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Original Article

I-Gel as an Alternative to Endotracheal Tube in Gynecologic Laparoscopic Surgeries: A Comparative Study

Sara Farzadi[1], Reyhaneh Shahrokhi Rad[2], Kian Khanjani[3], Hiva Varshavian[3], Soheil Soltanipour[4], Gelareh Biazar[2]* and Samaneh Ghazanfar Tehran[2]

1. Reproductive Health Research Center, Department of Obstetrics and Gynecology, Al-Zahra Hospital, School of Medicine, Guilan University of Medical Sciences, Rasht, Iran
2. Anesthesiology Research Center, Department of Anesthesiology, Al-Zahra Hospital, Guilan University of Medical Sciences, Rasht, Iran
3. Student Research Committee, School of Medicine, Guilan University of Medical Sciences, Rasht, Iran
4. Department of Community Medicine, School of Medicine, Guilan University of Medical Sciences, Rasht, Iran

Abstract

Background: Endotracheal Tube (ETT) intubation with rigid laryngoscopy evokes significant hemodynamic changes. Therefore, it is crucial to find an alternative for specific conditions like an irritative airway. For this purpose, the safety and efficacy of I-gel in gynecologic laparoscopic surgeries was examined.

Methods: This clinical trial was conducted at Al-Zahra Hospital affiliated with Guilan University of Medical Sciences (GUMS) from July 2023 to May 2024. Eligible women, aged 18 to 55 years, ASA class I and II, were randomly divided into two groups of I-gel and ETT. Hemodynamic status, ease of device placement, ventilation parameters and complications were compared between the two groups.

Results: Finally, the data from 92 women were analyzed. In terms of patients' demographic data ($p>0.05$), surgery duration ($p=0.730$), surgeons' satisfaction ($p=0.655$), airway pressure ($p=0.804$), leak volume ($p=0.430$), $ETCO_2$ values ($p=0.957$) and side effects ($p< 0.05$), the results showed no significant difference between the two groups. Easy insertion was observed among 80.4% of the patients in I-gel group and in 93.5% in ETT group ($p=0.063$). Regarding the hemodynamic parameters, including Heart Rate (HR) and Mean Arterial Pressure (MAP) values, the difference was not significant in any of the measurement times ($p< 0.05$).

Conclusion: I-gel could be suggested as a safe alternative to ETT in special conditions in laparoscopic surgeries.

Keywords: Arterial pressure, Hemodynamics, Intratracheal intubation, Laparoscopy, Laryngoscopy, Patient satisfaction, Respiration

*** Corresponding author**
Gelareh Biazar, MD
Anesthesiology Research Center, Al-Zahra Hospital, Guilan University of Medical Sciences, Rasht, Iran
Tel: +98 911 1350987
Email: gelarehbiazar1386@gmail.com

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Introduction

Laparoscopic surgery has extended from minor diagnostic procedures to advanced therapeutic urological, gynecological and gastrointestinal surgeries (1). In laparoscopic surgery under General Anesthesia (GA), airway management with tracheal intubation is accepted as the gold standard method. However, Endotracheal Tube (ETT) is associated with severe hemodynamic responses including tachycardia, hypertension, and increased cardiac workload as well as damage to oropharyngeal structures, hoarseness, laryngeal edema and bronchospasm. Today, with the availability of Supraglottic Airway Devices (SADs) with different capabilities, they have been discussed as an alternative to ETT (2,3). SADs are known to induce minimal hemodynamic changes, less irritating the airway and no compression trauma, thus they are specially suitable for patients with ischemic heart disease, hypertension and hyperactive airway conditions (4). I-gel is a second-generation SADs that has gained great popularity in the field of airway management. It is a single-use device with different sizes according to patient's weight. It is a structured device with airway anatomy and fits on top of the larynx with a soft and non-inflatable cuff made from an elastomer gel. This device also has a narrow channel for drainage, which provides greater safety against aspiration (5). It has been suggested that high intra-abdominal pressure during laparoscopic surgery increases the risk of aspiration, but research has shown that a gradual increase in intra-abdominal pressure is associated with an adaptation in the lower esophageal sphincter function, thereby preventing the regurgitation of stomach contents (6). Although there are few case reports of aspiration with SADs use, it has been suggested that it is likely to be due to insufficient experience of anesthesiologists in placing the device and choosing the proper type according to patients' conditions. Among the features of gynecological laparoscopic surgeries, which make the conditions favorable for airway management with SADs, one can mention the elective nature of the operation, acceptable duration, the need for the Trendelenburg position of about 15 degrees. Considering the importance of investigating the safety and efficacy of SADs as an alternative to ETT in special cases, this study was planned with the aim of comparison of I-gel and ETT in women undergoing gynecological laparoscopic.

Materials and Methods

This prospective, comparative single-blind, randomized trial with ID number IRCT20170314033069N6 was conducted in Al-Zahra Hospital, an academic and tertiary center in Northern Iran from July 2023 to May 2024. Firstly, the study protocol was approved by institutional ethical committee of GUMS (IR.GUMS.REC.1402.243) and informed consent was obtained.

Inclusion criteria

Women scheduled for elective gynecologic laparoscopic surgeries including myomectomy, hysterectomy, diagnostic surgeries under GA, aged 18–55 years, American Society of Anesthesiologists (ASA) Physical Status 1 (no medical comorbidities) or 2 (one or more medical comorbidities which do not impact the patient's function).

Exclusion criteria

Women with pathology in upper respiratory tract, cervical spine disease, anticipated difficult airway, and obese patients [with Body Mass Index (BMI) >35 kg/m^2]; patients with significant acute or chronic lung disease, and preoperative sore throat, and patients with a high risk of regurgitation and aspiration and all emergency surgeries mouth opening <2.5 *cm* pregnant women constituted the exclusion criteria.

The sequence of randomization blocks was performed in a ratio of 1:1 created by a computer (Win Pepi 11.65 software). The patients were divided into two groups of Group A; laryngoscopy-guided ETT and Group B, in which the airway was secured by I-gel. A nurse who did not participate in the project performed the allocation through the list of eligible women. Arriving at the operating room,

standard monitoring including peripheral oxygen saturation (SpO_2), Electrocardiogram (ECG) Non-Invasive Blood Pressure (NIBP) and End-Tidal Carbon Dioxide ($ETCO_2$) were applied. Premedication was done with midazolam 0.01 *mg/kg* and fentanyl 3 *μg/kg* IV. After 5 *min*, the patients were induced with propofol 1.5 *mg/kg* IV and atracurium 0.5 *mg/kg* IV. Trendelenburg positioning was performed between 30 and 45 degrees, according to the surgeon's request. In both groups, the appropriate size of the device (ETT or I-gel) was selected and placed by an experienced anesthesiologist. The manufacturing company had determined the size of I-gel based on the patients' weight. Accordingly, it is suitable for patients weighing 30-50 *kg* No. 3, 50-90 *kg* No. 4 and above 90 *kg* No. 5. The proper position of the device was assessed on the manual ventilation, and it was confirmed by symmetrical chest expansion, bilateral equal air entry sounds, absence of leak sounds, SpO_2>95% and normal $ETCo_2$ waves. After securing the airway, a gastric tube was fixed. Ease of insertion of the device was defined as Easy: insertion with no resistance through a single maneuver; Difficult: resistance to insertion or the need to more than one try, and Impossible: unable to insert I-gel/ETT in the pharynx. If I-gel was not placed correctly, neck flexion, jaw thrust, and head extension were performed, and if the problem were not resolved, the device was removed. If adequate ventilation was not established after two attempts, the procedure was considered as failure and the patient was excluded from the study. Airway pressure (*cm* H_2O), leak volume was calculated by subtracting inspiratory and expiratory tidal volume. During the operation, the satisfaction of the surgeon was assessed by the scoring system from 0 presented as empty stomach to 10; a completely distended stomach. In this way, the number zero was considered as complete satisfaction, a score of 1-3 as good satisfaction, a score of 4-6 as moderate satisfaction, and a score of 7-10 poor satisfaction. Anesthesia was maintained with O_2, Isoflurane 1% and controlled ventilation was performed with tidal volume of 6-8 *ml/kg* and respiratory rate was adjusted to maintain $EtCO_2$ between 35 and 45 *mmHg*. At the end of the surgery, atropine 0.02 *mg/kg* and neostigmine 0.04 *mg/kg* were administrated to reverse the effects of neuromuscular blockade . and after adequate muscle tone, the I-gel/ETT was removed. Hemodynamic parameters including Pulse Rate (PR), Mean Arterial Pressure (MAP), SpO_2, $ETCO_2$, and ventilation profile were recorded at six measurement point times including; before induction (baseline), just after I-gel insertion/intubation, before, 15 *min* after pneumoperitoneum, just after release of pneumoperitoneum and after I-gel removal/extubation. Adverse events such as coughing, laryngospasm, nausea and vomiting, regurgitation, aspiration, injuries (to lip, teeth, and gum), sore throat, dysphagia and dysphonia were recorded as well.

Statistical analysis

Statistical analysis was performed by IBM® SPSS® Statistics 21. and the collected data were analyzed. In case of normal data distribution, T-test was used to compare the means in two groups. To compare the nominal data, Chi-square test was applied. Student's t-test was used to compare the data between the two groups at different point times of the study. Repeated measure ANOVA test was utilized to analyze the quantitative repeated values. The results were expressed as mean±standard deviation and a p-value less than 0.05 was considered significant.

Ethical considerations

This clinical trial was approved by the Ethics Committee of Guilan University of Medical Sciences (IR.GUMS.REC.1402.243) and registered in Iran's clinical trial registration system with the number IRCT20170314033069N6. Informed consents were taken from all the participants before enrolment.

Sample size

Based on the study of Lai *et al* (7), and considering the mean and standard deviation of the airway pressure variable in two groups, the minimum sample size of 46 patients in each group was calculated. The power

of study was kept at 80% and Confidence Interval (CI) at 95%.

Results

Finally, 92 eligible women completed the survey. In the I-gel group, three patients were excluded due to the lack of proper ventilation in Trendelenburg position. In terms of patients' demographic data and surgery duration, there was no significant difference between the two groups (Table 1). Surgeons' satisfaction (p=0.655), had no significant difference between the two groups. Easy insertion was observed among 80.4% of the patients in I-gel group while in 93.5% in ETT group (p=0.063) (Table 2). Regarding the hemodynamic parameters, although higher HR (p=0.054) and MAP (p=0.039) values were recorded in group A at T1 to T4, the difference was not significant (Table 3). No statistically significant difference was observed in terms of the side effects between the two groups. Comparing the two groups, in terms of airway pressure (p=0.804), leak volume (p=0.430) and $ETCO_2$ values (p=0.957), the difference was not statiatically significant (Table 4).

Discussion

Studies have shown that, SADs may overcome some of the complications of ETT in laparoscopy surgeries, even in cases requiring high airway pressure. In few cases, nerve injury following the prolonged use of I-gel have been reported (8,9). But overall the majority of the studies confirmed its safety (10). In this study, unlike some other studies, there was no significant difference between the two groups in terms of hemodynamic status except one-point time. This finding indicates that the appropriate depth of anesthesia was maintained in accordance with the intensity of stimulation during surgery. Supporting the Shukla *et al* study, no significant difference was observed between the two groups in terms of adverse effects (11), and none of the patients were affected

Table 1. Patients'demographic data and surgery duration BMI: Body Mass Index

Values		I-gel (n=46)		Tracheal tube (n=46)		p-value
Age (Year) Mean±SD		8.05±34.39		7.62±33.02		0.404
BMI (kg/m^2) Mean±SD		2.52±27.22		1.96±27.05		0.714
ASA	I	34	73.9	36	78.3	0.625
	II	12	26.1	10	21.7	
Duration of surgery (*min*) Mean±SD		13.88±60.65		13.92±59.89		0.73
Thyro-mental distance (*cm*) Mean±SD		0.56±7.12		0.45±7		0.227
Opening the mouth (*cm*) Mean±SD		0.58±4.38		0.57±4.52		0.231

Table 2. Surgeon satisfaction and airway insertion characteristics

Values	Status	I-gel (n=46)	Tracheal tube (n=46)	p-value
Surgeon's satisfaction	Complete satisfaction (zero score)	6(13)	7(15.2)	0.655
	Good satisfaction (1-3 points)	27(58.7)	31(67.4)	
	Average satisfaction (score 4-6)	9(19.6)	6(13)	
	Poor satisfaction (score 7-10)	4(8.7)	2(4.3)	
Establishing airway	Easy	37(80.4)	43(93.5)	0.063
	Difficult	9(19.6)	3(6.5)	

Table 3. Comparing hemodynamic parameters between the two groups in 6-point times (T0-T5)

Point times	I-gel (n=46)	Tracheal tube (n=46)	p-value
	Mean Arterial Pressure		
Baseline	6.12±79.1	5.62±79.52	0.737
After I-gel insertion/intubation	6.18±81.28	6.78±84.39	0.024
Before pneumoperitoneum	6.93±79.23	8.5±79.52	0.892
15 minutes after pneumoperitoneum	7.25±82.28	9.21±83.21	0.59
After release of pneumoperitoneum	6.54±78.91	8.2±79.26	0.823
After I-gel removal/ extubation	6.72±78.5	8.07±79.04	0.827
Intergroup statistical estimation		**p=0.039**	
	Heart rate		
Baseline	5.55±92.84	7.4±94.54	0.217
After I-gel insertion/intubation	5.42±94.82	8.59±98.29	0.023
Before pneumoperitoneum	5.4±93.06	7.55±93.38	0.816
15 minutes after pneumoperitoneum	5.22±91.96	5.78±93.81	0.112
After release of pneumoperitoneum	4.49±93.26	5.65±94.26	0.35
After I-gel removal/ extubation	4.32±92.59	5.96±93.21	0.569
Intergroup statistical estimation		**p=0.054**	
	SaO2		
Baseline	1.14±98.43	1.31±98.56	0.613
After I-gel insertion/intubation	1.04±98.6	1.09 ±98.67	0.771
Before pneumoperitoneum	0.97±98.73	1.04±98.86	0.816
15 minutes after pneumoperitoneum	1.16±98.19	1.33±98.34	0.538
After release of pneumoperitoneum	1.2±98.47	1.22±98.58	0.562
After I-gel removal/ extubation	1.08±98.8	1.12±98.71	0.708
Intergroup statistical estimation		**p=0.718**	

Table 4. Ventilatory parameters of tracheal tube and I-gel

Point times	I-gel (n=46)	Tracheal tube (n=46)	p-value
	$ETCO_2$ *mmHg*		
After I-gel insertion/intubation	1.12±38.17	1.22±38.21	0.86
Before pneumoperitoneum	0.9±38.26	1.61±38.41	0.579
15 minutes after pneumoperitoneum	1.02±38.19	1.73±38. 3	0.716
After release of pneumoperitoneum	1.22±38.5	1.63±38.63	0.666
Intergroup statistical estimation		p=0.957	
	Air way pressure (cmH_2O)		
After intubation	0.94±16.66	1.41±17	0.177
Before pneumoperitoneum	1±16.7	1.57±16.91	0.45

Contd. table 4

15 minutes after pneumoperitoneum	0.83±19.82	1.16±20.11	0.175
After release of pneumoperitoneum	0.91±17.99	1.34±18.26	0.27
Intergroup statistical estimation		p=0.804	
Leak volume			
After intubation	0.31±15.54	0.3±15.48	0.322
Before pneumoperitoneum	0.78±16.54	0.89±16.58	0.805
15 minutes after pneumoperitoneum	0.77±19.63	0.88±19.51	0.478
After release of pneumoperitoneum	0.61±16.26	0.66±16.06	0.122
Intergroup statistical estimation		p=0.430	

by significant complications, such as regurgitation or aspiration as known concerning related adverse events (12).

It was also observed that I-gel did not cause obvious gastric insufflation and difficulty in the field of surgery which supported previous studies (13,14). It should be noted that in this study, the proper size of the I-gel was chosen according to the manufacturer's recommendations, with some degree of overlap of course and patient's thyromental distance and mouth opening. Studies had previously showed the efficacy and safety of the I-Gel size-4 in 100 non-paralyzed patients weighing 42-113 *kg* (15). No Significant difference was observed between the two groups in terms of the peak airway pressure and air leak between the two groups. This finding was in contrast with Lai's study (7). I-gel was placed in 1st attempt in 37.46 (80.4%) of the cases, and ETT in 43/46 (93.5%) cases with no significant difference, which was in line with Badheka's study (3) and in contrast with Dhawan's study that reported the superiority of I-gel in this regard (16). Zuberi *et al* compared I-gel and ETT in terms of efficacy and safety in laparoscopic cholecystectomy. They reported that I-gel required less time for insertion and causes fewer hemodynamic fluctuations. In addition, peak airway pressure was also higher in ETT group (17). Jian *et al* conducted a study to compare Baska Mask with I-gel regarding insertion parameters and oropharyngeal leak pressure in laparoscopic gynecological surgeries. They found that Baska Mask was more difficult to insert and with more postoperative laryngopharyngeal morbidity but provided more effective ventilation compared to I-gel (18). In Goyal *et al*'s study it was revealed that I-gel could be used successfully in elective laparoscopic gynecological surgeries under general anesthesia with excellent insertion conditions and positive pressure ventilation (19). Sule *et al* compared the two SADs, I-gel and Proseal Laryngeal Mask in terms of hemodynamic profile, ease of insertion, ventilatory parameters and adverse effects in patients undergoing diagnostic laparoscopic procedures. They found that both devices provided effective and safe ventilation during abdominal insufflation. I-gel had a better hemodynamic stability and less postoperative complications whereas PLMA provided a better oropharyngeal seal (4). Despite the concerns about the use of I-gel in laparoscopic surgery, the results of this study confirmed its safety and efficacy. The difference between this study and many other studies was that there was no significant difference in the hemodynamic parameters in the two groups, which could be the result of complying with General Anesthesia standards, which include pre-operative visits and preparing the patients for ideal conditions on the day of surgery, maintaining the sufficient depth of anesthesia and tight monitoring of patients during surgery and in the recovery ward. Of course, in this process, proper interaction between surgeon and anesthesiologist is crucial. It should be noted that despite the results of this study and other supporting researches, there are still potential risks of establishing an airway with the SAD in laparoscopic surgeries. Thus, exact case selection should be considered. It is crucial to choose the patient according to NPO times, BMI, airway conditions, and accompanying diseases,

especially neuromuscular problems. Moreover, the experience of the anesthesiologist and surgeon are important. Also, the facilities of the hospital, including the existence and capability of the Intensive Care Unit (ICU) and the availability of the standard monitoring should be considered. Mainly, it should be noted that the purpose of this research was not to replace ETT by SADs, but rather to introduce a safe alternative in specific conditions and pave the way for the use of supraglottic device in situations where laryngoscopy stimulation and intubation can be threatening for the patient such as asthmatic or cardiac disease.

Limitations

Not measuring the level of stress factors and hormonal changes such as adrenaline, noradrenaline and interleukins can be among the limitations of this research.

Conclusion

This study reveals that comparable with ETT, I-gel provides efficient positive-pressure ventilation after the pneumoperitoneum in the Trendelenburg position. It has potential advantages such as lower incidence of post-operative discomfort compared to tracheal tube, also does not cause trouble making gastric insufflations. Thus, I-gel can be widely used as an alternative to endotracheal in patients undergoing short laparoscopic surgeries.

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Informed Consent

Written consent form was completed by the participants.

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Conflict of Interest

There was no conflict of interest in this manuscript.

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