Original Article

A prospective randomised trial to compare three insertion techniques for i-gel™ placement: Standard, reverse, and rotation

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ABSTRACT

Background and Aims: This prospective randomised study was done to compare standard, reverse, and rotation techniques of i-gel™ placement in terms of insertion characteristics and success rate. **Material and Methods:** After institutional ethics committee approval, 135 patients aged 18-50 years, ASA I and II undergoing elective surgery under general anesthesia were included. After induction of anesthesia, i-gel™ was inserted by standard, reverse, and rotation technique in Groups I, II, and III, respectively. The primary objective was mean time of insertion. Secondary variables included ease of insertion, first attempt success rate, manoeuvres required, fiberoptic view of placement, oropharyngeal leak pressure, ease of placement of nasogastric tube, and complications if any. **Results:** Mean time of insertion was 18.04 ± 5.65 s, 15.00 ± 5.72 s and 16.12 ± 5.84 s for groups I, II, and III, respectively. Time taken for insertion was shortest and significantly lower (P = 0.048) for group II compared to group I. Insertion time was comparable between rest of groups. The overall success rate in groups I, II, and III were 91.1%, 95.6%, and 93.3% respectively (P = 0.7). The first attempt success rate was 82.2%, 89%, and 84.4% in groups I, II and III, respectively (P = 0.07). Manoeuvres were required in five (12.19%) patients in group I, four (9.30%) patients in group II, and three (7.14%) patients in group III (P = 0.602). Complications occurred in eight, three, and three patients in groups I, II, and III, respectively. **Conclusion:** All techniques of i-gel insertion are equally good and choice of technique depends upon the experience and comfort of the investigator with the particular technique.

Key words: Airway management, fiberoptic, general anesthesia, rotation, supraglottic airway

INTRODUCTION

i-gel™ (Intersurgical, Wokingham, UK), an innovative second generation supraglottic airway device (SAD), has a soft gel like cuff made up of thermoplastic elastomer which does not require inflation of cuff or adjustment of intra cuff pressure. This device is now being widely used in routine elective anaesthesia, resuscitation, and prehospital emergency airway management.[1] It has been found to be a better performing device when compared with other SADs for ease of insertion and can also be used as a conduit for fiberoptic intubation in patients with difficult airway.[2,3] The success rate of i-gel™ insertion by standard technique at the first attempt varies from 78 to 93%, with a relatively high success rate of 84-100% after two attempts.[4] With this technique, placement is not always easy because of the tongue folding caused by its large and semi-rigid cuff. Multiple attempts not only may cause trauma to the oral cavity and supraglottic structures but also increase the time to secure the airway in the operating room or in an emergency situation.

Tongue folding, a major obstacle in appropriate i-gel™ placement can be prevented by manual tongue

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stabilisation technique.[5] Insertion can also be managed by other techniques of insertion like rotation or reverse as with other supraglottic airway devices. There are very few studies that have shown improvement in successful placement of i-gel™ by rotation or reverse technique.[6,7] But no randomised controlled trial comparing all three techniques is conducted till now. In this study, we compared these three techniques of i-gel placement in terms of insertion characteristics, first attempt and overall success rate and incidence of complications if any.

MATERIAL AND METHODS

This prospective randomised study is registered with Clinical Trials Registry of India with registration no (CTRI/2018/12/016614). A total of 135 adult patients of either sex aged 18–50 years, belonging to American Society of Anaesthesiologists (ASA) physical status I and II scheduled to undergo elective surgery under general anesthesia in supine position were included. Patients with mouth opening <2.5 cm, known difficult airway, risk of aspiration, body mass index >35 $kg.m^{-2}$, acute sore throat and refusal to participate in the study were excluded. Each patient was kept fasting for 6 hours and prescribed routine premedication. All 135 patients were then allocated to one of the three groups: Group I (n = 45; standard technique), Group II (n = 45; reverse technique) and Group III (n = 45; rotation technique) using computer generated randomisation. The CONSORT diagram is shown in Figure 1.

In the operating room, after the establishment of intravenous (iv) line and attachment of standard monitors [non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry (SpO_2)], baseline hemodynamic parameters were recorded. Induction of anesthesia was done with standardised general anesthetic technique comprising of iv glycopyrrolate 0.2 mg, fentanyl 2 μg kg^{-1} followed by iv propofol 2 mg kg^{-1}. After checking for ability to ventilate, iv vecuronium 0.1 mg kg^{-1} was administered and airway was secured by an appropriate size i-gel™ based on patient's weight in accordance with manufacturer's guidelines (30-50 kg: i-gel™ 3), (50-90 kg: i-gel™ 4), (>90 kg: i-gel™ 5). An anesthesiologist with an experience of more than 25 i-gel™ insertions with standard technique inserted a well-lubricated i-gel™ using technique based on the study group. The patients were placed supine with head in sniffing position using a 5 cm firm pillow. In group I, i-gel™ was introduced in mouth with its concavity facing the mandible. Then it was pushed posteriorly while advancing along the hard palate, soft palate and posterior pharynx and placed in its final position. In group II, i-gel™ was inserted with its concavity facing toward the hard palate. On reaching the pharynx, the device was rotated 180°C and placed in its final position to facilitate positive pressure ventilation. In group III, the entire cuff of i-gel™ was placed in patient's mouth in a midline approach without finger insertion, rotated 90°C counter clockwise around the patient's tongue, advanced until resistance was felt at the hypopharynx and it was re-rotated clockwise to the standard orientation, at which point it returns to the midline. Appropriate placement of i-gel™ was confirmed by observing a square wave capnograph, auscultation, movement of chest wall, and no audible leak with peak airway pressure (PAP) ≥20 cm H_2O during manual ventilation. If leak occurred at pressure of ≤20 cmH_2O, then a variety of manipulations like chin lift, jaw thrust, head extension, neck flexion, gentle advancement, or withdrawal of i-gel™ were applied to improve the ventilation.[8] If air leak persisted despite the manipulations, then the attempt was considered a failure and the i-gel™ was reinserted using the same technique. In the second attempt gentle jaw thrust was applied by the assistant; if it did not resolve the problem, then one size smaller or larger was used.

A maximum of three attempts were allowed for the same technique. If not successful after three attempts, it was considered as failure and airway was managed using alternative device. The number of insertion attempts was recorded. The insertion time, defined as the time from picking up the i-gel™ until appearance of square wave capnograph, was recorded. The time between attempts was not added to the insertion time. Insertion was considered as easy if successful placement was possible in first attempt with or without manoeuvres. Insertion was considered as difficult if successful placement was done in more than one attempt. After confirming proper placement of i-gel,™ the attending anesthesiologist measured the oropharyngeal leak pressure (OLP) with APL valve fully closed and O_2 flow maintained at 3 $Lmin^{-1}$. The attending anesthesiologist then evaluated the placement of i-gel™ using fiberoptic view scoring system (1-vocal cords fully visible; 2-vocal cords partially visible or arytenoid cartilages visible; 3-epiglottis visible and 4-no laryngeal structures visible).[9] Haemodynamic variables were noted at baseline and 1, 3, and 5 min after i-gel™ insertion. Appropriate size nasogastric

tube was placed in the gastric channel of i-gel™; if it passed easily, placement was considered as easy and difficult otherwise. Anesthesia was maintained with sevoflurane 1.5-2.0% with 50% O_2 and 50% N_2O at low flows (1.5-2 $Lmin^{-1}$). Volume control ventilation was used with tidal volume of 8 ml kg^{-1} and respiratory rate was adjusted to maintain $EtCO_2$ between 30 and 40 mmHg. Intraoperative monitoring of heart rate (HR), electrocardiogram (ECG), blood pressure (BP), $EtCO_2$, peripheral oxygen saturation (SpO_2), peak airway pressure (PAP) was done and any significant changes were recorded. At the time of removal, complications like blood staining on the i-gel™, complaint of sore throat and cough up to 24 h after removal were noted.

The primary objective of the investigation was mean insertion time at first attempt. Secondary objectives were ease of insertion, first attempt and overall success rate, manoeuvres required, fiberoptic view of placement, OLP, ease of placement of nasogastric tube and postoperative complications if any. Sample size was determined with reference to the previous study and mean ± SD time taken was 26.9 ± 14.5 s for standard, 17.5 ± 6.9 s for reverse and 13.3 ± 2.9 s for rotation technique.[6,7] Assuming these as reference values, the minimum required sample size at 5% level of significance and 95% power was at least 41 patients in each group. To compensate for dropouts, we recruited 45 patients in each group. All data were compiled and statistical analysis was performed by the SPSS program for Windows, version 17.0 (SPSS, Chicago, Illinois). Categorical variables were analysed using Chi-square test. Success rate, presence of blood staining, and incidence of postoperative sore throat were compared using Chi-square test or Fisher's exact test as appropriate. Analysis of variance mean arterial pressure (ANOVA) was used to evaluate hemodynamic changes after i-gel insertion. For all statistical tests, a *P* value less than 0.05 was taken to indicate a significant difference.

RESULTS

A total of 135 patients were enrolled between February 2018 and march 2019 with 45 patients in each group. The demographic characteristics of all three groups were similar as shown in Table 1. The study data on insertion characteristics are shown in Tables 2 and 3.

Mean time of insertion was 18.04 ± 5.65 s, 15.00 ± 5.72 s and 16.12 ± 5.84 s for groups I, II and III, respectively. It was shortest and statistically lower ($P = 0.048$) for group II compared to group I. Insertion time was comparable between rest of groups [Table 2]. The first attempt success rate was 82.2%, 89%, and 84.4% in groups I, II, and III, respectively. The overall success rate and first attempt success rate of i-gel™ insertion was highest in group II followed by groups III and I, but the difference was statistically insignificant ($P = 0.07$, 0.7). Ease of insertion was also comparable among the groups. ($P = 0.651$) Manoeuvres were required in five (12.19%) patients in group I, four (9.30%) patients in group II, and three (7.14%) patients in group III ($P = 0.602$) [Table 3].

On the whole, all the groups had maximum number of grade 1 fiberoptic view placement. It was comparable in groups I and II and group II and III but view grading was better in group III compared to group I ($P = 0.016$). The mean OLP and PAP and nasogastric tube placement was comparable among the groups. Incidence of sore throat and blood staining was more in group I compared to groups II and III but the difference was not significant statistically ($P = 0.073$) [Table 4]. HR and MAP were comparable in all three groups at baseline and 1, 3, and 5 min after i-gel™ insertion.

DISCUSSION

The i-gel is a useful alternative to tracheal intubation in patients undergoing elective surgery. Correct positioning of the device is crucial to accomplish proper ventilation and oxygenation. All supraglottic airways including i-gel when inserted using the standard technique follow a midline path and advance over the tongue. The i-gel also has a characteristic non-inflatable cuff which is slightly more rigid and bulkier than those of other devices before cuff inflation. These may be the main reasons for impaction at the back of the mouth by tongue folding or its posterior displacement and subsequent placement failure and varied success rate.[5,10,11]

The rotation and reverse technique has been proposed to improve the insertion success rate of supraglottic airways but the results have been inconsistent. So, this study was undertaken to compare three techniques (standard, reverse, and rotation) of i-gel insertion and find out the best technique. The primary objective of our study was mean insertion time. It was found to be least in reverse technique and was also statistically lower when compared to standard technique. ($P = 0.048$) Reverse technique also resulted in a statistically insignificant higher overall and first attempt success rate, more easy

Table 1: Demographic characteristics. Values are mean±SD

Parameter	Group I (*n*=45) Standard	Group II (*n*=45) Reverse	Group III (*n*=45) Rotation	*P*
Age (years)	33.98±11.15	36.16±10.61	35.73±10.79	0.062
Male/Female	13/32	7/38	6/39	0.129
BMI (kgm^{-2})	23.33±3.46	22.70±2.55	23.09±2.91	0.615
ASA grade I/II	43/2	43/2	43/2	1.000
MPG grade I/II/III	11/28/6	10/28/7	8/30/7	0.731
Size of i-gel™ (3/4/5)	22/21/2	27/16/2	25/17/3	0.269
Duration of surgery (min)	69.13±26.69	72.49±23.24	67.84±20.27	0.619

Table 2: Mean insertion time and success rate for i-gel placement among different groups. Values are number (proportion) or mean±SD

Parameter	Group I (*n*=45) Standard	Group II (*n*=45) Reverse	Group III (*n*=45) Rotation	*P**
Mean time of insertion (sec)	18.04±5.65	15.00±5.72	16.12±5.84	0.043#
Success rate:				
First attempt	37 (82.2%)	40 (89.0%)	38 (84.4%)	0.07
Second attempt	3 (6.7%)	2 (4.4%)	3 (6.7%)	
Third attempt	1 (2.2%)	1 (2.2%)	1 (2.2%)	
Failure	4 (8.9%)	2 (2.2%)	3 (6.7%)	
Overall success rate	41 (91.1%)	43 (95.6%)	42 (93.3%)	0.7

*P<0.05 is significant. #Significant between groups I and II

Table 3: Insertion characteristics and complications among different groups. Values are number (proportion) or mean±SD

Parameter	Group I (*n*=41) Standard	Group II (*n*=43) Reverse	Group III (*n*=42) Rotation	*P**
Ease of insertion				
Easy	37 (82.2%)	40 (89%)	38 (84.4%)	0.651
Difficult	4 (8.9%)	3 (6.7%)	4 (8.9%)	
Manoeuvres required	5 (12.19%)	4 (9.30%)	3 (7.14%)	0.602
Fiberoptic view grading (1/2/3/4)	22/11/4/4	31/9/3/0	35/4/3/0	0.024$
Oropharyngeal leak pressure (cm H_2O)	24.8±5.83	27.14±5.04	28.26±4.96	0.112
Peak airway pressure (cm H_2O)	14.05±2.79	14.84±2.33	14.45±2.28	0.347
Ease of NG tube placement				
Easy/difficult/failure	38/3/0	40/2/1	41/1/0	0.548

*P<0.05 is significant. $Significant between groups I and III

Table 4: Complications among different groups

Complications	Group I (*n*=41) Standard	Group II (*n*=43) Reverse	Group III (*n*=42) Rotation	*P*
Sore throat	2 (4.8%)	2 (4.6%)	2 (4.8%)	0.073
Blood staining	8 (19.5%)	1 (2.3%)	2 (4.8%)	0.07

placements and less complications like sore throat and blood staining as compared to standard and rotation technique. Less number of complications in groups II and III might be due to smooth advancement of the i-gel™ as there is reduced resistance between the i-gel™ and pharyngeal wall.

Park *et al*. conducted a meta analysis to compare standard and rotation technique for insertion of supraglottic airway devices like LMA Classic, LMA Proseal, SoftSeal, and i-gel. In the seven trials conducted in adult patients, the rotation angles were 90° and 180° (rotation and reverse technique in the present study). In the subgroup analysis of the three studies using 90° rotation in adult patients showed better results with no heterogeneity using the rotation technique. However, a subgroup analysis of the three studies using 180° rotation in adult patients did not demonstrate an improved success rate with the rotation technique. Overall, the meta analysis reported that rotation technique provided higher first-attempt and overall success rates, faster insertion, lesser number of attempts, and a lower incidence of blood on the removed device, reflecting less mucosal trauma. But it could not confirm superior results for OLP, fiberoptic view and postoperative sore throat.[12] Our results are in agreement with this meta analysis with respect to reverse technique (180° rotation). The difference between this analysis and present study is that they considered both 90° and 180° rotation as a rotation technique and we studied these two as separate techniques. Moreover, the trials included in this meta-analysis studied four types of supraglottic airways and the specific features of each device could lead to the heterogeneous results.

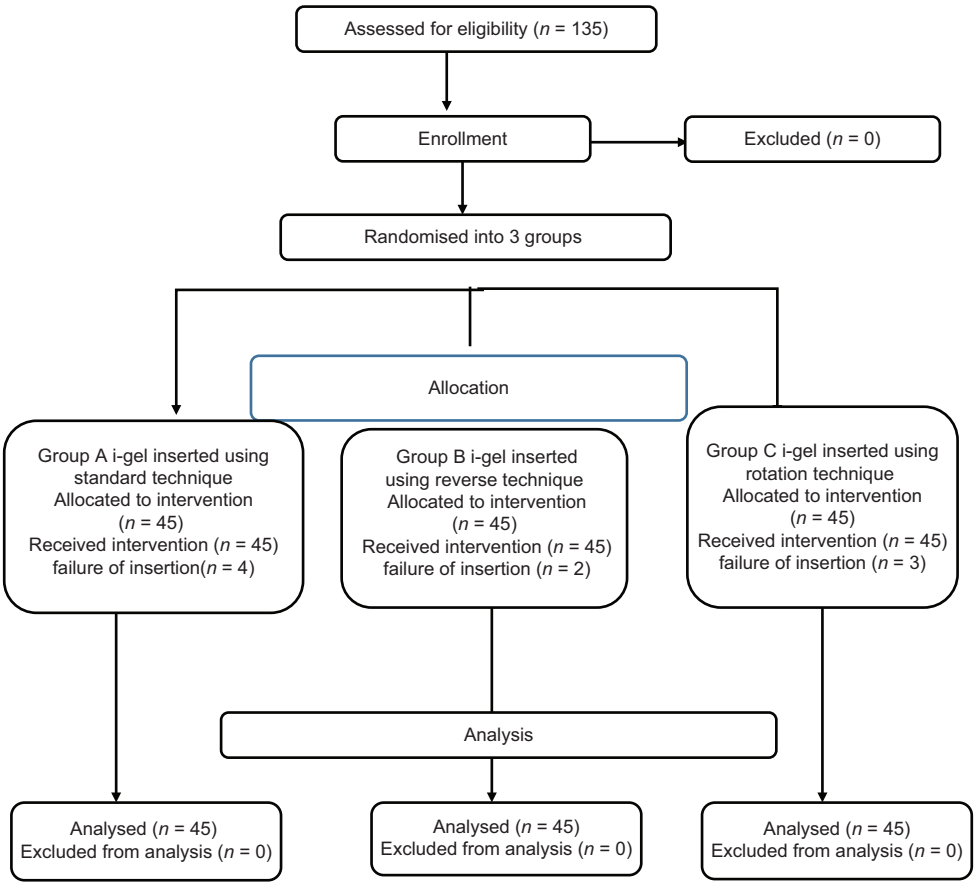

Figure 1: The CONSORT flow diagram

Our results are similar to the study done by Sharda *et al*. They compared reverse and conventional insertion of i-gel™ in 100 patients. They noted lesser mean insertion time in reverse group and the difference was statistically significant ($P = 0.012$). First attempt success rate was 86% and 96% in conventional and reverse group respectively ($P = 0.08$). Sore throat and blood staining of the device were more in patients in standard than reverse technique group.[7]

Kim *et al*.[6] and Muneer *et al*.[13] compared standard and rotation techniques of i-gel insertion. In contrast to present study, they reported a higher first attempt success rate, shorter insertion time, higher airway seal pressure, and less blood staining of the device with the rotation technique. Kim *et al*. also noted more easy insertions (86% vs 97%) and fewer number of patients requiring manipulations (29% vs 39%) with the rotation technique. But Brimacombe score was better in standard as compared to rotation group. ($P = 0.001$) This can be attributed to difference in the experience of the investigator (>300 i-gel insertions with standard technique) and study population.

Nasogastric tube placement was also comparable in all the three groups. Liew *et al*.[14] reported easy placement of nasogastric tube in 94% patients in rotation technique and Singh *et al*.[15] reported easy placement of nasogastric tube in 100% patients with standard technique of i-gel™ insertion. Baseline HR and MAP were comparable among all the groups. They were also comparable among the groups at 1, 3, and 5 min after insertion of i-gel™ ($P > 0.05$). Our results are similar to the studies done by Sharda *et al*. and Kim *et al*.[6,7] They did not find any difference in HR and MAP between the groups after insertion of i-gel™.

Although, in the present study mean insertion time was significantly less in reverse technique when compared to standard technique, faster insertion of the device by few seconds may not make any significant difference clinically as success rate was comparable among the groups. Fiberoptic view grading was significantly better in rotation group than the standard. This will also not cause any significant difference as the OLP was comparable among all groups. Hence, the three methods for i-gel placement are not different clinically.

Our study had few limitations. Blinding was not possible for insertion technique and recording insertion time. Moreover, results might not be applicable to anesthesiologists experienced in rotation and reverse techniques as i-gel was inserted by investigators experienced in standard technique only. Results of the study might not be applicable to different population groups like pediatric and elderly.

CONCLUSION

Based on our observations, we submit that all techniques of i-gel insertion are comparable clinically and choice of technique depends upon the experience and comfort of the investigator with the particular technique. We further suggest that because of higher first attempt and overall success rate, fewer attempts for successful insertion and less blood staining and sore throat, the reverse technique could be more effective when device insertion is unsuccessful on the first attempt.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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