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Research Article

A COMPARATIVE STUDY OF ENDOTRACHEAL TUBE, I-GEL AND PROSEAL LARYNGEAL MASK AIRWAY IN LAPAROSCOPIC SURGERIES. (A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY)

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ABSTRACT

Background: The mask of the I-Gel is designed anatomically to fit the perilaryngeal and hypo pharyngeal structures without the use of an inflatable cuff and has potential advantages including easier insertion and use, minimal risk of tissue compression and stability. **Aim:** To compare I-gel, LMA-Proseal and Endotracheal tube during laparoscopic surgeries (Haemodynamic changes and End tidal Carbon dioxide levels). **Methods:** Prospective Randomized Comparative study conducted on 120 patients between the age group of 20-50 years (male/female) of ASA grade I, forty patients each in three groups scheduled for laparoscopic surgeries done under general anaesthesia in Fortis hospital, Shalimar bagh, New Delhi which receives patients from the urban areas as well as from surrounding rural areas of the Delhi National Capital Region (NCR). **Results:** Mean change in heart rate before and after insertion in group E was 83.00±3.99 and 98.83±4.03,in group P was 84.70±3.82 and 94.18±4.04 and in group I was 83.53±4.17 and 92.98±3.89.The mean change in systolic blood pressure before and after insertion in group E was 121.15±3.09 and 137.93±2.04,in group P was 121.45±2.93 and 132.05±2.63,in group I was 120.35±2.99 and 131.65± 3.62 and the mean change in mean blood pressure before and after insertion in group E was 97.38±2.62 and 111.48±2.62,in group P was 97.15±2.26 and 06.95±2.17,in group I was 96.75±1.85 and 106.00±2.36 respectively. This statistically significant ($P<0.05$) increase in heart rate, systolic and mean blood pressure was observed immediately after insertion of airway devices, persisted till 3 minutes after intubation and during the time of extubation in group E (endotracheal tube). However statistically significant ($p<0.05$) increase in the heart rate in group P (Proseal LMA) and group I (I gel) was only after insertion of device. **Conclusion:** We concluded that both I-gel and Proseal LMA showed similar efficacy with improved hemodynamic stability, maintaining ventilation and oxygenation during laparoscopic surgeries.I-Gel and Proseal LMA are better than Endotracheal tube in terms of lesser haemodynamic response and a low incidence of intraoperative and postoperative laryngopharyngeal morbidities.

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INTRODUCTION

Laparoscopy results in multiple postoperative benefits including less trauma, less pain, less pulmonary dysfunction, quicker recovery and shorter hospital stay. These variations and benefits explain the increasing success of laparoscopy, which is now proposed for many surgical procedures [1].

The physiological effects of intraperitoneal CO2 insufflation combined with different patient positioning can have a major impact on haemodynamic and respiratory function [2]. Till date,the cuffed tracheal tube was considered as the gold standard for providing a safe glottic seal, especially for laparoscopic procedures under general anaesthesia[3]. The disadvantages of tracheal intubation, which involves rigid laryngoscopy, are in terms of concomitant haemodynamic responses and damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a serious concern. This precludes the global utility of the tracheal tube and requires a better alternative [4]. Over a period of time, new airway devices have been added to the anaesthesiologist"s armamentarium[5].

The benefits of the supraglottic airway devices include avoidance of laryngoscopy, less invasive for the respiratory tract, better tolerance by patients, increased ease of placement, improved haemodynamic stability during emergence, less sore throat, hands free airway, less trauma to soft tissue, vocal cords, teeth and easier placement by inexperienced personnel [6]. The development of Laryngeal Mask Airway by Archie Brain in 1981 was the most important milestone in the history of supraglottic airway devices [7]. PLMA besides providing all the inherent qualities of CLMA offers several advantages over

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CLMA [8] . It has an additional drain tube,an additional dorsal cuff that improves the seal, a built in bite-block . It is a reusable device, the cuff is made of a softer material than the CLMA which allows to conform to the contour of the hypopharynx and provides twice the seal pressure of CLMA at a given intracuff pressure, making it a better choice for situations requiring a better oropharyngeal seal [9].

METHODS

This study was conducted in 120 patients between the age group of 20-50 years (male/female) of ASA grade I, forty patients each in three groups scheduled for laparoscopic surgeries done under general anaesthesia in Fortis hospital, Shalimar bagh, New Delhi which receives patients from the urban areas as well as from surrounding rural areas of the Delhi National Capital Region (NCR).

Patients belonging to ASA grade I who were scheduled to undergo laparoscopic surgery under general anaesthesia were recruited for this Prospective randomized comparative study. Patients selected for surgery were admitted at least 24 hours prior to surgery. A pre-anaesthetic examination comprising history, general physical and systemic examination of all the patients was conducted. Airway assessment was done to predict any difficult intubation. Routine investigations including haemoglobin, total leucocyte count, blood sugar, serum creatinine and urine examination was carried out. All patients were kept fasting for at least 6 hours prior to surgery. The study excluded the patients with significant cardiopulmonary disease, hepatic or renal dysfunction, endocrine disturbances, neurological or psychiatric disorder, those with history of drug allergy or drug abuse, those on central nervous system (CNS) depressants, pregnant/ breastfeeding females and those who had undergone recent anaesthesia (within the previous 7 days).. The study was conducted at the Fortis Hospital Shalimar Bagh New Delhi.One hundred twenty patients of either sex in the age group of 20-50 years belonging to ASA Class I scheduled for elective laparoscopic surgeries under general anaesthesia were selected for this study and divided into three groups of forty each. Patients undergoing laparoscopic surgeries were divided into 3 groups:

- Group E- Airway secured with endotracheal tube
- Group P- Airway secured with Proseal LMA
- Group I- Airway secured with I-gel

Protocol for General Anaesthesia

In the operating room, an intravenous (IV) line was secured on the non-dominant hand of the patient, monitors were attached and baseline heart rate (HR), mean arterial pressure (MAP) and oxygen saturation (SpO2) were recorded. All patients received fentanyl citrate 1 mcg/ kg intravenously and were preoxygenated prior to induction of anaesthesia till etO2 was 90. Anaesthesia induction was done with propofol 1.5-2.5 mg/kg IV. After loss of consciousness, ventilation of lungs was done manually assisted. Following induction and adequate paralysis, the corresponding airway was inserted in each group:

1. In Group P, LMA Proseal of appropriate size (according to weight) was used. For the purpose of standardisation, introducer was used for inserting the Proseal LMA for all cases.
2. In group I, I-gel of appropriate size according to the patient's weight was used.
3. In Group E, Endotracheal intubation was performed.

***Correct placement of the devices* was confirmed by**

- Adequate chest movement on manual ventilation
- Square wave capnography
- Expired tidal volume of more than 7- 8 ml/kg
- No audible leak from the drain tube with peak airway pressure (PAP) less than 20 cm H2O.

Anaesthesia was maintained with Oxygen & medical air mixture (50:50), sevoflurane and. Inj. Atracurium besylate 0.1mg/kg body weight was used as a muscle relaxant intra-operatively for maintenance. A nasogastric tube was inserted to make the stomach empty of air and other contents. For laparoscopic surgical procedure, peritoneal cavity is insufflated with carbon dioxide to keep intra abdominal pressure <14 mmHg. Towards the end of the surgery patients were given injection Ondansetron 0.1mg/kg intravenously. At the end of surgical procedure, residual neuromuscular block was adequately reversed using intravenous glycopyrrolate 0.02mg/kg and neostigmine 0.05mg/kg and subsequently extubated. Before tracheal extubation, the nasogastric tube was suctioned and removed.

The outcomes measured were as follows:

Insertion characteristics

- Insertion at first attempt with no resistance;
- Difficult insertion - insertion with resistance or at second attempt; and
- Failed insertion - insertion not possible.

Haemodynamic responses (heart rate and mean arterial blood pressure) were recorded before induction; at the time of insertion; 1,2,3,and 5 min after insertion of device,and 10 seconds after achieving Carbo - peritoneum,and at the time of extubation.

***Oxygen saturation (SPO2) and end-tidal carbon dioxide (EtCO2)* was recorded.**

The aim was to maintain target SpO2 (>95%) and EtCO2 (<45 mm Hg) by adjusting the FiO2, respiratory rate and tidal volume. When SpO2 was 94-90% the oxygenation was graded as suboptimal and failed if it was <90%.

Incidences of regurgitation, aspiration, coughing, blood staining of device, trauma to lip, teeth, tongue and postoperative vomiting, sore throat were recorded.

Statistical Methods

Statistical software SPSS (version 16.0) and Microsoft Excel were 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 or Fisher‟s exact test, whichever appropriate, was used for categorical variables. Analysis of variance (ANOVA) test was employed for inter group analysis and for multiple comparisons least significant difference (LSD) test was applied. 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.

RESULTS

This study was conducted after ethical committee and scientific committee clearance and after obtaining an informed written consent from every patient. In this Prospective Randomized Comparative study all the patients were comparable with regard to demographic profile of the study population (table 1).

Table 1 Demographic profile of the study population

Parameters	Group E n=40	Group P n=40	Group I n=40	P value
Age (yrs)	36.1 ± 4.86	36.7 ± 5.42	45.4±4.58	0.519*
Sex M/F	15/25	13/27	10/30	0.481
Height (cm)	163.4±3.9	164.5±4.61	166.4±5.54	0.264*
Weight (kg)	62.5±6.29	61.6±8.23	62.1±5.76	0.833*

(Mean, SD= standard deviation,* = level of significance)

On comparing the trends within groups, statistically significant (P<0.05) increase in heart rate was observed immediately after insertion of Endotracheal tube, persisted till 3 minutes after intubation and during the time of extubation in group E (Endotracheal tube). However statistically significant (p<0.05) increase in the heart rate in group P (Proseal LMA) and group I (i-gel) was only after insertion of device (Table 2).

Table 1 changes in heart rate (beats/min) among various groups

Time Interval	Group E n=40	Group P n=40	Group I n=40	P value
Base Line	82.95 ± 3.72	84.38 ± 3.95	83.93±3.35	0.519
Before Ins.	83.00±3.99	84.70±3.82	83.53±4.17	0.0.154
After Ins	98.83±4.03	94.18±4.04	92.98±3.89	<0.001*
At 1 min.	96.03±3.72	92.03±4.25	90.93±3.82	<0.001*
At 2 min.	94.05 ± 4.13	86.20 ± 3.07	86.03 ± 4.19	<0.001*
At 3 min.	91.20 ± 3.94	85.33 ±3 .80	85.15 ±4.01	<0.001*
At 5 min	84.73 ± 3.45	83.65 ±4.05	84.25 ± 84.25	0.385
At AP.	84.10 ± 4.07	84.78 ± 4.18	84.00 ± 4.08	0.658
Extubation	92.10 ± 4.07	85.90 ± 3.47	85.13 ± 3.68	<0.001*

(Mean, SD= standard deviation,* = level of significance)

Mean blood pressure in group E (endotracheal tube), group P (LMA-Proseal) and group I (i-gel)at baseline, before insertion, immediately after insertion and at 1,2,3,5 minutes,10 seconds after pneumoperitoneum and at extubation. On comparing the trends within groups, statistically significant increase in mean arterial pressure was observed immediately after insertion of endotracheal tube, which persisted till 3 minutes after intubation and during the time of extubation in group E (Endotracheal tube). However statistically significant (p<0.05) increase in meanarterial pressure in group P (Proseal LMA) and group I (i-gel) was only after insertion of device (Fig 1).

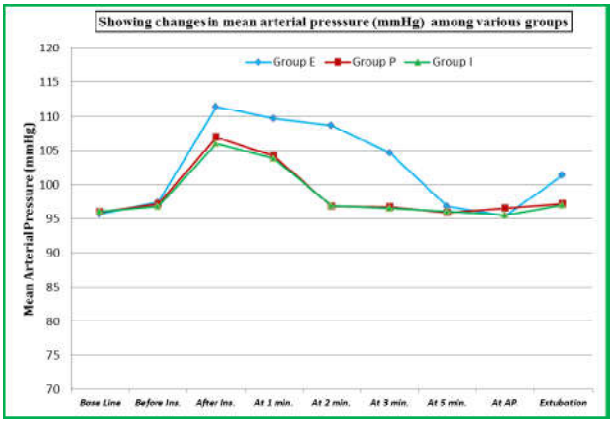

Fig 1

Coughing was seen in 8 patients (20%) in group E, in 2 patients (5%) in group P and in only 1 patient (2.5%) in group I, which was statistically significant difference. Blood staining was seen in 6 patients (15%) in group E, in 3 patients (7.5%) in group P and in 2 patients (5%) in group I which was statistically insignificant. Trauma to lip, teeth and tongue was seen in 2 patients (5%) in group E, in 4 patients (10%) in group P and in 1 patient (2.5%) in group I which was comparable among the three groups (Fig 2).

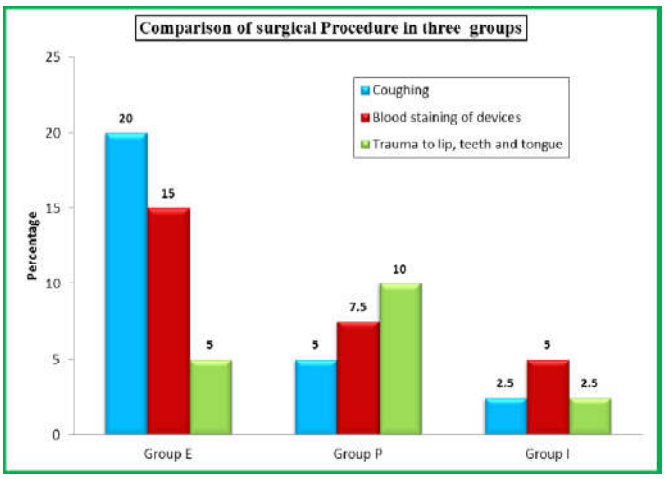

Fig 2

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‟, patient refusal of awake fiberoptic assisted intubation, complications following extubation are considered. Also one of the main disadvantage associated with tracheal intubation has been the exaggerated or enhanced pressor response which may be deleterious in patients with hypertension, coronary artery disease, increased intracranial pressure etc.

The present study was undertaken to compare I-Gel, Proseal LMA with standard endotracheal tube for the number of attempts taken for insertion, haemodynamic changes, oxygenation, ventilation and intraoperative and postoperative laryngopharyngeal morbidity during general anaesthesia in healthy adult patients undergoing laparoscopic surgeries.

Although i-gel was easier to insert with higher success rate in first attempt (95%) than Proseal LMA (87.5%) and Endotracheal tube (80%) but it was not statistically significant difference. Our study shows similar results as were obtained by Bimla *et al* in 2010 [10] who found that the patient characteristics were comparable in both the groups. Both PLMA and i-gel could be inserted in all patients with no failures ineither group. Another study had similar results as our study. Namita *et al* in 2011 [5] found that although Proseal LMA was easier to insert with higher success rate (86.67%) in the first attempt than the ETT (83.33%), this was not statistically significant.

Singh *et al* in 2009 [11] found that in all patients the supraglottic device, I-gel or LMA – Proseal, was inserted within three attempts. The ease of insertion was more with I-gel (29/30) than with LMA – Proseal (23/30) which was

statistically significant ($p<0.05$). The success rate at first attempt of insertion were 30/30 (100%) for I-gel and 28/30 (93.3%) for LMA – Proseal which was statistically not significant. Levitan and Kinkle[12] proposed that on insertion of LMA with inflatable mask the deflated leading edge of the mask can catch the edge of the epiglottis and cause it to downfold or impede proper placement beneath the tongue.

On comparing the trends within groups, statistically significant increase in heart rate,systolic and diastolic blood pressure 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 (endotracheal tube).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.

PP Shroff *et al* in 2005 [13] compared Proseal LMA and Endotracheal tube in laparoscopic surgery. They found that there was not much difference in the pulserate at the respective intervals between both the groups. Statistically significant difference was seen only in the values before and after pneumoperitoneum. The MAP was comparable in both the groups except after insertion of the PLMA or ETT the difference in values show statistical difference. The results in our study were similar to Namita *et al* in 2011 [5] who compared Proseal LMA and endotracheal tube in laparoscopic surgeries. They observed that on comparing the trends within groups statistically significant ($P<0.05$) increase in heart rate and the mean blood pressure was observed 10 seconds after intubation and persisted till 3 minutes after intubation and during the time of extubation in the ETT group. However, statistically significant ($P<0.05$) increase in the heart rate and mean blood pressure in PLMA group was seen only 10 seconds after insertion.

Our study is correlating with the study done by Helmy AM *et al* in 2010 [14] in which they concluded that there was no statistically significant difference found between both I-Gel and classical Laryngeal Mask Airway groups with regard to the assessment of patients after removal of the airway device.The result of our study was similar to the study done by Singh I *et al* in 2009 [11] in which they concluded that the tongue, lip and dental trauma was more with LMA-Proseal (5/30) than with I-Gel (1/30) and blood staining of the device was more with LMA-Proseal (6/30) than with I-Gel (1/30) but the results were not statistically significant.

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Ethical approval: obtained

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