

Comparison of Triple Airway Manoeuvre and Reverse Insertion Technique for I-gel[®] Placement in Paediatric Patients under General Anaesthesia: A Randomised Controlled Trial

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ABSTRACT

Introduction: I-gel[®], a second-generation supraglottic airway device with a soft, anatomically shaped cuff, which produces an airway seal without the need for air inflation. Distinctive features of the paediatric airway may interfere with ideal insertion of Supraglottic Airway Devices (SADs). Therefore, it is important to recognise the most effective technique for I-gel[®] placement in paediatric patients to minimise airway-related complications.

Aim: To compare the triple airway manoeuvre and reverse insertion technique for I-gel[®] placement in paediatric patients under general anaesthesia.

Materials and Methods: This single blinded, Randomised Controlled Trial (RCT) was conducted at Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, Haryana, India, over a period of 14 months from July 2023 to September 2024 in 100 paediatric patients (7-12 years), American Society of Anaesthesiologists-Physical Status (ASA-PS) grade I and II of either gender planned for elective surgery. Randomisation was performed into two groups using a computer-generated random number table, with 50 patients in each group. In Group R, I-gel[®] placement was done using the

reverse insertion technique (n=50) and in Group TAM, I-gel[®] was placed using the triple airway manoeuvre, i.e. head tilt, jaw thrust, mouth open (n=50). Mean insertion time was measured as the primary outcome. Other parameters studied were the number of attempts, overall success rate, ease of I-gel[®] insertion, ease of nasogastric tube insertion and postoperative complications. Wilcoxon-Mann-Whitney U test, Chi-squared test, Fisher's-exact test were used to analyse data. A p-value <0.05 was considered statistically significant.

Results: The demographic profile of all 100 patients was comparable in both groups, based on age, gender, Body Mass Index (BMI) and ASA-PS classification. The mean±SD of insertion time in group R was 18.65±8.07 sec and in group TAM was 16.84±6.93 sec. The device was successfully placed on the first attempt in 90% of patients in group R compared with 84% in group TAM. The overall success rate was 100% in both groups.

Conclusion: TAM and reverse insertion techniques of I-gel[®] placement were comparable clinically. The experience of the investigator with the technique should determine the choice of technique.

Keywords: Airway management, Elective surgical procedure, Hoarseness, Laryngeal masks, Paediatric

INTRODUCTION

Airway management in patients undergoing anaesthesia has transformed from the invasive approach of endotracheal intubation to the use of less invasive supraglottic devices, which provide better haemodynamic stability and reduce respiratory complications. The supraglottic airway device is presently the most common modality of airway management in children for short surgical procedures [1]. Second-generation supraglottic airway devices like I-gel[®] have been anticipated to emerge as the first choice of airway management in prehospital cardiac arrests [2].

I-gel[®], an innovative, second-generation supraglottic airway device that has a soft, anatomically shaped cuff which produces an airway seal without the need for air inflation and is manufactured using thermoplastic elastomer (styrene ethylene butadiene styrene) [3]. Recently, I-gel[®] has gained popularity among anaesthesiologists over other SADs in clinical anaesthesia as it is easy to use, cost-effective and sometimes reusable. Familiarity with a newer airway device is of importance, especially in difficult airway situations such as the 'can't ventilate, can't intubate' scenarios; an easy-to-use supraglottic airway device may help to improve the patient's outcome considerably [4].

Insertion of this device is found to be difficult during its passage beyond the teeth, tongue or the hypopharyngeal curvature [5]. Due to the slightly rigid structure and lack of a pilot balloon, placement of

the I-gel[®] using the standard technique may pose difficulties in some cases [6]. Additionally, distinctive features in paediatric airways like a large tongue, large epiglottis and hypertrophic tonsils interfere with ideal insertion of supraglottic devices. Improper supraglottic device placement can cause partial or complete airway obstruction, which can be detrimental, especially in paediatric patients who inherently have physiologically and anatomically difficult airways. Multiple attempts can cause trauma to supraglottic structures and increase the insertion time in operating rooms or in emergencies. Additionally, prolonged duration to secure the airway may lead to hypoxemia and haemodynamic instability. These challenges are particularly significant in pediatric patients, who have lower functional residual capacity and higher oxygen consumption, resulting in rapid oxygen desaturation [7]. Therefore, techniques that improve the ease of supraglottic airway device insertion are of significant anaesthetic importance.

A major challenge that was faced during I-gel[®] placement is tongue folding, which can either be prevented by the manual tongue stabilisation technique [8] or by other techniques of insertion like triple airway manoeuvre or reverse insertion technique. The triple airway manoeuvre is a combination of head extension, mouth opening and jaw thrust. It is one of the most effective methods for opening the airway. Triple airway manoeuvre increases the distance between the epiglottis and posterior pharyngeal wall and decreases

the incidence of downfolding of the epiglottis by laryngeal mask airway [9]. It also allows faster insertion of the laryngeal mask airway and therefore is valuable in cases with physiologically difficult airway [6,10].

The reverse insertion technique for insertion of the laryngeal mask airway involves the insertion of the I-gel® just like an oropharyngeal airway, followed by rotation and insertion into the hypopharynx. Rotation technique has also been shown to increase the first attempt insertion success rate when the first attempt by the standard technique fails, decrease the insertion time, provide better airway seal and less pharyngeal mucosal trauma, suggesting that the rotational technique is superior to the standard technique [11-15].

Both techniques have shown good results, but most of the existing studies have been conducted in adult patients. Insertion techniques effective in adults may not necessarily provide similar outcomes in children. Furthermore, most pediatric studies primarily compare the I-gel® with other supraglottic airway devices rather than focusing on different insertion techniques [14,16,17]. No randomised controlled trial comparing the triple airway manoeuvre and reverse insertion technique in paediatric patients has been conducted till now.

This absence of evidence indicates an important gap in the literature. Insufficient data exists for comparing these two insertion techniques in paediatric patients. Therefore, it was important to recognise the most effective technique for I-gel® placement in paediatric patients to minimise airway-related complications. Therefore, the present study aimed to compare the reverse insertion technique with the triple airway manoeuvre for I-gel® placement in paediatric patients planned for surgery under general anaesthesia. The primary objective was to compare the mean insertion time of the supraglottic device with both techniques. The secondary objectives were to compare the first attempt success rate, number of attempts required for successful placement, overall success rate, ease of insertion, ease of nasogastric tube placement and postoperative complications.

MATERIALS AND METHODS

This single-blinded, randomised controlled trial was planned at Pt. B. D. Sharma PGIMS, Rohtak, Haryana, over a period of 14 months (July 2023 - September 2024). The study was initiated after receiving Biomedical Research Ethics Committee approval (BREC/23/TH-Anaesthesia/5 dated 27/09/2023). This trial was registered under CTRI (CTRI/2024/01/061417). Written informed consent and assent were taken from all the patients.

Sample size calculation: The sample size calculation was based on data from Eglen M et al., and Bhardwaj M et al., [10,12]. Mean insertion time for I-gel® placement in the reverse technique group was reported to be 15±5.72 sec by Bhardwaj M et al., mean insertion time for placement of LMA-Unique using triple airway maneuver was reported to be 8.63±10.37 seconds by Eglen M et al., [10,12].

The sample size required in each arm of the study was calculated according to the formula given:

$$\text{Sample size (N)} = 1 + \frac{2(Z_{\alpha} + Z_{1-\beta})^2 \sigma^2}{\delta^2}$$

Where:

σ (Pooled SD)=8.37

δ (Difference of Means)=6.37

Type I error (α)=5%, Z_{α} (Value of standard normal distribution for α =5%)=1.96

Type II error (β)=5%, Power (1- β)=95%, $Z_{1-\beta}$ =1.65

Based on the formula given above, using the mentioned values, the sample size required was:

$$\text{Sample size (N)} = 1 + \frac{2(1.96 + 1.65)^2 8.37^2}{6.37^2} = 46.05 \approx 50$$

Thus, assuming 95% power and 95% Confidence Interval (CI), the minimum calculated sample size for each arm was 50 (total=100).

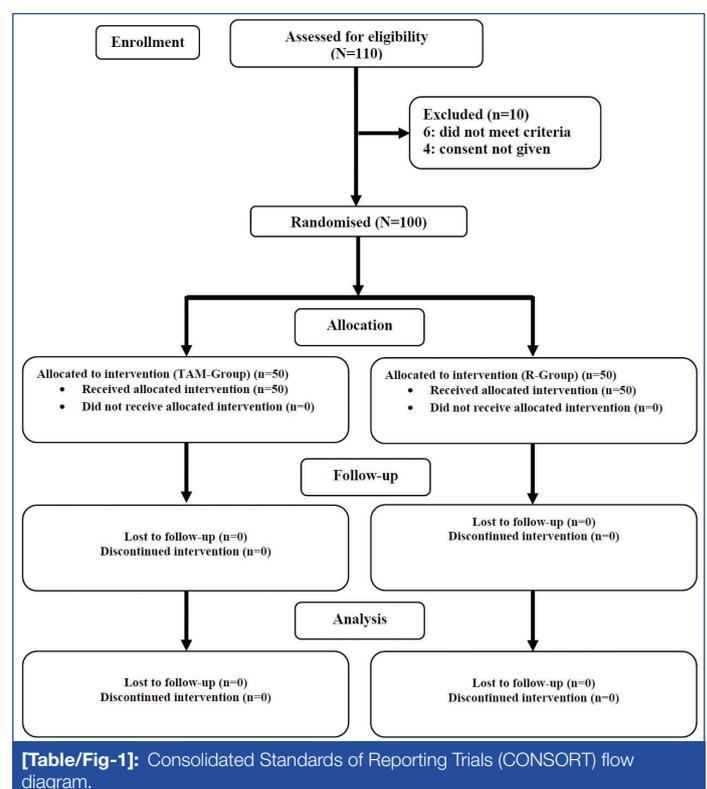
Inclusion criteria: A total of 100 patients (50 in each group), aged 7-12 years of either gender, ASA-PS 1 and 2 of either, belonging to ASA physical status I and II, undergoing elective surgery under general anaesthesia, were enrolled for this RCT.

Exclusion criteria: Patients with active upper respiratory tract infection, risk of regurgitation, complicated airway, refusal to consent, emergency surgeries and surgeries planned under prone position were excluded from the surgery.

A total of 110 patients were enrolled, out of which 10 did not meet the inclusion criteria and were hence excluded. Therefore, 100 patients were accounted for the study.

Study Procedure

A pre-anaesthetic check-up was conducted a day before surgery. The protocol was informed to the guardian and patient. Written informed consent from the guardian and assent from the patient were obtained. Patients were kept fasting for six hours for solids and two hours for clear liquids before surgery. Patients were randomised into two groups using a computer-generated random number table with 50 patients in each group [Table/Fig-1]. The random allocation sequence, enrollment of participants and assigning participants to interventions were done by the primary investigator. In group R, I-gel® was placed using the reverse insertion technique and in group TAM, I-gel® was placed using the Triple airway manoeuvre, i.e., head tilt, jaw thrust, mouth opening. Single blinding was done and patients were blinded. I-gel® was inserted by an anaesthesiologist of >3 years of experience. Only one anaesthesiologist was chosen for I-gel® insertion to reduce bias.



In the operating room, standard ASA monitoring (Electrocardiogram (ECG), Non Invasive Blood Pressure (NIBP), Saturation of Oxygen (SpO₂), End-tidal Carbon dioxide (EtCO₂), temperature) was initiated. Anaesthesia was maintained at 1 Minimum Alveolar Concentration (MAC) of sevoflurane.

Once the line was secured, fentanyl (1- 2 µg/kg), propofol (1-2 mg/kg) and atracurium (0.1 mg/kg) were administered. Bag-mask ventilation was confirmed and anaesthesia was maintained

with 1.5-2% sevoflurane in a 50% oxygen-nitrous oxide mixture. Injection Atracurium (0.02 mg/kg) was used for maintenance. The size of the device was selected based on the manufacturer's recommendations and clinical judgement. After adequate lubrication with a water-based lubricant, I-gel® was inserted using the assigned technique. Patient was placed in 'sniffing the morning air' position in both groups.

Group R: Reverse insertion technique

After placing the patient in sniffing the morning air position, I-gel® was inserted with its concavity facing the hard palate like a Guedel's airway. Once it reached the pharynx, it was rotated 180° and advanced along the palate until the anaesthesiologist felt a definitive resistance.

Group TAM: Triple Airway Manoeuvre (TAM) technique

In TAM, an assistant applied the Triple airway manoeuvre, i.e., head tilt, mouth opening and jaw thrust. I-gel® was inserted in the oral cavity with its concavity facing the mandible. The device was pushed posteriorly while advancing along the hard palate and soft palate until a definitive resistance was felt.

A well-lubricated Ryle's tube was inserted from the gastric port. After that, the I-gel® was connected to the breathing circuit and effective ventilation was checked. Effective ventilation was defined as the presence of a square wave end tidal carbon dioxide waveform and simultaneous bilateral chest expansion. An absent capnography trace and inadequate chest expansion were taken as inadequate ventilation. When inadequate ventilation was encountered, manoeuvres like: 1) Chin lift; 2) Jaw thrust; 3) Head extension; 4) Neck flexion; 5) Gentle advancement; 6) Withdrawal of I-gel® were done successively to improve ventilation. If the ventilation was not found to be effective even after the manoeuvres, the device was taken out. A different size of device was used for the second attempt. The decision to increase or decrease the size of the I-gel® was made by the attending anaesthesiologist based on clinical judgement. If two attempts with the same technique failed, another group technique was used as a rescue technique with the initial I-gel® size. In the event of a third attempt failure, tracheal intubation was performed to secure the airway. After the completion of the surgical procedure, standard reversal protocol, i.e., glycopyrrolate (0.005 mg/kg) and neostigmine (0.05 mg/kg), was followed to reverse neuromuscular blockade. The I-gel® was removed and examined for the presence of blood.

Primary outcome, i.e., mean insertion, was defined as the time from picking up the I-gel® to the presence of square wave capnography on the monitor.

Secondary outcome, i.e., total insertion time, was defined as the sum of time taken in each attempt. The number of attempts for the correct placement of the I-gel® with effective ventilation was recorded. Ease of insertion was graded on a scale of 1 to 3 as very easy, easy or difficult [3]. Ease of placement of nasogastric tube through I-gel® was graded from 1 to 3 as easy, difficult and failure [12]. Postoperative complications like the presence/absence of blood after the device was taken out, the presence of sore throat and hoarseness of voice were recorded. Hoarseness was measured in a subjective manner.

STATISTICAL ANALYSIS

Data was coded and recorded in MS Excel spreadsheet program. The Statistical Package for Social Sciences (SPSS) version 23.0 (IBM Corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/ Interquartile Range (IQRs) for continuous variables and frequencies and percentages for categorical variables. Data was presented in a graphical manner wherever appropriate for data visualisation using histograms/box-and-whisker plots/column charts for continuous data and bar charts/pie charts for categorical data.

Group comparisons for continuously distributed data were made using an Independent sample t-test when comparing two groups and One-way Analysis of Variance (ANOVA) when comparing more than two groups. Post-Hoc pairwise analysis was performed using Tukey's HSD test in the case of One-way ANOVA to control for alpha inflation. If data were found to be non normally distributed, appropriate non parametric tests in the form of the Wilcoxon Test/ Kruskal-Wallis test were used for these comparisons. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25(%) of the cells, Fisher's-exact test was used instead. Linear correlation between two continuous variables was explored using Pearson's correlation (if the data were normally distributed) and Spearman's correlation (for non normally distributed data). Statistical significance was kept at p-value <0.05.

RESULTS

Demographic parameters showed no statistically significant difference between the groups [Table/Fig-2].

| Parameters | Group R (n=50) | Group TAM (n=50) | p-value |
|-----------------------------|----------------|------------------|---------|
| Age (in years) | 9.62±1.97 | 9.76±2.16 | 0.602 |
| Gender (M/F) | 31 / 19 | 36 / 14 | 0.288 |
| Height (in cm) | 127.76±10.59 | 126.68±11.19 | 0.621 |
| Weight (in kg) | 27.50±7.89 | 28.40±8.03 | 0.609 |
| BMI (in kg/m ²) | 16.88±3.56 | 17.49±3.37 | 0.388 |
| ASA-PS I/II | 49/1 | 49/1 | 1.00 |

[Table/Fig-2]: Demographic characteristics (Values are mean±SD). Non parametric tests (Wilcoxon Mann-Whitney U Test) were used to make group comparisons in terms of age and weight. Chi-squared test was used to explore the association between 'Group' and 'Gender'. Parametric tests (t-test) were used to make group comparisons for BMI and height. Fisher's-exact test was used to explore the association between 'Group' and 'ASA'.

The mean±SD of insertion time in group R was 18.65±8.07 sec and in group TAM was 16.84±6.93 sec. The median (IQR) of insertion time (s) in group R was 16 (14 - 20) sec and in group TAM was 14.5 (13 - 16) sec. A significant difference between the two groups in terms of Insertion time (sec) (W=1584.500, p-value=0.021), was noted, with the median insertion time (s) being highest in group R [Table/Fig-3].

| Insertion Time (s) | Group | | Wilcoxon Mann-Whitney U Test | |
|--------------------|-------------|-------------|------------------------------|---------|
| | R | TAM | W | p-value |
| Mean±SD | 18.65 ±8.07 | 16.84 ±6.93 | 1584.500 | 0.021 |

[Table/Fig-3]: Comparison of groups in terms of insertion time (s). The variable insertion time (s) was not normally distributed in the 2 subgroups of the variable group. Thus, non parametric tests (Wilcoxon Mann-Whitney U Test) were used to make group comparisons.

The device was successfully placed in 90% of the participants in group R in the first attempt, in contrast to 84% patients in group TAM. 10% of patients required a second attempt in group R compared to 16% in group TAM. There was no significant difference between the two groups in terms of the distribution of the number of attempts. ($\chi^2=0.796$, p-value=0.372) [Table/Fig-4]. Therefore, the overall success rate was 100% in both groups.

| Number of attempts | Group | | | Chi-squared test | |
|--------------------|-------------|-------------|--------------|------------------|---------|
| | R | TAM | Total | χ^2 | p-value |
| 1 Attempt | 45 (90.0%) | 42 (84.0%) | 87 (87.0%) | 0.796 | 0.372 |
| 2 Attempts | 5 (10.0%) | 8 (16.0%) | 13 (13.0%) | | |
| Total | 50 (100.0%) | 50 (100.0%) | 100 (100.0%) | | |

[Table/Fig-4]: Comparison of groups in terms of number of attempts. Chi-squared test was used to explore the association between 'group' and 'number of attempts'.

A total of 64% of the participants in group R had grade 1 ease of I-gel® insertion. A total of 32% of the participants in group R had grade 2 ease of I-gel® insertion. A 4% of the participants in the group R had

grade 3 ease of I-gel® insertion. A 76% of the participants in the group TAM had grade 1, 24% had grade 2 and 0% had grade 3 ease of I-gel® insertion. The two groups were similar in terms of the distribution of ease of I-gel® insertion. ($\chi^2=3.086$, p-value=0.244) [Table/Fig-5].

| Ease of I-gel® insertion | Group | | | Fisher's-Exact Test | |
|--------------------------|-------------|-------------|--------------|---------------------|---------|
| | R | TAM | Total | χ^2 | p-value |
| Grade 1 | 32 (64.0%) | 38 (76.0%) | 70 (70.0%) | 3.086 | 0.244 |
| Grade 2 | 16 (32.0%) | 12 (24.0%) | 28 (28.0%) | | |
| Grade 3 | 2 (4.0%) | 0 (0.0%) | 2 (2.0%) | | |
| Total | 50 (100.0%) | 50 (100.0%) | 100 (100.0%) | | |

[Table/Fig-5]: Comparison of groups in terms of Ease of I-gel® insertion. Fisher's-exact test was used to explore the association between 'Group' and 'Ease of I-gel® insertion', as more than 20% of the total number of cells had an expected count of less than 5.

A total of 84% of the participants in the group R had grade 1, 16% had grade 2 ease of nasogastric tube insertion. A total of 88% of the participants in the group TAM had grade 1, 12% had grade 2 ease of nasogastric insertion. There was no significant difference between the two groups in terms of ease of nasogastric tube insertion ($\chi^2=0.332$, p-value=0.564) [Table/Fig-6].

| East of NG tube insertion | Group | | | Chi-squared test | |
|---------------------------|-------------|-------------|--------------|------------------|---------|
| | R | TAM | Total | χ^2 | p-value |
| Grade 1 | 42 (84.0%) | 44 (88.0%) | 86 (86.0%) | 0.332 | 0.564 |
| Grade 2 | 8 (16.0%) | 6 (12.0%) | 14 (14.0%) | | |
| Total | 50 (100.0%) | 50 (100.0%) | 100 (100.0%) | | |

[Table/Fig-6]: Comparison of groups in terms of Ease of NG tube insertion. Chi-squared test was used to explore the association between 'Group' and 'East of NG Tube Insertion'.

A 94% of the participants in the group R had no postoperative complications. A 6% of the participants in group R reported hoarseness. 96% of the participants in group TAM had no postoperative complications. A total of 4% of the participants in the group TAM had hoarseness. Both groups were comparable in terms of postoperative complications. ($\chi^2=0.211$, p-value=1.00) [Table/Fig-7].

| Postoperative complication | Group | | | Fisher's-exact test | |
|----------------------------|-------------|-------------|--------------|---------------------|---------|
| | R | TAM | Total | χ^2 | p-value |
| None | 47 (94.0%) | 48 (96.0%) | 95 (95.0%) | 0.211 | 1.000 |
| Hoarseness | 3 (6.0%) | 2 (4.0%) | 5 (5.0%) | | |
| Total | 50 (100.0%) | 50 (100.0%) | 100 (100.0%) | | |

[Table/Fig-7]: Comparison of groups in terms of postoperative complication. Fisher's-exact test was used to explore the association between 'group' and 'postoperative complication' as more than 20% of the total number of cells had an expected count of less than 5.

DISCUSSION

Mean insertion time of the I-gel® was less with the triple airway manoeuvre as compared to the reverse insertion technique. In a study conducted by Kim HC et al., the authors noted almost similar insertion time with the reverse insertion technique [14]. Almost similar insertion time for I-gel® placement was recorded using TAM in studies conducted by Akkuş İB et al., and Priyadarshi P et al., [6,13]. Similarly, various studies had reported almost similar insertion time (10–25 sec) for I-gel® placement using reverse insertion technique [12,13,18]. Conversely, Eglen M et al., reported a lower insertion time of 8.63 seconds in the triple airway manoeuvre group as compared to the present study [10]. This might be due to the usage of a different supraglottic device i.e., LMA-Unique. Tiwari NK et al., found that insertion time was 12.17 seconds in the rotational method, which was slightly less than that in the present study [3]. This could be because of the employment of 90° rotational techniques and the inclusion of children of age group one to six years. Ahuja S

et al., recorded the mean insertion time of 13.98±1.97 seconds in the reverse technique, which was slightly less than the time taken by the reverse technique in the current study [19].

the first attempt success rate was found to be higher in group R than in group TAM. Various studies showed a higher first attempt success rate in the reverse technique group, corroborating current study findings [3,12,18,20]. Eglen M et al., recorded that the successful insertion of LMA-unique in the first attempt was 88.3% in TAM group, which was comparatively higher than the current study. The difference might be because of the usage of different supraglottic devices and the different experience of the investigator [10]. Akkuş İB et al., reported that successful insertion at the first attempt was 92% in triple group, which was comparatively higher than the present study [6].

Reverse insertion technique required a smaller number of attempts as compared to TAM technique. Tiwari NK et al., recorded that 96.6% participants had one attempt and 3.3% had two attempts in the rotation group [3]. Ahuja S et al., found that both conventional and reverse insertion groups had a high success rate in the first attempt (98%) [19]. We found that the success rate was 100%. Previous studies had reported an almost similar (90–100%) overall success rate for I-gel® placement using the reverse technique group [3,12–14,18,20]. Conversely, Theiler L et al., reported successful placement of LMA in 93.4% participants using TAM, which was comparatively lower than the present study. This might be due to the usage of a different supraglottic device than the I-gel® [5].

I-gel® insertion was comparatively easier with the TAM technique than group reverse insertion in the current study. Various studies have reported almost similar ease of I-gel® insertion in the reverse technique group and in the TAM group [3,5,18]. In contrary, few studies have shown comparatively lesser ease of insertion of I-gel® in the reverse technique group and in the TAM group [12,13]. In the present study, placement of the nasogastric tube was easier in group TAM than in group R. In contrast, Bhardwaj M et al., found that nasogastric tube placement was easy in 93.02%, difficult in 4.65% and failure in 2.32% patients of the reverse technique group, which was comparatively higher than the present study [12].

In the present study, postoperative hoarseness was found to be comparatively less in group TAM than in group R. Bhardwaj M et al., found that the incidence of sore throat was 4.6% and blood staining was 2.3(%) in the reverse insertion technique [12]. Ahuja S et al., also did not report any intraoperative or postoperative complications [19]. Unlike the present study findings, Tiwari NK et al., observed that blood staining of the tip of the device in 6.6(%) patients in the rotational technique group (90° rotations) [3]. Duan J et al., recorded that hoarseness, sore throat and postoperative airway complications occurred significantly more in patients of the rotational group than the standard group [20].

Limitation(s)

Ease of I-gel® and nasogastric tube placement was evaluated using a subjective scale. The study included patients with normal airway; hence the findings cannot be extrapolated to patients with complicated airway. Successful and appropriate placement of I-gel® was determined clinically only. The use of fiberoptic bronchoscope to grade the view of glottis for proper placement would have given an objective assessment.

CONCLUSION(S)

The TAM and reverse insertion techniques of I-gel® placement were comparable clinically. The experience of the investigator with the technique should determine the choice of technique. All secondary parameters suggested no significant statistical difference between the two groups. Because of the shorter mean insertion time in the triple airway manoeuvre than the reverse insertion technique, it may be preferred when minimising insertion time is a priority.

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