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COMPARISON BETWEEN TWO SUPRAGLOTTIC AIRWAY DEVICES, I-GEL VS LMA (LARYNGEAL MASK AIRWAY) IN ELECTIVE GYNECOLOGICAL LAPAROSCOPIC SURGERY.

Anaesthesiology

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ABSTRACT

Introduction: Supraglottic airway devices have been widely used as an alternative to tracheal intubation during general anesthesia both in adults and children. This study was carried out to compare classical laryngeal mask airway (LMA) and i-gel, regarding ease of insertion, adequate placement of device, ability to maintain $ETCO_2$ and SPO_2, perioperative hemodynamic parameters and intra operative and postoperative complication.

Methodology: Thirty patients of American Society of Anesthesiologist grade I and II between age of 18 to 60 years coming for laparoscopic gynecological procedures were divided into two groups of I-gel and LMA. Among them ease of insertion, insertion time, attempt of insertion, hemodynamic changes were observed. Patients were observed for any post-operative complications such as hypoxia, laryngospasm, regurgitation, coughing, blood stained devices, trauma to lip, tongue or teeth, hoarseness and sore throat.

Results: I-gel was easier to insert with a better anatomic fit. Insertion time for I-gel was significantly lower than the LMA. I-gel was successfully inserted in the first attempt compared to LMA. Incidence of blood stained device, sore throat and coughing were observed more in LMA group. No other complications were observed in either group.

Conclusion: Successful and shorter duration of insertion, with less hemodynamic response and post op complications, makes I-gel a suitable alternative to LMA during elective gynecological laparoscopic surgery.

KEYWORDS

I-gel, LMA, insertion time, post op complications

INTRODUCTION

Administration and maintenance of general anesthesia necessitates tracheal intubation in most of the cases. The procedure is associated with major sympathetic stimulations. Among them, hemodynamic pertubations are of major concern to us during intra-operative period. To minimize these effects, supraglottic airway devices (SAD) like laryngeal mask airway (LMA) or I-gel can be used instead of tracheal intubation in selected elective cases. [1,2]

Airway management devices and strategies have been subjects of discussion and study for many years. [3]

Laparoscopic surgery has been shown to adversely affect intra-op pulmonary mechanics, thus providing the most severe test of the efficacy of an airway device. [3]

Tracheal intubation is considered ideal for airway management in laparoscopic surgeries, as it provides adequate ventilation and protects against pulmonary aspiration even in presence of raised airway pressure due to carboperitoneum. [3]

I-gel and other SADs may overcome some of these problems, even in obese patient and in those who require high airway pressure for adequate ventilation. [3, 4] They are reasonable alternative to tracheal intubation during pressure controlled ventilation and can be used as a conduit for tracheal intubation and rescue airway management. [5,6]

There is a wide range of SAD for airway management that includes the I-gel, classic LMA (cLMA), proseal LMA (pLMA), intubating LMA fastrach, laryngeal tub, combitube, cobra perilaryngeal airway and so on. [7]

In LMA classic, once the device is inserted, the cuff needs to be inflated to create a seal around perilaryngeal tissues. This is likely to cause tissue oedema, venous congestion and nerve injury. Depending on the material from which the cuff is manufactured, they may absorb anaesthetic gases which can lead to increased mucosal pressure. In addition it could lead to the potential risk of aspiration. [1]

The other second generation newer airway device I-gel is a new SAD designed to fit the pharyngeal, laryngeal and perilaryngeal structures without the use of an inflatable cuff , made of a thermoplastic elastomer (styrene ethylene butadiene styrene) which is soft gel like and transparent. It provides a seal in patients with a wide range of anatomical variation. [1,4,6,8,9]

The claimed potential advantages of I-gel include ease of insertion and use with minimal tissue compression, displacement trauma, congestion and airway complications. It also provides better stability following insertion. [1,4,9]

A previous anatomical study in cadavers has shown that the I-gel is capable of achieving a good perilaryngeal seal without the requirement for an inflatable cuff. [1,9]

So, this study will be conducted to compare the use of I-gel and LMA for ease of insertion, attempt of insertion, hemodynamic changes and post-operative complications in patient undergoing planned laparoscopic gynecological procedure.

MATERIAL AND METHOD

After approval from the institution's ethical committee, written informed, valid consent was obtained from all patients after explaining the study protocol.

Sixty patients of female, 18-60 years, American Society of Anesthesiologists Grade I/II undergoing gynecological laparoscopic surgical procedures lasting for less than 60 min were included in the study.

Patients with anticipated difficult airway, restricted mouth opening, pregnant females, cervical spine disease, obese with body mass index >30 kg/m^2, significant acute and chronic lung disease, pre-operative sore throat, emergency surgery, patients with history of regurgitation and risk of aspiration were excluded from the study.

Patients were randomly allocated into two groups each Group I in whom I-Gel was inserted and Group L in whom LMA was inserted.

Pre-anesthetic assessment included medical/surgical history, general/systemic examination, vitals, airway examination and investigations such as complete haemogram, chest X-ray and electrocardiogram.

After peripheral venous cannulation, monitors including blood pressure (BP) cuff and pulse oximeter were attached and baseline parameters such as pulse, BP, oxygen saturation were noted.

After standard premedication with injection Glycopyrrolate 0.004 mg/kg, Ondansetron 0.05 mg/kg, Ranitidine 1 mg/kg, Midazolam 0.01-0.02 mg/kg and Fentanyl 1.5-2 mcg/kg, all patients were pre-oxygenated with 100% oxygen for 5 min. Each patient then received induction dose of injection Propofol (2-2.5 mg/kg) until the loss of eyelash reflex and achievement of adequate jaw relaxation. To prevent bias, appropriate size device was inserted by a qualified anesthesiologist. The patient's head was placed in sniffing the morning air position. The supraglottic airway device was inserted after lubricating the cuff with a water based jelly. LMA cuff was inflated with half the recommended volume of air and in case of inadequate seal entire recommended volume of air was used to inflate the cuff. In case of further leak, the device was removed and one size bigger was inserted. Additional doses of Propofol were used in case of reinsertion if required.

After device insertion, if the placement of device was found to be inadequate, manipulations were done in the following sequence-gentle pulling and pushing of the device, head flexion and extension, jaw thrust, chin lift, and deep rotation and any manipulation done, was recorded. A maximum of three attempts were tried for adequate placement, after which insertion was recorded as a failure, and the airway was secured with an appropriate-sized ETT and case was excluded from the study.

The device was then connected to the breathing circuit and capnometer assembly and secured after confirming bilaterally equal air entry. Nasogastric tube was inserted if required.

Ease of insertion was defined as
- Easy-Insertion at first attempt with no resistance
- Difficult-Insertion with resistance or at second attempt
- Failed-Insertion not possible

The time taken for insertion of device was noted as time taken from picking up the device upto the time of confirmation of effective ventilation (by bilateral symmetrical chest movement and square waveforms on capnograph with normal range end-tidal Co_2).

Anaesthesia was maintained on oxygen, nitrous oxide and sevoflurane with spontaneous respiration/ assist controlled. Hiccups were tackled by increasing the depth of anesthesia by increasing the maintenance dose of Injection Propofol.

At end of the procedure, all the patients were ventilated with 100% oxygen during emergence from anesthesia. The device was removed when the patient was able to open the mouth on command. The patient was inspected for any injury to lips, teeth or tongue and the device was inspected for the presence of any blood stains. The supraglottic device was inspected for the presence of any gastric contents to confirm regurgitation. All the patients were observed for a period of 24 h for any complaints of hypoxia, laryngospasm, coughing, hoarseness, dysphonia, sore throat and dysphagia. Sore throat in the postoperative period was treated using warm saline nebulization and in patients with sore throat 24 h later warm saline gargles were advised. Laryngospasm was given standard treatment with 100% oxygen followed by appropriate pharmacological treatments.

STATISTICALANALYSIS

Data were entered in Excel sheet and imported to Statistical Package for Social Sciences software version 20.0 (softronics). Quantitative variables have been expressed as mean and standard deviation. Qualitative variables have been expressed as percentages.

The two groups were compared with each other in terms of age, height and weight. The statistical test used was Unpaired Student's *t*-test for age, height and weight.

Hemodynamic parameters such as mean heart rate, BP both systolic and diastolic, SpO_2 and end tidal CO_2 were compared using analysis of variance.

The mean time required for insertion was compared using unpaired Student's *t*-test. The ease of insertion, attempts required for insertion, airway manipulations and the incidence of adverse events were compared using Chi-square test. In all the parameters, $P < 0.05$ was considered to be significant.

RESULTS

Table 1 demographic data

Variable	Group I	Group L
Age(years)	29.2±3.925	30.06±5.08
Height(cm)	144.56±3.3	149.97±3.75
Weight(kg)	49.03±2.67	50.46±3.78
BMI(kg/m^2)	22.01±1.03	21.76±1.43
ASA grade(I:II)	26 : 04	23 : 07

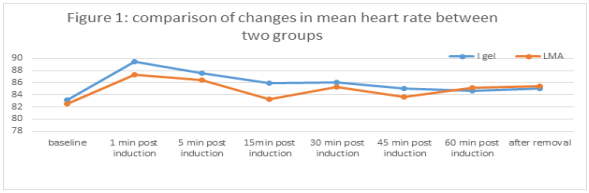
The demographic profile was comparable among both groups as shown in Table 1.

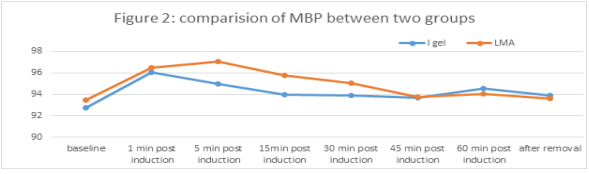
Table 2 comparison of ease of insertion, mean insertion time and attempt of insertion

Parameters	Group I	Group L	P value
Ease of insertion			
Easy	28	23	<0.05(S)
Difficult	2	7	
Failed	0	0	
Mean insertion time (seconds)	17.12±3.42	25.62±5.28	<0.0001(HS)
Attempt of insertion			
1	27	23	<0.05(S)
2	3	7	
3	0	0	

S = significant, HS = highly significant

Statistically significant difference was observed in ease of insertion, attempt of insertion and insertion time between both the groups. It was easy to insert on first attempt with shorter duration and minimum manipulations were required in group i-gel as shown in Table 2.





No statistically significant difference was found in hemodynamic parameters in between both the groups as shown in Figure 1 and 2.

Table 3 profile of complication

complications	Group I (N = 30) No. (%)	Group L (N = 30) No. (%)	P value
Hypoxia	00	00	
Laryngospasm	00	01(3.3)	0.3198
Regurgitation/ vomiting	00	00	
Coughing	00	2(6.7)	0.1527
Blood stained devices	00	05(16.67)	0.0205(S)
Trauma to lip, teeth, tongue	00	05(16.67)	0.0205(S)
Hoarseness	00	00	
Dysphonia	00	00	
Sore throat	3(10)	07(23.33)	0.1695
Dysphagia	00	2(6.7)	0.1527
hiccups	01(3.3)	00	0.3198

S = significant, HS = highly significant

In group LMA complications like laryngospasm, post extubation cough, blood stained device on removal, trauma to lip, teeth, tongue, sore throat and dysphagia were observed in higher percentage as shown in Table 3.

DISCUSSION

Various types of supraglottic devices are widely used for securing and maintaining a patent airway for surgeries requiring general anaesthesia and are alternative to tracheal intubation. [10]

As controlled ventilation is routinely used with endotracheal intubation so with SGA devices.

The advantages of the supraglottic airway devices include avoidance of tachycardia, hypertensive response to laryngoscopy and intubation, less invasive for the respiratory tract, better tolerated by patients, increased ease of placement by inexperienced personnel, improved hemodynamic stability in emergence, less coughing and sore throat. The LMA a novel device is inserted blindly into the pharynx, forming a low-pressure seal around the laryngeal inlet and permitting gentle positive-pressure ventilation. It allows the administration of inhaled anaesthetic agents through a minimally stimulating airway. [11]

I-gel is a new single use non inflatable supraglottic airway device. It's shape and contours accurately mirror the perilaryngeal anatomy to create the perfect fit. I-gel works in harmony with the patient's anatomy so that compression and displacement trauma are significantly reduced or eliminated. [12]

It's drain tube allows access to the gastrointestinal tract and it is designed to reduce the risk of gastric inflation and regurgitation. [13]

The small width and height of i-gel tip is intended to fit into the postcricoid cervical oesophagus just proximal to distal tip. The bowl enlarges slightly in width but more significantly in height.[14]

Levitan and Kinkle studied the positioning of i-gel in 65 non-embalmed cadavers using glidoscope video laryngoscope, block dissection of neck and neck radiographs in lateral view. [14] They found that the i-gel effectively conformed to the perilaryngeal anatomy despite the lack of an inflatable cuff and it consistently achieved proper positioning for supraglottic ventilation.

Studies comparing ease of insertion of i-gel and cLMA reported statistically significant easy insertion with I gel in normal patient and in contracture neck patients. Similarly Trivedi et al and Chauhan et al found i-gel airway was easier to insert with less attempt when compared to PLMA. [15, 16, 17] Das et al had observed higher number of manipulations to insert LMA than i-gel. [18]

In our study device was placed in first attempt in 90% patients of group i-gel compared to 77% of group LMA. In group LMA 23% patient required second attempt while in I-gel only 10%. Reason: - if LMA cuff doesn't give proper seal, cuff need to be deflated and repositioning the device and inflate the cuff again. So it is considered 2nd attempt while in case of I-gel even slightest movement can give proper seal with 1st attempt.

As no cuff inflation is required in the I-gel, shorter time was required to achieve an effective airway. [8] Mean insertion time for group i-gel was 17.12±3.42 seconds while for group LMA it was 25.62±5.28 seconds. Both the data were statistically significant (p= <0.05).

Study by Chauhan et al mentioned that in all patients i-gel or LMA was inserted within 3 attempts. Mean insertion time for the i-gel was significantly lower than LMA. [20]

Wharton et al evaluated the performance of i-gel supraglottic airway device in manikins and anesthetized patients. Their results suggest the i-gel is rapidly inserted in both manikins and patients by an inexperienced person and compares favorably to other supraglottic airways available. [13]

Successful insertion of PLMA and i-gel in the first attempt without statistically significant difference in insertion time was observed in study by Jeon et al. [21] Similar finding of successful insertion in first attempt were also observed in studies done by Das et al and Chen et al. [18,22]

In our study mean pulse rates (figure 1), systolic and diastolic blood pressure, mean blood pressure (figure 2), SpO_2 and $EtCO_2$ at all points of time interval were comparable and there was no statistically significant difference between the two groups with p value >0.05. Similar findings were observed by Helmy et al, Das et al, Chauhan et al in their study comparing LMA and i gel. Study done by Trivedi et al mentioned that i-gel produced fewer changes in Mean arterial pressure than PLMA. [16,17,18,23]

Uppal et al compare the i-gel with endotracheal tube. He found increase in heart rate, systolic and diastolic blood pressure with ETT than i-gel. [24] Complications like laryngospasm, coughing after removal of device, presences of blood on device, sore throat and dysphagia were found in higher percentage patients of group LMA.

With LMA blood staining of the devices, minor regurgitation without aspiration, tongue, lip and dental trauma, numbness of tongue, nausea and vomiting major airway obstruction, sore throat and dysphagia were observed. [15,16,23,18]

CONCLUSION

Both the devices LMA and i-gel were tolerated well and a clear airway were maintained throughout the anaesthesia. I-gel is comparatively easier to insert than LMA. I-gel effectively confirms to the perilaryngeal anatomy despite of lack of inflatable cuff and it consistently achieves proper positioning for supraglottic ventilation. Further, there is minimal risk of tissue compression and trauma to the peripheral tissues with i-gel than LMA. Also I-gel device provide gastric channel that can be used to deflate stomach content perioperatively thus reducing the risk of regurgitation and aspiration. I-gel is a better alternative supraglottic airway device than LMA in view of ease of insertion, lesser time required for insertion with minimal manipulations and minimal complications.

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