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Comparison of I gel, Proseal LMA and Endotracheal Tube in laparoscopic surgeries

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Abstract: *This study was undertaken to compare I-gel, Proseal LMA with standard endotracheal tube for the number of attempts taken for insertion, hemodynamic changes and postoperative complications during general anaesthesia in healthy adult patients undergoing laparoscopic surgeries. One hundred twenty patients of either sex in the age group of 20-50 years divided into three groups of 40 patients each. Group E (n=40) receiving endotracheal tube, Group P (n=40) receiving Proseal LMA and Group I (n=40) receiving I-gel for airway maintenance. The patients were assessed for insertion characteristics of airway devices (insertion at first attempt with no resistance; insertion at second attempt; insertion at third attempt and failed insertion - insertion not possible), hemodynamic responses (heart rate and blood pressure), intraoperative and postoperative complications.Haemodynamically the significant increase in heart rate and the mean blood pressure were observed immediately after insertion, persisted till 3 minutes after intubation and during the time of extubation in group E .However statistically significant (p<0.05) increase in the heart rate and mean blood pressure in group P (Proseal LMA) and group I (I-gel) was only after insertion of device. Incidence of blood staining of the device, sore throat and dysphasia were observed more in group E. No other complications were observed in either of the groups.I-gel and ProSeal LMA prove to be suitable and safe alternative to endotracheal tube for airway management in elective adult patients undergoing laparoscopic surgeries.*

Keywords*: Endotracheal tube ,Haemodynamic, I-gel, laproscopic surgery, ProSeal LMA.*

I. Introduction

I-gel supraglottic airway device was developed to overcome the limitations of Proseal laryngeal mask airway (e.g. high cost, demand for careful handling to prevent cuff damage and relative difficulty of insertion). I-gel mirrors the shape, softness and contours accurately with the perilaryngeal anatomy to create the perfect fit. This innovative concept means that no cuff inflation is required. I-Gel works in harmony with the patient's anatomy so that compression and displacement trauma is significantly reduced or eliminated. [1] A supraglottic airway without a cuff has potential advantages including easier insertion and use, minimal risk of tissue compression, stability after insertion (i.e. no position change with cuff inflation) and manufacturing advantages in terms of simplicity and decreased cost. I-Gel is designed as a single patient use; disposable device. [2] But there are very few studies with literary evidence comparing I-gel with LMA-ProSeal (PLMA) to assess their performance in anesthetized and artificially ventilated. So, present study was undertaken to compare I-Gel, Proseal LMA with standard endotracheal tube for the number of attempts taken for insertion, hemodynamic changes, oxygenation, and intraoperative and postoperative laryngopharyngeal morbidity during general anaesthesia in healthy adult patients undergoing laparoscopic surgeries.

II. Materials And Methods

The present hospital based randomised comparative study was conducted at the Government Medical College, Srinagar over a period of one and half year (March 2013 to August 2104). After obtaining approval from Hospital Ethics Committee, a written informed consent was taken from the patients for participation in this study. One hundred twenty patients of either sex in the age group of 20-50 years belonging to ASA Class 1 scheduled for elective laparoscopic surgeries under general anaesthesia were selected for this study and divided into three groups of 40 patients each. Group E- Airway secured with endotracheal tube, Group P- Airway secured with Proseal LMA and Group I- Airway secured with I-gel. Patients with anticipated difficult airway, severe obesity, oropharyngeal pathology, cardiopulmonary disease, cervical spine fracture or instability, increased risk of aspiration (gastroesophageal reflux disease, hiatus hernia, pregnant patients), restricted mouth opening (<2.5 cm) were excluded from the study. Patients selected for surgery were admitted at least 24 hours prior to surgery. Airway assessment was done to predict any difficult intubation. All Patients were advised to remain fasting overnight. Patients were premedicated with injection Rabeprazole 20mg. Multichannel monitor

was attached to the patient. Standard monitoring including baseline pulse, non-invasive blood pressure (BP), oxygen saturation (SpO_2) and electrocardiography (ECG) were instituted. Patient was administered injection midazolam 0.02 mg/kg, glycopyrrolate 0.005mg/kg 1-2 minutes before induction. After preoxygenation with 100% oxygen for 3-5 minutes, induction was done with injection of Propofol 1.5-2.5mg/kg till the loss of verbal commands. Neuromuscular blockade to facilitate placement of device was achieved with injection atracurium 0.5 mg/kg body weight. Following induction and adequate paralysis, the corresponding airway was inserted in each group. Correct placement of the devices was confirmed by auscultation. Anaesthesia was maintained with oxygen and nitrous oxide mixture, isoflurane and atracurium besylate body weight was used as a muscle relaxant intra-operatively for maintenance. Inj. Tramadol 2mg/kg body weight and Inj.paracetamol 20mg/kg was administered intravenously for intraoperative analgesia. A nasogastric tube was inserted to make the stomach empty of air and other contents.

The outcomes measured were as follows:

- Insertion characteristics - insertion at first attempt with no resistance; insertion at second attempt; insertion at third attempt and failed insertion - insertion not possible.
- Hemodynamic responses (heart rate and mean arterial blood pressure) were recorded at baseline, before induction; at the time of insertion; 1, 2, 3 and5 min after insertion of device; after achieving carboperitoneum, and after removal of devices.
- Incidences of regurgitation, aspiration, coughing, blood staining of device, trauma to lip, teeth, tongue and postoperative hoarseness, dysphonia and sore throat were noted and recorded.

Oxygen saturation (SPO_2) and end-tidal carbon dioxide ($EtCO_2$) was recorded. The aim was to maintain target SpO_2 (>95%) and $EtCO_2$ (<45 mm Hg) by adjusting the FiO_2, respiratory rate and tidal volume. When SpO_2 was 94-90% the oxygenation was graded as suboptimal and failed if it was <90%.

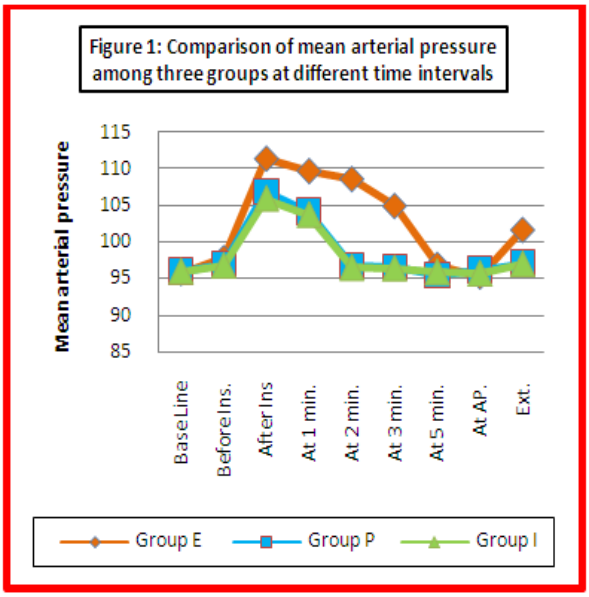
Statistical software SPSS (version 16.0) was used to carry out the statistical analysis of data. Data was analysed by means of descriptive statistics viz. means, standard deviations and percentages. Chi-square test was used for qualitative data. Analysis of variance (ANOVA) test was employed for inter group analysis and for multiple comparisons least significant difference (LSD) test was used. Intra group analysis was carried out with the help of Paired t-test. Graphically the data was presented by bar and line diagrams. A P-value of less than 0.05 was considered statistically significant.

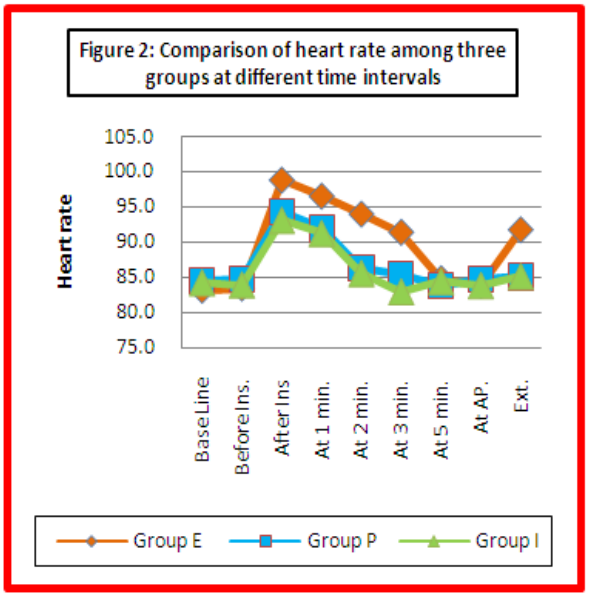
III. Results

There was no statistically significant difference with respect to demographic data (table1).In this study, we found that endotracheal tube (ETT), ProSeal-LMA (PLMA) and I gel were successfully inserted in all patients and there was no failed case of insertion in any of the three groups. First attempt insertion success rate was 82.5% (33 patients) for ETT, 85% (34 patients) for PLMA and 92.5% (37 patients) for I gel which was comparable. Second attempt for device insertion was required in 5 patients (12.5%) in group E, 6 patients (15%) in group P and 3 patients (7.5%) in group I. A third attempt was necessary for 2 patients (5%) in group E. The overall insertion rate was 100% for both devices (table 2). Attempts of insertion were comparable for both the groups and the difference found was not statistically significant. Although I-gel was easier to insert with higher success rate in first attempt (92.5%) than Proseal LMA (85%) and endotracheal tube (82.5%) but it was not statistically significant difference. On comparing the hemodynamic trends within groups, statistically significant increase in heart rate and the mean blood pressure was observed immediately after insertion, persisted till 3 minutes after intubation and during the time of extubation in group E (figure 1 and 2). However statistically significant ($p<0.05$) increase in the heart rate and mean blood pressure in group P (Proseal LMA) and group I (i-gel) was only after insertion of device. There were no statistically significant differences in oxygen saturation (SpO_2) and end tidal carbon dioxide ($EtCO_2$) among the three groups before or during peritoneal insufflations. There was no incidence of aspiration or regurgitation in any group. Incidence of coughing and sore throat was more in group E than group P and group E which was statistically significant (table 2). Incidence of blood staining of devices, trauma to lip, teeth and tongue, dysphonia and hoarseness were comparable among three groups (table 2).

Table 1: Demographic characteristics				
Parameter	Group E (n=40)	Group P (n=40)	Group I (n=40)	P value
Age (yrs)	36.0±4.71	36.6±5.52	35.7±4.60	0.732
Gender (M/F)	13/27	13/27	11/29	0.855
Weight (kg)	62.4±6.42	61.6±8.03	61.6±6.2	0.758
Type of surgery (n) • Cholecystectomy • Appendicectomy • Mesh Hernioplasty • Diagnostic	 29 5 3 3	 28 5 5 2	 25 7 4 4	0.946
Data is expressed as mean±standared deviation, numbers(n), M=male, F=female				

Table 2: Laryngopharyngeal Morbidity among various groups				
Parameter	Group E (n=40)	Group P (n=40)	Group I (n=40)	P value
Attempt of Insertion				
First	33 (82.5%)	34 (85%)	37 (92.5%)	0.262
Second	5(12.5%)	6 (15%)	3 (7.5%)	
Third	2(5%)	0(0%)	0(0%)	
Failed	0(0%)	0(0%)	0(0%)	
Laryngopharyngeal Morbidity At removal of device				
Coughing	7 (17.5%)	2 (5%)	1 (2.5%)	0.034
Blood staining of devices	6 (15%)	4 (10%)	2 (5%)	0.329
Trauma to lip, teeth and tongue	2 (5%)	4 (10%)	1 (2.5%)	0.346
Laryngopharyngeal Morbidity Post Operative (24 hrs after surgery)				
Hoarseness	2 (5%)	2 (5%)	1 (2.5%)	0.812
Dysphonia	2 (5%)	1 (2.5%)	0 (0%)	0.359
Sore throat	8 (20%)	3 (7.5%)	1 (2.5%)	0.027
Data is expressed as mean±standared deviation, numbers (n) or percentages (%)				





IV. Discussion

Control and protection of airway are fundamental considerations in anaesthesia. Many anaesthesiologists consider tracheal intubation to be the gold standard for airway management. However, the gold loses its glitter when situations such as failed intubation, 'can't ventilate, can't intubate', and patient refusal of awake fiberoptic assisted intubation, complications following extubation are considered. Also one of the main disadvantages associated with tracheal intubation has been the exaggerated or enhanced pressor response. Thus, over a period of time, new airway devices have been added to the anesthesiologist's armamentarium to tackle these technical problems and this ultimately led to the development of supraglottic airway devices in the form of Laryngeal Mask Airway (LMA) in 1981 by the British anesthesiologist, Dr Archie I. J. Brain. [3] One of the most limiting features of the (LMA) is a lack of airway protection from regurgitated gastric contents. [4,5,6] Malpositioning of LMA can considerably increased the risk of gastric air insufflations. [7] In January 2007 the I-

Gel supraglottic airway was unveiled to the world at the Winter Meeting of the Association of Anesthetists in central London to overcome the these limitations of LMA. We therefore compared the three airway devices for the number of attempts taken for insertion, hemodynamic changes, and intraoperative and postoperative laryngopharyngeal morbidity during general anaesthesia in healthy adult patients undergoing laparoscopic surgeries.

In this study, we found that endotracheal tube, ProSeal LMA and I gel were successfully inserted in all patients and there was no failed case of insertion in any of the three groups. Although i-gel was easier to insert with higher success rate in first attempt (92.5%) than Proseal LMA (85%) and Endotracheal tube (82.5%) but it was statistically insignificant. Anjan Das and their co-workers also found that I-gel was easier to insert with higher success rate than proseal .[8] Singh et al found that the ease of insertion was more with I-gel (29/30) than with LMA – Proseal (23/30). [9] Other studies of using the I-gel and LMAs have shown similar results. [10,11,12} It is presumed that the difficulties in inserting LMA – Proseal were caused by larger cuff, impeding digital intra – oral positioning and propulsion into the pharynx, the lack of a backplate making cuff more likely to fold over at the back of mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube.[13,14]

Comparing the hemodynamic trends in our study, the significant changes were found in immediately after insertion, persisted till 3 minutes after intubation and during the time of extubation in group E .However statistically significant ($p<0.05$) increase in the heart rate and mean blood pressure in group P (Proseal LMA) and group I (i-gel) was only after insertion of device. The increase in heart rate during intubation is attributed to sympathetic stimulation during laryngoscopy and the passage of the ETT through the vocal cords. The ProSeal LMA and I gel being supraglottic devices do not require laryngoscopy and probably do not evoke a significant sympathetic response. Attenuation of this response may be due to diminished catecholamine release. Our results correlates with the other studies, in which they observed hemodynamic perturbations, were maximum with tracheal intubation and moderate with laryngeal mask airway while stable hemodynamic observed with I-gel. [15,16,17] In our study, coughing, blood staining of device and trauma to lip, tongue and teeth's were significantly found in group E as compared to other two groups.2 patients in group P (5%) and 1 patient in group I (2.5%) which was statistically significant. Similar result was seen in study by Maltby et al and other colleges , who noticed coughing during emergence from anaesthesia in patients in which airwau secered with endotracheal tubeas compared to proseal LMA .[18,19,20,21] The sore throat, hoarseness of voice and dysphonia after surgery were more common in group E in our study. The virtual absence of sore throat in group P and group I could be explained by the fact that they are supraglottic devices and mucosal pressures achieved are usually below pharyngeal perfusion pressure. [19,22]

So from our study, it can be concluded that both I-gel and Proseal LMA show similar efficacy with improved hemodynamic stability, maintaining ventilation and oxygenation during laparoscopic surgery. I-Gel and Proseal LMA are better than endotracheal tube in terms of lesser hemodynamic response with a low incidence of intraoperative and postoperative complications. Hence we conclude that I-gel and Proseal LMA prove to be suitable and safe alternative to endotracheal tube for airway management in elective adult patients undergoing laparoscopic surgeries.

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