Print ISSN: 2321-6379
Online ISSN: 2321-595X
DOI: 10.17354/ijss/2017/232

Original Article

# A Prospective Randomized Comparative Study on i-gel versus Laryngeal Mask Airway Fastrach as a Conduit for Blind Tracheal Intubation Using Conventional PVC Endotracheal Tubes in Reverse Orientation

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## Abstract

**Introduction:** Laryngeal mask airway (LMA) Fastrach was specially designed as a conduit for blind tracheal intubation in anticipated difficult airway and where we do not require neck extension. i-gel is a disposable, cheap supraglottic device with wide bore stem which facilitates direct passage of a conventional polyvinylchloride (PVC) endotracheal tube.

**Materials and Methods:** A total of 80 adult patients of the American Society of Anaesthesiologist Physical status 1 and 2 of either sex undergoing elective surgical procedures under general anesthesia were randomly allocated into two groups, Group F: LMA Fastrach ($n$ = 40) and Group G: i-gel ($n$ = 40). Primary outcome measures: Ease of tracheal intubation through the supraglottic device assessed by the first attempt and overall success rate of intubation. The secondary outcome measures: Time required for the successful intubation in the first attempt, ease of supraglottic device placement and hemodynamic changes with intubation.

**Results:** The overall success rate, as well as the first attempt success rate for blind endotracheal intubation, was high with LMA Fastrach and were 95% and 87.5%, respectively. The mean time for successful first-attempt tracheal intubation was equal in both the groups. Overall success rate for supraglottic device placement and hemodynamic changes were comparable in both groups. The failure rate for blind endotracheal intubation through the supraglottic airway device was significantly high in i-gel (27.5%) with the high incidence of esophageal intubation when compared to LMA Fastrach ($P$ < 0.05).

**Conclusion:** Ease of placement of i-gel masskes it a good supraglottic device. Insertion of conventional PVC endotracheal tubes in reverse orientation does not increase the success rate of tracheal intubation in i-gel. LMA Fastrach has the higher first attempt and overall success rate for blind tracheal intubation when compared to i-gel. We would suggest that when our goal is intubation in reverse orientation with conventional PVC tubes; we should go for LMA Fastrach rather than i-gel.

**Key words:** Conventional polyvinylchloride endotracheal tube, i-gel, Laryngeal mask airway Fastrach

## INTRODUCTION

Securing an airway is an ultimate aim of an anesthesiologist, failing which, can lead to disastrous and life threatening issues to the anesthetized patients. When conventional laryngoscopy fails, supraglottic devices are used as a rescue device for maintaining oxygenation and ventilation. Blind Tracheal Intubation through a supraglottic airway device is an accepted alternative.

Access this article online

www.ijss-sn.com

Month of Submission : 03-2017
Month of Peer Review : 04-2017
Month of Acceptance : 05-2017
Month of Publishing : 05-2017

The laryngeal mask airway (LMA) Fastrach has shown a high success rate for blind or fiberoptic-guided tracheal intubation in patients with both anticipated and unanticipated difficult airways.[1-4] i-gel, a relatively newer, cheaper and single use supraglottic airway (Intersurgical Ltd., Wokingham, UK) are an uncuffed peri-laryngeal

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sealer.[5] It has an additional gastric channel and wide bore stem without bars in the bowl facilitating tracheal intubation.[6] Several workers have shown improved view of glottic aperture with fiber optic visualisation.[7] Case reports of successful fiberoptic tracheal intubation through i-gel have been reported.[8-11]

The tube used in LMA Fastrach is a wire-reinforced flexible silicone tube which is very costly, and there is a chance of cuff getting damaged. Hence, we tried using conventional polyvinylchloride (PVC) tubes for tracheal intubation through supraglottic airway devices (SAD). Kundra *et al.* showed higher success rates of tracheal intubation were documented with the insertion of pre-warmed conventional PVC endotracheal tubes (ETT) in the reverse orientation through LMA Fastrach.[12]

Recent studies have shown higher success rate with the technique of 90° counter-clockwise rotation of PVC ETT before insertion in i-gel.[13,14] Insertion of PVC ETT in natural curvature had resulted in inferior success rate in tracheal intubation through i-gel.[15] In this study, we hypothesized that the success rate of tracheal intubation through i-gel would improve with reverse orientation pre-warmed PVC ETT insertion.

### Aim of the Study

We compare the two devices on the following metrics.

Primary outcome measures:

1. Ease of tracheal intubation.
    a. First attempt success rate of blind endotracheal intubation in reverse orientation through SAD.
    b. Overall success rate of blind endotracheal intubation through the SAD.

Secondary outcome measures:

1. The time required for first attempt tracheal intubation through SAD.
2. Ease of placement of SAD.
    a. Number of attempts required for the placement of the SAD
    b. Time required for the placement of the SAD.
3. Hemodynamic changes after intubation.

## MATERIALS AND METHODS

### Study Design

This study was a prospective, randomized, comparative study conducted in Chennai.

### Study Setting and Population

After obtaining the Institutional Ethical committee approval and written informed consent from the patients, eighty adult patients of the American Society of Anaesthesiology Physical status 1 and 2 of either sex of age group 20-50 years undergoing elective surgical procedures under general anesthesia were enrolled in the study.

The study was conducted at the General Surgery theater complex of a Tertiary care hospital in Chennai, India. The SAD insertion and blind tracheal intubation were done by the author.

### Patient Selection

#### *Inclusion criteria*

- Age 20-50 years
- Both sexes
- Weight 40-70 kg
- Mallampatti 1 and 2
- American Society of Anaesthesiologist physical status 1-2
- Patients undergoing elective surgery under general anesthesia, requiring endotracheal intubation.

#### *Exclusion criteria*

- Patients with limited mouth opening (<2 cm)
- Anticipated difficult airway
- Patients at increased risk of aspiration, or having a history of symptomatic gastroesophageal reflux or a hiatus hernia
- Symptoms related to the laryngopharyngeal anomaly
- Musculoskeletal abnormalities affecting the cervical vertebrae.

### Materials

Intubating LMA Fastrach, i-gel, Endotracheal tube, IV cannulae, monitors, and drugs for general anesthesia.

### Study Method

After obtaining ethical committee approval, the patients were randomized into one of the two groups using a closed envelope method with predetermined group numbers: Group G: i-gel ($n$ = 40) and Group F: LMA Fastrach ($n$ = 40). The patients were advised for pre-operative overnight fasting for 8 h. They were given aspiration prophylaxis with tab ranitidine 150 mg and tab metoclopramide 10 mg on the night before surgery. Standard monitoring was applied before induction and included electrocardiogram, pulse-oximeter, capnography, non-invasive blood pressure monitor, temperature monitoring, and neuromuscular monitoring. Intravenous access was obtained with an 18G peripheral venous cannula in the forearm. The patient was placed in supine position with the patient's head on a pillow of 10 cm height.

Pre-oxygenation was done for 3 min with 100% oxygen. All patients were given injection glycopyrrolate 5 mcg/kg I.V., Injection midazolam 0.02 mg/kg I.V., and injection fentanyl 2 mcg/kg I.V. Anesthesia was induced with

**Figure 1: Angle of emergence of conventional endotracheal tube through intubating laryngeal mask airway in reverse orientation**

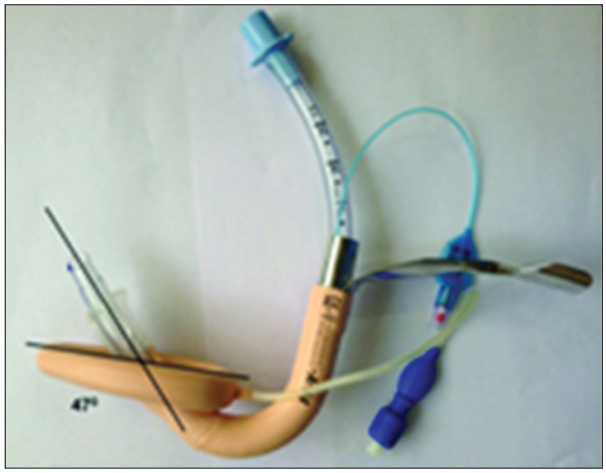

**Figure 2: Angle of emergence of conventional endotracheal tube through intubating laryngeal mask airway in normal orientation**

injection propofol 2 mg/kg I.V. and injection atracrurium 0.5 mg/kg I.V. The patients' lungs were manually ventilated by face mask with 1% sevoflurane in oxygen for 3 min. An appropriate size SAD according to the body weight of the patient was then inserted by the author (previous experience with both devices >20 uses).

i-gel was introduced with the patient in "sniffing the morning air" position and after adequate relaxation. The Intubating LMA was inserted with the patient's head in neutral position. Both the SADs were inserted according to the manufacturer's manual. Adequate ventilation was assessed by chest excursions and $EtCO_2$. If the placement was not adequate, usually detected by inadequate ventilation and audible leak, we tried maneuvers like Chandy maneuver I and II for LMA Fastrach. In a case of i-gel, we changed the head position and device position by pushing down and pulling up for better optimization of device position with the glottic aperture.

In both the groups, an appropriate size conventional PVC ETT was softened by pre-warming at 40°C for 1 min. The PVC ETT was kept immersed in a sterile water bath heated up to 40°C for 1 min. Subsequently, the PVC ETT was lubricated and inserted through SAD with the ETT inserted backward, such that the concave bend was facing down.

When the ETT was advanced smoothly with no resistance, the ETT cuff was inflated and ventilation confirmed by capnograph. An intubation attempt was considered successful if the tracheal tube was advanced smoothly without resistance and a positive capnographic tracing was obtained. The 15 mm ETT adaptor was then removed, and SAD was removed after stabilizing the tube using a second, smaller size ETT as stabilizing rod and by grasping the ETT with the gloved fingers.

After attaching the adaptor to the ETT, the ventilation was resumed, and the ETT position was reconfirmed by chest wall movement, auscultation of breath sounds, a square-wave capnograph trace.

A "failed intubation attempt" was considered when tactile resistance was felt while advancing the tracheal tube or esophageal intubation. The second attempt was made with the reinsertion of either the same or different size SAD and after optimizing ventilation, the tracheal intubation was attempted through the device. In both groups, intubation through the SAD was limited to two attempts. Intubation failure was recorded if, despite two attempts, repeated tactile resistance or esophageal intubation was encountered. When intubation was unsuccessful after two attempts, the procedure was abandoned, and tracheal intubation was performed under direct laryngoscopy.

The primary outcome measure was first attempt and overall success rate of blind endotracheal intubation between i-gel and LMA Fastrach. The secondary outcome measures included a time required for first attempt tracheal intubation and ease of insertion of SAD and hemodynamic changes to tracheal intubation. Ease of insertion of the SAD would include a number of attempts and time required for insertion of the device.

"SAD insertion time" was defined as the time from removal of the face mask to the time ventilation was established through the SAD with $CO_2$ confirmation. "Tracheal intubation time" was defined as the time from loss of $CO_2$ due to disconnection of the circuit from the supraglottic device to the time of reappearance of the $CO_2$ from the tracheal tube with no evidence of cuff leak with positive pressure ventilation.

Intubation failure was recorded if, despite two attempts, repeated tactile resistance or esophageal intubation was encountered. Patients with unsuccessful intubation were excluded from the analysis of total intubation time. A

number of failed attempts at intubation were also noted. Ease of removal of SAD after establishing tracheal intubation was noted by the time taken to remove the device (time from insertion of the pusher to reconnection of breathing circuit to the tracheal tube). Any critical incident during device removals, such as accidental extubation or tube displacement was noted.

The heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded pre-induction, post- induction, 1 min, and 5 min after intubation. Any problem encountered during intubation was recorded. Complications such as saturation <95%, dental trauma, esophageal intubation, laryngospasm, blood staining of the device (mucosal trauma), lip or dental injury were looked for.

### Statistical Analysis

The data were collected and analyzed with SPSS Version 15 (SPSS Inc., Chicago, IL). Demographic data and the time taken for device placement, tracheal intubation and device removal among the groups were analyzed with unpaired *t*-test. Chi-square analysis was used for comparing sex. Chi-square analysis with Yates' continuity correction was applied to the number of attempts required for SAD insertion and successful intubation. $P < 0.05$ was considered statistically significant.

## RESULTS

A total of 80 patients were randomized into two groups of 40 each. The demographic variables such as age, weight, and sex were similar in both the groups. The mean age in both the groups was around 29 years (Table 1). The average weight being similar was around 60 kg in both groups. In both the groups, a majority of the patients were in the range of 61-70 kg. The size 3 and 4 SADs accommodated 6 mm I.D and 7 mm I.D ETT s, respectively. Size 4 SADs were predominately used in both the groups.

The time for successful supraglottic device placement was less with i-gel (15.625 ± 2.65 s) when compared with LMA Fastrach (17.17 ± 1.98 s) ($P < 0.05$). The first attempt success rate of supraglottic device insertion is 95% in LMA Fastrach group and 90% in i-gel group. With the second attempt of supraglottic device insertion, the successful ventilation rate was 100% in both the groups (Table 2).

**Table 1: Demographic variables**

| Variable | i-gel | LMA Fastrach | *P* value |
|---|---|---|---|
| Age (years) | 29.17±5.47 | 28.65±6.33 | 0.693 |
| Weight (kg) | 60.82±7.44 | 60.77±7.62 | 0.976 |
| Sex (male/female) | 15/25 | 16/24 | 0.818 |

Blind tracheal intubation was successful in the first attempt in 60% cases (24 patients) of i-gel group and 87.5% cases (35 patients) of LMA Fastrach group. With the second attempt, blind tracheal intubation was successful in 72.5% cases (29 patients) of i-gel group and 95% cases (38 patients) of group LMA Fastrach (Table 2). Time for the first attempt tracheal intubation through the supraglottic device was shorter with i-gel group (15.88 ± 2.49 s).

The incidence of esophageal intubation was more with i-gel in comparison with LMA Fastrach. The blood staining of the device was noted and it was an indication of mucosal trauma. 6 patients in i-gel group had mucosal trauma against 5 patients in LMA Fastrach group (Table 3).

## DISCUSSION

The success rate of tracheal intubation is determined by the angle, at which the tracheal tube emerges from the distal aperture of the LMA Fastrach and i-gel. The reverse orientation of the pre-warmed conventional PVC ETT through LMA Fastrach reduced the emerging angle of the tube from the device (from 40° to 20°) and improved the success rate of intubation even though the silicone reinforced tube was not used (Figures 1 and 2).[12]

The first-attempt success rate is an important performance indicator for tracheal intubation. Our study shows that the first attempt success rate of blind tracheal intubation through the supraglottic device was significant with LMA Fastrach (87.5%) unlike the results of Halwagi *et al.* and Kapoor *et al.* who noticed comparable results in both the groups.

Even though the emerging angle of the tube in reverse orientation from the i-gel is reduced, the success rate of tracheal intubation was less (60%) which requires further research and larger population. In other studies, they had achieved a higher success rate with 90° counter-clockwise rotation of the tube before insertion due to a prevention of impingement of bevel on the glottis structures.[13,14] However, Halwagi *et al.* could not achieve similar high results with i-gel with this technique.

The overall success rate of blind endotracheal intubation through LMA Fastrachwith conventional PVC tubes with curvature facing downward in patients with Mallampatti 1 and 2 was 95% and was significantly higher than in i-gel (72.5%). The results obtained for overall success rate of blind tracheal intubation were comparable with those in published studies.[12-14] The curved shape of the LMA Fastrach stem which directs the tube anteriorly and the adjusting Chandy maneuver of LMA Fastrach used before intubation probably improved the success rate.[16]

**Table 2: Success rates and time for device insertion, tracheal intubation**

| Success rate | i-gel *n*=40 (%) | LMA Fastrach (*n*=40) | Chi-square (*t*-test) | *P* value |
|---|---|---|---|---|
| 1. Supraglottic device insertion | | | | |
| First attempt success rate | 90 | 95% | | |
| Overall success rate | 100 | 100% | | *P*=0.671 |
| Overall insertion time(s) mean±SD | 15.625±2.65 | 17.17±1.98 | *t*=2.955 | *P*=0.004 |
| 2. Tracheal Intubation | | | | |
| First attempt success rate | 60 | 87.5% | | *P*=0.005 |
| Overall success rate | 72.5 | 95% | | *P*=0.0124 |
| Time for first attempt tracheal intubation(s) mean±SD | 15.88±2.49 | 16.31±3.04 | *t*=0.584 | *P*=0.5611 |
| Time for device removal | 15.82±1.61 | 16.55±1.50 | *t*=2.079 | *P*=0.041 |
| Total time for tracheal intubation in successful intubation (SAD Insertion time+tracheal intubation time+SAD removal time) (s) Mean+/-SD | 49.69±6.68 | 51.13±6.13 | *t*=0.918 | *P*=0.3621 |

**Table 3: Complications**

| Variables | i-gel | ILMA |
|---|---|---|
| Saturation<95% | 0 | 0 |
| Dental trauma | 0 | 0 |
| Esophageal intubation | 12 | 4 |
| Laryngospasm | 0 | 0 |
| Mucosal trauma | 6 | 5 |

Inferior overall success rates in blind tracheal intubation were recorded in i-gel group. Michalek *et al.* had observed similar results in his study. Consequently, when the tracheal intubation through i-gel was unsuccessful on the first attempt, the success rate did not improve significantly in subsequent attempts, and there were more incidences of esophageal intubation which is comparable with Halwagi *et al.* The reason attributed to this was the relatively straight shape of i-gel stem which has a tendency to direct them posteriorly and thus increases the risk of esophageal intubation or snaring on the arytenoids.[5]

We failed to intubate in eleven patients in i-gel group and two in the LMA Fastrach group. Subsequently, they were intubated using direct laryngoscopy (macintosh). Those patients who required direct laryngoscopy had a Cormack-Lehane Grade 1 and 2 laryngeal view and the airway anatomy appeared normal.

When considering solely the patients successfully intubated on the first attempt, the two groups had similar intubation times. The mean time for successful first attempt tracheal intubation was 15.88 ± 2.49 s and 16.31 ± 3.04 s in i-gel and LMA Fastrachgroup, respectively. There was no statistically significant difference between the two groups.

Total tracheal intubation time (summation of supraglottic device insertion time, tracheal intubation time and SAD removal time) was comparable in both the groups. Although our data suggest that tracheal intubation was achieved faster with i-gel, the difference is not clinically significant. Furthermore, more patients' trachea was intubated successfully on the second attempt using LMA Fastrach, hence artificially prolonging the intubation times within that group.

Many workers had observed the overall success rate of insertion of SAD in both the groups as 100% which was similar to our study. The mean insertion time for SAD was significantly less for i-gel in comparison with LMA Fastrach. i-gel being an uncuffed, peri-laryngeal sealer, the insertion was easy and quick. Complications such as esophageal intubation and mucosal trauma were high with i-gel.

The increase in systolic blood pressure, diastolic blood pressure and mean arterial pressure from the baseline values were insignificant ($P > 0.05$) at 1 min after tracheal intubation in both the groups. When compared among the groups, there was no significant difference in the increase in blood pressure (systolic, diastolic, mean arterial pressure) from the baseline values.

In both the groups, there was a significant ($P < 0.05$) increase in heart rate at 1 min after intubation but they return to baseline at 5 min. Among the groups, there was no significant difference between an increase in heart rate at 1 min after intubation from the baseline values.

### Limitations of Our Study

The etiology of failed intubation was not evaluated systematically with fiberoptic visualization. Usage of other types of tracheal tubes (more malleable, wire reinforced tubes) instead of conventional PVC tubes could have improved the intubation success rates in i-gel group, but we had used conventional PVC tubes for our study as it is readily available and cheaper. However, there was no difference in the success of tracheal intubation with conventional PVC tubes and silicone reinforced tubes in LMA Fastrach according to Kundra *et al.* and Lu *et al.*, but further studies are required for i-gel.

## CONCLUSION

The time for first attempt tracheal intubation is less for i-gel in comparison with LMA Fastrach. Ease of placement of i-gel makes it a superior supraglottic device. Insertion of conventional PVC ETT in reverse orientation does not increase the success rate of tracheal intubation in i-gel. LMA Fastrach has the higher first attempt and overall success rate for blind tracheal intubation when compared to i-gel. We would suggest that when our goal is intubation in reverse orientation with conventional PVC tubes; we should go for LMA Fastrach rather than i-gel.

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**How to cite this article:** Anuradha N, Anandhakumar G, Deepa David, Shanmugapriya V. A Prospective Randomized Comparative Study on i-gel versus Laryngeal Mask Airway Fastrach as a Conduit for Blind Tracheal Intubation Using Conventional PVC Endotracheal Tubes in Reverse Orientation. Int J Sci Stud 2017;5(2):130-135.

**Source of Support:** Nil, **Conflict of Interest:** None declared.