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Original Research Article

Randomized controlled trial comparing conventional versus reverse insertion techniques for i-gel supraglottic airway placement and guided intubation

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Abstract

Background and Aims: Supraglottic airway (SGA) devices are pivotal for airway management and can serve as effective conduits for tracheal intubation. The i-gel® is a commonly used second-generation SGA. While its conventional insertion technique is well-established, a 'reverse' technique has been proposed to potentially improve performance. This randomized controlled trial aimed to compare the conventional versus the reverse i-gel insertion technique with respect to first-attempt placement success and the efficacy of subsequent blind tracheal intubation.

Materials and Methods: Eighty adult patients (aged 18–60 years, American Society of Anesthesiologists physical status I/II) undergoing elective surgeries under general anesthesia were enrolled. They were randomly allocated into two groups (n=40 each): Group C (Conventional i-gel insertion) and Group R (Reverse i-gel insertion). Following correct device placement, blind tracheal intubation through the i-gel was attempted. The primary outcomes were the first-attempt success rate for both i-gel placement and blind tracheal intubation. Secondary outcomes included total insertion and intubation times, number of attempts required, oropharyngeal leak pressure (OLP), and the incidence of postoperative airway complications (sore throat, hoarseness).

Results: The reverse insertion technique (Group R) demonstrated statistically significant superiority across several metrics. It yielded a significantly higher first-attempt insertion success rate (97.5% vs. 72.5%; p = 0.002), a markedly shorter mean insertion time (4.72 ± 1.17 s vs. 11.22 ± 2.21 s; p = 0.001), and a higher OLP (34.25 ± 2.42 cmH_2O vs. 28.07 ± 3.68 cmH_2O; p = 0.003) compared to the conventional technique. Furthermore, Group R also showed a greater first-attempt success rate for blind tracheal intubation (32.5% vs. 12.5%; p = 0.005) and a faster mean intubation time (17.97 ± 3.69 s vs. 22.77 ± 9.46 s; p = 0.014). The incidence of postoperative airway complications was low and comparable between both groups.

Conclusion: The reverse technique for i-gel insertion is demonstrably superior to the conventional method. It offers a higher first-attempt success rate, faster and more reliable device placement, a better seal, and improved efficacy for blind tracheal intubation, without increasing postoperative morbidity. It should be considered a valuable alternative in clinical airway management.

Keywords: Airway management, Intubation, Supraglottic airway device, i-gel, Difficult airway, Randomized controlled trial.

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1. Introduction

In recent years, supraglottic airway (SGA) devices have become indispensable for both elective ventilation and rescue airway management in anticipated or unexpected difficult airways. They not only maintain ventilation and oxygenation but also act as a conduit for tracheal intubation.[1,2] The i-gel (Intersurgical Ltd., Wokingham, UK) features a soft, thermoplastic cuff that conforms to peri-laryngeal anatomy, providing a reliable seal.[3] Its short, wide airway channel accommodates an adult sized endotracheal tube (ETT), permitting blind intubation.[4,5]

Although the conventional technique of insertion yields first-attempt success rates of 78–93 %,[6-8] the semi-rigid cuff and tongue folding can hinder insertion and placement, prolonging time required for airway securement and increasing risk of trauma to oral cavity and supraglottic

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structures. The reverse technique has been proposed to overcome these issues and improve first-attempt success.[7]

Tracheal intubation through the i-gel, whether blind or fibre-optic-guided, succeeds in 15–100 % of cases, with fibreoptic guidance generally outperforming blind techniques.[9,10] However, this may not always be feasible in emergencies or resource-limited settings. We hypothesised that improved alignment provided by the reverse insertion technique would enhance blind intubation success. This study, therefore, compared conventional and reverse techniques of i-gel insertion in terms of first-attempt success rate and ease of blind intubation.

2. Materials and Methods

This prospective, randomized, controlled trial was conducted at a tertiary-care teaching hospital between January 2021 and August 2022. The study protocol received approval from the institutional ethics committee, and was registered with the Clinical Trials Registry of India (CTRI/2021/01/030525). Written informed consent was secured from all participants. Patients aged 18 to 60 years of both genders, classified as American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective surgeries under general anaesthesia were considered for inclusion. Exclusion criteria comprised of anticipated difficult airways, pregnancy, gastroesophageal reflux disease, hiatus hernia, oesophageal varices, and body mass index exceeding 35 kg/m².

Sample size determination was based on pilot study data indicating first-attempt blind intubation success rates of 21% for conventional versus 47% for reverse insertion techniques. Assuming a 5% α error, 80% statistical power (1-β) and an equal allocation ratio between the two groups, the minimum sample size was calculated to be 40 in each group with a total of 80 patients.[11] A computer-generated sequence and sealed, opaque envelopes ensured concealed allocation. To ensure blinding, the i-gel insertion was performed by one anaesthesiologist who then exited the operating room before a second anaesthesiologist, unaware of the insertion technique used, entered to perform the blind intubation attempt.

During the preoperative visit, a comprehensive patient history was taken, followed by a general physical and systemic examination and routine laboratory investigations. Patients were advised to fast for six hours before surgery. After arrival into the operating room, intravenous access was established, and standard monitors were attached. Premedication included glycopyrrolate 0.2 mg IV and nalbuphine 0.1 mg kg^{-1} IV. Anaesthesia was induced with propofol 2 mg kg^{-1} following three minutes of pre-oxygenation with 100% oxygen; vecuronium 0.1 mg kg^{-1} provided neuromuscular relaxation. An appropriate i-gel size was selected according to body weight.[2] For Group C (Conventional Insertion), the device was inserted per manufacturer instructions.[2] For Group R (Reverse Insertion), the device was introduced with concavity facing the hard palate, advanced to the oropharynx, rotated 180° and seated over the laryngeal inlet.[7]

First-attempt success for i-gel placement was strictly defined as successful insertion with adequate ventilation confirmed by bilateral chest rise, square-wave capnography pattern, and absence of audible leak, achieved with the first insertion attempt.[6] If an air leak occurred at peak airway pressures below 10 cm H_2O, adjustments such as gentle advancement or withdrawal, chin lift, jaw thrust, head extension, or neck flexion were performed.[12] If the leak persisted despite these manoeuvres, the attempt was deemed unsuccessful,[13] and the device was reinserted using the same technique. Key parameters recorded included the number of insertion attempts, insertion time, and oropharyngeal leak pressure (OLP). Insertion time was defined as the duration from picking up the i-gel to achieving adequate chest wall movement. OLP was determined by noting the equilibrium airway pressure. A maximum of two attempts were allowed before considering placement unsuccessful. If significant airway obstruction or leakage occurred, the device was removed and reinserted. Following successful placement, an orogastric tube was inserted through the gastric channel for suctioning.

A well-lubricated Rusch polyvinyl chloride endotracheal tube (ETT) of appropriate size was inserted through the airway channel. Successful tracheal intubation was defined by the presence of a square-wave capnography trace, bilateral chest wall movement, and equal bilateral breath sounds on auscultation. A maximum of three intubation attempts was permitted with standardized interventions for failed attempts: lateral displacement of the larynx for the second attempt, and use of a smaller-sized endotracheal tube for the third attempt.[6]

The ease of intubation was assessed based on the number of attempts required and the time taken to intubate via the i-gel. Intubation time was measured from the introduction of the ETT to the appearance of a square-wave capnography pattern, with a separate time recorded for each attempt. First-attempt success of blind intubation was defined as successful intubation through the i-gel on the first attempt. If intubation remained unsuccessful after three attempts, surgery proceeded with the i-gel in place.[6] For reversal, Neostigmine (0.05 mg/kg IV) and Glycopyrrolate (0.01 mg/kg IV) were administered. The airway device was removed once the patient was fully awake and met all criteria for recovery from neuromuscular blockade. Postoperative complications, including sore throat and blood-staining, were monitored. The procedure was performed by anaesthesiologists with over 10 years of experience in supraglottic airway device placement and endotracheal intubation, and were required to have successfully performed at least 10 intubations using the i-gel as a conduit before enrolling study participants.

Data were analysed with IBM SPSS v20. Continuous variables (mean ± SD) were compared using the independent-samples t-test. Categorical data (frequency %) were analysed using Chi-square or Fisher's exact test. $P < 0.05$ indicated statistical significance. Out of 82 patients assessed for eligibility, 80 were included in the final statistical analysis, as illustrated in the CONSORT flowchart (**Figure 1**).

3. Results

The study was conducted on 80 patients scheduled for elective surgical procedures under general anaesthesia, with all demographic variables including gender, age, BMI, ASA status, Mallampati (MP) grade, and i-gel size showing no statistically significant differences between the two groups (**Table 1**), thereby ensuring study validity and minimizing potential confounding factors.

Analysis of i-gel placement revealed that the reverse insertion technique demonstrated superior performance across all measured parameters, achieving a significantly higher first-attempt success rate (97.5 % vs 72.5 %; $p = 0.002$), a markedly shorter insertion time (4.72 ± 1.17 s vs 11.22 ± 2.21 s; $p = 0.001$), and a higher oropharyngeal leak pressure (OLP) (34.25 ± 2.42 cmH_2O vs 28.07 ± 3.68 cmH_2O; $p = 0.003$) when compared to the conventional insertion method (**Table 2**). Regarding intubation outcomes, the overall success rate of blind tracheal intubation through the i-gel was substantially greater in Group R (75%), with 32.5% of cases achieving successful intubation on the first attempt, followed by 22.5% on the second attempt, and 20% on the third attempt.

The mean intubation time was also significantly lower in the reverse insertion group, averaging 17.97 ± 3.69 seconds (**Table 2**, **Figure 2**). The complication profile indicated a lower incidence of post-operative sore throat in Group R (20 %) compared to Group C (42.5 %), though this difference did not reach statistical significance ($p = 0.06$). Minor blood staining was observed exclusively in the conventional group (7.5 %), and no serious adverse events were recorded in either group (**Table 3**).

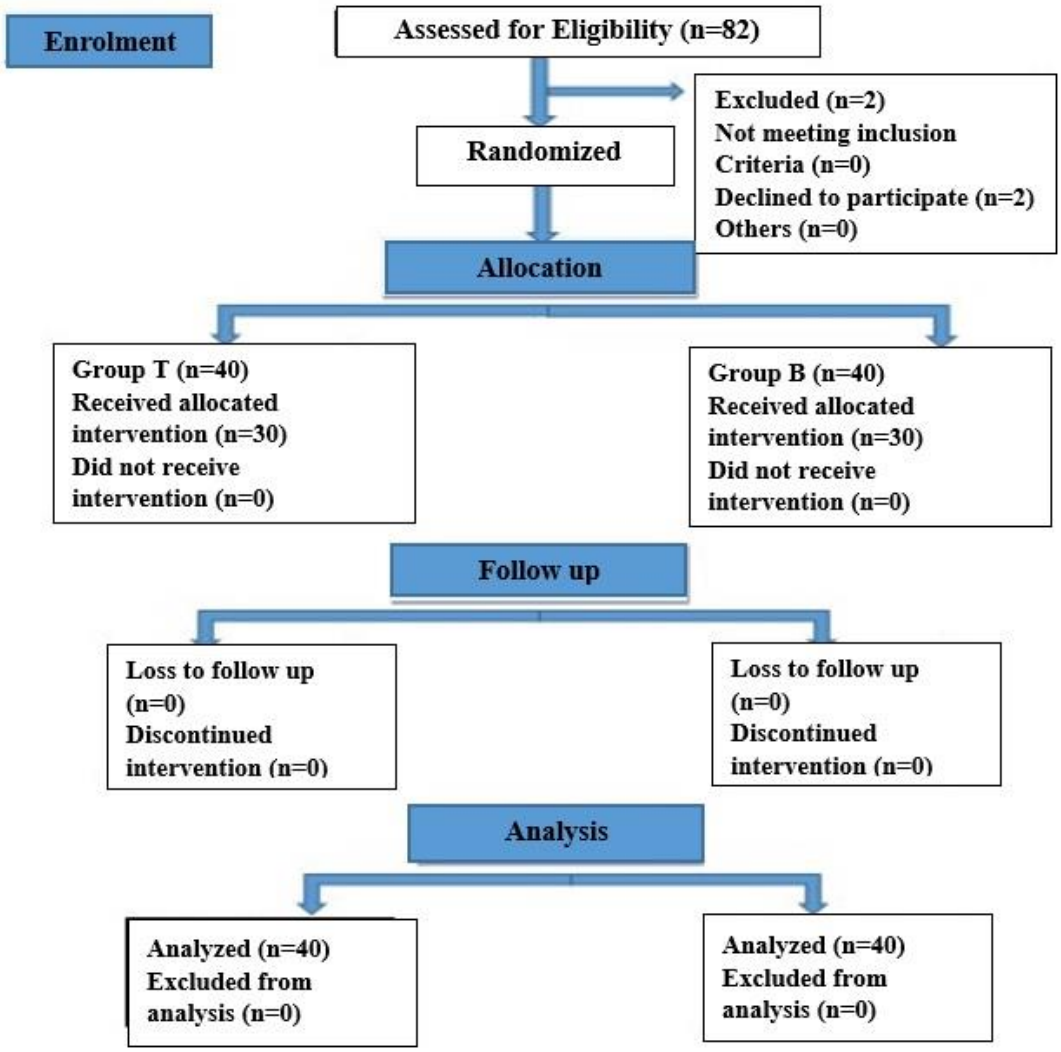

Figure 1: CONSORT diagram

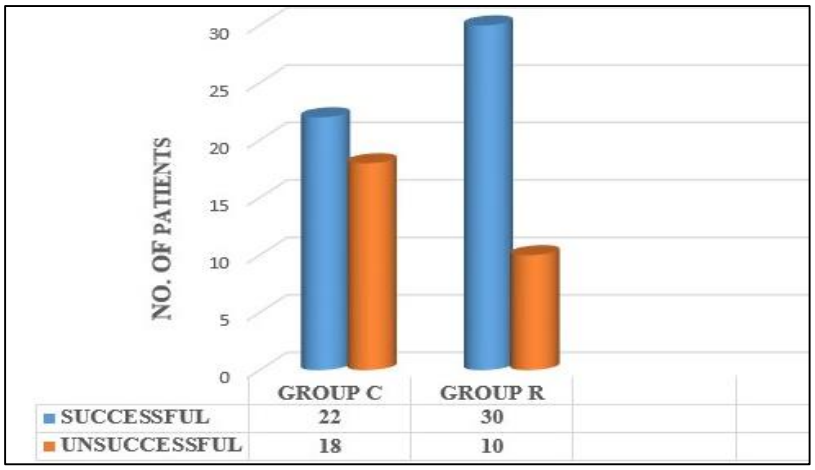

Figure 2: Cumulative successful and unsuccessful intubations

Table 1: Demographic data

	Group C (n=40)	Group R (n=40)	p-value
Gender M/F†	18 (45.0%) / 22 (55.0%)	16 (40.0%)/ 24 (60.0%)	0.651
Age (years)*	31.92 ±11.32	36.5±12.53	0.91
Body mass index (Kg/m^2)*	25.20 ±2.28	25.42 ±2.69	0.69
ASA status I/II†	29 (72.5%)/ 11 (27.5%)	26 (65.0%)/ 14 (35.0%)	0.46
Mallampati grade 1/2†	24 (60.0%)/ 16 (40.0%)	24 (60.0%)/ 16 (40.0%)	1.00
i-gel size 3/4†	25 (62.5%)/ 15 (37.5%)	23 (57.5%)/ 17 (42.5%)	0.64

*****Data represented as mean ± SD
†Data represented as number (percent)

Table 2: Various parameters of i-gel insertion and intubation

	Group C (n=40)	Group R (n=40)	p-value
I-gel insertion (n=80)			
First attempt success rate, n (%)	29 (72.5)	39 (97.5)	0.002
Second attempt success rate, n (%)	11 (27.5)	1 (2.5)	0.002
Overall insertion time (seconds), mean ± SD	11.22 ± 2.21	4.72 ± 1.17	0.001
Oropharyngeal leak pressure (cm H_2O), mean ± SD	28.07 ± 3.68	34.25 ± 2.42	0.003
Blind tracheal intubation through i-gel			
First attempt success, n (%)	5 (12.5)	13 (32.5)	0.005
Second attempt success, n (%)	10 (25.0)	9 (22.5)	0.793
Third attempt success, n (%)	7 (17.5)	8 (20.0)	0.775
Overall successful intubation, n (%)	22 (55.0)	30 (75.0)	0.043
Time for successful intubation (seconds), mean ± SD	22.77 ± 9.46	17.97 ± 3.69	0.014

OLP: Oropharyngeal leak pressure

Table 3: Post-operative complications

	Group C (n=40)	Group R (n=40)	p-value
Sore throat, n (%)	17 (42.5)	8 (20.0)	0.051
Blood stained, n (%)	2 (5.0)	0 (0.0)	0.494*
Both, n (%)	1 (2.5)	0 (0.0)	1.000*

p-values were calculated using Chi-square/Fisher's exact test and were not significant for any inter-group comparison.

4. Discussion

Traditional airway management relies primarily on direct laryngoscopy followed by endotracheal intubation. However, alternative devices, such as the i-gel, have demonstrated increasing effectiveness, particularly in challenging airway situations and emergency scenarios, due to their ease of insertion and utility as tracheal intubation conduits.[4-9]

This randomized controlled trial provides strong evidence supporting the superiority of the reverse i-gel insertion technique over the conventional method across multiple clinically relevant parameters. Our findings demonstrate significant improvements in first-attempt placement success, insertion time, seal quality, and subsequent blind intubation success rates, establishing the reverse technique as a valuable advancement in supraglottic

airway management. These results are particularly relevant given that recent studies have shown the importance of optimizing insertion techniques to maximize the effectiveness of supraglottic airways as intubation conduits.[14]

Several factors may have contributed to the superior outcomes observed with the reverse technique. First, the initial insertion with concavity facing the hard palate appears to minimize tongue folding into the device cuff, a common cause of placement difficulty with conventional insertion. This mechanism likely explains both the higher first-attempt success rate and shorter insertion time observed in our study.

Second, the 180-degree rotation during reverse insertion may facilitate better anatomical alignment with the laryngeal inlet, as evidenced by the significantly higher oropharyngeal leak pressures achieved. This improved positioning creates optimal conditions for subsequent blind intubation attempts by ensuring proper endotracheal tube trajectory toward the glottis.

Patient factors, including age, body mass index, Mallampati grade, and ASA status, were well-balanced between groups and showed no correlation with insertion success in our analysis, confirming that the observed differences were attributable to technique rather than patient characteristics. Operator experience was standardized through strict inclusion criteria requiring extensive prior experience with i-gel guided intubation, minimizing learning curve effects.

Our results align with and extend previous research on alternative i-gel insertion techniques. Sharda et al. reported first-attempt insertion success rates of 96% with the reverse technique versus 86% with the conventional approach,[15] while Bhardwaj et al. demonstrated success rates of 89% versus 82.2% respectively.[7] Our study revealed a significantly greater difference (97.5% vs 72.5%), possibly due to our strict definition of first-attempt success and standardized operator expertise.

Regarding insertion time, our findings of significantly shorter duration with reverse technique (4.72 vs 11.22 seconds) are consistent with previous studies, though absolute times varied based on measurement methodology. Sharda et al. reported insertion times of 17.5 ± 6.9 seconds versus 20.8 ± 5.9 seconds,[15] while Bhardwaj et al. found 15.0 ± 5.72 seconds versus 18.04 ± 5.65 seconds for reverse versus conventional techniques respectively.[7]

The higher oropharyngeal leak pressure with reverse insertion (34.25 vs 28.07 cmH_2O) corresponds with findings of Kim et al.[16] and Muneer et al.[17] that rotational techniques provide superior seal pressures. This improvement has practical implications for ventilation efficacy and patient safety during positive pressure ventilation.

Our blind intubation results showed first-attempt success rates of 32.5% with reverse versus 12.5% with conventional insertion, representing substantial clinical improvement. While overall success rates (75% vs 55%) did not reach statistical significance, the trend suggests a potential benefit that might become significant with larger sample sizes. The faster intubation times observed with the reverse technique (17.97 vs 22.77 seconds) support the hypothesis that improved device alignment facilitates endotracheal tube passage.

Regarding postoperative complications, we observed a slightly higher incidence of sore throat with conventional insertion (42.5%) compared to the reverse group (20%), though without a statistically significant difference. Additionally, blood staining and concurrent occurrence of both complications were minimal and present only in the conventional group, consistent with Sharda et al., who also noted reduced airway trauma and complications associated with the reverse technique.[15] The smoother insertion likely reduces mucosal damage, explaining lower complication rates, as similarly supported by Kumar et al., who reported decreased trauma with rotational insertion techniques in airway device placement.[18]

While our study demonstrates clear advantages of the reverse technique, both methods have inherent limitations that merit discussion. The conventional technique, despite lower success rates in our study, remains familiar to most practitioners and requires no additional training. Its predictable insertion pathway may be preferred in certain anatomical variants or when teaching novice practitioners. The reverse technique, while superior in our study parameters, requires a learning curve for practitioners accustomed to conventional insertion. The 180-degree rotation step demands spatial orientation awareness and may be challenging in patients with limited mouth opening or cervical spine restrictions. Additionally, the technique requires slightly more time for the rotation manoeuvre, though our overall insertion times were still faster due to reduced repositioning attempts. Both techniques share common limitations inherent to supraglottic airway devices, including contraindications in patients with pharyngeal or laryngeal pathology, limited effectiveness in severe obesity, and potential difficulties in patients with anatomical variants. Neither technique guarantees successful blind intubation, emphasizing the continued importance of alternative airway management strategies.

Limitations of our study includes the absence of fibreoptic evaluation which prevented detailed analysis of laryngeal view quality and identification of specific reasons for intubation failures; lack of complete blinding which was impossible due to the interventional nature of the study, potentially introducing bias in subjective assessments and operator experience variability, which while controlled through minimum experience requirements, could still influence results. The relatively small sample size, while adequate for primary endpoints, may have been insufficient

to detect smaller but clinically meaningful differences in secondary outcomes such as overall intubation success rates and complication frequencies.

Based on our findings, we recommend the reverse i-gel insertion technique for routine clinical practice due to its superior first-attempt success rate, faster insertion time, and better seal quality. Training programs should include instruction on both the reverse and conventional techniques to ensure practitioner proficiency. The reverse technique is particularly advantageous in emergencies requiring rapid airway securement. However, maintaining competency in the conventional method remains important as a backup for specific anatomical considerations. When intubation through the i-gel is planned, the reverse technique should be prioritized, though providers should be prepared with alternative strategies, such as fiberoptic guidance, as blind intubation success rates remain imperfect.

5. Conclusion

The reverse technique facilitates smoother insertion of the i-gel by preventing tongue in folding into the cuff, thereby ensuring quicker placement, improved seal pressure, and potentially higher first-attempt success rates for blind intubation. These advantages make the reverse technique a superior alternative to the conventional method for i-gel insertion.

6. Disclosure Statement

No potential conflict of interest was reported by the author(s).

7. Source of Funding

Nil.

8. Conflict of Interest

Nil.

9. Ethical Committee Approval

Institutional Review Board approval number: KIIT/KIMS /IEC/415/2020 (03.11.2020).

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