Original Article

Comparison of four different techniques of i-gel insertion by anaesthesia trainees in children undergoing daycare surgery: A single-blind, randomised, comparative study

Address for correspondence:
Dr. Bikram Kishore Behera, Department of Anesthesiology and Critical Care, AIIMS, Bhubaneswar - 751 019, Odisha, India.
E-mail: bikrambehera007@gmail.com

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Priya Priyadarshi, Bikram Kishore Behera, Satyajeet Misra
Department of Anesthesiology and Critical Care, AIIMS Bhubaneswar, Odisha, India

ABSTRACT

Background and Aims: Different techniques of i-gel insertion have been described with variable success rates. This study aimed to assess the incidence of malposition of i-gel in children with 90° rotation, 180° rotation, jaw thrust–assisted and standard insertion techniques. **Methods:** The study included 132 children undergoing elective surgery under general anaesthesia without neuromuscular blockade after approval from the Institutional Ethics Committee. The i-gel was inserted using one of the four randomised techniques (90° rotation, 180° rotation, jaw thrust–assisted insertion or standard insertion technique) by anaesthesia trainees. The primary objective of this study was to assess device malposition using three alternative techniques compared to the standard insertion technique by flexible video bronchoscopy. **Results:** The incidence of malposition was the least in the 180° rotation technique group (27%) versus 39% in the standard and 90° rotation technique groups and 70% in the jaw thrust technique group ($P = 0.004$). Oropharyngeal leak pressure (OLP) was highest in the 180° rotation technique group, that is, 27.1 (5.3) cm H_2O in the 180° rotation technique group versus 23 (4.3), 25.8 (4.1) and 24.7 (5.6) cm H_2O in the standard, 90° rotation and assisted jaw thrust groups, respectively ($P = 0.006$). The time to i-gel insertion was the least with the standard insertion technique, that is, 16.9 (3.3) s, compared to 18.4 (3.1) s in the 90° rotation group, 19.5 (3.2) s in the180° rotation group and 20.1 (3.4) s in the assisted jaw thrust technique group ($P < 0.001$). **Conclusion:** The 180° rotation technique for i-gel placement in children by anaesthesia trainees has the lowest incidence of malposition and the best OLP versus other techniques but lacks any clear advantage in clinical performance and ventilation.

Keywords: Airway management, general anaesthesia, i-gel, paediatrics, supraglottic airway devices

INTRODUCTION

Supraglottic airway devices (SADs) are routinely used for airway management in children undergoing surgery. i-gel® (Intersurgical Ltd, Wokingham, UK) is a second-generation SAD conventionally inserted with its concave curvature facing the mandible, which is considered the standard insertion technique. In children, during the passage of i-gel in the oral cavity to the pharynx, the large tongue may get impacted and folded or result in posterior displacement of the device, leading to device malposition.[1-4] The technique that decreases the tongue's resistance during insertion of the i-gel should reduce the device malposition and improve successful placement.[5,6] This study compared four different techniques of i-gel insertion, that is, 90° rotation, 180° rotation, or jaw thrust–assisted

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insertion, with the standard insertion technique by anaesthesia trainees in children undergoing elective daycare surgery.

We hypothesised that there would be a lower incidence of device malposition with the alternative insertion techniques, which may decrease the resistance offered by the tongue compared to the standard insertion method. The primary objective of this study was to assess device malposition using three alternative techniques compared to the standard insertion technique by flexible video bronchoscopy (FVB). Other secondary study objectives were to evaluate the success rate at the first attempt, overall success rate, insertion failure, time to successful insertion, ease of placement, ease of ventilation, oropharyngeal leak pressure (OLP) and incidence of airway trauma.

METHODS

This randomised, single-blind study was conducted from 8 September 2020 to 31 August 2021 after obtaining approval from the Institutional Ethics Committee (vide approval number ECR/534/Inst/OD/2014/RR-20 dated 20 July 2020). The study was registered with the Clinical Trials Registry-India (vide registration number CTRI/2020/09/027606, http://ctri.nic.in). The study was conducted in accordance with the principles of the Declaration of Helsinki, 2013. Written informed consent was taken from parents and assent from patients >8 years of age after explaining the study protocol. Children of either gender, in the age group of 6 months–12 years with American Society of Anesthesiologists (ASA) physical status I–II, undergoing elective daycare surgery under general anaesthesia, were included in the study. Children with oropharyngeal or laryngeal pathology, upper respiratory tract infections, anticipated difficult airways, gastro-oesophageal reflux disease or hiatus hernia were excluded from the study.

All included children in the study were randomised into four groups: standard insertion technique, 90° rotation technique, 180° rotation technique and assisted jaw thrust technique. The primary investigator generated a computerised randomisation sequence, and the patients were allotted to any of the above four groups as per the randomisation sequence using sequentially numbered opaque, sealed envelopes for allocation concealment.

Children were fasted for 2 h for clear liquids and 6 h for milk and solids. Children without an intravenous (IV) cannula received syrup midazolam 0.5 mg/kg up to a maximum dose of 20 mg, while those with an IV cannula received IV midazolam 0.02 mg/kg. The monitors were attached as per ASA standards and consisted of an electrocardiogram (ECG), peripheral oxygen saturation (SpO_2), non-invasive blood pressure monitoring, and bi-spectral index (BIS) (Infinity® BISX® Smart Pod®; Draeger Medical, Lübeck, Germany). Anaesthesia was induced with IV propofol 2–3 mg/kg and fentanyl 1–2 μg/kg to achieve a bi-spectral index of 40-50 before device insertion. Appropriately sized i-gel was lubricated using a water-based jelly and was introduced in a sniffing position in all four groups. No neuromuscular blocking drugs were administered. An anaesthesia trainee performed all device insertions after positive pressure mask ventilation following anaesthesia induction. The trainees selected had some experience (<20 device insertions) with the standard insertion technique but not with the alternative insertion techniques.

Standard insertion technique group (Group A): The i-gel was grasped by the integral bite block, and its tip was directed towards the hard palate. The tip was introduced in the direction of the hard palate. It was further advanced downwards and backward, pressing against the palate until resistance was felt.

90° rotation technique group (Group B): The i-gel was introduced with the cuff facing the patient's left side along the lateral border of the tongue until resistance was felt. Then, it was rotated clockwise 90° in the oral cavity.

180° rotation technique group (Group C): The i-gel was positioned with the cuff facing the palate and inserted into the oral cavity along the hard palate until resistance was felt. Then, it was rotated clockwise through 180° in the oral cavity.

Assisted jaw thrust technique group (Group D): An assistant anaesthesiologist standing near the patient's shoulder applied gentle jaw thrust in an upward and outward direction. As in the standard insertion technique, the i-gel was inserted into the oral cavity until resistance was felt.

End-tidal carbon dioxide ($EtCO_2$) monitoring was commenced after insertion of the i-gel. Anaesthesia was maintained with isoflurane in a mixture of air and oxygen (50:50). The lungs were ventilated with a tidal volume of 8 ml/kg, and the respiratory rate

was adjusted to maintain an $EtCO_2$ of 32–38 mmHg. After inserting the i-gel, with the head in the neutral position, adequate chest rise along with the $EtCO_2$ trace was observed. The i-gel insertion was successful if sine wave square $EtCO_2$ waveform was obtained along with bilateral chest rise. Insertion time in seconds was recorded with a stopwatch and noted from holding the i-gel until the first waveform capnograph was obtained. If the i-gel could not be inserted in two attempts by the anaesthesia trainee, it was inserted by the attending consultant anaesthesiologist using the same technique. Features of airway obstruction or no capnography tracing in three tidal breaths, even after the third attempt at insertion, were declared as a failure of insertion. Further airway management was at the discretion of the attending anaesthesiologist, and the child was excluded from the study. Once satisfactory ventilation was confirmed, the i-gel was fixed securely.

The trainee graded the placement of i-gel on a scale of 1–3 as follows: 1- i-gel placement without any difficulty, 2- i-gel placement with some difficulty and 3- inability to place the device.[7] Similarly, the attending anaesthesiologist assessed ventilation as 1- optimal ventilation with bilateral chest rise, good air entry (auscultation) and adequate capnography trace; 2- ventilation possible, but signs of partial obstruction present (high peak airway pressures and/or some wheeze/ronchi); 3- leak with ventilation and/or ramp or triangular capnography trace and 4- no ventilation possible.[8] Only a ventilation score of 1 was acceptable, and the i-gel was removed and reinserted if the score was higher.

After stable ventilation, an independent anaesthesiologist, blinded to the insertion technique, measured OLP. The anaesthesia ventilator was put in manual mode with 3 l/min of fresh gas flow. OLP was measured by closing the airway pressure release valve and noting the airway pressure at which the dial on a calibrated aneroid manometer reached equilibrium, that is, the point at which further increases in aneroid pressures were not observed. After determining OLP, the same anaesthetist evaluated the placement of the i-gel using a FVB with the patient's head in a neutral position. A neonatal flexible scope (Karl Storz, Tüttlingen, Germany) was introduced into the ventilating tube of the i-gel and placed 0.5 cm proximal to the distal end. More than 50% of the visible larynx was considered as having no malposition, and less than 50% of the larynx was considered malposition.[1] At the end of the surgery, the i-gel was removed after ensuring adequacy of spontaneous ventilation. Any bloodstains on the device were noted.

The study's primary outcome was the incidence of device malposition as assessed by bronchoscopy. Assuming a 30% improvement in the incidence of malposition to be significant and an effect size of 30% based on a previous study,[9] 122 patients were needed to reach a power of 80% and significance of 5% (2-tailed). Considering a 10% attrition rate, the sample size required was 132 to have 33 children in each group.

The normality of the data variables was checked using the Shapiro–Wilk test and expressed as mean (standard deviation [SD]) or median (interquartile range [IQR]) as appropriate. The Chi-square test or Fisher's exact test was used for the incidence of device malposition, ease of placement, ease of ventilation, success rate at the first attempt, overall success rate and insertion failure rate. One-way analysis of variance (ANOVA) or the Kruskal–Wallis test was used for time to successful insertion and OLP. All analyses were performed with Statistical Package for the Social Sciences (SPSS) statistics (Version 26.0; International Business Machines Corp., Armonk, New York, USA). A *P*-value less than 0.05 was taken for all statistical tests to indicate a significant difference.

RESULTS

One hundred and thirty-two eligible children, 33 in each group, were recruited for the study [Figure 1]. The demographic characteristics were comparable among the groups [Table 1].

The incidence of malposition was least in the 180° rotation technique (27%) group compared to the standard and 90° rotation groups (39% in each) and the assisted jaw thrust technique group (70%) ($P = 0.004$) [Table 2].

The mean (SD) (95% confidence interval [CI]) OLP was highest in the 180° rotation group that is 27.1 (5.3) (25.29–28.91) cm H_2O in the 180° rotation group versus 23 (4.3) (21.53–24.47), 25.8 (4.1) (24.40–27.20) and 24.7 (5.6) (22.79–26.61) cm H_2O in the standard, 90° rotation and assisted jaw thrust groups, respectively ($P = 0.006$). The i-gel insertion success in the first attempt was 94%, 91%, 85% and 79% in the standard, 90° rotation, 180° rotation and jaw thrust techniques, respectively. The difference in first-attempt insertion success was not statistically

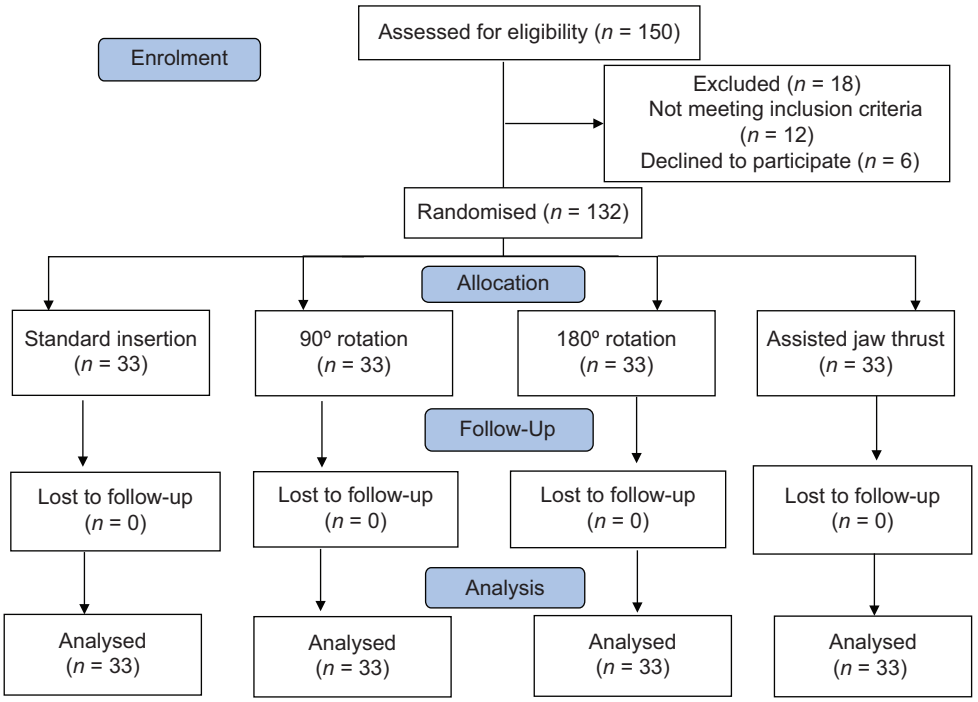

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) diagram showing the flow of children in the study. n=numbers

Table 1: Demographic data

Variables	Group A (standard insertion) (*n*=33)	Group B (90° insertion) (*n*=33)	Group C (180° insertion) (*n*=33)	Group D (assisted jaw thrust) (*n*=33)
Age (years)	6 (6.50)	4 (5.50)	4 (6)	5 (2.50)
Weight (kg)	18 (19)	12 (10)	16 (11)	17 (8)
Gender				
Male/Female	20/13	22/11	22/11	23/10
American Society of Anesthesiologists physical status				
I/II	33/0	33/0	33/0	33/0
Size of i-gel				
1/1.5/2/2.5/3	0/6/16/2/9	0/11/15/3/4	0/7/18/4/4	2/2/23/3/3

Data expressed as mean (standard deviation) or number. n=numbers

Table 2: Incidence of malposition, ease of placement and ease of ventilation of i-gel

Parameters	Group A (standard insertion) (*n*=33)	Group B (90° rotation) (*n*=33)	Group C (180° rotation) (*n*=33)	Group D (assisted jaw thrust) (*n*=33)	*P*
Incidence of malposition	13	13	9	23	0.004
Ease of placement (Grade 1/2/3)	30/3/0	27/6/0	29/4/0	24/9/0	0.3
Ease of ventilation (Grade 1/2/3/4)	31/2/0/0	30/3/0/0	28/4/1/0	26/4/3/0	0.9

Data expressed as expressed in numbers. n=numbers

significant among the groups ($P = 0.3$). The trainees could not insert the i-gel in two patients, one each in the 90° and 180° rotation groups. In these children, the i-gel was inserted by the attending consultant. Thus, the overall success rate by trainees was 100% with the standard and assisted jaw thrust techniques and 96.9% with the 90° and 180° rotation techniques. There were no cases of failure.

The mean (SD) (95% CI) time to i-gel insertion was 16.9 (3.3) (15.77–18.03) s, 18.4 (3.1) (17.34–19.46) s, 19.5 (3.2) (18.41–20.59) s and 20.1 (3.4) (18.94–21.26) s in the standard, 90° rotation, 180° rotation and assisted jaw thrust groups, respectively. The time to insertion was the least in the standard insertion group ($P < 0.001$). The ease of placement was similar in all four groups ($P = 0.3$) [Table 2]. The ease of ventilation was also similar in all four groups, and there were no instances of inability to ventilate in any of the children ($P = 0.9$). However, the i-gels had to be removed and reinserted in two, three, five, and seven patients in the standard insertion, 90 degrees rotation,

180 degrees rotation, and assisted jaw thrust groups respectively by the trainees as the ventilation was unacceptable in the first insertion attempt. Bloodstain was noted in 13 children, with similar incidence across all groups. There was no malposition in the two children in whom the consultant anaesthesiologist inserted the i-gels (>50% of glottic visualisation). OLPs were similar, with ~28 cm H_2O in both children. All other parameters were similar to those of the trainees.

DISCUSSION

We observed the lowest incidence of malposition of i-gel and best OLPs when inserted with the 180° rotation technique by anaesthesia trainees, compared to the standard technique, 90° rotation technique or the assisted jaw thrust technique in children undergoing daycare surgery. However, this did not impact any other parameter, including ventilation.

Several anatomical differences exist in paediatric patients, including a large occiput, cephalad and floppy overhanging epiglottis, and a larger tongue in relation to the oral cavity.[10] This increases the probability of impaction or folding of the cuff of SAD on the tongue or epiglottis. Unlike other SADs, which may be partially inflated during standard insertion to prevent SAD from folding on itself,[11] i-gel has been designed to create an anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures, which occurs a few minutes after the device is positioned in the oropharynx due to its thermoplastic properties, and this may increase the risk of malposition of the device. The i-gel however achieves better sealing pressures compared with other SADs like Ambu Aura Once,[12] LMA classic or Air-Q;[13] is easier to insert compared with the Air-Q LMA,[14] and is thus well suited for ventilation in pediatric patients.[1]

Rotational techniques of SAD insertion have been shown to improve the first insertion success rate and with less airway trauma.[5,6] Similarly, jaw thrust manoeuvre also improves the success rate of SAD insertion.[7] However, previous studies have compared these techniques in various other SADs with inflatable cuffs. None of them has compared the incidence of malposition with these techniques for i-gel insertion in the paediatric population. In a study of 78 children, Ghai *et al.* found superior fibreoptic views (grades 1 and 2) in 92.3% of children who underwent SAD insertion with 180° rotation, compared to 61.5% with the standard insertion technique.[15] In a similar study, Ghai *et al.*[11] compared standard, 90° and 180° rotation techniques of insertion of SAD with a partially inflated cuff in anaesthetised but non-paralysed children undergoing elective surgery. The authors concluded that the 180° rotation technique could be the technique of choice for SAD insertion in terms of success at the first attempt and the time to insertion, but they did not evaluate the incidence of malposition of SADs in their study.

The incidence of malposition with the 180° rotation technique of 27% in our study is considerably higher than that reported by Ghai *et al.* (7.7%).[15] This can be explained by the differences in SADs and the operator's experience (trainees in our study versus experienced anaesthesiologists in Ghai *et al*.'s study). However, the other parameters were not different among the techniques in our study, whereas the insertion time was shorter with the standard technique. This may be explained by the fact that, in general, i-gel is easier to insert than other SADs and, thus, may not result in differences in other parameters like insertion success or complication rates.[16,17] The shorter insertion time in the other group was probably related to the absence of an additional manoeuvre like rotation during insertion. In addition, the shorter insertion time in the standard group could be explained by the fact that it was performed by anaesthesia trainees, who would take time to adjust to any new technique. This phenomenon may not be present with experienced anaesthesiologists. However, a mean difference of 4 s between the least and the maximum time taken, though statistically significant, probably does not hold any clinical significance; thus, this parameter was comparable in all groups.

In this study, the position of the i-gel correlated with OLPs. While ventilation (which is the primary function of a SAD), may not be affected as long as the vocal cords are seen, a suboptimal position may result in deterioration of ventilation with changes in the neck position and the inability to pass a tracheal tube. Also, this may be relevant where higher ventilating pressures are required, as in laparoscopic surgeries. Of note, there was no difference in OLPs with the 180° rotation technique by trainees and consultant anaesthesiologists, implying that irrespective of the level of training, an adequately placed SAD will have a good seal.

Our study is associated with a few limitations. The operators were novices in three of the four techniques but not in all of them – for this to be a fair

comparison, they should be equally experienced in all techniques. The influence of different neck positions on i-gel performance characteristics was not studied. Significant increases in peak inspiratory pressure decreases in tidal volume, and worsening ventilation scores have been seen with the i-gel in children with neck flexion of 30° and 45°.[18] Similarly, head rotation also reduces OLPs,[19] which was not evaluated in our study. The impact of the position of i-gels on the ease of intubation was not studied; thus, it is unknown whether this would have made a difference in the groups. The bronchoscopy grading was subjective. Finally, the results of our study are valid only for i-gel™ and not for other SADs.

CONCLUSION

Our study suggests that the 180° rotation technique for i-gel placement in children by anaesthesia trainees has the lowest incidence of malposition and the best OLP versus other techniques but needs a clear advantage in clinical performance and ventilation. Thus, while any technique of i-insertion may be applied for i-gels, the 180° rotational technique may be used by anaesthesia trainees to achieve better position and sealing.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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