

# Comparison of I-gel for general anesthesia in obese and nonobese patients

## ABSTRACT

**Context:** I-gel is a second-generation supraglottic airway device. Despite several studies on i-gel, there are very few studies on the use of i-gel in obese patients.

**Aims:** The aim of the study was to compare the clinical performance of i-gel between obese and nonobese patients.

**Settings and Design:** Prospective, controlled, nonrandomized, hospital-based study.

**Subjects and Methods:** After obtaining informed consent, patients were divided into two groups of 16 patients each: group O consisted of patients with body mass index (BMI) >30 kg/m<sup>2</sup> and Group C consisted of patients with BMI 18.5–29.9 kg/m<sup>2</sup>. I-gel was inserted after induction of anesthesia and muscle relaxation. Oropharyngeal leak pressure (OLP) (primary outcome variable), leak fraction, time taken to insert the device, ease of insertion, fiberoptic view of glottis through i-gel's airway tube, and adverse effects were recorded.

**Statistical Analysis Used:** Data were analyzed using SPSS 20. Continuous, ordinal, and categorical variables were analyzed using students *t*-test, Mann–Whitney U–test, and Fischer's exact test, respectively.

**Results:** OLP was slightly higher in Group O (25.38 ± 4.79 cm H<sub>2</sub>O) but was not statistically different than Group C (27.38 ± 4.38 cm H<sub>2</sub>O). Other parameters except weight and BMI (which were higher in Group O) were statistically similar in both groups. There was no statistical difference in side effects.


**Conclusions:** We concluded that i-gel is as effective in obese patients as in nonobese patients when used for securing the airway for surgical procedures.

**Key words:** Airway management; airway management; bronchoscope; laryngeal masks; obesity

## Introduction

I-gel is well known for its simplicity, ease of insertion and low complication rate; and has been studied by several authors.<sup>[1-4]</sup> It has high oropharyngeal leak pressure (OLP) and a gastric channel which reduces the risk of reflux and regurgitation. I-gel has been successfully inserted in 100% patients by inexperienced users.<sup>[4,5]</sup> Komayama *et al.* used

this device to secure airway in an obese patient undergoing awake craniotomy.<sup>[6]</sup> I-gel and laryngeal mask airway unique was compared in obese patients by Weber *et al.*<sup>[7]</sup> They concluded that this device can be used as an alternative to laryngeal mask airway in obese patients.

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<b>DOI:</b> 10.4103/sja.SJA_79_18	

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**How to cite this article:** Prabha R, Raman R, Khan MP, Kaushal D, Siddiqui AK, Abbas H. Comparison of I-gel for general anesthesia in obese and nonobese patients. Saudi J Anaesth 2018;12:535-9.

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However, there is no prospective controlled study comparing the use of i-gel in obese versus nonobese patients. This trial was devised with an objective to study the clinical performance of i-gel in obese patients and compare it with nonobese patients.

## Subjects and Methods

This study was done at a tertiary care hospital, after obtaining approval from Institute Ethics Committee. It was registered with Clinical Trials Registry-India under CTRI/2017/03/008059. A written informed consent was taken from all the participating subjects. The American Society of Anesthesiologists (ASA) physical status I–III patients of the age group of 18–60 years, scheduled to undergo elective surgery of duration <2 h under general anesthesia were included in this study. Patients with gastroesophageal reflux disease, cardiovascular or respiratory disease, pregnancy, mouth opening <3 cm, body mass index (BMI)  $\geq 40$ , planned for cardiothoracic surgery, laparoscopic surgery, or head and neck surgery were excluded from the study.

Patients were divided into two groups. Group C consisted of patients with BMI 18.5–29.9 kg/m<sup>2</sup>. Group O consisted of patients with BMI 30.0 kg/m<sup>2</sup> or more. After application of standard anesthetic monitors, induction of anesthesia was carried out with intravenous fentanyl (2 µg/kg), titrated dose of propofol (1.5–3 mg/kg), and vecuronium (0.12 mg/kg). After induction of anesthesia and adequate muscle relaxation, appropriate sized i-gel was inserted according to manufacturer's recommendations. Correct placement was defined as visible chest movement with ventilation, SpO<sub>2</sub> >95%, and square wave capnogram. In case of improper placement, minor manipulations (changing the depth of insertion, extension or flexion of the head, jaw thrust) were done to achieve optimal positioning before removing and reinserting the device one more time, followed by manipulation, if needed. If placement was still not satisfactory, i-gel was removed, and the patient was intubated with endotracheal tube. All devices were placed by anesthetists having >3 years of experience in airway management with i-gel. After successful placement of i-gel, patients were ventilated with 7 ml/kg of tidal volume. Anesthesia was maintained with oxygen, sevoflurane, nitrous oxide mixture with intravenous vecuronium, and fentanyl. At the end of surgery, muscle relaxation was reversed, and the device was removed.

Insertion time (time elapsed between anesthesiologist first picking up the i-gel and correct i-gel placement), number of insertion attempts and ease of insertion (on following scale:<sup>[1]</sup> successful placement in the first attempt;<sup>[2]</sup> placement in the

first attempt but with resistance;<sup>[3]</sup> placement required two attempts; and<sup>[4]</sup> failed placement) were recorded. OLP was measured by closing the adjustable pressure limiting valve of the circle breathing system and noting the pressure at which leak developed (detected by a stethoscope placed just lateral to thyroid cartilage) at fresh gas flow of 3 L/min. A maximum airway pressure of 40 cm H<sub>2</sub>O was allowed during the test. The best view of larynx obtained with fiberoptic bronchoscope (recorded as fiberoptic view [FOV]) inserted through the airway tube of i-gel was graded and recorded as: (1) full view of glottis obtained; (2) glottis visible partially; (3) glottis not visible but only epiglottis visible; and (4) no recognizable laryngeal structures visible. Leak fraction (LF) was recorded and defined as the difference between inspiratory and expiratory tidal volumes and divided by inspiratory tidal volume. Side effects such as sore throat, gastric distension, blood on device, and dysphonia were also recorded.

Primary outcome variable of this study was OLP while secondary outcome variables were insertion time, number of insertion attempts, ease of insertion, FOV, and side effects.

A sample size of 16 patients was required in each group to detect a clinically important difference of 5 cm H<sub>2</sub>O with a standard deviation of 5 cm H<sub>2</sub>O in OLP using a two-sided *t*-test for two independent groups. The power of our study was 80% and two-sided alpha error was 5%. Parametric continuous variables (age, weight, height, BMI, duration of surgery, OLP, LF, and time to insert i-gel) were analyzed using Student's *t*-test. Fischer's exact test was used to analyze categorical variables (sex, type of surgery, and side effects). Mann–Whitney U-test was used to analyze ordinal variables (ASA grade, number of attempts, FOV grade, and ease of insertion). *P* < 0.05 was considered significant for all the statistical tests. All analyses were performed with SPSS version 20 (SPSS Inc., Chicago, Illinois, USA) for windows.

## Results

Figure 1 depicts the flow of participants through the trial. Baseline and demographic characteristics are depicted in Table 1. Analysis revealed that baseline and demographic characteristics were similar between the groups except for weight and BMI which was significantly higher in Group O. Table 2 shows comparison of clinical performance of i-gel in the two groups. Insertion of i-gel and ventilation was successful in all the patients. OLP of pressure limit 40 cm H<sub>2</sub>O was not achieved in any patient. OLP, LF, time taken to insert i-gel, ease of insertion, number of attempts taken, and FOV in the two groups were statistically similar. The incidence

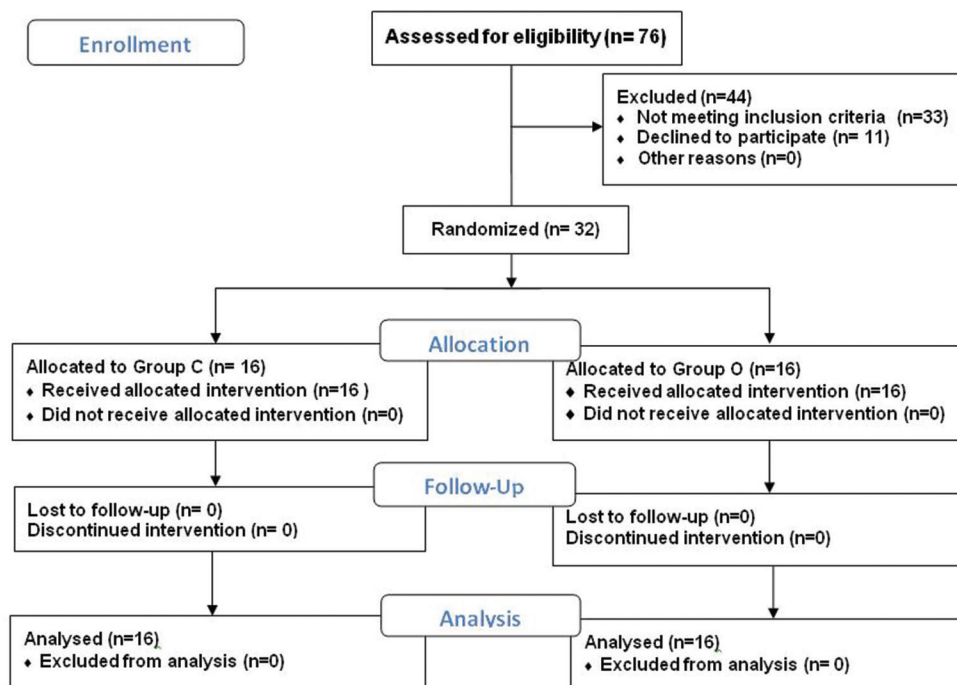


Figure 1: Flow of patients through the trial

Table 1: Comparison of baseline and demographic characteristics (n=16)

Group	Group C	Group O	P
Age (years)	39.06±10.06	38.06±14.52	0.882
Weight (kg)	66.25±13.47	93.50±18.09	<0.001*
Height (cm)	162.69±16.28	160.56±15.71	0.710
BMI (kg/m <sup>2</sup> )	24.92±2.86	36.09±3.30	<0.001*
ASA grade, n (%)			
I	5 (31.25)	0	0.131
II	6 (37.50)	9 (56.25)	
III	5 (31.25)	7 (43.75)	
Sex, n (%)			
Male	9 (56.25)	7 (43.75)	0.724
Female	7 (43.75)	9 (56.25)	
Duration of surgery (min)	83.06±12.46	79.00±22.70	0.535
Type of surgery, n (%)			
Orthopaedic	6 (37.50)	4 (25.00)	0.819
Gynecologic	4 (25.00)	5 (31.25)	
General surgery	6 (37.50)	7 (43.75)	

\*Statistically significant difference. Values are expressed as mean±SD and n (%). ASA: American Society of Anesthesiologists; BMI: Body mass index; SD: Standard deviation

of side effects occurring during the study was statistically similar and is shown in Table 3.

## Discussion

In this trial, we studied the role of i-gel in airway management of obese patients and compared its clinical performance with that of nonobese patients. We found that indices regarding

i-gel placement, ventilation using i-gel and FOVs were similar between the obese and nonobese patients.

There is very little scientific evidence on the use of i-gel in obese population.<sup>[2,8-10]</sup> In a prospective randomized study, Weber *et al.* compared laryngeal mask airway unique and i-gel in mild to moderately obese patients.<sup>[7]</sup> It was found that i-gel had significantly higher OLP than LMA unique. Theiler *et al.* conducted a prospective observational multicenter trial to study success rates, airway leak pressure and risk factors for i-gel failure.<sup>[11]</sup> They observed that male sex, impaired mandibular subluxation, poor dentition, and older age were associated with failed i-gel insertion and use. Obesity was not associated with i-gel failure. However, other details about insertion and ventilation characteristics were not analyzed in this study.

Primary outcome variable of our study was OLP, which is one of the most important factors in the evaluation of a supraglottic device performance, especially when used for positive pressure ventilation. Mean OLP was slightly higher in obese patients compared to nonobese patients (28.7 vs. 25.8 cm H<sub>2</sub>O). There are several trials studying OLP of i-gel under various conditions. Use of muscle relaxants, as we did in our study, decreases the tone of laryngeal and pharyngeal muscles and reduces the OLP of supraglottic airway (SGA) devices.<sup>[12]</sup> Studies using muscle relaxation in their study protocol have found OLP similar to our study.<sup>[2,13-17]</sup> OLP depends on the seal between cuff of SGA, laryngeal inlet,

**Table 2: Comparison of clinical performance of i-gel between the two groups (n=16)**

Group	Group C	Group O	P
OLP (cm H <sub>2</sub> O)	25.38±4.79	27.38±4.38	0.227
LF	8.81±2.07	9.19±1.91	0.598
Time to insert i-gel (s)	16.19±6.89	17.19±6.25	0.670
Ease of insertion (Grade), n (%)			
1	10 (62.50)	6 (37.50)	0.223
2	5 (31.25)	8 (50.00)	
3	1 (6.25)	2 (12.50)	
Number of attempts, n (%)			
1	15 (93.75)	14 (87.50)	1.000
2	1 (6.25)	2 (12.50)	
FOV Grade, n (%)			
1	10 (62.50)	9 (56.25)	0.899
2	5 (31.25)	6 (37.50)	
3	1 (6.25)	1 (6.25)	

Values are expressed as mean±SD and n (%). OLP: Oropharyngeal leak pressure; LF: Leak fraction; FOV: Fiberoptic view; SD: Standard deviation

**Table 3: Comparison of complications (n=16)**

Complications	Group C, n (%)	Group O, n (%)	P
Sore throat	3 (18.75)	2 (12.50)	1.000
Airway trauma	1 (6.25)	2 (12.50)	1.000
Cough	3 (18.75)	4 (25.00)	1.000

and the surrounding soft tissues of perilaryngeal area.<sup>[12]</sup> The anatomically shaped and pliable nature of i-gel's cuff may be able to conform to the patients' laryngeal anatomy well despite patients' excess perilaryngeal soft tissue. Excess perilaryngeal soft-tissues pushing i-gel's cuff more effectively against the laryngeal inlet may lead to better seal between the cuff of i-gel and laryngeal inlet in obese patients. This may explain the observation of study by Weber *et al.* in which the OLP was more in patients with moderate obesity than the patient with mild obesity.<sup>[7]</sup> Theiler *et al.* also found in their prospective study that BMI was not related to i-gel failure. We could not do any subgroup analysis in our study.<sup>[11]</sup>

LF was slightly higher in obese patients as compared to nonobese patients, but the difference was not statistically significant. Anesthetized obese patients have higher airway resistance and lower lung compliance than nonobese patients.<sup>[10,18]</sup> Given similar OLP, this may translate to higher LF in obese patients when ventilating through i-gel at same tidal volumes as compared to nonobese patients. However, our study was not adequately powered to detect this difference. Equivalent OLP and LF achieved in obese and nonobese patients indicate that i-gel is suitable for positive pressure ventilation in obese patients also.

In our study, indices regarding insertion of i-gel: time taken to insert, ease of insertion, and number of attempts taken

needed were similar in both groups. I-gel was designed to have insertion time of <5 s.<sup>[19]</sup> Design features including the absence of inflatable cuff, semi-rigid flattened stem, and insertion depth gauge may contribute to rapid and easy placement of i-gel.<sup>[5,20]</sup> Trials investigating insertion characteristics of I-gel have consistently found it easy to insert, even with novice users. Successful insertion rates are generally higher than 80% in the first attempt and increase to >90% on subsequent attempts.<sup>[2,5,11,13,21]</sup> Theiler *et al.* in found in their study that overall success rate of i-gel insertion was 96%.<sup>[11]</sup> In this aspect, findings of our study are similar to those of previous studies.

FOV was also similar in both groups with both having median grade FOV as one and glottis was visible in 93.75% in both groups, indicating excellent anatomical position of i-gel cuff in relation to the laryngeal inlet in both obese and nonobese patients.<sup>[13,22,23]</sup> As different grading of FOV was used by different studies, comparison with previous studies is difficult. However, FOV through i-gel was good (glottis at least partially visible) in >90% of patients in these studies. Studies evaluating the suitability of i-gel as conduit for fiberoptic-guided intubation have concluded that i-gel is an excellent device for this purpose.<sup>[24-27]</sup> Excellent visibility of the glottis in obese patients suggests that i-gel may be used as a conduit for fiberoptic-guided endotracheal intubation in obese patients also.

Adverse events encountered during our study were minor, and the incidence was statistically similar in both groups. However, the present study was not enough powered to detect the differences in secondary outcome variables.

One of the limitations of this study was that we did not include patients with morbid obesity in our study; hence, the results of this study may not be applicable to them. Furthermore, it was not possible for us to use randomization or blinding in the study. All patients in our study had a duration of surgery <2 h. Application of the results of our study to patients undergoing surgery of longer duration may not be appropriate.

## Conclusions

Our study showed that OLP is similar in obese and nonobese patients when i-gel is used for securing the airway. However, further studies, especially regarding LF, ease of use, and adverse effects are needed to establish the equivalency of i-gel in obese and nonobese patients.

## Financial support and sponsorship

Nil.



## Conflicts of interest

There are no conflicts of interest.

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