

To Compare and Evaluate the Role of I-gel, PLMA and ET Tube in Patients Undergoing Elective LSCS under GA

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Abstract: Background: Obstetric patients undergo many physiological and anatomical changes, making them vulnerable to difficult airway situation. To deal with difficult airway is a challenging opportunity for every anesthesiologist. Regional anesthesia is preferred choice but in many situations general anesthesia is given, to conduct an elective cesarean section. Endotracheal tube (gold standard) and SGDs are airway securing devices to provide GA. Over the years many authors studied the role of various SGDs to secure airway in elective LSCS. I-gel has been used as rescue device but not as an airway securing device in elective LSCS, therefore we conducted our study to compare and evaluate the role of I-gel, PLMA and ET tube in patients undergoing elective LSCS under GA. Material and methods: A prospective, randomized controlled study with a sample size of 90, with 30 patients in each group was conducted. A standard anesthesia protocol was followed. Patient was pre-oxygenated and underwent rapid sequence induction then depending on the group decided by random number table, appropriate size I-gel / PLMA or endotracheal tube was inserted and confirmation of successful placement was done. Primary objective of this study was to compare the time to achieve effective airway with these three devices. The secondary objectives were to compare ease of insertion, hemodynamic changes and the complications. Results: The mean time to achieve effective airway for I-gel was 13.27±2.17 seconds, for PLMA it was 30.45±3.84 seconds, and for ETT was 28.05±4.64 seconds. Conclusion: Time to achieve effective airway was minimum with I-gel followed by ETT and was maximum with PLMA. I-gel insertion was easier as compared to PLMA and ETT.

Keywords: Elective LSCS, GA, I-gel, Insertion characteristics

1. Introduction

Obstetric patients pose a special concern for anesthesiologist, due to the changes in physiology as well as in airway anatomy, making them vulnerable to difficult airway situation.¹ Anesthesia technique is often based on indication of surgery, its urgency, maternal and fetal status and also patient's choice for anesthesia.¹ Although, neuraxial anesthesia is preferred in obstetric patients but there are certain situations where general anesthesia is considered appropriate for cesarean section.^{1,2} Over the years tracheal tube intubation with RSI along with application of cricoid pressure is considered as the gold standard for GA in obstetric patients.^{1,3}

The incidence of difficult airway is reported to be 8 times higher in obstetric patients than the nonpregnant female.⁴ Role of SGDs is well accepted in obstetric practice as rescue device for difficult intubation.⁵⁻⁷ Various authors have studied the role of SGDs to secure airway and provide anesthesia to obstetric patients.⁸⁻¹⁰ I-gel is a preformed SGD meant for single use and has a softer, non-inflatable cuff made up of thermoplastic elastomer gel. The cuff forms a good seal over time due to its thermoplastic property. Being a 2nd generation device I-gel also provides an effective gastric drainage.¹¹⁻¹³ In all these years the role of I-gel to secure airway and provide anesthesia has been studied for various procedures including laparoscopic surgeries.¹⁴ In obstetric practice its

role as rescue device has been reported.¹⁵ Recently its use as a sole airway securing device, as compared to ETT, to provide anesthesia in obstetric patients is reported.¹⁶ But the role of I-gel is yet not compared to PLMA in patients posted for caesarean section.

2. Material and Methods

The present study was designed to evaluate the role of I-gel as compared to PLMA and ETT in patients undergoing elective cesarean section. After obtaining approval of the institutional ethical committee and written informed consent, a prospective, randomized controlled study was conducted in 90 patients, with 30 patients in each group. Patients undergoing LSCS under general anesthesia belonging to ASA grade I and II were included for use of I-gel, PLMA or endotracheal tube to secure the airway. Those with history of less than 6 hrs of fasting, known/predicted difficult airway, symptoms of pharyngeal reflux or GERD & BMI >30 kg/m² were excluded from the study. Patients were assigned to one of the three groups by computer generated random number table. The groups were, group T- Patients with Tracheal tube insertion, group P - Patients with Proseal LMA insertion, group I- Patients with I-gel insertion. After a fasting period of 6 hours, patients received aspiration prophylaxis in the form of Inj. Ranitidine 50 mg IV and Inj. Metoclopramide 10 mg IV one hour before surgery. In the OT patients were placed in supine position with lateral tilt for left uterine displacement. A standard anesthesia protocol was followed, routine monitoring was applied, patients were

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preoxygenated and rapid sequence induction technique was applied using inj. thiopentone sodium 3-4 mg/kg i.v, inj. suxamethonium 1.5 mg/kg i.v and cricoid pressure was applied by an assistant, following this based on randomisation, appropriate size I-gel / PLMA or an ET tube was inserted according to the recommended guidelines. For Group I, the I-gel was selected according to manufacturer's instructions, size 3 (for 30-60kg weight) and size 4 (for 50-90kg weight). The device was then inserted according to the guidelines for use by lubricating the cuff in front, back and sides with water based lubricant jelly. Then I-gel was fixed by taping from maxilla to maxilla with the bite block in between the teeth.⁵

For Group P, the PLMA was prepared according to the guidelines. Then the device was inserted and cuff was inflated with appropriate volume of air according to the size of PLMA.

For Group T, appropriate size (7mm ID or 7.5mm ID) Tracheal tube was inserted following laryngoscopy under vision. The cuff was inflated and tracheal tube was fixed following confirmation.

After connecting the airway device to anesthesia breathing circuit, manual ventilation was started and the correct placement was confirmed by auscultation of chest and appearance of square wave capnograph on the monitor.⁹⁻¹¹

The time to effective ventilation, defined as time from picking up the device and appearance of square wave capnograph, was noted.¹¹ Ease of insertion was assessed as, 1=easy, 2=difficult, 3=impossible⁹ and number of attempts were also noted. If more than 2 attempts with the supraglottic device were required then ET tube was inserted and patients were excluded from the study.

After successful placement, a jelly plug was placed in the proximal 1cm of the gastric drain outlet and by gently tapping the suprasternal notch causing the jelly to pulsate, confirming the tip location behind the cricoid cartilage then an orogastric tube was advanced via gastric drain outlet.⁹

The oropharyngeal leak pressure was measured after closing the APL valve with a fresh gas flow of 3L/min, noting the pressure at equilibrium or when there was an audible leak from the throat. The maximum pressure allowed was 40 cm H₂O.^{9,13} Oxygen saturation, Et CO₂, hemodynamic variables, i.e. BP and HR, were monitored throughout the procedure. Any change of $\pm 20\%$ from the baseline in BP and HR, at the time of insertion and removal of device was noted.

Anesthesia was maintained with 50% N₂O and 50% O₂ and isoflurane 0.5-1.5% and vecuronium bromide for neuromuscular blockade. The obstetricians were instructed to avoid excessive fundal pressure during the extraction of fetus. Following delivery of baby, gas flows were adjusted to deliver 40% of oxygen with 60% of N₂O, oxytocin (20 units) was given to contract the uterus. Morphine was given for analgesia. Neuromuscular blockade was reversed after skin closure with neostigmine 0.05-0.08 mg/kg IV and glycopyrrolate 0.008-0.01 mg/kg IV. The

device I-gel/PLMA/ET tube was then removed after patients were awake and spontaneous respiration was achieved. The device was examined for blood stain or any signs of regurgitation as visible gastric contents and litmus paper test of the secretions present around the cuff or inner side of bowl. During the study the various parameters observed were insertion characteristics (time to achieve effective airway, ease of insertion, number of attempts) at the time of insertion along with oropharyngeal leak pressure, Et CO₂, SpO₂, hemodynamic variables. Post insertion at 1minute, at delivery 15minute, 30minute, 45 minute and end of surgery OPL, Et CO₂, SpO₂, Hemodynamic variables. At the time of removal of device hemodynamic variables, soiling of cuff either with blood or regurgitant fluid was seen and postoperatively Incidence of sore throat, dysphagia, dysphonia graded as mild, moderate, severe were asked by questioning to patient at 1 hour and 24 hours post operatively.¹³

Data was analysed using SPSS version 17 computer software. The recorded parameters including age, weight, BMI, time of insertion were evaluated by unpaired t-test. The inter-group comparison of rest of the parameters i.e. ease of insertion, number of attempts, hemodynamic changes at insertion, intraoperatively and removal of device, incidence of post-operative complications (sore throat, dysphonia, dysphagia) was done using Chi-square test/Fisher's exact test. p value <0.05 was considered as significant.

3. Results

The study was conducted in the Department of Anesthesiology & Critical Care, U.C.M.S and G.T.B Hospital (University of Delhi) from November 2012 – April 2014. The study was designed to compare and evaluate the use of I-gel, Proseal LMA and Tracheal tube in patients undergoing elective caesarean section delivery under GA and the main objective was to compare the time to achieve effective airway with these three devices.

The demographic data of the patients are depicted in Table 1. The p value was statistically significant when group T was compared with group I and P.

Table 1: Demographic Profile

Variable	Group I	Group P	Group T	p- value
Age(years)	25.43 \pm 3.19	25.23 \pm 3.36	24.47 \pm 3.53	0.504
Weight(Kg)	56.83 \pm 2.92	58.40 \pm 3.90	62.57 \pm 5.64	0.000*
BMI	23.65 \pm 1.37	24.04 \pm 1.59	23.58 \pm 1.69	0.462

*p value < 0.05 is statistically significant

At the time of insertion, insertion characteristics were noted. The mean time to achieve effective airway is shown in Table 2. The time to achieve effective airway was least with I- gel.

Table 2: Time to achieve effective airway

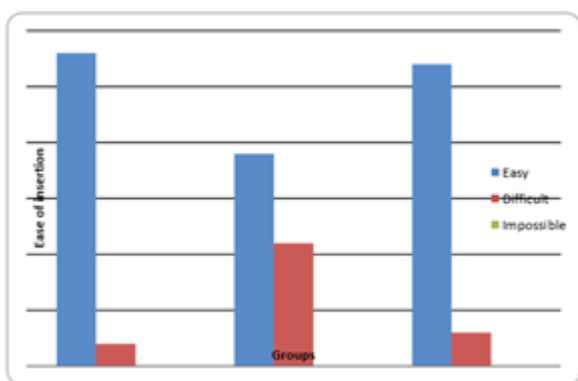
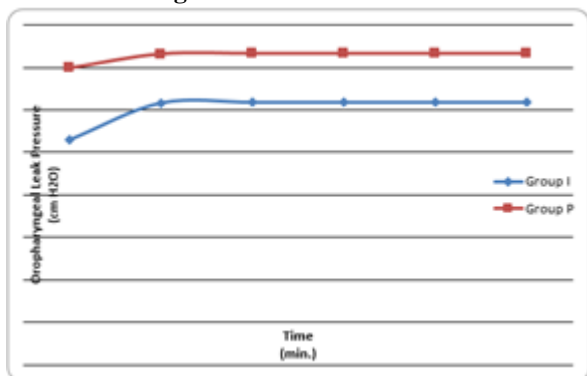
Variable	Insertion Time (mean \pm SD) (Sec.)	p-value
I-gel	13.27 \pm 2.17	0.001*
PLMA	30.45 \pm 3.84	0.001*
EETT	28.05 \pm 4.64	0.037*

The ease of insertion is shown in Figure 1. Insertion was more difficult in group P. Number of attempts required are shown in Table 3.

Table 3: Number of attempts

No. of attempts	I	P	T
1	26 (86.66%)	23 (76.66%)	27 (90%)
2	4 (13.33%)	7 (23.33%)	3 (10%)
3	0	0	0

OPI measured is shown in Figure 2. There was statistically significant difference in oropharyngeal leak pressure between group I and group P while it could not be measured for group T. Patients in all the three groups maintained saturation of more than 97% throughout the operative period. There was no clinically significant difference ($\pm 20\%$) in heart rate and SBP from baseline during insertion, delivery or removal of the device in group I and P. However there was a clinically significant increase ($+20\%$) in the heart rate and SBP from baseline during insertion and during removal of endotracheal tube (group T). Regurgitation was not observed in any of the patient. None of the devices showed staining with blood due to mucosal trauma. In postoperative period none of the patient complained of sorethroat, dysphonia and dysphagia in group I and group P. All patients in group T where endotracheal tube was inserted complained of sorethroat in postoperative period and the pain persisted even after 24 hrs in 14/30 patients.

**Figure 1:** Ease of insertion**Figure 2:** Oropharyngeal Leak Pressure

4. Discussion

The challenge while providing anesthesia for caesarean section is unique to obstetric anesthesiologist where one has to provide care for both the mother and the unborn baby. Although spinal anesthesia is the preferred technique for caesarean section, G.A at times becomes imperative under certain circumstances due to the specific advantages it provides.¹ However, failed intubation

remains a matter of concern in this subset of patients due to various anatomical and physiological changes in pregnancy. Thus, the need for a safe and easy to use airway device has been recognized and supraglottic airway devices have been taken under consideration by researchers.⁸⁻¹⁰

PLMA has been used successfully by various anesthesiologists across the world when failed intubation was encountered during induction of anesthesia in obstetric patients. In 2004, Keller and colleagues and also Awan and colleagues reported use of PLMA after failed intubation in an unanticipated difficult airway in a patient undergoing LSCS.^{7,17} These authors opined that PLMA have several advantages such as protection against aspiration when correctly positioned and a gastric drain tube through which fluid and air can be suctioned out. Successful use of PLMA for caesarean section has also been reported by Halaseh et al in a large number of patients.⁹

According to a preliminary study conducted in our department the insertion of PLMA requires high level of skill and expertise especially in obstetric patients because of anticipated difficult airway.¹⁹ Also problems like retroversion of bowl and erroneous insertion have been reported.¹⁸ Recent advances provided us with a newer supraglottic device, I-gel, which has better insertion and hemodynamic characteristics²⁰⁻²². Since no comparative studies has been reported regarding use of I-gel and PLMA in obstetric patients, present study was designed to compare these two devices for obstetric patients posted for elective LSCS. In the present study the mean time of insertion for I-gel was significantly lower (13.27 ± 2.17 seconds) than both PLMA and ETT. This was longest for PLMA insertion and could be attributed to the time required for the removal of introducer device and inflation of the cuff of PLMA

In our study of selected group of patients, we were able to achieve easy insertion in 93.3% patients in I-gel group whereas in 66.6% patients in PLMA group, this was clinically significant. Brimacombe et al. have opined that difficulties in inserting PLMA were caused by larger cuff requiring digital intraoral positioning at times and leading to propulsion into pharynx.^{23,24}

The oropharyngeal leak pressure was one of the parameter observed during our study and was measured by manometric stability test.²⁵ The high oropharyngeal leak pressure is necessary to deliver the required peak airway pressures.²⁶ The oropharyngeal leak pressure for I-gel in the present study was 30.87 ± 3.51 cmH₂O which is comparable to the mean oropharyngeal leak pressure reported by Gatward et al is $24(18-30)$ cmH₂O^{14,27,28} and 30 ± 7 cm H₂O by Richez et al.²⁹ The seal pressure of I-gel appeared to improve over time in a number of patients and this was due to the thermoplastic properties of the gel cuff which helps to form a more efficient seal around the larynx after warming to body temperature^{13,27} and the same has been observed in every patient in our study also. The mean oropharyngeal leak pressure was higher for PLMA and is most likely due to the deeper bowl, a bigger cuff with its dorsal and ventral components, the proximal wedge shape of the cuff, the corresponding larger surface area in comparison to I-gel and also due to the inflatable nature of the cuff in comparison to the cuffless I-gel.^{26,30} Though OPL of I-gel was significantly lower than the oropharyngeal leak pressure observed for PLMA but the seal created by I-gel was sufficient in providing positive

pressure ventilation and also the device separated the GI tract from Respiratory tract quiet well in all the patients.

In all the patients in the three groups the mean EtCO₂ and oxygen saturation were within normal limits. There was no episode of desaturation in the patients. Our study reflects hemodynamically stable characteristics of SGDs in comparison to Tracheal tube. Ismail et. al also concluded that I-gel provides better hemodynamic stability in comparison to both ETT and LMA in patient's undergoing elective non ophthalmic surgery.²¹ Nasogastric tube was inserted whenever SGD (PLMA and I-gel) was used and there was no visual evidence of regurgitation or aspiration and blood staining of the device. Regurgitation was reconfirmed with litmus paper test of the secretions present in and around the bowl of the cuff. Similar results were observed by Halaseh et.al & Han et. al in large number of patients with SGDs.^{8,9}

Association of any post-operative morbidity, like sorethroat, dysphonia & dysphagia in patients undergoing caesarean section has implications on an immediate bonding of mother with the new born. In our study none of the patients in either group with SGDs complained of sore throat, dysphonia and dysphagia while all the patients complained of sore throat in ETT group but none reported dysphonia and dysphagia. This could be explained due to better anatomic fit and less tissue compression by the SGD.

Thus from the findings of our study, we conclude that this single use 2nd generation SGD, I-gel, being disposable device reduce the risk of cross infection & provide adequate ventilation in selected group of patients.

There are certain limitations to our study like the sample size we studied was small so further studies with more number of patients is required. The study group included only elective cesarean section with adequate fasting, so patients posted for emergency surgeries further need to validate the findings. Although experienced anesthetist inserted the devices but a single experienced hand would have affected the outcome.

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