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A comparative study of change in Hemodynamics between I-gel and Proseal LMA in adult patients under going elective Laparoscopic cholecystectemy under general anaesthesia

Bharat Verma[1] , Amrita Nidhi[2]

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.

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. Till date the cuffed tracheal tube was considered as ideal for providing a safe glottis seal especially for laparoscopic procedures under general anaesthesiaa. But over a period of time new airway devices have been added to the anesthesiologist's armamentarium. the I-gel airway (intersurgical Ltd, workingham, Berkshire, UK) and ProSeal Laryngeal Mask Airway (PLMA) (The laryngeal mask company st heiler , jersey, UK) are two recently introduced devices for maintaining the airway during controlled ventilation under general anaesthesia.

The proseal laryngeal mask airway (PLMA) was introduced by Archie Brain in clinical practice in 2000.

The I-gel is the most recent development in supraglottic airway devices. It was developed by Dr. Mohammad Aslam Nasir in January 2007. 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.

AIMS AND OBJECTIVES

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 with following aims.

Aims:

1. Evaluation of hemodynamic change at the time of insertion of I-Gel
2. Evaluation of hermodynamic changes at the time of iinsertion of proseal LMA.
3. 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.

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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, SpO2, EtCo2, spirometery, ECG (5lead) . 18G i.v canula was secured & ringer lactate solution at 100ml/hr. was started.

Patients were premedicated with IV inj. Glycopyrrolate (0.005mg/kg), inj. Midazolam (0.05mg/kg), inj, fentanyl ($2\mu gm/kg$). Anaesthesia was induced with Inj. Propofol 1% (2mg/kg) followed by vecuronium 0.1mg/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 60cm of H20. 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 Co_2 within 30-40 mm of Hg.

All procedures were performed by a single experienced investigator.

Following parameters were recorded:

- **HEMODYNAMIC PARAMETERS** – (HR, SBP, DBP, MAP) SPO2, and EtCo2 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

This results obtained in the study were presented in a tabulated manner as mean ± SD and were analyzed using with statistical package for social sciences (SPSS20.0). categorical variables are expressed as frequencies. Differences between groups were assessed with chi-square or fisher's exact test for categorical variables. Unpaired t tests were used for comparison of continuous variables between the two groups. I-GEL or PLMA insertion characteristics were compared using mann whitney test. 'p' value of <0.05 was considered as statistically significant.

OBSERVATION & RESULTS

Table no 1 : Shows demographic 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%)	.0235
	Female		22 (73.3%)		23 (76.7%)	
ASA grade	I		30 (100%)		27 (90%)	0.237
	II		0 (0%)		3 (10%)	
MP grade	I		2 (6.7%)		6 (20%)	0.2524
	II		28 (93.3%)		24 (80%)	
HR (bpm) Before induction		30	84.50± 7.3	30	88.75± 9.4	0.055

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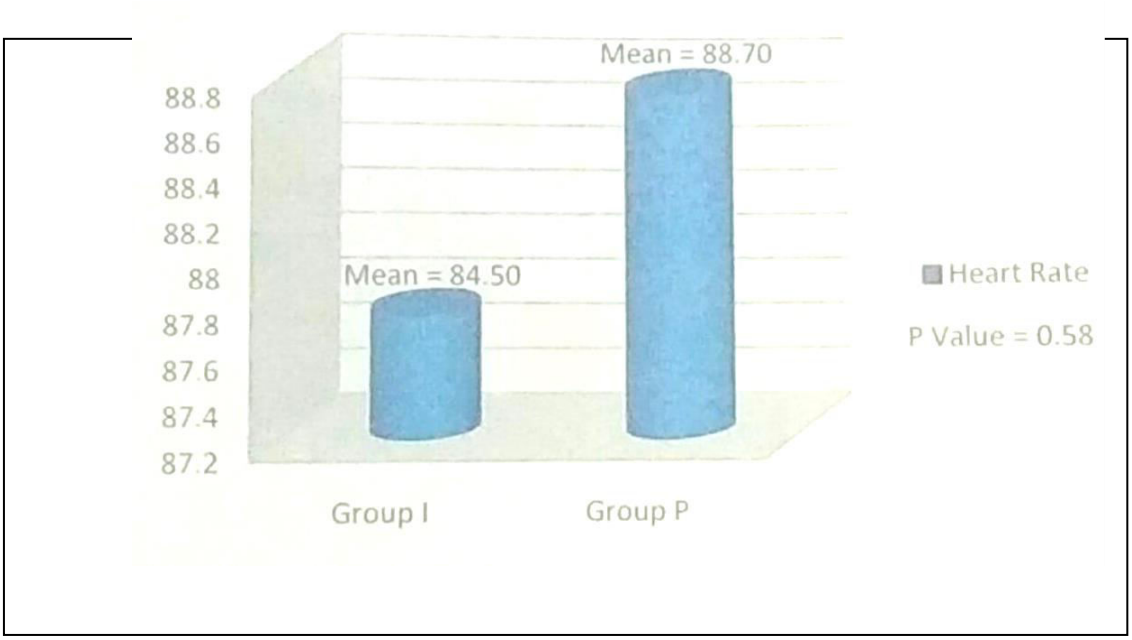
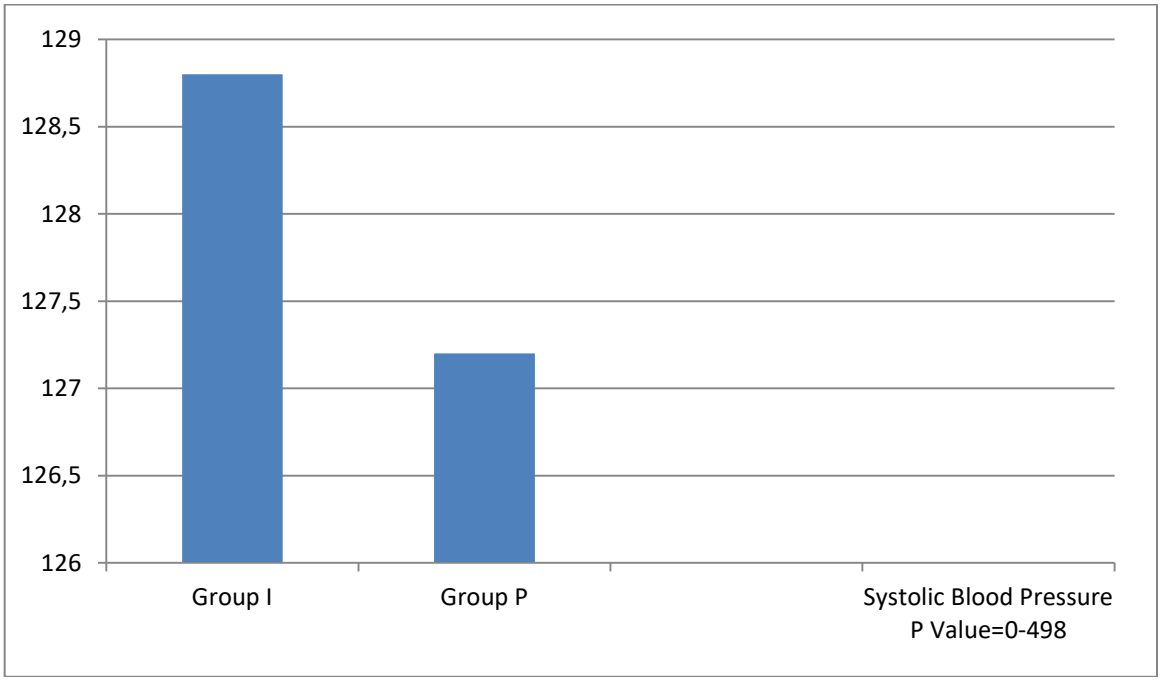
SBP (mmHg) Before Induction	30	128.80± 8.9	30	127.20± 9.3	0.498
DBP (mmHg) Before Induction	30	81.07±3.0	30	76.60±12.7	0.065
MAP (mmHg) Before Induction	30	102.40±7.5	30	98.71±11.70.151	



Graph no. 1.6 bar graph shows Heart Rate between both groups



Graph No. 1.7 : bar graph shows systolic blood pressure between both groups.

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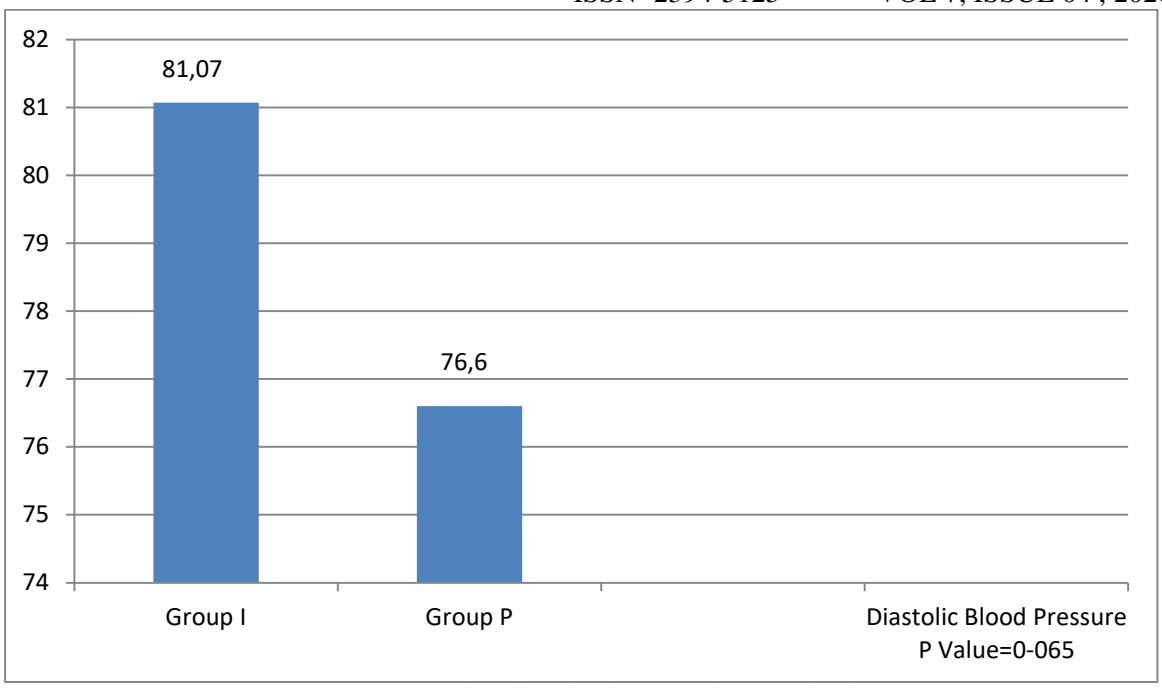
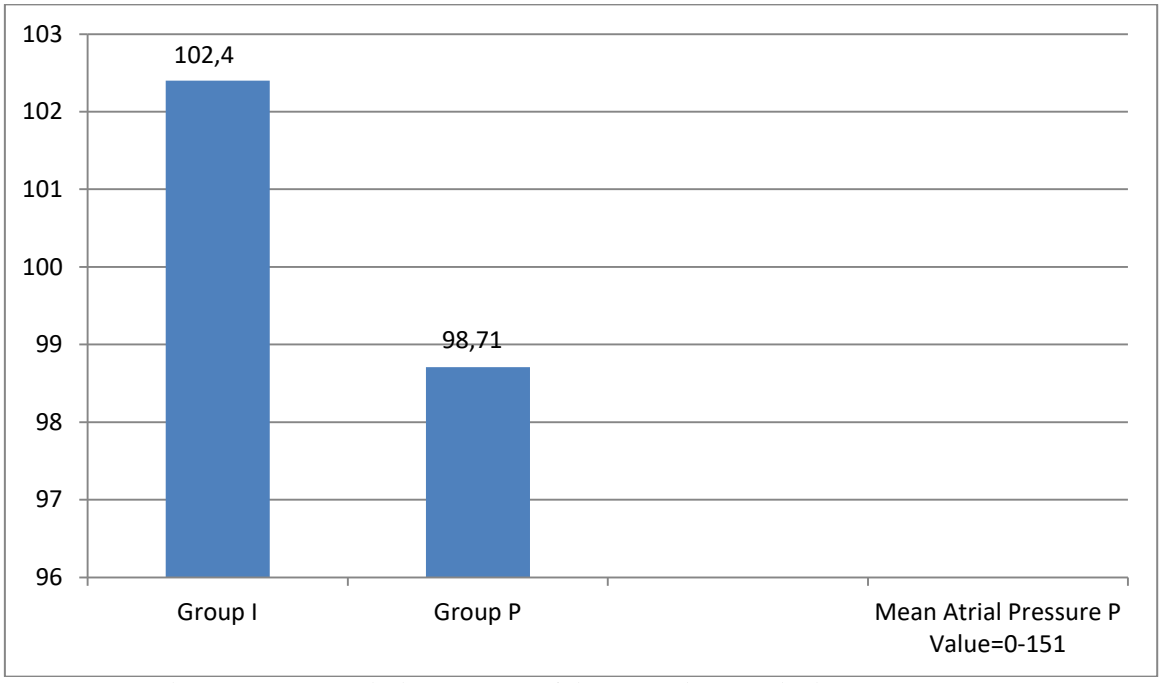


Graph no. 1.8: Bar graph shows Diastolic Blood Pressure between both groups.



Graph no 1.9 : Bar graph shows mean atrial pressure between both groups.

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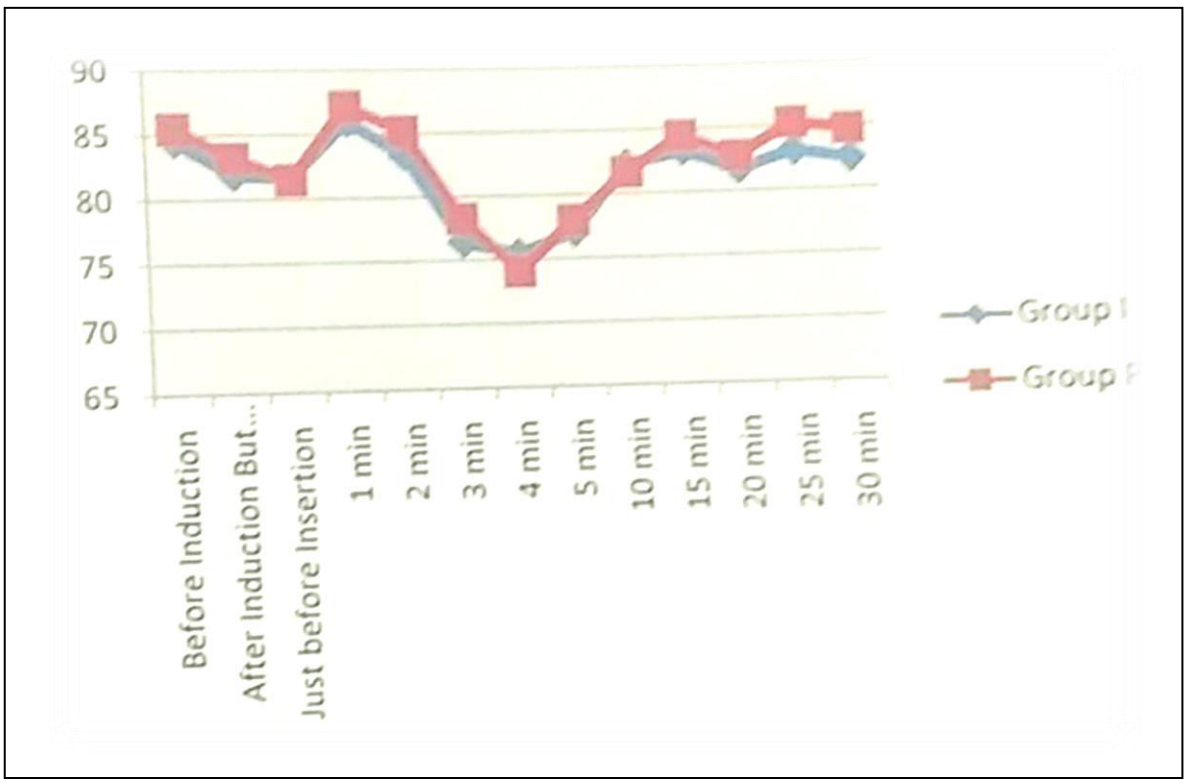
Table No. 2 : Shows Hart rate between both groups.

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



Graph no. 6 : line graph shows Heart rate between both groups

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Table N0.3 : Shows systolic blood pressure between both groups.

SBP	Groups				P Value
	Group I		Group P		
	N	Mean±SD	N	Mean±SD	
Before Induction	30	128.80 ± 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

Table No 4 : Shows diastolic blood pressure 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

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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

Table No 5 : Shows mean atrial pressure between both groups.

MAP	Groups				P Value
	Group I		Group P		
	N	Mean±SD	N	Mean±SD	
Before Induction	30	102.40 ± 7.5	30	98.71±11.7	0.151
After Induction But just before insertion	30	72.87±14.4	30	76.20±11.7	0.329
At Insertion	30	74.47±25.5	30	78.80±23.5	0.496
1 min	27	85.56±3.7	28	82.14±8.1	0.050
2 min	30	70.30±25.5	30	7150±21.7	0845
3 min	30	67.70±23.0	30	70.47±20.7	0.626
4 min	27	77.61±5.9	28	76.71±6.8	0.582
5 min	27	80.52±8.5	28	85.82±14.3	0.086
10 min	27	87.41±7.4	28	91.54±11.9	0.111
15 min	27	91.30±5.4	28	95.07±*12.9*	0.167
20 min	27	87.41±*6.7*	28	90.89±*10.2*	0.142
25 min	27	85.78±*5.1*	28	88.89±*8.6*	0.093
30 min	27	85.33±*5.4*	28	85.71±*6.2*	0.808

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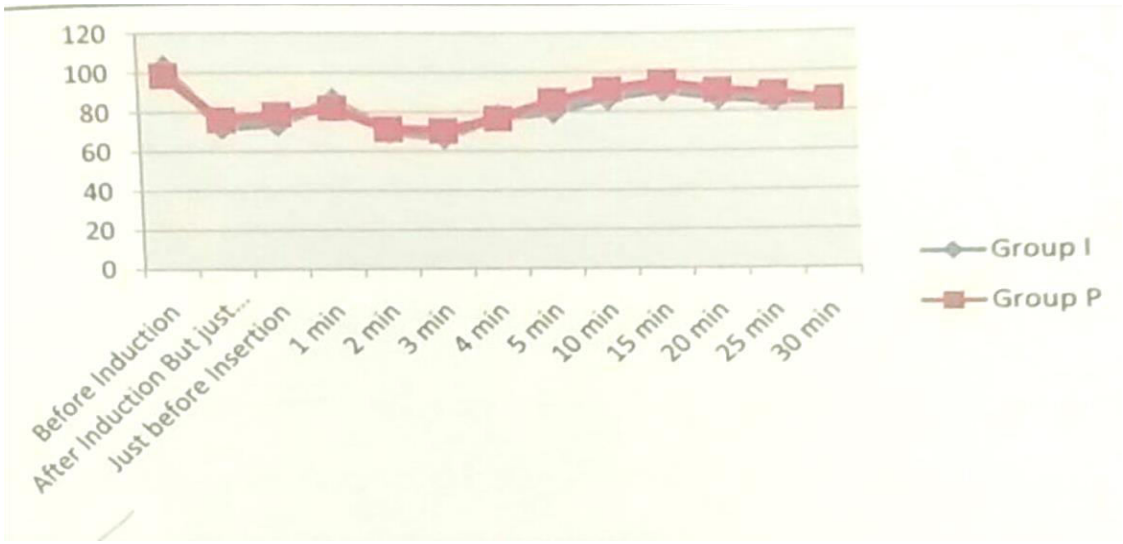

Graph no 9 : line graph shows mean atrial pressure between both groups.

SUMMARY AND CONCLUSION

This randomized prospective study was carried out in Govt. Medical College Datia. 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).

Results Observed

1. Demographic profile like age, gender, ASA grade and MP grade were comparable between groups. ($p>0.05$)
2. 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)

We conclude that both the devices can be effectively used in laparoscopic surgeries though their frequent use and safety needs further evaluation.

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