

Comparative study of fiber-optic guided tracheal intubation through intubating laryngeal mask airway LMA Fastrach™ and i-gel in adult paralyzed patients

ABSTRACT

Background: The i-gel is a novel and innovative supraglottic airway management device used both as an airway rescue device and as a conduit for fiberoptic intubation. In this prospective randomized study, we compared fiberoptic-guided tracheal intubation through the i-gel and LMA Fastrach™ in adult paralyzed patients.

Materials and Methods: After ethical committee approval and written informed consent, 60 patients of either sex were randomly allocated to either group of supraglottic airway device (SGAD). After successful insertion of the SGAD, the fiberoptic bronchoscope (FOB)-guided tracheal intubation was done through the respective SGAD. The primary objectives were the ease and time taken for fiberoptic-guided intubation in either group. Secondary variables included time taken for successful placement of SGAD, ease of insertion of SGAD, airway seal pressure, ease and time of removal of SGAD, variation in hemodynamic parameters, and complications if any.

Results: Time taken for tracheal intubation in LMA Fastrach™ group was 69.53 ± 5.09 s and for the i-gel group it was 72.33 ± 6.73 s. It was seen that it was easy to insert the endotracheal tube (ETT) in 93.3% patients in the LMA Fastrach™ group and 96.7% patients in the i-gel group. Airway seal pressure was higher for the LMA Fastrach™ group. Both the SGADs were comparable in the number of attempts of insertion, ease of insertion, and insertion time. In addition, the hemodynamic variables noted did not show any increase after insertion of SGAD. There was no difficulty encountered in removal of either SGAD.

Conclusion: I-gel may be a reliable and cost-effective alternative to LMA Fastrach™ for fiberoptic-guided tracheal intubation.

Key words: Airway seal pressure; endotracheal tube; fiberoptic intubation; i-gel; LMA Fastrach

Introduction

In 1983, the first SGAD was developed, and they assumed various advantages over traditional endotracheal intubation. Their placement is less invasive, better tolerated by the patient and does not require laryngoscopy. LMA can be used as an airway device on its own and can also be used as a conduit for blind and fiberoptic-guided intubation.^[1-3]

Various SGADs have been designed, each incorporating a new and different feature. Some are reusable vs. disposable, some incorporate a separate gastric drain tube, and few come with inflatable cuffs and others not.^[4,5]


The LMA Fastrach™ airway is an advanced type of SGAD, especially designed to facilitate tracheal intubation with

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an endotracheal tube (ETT). It permits single-handed insertion with the head and neck in a neutral position. The dorsal surface of the LMA Fastrach™ tube is calibrated at approximately 1 cm interval. In addition, it is fitted with a rigid handle, permitting one-handed insertion, removal, and “steering” of the device in relation to the larynx.^[6]

Historically, the LMA brands have all had inflatable cuffs, but the i-gel is a novel and innovative SGAD discovered in 2007. It is made of medical grade thermoplastic elastomer and has a noninflatable cuff. The short and wide stem, large bowl, better alignment with glottis along with the absence of aperture bars makes i-gel a favorable conduit for fiberoptic-guided tracheal intubation.^[7-9]

The primary aim of the present study was to compare fiberoptic-guided tracheal intubation through intubating laryngeal mask airway LMA Fastrach™ and i-gel in terms of total time taken for intubation and ease of tracheal intubation. Time taken for successful placement of SGAD, ease of insertion of SGAD, airway seal pressure, ease and time of removal of SGAD, variation in hemodynamic parameters, complications if any, were observed as secondary objectives.

Materials and Methods

With the written informed consent and approval of institutional review board, 60 patients of either gender in the age group of 18–60 years, belonging to American Society of Anesthesiologists physical status I or II, scheduled to undergo elective surgery in the supine position under general anesthesia, were enrolled in the study. The patients with known difficult airways, cervical spine disease, body weight <30 kg, mouth opening <2 cm, a history of upper gastrointestinal surgery, bleeding or clotting abnormalities, hiatus hernia, gastroesophageal reflux disease, and a full stomach were excluded from the study. Selected patients for the study were examined preoperatively and subjected to a complete history taking and general physical examination was done. Routine investigations including complete blood count, blood urea, serum electrolyte, and liver function test were carried out. Patients fasted for 6 hours and were then premedicated with oral alprazolam 0.25 mg and tablet ranitidine 150 mg on the previous night, and 2 hours preoperatively. After the establishment of an intravenous line and attachment of standard monitors for noninvasive blood pressure, electrocardiography and pulse oximetry in the operating room, general anesthesia was induced. Induction of anesthesia was achieved using a standard technique comprising of intravenous administration of injection glycopyrrolate 0.4 mcg kg⁻¹, followed by injection

fantanyl 1.5 mcg Kg⁻¹, injection propofol 1-1.5 mcgkg⁻¹ till eyelash reflex is abolished. Injection vecuronium bromide (0.1 mgkg⁻¹) was administered to facilitate SGAD placement. After following manual ventilation for 180 s with 3% sevoflurane and 50% mixture of nitrous oxide and oxygen via face mask at the fresh gas flow of 4 L each as shown on rotameter via face mask a proper size SGAD; LMA Fastrach™ or i-gel was inserted as per manufacturer’s instructions as was in opening slipped number opaque slips. Its correct placement was verified by auscultation of breath sounds, together with a square wave capnography. A maximum of three insertion attempts was permitted before placement of the device was considered to be a failure, in which case, an alternative airway device was used to secure the airway. The number of attempts, ease of insertion, insertion time, and airway seal pressure were recorded.

Ease of insertion was graded as easy, difficult, or a failure. An easy insertion was defined as placement without resistance, following a single attempt. More than one attempt to seat the device was considered a difficult insertion. A failed insertion was deemed to have occurred when it was not possible to insert the device after three attempts.

Airway seal pressure was determined by switching off the ventilator at a fresh gas flow of 3 L/min⁻¹, with the expiratory valve completely closed and recording the airway pressure (maximum allowed 40 cm of water) at which equilibrium reached.

Subsequently, patient was disconnected from the breathing circuit. A flexible pediatric FOB (3.5 mm Karl Storz GmbH & Co. KG, Tuttlin-gen, Germany fiberscope) preloaded with a well-lubricated ETT of adequate size was inserted through the SGAD. Fiberoptic grading of the glottis was done from the outlet of respective SGAD and recorded as follows:

1. vocal cords entirely visible
2. vocal cords or arytenoid cartilages partially visible
3. epiglottis only visible
4. no laryngeal structures visible.

Subsequently, FOB was inserted into trachea till the carina was visualized, then the tracheal tube was railroaded over the FOB into the trachea 3–4 cm proximal to the carina. The bronchoscope was then removed and the tracheal tube was connected to the breathing circuit. Manually ventilating and simultaneously auscultation of breath sounds and square waveform capnograph confirmed the correct placement of ETT.

In LMA Fastrach™ group, fiberoptic-guided tracheal intubation was done according to manufacturer’s recommendation. ETT

was inserted up to 15 cm depth initially and then verified with the FOB that the endotracheal tube tip contacts the epiglottis elevating bar (EEB) of the device, the ETT was advanced little further so that it lifts the EEB showing the glottis, then the ETT was advanced into the trachea. Care should be taken that the FOB should not protrude through the end of the assembled ETT and it should also not pass beyond the EEB of LMA Fastrach™ unless protected by the ETT, otherwise its tip may be damaged.

In the i-gel group, fiberoptic-guided tracheal intubation was done by conventional method. After recording the laryngeal view grading, the fibroscope, with a well-lubricated ETT, was passed through the airway tube of the i-gel and upon visualization of glottis, ETT was railroaded over the fibroscope into the trachea.

The standard polyvinylchloride (PVC) ETT size 6.5 or 7 for a size 3 or 4 SGAD, respectively, was used in both the groups.

The ease of ETT placement was graded as easy, difficult, or failure. An easy tracheal tube placement was defined as placement of the ETT in a single manoeuvre. A difficult tracheal tube placement was the one where more than one attempt was required to place the ETT in correct position. In case it was not possible to intubate the trachea through SGAD in three attempts, it was labeled as failure and surgery was continued with either the SGAD or it was substituted by definitive airway depending on the nature of the surgery. Time of endotracheal tube placement was defined as the time interval between picking up of fibroscope loaded with ETT till the correct tracheal tube placement was noted. Following that, in either group, ETT cuff was deflated and SGAD was removed using tube stabilizer rod provided with LMA Fastrach™. Ease of removal of SGAD and time required to remove SGAD was noted. After removal of SGAD in both the group's damage to cuff, bloody secretion or mucus was noted, following which the tube cuff was reinflated and connected to the ventilator circuit. Anesthesia was then maintained by circle absorber system with 1% dial concentration of isoflurane in 67% nitrous oxide and 33% oxygen to achieve MAC value of 1. Adequate intraoperative analgesia was given and after the completion of surgery the patient was reversed and extubated. The patient was then monitored in post anesthesia care unit for the next 24 hours.

Results

Primary objectives for our study were to compare fiberoptic-guided tracheal intubation through intubating laryngeal mask airway LMA Fastrach™ and i-gel in terms of total time taken for intubation and ease of tracheal intubation as primary objectives. To find insertion success rate, airway

seal pressure, ease of removal of SGAD were observed as secondary objectives [Tables 1 and 2].

The number of attempts made during insertion of SGAD was studied, showing single attempt success rate in 93.3% patients in the LMA Fastrach group (FT) and 96.7% patients in the i-gel group (IG). Two attempts were required for insertion in 6.7% patients in the FT group and in 3.3% of patients in the IG group. Three attempts for the insertion of SGAD were not required in either of the groups. In the patients who required a second attempt, the common maneuvers employed were neck extension and chin lift. There is no statistically significant difference in the number of attempts required for insertion of the two SGADs.

Ease of insertion of SGAD was assessed in the present study. In 93.3% patients in FT group and 96.7% patients in the IG group, SGAD insertion was easy. Difficulty in the insertion of SGAD was encountered in 6.7% patients of FT group and 3.3% patients of IG group. Failure to insert was not recorded in either of the group.

The mean insertion time taken to insert the SGAD was noted in seconds in the present study. The mean insertion time recorded was 25.37 ± 4.19 s and 23.60 ± 3.47 s in FT and IG groups, respectively.

Fiberoptic view was recorded and it was found that all the patients in FT group were graded as Grade I on fiberoptic examination, whereas only 86.7% patients in IG group were graded as Grade I on fiberoptic examination. Grade II and Grade III were recorded in 10% and 3.3% patients of only IG group, respectively.

The number of attempts needed to insert the ETT was recorded and it was found that ETT was inserted in the single attempt in 93.3% patients in FT group and 96.7% patients in IG group. The second attempt was required in 6.7% patients in the FT group and 3.3% patients in the IG group. The third attempt was not required in either group and there was no failure in either of the group.

Ease of insertion of tracheal tube was noted and it was easy to insert the ETT in 93.3% patients in FT group and 96.7% patients in IG group, difficulty to insert the ETT was noticed in 6.7% patients in FT group and 3.3% patients in IG group. There was no failure in either of the group.

The mean time required for placement of ETT was recorded and was found to be 69.53 ± 5.09 s in FT group and 72.33 ± 6.73 s in IG group.

Mean total time required to intubate the trachea was calculated by adding time required to insert the SGAD and time required for tracheal tube placement. It was found to be 94.90 ± 5.77 seconds in FT group and 95.93 ± 8.11 seconds in IG group.

Meantime required for removal of SGAD was noted. It was 20.37 ± 1.85 seconds for FT group and 19.67 ± 2.19 seconds for IG group.

Individual complications were recorded in each patient of the study groups. Blood on LMA after removal was observed in one patient of the FT group but none in IG group. It was statistically insignificant. No specific reason can be given for this as in this patient; LMA Fastrach™ could be inserted easily in the first attempt and had fiberoptic grading I. Sore throat was observed in 13.3% and 10% patients in and IG groups, respectively. Vomiting was observed in one patient of the FT group. Similarly, no specific reason can be given for this as in this patient also, LMA Fastrach™ could be inserted easily in the first attempt and had fiberoptic grading I.

Discussion

In this prospective randomized parallel study, we did not find any significant difference in our primary objectives, which were to compare fiberoptic-guided tracheal intubation through intubating laryngeal mask airway LMA Fastrach™ and i-gel in terms of total time taken for intubation and ease of tracheal intubation.

In our study, there was no significant difference in the number of attempts needed to insert either of the SGAD, ease of insertion of SGAD, and insertion time. Kapoors *et al.* (2014), Kleine-Brueggene *et al.* (2011), and Theiler *et al.* (2011) also couldn't find any significant difference in the number of attempts required for insertion of SGAD and the insertion time in their study was also comparable among the two groups.^[10-12] Most of the studies available comparing LMA Fastrach™ and i-gel have not noted the ease of insertion, but the similar result was found by Siddiqui *et al.* (2012) where insertion of i-gel was found very easy in 67% patients, easy in 30% patients, while difficulty was noticed only in 3% cases.^[10-13]

Airway seal pressure of both the SGAD was noted and it was found to be 28.67 ± 0.48 in the FT group and 24.33 ± 1.06 in the IG group. The *P* value <0.001 shows that a statistically significant difference occurs in airway seal pressure of FT and IG groups. Kleine-Brueggene *et al.* (2011) and Theiler *et al.* (2011) also noted increased airway seal pressure in LMA Fastrach™.^[11,12] Although it was significantly

different in both the groups, its clinical significance cannot be assured. We need larger studies with greater sample size to conclude this.

Although difference exists in the two groups on fiberoptic grading in our study, it was statistically insignificant. The difference in number of attempts required to insert the ETT in either of the two groups in our study was statistically insignificant. Similarly, Kleine Brueggene *et al.* (2011) also found no statistically significant difference in the success rate at first attempt of fiberoptically guided tracheal intubation using i-gel with Magill PVC tracheal tube and the intubating LMA (ILMA) with its ILMA tracheal tubes.^[12]

Ease of insertion of the ETT was comparable in either of the groups in our study. Most of the studies available comparing intubation through LMA Fastrach™ and i-gel have not noted the ease of insertion but Taxak *et al.* (2013) in their study on fiberoptic-guided intubation through i-gel graded the ease of tracheal tube placement as easy, difficult, or failure. It was found to be easy in 91.4% of the cases and difficult in 5.2% of cases in their study.^[14]

In our study, the difference in the time required for insertion of ETT in either of the study group was statistically insignificant. Kleine Brueggene *et al.* (2011) also found that the time necessary for the FOB to intubate the trachea did not differ significantly between i-gel and ILMA. However, the time to railroad the tubes over the FOB varied greatly between the two SGAD (i-gel mean 28 sec, ILMA mean 18 s) in their study. This difference is probably because of the different type of tracheal tubes used in both the groups and the softer tip of the ILMA tracheal tubes allowed easier advancement as compared with the PVC tubes. Total time required for intubation by them was 72 s for i-gel and 65 s for sILMA. In our study, there was no significant difference as we used PVC tubes in both groups.

Ease of removal, time required for removal of SGAD, was noted and it was shown that removal of SGAD was easy in all the patients in both the group. The similar observation was recorded by Theiler *et al.* (2011) and Kleine Brueggene *et al.* (2011) where all inserted SGADs were removed easily without complications using the sILMA exchange rods.^[11,12] There is statistically no significant difference in the time required for removal of SGAD in either of the study groups. Similarly, Kleine Brueggene *et al.* (2011) and Theiler *et al.* (2011) found no difference in removal time between the two SGAD.^[11,12]

We found no significant difference in the rate of complication between both the groups in our study. Kleine Brueggene

Table 1: Patient characteristics

Demographic profile	i-gel	LMA Fastrach
SEX (Male, Female)	4/26	3/27
AGE (years)	34.53±7.83	35.53±9.55
Weight (kg)	61.40±6.39	58.43±8.88
Body mass index (kg/m ²)	23.73±2.73	23.72±2.73
ASA Status (1/2)	26/4	25/5
Mallampati score (1/2/3/4)	26/4/0/0	28/2/0/0

Table 2: Success rates and times for SGAD insertion and fiberoptic guided tracheal intubation

Supraglottic device insertion	i-gel	LMA fastrach
First attempt success rate	96.7%	93.3%
Ease of insertion (easy/difficult/failure)	29/1/0	28/2/0
Time taken for insertion (seconds)	23.60±3.47	25.37±4.19
Airway seal pressure	24.33±1.06	28.67±0.48
Tracheal Intubation	i-gel	LMA fastrach
Fiberoptic view (1/2/3)	26/3/1	30/0/0
FIRST attempt success rate	96.7%	93.3%
Intubation time	72.33±6.73	69.53±5.09
Ease of intubation (easy/difficult/failure)	29/1/0	28/2/0
Ease of removal of SGAD (easy/difficult/failure)	30/0/0	30/0/0

et al. (2011) also found four i-gel (5%) and two sILMA (3%) were stained with blood after removal and the incidence of a postoperative sore throat was 14% (i-gel) and 9% (sILMA), respectively. The difference was statistically insignificant for both the complications. However, none of the patients in their study had vomiting in contrast to our study but no specific reason can be given for this.

Based on our study, we recommend that i-gel may be a reliable and cost-effective alternative to LMA Fastrach™ for fiberoptic-guided tracheal intubation. Graf *et al.* also recommended that i-gel might be an alternative approach for fiberoptic-assisted endotracheal intubation, particularly when the costs of the ETs and both the SGAD were compared.^[15]

However, we recommend more studies with large sample size are required to substantiate the current findings and beneficial effects of SGADs as enumerated above.

Conclusion

Based on our observations, and in comparison with prior studies in the literature, we submit that both the LMA Fastrach™ and the i-gel were technically comparable to one another as conduits for fiberoptic-guided intubations in adult, paralyzed patients. There were no significant differences in the secondary aims to find the insertion success rate,

insertion time, ease of insertion, ease of removal, and time required for removal of both the SGAD studied. Airway seal pressure was significantly different with LMA Fastrach™ having higher seal pressure than i-gel, but its clinical significance cannot be assured.

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Conflicts of interest

There are no conflicts of interest.

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