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A Comparative study between the I-gel and the Endotracheal Tube in Patients Going Through the Laparoscopic Cholecystectomy

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Abstract

Background: Because the I-gel as a supraglotic airway devices can produce high oropharyngeal seal pressure and also gastric decompression, have been used in patients who would have been usually intubated for general anesthesia, This study was designed to compare safety and efficacy I-gel with tracheal tube in patients undergoing laparoscopic cholecystectomy. Materials & Methods: Sixty patients, class I or II ASA, who were candidates for elective cholecystectomy recruited to this study to one of the two groups of 30 patients each; with either I-gel or tracheal tube as their airway device. Ease, and the number of attempts for insertion of airway device, the difference between the inspired and expired tidal volumes, which was calculate as the leak volume. The leak fraction was defined as the leak volume divided by the inspired tidal volume, were recorded and compared among two groups. Results: The first attempt success rate was similar with both I-gel and tracheal tube. There was significant difference between the leak volume of the i-gel and the tracheal tube groups(p=0.001).We had also found significant difference in leak fraction(p=0.001).Despite these significant different, ventilation and oxygenation was optimal in both of two groups. ETCO2 during C02 pneumoperitoneum was between two groups was not significant (p=0.78). The airway pressure among I-gel group and tracheal tube group during C02 pneumoperitoneum was significantly different(p=0.04). Sore throat was significantly higher in tracheal tube group than I-gel group (p=0.02). Conclusion: The results of this study demonestrated that the I-gel is a valuable substitute to endotracheal intubation for controlled ventilation during laparoscopic cholecystectomy.

Key words: I-gel, Endotracheal tube, Sealing pressure, laparoscopic cholecystectomy.

Introduction

Although the endotracheal tube (ETT) is regard as gold standard for airway management, in recent times a number of supraglottic airway devices (SADs) particularly second generation of them are commonly used in clinical practice. These devices have various benefit beyond the tracheal tube concerning to, ease of insertion, less hemodynamic unstability, good respiratory mechanics and reduced airway

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morbidity. (Cork et al., 1994; Bhatt et al., 1992; Higgins et al., 2002) However there are some suspicions about the use of SADs with positive pressure ventilation (PPV) such as laparoscopic procedures, because after carbon dioxide pneumoperitoneum the airway pressures may increases above the oropharyngeal seal pressure (OSP) of the used SADs, and result in insufficient ventilation, gastric insufflation and increased risk of regurgitation and even pulmonary aspiration. (Sharma et al., 2010; Cooper, 2003) The I-gel (Intersurgical Ltd, Wokingham, UK) is a novel supraglottic airway device, it was invented by Mohammad Aslam Nasir in 2007, it made of thermoplastic elastomer which is soft, gel-like, and transparent. it does not have an inflatable cuff. The rim of the mask is designed to adapt to the anatomical shape of the larynx, and can produce an airtight seal without the cuff mechanism. The tube is contained of two conduit, where it is possible to intubate the trachea through the breathing channel and to placement of a gastric tube by the drain channel. Prior studies have demonestrated that insertion of this devices could be very easy with sufficient sealing pressures. Therefore it has been built for use with spontaneous as well as ppv. (Asai and Liu, 2010; Wharton et al., 2008; Uppal et al., 2009)

Since, there is only limited studies about use of the I-gel as a safe instead of tracheal intubation in anesthesia with (positive pressure ventilation) PPV, (Uppal et al., 2009; Badheka et al., 2015; Maharjan, 2013) our trial designed to whether I-gel as alternative to tracheal tube can creates adequate laryngeal seal in patients undergoing elective laparoscopic cholecystectomy and comparing the others safety and efficacy these two devices.

Materials and Methods

Study design and participants

This prospective, randomized, single blind clinical trial study was conducted at Imam Khomeini teaching Hospital between the last part of January and first part of April 2019 in Urmia, Iran. The project was reviewed and approved by Urmia University of Medical Sciences Institutional Board. Medical ethics research committee of Urmia Medical Sciences University also approved the design of study [approved project No. 1394.386 (IR.umsu.vec); IRCT number=20160430027677N10 (www.irct.ir)]. The aim of the study and possible harm were explained to patients and all of them have signed the consent form to confirm their awareness of all procedures. Patients of either sex who were comparable with American Society of Anesthesiologists physical status (ASA) I or II (http://www.asahg.org/clinical. physicalstatus.htm), aged 18–60 years, candidate for elective laparoscopic cholecystectomy under general anaesthesia were enrolled in the study. The exclusion criteria included: age<18yr, presence of any significant acute or chronic lung disease, predictors of difficult intubations, increased risk of aspiration (non fasted, hiatus hernia, gastroesophageal reflux disease), patients with body mass index(BMI) >35 kg/m2 . Sixty patients were recruited as eligible population and assigned to airway placement of the one of two groups, Tracheal tube or I-gel by using computer generated numbers. A concealed envelope was used to assign participants for each arm. A trained nurse was responsible for randomization. In this study the primary outcome was calculating sealing sufficiency of the I-gel as alternant to the ETT that was defined as the leak fraction. The leak fraction was determined by leak volume divided by inhaled tidal volume (LF=LV/IVT). The leak volume (LV) that is difference between inhaled (set) tidal volume (ITV) and exhaled tidal volume (ETV), the number of attempts required for insertion of airway device, airway leak pressure in I-gel group, measurement of airway pressure, ETCO2 before and after CO2 insufflation ,pulmonary aspiration, and the side effect due to airway placement in both of two groups were considered as secondary outcomes.

Study protocol

After arrival to the operating room, standard monitoring including electrocardiography, noninvasive blood pressure cuff, pulse oximetry, and end-tidal CO2 for vital sign recording; and intravenous line were established. After premedication with midazolam 0.02 mg/kg and fentanyl 2 μg/kg anesthesia was induced with propofol 2 mg/kg, on loss of conciseness for full relaxation of patients, 0.6mg/kg atracurium was administred, then the selected airway device (ETT or I-gel) was inserted. The selected airway device (ETT or I-gel) was inserted by a single and experienced anesthesiologist based on appropriate size. In I-gel group, placement of the I-gel was performed based on manufacturer's guidelines. Size choosing was coincidence with patient's weight (weight < 50 kg: I-gel size 3; 50-70 kg: size 4; and > 70 kg: size 5). In Tracheal group, ETT with Size 8 or 8.5for male patients and size 7or 7.5 for female airway were selected and secured with laryngoscopy –guided. Successful placement of the airway devices and adequate of positive-pressure ventilation were assessed by observing the end-tidal carbon dioxide waveform and chest movements by manual ventilation, bilateral equal air entry on auscultation, and normal SpO2 (>95%). Gastric insufflation was recorded by auscultation over the epigastrium after manual ventilation and mechanical ventilation. In I-gel group airway leak pressure was measured after closing the adjustable pressure limiting valve with a fresh gas flow of 3li/min in circuit system, when there was an audible gurgling sound indicating an air leak from throat. This pressures was not allowed more than 40 cm H2O.

The number of attempts required for airway placement was recorded. A 'failed attempt' was defined as removal of the device from the mouth before re-insertion. After fixing the airway device, appropriate sized gastric tube was inserted. Anesthesia was maintained with isoflurane 1-1.5 MAC, 50% oxygen with air, and administration of intermittent doses of atracurium. Controlled ventilation was provided

with tidal volume of 7-10 ml/kg and respiratory rate set to obtain an end tidal carbon dioxide (EtCO2) 35 -45 mmHg and oxygen saturation ≥95%.

In this study the difference between inhaled(set) tidal volume(ITV) and exhaled tidal volume (ETV)determined as leak volume(LV), and the. The leak fraction was leak volume divided by inhaled tidal volume (LF=LV/IVT) as leak fraction were recorded in all of patients. We also measured airway pressure and ETCO2 before and after CO2 insufflation in both of two groups. Monitoring of PR, MBP, SpO2, EtCO2, and ECG was done throughout the perioperative period.

At the end of anesthesia neuromuscular blockade was reversed with atropine0.02µg/kg and neostigmine 0.04 mg/kg. Removal of I-gel/ETT was done after recovery of adequate spontaneous respiration and muscle tone, and any visible blood on the device for assessment of airway truma was noted. In the recovery unit patients were interviewed 45 min later in the recovery unit by a blinded independent observer for sore throat, dysphonia or dysphagia.

Sample size

We are planning a study with 60 experimental subjects and 60 control subjects. In a previous study (Uppal et al., 2009) the response within each subject group was normally distributed with standard deviation 0.15. If the true difference in the experimental and control means is 0.015, we will be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) .084.The Type I error probability associated with this test of this null hypothesis is 0.05.

Statistical Analysis

Data was collected during nearly three months. In descriptive analysis we used mean ± standard deviation for continuous variables and frequency for categorical variables. In order to compare outcomes in two groups, independent t-student test was used to compare categorical variables and chi square was applied to comparison of categorical variables between two groups.

Results

Sixty patients were participated in this study, the mean (SD) sex, age, weight, duration of surgery and anesthesia of two groups are demonestrated in Table 1. There was not significant difference between these data.

Airway pressure before CO2 pneumoperitoneum was20.76± 2.35 cmH20 in I-gel group and 19.86±0.89 cm H20 in tracheal tube group with insignificant difference (p=0.39). Following CO2 pneumoperitoneum this pressure was 25.50± 3.27 cmH20 in I-gel group and 23.23±1.30 cm H20 in tracheal tube group (p=0.001). The airway pressure steadily raised after CO2 insufflation in both group(Table 2). On analysis of EtCO2 previous and after CO2 pneumoperitoneum we had comparable tendency(Table 2).

The leak volume between two groups, had significant difference as 28.83±19.55 in i-gel group and 10.66±8.6 in ETT group (p=0.0001). Furthermore leak fraction between patients of two groups was significantly different, it was 0.04±0.03 in i-gel group and 0.01±0.01 in ETT group (p=0.0001),These data are demonestrated in Table 2.

The mean airway leak pressure for i-gel was 26(19.5-33.5) cmH2o with auscultation method. Airway leak pressures for all intubated group consistently reached 40 cm H2O.

All of the i-gel were placed at the first attempt.

six patients In I-gel group and 12 in ETT group had sore throat, with significant differences (P=0. 02). On removal, visible blood was observed on 4 I-gel(%13.5). None of patients in two groups had dysphagia or dysphonia.

Table 1. Baseline demographic and clinical characteristics among patients

Characteristics	I-gel group(n=30)	ETT group(n=30)	P.value
Age(y)	39.43 ± 12.46	40.16 ± 12.93	0.82
Male/ Female	6/24	7/23	0.5
Weight(Kg/m2)	62.76 ± 7.55	63.63± 7.44	0.65
Surgery time (min)	46.23 ± 5.50	48.46± 6.87	0.27
Anesthesia (min)	54.90±10.64	59.50±14.70	0.17

Data are presented as Mean±SD or 95% CI

Table 2. Airway pressure, End tidal CO2,Leak volume, Leak fraction

Characteristics	I-gel group(n=30)	ETT group(n=30)	P.value
ETCO2(mmHg) before CO2 insufflation	29.60± 2.54	30.06±1.38	0.38
ETCO2(mmHg)after CO2 insufflation	34.73±3.16	34.56± 1.04	0.78
Airway pressure(mmHg) before CO2 insufflation	20.76±2.35	19.26±1.36	0.39
Airway pressure(mmHg) after CO2 insufflation	25.50± 3.27	23.23± 1.30	0.001
Leak volume(ml)	28.83±19.55	10.66±8.68	0.001
Leak fraction(ml)	0.04±0.03	0.01±0.01	0.001

Data are presented as mean ± SD or 95% CI

Discussion

Laparoscopic surgery has been shown to negatively act on intraoperative respiratory mechanics, thus the effectiveness of airway device is very important. (Maltby et al., 2002) Tracheal intubation is as ideal for airway management in laparoscopic surgeries, because it serves adequate ventilation and prevent pulmonary aspiration even in the presence of raised airway pressure due to pneumoperitoneum. In the other hand, this instrument is not completely safe versus aspiration. In addition to endobronchial intubation is not unusual during laparoscopic procedures, and in difficult airway condition this may be unsuccessful. For these reasons, recently there has been tendency towards switching of tracheal tube with a supraglotic devices (SADs) for controlled ventilation in patients with low risk of aspiration. Some studies have demonestrated I-gel and the other extraglotic devices (EGDs) can overcome some of these challenges, even in obese patients and in those who need high airway pressure for acceptable ventilation. (Sharma et al.,2010)

In this study, we compared the safety and efficacy of the ETT and I-gel in laparoscopic cholecystectomy procedure. We found that both the ETT and I-gel were placed identically fast and simply, also two devices had equally to first attempt insertion success. I-gel without inflatable cuff may be vulnerable to gas leak during controlled ventilation, in our study leaks volume and leak fraction were significantly higher in I-gel group than ETT group, and we thought, a part of the difference perhaps caused by the compliance of the respiratory system. Despite significant statically differences between two groups. There was not clinically different about oxygenation and/or ventilation between themes. Indeed, Uppal *et al.* (2009) had earlier determined that the I-gel was a competent to tracheal tube during pressure controlled ventilation employing moderate airway pressures up to 25 cm H2O, with no considerable gas leak. The reason for this difference between results could be use of volume controlled ventilation instead of PCV In our study. In the other Maharjan was showed leak volume and leak fraction between I-gel and ETT groups were similar, cause of this discrepancy is not clear, but clinical results between two studies was equal. (Maharjan, 2013)

Because the I-gel formed an adequate seal around the glottis, it can provide adequate oxygenation during controlled ventilation as well as tracheal intubation. Oxygenation and ventilation and the others vital signs were favorable in all of patients in every part of surgery and anesthesia as well as in post-operative duration. Our results about ETCO2 before and after CO2 pneumoperitoneum were identical with the earlier investigation have been done by Maltby *et al.* (2002) Lu *et al*. (2002) who compared proseal LMA with ETT and classic laryngeal mask(CLMA) respectively.

Mean leak pressure in I-gel group was 26cm of H2O, which is upper than those of the usual LMA(20 cm H2O), and this higher airway leak pressure suggested better seal and I-gel was substitute to the LMA- Unique for controlled ventilation. (Francksen et al., 2009) This finding was consistent with Uppal et al study. (2009)

since the laparoscopic surgery result in increase of intra-abdominal pressure, usually 15 mm Hg, the patients undergoing this procedure conceivability are at risk of manifestation pulmonary aspiration. (Versichelen et al., 1984) However, the increased intra-abdominal pressure leads to increment in the tone of the lower esophageal sphincter, which allows keeping of the pressure gradient between the gastro-esophageal junction, that which could be decrease the risk of regurgitation and/or aspiration. (Lind et al., 1966; Halevy et al., 1994)

In the current study, we did not observe the gastric insufflation, regurgitation, or pulmonary aspiration during surgery in each of patients in two groups. Some of the previous studies were showed similar results. (Uppal et al., 2009; Badheka et al., 2015; Maharjan, 2013) We had no cases of failed insertions. In present study the visible blood on the I-gel after removal, was 4/25(13.5%). This is similar to those reported with others SAD. The frequency of visible blood with the use of other SAD has been demonestrated from 12% to 18%; depends on kind of SAD, the method and simply of insertion. (Inagawa et al., 2002; Van Zundert et al., 2006)

This study had some limitations which affect the interpretation of these data. First there was airway selection bias by the anesthesiologist, which was not possible to eliminate, since the anesthesiologist was aware of the device he was using, because there was difference in

shape among the devices. Second, all airway placement were achieved by a skilled anesthesiologist; thus, our outcomes may not be valid to beginner users. Third, patients recruited in this study had normal airways; thus, no conclusions can be consider to patients who had difficult airway. Finally, our study was accomplished on a small population of patients large enough, while a larger sample size is required, to reach better results.

Conclusion

Based this study we concluded that despite a large gas leak in small of part of patients, I-gel can provide optimal ventilation and oxygenation as endotracheal intubation for positive pressure ventilation. Thus I-gel can be used successfully in laparoscopic cholecystectomies with appropriate patients and trained user instead of the endotracheal tube.

Conflict of Interest:

There is no conflict of interest to be declared.

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Ethical approval

The Trial was registered at the Iranian Registry of Clinical Trials (http://WWW.irct.ir) with IRCT number: IRCT2016112027677N5

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Disclosures

Authors have no conflict of interest or financial consideration.

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