Clinical Performance of the I_Gel Versus Endotracheal Tube in Patients Undergoing Abdominal Laparoscopic Surgery: A Comparative Study

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Abstract- Background and Aims: For laparoscopic surgery, the cuffed endotracheal tube was considered as gold standard for providing a safe glottic seal under general anaesthesia. But, the most common complication is haemodynamic surge and another life-threatening complication of 'Cannot Intubate, Cannot Ventilate' can arise anytime. There are numerous devices which can be used in unanticipated difficult airway. Commonly, I-gel is being used in unanticipated difficult airway and can reduce haemodynamic surge also. But, there are very few studies on comparing I-gel with endotracheal tube in anaesthetized patients. So, the aim of this study was to compare the efficacy and complications of I-gel with standard endotracheal tube during general anaesthesia in elective laparoscopic abdominal surgery.

METHODS: Total ninety six healthy adult patients were randomly allocated into two groups. Group E (endotracheal group, n=48) and group I (I-gel group, n=48), where the time securing the airway, number of attempts for successful device placement, cardiovascular changes, and complications if any were observed and compared between patients receiving the ET tube and I-gel taken up for laparoscopic abdominal surgery.

Results: I-gel shows similar efficacy like endotracheal tube in maintaining ventilation during general anaesthesia and time taken to insert I-gel was significantly less than that of endotracheal tube. I-gel caused significantly less haemodyanamic change than endotracheal tube at various time intervals.

Conclusion: We conclude that I-gel is an effective and safe alternative to endotracheal tube in elective abdominal laparoscopic surgery under general anaesthesia.

Keywords: laparoscopic abdominal surgery, endotracheal tube, I-gel, haemodynamic change.

BLINDED MAIN TEXT

BACKGROUND: Laparoscopic surgery is a continuously evolving subspecialty in cholecystectomy, appendicectomy, hernia repairs, gastrointestinal, urologic procedures. Due to carbon di-oxide insufflation related raised intra-abdominal pressure gastric regurgitation and pulmonary aspiration may be the dangerous complication. Tracheal intubation provides the direct airway ventilation and protection against aspiration. Difficult tracheal intubation and inability to maintain a patent airway also remains an important cause of anaesthetic morbidity and mortality [1]. The unanticipated difficult airway occurs with a low but consistent incidence in anaesthesia practice [2]. Therefore, although endotracheal Intubation is regarded as the gold standard for maintenance of airway, the immediate and life-threatening complication of 'Cannot Intubate, Cannot Ventilate' can arise anytime with anyone and anywhere. There are numerous devices and techniques available, which can bail us out of such situations where conventional laryngoscopy and intubation fails. Devices such as the I-gel™ (Intersurgical Ltd, Wokingham, UK), in the setting of unanticipated difficult airway, are effective in establishing a patent airway, may reduce morbidity and are lifesaving. I-gel™ is a single use second generation supraglottic airway device [3,4] made of thermoplastic elastomer with a non-inflatable cuff which conforms to the shape of peri laryngeal structures and provides an adequate seal during spontaneous and controlled ventilation [5]. But there are very few studies with literary evidence comparing I-gel with endotracheal tube to assess its performance in anaesthetized and artificially ventilated patients. So, present study was undertaken to compare the clinical efficacy and complications of I-Gel™ with standard endotracheal tube during general anaesthesia in healthy adult patients undergoing elective laparoscopic abdominal surgery.

The aims and objectives of our study was to compare ease of insertion (time of airway securing, number of attempts for successful device placement, failure attempts) and to compare oxygenation and ventilation status (SpO2, EtCO2), perioperative haemodynamic stability (pulse rate, systolic, diastolic, mean arterial pressure) of these two devices, relative incidence of postoperative laryngospasm, cough, aspiration, sore throat.

MATERIALS AND METHODS

A total of 96 normotensive patients were selected for this study. They were chosen among the patients posted for planned laparoscopic abdominal surgery, aged 20 to 60 years with BMI between 18.50 – 24.99 kg/m2 of both genders. The study was conducted in operation theatre in Medical College, Kolkata. The patients were randomized into two groups of 48 each. Randomization has been done using systematic random sampling [6]. One group was administered the I-gel (group I) and the other group was given endotracheal intubation (group E). A thorough preoperative assessment was done before selecting the patient for the study. Written informed consent was taken. After shifting the patient to operation theatre, an intravenous line was established using 18G IV cannula and standard monitors like automated noninvasive blood pressure (NIBP), continuous 5 lead ECG and pulse oximetry were attached. Base line vital parameters were recorded. Each patient was uniformly premedicated with inj ranitidine (50mg i.v), inj ondansetron (0.1mg/kg i.v) inj glycopyrrolate (0.005mg/kg i.v), inj fentanyl (1mcg/kg i.v), inj midazolam (0.02mg/kg i.v) before induction. After preoxygenation for 5 minutes, anaesthesia was induced with inj i.v. propofol (2 mg/kg). Inj. atracurium (0.5 mg/kg) was used as neuromuscular blocking agent (NMBA) for relaxation required for placement of ET tube or Igel ™. Anaesthesia was maintained with 66% N2O, 33% O2 and isoflurane. Volume controlled positive pressure ventilation was administered via a circle system at a TV(tidal volume) of 8ml/kg and respiratory rate of 12/min, so as to maintain an ETCO2 of 30-40mmHg and arterial oxygen saturation >95%. In case of increasing ETCO2, ventilation was increased by increasing the respiratory rate to achieve normocapnia. Insufflation of CO2 to produce pneumoperitoneum was done so as to maintain an intra-abdominal pressure of 12-15mm Hg. Neuromuscular blockade was maintained with intermittent injection of atracurium. At the end of the surgery isoflurane and N2O were discontinued and patients were put on 100% O2. Residual neuromuscular blockade was reversed with injection neostigmine (0.05 mg/kg) and injection glycoprrolate (0.01 mg/kg). After adequate reversal of neuromuscular paralysis, I –gel or ET (endotracheal) tube was removed. Postoperative oxygenation was done for 10 minutes in operation theatre and then the patients were transferred to recovery room. In intraoperative period, the time taken to secure the airway was observed and noted. The monitoring of heart rate(HR), blood pressure (BP) and SPO2 preoperatively (as baseline), after ET tube intubation or placement of I-gel at 3 min, 5mins,10 mins then at removal of the device and 5 mins after removal was done and noted. For both the groups baseline ETCO2 was taken from connection of ETCO2 cable following placement of airway devices. For statistical analysis, data were analyzed by SPSS (version 25.0; SPSS Inc., Chicago, IL, USA). The study evaluated the control of the patients' airway using the two devices on the basis of the following parameters: ease of insertion, time taken for placement of device, insertion attempts (a maximum of three attempts were allowed), attempts at gastric tube insertion, haemodynamic responses, changes in SpO2 and ETCO2, intraoperative complications like device malposition/ displacement, regurgitation of gastric contents and postoperative airway complications like cough, sore throat, aspiration, laryngospasm assessed after device removal.

RESULTS

A total of 96 normotensive adult patients were taken for this study, where the time securing the airway, cardiovascular changes, emergence and complications if any were observed and compared between patients receiving the ET tube and I-gel taken up for laparoscopic abdominal operation of duration less than 90 minutes. statistical analysis data were analyzed by SPSS (version 25.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. From table 1, it was found that the two groups were similar in terms of mean age, mean weight, mean height and BMI. Distribution of parameters between two groups were not statistically significant (p=0.6489, 0.2688, 0.9219 and 0.611 respectively) i.e.>0.05. From table 2, it was seen that

the difference of mean heart rate baseline in two group was not statistically significant (p=0.1158) but the difference of mean value of heart rate after placement, heart rate at 3 min, heart rate at 5 min were highly significant (p<0.01). Difference of mean heart rate at 10 min in two group was not statistically significant (p = 0.6372) and the mean value of heart rate at removal was statistically highly significant (p<0.01). Difference of mean heart rate 5 min after removal in two group was not statistically significant (p=0.0854). Difference of mean SBP(systolic blood pressure) baseline in two group was not statistically significant (p=0.6395). The mean value of SBP after placement, SBP at 3 min, SBP at 5 min and mean SBP at removal were highly significant (p<0.01). Difference of mean SBP at 10 min and SBP at 5 min after removal in two group was not statistically significant (p=0.6693 and 0.5687 respectively). Difference of mean DBP(diastolic blood pressure) baseline, at 5 minutes, 10 minutes and 5 minutes after removal in two group was not statistically significant (p=0.9302, 0.9819, 0.8124 and 0.9691 respectively). But it was observed that differences in mean value of DBP after placement, at 3 minutes, DBP at removal were highly significant (p<0.01). From table 3 it can be observed that difference of mean EtCO2 after placement in two group was NOT statistically significant (p=0.4421). In GRP2-E, the mean value of ETCO2 at 3 and 5 min was significantly higher than GRP1-I and difference of mean ETCO2 at 3 min and 5 min in two group was statistically significant (p<0.05). Difference of mean ETCO2 at 10 min in two group was NOT statistically significant (p=0.0756). Difference of mean ETCO2 just before removal in two group was NOT statistically significant (p=0.2669). Table 4 shows that the incidence of post-operative cough, post-operative sore throat among the patients of two groups statistically not significant.

DISCUSSION

For laparoscopic surgery, the cuffed tracheal tube was considered as gold standard for providing a safe glottic seal for procedures under general anaesthesia. But,the problems and complications related to the practice of laryngoscopy and intubation may be the major causes of morbidity and mortality in the practice of anaesthesia. Endotracheal intubation causes a reflex increase in sympathetic activity that may result in hypertension, tachycardia, and arrhythmia. Though it may not usually cause adverse effect in healthy persons, but this change may be hazardous to patients with pre-existing hypertension, myocardial insufficiency, cerebrovascular diseases, increased intracranial pressure as well as increased intraocular pressure. Injury to the oropharyngeal structures during endotracheal tube insertion, postoperative sore throat is also a serious concern. This precludes the global utility of the tracheal tube and requires a better alternative. The introduction of I -gel in clinical practice improves the airway management and changed the scenario from “unable to intubate and ventilate” to “unable to intubate but able to ventilate”. The I-gel is a new supraglottic airway device for use in anaesthesia which has successfully combined the concept of non-cuffed supraglottic airway device like the SLIPA and gastric tube of PLMA. It is made up of medical grade thermoplastic elastomer called SEBS (Styrene Ethylene Butadiene Styrene). The shape, softness and contour of I-gel is accurately mirror framework of pharyngeal, laryngeal and perilaryngeal anatomy. We compared ET Tube with I-gel in terms of ease of insertion, time taken for placement of device, insertion attempts, attempts at gastric tube insertion, airway trauma and haemodynamic responses, any change in SpO2 and ETCO2. We compared our findings with the findings of other studies. Patients were randomly allocated into two groups of 48 patients each. Group E for Endotracheal tube and Group I for I –gel. The demographic data with respect to age, body weight, height and sex were comparable in both groups. In the present study, the ET(endotracheal) tube was easily inserted in 42 patients (87.5%)while in I-gel group the easy insertion was in 45 patients (93.8%). Our observations are consistent with observations of Richez B et al (2008) [7] studied over I-gel insertion where very easy insertion was 93% and in Singh I et al (2009) [8] study where easy insertion was 96.67%. Rukhsana Najeeb et al (2015) had studied over I-gel and ET tube insertion like our present study. Rukhsana Najeeb et al had got the result where Igel insertion was easy in 93.8%, difficult in 6.3%, whereas in ET tube easy insertion was in 87.5%, difficult in 12.5%. In our study, insertion was scored as easy in 93.8%, difficult in 6 patients (12.5%) in group E while in I-gel group easy insertion was 87.5% and difficult insertion took place in 3 patients (6.3%). We observed that mean insertion time or median insertion time of I-gel is much shorter than

endotracheal tube insertion time. However, median insertion time of I-gel according to study of Kannaujia et al (2009)[9] was much shorter(11seconds) than our result and mean insertion time of endotracheal tube according to study of M G Patel et al (2010) was much longer (33.03 ± 4.61 seconds) than our result. This difference with some authors might be a result of using different criteria to measure the total time needed that are different from those used in this study. However, we can say that statistically significant higher time taken for placement of endotracheal tube in group E patients may be due to additional time required for laryngoscopy and to inflate the cuff of the endotracheal tube. In our study, in group E, the gastric tube was easily inserted in 42patients (87.5%), while in group I-gel, insertion of gastric tube was easy in 45 patients (93.8%).Our observation are consistent with observations of StevenOzer et al (1999) and M C Mandal et al (2010) with respect to gastric tube insertion in patients with endotracheal tube. Our observations are also consistent with observations of Richez B et al (2008)[7], Amr M Helmy et al (2010), Bhandari G et al (2013) with respect to gastric tube insertion in I-gel group of patients. At last, we can say that there is no significant difference in attempts at gastric tube insertion between group ET tube and group I-gel patients and two devices are comparable in terms of ease of gastric tube insertion. Comparison between the two groups showed that rise in HR in group E was significantly higher than group I. There was a significant increase in HR during extubation in group E which touched baseline 5mins after extubation. With removal of I-gel, the HR change was not significant from baseline. Thus it can be interpreted that the HR increased after both ET tube and I-gel placement, but the magnitude and duration of increased HR was less in group I-gel as compared to group E. At removal of ET tube, there was a significant rise in HR but, HR change was insignificant during I-gel removal. The observations in this study relating to HR changes in group E were in accordance with Suresh L et al (2012).The observations of current study relating to better heart rate stability of I-gel group in comparison to ET tube group were in accordance with those by Hosam M Atef et al (2013) and Rukhsana Najeeb et al (2015). The observation of Jindal P et al (2009) also supports better haemodynamic stability of I-gel.The two groups became significant at 5min ($P<0.05$) after which the variation was insignificant and again the SBP variation was highly significant at removal and it became insignificant 5 mins after device removal. The rise in DBP from baseline on instrumentation was significantly more with ET tube as compared to I-gel. Also extubation was associated with a significant rise in DBP (92.72mmHg) in group E whereas removal of I-gel was not associated with any significant rise in DBP (83.33mmHg) in group I. Placement of any infraglottic airway device is expected to be associated with changes in heart rate, SBP, DBP due to reflex sympathetic response. Since, I-gel is a non-inflattable supraglottic device; it would not be expected to cause similar haemodynamic changes like group E. The observations made in this study relating to haemodynamic changes in group E are in accordance with those by Shribman AJ et al (1987), Suresh L et al (2012), Ebra Salman et al (2012). The observations made in this study relatingto better haemodynamic stability of I-gel group than ET tube group are in accordance with those by Hosam M Atef et al (2013) and Rukhsana Najeeb et al(2015). The observation of Jindal P et al (2009) also supports better haemodynamic stability of I-gel. At last, we can say that I-gel offers better haemodynamic stability than ET tube. It is to be noted from above studies that post-operative sore throat after tracheal intubation varies from 20% to 65% and after I-gel insertion sore throat may occur from 2.5% to 11% of patients within 24 hours. It is clear from the above mentioned studies that incidence of sore throat is more frequent after tracheal intubation than I-gel insertion probably due absence of inflatable cuff in I-gel. Our study also support this observation because in our study incidence of post oprerative sore throat in ET tube group was 6.3% whereas in I-gel group it is 0%. So, this finding is not significant in statistical point of view. Post-operative sore throat can be minimized to some extent by lubricating the tube with water soluble jelly, careful airway instrumentation, intubation only when patient is fully relaxed, careful suctioning technique, and extubation when the tracheal tube cuff is fully deflated. In our study there was no incidence of post-operative laryngospasm or aspiration in both the groups.

CONCLUSION

After conducting the study we came to conclusion that time taken to insert I-gel is significantly less than that

of endotracheal tube. I-gel causes significantly less haemodynamic perturbations than endotracheal tube at various time intervals. I-gel shows similar efficacy like endotracheal tube in maintaining ventilation and oxygenation status during general anaesthesia. Both the devices have their own profile of complications which need to bedealt with vigilance and caution. Hence, we conclude that I-gel is an effective and safe alternative to endotracheal tube for airway management in adult patients undergoing elective abdominal laparoscopic surgery under general anaesthesia.

Financial support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

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TABLES

Table 1: Demographic characteristics

Parameters	Group I (Mean±SD)	Group E (Mean±SD)	P-Value
Age in years	35.89± 9.05	35.06±8.81	0.6489(NS)
Weight in Kg	55.47±4.19	56.37±3.68	0.2688(NS)
Height in metre	1.59±0.06	1.59±0.05	0.9219(NS)
BMI (Kg/M^2)	22.83±1.38	22.60±1.50	0.611 (NS)

Table 2: Distribution of Haemodynamic parameters in two Groups

Parameters	Group I (Mean±SD)	Group E (Mean±SD)	P-Value
Baseline Heart Rate	80.14±7.42	82.25±5.40	0.1158(NS)
Heart Rate after placement	88.14±9.13	104.37±7.96	<0.01 (HS)
Heart rate at 3 min	83.60±7.90	94.70±5.11	<0.01 (HS)
Heart rate at 5 min	81.37±7.15	86.91±4.84	<0.01 (HS)
Heart rate at 10 min	82.29±7.42	84.10±5.54	0.6352(NS)
Heart rate at removal	82.50±7.00	93.60±4.77	<0.01 (HS)
Heart rate 5 min. after removal	82.64±7.38	83.33±5.03	0.0854(NS)
Baseline Systolic BP	123.41±7.33	122.68±7.86	0.6395(NS)
SBP after placement	136.85±11.74	145.08±9.15	<0.01(HS)
SBP at 3 min	131.31±12.70	139.83±5.85	<0.01(HS)
SBP at 5 min	124.14±10.05	127.85±6.12	<0.01(HS)
SBP at 10 min	123.45±6.50	122.85±7.29	0.6693(NS)

SBP at removal	124.16±8.06	138.52±7.16	<0.01(HS)
SBP 5 min after removal	123.54±6.50	122.68±8.05	0.5687(NS)
Baseline Diastolic BP	82.31±4.76	82.39±4.52	0.930(NS)
DBP after placement	93.02±8.41	98.33±6.11	<0.006(HS)
DBP at 3 min	82.79±3.87	94.31±5.47	<0.01(HS)
DBP at 5 min	82.72±4.60	82.70±4.35	0.981(NS)
DBP at 10 min	82.72±4.10	82.50±5.25	0.812(NS)
DBP at removal	83.33±7.76	92.72±4.35	<0.01(HS)
DBP 5 min after removal	82.62±6.46	82.58±3.66	0.965(NS)

Table 3: Distribution of mean EtCO2 in different time interval in twogroups

		Number	Mean	SD	Minimum	Maximum	Median	p-value
EtCO2 (mmHg) after placement	GRP1- I	48	35.6667	2.3460	32.0000	39.0000	36.0000	0.4421
	GRP2-E	48	36.0000	1.8566	33.0000	39.0000	36.0000	
EtCO2 (mmHg) 3min	GRP1- I	48	39.8542	1.3525	37.0000	43.0000	40.0000	0.0350
	GRP2-E	48	40.4375	1.3194	38.0000	43.0000	40.0000	
EtCO2 (mmHg) 5min	GRP1- I	48	38.6042	1.6726	34.0000	41.0000	38.5000	0.0009
	GRP2-E	48	39.6250	1.1962	38.0000	42.0000	40.0000	
EtCO2 (mmHg)10min	GRP1- I	48	36.3333	1.8604	34.0000	40.0000	36.0000	0.0756
	GRP2-E	48	36.8958	1.1155	35.0000	39.0000	37.0000	
EtCO2 (mmHg) justbefore removal	GRP1- I	48	35.2083	1.8561	32.0000	38.0000	35.0000	0.2669
	GRP2-E	48	35.6042	1.6077	33.0000	38.0000	36.0000	

Table 4: Post-operative complications in two groups

Parameters	Group I (Mean±SD)	Group E (Mean±SD)	P-Value
Postoperative cough	0	3	0.240(NS) Chi-Square test
Post-operative sore throat	0	3	0.240(NS) Chi-Square test
Laryngospasm and Aspiration	0	0	