Comparison of Success Rate of Three Different Techniques of I-Gel Insertion I.E. Standard, Rotational, Triple Airway Maneuver in Anaesthetised Paralysed Adults - A Prospective Randomised Trial

Abstract: Background: The present study was aimed to compare the success rate of three different techniques of i-gel insertion i.e. standard, rotational, triple airway maneuver in anaesthetised paralysed adults. Material & Methods: A total of 150 patients were included in this Prospective Randomised Trial at Department of Anaesthesiology, Dr. R.P.G.M.C. Kangra at Tanda during the study period. The patients were divided into 3 groups with 50 patients each. The patients in group A included standard technique, group B with rotational technique, and group C included triple airway maneuver. The primary endpoint of this investigation was the first attempt insertion success rate. The secondary endpoints were insertion time, number of attempts. Results: In our study, in standard group first attempt success rate was 86% and second attempt success rate was 14%. In rotational group, first attempt success rate was 96% and 4% in second attempt and lastly triple airway maneuver group first attempt success rate was 94% and 6% in second attempt. Though success rate was higher in rotational and triple airway group than standard group, there was no significant difference of success rate distribution between three groups (P = 0.149). Hence all the three groups were comparable for first attempt success rate. Number of insertion attempts were significantly higher in standard group in comparison to rotational group (1.3±0.46 vs. 1.04±0.19; P<0.0001) and triple airway maneuver group (1.3±0.46 vs. 1.06±0.24; P = 0.001). In our study, insertion time in standard group was 11.76±4.92sec, in rotational group was 10.4±2.89 sec and 8.50±2.44sec in triple airway maneuver group. On comparison, insertion time was significantly shorter in triple airway maneuver group in comparison to standard group (8.50±2.44 sec vs. 11.76±4.92sec; P<0.0001) and significantly shorter in comparison with rotational group (8.50±2.44sec vs 10.42±2.89sec; P = 0.027). Conclusion: The triple airway maneuver technique shows higher overall success rate in first attempt of insertion, shorter insertion time, lesser insertion attempts in comparison to rotational and standard techniques of i-gel insertion. Keywords: Comparison, Success rate, Techniques of I-Gel Insertion, I.E. Standard, Rotational, Triple Airway Maneuver, Anaesthetised Paralysed Adults.

INTRODUCTION

The i-gel is a useful alternative to tracheal intubation in patients undergoing elective surgeries and useful tool in emergency airway management. Therefore, correct positioning of the device is very crucial to accomplish proper oxygenation and ventilation.

A more commonly employed classification is first generation and second generation Supraglottic airway devices (SADs). First generation devices are simple airway tubes that do not have specific design characteristics to reduce the risk of pulmonary aspiration of gastric contents. Second generation SADs incorporate specific features to improve positive pressure ventilation (PPV) and reduce the risk of aspiration.1

The i-gel (Intersurgical, Wokingham, UK) is a novel SAD. The i-gel is a second generation supraglottic airway device that has a soft anatomical shaped cuff that produces an airway seal without need for air inflation. The i-gel is notably easy to insert due to a combination of a very low coefficient of friction when lubricated and the fact there is no cuff to inflate. There are increasing numbers of formal evaluations, with most reporting positive findings. First time insertion success rates are >85%, and this approaches 100% with three attempts.8
The success rate of i-gel insertion at the first attempt varies from 78% to 93%, with a relatively high success rate after two attempts of 84–100%. Previous studies demonstrated that the rotational technique provides a higher success rate at the first attempt with minor pharyngeal mucosal trauma than the standard technique for insertion of the ProSealTM LMA. In paralyzed patients, LMA insertion with triple airway maneuver provides wider pharyngeal space and decreases the incidence of epiglottic downfolding by LMA compared with the standard insertion method.

There have been no previous studies regarding the efficacy of rotational and triple maneuver techniques for i-gel insertion when searching web based data. The present study hypothesizes that the rotational and triple airway maneuver techniques would decrease tongue folding by reducing resistance between device and tongue, allowing the i-gel to smoothly advance into the posterior hypopharynx compared to the standard technique. Hence it would be worthwhile to compare the clinical efficacy of three different techniques in terms of success rate in insertion, insertion time and number of attempts.

**AIM & OBJECTIVES:**
To compare the success rate of three different techniques of i-gel insertion i.e. standard, rotational, triple airway maneuver in anaesthetised paralysed adults.

**MATERIAL AND METHODS:**

- **Study Area:** Department of Anaesthesiology, Dr. R.P.G.M.C. Kangra at Tanda, Himachal Pradesh, India.

- **Study Population:**
After approval by institutional ethics committee, this study was carried out on 150 patients, 50 in each group, planned to undergo surgery under general anaesthesia with i-gel as a primary airway device.

- **Study Duration:**
After approval by Institutional Ethics Committee (IEC), this prospective randomized study was conducted for period of 12 months including data collection, data organization, presentation, data analysis and data interpretation.

- **Sample Size:**
All patients within this duration and fulfilling our inclusion criteria were included in the study. For all three groups, 50 patients in each group were evaluated after randomization.

- **Inclusion Criteria:**
  - Patients with age 18-65 years.
  - Patients with ASA I and ASA II.
  - BMI – 18.5-29.9kg/m².

- **Exclusion Criteria:**
  - Duration of surgery > 4 hours.
  - Mouth opening <2.5cm.
  - Presence of sore throat.
  - Any contraindication for SGA placement e.g., facial trauma, facial deformity.
  - Pregnancy.
  - Patient at risk of aspiration e.g. patients of gastroesophageal reflux disorder, previous history of PONV and hiatus hernia.
  - Patient refusal to give consent for study.

- **Study Design:**
The study commenced after obtaining institutional scientific review, protocol and ethics committee approval.

It was a prospective and randomized study. The patients were randomly assigned to three groups (Group-A) standard (n = 50), (Group-B) rotational (n = 50), and (Group-C) triple airway maneuver (n = 50) group using computer generated random numbers. Randomisation sequences were kept in opaque sealed envelopes and were opened at time of induction of GA by a person not involved in the study and handed over to anaesthesia team.

- **Methodology:**
Standard ASA fasting guidelines was followed in all patients. The patients were pre-medicated using oral alprazolam 0.25mg a night before surgery. On patient’s arrival in operating room, the standard anaesthesia monitoring i.e. ECG, NIBP, SPO₂ were applied. Following preoxygenation with 100% oxygen for 3min, anaesthesia was induced with propofol 2mg/kg, fentanyl 2µg/kg and atracurium 0.5mg/kg. The i-gel insertion was performed after 4minutes of administration of injection atracurium. The i-gel was inserted by using one of the study insertion techniques. I-gel size was standardized by weight (i-gel size 3 for 30-60kg and size 4 for 50 to 90kg and size 5 for more than 90kg).

In the Group-A (Standard group) (n = 50), the i-gel was inserted using the standard method described by AI Brain.

In the Group-B (Rotational group) (n = 50), i-gel was inserted using the rotational technique. The i-gel was inserted back-to-front, like a Guedel airway, and then rotated counterclockwise through 180 degrees as it was pushed into the hypopharynx.

In the Group-C (Triple airway maneuver group) (n = 50), the technique involved the following steps described by Kuvaki et al., It involves:
  - holding the i-gel from the middle third between the index finger and thumb of the dominant hand.
performing a triple airway maneuver, the combination of head extension, mouth opening, and jaw thrust

- pressing the i-gel directly (front-to-back) against the hard palate and pushing it along the posterior palatopharyngeal curve using the index finger and thumb
- when the index finger and thumb reach the mouth, the position of the index finger was adjusted so that it pulled upward on the lower surface of the tube
- pushing the i-gel into its final position holding the shaft.

After i-gel insertion, anaesthesia was maintained with isoflurane, oxygen and nitrous oxide. An anaesthesiologist with a clinical experience of 50 i-gel insertion with standard technique placed the i-gel in one of the three techniques and judged the effectiveness of the i-gel based on a square-wave capnograph trace and no audible leak with peak airway pressures ≥ 10cm H₂O during manual ventilation. If air leak occurred at peak airway pressures < 10cm H₂O, the attempt was considered a failure and the i-gel was reinserted using the same technique. The numbers of insertion attempts were noted.

The insertion time defined as the time from picking up the i-gel until the initiation of mechanical ventilation was recorded. We allowed a maximum of two i-gel insertion attempts, with 60 seconds permitted for each attempt. The time between attempts was added to the insertion time.

After completion of procedure, patient was reversed with neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg and the i-gel was removed when the patient was able to breathe spontaneously and open his/her eyes to command. The primary endpoint of this investigation was the first attempt insertion success rate. The secondary endpoints were insertion time, number of attempts.

**Statistical Analysis:**

The data were recorded into Microsoft® Excel workbook 2019 and exported into SPSS v21.0 (IBM, USA) for statistical analysis. Categorical variables were expressed as frequency, percentage and compared using Chi square test. Quantitative variables were expressed as mean, standard deviation and compared using one-way analysis of variance (ANOVA). P value <0.05 was considered significant.

**OBSERVATIONS & RESULTS:**

The present study was aimed to compare the success rate of three different techniques of i-gel insertion i.e. standard, rotational, triple airway maneuver in anaesthetised paralysed adults. A total of 150 patients were included in this study at Department of Anaesthesia, Dr. R.P.G.M.C. Kangra at Tanda during the study period.

The patients were divided into 3 groups with 50 patients each. The patients in group A included standard technique, group B with rotational technique, and group C included triple airway maneuver.

In this study, there was no significant difference of age between three groups (P = 0.422). In this study, male to female ratio was 0.4:1 in standard group, 0.7:1 in rotational group and 0.6:1 in triple airway maneuver group. There was no significant difference of gender distribution between three groups (P = 0.466). In this study, there was no significant difference of weight (P = 0.395), height (P = 0.321), and BMI (P = 0.660) between three groups (Table-1).
In present study, in standard group first attempt success rate was 86 % and second attempt success rate was 14%. In rotational group, first attempt success rate was 96% and 4% in second attempt. In triple airway maneuver group first attempt success rate was 94% and 6% in second attempt. Though success rate was higher in rotational and triple airway group than standard group, there was no significant difference of success rate distribution between three groups (P = 0.149). Hence all the three groups were comparable for first attempt success rate. We also found that out of 12 patients with second attempt, 58% were in standard group, 17% in rotational group and 25% in triple airway group, showing rate of second attempt was higher in the standard group in comparison to other groups. (Table-3)

<table>
<thead>
<tr>
<th>MPS grade</th>
<th>Group-A (n=50)</th>
<th>Group-B (n=50)</th>
<th>Group-C (n=50)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPS-1</td>
<td>35 (70%)</td>
<td>31 (62%)</td>
<td>34 (68%)</td>
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<tr>
<td>MPS-2</td>
<td>10 (20%)</td>
<td>17 (34%)</td>
<td>13 (26%)</td>
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</tr>
<tr>
<td>MPS-3</td>
<td>3 (6%)</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
<td></td>
</tr>
<tr>
<td>MPS-4</td>
<td>2 (4%)</td>
<td>0</td>
<td>1 (2%)</td>
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<td>ASA Class</td>
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</tr>
<tr>
<td>Class-1</td>
<td>43 (86%)</td>
<td>37 (74%)</td>
<td>38 (76%)</td>
<td>0.292</td>
</tr>
<tr>
<td>Class-2</td>
<td>7 (14%)</td>
<td>13 (26%)</td>
<td>12 (24%)</td>
<td></td>
</tr>
</tbody>
</table>

In this study, number of insertion attempts were significantly higher in standard group in comparison to rotational group (1.3±0.46 vs. 1.04±0.19; P<0.0001) and triple airway maneuver group (1.3±0.46 vs. 1.06±0.24; P=0.001). In current study, insertion time observed in standard group was 11.76±4.92sec, in rotational group it was 10.42±2.89sec and 8.50±2.44sec in triple airway maneuver group. On comparison, insertion time was significantly shorter in triple airway maneuver group when compared to standard group (8.50±2.44 sec vs 11.76±4.92sec; P<0.0001) and to rotational group (8.50±2.44sec vs 10.42±2.89sec; P = 0.027). (Table-3).

DISCUSSION:
Though tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia, the i-gel is a useful alternative to tracheal intubation. It has been used for routine elective anaesthesia and has also been effective in pre-hospital emergency airway management.6

Insertion of supraglottic airways using the standard technique is not always successful. Previous studies have reported varied success rates for the first attempt at inserting supraglottic airways.8 Various techniques have been described to ensure a high successful insertion rate. Among the alternative methods, the rotation technique derived from the back-to-front insertion technique of the Guedel airway and consists of inserting the device with a 90 or 180 degree rotation and then rotating it to the final position as it enters the hypopharynx. There are very few studies that have shown improvement in successful placement of i-gel by rotational or triple airway maneuver technique. But no randomised controlled trial comparing all three techniques is conducted till now.

These three groups were compared with respect to primary outcome of success rate in first attempt of i-gel insertion and secondary outcome that were insertion time and number of insertion attempts.

In this study, the differences in age, gender, weight, height and BMI among all three groups were statistically not significant. Hence these three groups were comparable with respect to demographic profile. In our study, these three groups were comparable in terms of ASA and MPS as the difference was statistically insignificant.

In our study, in standard group first attempt success rate was 86 % and second attempt success rate was 14%. In rotational group, first attempt success rate was 96% and 4% in second attempt and lastly triple airway maneuver group first attempt success rate was 94% and 6% in second attempt. Though success rate was higher in rotational and triple airway group than standard group, there was no significant difference of success rate distribution between three groups (P = 0.149). Hence, all the three groups were comparable for first attempt success rate . We also found that out of 12 patients with second attempt, 58% were in standard group, 17% in rotational group and 25% in triple airway group, showing rate of second attempt was higher in the standard group.
In the study by Bhardwaj et al., first attempt success rate was 82.2%, 89% and 84.4% with standard, reverse, and rotational technique of i-gel insertion in anaesthetised adults, which was statistically not significant (P = 0.07). In the study by Baran et al., successful insertion at the first attempt was 78% and 92% for the standard and triple airway group respectively, which was statistically not significant (p = 0.092). In the study conducted by Eglen et al., they compared three different insertion techniques of the LMA-Unique in adults. Patients were randomly allocated to the standard, rotational and triple airway maneuver (triple) group. Successful insertion at the first attempt was 88.3%, 78.3% and 88.3% for the standard, the rotational and the triple group. All the three groups were comparable in first attempt success rate (P = 0.2). In the study done by Sharda et al., they hypothesized that the i-gel can be inserted with relative ease in a reversed manner just like a Guedel's airway in comparison to standard technique of i-gel insertion. Better success rate of the first attempt insertion was achieved using the reversed technique in comparison to standard technique (96% vs. 86%), but it was not statistically significant (P = 0.08).

Our study had similar results like the studies of Bhardwaj et al., Baran et al., Eglen et al., and Sharda et al., showing first attempt success rate was statistically not significant and was comparable in all the three groups.

In our study, number of insertion attempts were significantly higher in standard group in comparison to rotational group (1.3±0.46 vs. 1.04±0.19; P<0.0001) and triple airway maneuver group (1.3±0.46 vs. 1.06±0.24; P = 0.001).

In the study conducted by Muneer et al., they compared standard and rotational technique of i-gel insertion, number of attempts in standard group (1.28±0.5) was significantly higher than rotational group (1.1±0.3) (P = 0.04).

Our study had similar results to this study, showing number of attempts were significantly higher in standard group than both the groups. This might be because of obstruction of passage from the oral cavity to the pharynx due to folding of tongue and due to increase resistance in between i-gel and pharyngeal wall in standard technique.

In our study, insertion time in standard group was 11.76±4.92 sec, in rotational group it was 10.42±2.89 sec and 8.50±2.44 sec in triple airway maneuver group. On comparison, insertion time was significantly shorter in triple airway maneuver group in comparison to standard group (8.50±2.44 sec vs 11.76±4.92 sec; P<0.0001) and significantly shorter in comparison with rotational group (8.50±2.44 sec vs 10.42±2.89 sec; P=0.027).

Bhardwaj et al., compared standard (group I), reverse (group II), and rotational (group III) techniques of i-gel placement in terms of insertion characteristics and success rate. 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. Baran et al., compared the standard technique with the triple airway maneuver technique of i-gel insertion in terms of successful device insertion time and first-attempt success. Time for successful insertion was significantly shorter in the triple group (20±7 s) than with the standard group (32±11 s; p < 0.001). In the study conducted by Eglen et al., they compared standard, rotational and triple airway maneuver technique for LMA insertion, they concluded that the time for successful insertion was significantly shorter in triple airway maneuver group (8.63 s) when compared with standard technique (11.78 s) (P = 0.0001) and rotational technique (11.57 s) (P = 0.001). Standard and rotational technique groups did not differ from each other (P>0.05).

In the study conducted by Kim et al., they compared two techniques for i-gel insertion- standard group and rotational group. The mean (SD) insertion time was longer in standard group than rotational group, but it was statistically insignificant 26.9 (14.5) s vs. 22.4 (10.2) s (p = 0.016).

In the meta-analysis by Park et al., they compared the rotational and standard techniques for inserting supraglottic airways. Device insertion was completed faster with the rotation technique in comparison to standard technique (mean difference: -4.6 seconds; 95% CI: -7.37 to -1.74; p = 0.002).

Our study had results similar to the study done by Baran et al., and Eglen et al., showing insertion time was significantly shorter in triple airway maneuver technique in comparison to standard and rotational technique. This might be due to wider pharyngeal space and decrease in the incidence of epiglottic downfolding leading to smooth advancement of i-gel in triple airway maneuver technique.

**CONCLUSION:**

To conclude, this study demonstrated that the triple airway maneuver and the rotational technique both are acceptable alternative to standard technique of i-gel insertion in adults. Considering the possibility of infection and trauma to the operator due to intraoral manipulation, triple airway technique and rotational technique are advantageous. The triple airway maneuver technique shows higher overall success rate in first attempt of insertion, shorter insertion time, lesser insertion attempts in comparison to rotational and standard techniques of i-gel insertion.
REFERENCES: