in this study as the devices could be seen from outside, hence we used objective measures where ever possible to ensure uniformity.

5. Conclusion

I-Gel is associated with higher oropharyngeal seal pressure, mean airway pressure and dynamic compliance and lower peak airway pressure compared to PLMA when used as airway conduit in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

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