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Comparative Study of I-GEL and Endotracheal Tube in Elective Laparoscopic Gynecological Surgeries under General Anesthesia

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Abstract

Introduction: Laparoscopic procedures have become the need of the hour. Pneumoperitoneum and positional variations in laparoscopy causes alterations in hemodynamic and ventilatory parameters, which results in making the task of anesthesiologist more challenging. Endotracheal tube (ETT) has been the gold standard for induction of general anesthesia but the newer supraglottic airway devices (SADs) (LMA, I-Gel) has increased the armamentarium of anesthesiologists. Our main aim was to compare I-Gel and endotracheal Tube and to consider I-Gel as safe and effective alternative to endotracheal tube for general anesthesia in elective laparoscopic surgeries. **Materials and Methods:** It was a comparative prospective randomized study conducted on 128 patients (ASA I/II) after consent from institutional ethical committee. Patients were divided in two groups 64 each. Group A induced with I-Gel without muscle relaxant and Group B with endotracheal tube after laryngoscopy and muscle relaxant. Alterations in pulse rate, blood pressure were noted down and ease and time of insertion were compared. **Results:** The ease of insertion and the attempts of insertion were comparable but the time of insertion was less with I-Gel with results being statistically significant. The rise in hemodynamic parameters from baseline was more in endotracheal tube intubated patients and so was the incidence of postoperative complications. **Conclusion:** We concluded that I-Gel requires less time for insertion with minimal hemodynamic changes in comparison to endotracheal tube. I-Gel also provided adequate positive-pressure ventilation, comparable with endotracheal tube. Thus I-Gel can be considered safe and suitable alternative to endotracheal tube for laparoscopic surgeries.

Keywords: Endotracheal Tube, General Anesthesia, Hemodynamic Parameters, I-Gel, Laparoscopy

1. Introduction

Laparoscopy is derived from the Greek word "lapara" which means 'flank or loin' and "scope in" which means 'to visualize or to see'. It is an example of 'minimally invasive surgery' in which operative procedures are done with small incisions (0.5-1.5 cm). This surgical technique uses gas insufflations to create a distended abdominal plane and also uses a camera and a scope to visualize abdomen without actually being there[1]. In 1990's it was the field of gynecology which accepted laparoscopy as a novel technique before any other branch of medicine. It has advanced from its use in short, uncomplicated diagnostic procedures to therapeutic ones in all fields of surgery especially gynecology[2–4]. Laparoscopic procedures have become the need of the hour.

Anesthesia is derived from the word 'aesthesis' which means 'insensitivity to perception of pain'. There are different techniques by which anesthesia is provided but still 'general anesthesia' remains the most widely accepted technique in laparoscopic surgeries[5]. Respiratory and cardiovascular changes due to pneumoperitoneum and Trendelenburg position challenges the anesthesiologists to maintain ventilation and circulation during laparoscopic surgeries[6].

General anesthesia simply means inducing medical coma like state with loss of protective reflexes. It provides

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amnesia, hypnosis, analgesia and paralysis which allow surgical interventions without interruption. The advent of inhalational anesthetic gases, endotracheal intubation and laryngoscopy popularized general anesthesia as the best mode of inducing a patient[7].

Securing the airway with endotracheal tube has been the golden standard since decades[8] but however today newer supraglottic airway devices with lesser complications are serving as an alternative to endotracheal tube intubation[9]. Laryngoscopy during endotracheal intubation augments the vasopressor response which causes tachycardia, hypertension and thus increases cardiac workload[10]. Post intubation concerns of sore throat, laryngeal edema and bronchospasm also led to finding of lesser invasive supraglottic devices.

The first supraglottic airway device was a Laryngeal Mask Airway (LMA) which was a combination of a face mask and endotracheal tube. It was first used in 1981[11] and it led to introduction of various other Supraglottic Airway Devices (SAD). I-Gel is a second generation LMA which is gaining popularity as an alternative to tracheal intubation in general anesthesia[12]. I-Gel is a true anatomical device without an inflatable cuff which fits into the laryngeal, pharyngeal and para laryngeal framework mirroring the shape of epiglottis, aryepiglottic folds, pyriform fossa, parathyroid, posterior cartilages and spaces. The non-inflatable cuff snugly fits onto the above structures and provides a tight seal sufficient for maintaining spontaneous as well as intermittent positive pressure ventilation. It was first used by Dr. Muhammad Nasir and it is made up of thermo elastic elastomer making it body temperature sensitive. It also has a gastric channel incorporated in it which provides additional protection against aspiration and regurgitation which in has made it a safe and effective tool for induction in laparoscopic surgeries under general anesthesia[13].

The main aim/rationale of this study is to compare the efficacy of I-Gel and Endotracheal tube (ETT) as rescue device in rapid establishment of airway and protection against aspiration in laparoscopic gynecological under general anesthesia.

2. Aim

The main aim of the study is to compare the hemodynamic stability, the adequacy of ventilation and ease of insertion of I-Gel and Endotracheal tube when used as rescue devices in rapid establishment of airway during elective laparoscopic gynecological surgeries under general anesthesia.

3. Objectives

1. To compare the hemodynamic changes and ventilatory parameters post insertion between I-Gel and ETT in laparoscopy.
2. To assess the ease and time of insertion under general anesthesia between I-Gel and ETT.
3. To compare the complications faced during induction with both the airway devices.

4. Materials and Methods

After approval from ethical committee and informed consent this study was conducted.

Type - Randomized Prospective Comparative study.

Sample size - 128 patients (64 in each group).

4.1 Inclusion Criteria

Female patients (18-65 yrs) undergoing elective gynecological laparoscopic surgeries (ASA I & ASA II) were willing to participate in the study were included.

4.2 Exclusion Criteria

- Patients not willing to participate.
- Patients having problem of pathology of the neck or upper respiratory tract.
- Increased risk of aspiration (hiatus hernia, gastro-esophageal reflux disease, full stomach.
- Mouth opening less than 2.5 cm.
- Obese (BMI > 35kg/m^2)
- Emergency surgeries.

4.3 Methodology

Patients were randomly divided into two groups with (n=64) in each group.

Group A: was induced with I–Gel of appropriate size under deep plane without laryngoscopy and muscle relaxant.

Group B: was induced with endotracheal tube after laryngoscopy and muscle relaxant. A thorough pre anesthetic evaluation was done and patients were fasted for 8 hrs prior to time of operation. Consent of the patient was checked and intravenous access was secured. Monitor lines were connected and baseline heart rate, blood pressure (NIBP), ECG, and SPO2 were noted down.

All patients were given Inj. Ondansetron (0.1mg/kg) IV, Inj. Ranitidine (1mg/kg) IV, Inj. Glycopyrrolate (4ug/kg) IV and all patients were preoxygenated by Hudson's mask. Inj. Fentanyl (2ug/kg) IV was given 10 minutes

before induction. All patients were then preoxygenated for 3-4 minutes with 100% O_2 by mask ventilation.

Group A patients (I-Gel) were induced with Inj. Propofol (2–2.5 mg/kg) IV without any muscle relaxant. I-Gel of appropriate size was inserted without laryngoscopy.

Group B patients (ETT) were induced with Inj. Propofol (2-2.5 mg/kg) IV and Succinylcholine (1-1.5 mg/kg) IV to facilitate endotracheal intubation after laryngoscopy.

The correct placement of the devices was confirmed by chest wall movements, bilateral chest auscultation and presence of square wave of capnogram. The endotracheal tube cuff was then inflated with 6-8 ml of air while there was no need of such in the case of I-Gel.

Anesthesia was maintained with isoflurane/sevoflurane, O_2, and N_2O. SPO2 ≥ 95% and end-tidal CO_2 between 35 and 45mmHg were maintained throughout. Ease and attempts of insertion were assessed and compared between I-Gel and ETT.

Attempts of insertion- inability to pass through cords or the absence of square wave ETCO2 trace denoted failure of establishment of effective ventilation and the device was completely removed for another insertion attempt. Two attempts were allowed.

Hemodynamic and ventilatory parameters were recorded pre-operatively, intra-operatively at various intervals. Post-operative complications were assessed and noted down and their incidences were compared between two groups.

On completion of surgery, residual neuromuscular block was reversed with Inj. Neostigmine (0.05 mg/kg) IV and Inj. Glycopyrrolate (8 ug/kg) IV once patient started breathing spontaneously. Airway devices were removed on return of airway reflexes and muscle tone.

4.4 Statistical Analysis

Results were expressed using statistical analysis. All the values were expressed as mean +/- SD. The data was analyzed using Student's T-test (unpaired) and Chi Square test.

5. Results

In both the groups, patient's demographic data was comparable. There was no significant difference in age, weight and duration of surgery in both the groups.

5.1 Ease of Insertion

Ease of insertion was assessed as:

Easy - No resistance to insertion in the pharynx in a single maneuver

Difficult - Resistance to insertion or more than one maneuver was required for the correct placement of the device

Impossible - Resistance to insertion or more than one maneuver was required for the correct placement of the device

Easy insertion was seen among 93.75% patients in I-Gel group while in 85.94% patients in ETT group. Results were non-significant (p value 0.14; chi-square test) (table 1).

Table 1. Ease of Insertion

Ease of Insertion	Easy	Difficult
I-Gel	93.75%	6.25%
ET Tube	85.94%	14.06%

Chi-Square value: 2.14, p-value: 0.14, NS

5.2 Time of Insertion

It is the time which is calculated in seconds from the time of inducing with Inj. Propofol (1.5-2 mg/kg) to the appearance of square wave of capnogram (table 2).

Table 2. Time of insertion

I-Gel(in sec)	ET Tube (in sec)	p-value
10.41	13.91	0.000**, HS

The mean time of insertion were assessed and compared and results were highly significant (p-value 0.000**, unpaired t-test).

5.3 Heart Rate

The heart rate was compared between I-Gel and ETT at various intervals (table 3).

Table 3. Heart Rate

Time Interval	I-Gel (bpm)		ET (bpm)		t-value	p-value
	Mean	SD	Mean	SD		
Baseline	81.38	5.91	84.75	9.43	-0.91	0.36, NS
Induction	80.67	6.33	97.19	10.33	-10.91	0.000**, HS
1 min	80.66	6.03	100.97	10.36	-13.56	0.000**, HS
3 min	81.27	6.21	101.94	10.41	-13.65	0.000**, HS
5 min	82.14	6.1	102.59	11.33	-12.71	0.000**, HS
At insufflation	82.16	6.12	94.48	9.87	-8.49	0.000**, HS
P-10 min	83.33	6.15	90.73	9.75	-5.14	0.000**, HS
At extubation	80.17	10.84	96.09	10.37	-8.49	0.000**, HS

Unpaired 't' test used to check any significant difference between mean of the heart rate of both the groups.

5.4 Mean Arterial Pressure

The mean readings of I-Gel and ETT were assessed and compared using unpaired 't' test at various intervals. Baseline values were comparable, rest all values were highly significant showing that the rise of MAP was more in ETT as compared to I-Gel (table 4).

Table 4. Mean Arterial Pressure

	I-Gel(mmHg)		ET(mmHg)			
Time Interval	**Mean**	**SD**	**Mean**	**SD**	**t-value**	**p-value**
Baseline	95.87	5.99	96.11	6.53	-0.22097	0.82, NS
Induction	96.08	5.93	101.92	6.57	-5.28639	0.000**, HS
1 min	97.32	6.99	105.55	7.09	-6.61699	0.000**, HS
3 min	96.95	7	106.36	7.03	-7.58115	0.000**, HS
5 min	96.05	6.34	106.22	7.14	-8.51976	0.000**, HS
At insufflation	95.33	6.62	106	7.06	-8.82202	0.000**, HS
P-10 min	94.53	7.34	102.64	7.1	-6.35132	0.000**, HS
At extubation	94.27	6.26	104.62	7.34	-8.58302	0.000**, HS

5.5 SPO2 and EtCO2

SPO2 and EtCo2 were comparable at all time and no significant difference was noted between I-Gel and endotracheal tube which makes I-Gel comparable for ventilation with tracheal tubes.

5.6 Airway Pressure

The values were expressed as Mean±SD. Unpaired test was applied. Results were highly significant after creation of pneumoperitoneum (table 5).

Table 5. Airway Pressure

	I-Gel (cm H20)		ET (cm H20)			
Time Interval	**Mean**	**SD**	**Mean**	**SD**	**t-value**	**p-value**
Induction	16.92	2.19	17	1.94	-0.21336	0.83, NS
1 min	17.13	1.58	17.78	2.33	-1.86368	0.06, NS
3 min	16.75	2.72	17.44	1.63	-1.7341	0.08, NS
5 min	16.59	2.82	17.84	1.9	-2.94199	0.003, HS
At insufflation	18.3	1.8	20.34	2.75	-4.98496	0.000*, HS
P-10 min	19.33	2.15	21.08	2.53	-4.20988	0.000*, HS
At extubation	19.02	1.03	20.97	2.08	-6.33775	0.000*, HS

5.7 Postoperative Complications

Incidence of sore throat was higher in ETT patients in comparison to I-Gel. Postoperative coughing was also noted more with the use of ETT. No episodes of aspiration and bronchospasm were seen in either of the groups.

6. Discussion

The supraglottic airway devices have radically changed anesthesia practice and have become a key component of airway management in patients.

Newer SAD like I-Gel has truly revolutionized the approach of general anesthesia in laparoscopies[14]. 128 patients (ASA I or II grade) aged between 18 to 65 years were randomly allocated into two groups.

I-Gel airway was chosen according to the weight criteria. (Size 3) for 30-60 kg and (size 4) for 50-90 kg, but some degree of overlap existed.

Gatward et al.[15] have previously demonstrated the suitability of the size-4 I-Gel in 100 non-paralyzed patients weighing 42-113 kg, with findings comparable to ours.

It was observed that in I-Gel group 93.75% patients were easily induced while in ETT group 85.94% cases were easily intubated at the first attempt. Similar success rates were observed in previous studies[16, 17].

The mean time of insertion of I-Gel in our study was observed to be (10.37 sec) and mean time of insertion of ETT was (14.56 sec). These results were also comparable with results of previous studies[18,19] in which mean time of insertion of I-Gel was 13.67 seconds and 12.2 seconds.

Endotracheal intubation requires laryngoscopy and laryngoscopic guided intubation evokes further rise in hemodynamic response[20] which correlated with our findings.

Significant difference in the peak and mean airway pressure in the supine position for I-gel and ETT groups was found in a study of 40 patients conducted by Chih Jun Lai[13] et al which was comparable to our results.

The hemodynamic parameters were assessed intraoperatively at various intervals. I-Gel was also found to be superior to classical LMA and endotracheal tube in maintaining stable hemodynamics under general anesthesia as stated in previous studies[21,22].

The SPO2 and ETCO2 were comparable all throughout the procedures thus it was concluded that ventilation provided by I-Gel was more or less similar to that provided by endotracheal tube. Similar results were given by previous studies[23].

Patients undergoing laparoscopy might be considered to be at risk of developing the acid aspiration syndrome[24]. However in our study, we did not observe any incidence of regurgitation or aspiration[16, 18, 22].

We observed 9.3% (9/64) patients with ETT insertion developed sore throat and only 4/64 had with I-Gel. Singh et al[17] reported comparable results with I-Gel. The use of I-gel has now been shown clinically to result in fewer post-operative sore throat and neck complaints compared with disposable LMA's and endotracheal tubes[17,22].

7. Conclusion

I-Gel takes less time for insertion in comparison to endotracheal tube without the use of muscle relaxant and with minimal hemodynamic response.

The positive pressure ventilation provided by both I-Gel and ETT was comparable with no major changes in ETCO2 and SPO2.

The complications like coughing, sore throat and bleeding were more with endotracheal intubation than observed with I-Gel.

Thus, I-Gel suits to be an ideal alternative to ETT in elective laparoscopic surgeries under general anesthesia.

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