A Comparative Study between I-gel and Proseal LMA in Adult Patients Undergoing Elective Laparoscopic Cholecystectomy under General Anaesthesia

Bharat Verma[1], Amrita Nidhi[2], Manish Jain[3]

ABSTRACT

Introduction: Supraglottic airway devices are recommended as good alternatives to intubation for laparoscopic surgeries. This study was thus undertaken to compare I-gel and PLMA for airway sealing pressure during positive pressure ventilation and post operative complications for their use in elective laparoscopic cholecystectomy.

Material and Methods: After approval from hospital ethical committee and written informed consent from patient, this randomised prospective study was performed on 60 ASA Grade I and II patients of either sex (30 patients for I-gel and PLMA each) admitted in CSS Hospital undergoing elective laproscopic cholecystectomy under general anaesthesia. An evaluation of hemodynamic changes at time of insertion, number of attempts required and time taken for insertion was done.

Results: The results for Mean systolic blood pressure (SBP), Mean diastolic blood pressure (DBP), Mean arterial pressure (MAP), Mean arterial oxygen saturation (SpO2), Mean of End tidal CO2 (ETCO2) before induction were comparable for two groups. The variation in readings for heart rate after insertion of devices in the two groups was comparable. An average of 0.90 attempts and 0.93 attempts for insertion of devices was recorded for Group I and Group II respectively (p value = 0.647). Mean time taken for insertion of devices was 6.60 seconds and 6.70 seconds for Group I and Group II respectively (p value = 0.865).

Conclusions: Both the I-gel and PLMA devices are equally efficient for their use in patients undergoing laparoscopic cholecystectomy. They present with similar ease of insertion in terms of attempts and time required for insertion of devices.

Key Words: I-gel, Laparoscopic Cholecystectomy, PLMA

INTRODUCTION

Laparoscopic surgery is not only limited to minor surgeries these days but cover a wider area extending to procedures such as appendecectomy, repair of hernias, gastrointestinal, urologic, gynaecologic procedures and cholecystectomy. A patent airway and adequate ventilation are important points to be kept in mind by anaesthesiologist while performing them. Cuffed tracheal tube has been used as an ideal and safe method for laproscopic surgeries under general anaesthesia till date. Recently, new devices have been come to use for anaesthesiologist's convenience.[1]

Classic Laryngeal Mask Airway (LMA) is one such new device but because of the fear of gastric distension and aspiration of contents of stomach, its modification ProSeal laryngeal mask airway (PLMA) has been developed. PLMA has a specially designed cuff which provides a more effective seal around the glottis which has almost twice the seal pressure as compared to the Classic LMA.[2] The drain tube that comes as a part of PLMA acts as a bypass channel for regurgitated gastric contents. Thus, it lowers mucosal pressures and helps in isolation of alimentary tract from the respiratory tract. PLMA has wider applications with use in pediatric and adult patients under both controlled and spontaneous ventilation.[3,4] It is the most widely studied supraglottic airway device (SAD). More devices have been brought in this field since the introduction of PLMA to improve the SAD´s indications.[5]

The I-gel supraglottic airway device (Intersurgical Ltd, Wokingham, Berkshire, UK) a single use non-inflatable SAD with a (gastric) drain tube was developed in 2007 and has been incorporated into practice recently to overcome the limitations of PLMA.[6,7] The device provides a gel like feel as it is composed of a thermoplastic elastomer (SEBS - styrene ethylene butadiene styrene) with a soft durometer. It helps in avoiding compression trauma as it creates a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures.[6] It is well aligned with curvature of oropharyngeal region through its buccal cavity stabilizer and integral bite block. Down folding of epiglottis during its insertion is prevented by its epiglottic rest with a protective ridge.[7] It also has an advantage of cheaper manufacturing costs due to its simple design.[8]

The safety of these SAD'S with gastric access has been assessed through some studies over last decade. Though studies have been done for LMA, but few have been performed to evaluate i-gel for laparoscopic procedures.[5] This study was thus undertaken to compare i-gel and PLMA for airway sealing pressure during positive pressure ventilation and post operative complications for their use in elective laparoscopic

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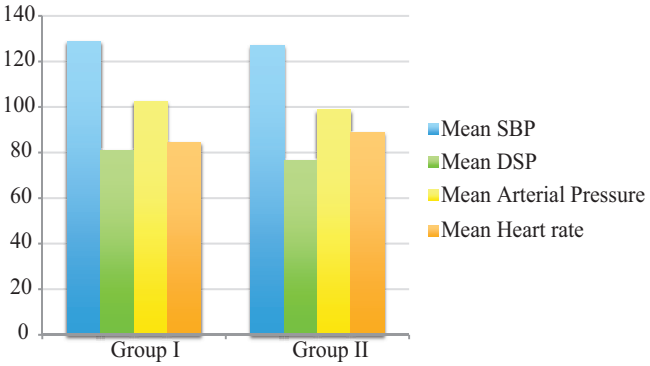
cholecystectomy. An evaluation of hemodynamic changes at time of insertion, number of attempts required and time taken for insertion was done.

MATERIAL AND METHODS

After approval from hospital ethical committee and written informed consent from patient, this randomised prospective study was performed on 60 ASA Grade I and II patients of either sex (30 patients in each group) admitted in CSS Hospital undergoing elective laproscopic cholecystectomy under general anaesthesia from June 2013 to May 2015. Inclusion criteria comprised of patients undergoing elective laproscopic cholecystectomy under general anaesthesia of age range 18 - 58 years with surgery time of less than 2 hours. Patients with high risk of aspiration (hiatus hernia, GERD and full stomach), pregnant females, difficult airway, BM > 30kg/m2, Mp Grade III and IV, inter incisor gap < 2 cm, ASA III and IV, pre op sore throat, surgery duration > 2 hours and those who refused for the procedure were excluded from the study. Two groups were constituted of which Group I included 30 patients for whom I-GEL was used for insertion and Group II included 30 patients for whom PLMA was used for insertion. A total of 60 cards (30 in each Group) were prepared by a person who was blinded about the study. After recruitment, every patient was allowed to draw one card and was grouped accordingly.

Pre-anesthetic evaluation was done a day before for all the patients by the anaesthesiologist. Detailed clinical history, careful evaluation of airway and written informed consent was taken and patients were advised pre operative fasting as per ASA guidelines. Anesthetic technique was standardised by monitoring through GE Cardiocap - 5 including HR, NIB, SpO2, EtCo2, spirometry, ECG (5 lead). 18G i.v canula was secured and ringer lactate solution was started at 100 ml/hour. Each patient was premeditated with IV injection glycopyrrolate (0.005mg/kg), midazolam (0.05 mg/kg), injection Fentanyl (2 microgram/kg). Anesthesia was introduced with Propofol 1% (2mg/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.[9] In accordance with manufacturing details, manual size of I-GEL is dependant on weight of the patient. Size 3 was used for patients with weight less than 50 kg and size 4 was used for patients with weight between 50 and 90 kg. Similarly, the size of PLMA was selected according to the weight of the patient. Anesthesia was maintained with Isoflurane, nitrous oxide and oxygen. The insertion technique included neck flexion, head extension followed by insertion into airway. Cuff pressure was measured by Pressure Manometer (VBM, Germany) and was maintained to not exceed 60 cm of H2O for PLMA. Gastric tube was passed into the stomach and its position was assessed by suction of gastric fluid if needed. All patients were ventilated with 8 - 10 ml per kg of tidal volume to maintain end tidal Co2 within 30 - 40 mm go Hg. All procedures were performed by single experienced investigator.



Graph-1: Mean Systolic blood pressure, Diastolic BP, Mean Artial Pressure and heart rate in Group I and Group II

RESULTS

Mean age for Group I was 40.30 years and that for Group II was 41.43 years (p value = 0.624). Mean weight for Group I was 59.40 kg and for Group II was 61.33 kg (p value = 0.159). In group I, 26.7% were males and 73.3% were females whereas in Group II, 23.3% were males and 76.7% were females (p value = 0.235).

In group I, 100% patients had ASA Grade I whereas in

	Group I	Group ii	P value
Age (years)	40.30	41.43	0.624
Weight (kgs)	59.40	61.33	0.159
Males	8 (26.7%)	7 (23.3%)	0.235
Females	22 (73.3%)	23 (76.7%)	
ASA Grade I	30 (100%)	27 (90%)	0.237
ASA Grade II	0 (0%)	3 (10%)	
MP Grade I	2 (6.7%)	6 (20%)	0.254
MP Grade II	28 (93.3%)	24 (80%)	
HR (bpm) Before induction	84.50	88.75	0.055
SBP (mmHg) Before induction	128.80	127.20	0.498
DBP (mmHg) Before induction	81.07	76.60	0.065
MAP (mmHg) Before induction	102.40	98.71	0.151
SpO2 (mmHg) Before induction	100.00	99.97	0.321
ETCO2 (mmHg) Before induction	24.10	23.87	0.294

Table-1: Mean demographic data and hemodynamic parameters for Group I and Group II

Group II, 90% patients were of ASA Grade I and 10% were of ASA Grade II (p value = 0.237). MP grade distribution showed 93.3% and 6.7% in Group I for Grade I and Grade II respectively whereas for Group II, it was 20% Grade I and 80% Grade II (p value = 0.254).

Mean systolic blood pressure (SBP) before induction was 128.80 mmHg and 127.20 mmHg for Group I and Group II respectively (p value = 0.498). Mean diastolic blood pressure (DBP) before induction was found to be 81.07 mmHg and 76.60 mmHg for Group I and Group II respectively (p value = 0.065). Mean arterial pressure (MAP) before induction was recorded to be 102.40 mmHg and 98.71 mmHg for Group I and Group II respectively (p value = 0.151). Mean arterial oxygen saturation (SpO2) before induction was 100.00 mmHg and 99.97 mmHg for Group I and Group II respectively (p value = 0.321). Mean of End tidal CO2 (ETCO2) was 24.10 mmHg and 23.87 mmHg for Group I and group II respectively (p value = 0.294). While there was no significant difference between the cases of two groups in respect of all other mean hemodynamic parameters. (Table 1)

Mean heart rate for Group I was recorded as 84.50 beats/min whereas for Group II, it was 88.70 beats/min (p value = 0.58). There was variation in the heart rate after induction but before insertion and also immediately before insertion. The variation in all the three situations was comparable. Immediately after insertion of devices, heart rate showed an upward trend in both the groups as evident from readings at 1 minute after insertion. For next 4 to 5 minutes, a descending trend was noted. After that, heart rate again began an upward trend as drawn from readings after 10 minutes. The variation in readings after insertion in the two groups was comparable. (Graph no 1)

An average of 0.90 attempts and 0.93 attempts for insertion of devices was recorded for Group I and Group II respectively (p value = 0.647). Mean time taken for insertion of devices was 6.60 seconds and 6.70 seconds for Group I and Group II respectively (p value = 0.865).

DISCUSSION

Laparoscopic surgery is an evolving subspecialty and is not only limited to minor surgeries. The problems common to all such procedures are a) carbon dioxide insufflation in the body-intraperitoneal or extraperitoneal b) raised abdominal pressure and c) potential danger of regurgitation and pulmonary aspiration. The anaesthesiologist must ensure a patent airway and adequate ventilation. Till date the cuffed tracheal tube was considered as ideal for providing a safe glottic seal especially for laparoscopic procedures under general anaesthesia. But over a period of time new airway devices have been added to the anaesthesiologist's armamentarium.

A relatively new device, the PLMA is an improved version of the Classic LMA with some added safety features. **1** But PLMA posed with different malpositions following its insertion because of its inflatable cuff leading to improper placement.[10] A fold over malposition may also appear due to lack of a back plate in PLMA. Recent device I-gel has been shown to overcome these limitations of PLMA as it creates a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures.[6]

We studied the PLMA and I-gel in 60 patients undergoing laparoscopic cholecystectomy. These patients were segregated into groups based on the device used. We used sizes 3 and 4 for our study as similar to earlier studies.[1,11] Demographic and hemodynamic parameters were comparable between the two groups throughout the course of the surgical procedures. The values for MSBP, MDBP, MAP, SpO2 and ETCO2 had higher scores for Group I with I-gel as compared to Group II with PLMA. There was variation in heart rate for all the situations (Before induction, after induction but before insertion and after insertion). The readings were comparable for both the groups. Average number of attempts for insertions was lesser for I-gel group as compared to PLMA group but none required second attempt which is similar to as observed in other studies.[6] Mean time taken for insertion of device was little less for Group I as compared to Group II. This finding was similar to other recent studies done for comparison of I-gel with PLMA.[6,12-14]

An important limitation of the study could be that all the device insertions were performed by a single experienced anesthesiologist; thus the results for non experienced users could not be obtained.

CONCLUSION

Both the I-gel and PLMA devices are equally efficient for their use in patients undergoing laparoscopic cholecystectomy. They present with similar ease of insertion in terms of attempts and time required for insertion of devices. More studies for comparison of I-gel and PLMA devices for cholecystectomy surgeries with larger samples can further validate the results.

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