Original Research Article

Comparison of Standard Versus Reverse Technique for I-Gel Insertion in Anaesthetised Paralysed Patients: A Prospective Randomized Study

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ABSTRACT

Background

I -gel is a second generation supraglottic airway device that has a soft gel like cuff made up of thermoplastic elastomer which does not require inflation of cuff to provide an airway seal [1]. This device is now being widely used in routine elective anesthesia, resuscitation and pre hospital emergency airway management the success rate of I -gel insertion by standard technique at the first attempt varies from 78-93%, with relatively high success rate of 84-100% after two attempts.^[1]

When multiple attempts are made not only it causes trauma to oral cavity and supraglottic structures it also increases the time to secure the airway in operating room or in emergency situation. Tongue folding is a major obstacle for appropriate placement of I-gel. With the extensive use of I-gel for anesthesia learning of alternative techniques of insertion is essential for safe and quick use in some cases. Recent studies have shown improvement in successful placement of I-gel by rotation or reverse technique.^[1] Hence this study was done to compare the standard vs reverse technique of I-gel insertion in anaesthetized paralyzed patients.

Methods

50 patients, 25 patients in each group 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 technique in Groups I and II respectively. The primary objective was mean time of insertion.

Secondary variables included ease of insertion, first attempt success rate, maneuvers required, fiberoptic view of placement, oropharyngeal leak pressure, ease of placement of nasogastric tube, and complications if any.

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Results

Mean time of insertion was 18.04 ± 5.65 s, 15.00 ± 5.72 s for groups I and II respectively. Time taken for insertion was shortest and significantly lower (P = 0.043) for group II compared to group I. Insertion time was comparable between rest of groups.

The overall success rate in groups I and II were 91.1% and 95.6% respectively (P = 0.7). The first attempt success rate was 70% and 80% in groups I and II respectively (P = 0.07).

Maneuvers 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).

Conclusion

Both techniques of i-gel insertion are equally good and choice of technique depends upon the experience and comfort of the investigator with the particular.

Keywords: mean time of insertion, first attempt success.

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 stabilization 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 different techniques of i-gel placement in terms of insertion characteristics, first attempt and overall success rate and incidence of complications if any.

AIMS & OBJECTIVES

Aims

This prospective randomised study was done to compare standard and reverse techniques of igel placement in terms of insertion characteristics and success rate.

Objectives

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, maneuvers required, fiberoptic view of placement, OLP, ease of placement of nasogastric tube and postoperative complications if any.

MATERIALS AND METHODS

The current prospective comparative study was collected from the patients admitted to S.S. INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTRE, undergoing surgeries under general anaesthesia for a period of 6 month.

Sample size

Sample size

$$SS = \begin{array}{c|c} \hline r+1 & Sd^2 x (Z_{\beta}+Z\alpha)^2 \\ \hline 1 & d^2 \end{array}$$

r = Ratio of case

$$Z_{\beta}$$
 Std normal variate for power 90% power = 1.28

d= mean difference between two groups

Sample size was calculated based on previous studies.

The mean difference of 39 seconds $(94.37 \pm 3.52 \& 54.87 \pm 3.75)$ between the groups for onset time of intubation with a standard deviation of 3.75 for a type 1 error of 99% and a power of 90% has been considered.

The minimum sample size needed to conduct this study was 50 cases.

Inclusion criteria:

- 1. Age 18-65 years
- 2. Weight 40 to 90 kgs
- 3. ASA PS I and II.
- 4. Surgeries in supine position
- 5. Surgical duration less than 90 minutes

Exclusion Criteria

- 1. Patient belonging to ASA PS III and IV
- 2. Presence of sore throat
- 3. Mouth opening <2.5cm and any oral pathology
- 4. Surgeries with risk of pulmonary aspiration.
- 5. Surgeries in prone position

Method of collection of data

A total of 50 patients of either sex belonging to ASA I and II scheduled to undergo elective surgery under general anaesthesia in supine position was included. Pre anaesthetic evaluation was be done the day before surgery and a written informed consent was obtained from all the patients.

All the patients were kept nil per orally for 6 hours prior to procedure and premedication in the form of tab anxit 0.5 mg and tab pantoprazole 40 mg was given in night and 30 minutes prior to shifting to operation theatre.

After arriving in the operation theatre patients were randomized in to two groups: Group S (standard technique) and Group R (reverse technique) by computer generated randomization. In operation room, an intra-venous access was secured using 18 g cannula and monitors like 3 lead electrocardiogram, pulse oximeter and non-invasive blood pressure connected [1]. Baseline Haemodynamic parameters are noted.

After preoxygenation with 100% oxygen for 3 minutes induction of anaesthesia done with standard anaesthetic drugs comprising IV glycopyrrolate 0.2mg/kg, IV midazolam mg/kg, fentanyl 2mcg/kg and propofol of 2mg/kg.

After checking for ability to ventilate, IV vecuronium 0.1 mg/kg administered after three minutes airway secured by an appropriate size I-gel based on patient's weight (30-50 kg: I-gel 3), (50-90 kg: I-gel 4), (>90 kg: I-gel 5) [1]. A well lubricated I gel devices was inserted by an experienced anesthesiologist. The patients placed supine with head in sniffing position (neck flexed and extended at atlanto-axis joint).

In group S, I-gel introduced in mouth with its concavity facing the mandible ^[1-2]. Then it is pushed posteriorly while advancing along the hard palate, soft palate and posterior pharynx and placed in its final position.

In group R, I-gel was inserted with its concavity facing toward the hard palate ^[1-2]. On reaching the pharynx, the device was inserted 180°C anticlockwise and to be placed in its final position ^[2].

Correct placement of I-gel confirmed by observing a square wave capnograph, auscultation, movement of chest wall, and no audible leak with peak airway pressure during manual ventilation.

If there was a leak seen variety of manipulations like chin lift, jaw thrust, head extension, neck flexion, gentle advancement, or withdrawal of I-gel are considered to improve the ventilation [2].

If air leak persisted despite the manipulations, then the attempt is to be considered a failure and the I-gel was reinserted using the same technique ^[2]. In the second attempt gentle jaw thrust was applied by the assistant.

A maximum of three attempts was considered for each technique [1]. The time between the attempts was not considered in insertion time.

If not successful after three attempts, it is to be considered as failure and alternative airway device was used.

The insertion time was defined as the time from picking up the I-gel until appearance of square wave capnograph was recorded.^[1-2]

The number of insertion attempts recorded. Insertion was considered as easy, if successful placement was possible in first attempt with or without maneuvers.

Insertion considered as difficult if successful placement done in more than one attempt. [1-4]

Haemodynamic variables noted at baseline, 1, 3 and 5 minutes after I-gel insertion. Anaesthesia was maintained with isoflurane 1-1.5% with 50% O2 and 50% N2O and paralyzing agent Vecuronium. [3]

Volume control mode of ventilation used with tidal volume of 6-8 ml/kg and respiratory rate was adjusted to maintain EtCO2 between 30 and 40 mmHg.

Intraoperative monitoring of heart rate (HR), electrocardiogram (ECG), blood pressure (BP), EtCO2, peak airway pressure (PAP) was done and any significant changes was recorded. At the time of removal of I-gel, complications like blood staining on the I-gel, complaint of sore throat in post operative period up to 24hrs was noted. [4]

Patients were be transferred to post operative ward, where vitals were monitored and then shifted to respective wards based on the Modified Aldrete's score by anaesthesia resident.

Statistical analysis

Quantitative data was expressed as mean+sd, numbers and percentages. Student's t-test, chi-square test and other suitable tests of significance are applied.

RESULTS

A total of 50 patients were enrolled in each group. The demographic characteristics of two groups were similar as shown in Table 1. The study data on insertion characteristics are shown in Tables 2 and 3.

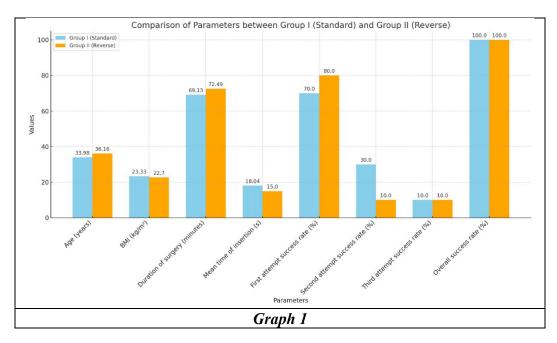
Mean time of insertion was 18.04 ± 5.65 s, and 15.00 ± 5.72 s for groups I and II respectively. It was shortest and statistically lower (P = 0.043) for group II compared to group I.

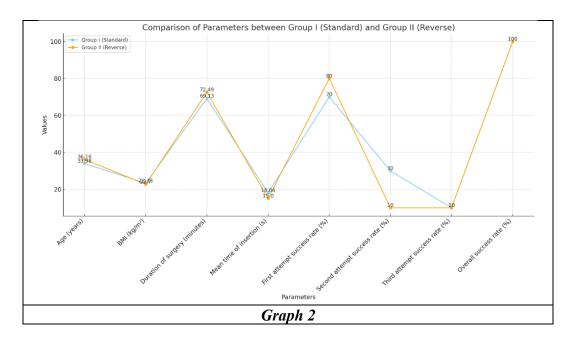
Parameter	Group I (n=25) Standard	Group II (n=25) Reverse	P Value	
Age (years)	33.98 ± 11.15	36.16 ± 10.61	0.48	
Male/Female	12/13	11/14	0.1.0	
BMI (kg/m²)	23.33 ± 3.46	22.70 ± 2.55	0.467	
ASA grade I/II	10/15	20/5	0.009	
MPG grade I/II/III	11/14	10/5	0.288	
Size of i-gel TM (3/4/5)	13/12	9/14	0.56	
Duration of surgery (minutes)	69.13 ± 26.69	72.49 ± 23.24	0.637	
Table 1				

Parameter	Group I (n=10) Standard	Group II (n=10) Reverse	P Value		
Mean time of insertion (s)	18.04 ± 5.65	15.00 ± 5.72	0.247		
Success rate: First attempt	19	21	0.724		
Success rate: Second attempt	5	3	0.700		
Success rate: Third attempt	1	1	1.00		
Overall success rate	25 (100%)	25 (100%)	-		
Failure	0	0	-		
Table 2					

The first attempt success rate was 76% and 84%, in groups I and II respectively. The overall success rate and first attempt success rate of i-gel insertion was highest in group II followed by group I, but the difference was statistically insignificant. Ease of insertion was also comparable among the group (P = 0.72) Maneuvers were required in six patients in group I, four patients in group II. 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 but the difference was not significant statistically (P=0.073). HR and MAP were comparable, at baseline and 1 and 3 min after i-gel insertion





DISCUSSION

The i-gel is a valuable alternative to tracheal intubation for patients undergoing elective surgery. Proper positioning of the device is essential to ensure effective ventilation and oxygenation. Like other supraglottic airways, the i-gel, when inserted using the standard technique, follows a midline path over the tongue. However, due to its non-inflatable cuff, which is slightly more rigid and bulkier compared to other devices prior to cuff inflation, there

is a risk of impaction at the back of the mouth, leading to tongue folding, posterior displacement, and subsequent placement failure, contributing to its variable success rate. ^[5,8,9] The rotation and reverse techniques have been suggested to improve the insertion success rate of supraglottic airways, but the results have been inconsistent. Therefore, this study aimed to compare three techniques (standard and reverse) of i-gel insertion to determine the most effective method. The primary outcome of the study was the mean insertion time, which was found to be shortest with the reverse technique, showing a statistically significant reduction compared to the standard method.

Park et al. conducted a meta-analysis comparing the standard and rotation techniques for inserting supraglottic airway devices such as the LMA Classic, LMA ProSeal, SoftSeal, and i-gel. In seven trials involving adult patients, rotation angles of 90° and 180° (corresponding to the rotation and reverse techniques in the present study) were assessed. Subgroup analysis of three studies using a 90° rotation in adult patients showed better outcomes with no heterogeneity for the rotation technique. However, a similar analysis of three studies using a 180° rotation in adult patients did not show an improved success rate with the rotation technique.

Overall, the meta-analysis concluded that the rotation technique resulted in higher first-attempt and overall success rates, faster insertion times, fewer attempts, and a lower incidence of blood on the removed device, indicating less mucosal trauma. However, it did not confirm superior outcomes for oropharyngeal leak pressure (OLP), fiberoptic view, or postoperative sore throat.^[10,11]

Our findings align with this meta-analysis regarding the reverse technique (180° rotation). The main difference between the meta-analysis and our study is that they considered both 90° and 180° rotations as part of the rotation technique, while we evaluated these as distinct methods. Additionally, the trials in the meta-analysis included four types of supraglottic airways, and the unique characteristics of each device may have contributed to the heterogeneity in the results.

Nasogastric tube placement was comparable across all three groups. Liew et al.^[12] reported successful nasogastric tube placement in 94% of patients using the rotation technique, while Singh et al.^[13] achieved 100% success with the standard i-gelTM insertion technique. Baseline heart rate (HR) and mean arterial pressure (MAP) were also similar among the groups. Additionally, HR and MAP remained comparable at 1, 3, and 5 minutes post-i-gelTM insertion (P > 0.05). Our findings align with those of Sharda et al,Kim et al and singh et al^[6,7,14,15], who also observed no significant differences in HR and MAP between groups following i-gelTM insertion.

While the mean insertion time in our study was significantly shorter for the reverse technique compared to the standard method, this faster insertion time by a few seconds is unlikely to have a meaningful clinical impact, as the overall success rate was comparable among the groups.

Sharda et al. conducted a study comparing reverse and conventional i-gelTM insertion techniques in 100 patients. They found that the reverse group had a significantly shorter mean insertion time (P = 0.012). The first attempt success rate was 96% in the reverse group and 86% in the conventional group, though this difference was not statistically significant (P = 0.08). Additionally, the incidence of sore throat and blood staining on the device was higher in the conventional group compared to the reverse group. Our results are similar to the above study. [7]

LIMITATION

The nature of the insertion technique and the measurement of insertion time precluded the possibility of blinding. Furthermore, the findings may not be generalizable to anesthesiologists

proficient in reverse techniques, as the i-gel insertions were performed exclusively by investigators experienced in the standard method.

Additionally, the results of this study may not extend to diverse population groups, such as pediatric and elderly patients.

CONCLUSION

In conclusion in our study the reverse technique exhibited a marginally higher overall and first-attempt success rate, facilitated easier placements, and resulted in fewer complications, such as sore throat and blood staining, when compared to the standard techniques.

Based on our observations, we propose that all i-gel insertion techniques are clinically comparable. The choice of technique should be guided by the investigator's experience and comfort with the specific method.

The study suggests that due to the higher first-attempt and overall success rates, fewer required attempts for successful insertion, and reduced incidence of blood staining and sore throat, the reverse technique may be more effective when device insertion is unsuccessful on the initial attempt.

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