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Comparative Evaluation of Airway Management And Hemodynamics With Use Of I-GEL (Intersurgical Gel), Proseal LMA (Laryngeal Mask Airway) And Endotracheal Tube In Laparoscopic Surgeries.

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I. Introduction

Laparoscopic surgery has dramatically taken over many conventional surgical techniques of the past ,anesthetic techniques for same have also been refined to anticipate these differences[1]. In past, cuffed tracheal tube was considered as ideal device for providing safe glottic seal, especially for laparoscopic procedures under general anaesthesia as it provided adequate ventilation and protected against pulmonary aspiration but required laryngoscopy & initiated hemodyanamic stress response during insertion. So this warrants searching for a newer alternative device which reduces haemodynamic variations along with other complications[2,3]. To overcome this, Supraglottic Airway Devices (SADs) were introduced. Their use in laparoscopic surgeries has been described as inconventional but feasible.

ProSeal LMA (LMA-P) & I-gel airway (Intersurgical Ltd, Workingham Berkshire, United Kingdom) are second generation SGAs that were introduced in the year 2000 & 2007, respectively. They have additional safety features that enhance oesophageal and pharyngeal seal and risk of aspiration is also minimised with introduction of gastric channel. Both devices provide a higher oropharyngeal leak pressure (OLP) and are designed for use in spontaneous as well as positive pressure ventilation[4].

There are many studies comparing ETT with PLMA/ I-GEL or I-GEL with PLMA but studies comparing all the three devices are still rare. Hence in our research, we tried to find out efficacy of the three most popularly used anaesthetic devices (i.e. ETT, PLMA & I-GEL) with respect to airway management and hemodynamics and to compare complications related to them in elective laparoscopic surgeries.

II. Materials And Methods:

Study population: - 90 patients of ASA grade I and II, between 18-60 years of age, pertaining to departments of general surgery & gynecology, scheduled for elective laparoscopic procedures under general anesthesia, were included in the study. Informed written consent in patient's language was taken and they were divided into 3 groups of 30 patients each, by computer generated table;
Group E (n=30): Airway secured with ET tube.
Group I (n=30): Airway secured with I-Gel.
Group P (n= 30): Airway secured with proseal LMA.

Study design: This randomized controlled, prospective, comparative, double blinded study was conducted in the department of Anesthesiology during the period of January 2017 to September 2018. It involved comparison of ETT, PLMA & I-gel regarding efficacy, hemodynamic changes and airway complications assessing their clinical outcome. Randomization was done using closed envelop, double-blinded method.

Using the results of previously conducted study, the sample size of 30 in each group was derived by the given formula:

$$\text{Sample size} = \frac{Z_{1-\alpha/2}^{2}\ p(1-p)}{d^2}$$

Here-
$Z_{1-\alpha/2^2}$ = is standard normal variant (at 5% type I error P< 0.05) it is 1.96 and at 1% type 1 error (P<0.01) it is 2.58. As in majority of studies P values are considered significant below 0.05 hence 1.96 is used in formula.
P = expected proportion in population based on previous studies or pilot studies.

d = absolute error or precision – Has to be decided by researcher.
Incidence of trauma-
P = 4% = 0.04
D = 7% = 0.07

$$\text{Sample size} = \frac{1.96^2 \times 0.04 \times (1 - 0.04)}{0.07^2}$$

= 30.10 = 30 patients needed in each group.
Study Reference **:** Eschertzhuber Et al [5].

Inclusion criteria:
1) American society of Anesthesiologists (ASA) status I & II.
2) Patients aged between 18-60 yr.
3) Malampatti grading I & II.
4) Patients scheduled for elective laparoscopic surgery under general anaesthesia.

Exclusion criteria:
- Patients not willing to take part in the study.
- anticipated difficult intubation.
- Morbid obesity (BMI>40%).
- History of active gastro oesophageal reflux.
- Cardio-respiratory/ cerebro-vascular disease.
- Epilepsy/on antipsychotic medication.
- Pregnant /lactating females.
- Emergency surgeries.

Materials required:
- Endotracheal tubes
- Proseal LMA
- I-gel
- Anesthesia work station

Tools for data collection:
- Continuous Electrocardiogram monitor
- Non-invasive blood pressure monitor
- Pulse oximeter
- $ETCO_2$
- stethoscope

Screening:

After clearance from the ethical committee of the institute, study was initiated on patients meeting the desired requirements. Patients were explained about the anesthesia technique & written informed consent was taken. Selected individuals were sent for pre anesthetic evaluation. It consisted of detailed history taking along with thorough examination. Pre operative investigations were carried out including complete blood count, kidney function test, serum sodium, serum potassium, random blood sugar, blood group & electrocardiography (ECG). Patients were kept nil per oral for minimum 6 hrs prior to surgery. They were randomly allocated into three groups. Randomization was by computer generated numbers and allocation into groups was done by the supervisor opening a sealed opaque envelope just before surgery. Patients were blinded to their group allocation. Device insertion was performed by expert anesthesiologists. All the patients were premedicated with oral alprazolam (0.25 mg) and oral ranitidine 150 mg the night before surgery.The anesthetic technique was standardized for all patients. Inside the operating room intravenous access was secured and ringer lactate started at 3-5 ml/kg/hr. Standard monitors like ECG, pulse oximeter, capnograph, and noninvasive blood pressure were attached. Anaesthesia machine, breathing circuits were checked and connected.Premedication in the form of inj. Ondansetron 0.08mg/kg, inj. Ranitidine 1 mg/kg, inj. glycopyrolate 5 µgm/kg, inj. midazolam 0.03mg/kg ,inj. Fentanyl 2 µg/kg were given to them. After preoxygenation with 100% oxygen for 3 min, anesthesia was induced with propofol (2-3mg/kg) & neuromuscular blockage was done using atracurium 0.5mg/kg. Patients were manually ventilated with 100% oxygen. The observations were made by an anaesthesiologist who was unaware of the study device. Thus making the study double blinded. After achieving adequate depth, devices were introduced accordingly.In group I, appropriately sized ETT were used, In group II, I-gel was used..In

group III PLMA was used. The size was chosen appropriately according to the patient's body weight. In group P, After insertion, the cuff was inflated with air to 60 cm H_2O and maintained at this pressure only. The gastric tube was inserted in the group E orally and I and P through the gastric inlet. In each group, breathing system was connected. Correct placement of the device was confirmed by: adequate chest movement & square wave capnography. After fixation of the device, oropharyngeal leak was determined by closing the expiratory valve at a fixed gas flow of 5 l/min and hearing an audible noise from the mouth directly or from neck using a stethoscope placed just lateral to thyroid cartilage. Balanced anesthesia was maintained with oxygen and nitrous oxide (50:50), 1% isoflurane, fentanyl infusion and atracurium top ups.

All the parameters i.e. HR, NIBP, oxygen saturation, end tidal CO_2 were recorded after device introduction and at 1, 3, 5, 10 min respectively. Inj. paracetamol 20mg/kg will be administered intravenously for intraoperative analgesia. After completion of the procedure, neuromuscular blockade was reversed with inj. Glycopyrrolate 0.01 mg/kg and inj. Neostagmine 0.05mg/kg after cessation of N_2O. NGT tube suctioning was done. Device was removed after return of adequate spontaneous respiratory efforts and when the patient followed commands. Auscultation of chest was done for any evidence of aspiration.

Demographic variables: Age, weight, height, BMI, ASA and duration of surgery were recorded. The HR,RR,SBP,DBP,MAP,SPO_2 were recorded at baseline (BL) after induction (AI), after intubation (AIT), and after insertion of the airway device at 1,3,5,10 (T1,T3,T5,T10) minutes,10 min after achieving pneumoperitoneum (AP), after removal of device at 1 and 5 minutes after extubation (E1, E5) respectively. The ease of insertion of the airway device was noted. "Easy insertion" was defined as insertion within the pharynx without resistance, in a single maneuver. A "difficult insertion" was the one in which there was resistance to insertion or where more than one maneuver required to seat the device within the pharynx. Insertion attempts were recorded. The insertion of the airway device was reported up to two attempts. However the third attempt was reported as failure .Number of insertion attempts & ease of insertion were described according to subjectiveness of single user as easy or difficult.End-tidal carbon dioxide was recorded after insertion of the airway device.Postoperative airway complications, including cough, blood on the device, hoarseness, sore throat trauma to tongue, lip & dental trauma, dysphonia were evaluated in the recovery postoperatively.

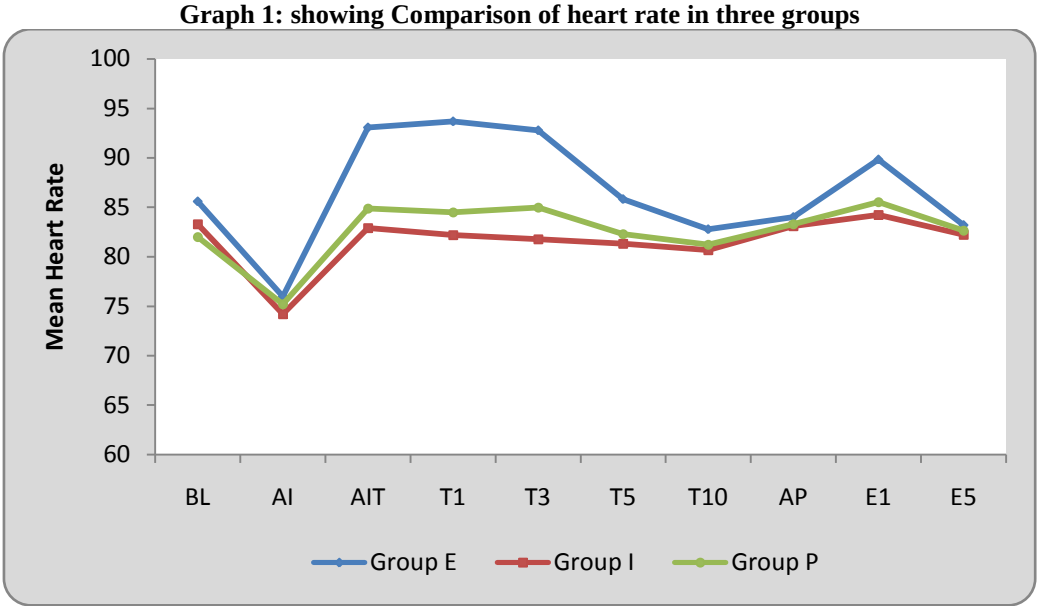
III. Results:

There was no statistically significant difference with respect to demographic data(table 1).

Table 1: Table showing the distribution of age, gender, MPC, weight, height, BMI and ASA, surgical procedure, duration of surgery over three groups

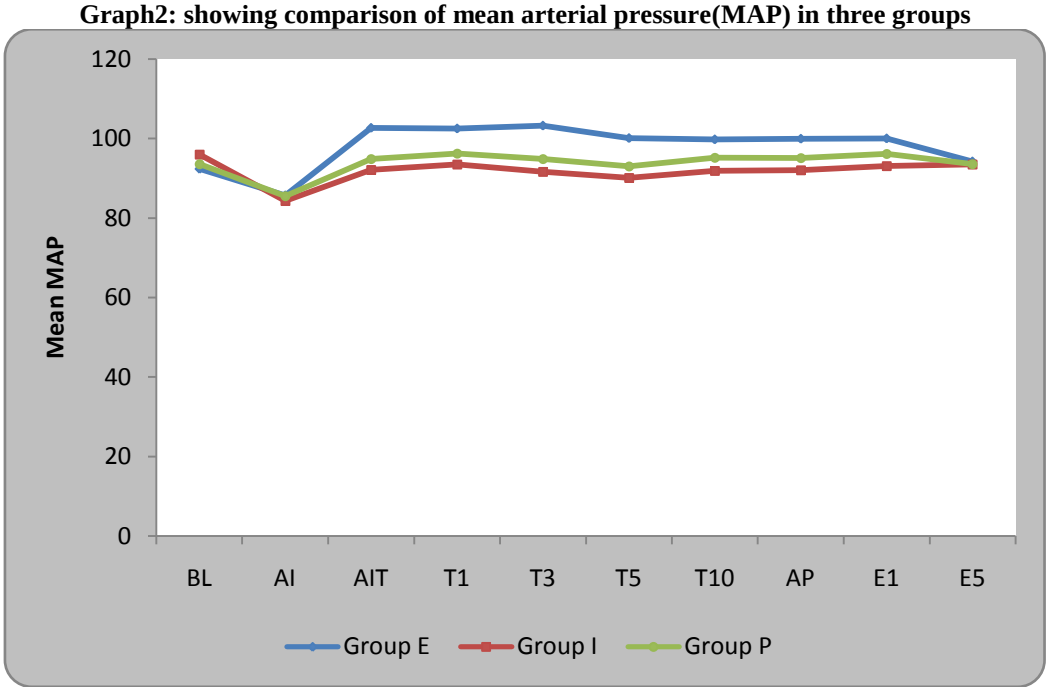
	Group E	Group I	Group P	p-value
Age (yrs) Mean±SD	38.06±12.15	37.43±11.93	40.56±12.77	0.58,NS
Gender	14M:16F	15M:15F	13M:17F	0.87,NS
MPC Grading				
MPC I	27(100%)	28(93.33%)	28(93.33%)	0.129,NS
MPC II	3(0%)	2(6.67%)	2(6.67%)	
Weight(kgs)	57.50±8.58	56.13±6.97	54.03±6.69	0.19,NS
Height(cms)	165.11±8.80	168.60±9.11	162.90±8.12	0.2,NS
BMI(kg/m2)	19.96±1.26	19.67±0.86	20.02±1.07	0.37,NS
ASA I	28	28	29	0.80,NS
ASA II	2	2	1	
Laparoscopic Appendicetomy	11	16	6	0.091,NS
Laparoscopic Cholecystectomy	9	9	13	
Laparascopic Herniorrhaphy	9	4	11	
Diagnistic Laparoscopy	1	1	0	
Duration of surgery(min)	40.66±9.07	39±8.84	41±9.94	0.67,NS

Graph 1: showing Comparison of heart rate in three groups



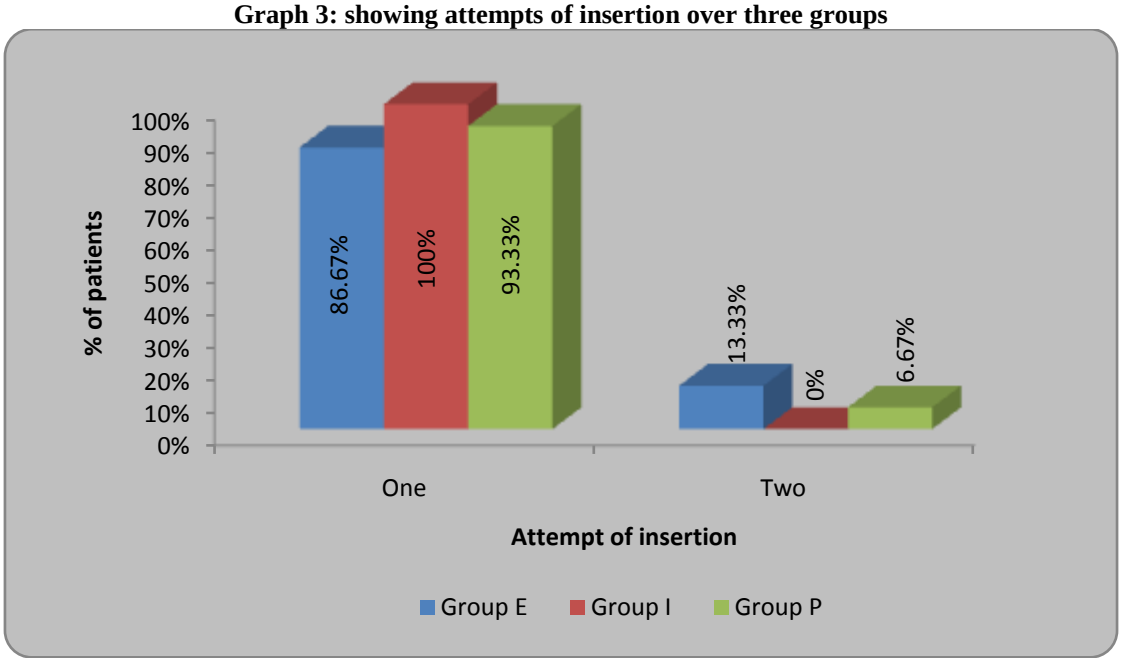
- As shown in graph 1 there was no significant change in HR at baseline and the response was comparable in all the three groups. The changes were significant between group E and I ($p<0.05$) and between group E and P($p<0.05$) Immediately after intubation(AIT), at T1, T3, at 1 min after extubation(E1) whereas it was non significant between group I and P($p>0.05$) at the same intervals.

Graph2: showing comparison of mean arterial pressure(MAP) in three groups



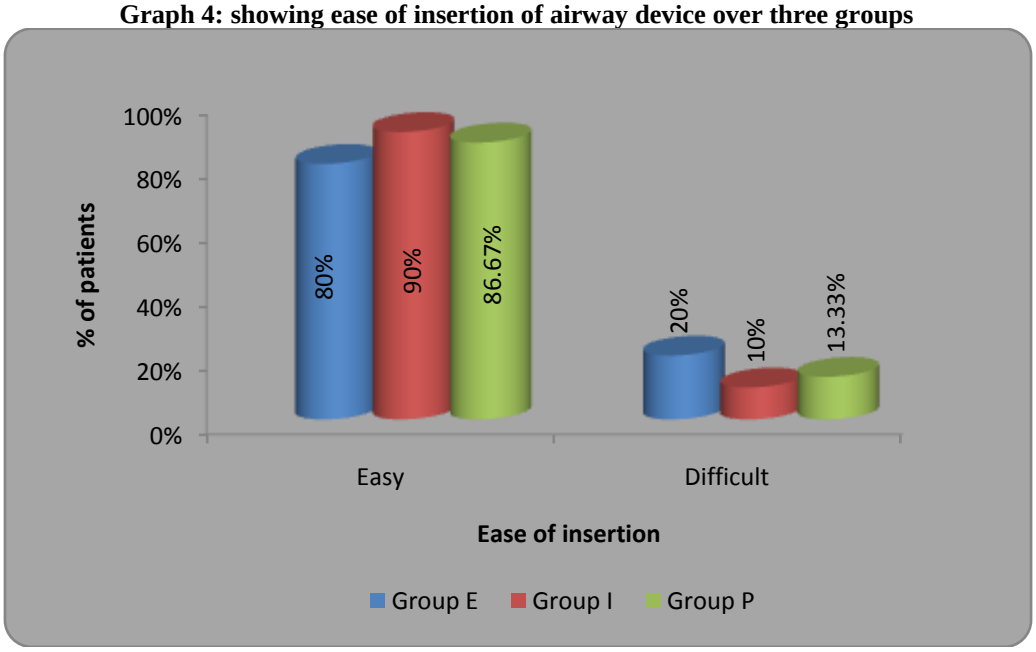
- As shown in graph 2 there was no significant change in MAP at baseline and the response was comparable in all the three groups. The changes were significant between group E and I ($p<0.05$) and between group E and P($p<0.05$) Immediately after intubation(AIT), at T1, T3, at 1 min after extubation(E1) whereas it was non significant between group I and P($p>0.05$) at the same intervals.

Graph 3: showing attempts of insertion over three groups



All the three groups were comparable without any statistically significant difference in terms of attempts of insertion, ease of insertion(graph3,graph 4). There was no third or failed attempt of insertion.

Graph 4: showing ease of insertion of airway device over three groups



Oropharyngeal leak, laryngopharyngeal morbidity at removal of device like coughing,blood staining, trauma to oral cavity were statistically non significant among three groups whereas hoarseness postoperatively was statistically significant in group E.(Table 2,3,4).

Table 2: showing oropharyngeal leak in three groups

OL	Group E	Group I	Group P	p-value
Present	0(0%)	4(13.33%)	2(6.67%)	0.11,NS
Absent	30(100%)	26(86.67%)	28(93.33%)	
Total	30(100%)	30(100%)	30(100%)	

Table 3:showing Laryngopharyngeal Morbidity at removal of device over three groups

Laryngopharyngeal Morbidity	Group E	Group I	Group P	p-value
Coughing	4(13.33%)	1(3.33%)	1(3.33%)	0.20,NS
Blood Staining	4(13.33%)	1(3.33%)	1(3.33%)	0.20,NS
Trauma to lip, teeth or tongue	4(13.33%)	1(3.33%)	1(3.33%)	0.20,NS

Table 4: Table showing Laryngopharyngeal Morbidity postoperatively over three groups

Laryngopharyngeal Morbidity	Group E	Group I	Group P	p-value
Hoarseness	3(10%)	0(0%)	0(0%)	0.045,S
Dysphonia	0(0%)	0(0%)	0(0%)	-
Sore Throat	2(6.67%)	0(0%)	0(0%)	0.12,NS

STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive and inferential statistics using Chisquare test, one way ANOVA and Multiple Comparison: Tukey Test and software used in the analysis SPSS 22 0 version, Sand Graph Pad Prism 6.0 version. EXCEL spreadsheet was used for electronic data entry. Descriptive data presented as mean +/- SD. The comparisons considered as not significant ($p > 0.05$), significant ($p < 0.05$).

IV. Discussion:

All through the 19th century, endotracheal intubation was considered as the only way of establishing a definitive airway. Although widely used, the procedure was associated with a lot of side effects. Laryngoscopy and intubation produces reflex sympathetic stimulation, raised levels of plasma catecholamines, rise in blood pressure and tachycardia[6]. They may even trigger myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. Postoperatively, endotracheal intubation resulted in sore throat, dysphagia, hoarseness of voice [7], excessive coughing, nausea or vomiting, decreasing patient satisfaction and sometimes extending hospital stay.

To facilitate faster turnover of patients undergoing short surgical procedures on day care basis, the SADs were preferred. Their insertion does not involve any laryngoscopy, any manipulation of the vocal cords or any stimulation of the trachea. Hence the frequency and the severity of the adverse effects discussed above are drastically reduced [8]. The SADs can be inserted without the need of any muscle relaxant, leading to faster recovery of the patients post-surgery.

Proseal LMA is a reusable SAD that allows easy insertion, higher glottis seal pressure and separation of respiratory tract from gastrointestinal tract via the gastric port which permits gastric drainage [9]. I-gel is a second generation SAD which consists of a non inflating laryngeal mask made from a gel like thermoplastic elastomer and an anatomically shaped cuff which is easier to insert and forms an effective seal around the perilaryngeal surface [10]. In this study we compare I-gel, PLMA and endotracheal tube in terms of ease of insertion, airway complication and hemodynamic changes in elective laparoscopic surgeries under general anesthesia.

Based on the results of our study**,**we found that overall success for airway insertion was 100% in all groups. I-gel has the highest success rate among the three devices. There was no third/failed attempt of insertion. Rukhsana Najeeb et al also found that I-gel was easier to insert with higher success rate in first attempt which was comparable to our result [11]. Singh et al found The success rate at first attempt of insertion was (100%) for I-gel & (93.3%) for PLMA, which was statistically not significant. In relation to this our study had no failure of insertion [12].

In our study The insertion of I-gel was found comparatively easier and required lesser skills as compared to endotracheal tube and PLMA but the results were not statistically significant (p>0.05). Brimacombe and colleagues, also found similar results [13].

The mean HR for I-gel was least throughout but I-gel and PLMA were comparable Our findings were similar to the study conducted by gehlot et al,Maharajan et al, Patodi et al[14,15,16].

Immediately after intubation, there was an increase in MAP of all groups, maximum in group E & least in group I from basal value . At the time of intubation and at 1,3 min MAP changes between group E and group I was significant and also between group E and P . Whereas insignificant between group I and P. Mean MAP changes between group E and group I, group E and P were significant at 1 min after extubation. whereas non significant between group I and P. our findings were consistent with Nazeeb et al, gehlot et al, Maharajan et al [11,14,15].

In our study mean oropharyngeal leak pressure was comparable between the groups, throughout the surgery**.** Maitra S et al, Shin HW et al [17,18] found that LMA ProSeal still remain the supraglottic device of

choice over I-gel in adult patients during general anesthesia as it provided better seal against leak pressure with comparable device insertion characteristics the results were comparable to our study.

We compared the incidence of laryngopharyngeal morbidity at removal of device and postoperatively over three groups. E group 3/30 patients developed hoarseness postoperatively which was statistically (p=0.045) significant where as none of the patient from group I & P developed hoarseness. Our results correlate with Nazeeb et al, Maltby et al, Saraswat et al [11,19,20].

V. Conclusion:

An attempt has been made through our present work to study the overall ease of airway management and hemodynamic response with the use of Endotracheal tube, I-gel, Proseal LMA in patient undergoing laparoscopic surgeries. The conclusions that can be drawn are ,Both I-gel and Proseal LMA are easier to insert with higher success rate in first attempt and are comparable than endotracheal tube, though insertion of i-gel is easier than proseal LMA. Both I-gel and Proseal LMA are better and comparable in terms of lesser hemodynamic response and lower incidence of complications than endotracheal tube and are suitable alternative for endotracheal tube in laparoscopic surgeries

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