EGYPTIAN JOURNAL OF ANAESTHESIA
2020, VOL. 36, NO. 1, 126–133
https://doi.org/10.1080/11101849.2020.1789811

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RESEARCH ARTICLE

Efficiency of I-gel supraglottic airway device during mechanical ventilation in supine and lateral decubitus position in obese patient; prospective observational study

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ABSTRACT

Background: I-gel supraglottic airway device has been widely used recently in anesthesia practice as an alternative to endotracheal intubation. However, its safety and feasibility in obese patients are still under investigations. **The aim of this work** was to evaluate the efficiency of I-gel in supine and lateral position in adult obese (BMI 30–40) mechanically ventilated patients undergoing short surgical procedures (60 – 120 min).

Methods: Prospective observational study was conducted at Kasr Alainy Hospital. A total of 40 obese patients with body mass index 30–40 aged between 20 and 60 years, American Society of Anesthesiologists class II & III scheduled for elective surgeries were enrolled in one group. We used the I-gel in supine position and lateral position in the same patient.

The primary outcome was comparison between Oropharyngeal leak airway pressure during controlled ventilation in supine position after insertion of I-gel by 1 min and in lateral position. The secondary outcomes were fiberoptic view , insertion attempts and postoperative upper airway complications

Results: The leakage pressure required for I-gel did not show statistically significant difference between both supine and lateral positions (33.88 ± 7.34 cmH_2O versus 33.10 ± 7.58 cmH_2O) respectively. Fiberoptic view ranged between score 2 (8 patients) and score 3 (32 patients) in both supine and lateral position. I-gel was inserted in the first trial in 37 patients, the second trial in two patients and the third trial in one patient. None of the patients experienced postoperative swallowing difficulties, throat pain, hoarseness or postoperative nausea and vomiting. Only two patients (5%) showed blood on I-gel after removal.

Conclusion: The use of I-gel supraglottic airway device is safe and effective in both supine and lateral position in obese patients under mechanical ventilation with reliable ventilation and no postoperative airway complications.

Clinical trial registration: clinicaltrial.gov. ID: NCT04119245

ARTICLE HISTORY
Received 2 June 2020
Revised 19 June 2020
Accepted 25 June 2020

KEYWORDS
I-gel supraglottic airway device; obese patient; oropharyngeal leak airway pressure; fiberoptic view

1. Introduction

Obesity is one of the anesthesia challenges especially during process of airway management including difficult mask ventilation, difficult intubation and upper airway obstruction. Obese patients may be difficult to intubate due to limited mobility of the temporomandibular and atlantooccipital joints, a narrowed upper airway, and shortened distance between the mandible and sternal fat pads.[1]

Supraglottic airway devices have been widely used in anesthesia practice as an alternative to endotracheal intubation and standard mask ventilation. They increased speed and reliability of placement, maintaining hemodynamic stability during induction and emergence, better oxygenation during emergence and increased patient satisfaction by decreasing the incidence of postoperative sore throat and voice alteration [2–4].

I-gel; a second generation noninflatable supraglottic airway device with a gastric channel is gaining popularity in anesthesia practice because of its ease of insertion and stable positioning. Having a range of 30–40 mm Hg pharyngeal seal leak pressure, it provides as many ventilation characteristics as an endotracheal tube can offer. The large oval structure of I-gel allows buccal stabilization and reduces the risk for axial rotation and malposition [5,6].

There are many studies evaluating I-gel for airway management during different head and neck position, in prone and lateral position showing successful results [7–13]. Moreover, it was evaluated in spontaneous [3] and mechanically ventilated [6] patients.

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Prabha et al. [14] compared I-gel in obese and non-obese patients demonstrating that it is as effective in obese patients as in nonobese patients when used for securing the airway during general anesthesia.

To the best of our knowledge no previous study evaluated the effect of I-gel in different position in obese patients. Therefore, we speculated that I-gel would be especially beneficial in obese patients (BMI 30–40) in supine and lateral position during short time elective surgeries.

Therefore, the **aim of this work** was to evaluate the efficiency of I-gel in supine and lateral position in adult obese with body mass index 30–40 (BMI) mechanically controlled patients undergoing short surgical procedures.

The primary outcome was comparison between Oropharyngeal leak airway pressure during controlled ventilation in supine position after insertion of I-gel by 1 min and in lateral position. The secondary outcomes were fiberoptic view in both supine and lateral position, number of insertion attempts and postoperative upper airway complications.

2. Methods

After approval of Cairo University Hospitals' Ethics Committee (S-12-2019), protocol registration in the clinical trial registry (ID: NCT04119245) and obtaining informed written consent from each patient, prospective observational study that was conducted at Kasr Alainy Hospital in the surgical operating theatre. 40 patients scheduled for elective surgeries were enrolled in one group. We used the I-gel in supine and lateral position in the same patient. The **inclusion criteria** were as follow: adult obese with BMI 30–40, aged between 20 and 60 years, patients with American Society of Anesthesiologists (ASA) class II or class III physical status, undergoing elective surgical procedures with duration 60 – 120 min. **The exclusion criteria** were: patients who refused to participate in the study, patients with impaired mental status, Patients with Obstructive sleep apnea, presence of neck or upper airway pathologies, risk of stomach contents regurge, e.g., pregnant, gastrointestinal ulcer, symptomatic reflux disease or hiatus hernia, presence of risk of pulmonary aspiration, e.g., full stomach or incompetent gastroesophageal sphincter, history of gastric band or gastric bypass surgeries, laparotomy or laparoscopic procedures and pregnant females.

Upon arriving the surgical theatre, Demographic data (age, sex, weight and height) of the patients were recorded and the following procedures were carried out: Monitoring (electrocardiography, noninvasive blood pressure measurement and pulse oximetry) was recorded before starting anesthesia. Intravenous access with 18-gauge cannula was established and. Premedication was given in the form of 10 mg Metoclopramide and 50 mg Ranitidine hydrochloride IV Infusion over 20 min in 100 cc saline before induction.

Induction of anesthesia started after pre-oxygenating the patient for 3 min, with administrating Propofol (2 mg/kg), Fentanyl (2 μg/kg) (based on lean body weight) [15] and Atracurium (0.5 mg/kg) (based on ideal body weight) [15].The patient was ventilated by a 100% oxygen and 1.2% isoflurane with fresh gas flow 6 L/min for 5 min.

A proper sized I-gel according to the patient's weight and manufacturer instructions (Intersurgical Ltd, UK) (4 or 5 adult size I-gel) [16] was lubricated with a water based lubricant from the front and back sides of the device, was inserted after complete muscle relaxation (train of four = zero).

I-gel insertion was facilitated by head flexion or extension, or slightly pulling or pushing the device in case of insertion problem. If insertion or ventilation fails three times in succession, Endotracheal tube would be immediately inserted and the patient was excluded from the study.

The circuit was connected to the device, Capnography was attached and end tidal carbon dioxide ($ETCO_2$) was recorded. The success of the ventilation was determined based on visible chest expansion, adequate tidal volume and drawing of six successive $ETCO_2$ waves. The ventilator parameters were set with tidal volume 4–6 ml/kg at a respiratory rate 12–15 breath/min to maintain $ETCO_2$ from 30 to 35 cmH_2O. Anesthesia was maintained by a mixture of 50% oxygen and 50% medical air, Isoflurane 1.2% and Atracurium 0.1 mg/kg given according to TOF.

In order to confirm proper positioning of the I-gel, a fiberoptic bronchoscope was passed through the device and pushed forward up to 1 cm proximal to the end of its lumen. The glottic view was scored as follows: score 4: only vocal cords can be seen, grade score 3: vocal cords and posterior epiglottis can be seen, score 2: vocal cords and anterior epiglottis can be seen, score 1: Vocal cords cannot be seen [17].

After confirmation of proper positioning of the I-gel, leak airway pressure test was done by putting the patient on apnea mode (close the ventilator and change into spontaneous ventilation), confirmation that fresh gas flow is 3 L/min, adjustment of the pressure limiting valve at 75 cmH_2O and monitor the increase in pressure gauge (GE-Datex ohmeda) until audible sound "puhh" was heard at angle of the mouth and over the thyroid cartilage using stethoscope.

The patient was kept in supine position for 10 min afterward the same patient was placed in the lateral decubitus position for 10 min. Confirmation of I-gel position using fiberoptic bronchoscope and the leak air way pressure test were done as previously in supine position.

The patient was returned to supine position where a proper size or gastric tube was inserted and the surgical procedure started.

By the end of the surgery, the neuromuscular block was reversed from general anesthesia by administrating Neostigmine (0.04 mg/kg and Atropine (0.01 mg/kg) intravenously at (train of four = 3) and the I-gel was removed at the end. The presence of blood on the I-gel device, or the occurrence of any complications, was recorded. The patient was transferred to the post operative care unit (PACU).

The primary outcome was comparison between oropharyngeal leak airway pressure during controlled ventilation in supine position after insertion of I-gel by 1 min and in lateral position. The secondary outcomes were fiberoptic view in both supine and lateral position, number of insertion attempts. The presence of swallowing difficulties, throat pain, hoarseness, nausea and vomiting were asked preoperatively and postoperatively as (yes/no) questions.

Mean arterial blood pressure, heart rate, oxygen saturation and end tidal CO_2 were recorded (1 min after I-gel insertion – 3 min interval readings for 10 min then 1 min after lateral decubitus position –3 min interval readings for 10 min).

2.1. Statistical analysis

2.1.1. Sample size

Based on a pilot study, sample size was calculated according to the difference in the mean value of oropharyngeal leak airway pressure in obese cases using I-gel supraglottic airway device in supine (34.6 ± 6.1) and lateral (35.5 ± 9.7) positions, with α = 0.05, type I error, two tailed, power of 80%, and an effect size of 0.64. So a sample size of 40 patients would be required (GPower 301 http:www.psycho.uni-duesseldorf.de)

2.1.2. Statistical analysis

Data were statistically described in terms of mean ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate.

Comparison of numerical variables between the study groups was done using paired *t* test in comparing 2 groups of normally distributed data and Wilcoxon signed rank test for paired (matched) samples when data are not normally distributed. Comparison between mean values of different hemodynamic variables measured at baseline and different times of measurement (1 min, 4 min, 7 min and 10 min, in position) within the same group was performed using repeated measures ANOVA test followed by Bonferroni test as post-hoc test. For comparing categorical data, Chi-square (χ^2) test was performed.

A probability value (*p* value) less than 0.05 is considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2007 (Microsoft Corporation, NY, USA) and IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

3. Results

A total of 64 patients scheduled for nonabdominal surgery under general anesthesia were tested for eligibility to participate in this study. A total of 24 patients were excluded (16 patients did not meet our inclusion criteria and 8 patients refused to participate in the study). A total of 40 patients completed the study and were allocated in one group, where the I-gel was investigated in supine and lateral decubitus position. The types of the performed surgeries included Breast lumpectomy (15 patients), fracture elbow fixation (3 patients), hand surgeries (17 patients) and knee arthroscopies (5 patients). Demographic data and patients' characteristics are shown in Table 1.

The leakage pressure required for I-gel did not show statistically significant difference between both supine and lateral positions (33.88 ± 7.34 cmH_2O versus 33.10 ± 7.58 cmH_2O) respectively. (Table 2)

Fiberoptic view score ranged between score 2 (8 patients) and score 3 (32 patients) in both supine and lateral position. Table 3 is showing the relation between fiberoptic view and leak airway pressure in both supine and lateral position.

I-gel was inserted in the first trial in 37 patients, the second trial in two patients and the third trial in one patient. (Table 4)

Heart rate did not show significant difference between both positions after 1, 4, 7 and 10 min of institution of the position. However, there was

Table 1. Demographic features and patients' characteristics.

	Studied patients (n = 40)
Age (years) mean ± SD	38.95 ± 12.54
Gender Females: Males (%)	35:5 (87.5%:12.5%)
ASA II: III (%)	24:16 (60%:40%)
BMI (kg/m^2) mean ± SD	36.23 ± 2.91
Duration of surgery (min) mean ± SD	86.75 ± 20.34
Baseline HR (beat/min) mean ± SD	84.78 ± 12.83
Baseline MABP (mmHg) mean ± SD	91.45 ± 11.71
Baseline SPO2 (%) mean ± SD	98.42 ± 1.34
Baseline ETCO2 (cmH_2O) mean ± SD	33.38 ± 5.08
Type of surgeries: Number (%)	
Breast lumpectomy	15(37.5)
Fracture elbow fixation	3(7.5)
Hand surgery	17(42.5)
Knee arthroscopy	5(12.5)

BMI: Body mass index, SPO_2: peripheral oxygen saturation, HR: heart rate, MABP: Mean arterial blood pressure, $ETCO_2$: End tidal CO_2

Baseline heart rate, mean arterial blood pressure and peripheral oxygen saturation data were obtained preoperatively, while baseline end tidal CO_2 was obtained 1 min after induction of anesthesia.

Table 2. Leak airway pressure in the two studied groups.

	Supine (n = 40)	Lateral (n = 40)	p value
Leak airway pressure (cmH_2O) mean ± SD	33.88 ± 7.34	33.10 ± 7.58	0.644

Table 3. Mean values of leak airway pressure in the two studied groups classified according to supra glottic view.

		Supine (n = 40)		Lateral (n = 40)		
		No. (%)	Mean ± SD	No.	Mean ± SD	p value
Supra glottic view	*2*	8 (20%)	30.0 ± 9.7	8 (20%)	32.0 ± 10.10	0.750
	3	32 (80%)	34.84 ± 6.46	32 (80%)	33.38 ± 6.99	0.386

Data are expressed as mean ± SD.

Table 4. Number of insertion attempts:

	Number of patients	Percent (%)
1	37	92.5
2	2	5.0
3	1	2.5

Data are expressed as number (%).

statistical difference compared to baseline heart rate (p value = 0.004, 0.001, 0.001 and 0.001 respectively). (Figure 1).

Similarly, mean arterial blood pressure didn't show significant difference between both positions after 1, 4, 7 and 10 min of institution of the position. However, there was statistical difference compared to baseline heart rate (p value = 0.001, 0.001, 0.002 and 0.001 respectively) (Figure 2).

Mean end tidal CO_2 did not show significant difference between both positions after 1, 4, 7 and 10 min of institution of the position and compared to baseline reading (after induction of aesthesia) (Figure 3).

Oxygen saturation did not show significant difference between both positions after 1, 4, 7 and 10 min of institution of the position. However, there was statistical difference compared to baseline reading (p value = 0.005, 0.001, 0.001 and 0.001 respectively) (Figure 4).

None of our patients experienced preoperative or postoperative swallowing difficulties, throat pain. hoarseness or postoperative nausea and vomiting. Only two patients (5%) showed blood on I-gel after removal. (Table 5)

4. Discussion

In our study, there was no difference in leak airway pressure regarding the same patients in both supine (33.88 ± 7.34 cmH_2O) and lateral decubitus (33.10 ± 7.58 cmH_2O) positions in patients with mild to moderate obesity (BMI 30–40) during elective short-term surgery.

The I-gel supraglottic airway device is made of a medical grade thermoplastic elastomer which is soft, gel-like and transparent. The device creates a non-inflatable anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures that avoids compression trauma which occurs with inflatable supraglottic airway devices. It has been successfully used during spontaneous or intermittent positive pressure ventilation or as a conduit for intubation under fiberoptic guidance in difficult intubation [18].

Obese patients with obstructive sleep apnea suffer from deposition of adipose tissue in their oral and pharyngeal tissues, including the uvula, tonsils, tonsillar pillars, tongue, aryepiglottic folds, and lateral

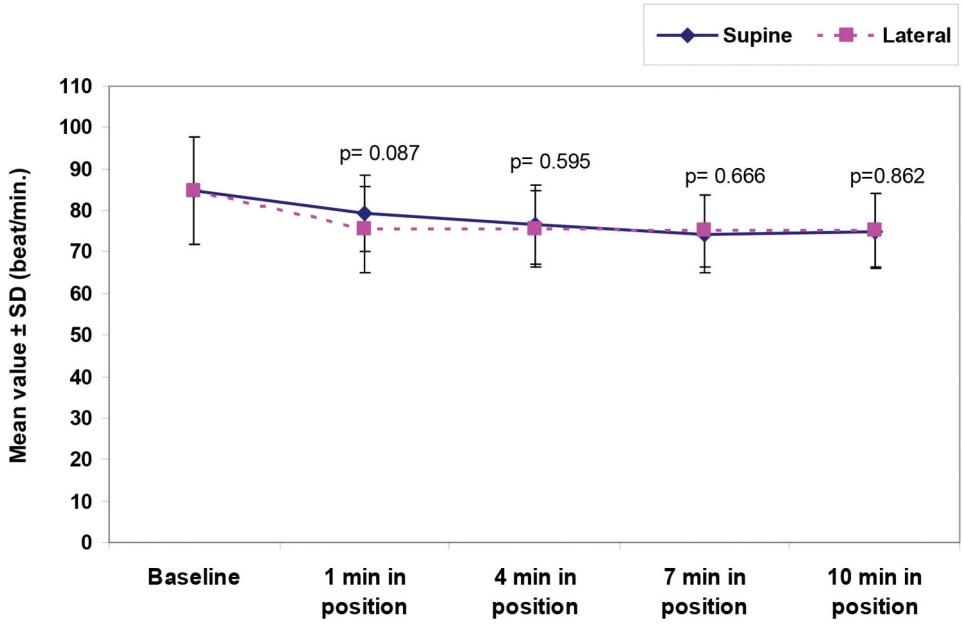

Figure 1. Mean values of heart rate in the two studied groups measured at different time points. p value = 0.004, 0.001, 0.001 and 0.001 relative to baseline. Baseline heart rate was obtained preoperatively.

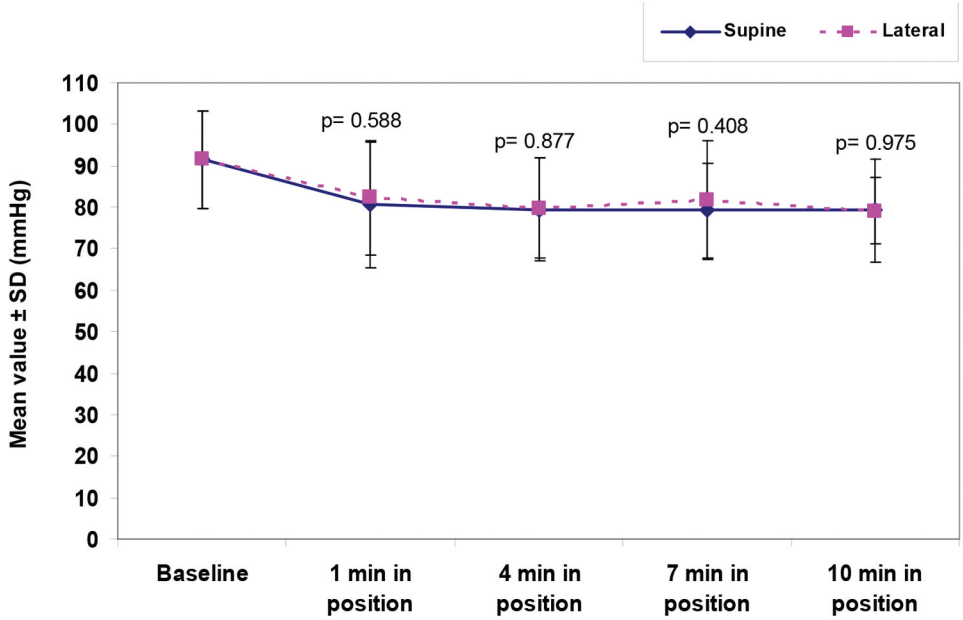

Figure 2. Mean values of mean arterial blood pressure in the two studied groups measured at different time of measurements. *p* value <0.001, 0.001, 0.002 and 0.001 relative to baseline. Baseline mean arterial blood pressure was obtained preoperatively.

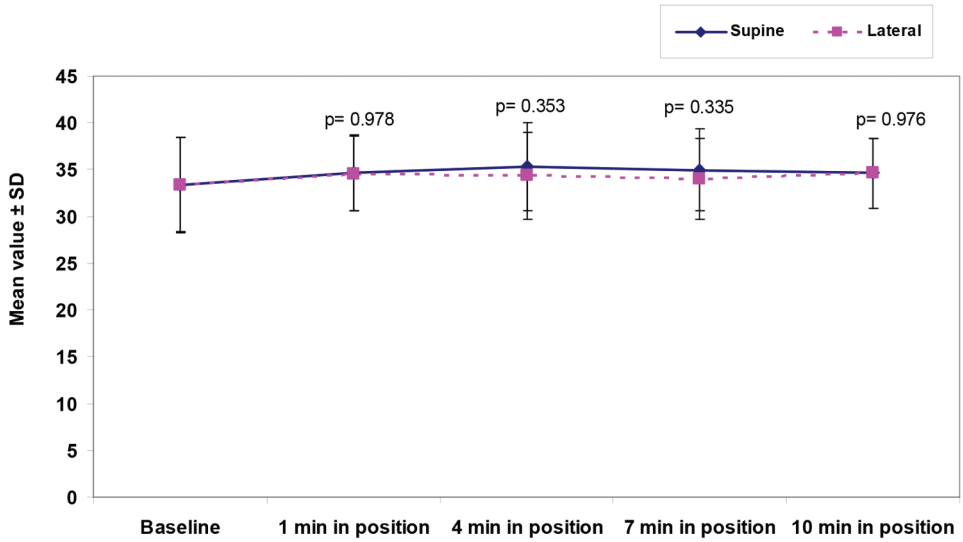

Figure 3. Mean values of $ETCO_2$ in the two studied groups measured at different time of measurements. Baseline end tidal CO_2 was obtained 1 min after induction of anesthesia.

pharyngeal walls causing decrease in the pharyngeal area and size of the airway. These factors could contribute in increasing the probability of development of airway obstruction, difficulty in maintaining airway patency during mask ventilation, performing direct laryngoscopy for endotracheal intubation with general anesthesia and tendency to decrease pharyngeal dilator tone [19,20].

Therefore, the characteristics of I-gel being ease in insertion, stable positioning, reduced risk for axial rotation and malposition, having up to 40 cmH_2O pharyngeal leak pressure and providing as many ventilation characteristics as endotracheal tube can offer. [5]

Many studies demonstrated efficacy and safety of I-gel in supine and lateral position [7,12,21–24]. However, there are limited number of researches that were done in pervious literature studying supraglottic devices in general and I-gel in specific for obese patients[12].

In a study done by Prabha et al. [14] the I-gel device was applied in supine position in obese versus non obese for general surgery, the mean leak air way pressure in obese group was (27.38 ± 4.38 cmH_2O) which is close to our result in supine position.

Also in a study done by Mishra et al. [25] where I-gel device was applied in neutral head position with mean leak airway pressure (22 ± 3.23 cmH_2O) and with

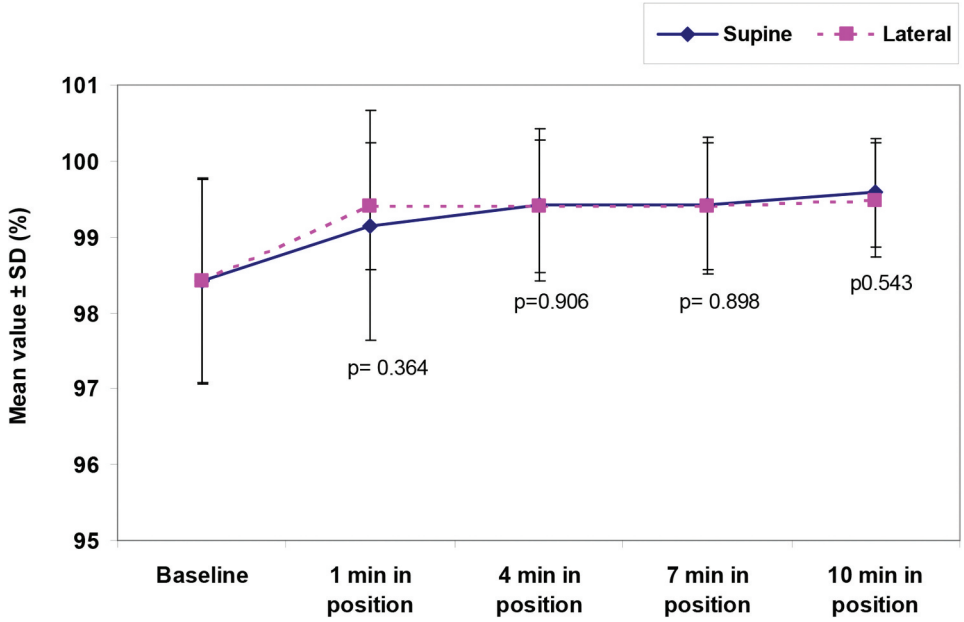

Figure 4. Mean values of SPO_2 in the two studied groups measured at different time of measurements. *p* value = 0.005, 0.001, 0.001 and 0.001 relative to baseline. Baseline peripheral oxygen saturation was obtained preoperatively.

Table 5. Postoperative complications in the studied patients.

	Number	Percent
Swallowing difficulties (yes)	0	0.0
Throat pain (yes)	0	0.0
Hoarseness (yes)	0	0.0
Nausea and vomiting (yes)	0	0.0
Blood presence after removal (yes)	2	5.0

Data are expressed as number (%).

turning the head to lateral position leak airway pressure (22 ± 2.74 cmH_2O) showing no difference among both positions in general anesthesia patient with muscle relaxation. However, the study population were overweight not obese, and they did not investigate I-gel device in lateral decubitus position.

Damodaran et al. [26] investigated I-gel device, air Q and laryngeal mask airway Supreme™ in adult patients with BMI<35 in supine position with mean leak airway pressure for I-gel in supine position was 23.75 ± 5.43 cmH_2O which is less than our study.

Our results confirmed that the use of muscle relaxants decreases the tone of laryngeal and pharyngeal muscles and reduces the oropharyngeal leak air way pressure of supraglottic airway devices which depends on the seal between cuff of supraglottic devices, laryngeal inlet, and the surrounding soft tissues of perilaryngeal area [27].

On the other hand, Gatward et al. [3] compared leak air way pressure in I-gel supine versus classic laryngeal mask in spontaneously breathing patients showing leak airway pressure with the I-gel median [interquartile range] was (24 cmH_2O [18–30]). In this study they only used size 4 I-gel, however 19 of their patients weighed more than 90 kg and the median seal pressure in these patients was higher than in patients weighing less than 90 kg (27 cmH_2O versus 24 cmH_2O).

In this study, we found no difference in the supraglottic view through I-gel device between supine and lateral position. The fiberoptic scoring was 3 in 80% (32) of cases and score 2 in 20% (8) of cases.

Similar to our study, Saracoglu et al. [12] study found that the fiberoptic view through the I-gel device did not indicate any difference between the two positions ($p = 0.542$)

Gupta et al. [28] found the improved fiberoptic supra glottic view that confirms that I-gel forms a good seal at laryngeal structures and ensures better ventilation and passage of a tracheal tube.

However, Asai [29] found that during the assessment of the correct position of the laryngeal mask airway that fiberoptic cannot confirm the correct position of the laryngeal mask airway, although it provides valuable information.

In our study, insertion of I-gel was done in 92.5% of patients during first trial of insertion, while there was 5% during second trial of insertion and 2.5% in third trial of insertion. This finding was similar to the study done by Saracoglu et al. [12]. (92% of patients successfully on the first attempt) and a simulator study done by Jackson and Cook [30].

We didn't record any intraoperative hypoxia, hypercapnia, or hemodynamic instability. Also, we didn't record postoperative swallowing difficulties, sore throat pain, hoarseness of voice, nausea or vomiting except for two cases with blood stain after removal of I-gel device.

5. Conclusion

The use of I-gel supraglottic airway device is safe and effective in both supine and lateral position in obese patients under mechanical ventilation providing

reliable ventilation and less postoperative complications. Future studies are recommended to use I-gel in surgical procedures in lateral position. Also, future studies are recommended to investigate feasibility of I-gel in morbidly obese patients.

Acknowledgments

We would like to thank our professors and colleagues in the Anaesthesia Department of Cairo University for their help and support.

Availability of data and material

The data that support the findings of this study are the possession of the Cairo University Hospital. However, data are available from the corresponding author upon reasonable request after permission from Cairo University.

Authors' contributions

BA and IF were responsible for idea conception of the study. BA, HM and IF contributed to the study design, data analysis, and manuscript writing. MW, BA and IF contributed to the data collection. BA, IF, MH, HM and MW contributed to the manuscript writing and revision. All the authors have read, revised and approved the final manuscript.

Disclosure statement

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Ethics approval from the Cairo University Hospital Research Committee - Department of Anaesthesia was obtained (S-12-2019). Written informed consent was obtained from the participants before inclusion.

Funding

No funding was obtained for this study. This research was conducted at the Cairo University Hospital using the equipment and resources available.

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