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Can I-Gel Replace Endotracheal Tube During Elective Cesarean Section?

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Introduction

It has been established that inability to successfully manage very difficult airway was been responsible for as many as 30% of death totally attributable to anesthesia [1].

The routine use of endotracheal tube is to secure the airway and prevent the aspiration of gastric content in case of regurge or vomiting but there is a case series demonstrated that the routine use of the endotracheal tube did not reduce maternal death due to aspiration [2].

Supraglottic airway devices have become a standard in airway management. These devices sit outside trachea but provide a hands free means of achieving a gas tight airway [3].

The i-gel is supraglottic airway devices. The soft non inflatable cuff fits snugly on to the perilaryngeal frame work, mirroring the shape of the epiglottis, aeryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation. It provides a better seal for positive pressure ventilation, separation of the respiratory from the alimentary tract [4]. The drain tube prevents gastric insufflations, allows easy placement of gastric tube it has been shown that the i-gel airway is better alternative device compared to PLMA for ease of insertion and maintenance of anesthesia [3,4].

The i-gel works in harmony with the patient's anatomy so that compression and displacement trauma are significantly reduced or eliminated [5].

Quick, easy and reliable to insert, i-gel is ideal for use as a routine airway in anesthesia as it is provides high seal pressures and reduced trauma. It also incorporates a gastric channel to provide additional protection against aspiration and has the versatility to be applicable for use during difficult airway management, as a rescue device and a conduit for intubation [5].

The aim of our study was to evaluate the efficacy of i-gel as rescue device in rapid establishment of airway and protect against pulmonary aspiration during elective CS under general anesthesia.

Hypothesis of study

The i-gel will be effective in protecting the airway during elective CS with no respiratory complications.

The incidences of pharyngolaryngeal morbidity will be low when compared to tracheal intubation.

Patients and Methods

This study was conducted on 1000 cases scheduled for elective CS under general (because of patients and obstetricians preference) in the obstetric department, Tanta University Hospital, after approval of the ethical committee and obtaining verbal and written informed consent from each patient. The duration of study from March 2015 to December 2016.

All patients' data were confidential with secret codes and was used for the current study only. Any unexpected risk appears during the course of the study was cleared to the patient and the ethical committee on time and the proper measures were taken to overcome these risks.

Ethical approval for this study was provided by the Ethical Committee of Tanta University Hospitals, Tanta, Egypt.

Exclusion criteria

Patient's refusal, multiple pregnancies, history of reflux, mouth opening less than 2.5 cm, morbid obese and emergency CS.

Preoperative preparation

All patients underwent preoperative assessment by history taking. Physical examination and laboratory investigations.

Premedication

All patients received 150 mg ranitidine and 30 ml of sodium citrate (non particulate antacid), and 10 mg of metclopramide one hour before anesthesia.

Intraoperative management

Patients were fasted for 8 hours before time of operation. On arrival to operating room an intravenous line was inserted. Patients were attached to monitor displaying ECG, HR, NIBP, $ETco_2$ and o_2 saturation. All patients received preoxygenation for 3 min, anesthesia was induced by propofol 2 mg/kg, rocuronium 0.6 mg/kg, assisted positive pressure ventilation was done, the size 4 i-gel for 50-90 kg or size 5 for more than 90 kg was inserted after lubricating the device with a water-based lubricant according to manufacturer's recommendations [5].

After insertion of the of the i-gel it was fixed by adhesive tape and adequate ventilation was confirmed by clinical observation of chest wall movement, listening to escape of gas from the mouth, bilateral chest auscultation, presence of square wave of capnogram and lack of gastric insufflation. 12 Fgasteric tube was inserted through gastric

channel. Decompression of patient's stomach was done and the gastric tube was connected to collection bag to drain freely during surgery.

The absence of square wave $ETCO_2$ trace denoted failure of establishment of effective ventilation, the device was completely removed for another insertion attempt. Two attempts were allowed. Insertion failure was defined if 2 unsuccessful attempts were encountered or if the entire process of insertion exceeded 60 s. In case of failure of insertion, the airway was secured with endotracheal tube.

If ventilation was inadequate, the following manipulations were allowed: gentle pushing or pulling of the device, chin lift, jaw thrust, head extension, or neck flexion. The number of attempts required for insertion was recorded. A 'failed attempt' was defined as removal of the device from the mouth before re-insertion. If the device was not successfully inserted by the second attempt, this was recorded as a failure of the i-gel.

Anesthesia was maintained with isoflurane 1% in oxygen. The tidal volume 6-8 ml/kg and respiratory rate 12-14/minutes and were adjusted to achieve $SpO_2 \geq 95\%$ and end-tidal CO_2 between 32 and 35 mmHg. The obstetricians were given instructions to avoid excessive fundal pressure during delivery of the fetus to avoid the increase in the intraabdominal pressure which may precipitate regurgitation and aspiration.

After delivery of babay 0.1 mg/kg morphine, 2 mg midazolam and 5 unites of oxytocine were given as bolus iv over 3 min then 10 unites of oxytocin in 500 ml ringers solution was infused to maintain uterine contraction.

After completion of surgery, residual neuromuscular block was antagonized with atropine 0.02 mg/kg and neostigmine 0.05 mg/kg. The i-gel airway device was removed once patient had spontaneous breathing, return of airway reflexes, spontaneous or on command eye opening and purposeful movement. The airway device was then inspected for the presence of visible blood on the surface. Patients were interviewed in the recovery room for sore throat, hoarseness, dysphagia, Coughing, laryngospasm or dysphonia.

Regurgitation was defined by the identification of gastric content (with a pH<4) into the mouth. The pH of the inner bowl of the i-gel was measured and a pH<4 was taken as being indicative of 'aspiration' with or without the evidence of regurgitation [6].

The primary outcome was defined as the number of patients developed respiratory adverse events as oxygen desaturation, Partial or Complete upper airway obstruction, Laryngospasm and /or Clinically apparent pulmonary aspiration.

Secondary outcomes

- -Numbers of attempts of insertion
- -Insertion time (the interval between I gel entering the mouth to first end-tidal carbon dioxide (ETCO2) trace on the monitor)
- -Peak airway pressure
- -Leak pressure
- -Leak volume (The difference between inspired and expired tidal volume)
- -The need of ETT
- -Recovery time,
- -Patients and obstetricians satisfaction,
- -The incidence of other adverse events rather than respiratory events as
- -Presence of visible blood on the surface of the i-gel
- -Sore throat
- -Hoarseness
- -Dysphagia
- -Coughing or laryngospasm

Result

A size-4 or 5 i-gel was inserted for airway management in all parturients. There were no clinical evidence of aspiration or regurgitation in any of the parturients; insertion of the i-gel was successful in all cases, and we were able to maintain ventilation and oxygenation in all parturients.

Patient demographics are shown in table 1, the mean age was 28.7 ± 5.4 years, the mean weight was 82.5 ± 8.7 kg and the mean body mass index (BMI) was 28.5 ± 3.4.

2% (20 patients) had cardiac disease, 5% (50 patients) had hypertensive disorders of pregnancy and 1% (10 patients) had bronchial asthma.

Characters	Result
Age (years)	28.7 ± 5.4
Weight (kg)	82.5 ± 8.7
Hight (cm)	170.6 ± 10.4
BMI (kg/m^{-2})	28.4 ± 3.4
Mallampati score	I-III
Cardiac diseases	2% (20) patients
Hypertensive disorder	5% (50)
Bronchial asthma	1% (10)
Diabetes	2% (20)
duration of anesthesia	45.7 ± 5.8min
Induction-delivery time (min)	10.3 ± 3.5min
Uterine incision –delivery time (sec)	80 ± 34.5sec
Values are means ± SD (standard deviation); BMI = body mass index	

Table 1: Demographic data, diseases with pregnancy, duration of anesthesia.

The insertion characteristics of the i-gel are shown in table 2, successful placement in the 1st attempt was 99%, the insertion time was 8.4 ± 3.3 sec, the time to successful airway insertion was 11.3 ± 2.4 (sec). Recovery time was (10.45 ± 2.56 min). The time needed to achieve Aldrete Recovery Scale Score of 9 was (14.35 ± 6.34 min).

Characters	Result
Successful placement in the 1st attempts	99%
Successful placement in the 2st attempts	1%

Time to successful airway insertion (sec)	11.3±2.4
Failure of insertion	0.0%
The need for endotracheal tube	0.0%
The ease of airway insertion: Grade I Grade II	98% 2%
Peak airway pressure (cm2H2O)	15.4±2.8
Leak pressure (cm2H2O)	22.4±4.4
Leak volume (mL)	25.8±4.5
Recovery time(min)	10.45 ± 2.56
The time needed to achieve Aldrete Recovery Scale Score of 9 was (min)	14.35 ± 6.34
Values are in number of Parturients (%), mean ± SD (standard deviation)	

Table 2: Insertion characteristic of the i-gel.

There were no incidences of bronchospasm, laryngospasm, aspiration, regurgitation, partial or complete airway obstruction in our study or postoperative nausea and vomiting as we see in table 3.

Characters	Result
Regurgitation	0%
Incidence of coughing/laryngospasm	0%
Sore throat	2%
Dysphagia	0%
Visible blood on the airway device	0.5%
Bradycardia	1%
Tachycardia	0.5%
Hypotension	1%
Hypertension	0.5%
pH of inner bowl of i-gel <4 after surgery	0%
Tingling in the tongue	0.1%
Patient satisfaction (0-100scale)	98%
Obstetricians satisfaction (0-100scale)	98%
Values are in number of Parturients (%)	

Table 3: The incidence of adverse events.

The adverse events other than respiratory were hypotension occurred in 10 patients (1%), while hypertension was recorded only in 5 patients (0.5%). Bradycardia was found in 10 patients (1%). Tachycardia occurred in 5 patients (0.5%), one patient (0.1%) complained of tingling in the tongue which resolved spontaneously within one week, sore throat was seen in 20 patients (2%), which resolved spontaneously within 24 hours with lozenges and analgesics.

Discussion

In our study in a large numbers of parturients, and somewhat over weight, we found that, the i-gel supraglottic airway provided an acceptable means of ventilation and oxygenation during elective Cesarean delivery. With no episode of hypercapnia or desaturation was observed, and the use of i-gel might potentially prevent the pressor response to laryngoscopy and tracheal intubation, which had particular importance in cardiac, hypertensive and pre-eclamptic patients.

The i-gel requires less time for insertion with minimal hemodynamic changes when compared to ETT. i-gel also provides adequate positive-pressure ventilation, comparable with ETT. In addition, the gastric channel in i-gel provides protection against aspiration. Hence, i-gel can be a safe and suitable alternative to ETT [7].

Ismail SA et al. concluded that, the insertion of the i-gel device provides better stability of the haemodynamic system compared with insertion of an endotracheal tube or LMA in patients undergoing elective non-ophthalmic surgery [8].

Trivedi V et al., concluded that, the i-gel airway is a better alternative user friendly device than Proseal LMA in patients with high risk and having predicting difficult airway because of ease of insertion and maintenance of hemodynamic stability [1].

The haemodynamic responses to LMA were diminished compared with tracheal intubation. The incidence of post-extubation complications was reduced but not eliminated by using the less invasive laryngeal mask airway [9].

The ETT was associated with greater hemodynamic response not only to airway placement but also to surgical incision and airway removal. The ETT resulted in more coughing after removal than did the LMA. The LMA induced less coughing at removal, and less analgesic was required during recovery [10].

Other studies show that, the supraglottic airways reduce the risk of mucociliary dysfunction [11], laryngeal oedema [12] and hoarseness of voice [13] compared to the tracheal tube.

The risk of difficult intubation is eight times greater in obstetric patients than general surgery with failed intubation range between 0.05-0.3 percent [14].

Intubation has resulted in complications, including regurgitation, aspiration, airway trauma, dental trauma, esophageal intubation, maternal and fetal hypoxemia, and even death. Difficult intubation with hypoxia not aspiration perse is the leading anesthetic cause of maternal death [15,16].

The use of i-gel reduces the complications of multiple attempts of tracheal intubation and providing a good method of oxygenation and ventilation. The i-gel showed adequate seal in all of our parturients with no incidence of any respiratory events. Also, the i-gel is a single-use disposable device that reduces the risk of transfer of infectious material or body fluids compared with improperly cleaned reusable devices.

In our study i-gel was used instead of Proseal LMA because of the cuff of Proseal LMA may impede its proper placement and lack of back-plate may lead to a fold over malposition [17,18].

Postoperative sore throat is a common adverse outcome in patients underwent surgeries. The method used for airway management has the

strongest influence on the incidence of sore throat. The association between postoperative stay and sore throat could result from the discomfort of a sore throat early in the postoperative period making patients reluctant to go home [19].

The incidence of sore throat in our study was low, this could explained by ease of insertion, proper anatomic fit, no manipulations were required to adjust the device, with no inflatable cuff. where postoperative sore throat is reported to be in excess of 25% with tracheal tube placement [20].

Devices with an inflatable cuff have the potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated postoperative morbidity [4] Trauma on insertion, multiple insertions, and pressure exerted by cuff against the pharyngeal mucosa, [21,22] cuff volumes [23] and pressure [24] have all been incriminated for postoperative complications.

Chauhan et al., concluded that the i-gel is better than PLMA in terms of faster insertion and ease of insertion with a low incidence of pharyngolaryngeal morbidity. It requires less manipulation and no cuff inflation is required, therefore securing an airway is rapid in most of the patients [25].

Our study in agree with Berger et al., [26] which reports the case of the use of i-gel in failed obstetric tracheal intubation. It suggests that the i-gel is likely to be a better choice as a primary rescue airway device in obstetric anesthesia because of easier insertion, requires fewer insertion attempts and is less traumatic than a laryngeal mask airway. Other studies which use the LMA conclude that "the LMA is effective and probably safe for elective Cesarean section [27-30].

Our findings suggested that, the supraglottic device i-gel can be a useful alternative to tracheal intubation for elective cesarean section in a selected population. We are not advice against the use of tracheal intubation, but we only put a high light on alternative method of airway management in the obstetric population. The use of the i-gel may decrease the risk of complications associated with difficult intubation or failed intubation scenarios, therefore potentially decreasing anesthesia-related maternal morbidity and mortality. We advise to add the i-gel to airway management guidelines/difficult airway protocols in obstetric anesthesia.

In conclusion, we can said that, the i-gel is useful supraglottic device and can replace the need of tracheal intubation in elective cesarean section with no reported serious complications and low incidences of pharyngolaryngeal morbidity when compared to tracheal intubation.

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