

A prospective study of I-gel in elective laparoscopic gynecological procedures



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ABSTRACT

Background: Many studies have been done to compare i-gel with other laryngeal mask airway. However, not many studies have been done to study the clinical uses of the supraglottic airway device, namely, i-gel. **Aims and Objectives:** The present study was undertaken to study of i-gel in elective laparoscopic gynecological procedures in tertiary health-care center. **Materials and Methods:** The present prospective observational study was conducted on patients admitted in OBGY ward for laparoscopic procedures during the period September 2019–2021. The study was undertaken after obtaining Ethical Committee Clearance. Informed consent was taken from each patient. Seventy patients, scheduled for various elective laparoscopic gynecological procedures under general anesthesia belonging to ASA class I and II, were included in the study. **Results:** Majority number of study participants belonged to age group of 50–59 years, that is, 52 (74.3%), while only 5 (7.1%) study participants belonged to age group of 30–39 years. I-gel insertion was successful in single attempt in 69 (98.6%) study participants, while two attempts were needed for 1 (1.4%) participant. In our study, there was no statistically significant difference of i-gel with regard to heart rate, systolic, diastolic and mean blood pressure, and arterial saturation, EtCO₂. There was no post-operative complication after completion of procedure. **Conclusion:** The present study revealed that i-gel may be used safely and successfully in elective laparoscopic gynecological surgeries under general anesthesia with positive pressure ventilation. It offers excellent insertion conditions and adequate jaw relaxation for easy i-gel insertion on the first try.

Key words: I-gel; Laparoscopic gynecological surgeries; Ease insertion; Hemodynamic changes

INTRODUCTION

The supraglottic airway devices (SADs) are a novel device that fills the gap in airway management between tracheal intubation and use of face mask, though the gold standard for airway management is endotracheal intubation, Dr. Archie Brain, a British anesthesiologist, for the 1st time introduced the laryngeal mask airway (LMA) in 1983, designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet, be simple and atraumatic to insert. Careful observations and clinical experience have led to several refinements of Brain's original prototype, leading to development of newer SADs with better features for airway maintenance.

The wide variety of airway devices available today may broadly be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway in both elective as well as emergency situations.¹ There are a large number of SADs, some of which appear similar to the LMA family and others that work under a different concept.

SADs are now used widely for surgeries requiring general anesthesia. It is an alternative to tracheal intubation as it secures and maintains patients airway during spontaneous or controlled ventilation in fasting patients by providing a perilaryngeal seal with a cuff.^{2,3}

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Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias, and intracranial hypertension.² This laryngoscopic reaction in such individuals may predispose to development of pulmonary edema, myocardial insufficiency, and cerebrovascular accident.^{4,5} LMA is a SADs with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation.⁶ The i-gel is a new SADs with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed lateral to the airway tube, which allows insertion of gastric tube.¹

The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients.⁷

The newer SADs, i-gel, was introduced by Dr. Muhammed Aslam Nasir in 2007. It has the potential advantages including easier insertion, minimal risk of tissue compression, and stability after insertion and an inbuilt bite block.⁸ It seals the laryngopharyngeal space without any air being insufflated and, additionally, has an esophageal lumen. It can be assumed that airway devices that offer an especially good seal and that are equipped with an additional esophageal lumen are superior for use in patients with an increased risk of aspiration.⁹

Many studies have been done to compare i-gel with other LMA. However, not many studies have been done to study the clinical uses of the SADs, namely, i-gel. Hence, this study was undertaken in tertiary health-care center.

Aims and objectives

The objectives of this study were to study a SADs i-gel, in anesthetized paralyzed adult patients posted for elective gynecological procedure under general anesthesia with respect to, insertion attempts, time of insertion, and hemodynamic changes.

MATERIALS AND METHODS

The present prospective observational study was conducted on admitted in OBGY ward for laparoscopic procedures during the period September 2019–2021. The study was undertaken after obtaining Ethical Committee Clearance. Informed consent was taken from each patient.

Seventy patients, scheduled for various elective laparoscopic gynecological procedures under general

anesthesia belonging to ASA class I and II, were included in the study.

Inclusion criteria

The following criteria were included in the study:

1. Adult normotensive patient aged between 18 and 60 years
2. Mallampatti grade I and II
3. Elective laparoscopic gynecological surgeries under general anesthesia with Controlled ventilation
4. Duration of surgery <60 min.

Exclusion criteria

The following criteria were excluded from the study:

1. Patient refusal
2. Age <18 years and >60 years
3. ASA class III and above
4. Mallampatti grade III and above
5. Emergencies surgeries
6. Patients with decreased mouth opening
7. Patients with increased risk of aspiration
8. Patients with abnormal or distorted anatomy of the pharynx
9. Patients with obstruction of the airway beyond the larynx
10. Patients with decreased compliance of the lung.

Data collection procedure

The study patients were randomly selected who fulfill the inclusion criteria. Pre-anesthetic evaluation was done on the evening before surgery. A routine pre-anesthetic examination was conducted including required investigations.

All patients included in the study were pre-medicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time the previous night before surgery. They were kept nil orally for solids 10 pm onward on the previous night and for clear fluids up to 2 h before induction.

On arrival of the patient in the operating room, an 18-gauge intravenous cannula was inserted under local anesthetic infiltration and an infusion of normal saline was started. The patient's head was placed on a soft pillow of 10 cm before induction of anesthesia with the neck flexed and head extended. The patient was connected to multiparameter monitor, which records heart rate, non-invasive measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), etCO₂ and continuous ECG monitoring, and oxygen saturation. The baseline systolic, DBP, MAP, and heart rate were recorded.

The i-gel supraglottic airway was used. The size of the device was decided by anesthetist based on patient's body

weight and manufacturer's recommendation viz. size 3 for patients weighing between 30 and 50 kg, size 4 between 50 and 90 kg, and size 5 for patients weighing >90 kg.

The standard pre-use tests for device were performed. The device was lubricated using Lignocaine jelly on the tip and posterior surface as recommended by the manufacturer.

After recording the baseline reading, the patient was pre-oxygenated with 100% oxygen for 3 min through a face mask with Bain's circuit. Then, the patient was pre-medicated with injection Midazolam 0.02 mg/kg, injection Glycopyrrolate 0.04 mg/kg, and injection Fentanyl 2 mcg/kg body weight. Basal hemodynamic readings were recorded. Anesthesia was induced with propofol 2.5 mg/kg body weight. Induction of anesthesia was confirmed by loss of verbal communication with the patient and loss of eyelash reflex. Once an adequate depth of anesthesia was achieved, the patient was paralyzed by giving intravenous succinylcholine (1.5 mg/kg body weight). The patient was mask ventilated with 100% oxygen for 1 min. The allotted device was inserted according to the manufacturer's instructions. The patient's head was placed in "sniffing the morning air" position.

The lubricated i-gel was grasped along the integral bite block and introduced into the mouth in the direction toward the hard palate and glided downward and backward along the hard palate until definite resistance was felt. The device was connected to breathing circuit and patient ventilated manually.

An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, normal end tidal CO₂ and stable arterial saturation (SpO₂) (>95%). The device was secured with adhesive tape.

The patient remained in the supine position and the device removed after the patient was fully awake and met all the reliable signs of recovery from neuromuscular blockade. The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain. 18–24 h after surgery, the patient was interviewed for any post-operative complications like sore throat, dysphagia, and hoarseness. The detailed are recorded on ease of insertion, time of insertion, time from picking up the device to the time of confirmation of effective ventilation, number of insertion attempts, and hemodynamic parameters were monitored on basal before premedication, at the time of insertion, 1 min after insertion, 3 min, 5 min, every 10 min, at the time of removal, 1 min after removal, and adverse effects, post-operative complications.

Statistical analysis

A collected data were entered in Microsoft Excel. The table and graphs were constructed using Microsoft excel.

Descriptive statistics such as mean, standard deviation, and percentage was used to present the data. Data analysis was performed using statistical software SPSS v20.0.

RESULTS

Majority number of study participants belonged to age group of 50–59 years, that is, 52 (74.3%), while only 5 (7.1%) study participants belonged to age group of 30–39 years. The mean age of study participants were 50.5±5.5 years.

Weight of most study participants was in the range of 50–59 kg, that is, 45 (64.3%), while 10 (14.3%) study participants had their weight in the range of 60–69 kg. The mean weight of study participants was 53.5±4.8 kg.

Most of the study participants were diagnosed with DUB, 43 (61.4%), while 21 (30.0%) participants were diagnosed with fibroid uterus and 6 (8.6%) were diagnosed with prolapse of uterus (Table 1).

I-gel size of 3 was used for 51 (72.9%) study participants and i-gel size of 4 was used in 19 (27.1%) study participants.

I-gel insertion was successful in single attempt in 69 (98.6%) study participants, while two attempts were needed for 1 (1.4%) participant. The average time of insertion of i-gel was less than 5 min in our study (Table 2).

Basal PR for study participants were 85.86±15.36. At the time of insertion, it was 87.94±14.68. PR at 1 min,

Table 1: Basic characteristics

Characteristics	Number	Percentage
Age (years)		
30–39	5	7.1
40–49	13	18.6
50–59	52	74.3
Weight (kg)		
40–49	15	21.4
50–59	45	64.3
60–69	10	14.3
Diagnosis		
DUB	43	61.4
Fibroid uterus	21	30.0
Prolapse of uterus	6	8.6

Table 2: Airway insertion details

During insertion	Number	Percentage
i-Gel size		
3	51	72.9
4	19	27.1
Number of insertion attempts		
One	69	98.6
Two	1	1.4

3 min, 5 min, and 10 min after insertion was 87.87 ± 15.41 , 85.54 ± 14.90 , 85.10 ± 14.31 , and 85.16 ± 11.60 , respectively. At the time of removal and 1 min, after removal PR was 84.37 ± 11.59 and 82.54 ± 12.15 , respectively (Figure 1).

Basal SBP for the study participants were 122.44 ± 13.75 . At the time of insertion, it was 111.07 ± 17.55 . SBP at 1 min, 3 min, 5 min, and 10 min after insertion was 108.37 ± 21.52 , 115.63 ± 21.34 , 120.03 ± 17.09 , and 123.97 ± 13.81 , respectively. At the time of removal and 1 min, after removal SBP was 118.87 ± 9.60 and 120.13 ± 13.10 , respectively (Figure 2).

Basal DBP for study participants was 79.26 ± 13.21 . At the time of insertion, it was 72.83 ± 15.48 . DBP at 1 min, 3 min, 5 min, and 10 min after insertion was 71.44 ± 18.65 , 81.61 ± 19.75 , 84.17 ± 15.47 , and 88.87 ± 12.29 , respectively. At the time of removal and 1 min, after removal DBP was 81.50 ± 9.36 and 82.53 ± 10.87 , respectively (Figure 3).

Basal MAP for study participants was 93.96 ± 12.05 . At the time of insertion, it was 85.90 ± 15.13 . MAP at 1 min, 3 min, 5 min, and 10 min after insertion was 83.71 ± 19.38 ,

93.27 ± 20.43 , 96.27 ± 15.40 , and 100.64 ± 13.83 , respectively. At the time of removal and 1 min, after removal MAP was 93.99 ± 8.73 and 95.31 ± 10.96 , respectively (Figure 4).

Basal EtCO₂ for study participants was 36.69 ± 1.63 . At the time of insertion, it was 36.76 ± 0.98 . EtCO₂ at 1 min, 3 min, 5 min, and 10 min after insertion was 36.59 ± 0.65 , 36.49 ± 0.79 , 36.24 ± 0.43 , and 36.43 ± 0.53 , respectively. At the time of removal and 1 min, after removal EtCO₂ was 36.53 ± 0.53 and 36.19 ± 0.57 , respectively (Figure 5).

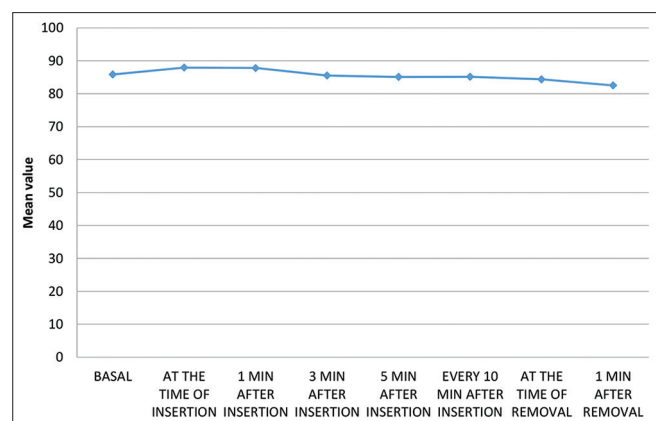


Figure 1: Changes in pulse rate

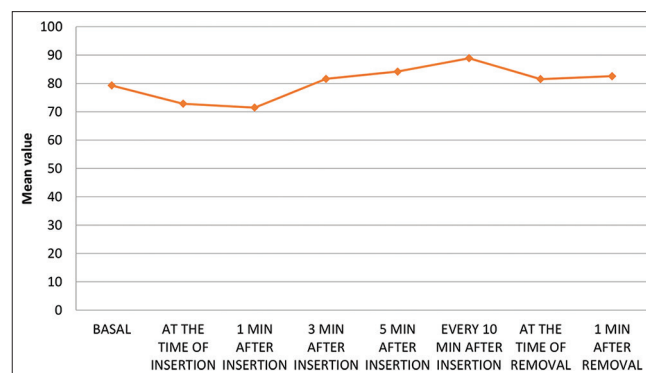


Figure 3: Changes in systolic diastolic pressure

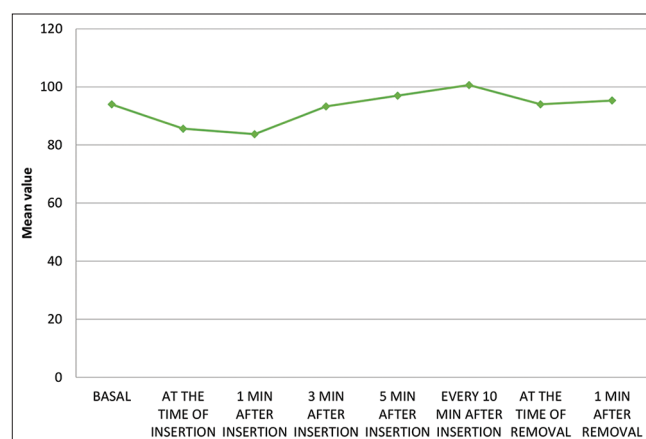


Figure 4: Changes in mean arterial pressure

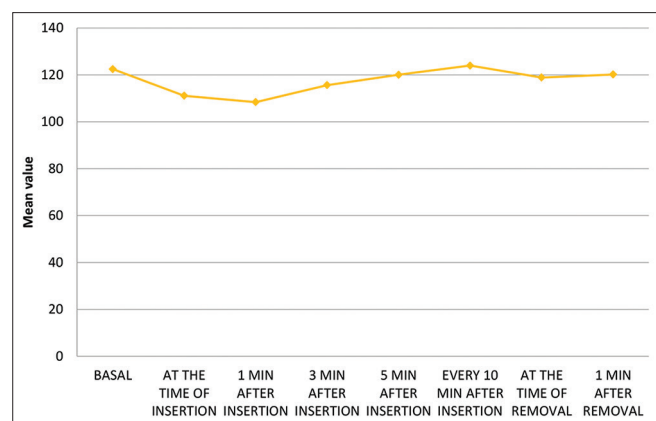


Figure 2: Changes in systolic blood pressure

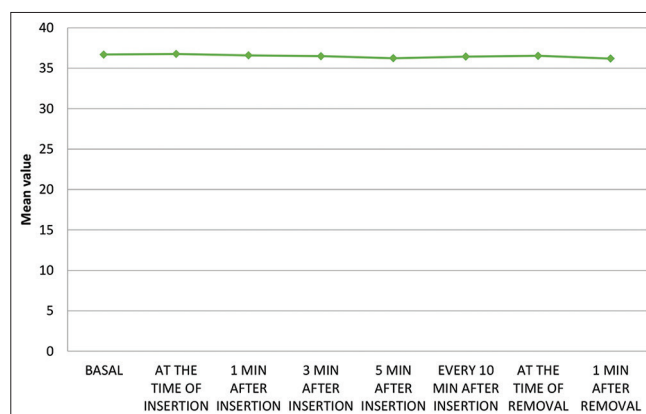


Figure 5: Changes in ETco₂

There was no any post-operative trauma to tongue, lip, or teeth. There were 3 (4.3%) cases of blood stain on the device on completion of the procedure (Table 3).

DISCUSSION

Basic characteristics

In the present study, the mean age in years is 50.5 ± 5.5 and mean weight in kg was 53.5 ± 4.8 .

Similar findings were reported by Francksen et al.,² age 55.10 and weight 68.10, Uppal et al.,³ average age 47.8 ± 12.2 and weight 70.3 ± 11.9 , whereas in study done by Trivedi and Patil¹⁰ reported age 31.16 ± 11.16 and weight 51.4 ± 6.70 .

In Trivedi and Patil¹⁰ study, there were no statistically significant differences between the two groups with respect to age, sex, weight, ASA physical status, and the duration of surgery.

Airway insertion details

In the present study, insertion of i-gel was successful in first attempt in 69 (98.6%) patients. Airway manipulation like jaw thrust was required during second attempt insertion in one patient of i-gel insertion.

In Janakiram et al.,¹¹ study, the success rate with 1st time i-gel insertion was only 54%, which was statistically highly significant. This was because, during the use of i-gel in 14 patients, a larger size i-gel had to be used due to presence of audible leak and, hence, required 2nd attempt. However, in our study, we did not have such problem, and hence, the success rate of 1st time insertion was more which is similar findings reported by study done by Uppal et al.,³ (97.4%), Helmy et al.,¹ (90%), and Francksen et al.² (90%).

Ease of insertion

The grading of insertion was done similar to the study conducted by Siddiqui et al.,¹² where insertion of device was recorded as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant), and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).

In the present study, the ease of insertion of i-gel was very easy (score 1) in 69 (98.6%) patients and difficult (score 3)

only in 1 (1.4%) patient. The insertion of i-gel was found comparatively easier and required less skill, but the results were not statistically significant ($P > 0.05$). The i-gel having a non-inflatable cuff and firm in consistency is much easier for insertion.

Our present study compared the ease of insertion of the device with the study conducted by Ali et al.,¹³ Siddiqui et al.,¹² and Janakiram et al.,¹¹ who also did not find any statistically significant difference.

Hemodynamic changes

During the insertion of i-gel, patient response may be induced by the passage of the i-gel through the oral and pharyngeal spaces, pressure produced in the larynx, and the pharynx by the inflated cuff and the dome of the i-gel.¹⁴ During removal of i-gel, the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff.¹⁴

In our study, there was no statistically significant difference of i-gel with regard to heart rate, systolic, diastolic and mean blood pressure, and SpO_2 , $EtCO_2$. The results of our study were similar to the studies done by Helmy et al.,¹ Francksen et al.,² who, in their studies, found no significant difference with regard to heart rate, arterial BP, SpO_2 and end tidal CO_2 .

Jindal et al.,¹⁴ in their study, observed that i-gel produced less hemodynamic changes compared to other SADs. The authors concluded that i-gel effectively conforms to the perilaryngeal anatomy despite the lack of cuff; it consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other SADs like c-LMA which due to inflation of cuff with air can produce more hemodynamic changes.

Badheka et al.,¹⁵ concluded that i-gel requires less time for insertion with minimal hemodynamic changes when compared to ETT and, in our study, no significant hemodynamic changes occurs.

Trivedi and Patil¹⁰ concluded that i-gel airway is a better alternative supraglottic device than PLMA with controlled ventilation and for securing airway in difficult airway management especially in high-risk cardiac patients since it produces lesser hemodynamic changes and easy to insert than PLMA, and in our study, no significant hemodynamic changes occurs.

In our study, there was no statistically significant difference of i-gel with regard to hemodynamic changes. The results of our study were similar to the studies done by Lai et al.,¹⁶ Badheka et al.,¹⁵ and Chhabra et al.,¹⁷ who, in

Table 3: Post-operative trauma and blood stain on device

Post-operative parameters	Number	Percentage
Post-operative trauma		
Tongue	0	0
Lip	0	0
Dental	0	0
Blood stain on device	3	4.3

their laparoscopic procedure studies, found no significant difference.

Post-operative complications

Trivedi and Patil¹⁰ study shows that no significant complications were noted in any patients. Only two patients in each group complained sore throat. Later, sore throat resolved within 2 h without necessity of active treatment, and in our study, there was no post-operative complication.

Joly et al.,¹⁸ study shows that there was no difference between groups regarding pre-operative or post-operative complications, and in our study, there was no post-operative complication.

In the present study, there was no post-operative complication after completion of procedure while in Chew et al.,¹⁹ compared the performance of the LMA Supreme (SLMA) with the I-Gel during anesthesia in spontaneously breathing adult patients, the incidence of complications was low in both the groups.

Amini and Khoshfetrat²⁰ compared the performance of the intersurgical solus LMA with that of the i-gel concluded that both devices have good performance with very low peri-operative complications, and in our study, there was no post-operative complication.

Helmy et al.,¹ study shows that the post-operative complications are not significantly different among both LMA and I-gel patients.

In our study, the patients were inspected for any injury of the lips, teeth, or tongue and the device for blood stain after its removal at the end of the surgery similar to study done by Siddiqui et al.,¹² However, the incidence was not statistically significant ($P=0.695$).

None of the patient complaints in our study had any injury of the lips, teeth, or tongue and none of the patient have sore throat and blood stain on device have noticed in three patients which are not statistically significant.

Limitations of the study

More studies with larger numbers of patients need to be carried out to confirm our findings to further widen the scope of these devices in laparoscopic surgery.

CONCLUSION

The present study revealed that i-gel may be used safely and successfully in elective laparoscopic gynecological surgeries under general anesthesia with positive pressure ventilation. It offers excellent insertion conditions and adequate jaw

relaxation for easy i-gel insertion on the first try. It also delivers improved hemodynamic responses with fewer or no intraoperative and post-operative problems, as well as a faster recovery.

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Authors' Contributions:

MSP- Concept and design of the study, prepared first draft of manuscript and revision of the manuscript; **GRC**- Statistical analysis, Interpreted the results; reviewed the literature and manuscript preparation; **SSP**- Concept, Statistical analysis and interpretation, preparation of manuscript and revision of the manuscript.

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