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Original Article

Reverse technique of i-gelTM insertion in children -A prospective observational study

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ABSTRACT

Background and Aims: I-gelTM , a novel supra glottic airway device, is now widely used for both spontaneous and controlled ventilation. As there is lack of studies regarding reverse technique of i-gelTM insertion in children, our primary objective was to compare the ease of insertion by conventional or reverse technique. Secondary objectives were to look for any complications with both the techniques. **Materials and Methods :** Among the 90 children in this prospective study, i-gelTM was inserted conventionally in Group C (Conventional , n = 45) while in Group R (Reverse, n = 45) , reverse technique with concavity of the device facing the hard palate was used. The time taken and ease of insertion, number of attempts, mean oropharyngeal leak pressure, blood staining of device, trauma to oral structures and incidence of postoperative sore throat or hoarse cry were assessed. "The Chi-square test, Fisher's exact test, and independent t-test were employed for statistical evaluation, depending on the nature of the data. **Results:** Mean time required for inserting i-gelTM in Group R was 20.77 ± 2.77 seconds as compared to 23.07 ± 3.82 seconds in Group C (p= 0.001) which was statistically significant. Of the two groups, Group R had better first attempt success rate compared to Group C 95.6% versus 84.4%, p=0.157), but it was statistically insignificant. There was no incidence of significant complications in either groups. **Conclusion:** Reverse technique is a better alternative to conventional technique of i-gelTM insertion in children.

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INTRODUCTION

Supraglottic airway devices have successfully secured and maintained a patent airway in children routine and emergency procedures. These devices ensure effective airway protection despite being placed outside the trachea.[1] I-gelTM, a second generation supraglottic airway device, very similar to classic Laryngeal Mask Airway (LMA) is now widely used for both spontaneous and controlled ventilation during general anaesthesia. Constructed from a thermoplastic elastomer, it incorporates a mouldable, non-inflatable cuff designed to achieve an efficient seal over the laryngeal inlet and associated anatomical structures.

Similar to LMA, i-gelTMis conventionally placed with its concavity facing mandible. Here, the device is inserted via holding the proximal end and gliding the leading tip against the hard palate into hypopharynx. This technique of insertion may be difficult or may fail due to repeated tongue folding, thus preventing its further movement. Rotational and reversed techniques have also been tried in adults to avoid difficulty in supraglottic airway insertion.[2,3,4,5,6,7] Even though there are studies of reverse technique of i-gelTMinsertion in adults, there has been lack of similar studies in paediatrics.

Here, we hypothesized that reverse technique of i-gelTM insertion would be a better alternative to conventional technique in children.This study was designed to evaluate the efficacy of the reverse insertion technique and compare it with the conventional approach in pediatric patients.

Methods

This prospective observational study was conducted at a tertiary hospital from January 2019–February 2020. Institutional Research and Ethical Committee approval was obtained before starting the study with the corresponding IEC number GMCKKD/RP2018/IEC/193.

Sample size was calculatedemploying formula

$$n = (Z\alpha + Z\beta)^2 SD^2 * 2 \ / \ d^2$$

$Z\alpha = 1.96$, $Z\beta = 0.84$, d = effect size,

SD =Standard Deviation
From the study by Sharda M et al,

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Standard deviation was calculated as (SD1+ SD2)/2 = (6.9 + 5.9)/2 = 6.4, which is the average of standard deviation of mean insertion time (Conventional: 20.8 ± 5.9; Reverse : 17.5 ± 6.9).[4] Although the mean difference observed in the above study was 3.3 seconds, the present study used d (mean1-mean2) = 3.8 seconds to account for potential variability in clinical practice and to ensure adequate power to detect a difference that is both clinically and statistically significant.

So, by substituting SD and d, n is obtained as 44.47 and sample size has been taken as 45 in each group. The main objective of this study was to compare the conventional and reverse techniques of i-gel™ insertion in children, focusing on mean insertion time and the number of attempts required. Secondary objectives included evaluating differences in mean oropharyngeal leak pressure, the presence of blood staining on device removal, trauma to the lips and teeth, and the incidence of postoperative hoarse cry or sore throat between the two techniques.

Children aged among 1-12 years, who were classified as American Society of Anaesthesiologists Physical Status 1or 2, scheduled for infra umbilical surgeries of less than 2 hours duration were enrolled in this study. Children with known difficult airway, Body Mass Index >30kg/m2, cervical spine disease, poor dentition and surgeries more than 2 hours were excluded from the study.

Each subject was selected by consecutive sampling technique to undergo either conventional (Group C, n= 45) or reverse technique (Group R, n = 45) of insertion. A proper pre anaesthetic evaluation was done and informed consent taken. All children were fasted for 8 hours for solids and 2 hours for clear fluids. 30min prior to surgery, they received oral midazolam at a dose of 0.5 mg/kg as premedication. Standard monitoring was instituted, including electrocardiogram (ECG), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), or end-tidal carbon dioxide ($EtCO_2$). The patient's head was kept in neutral position. After preoxygenation for three minutes, anaesthesia was induced with oxygen and sevoflurane, started at 2 % and stepped up by 1 % every 2 to 3 breaths until adequate depth was obtained, which was assessed by unobstructed regular respiration and no response to jaw thrust. Intravenous access was secured with 22G cannula on one of the forearms if not already secured and injection fentanyl 2 microgram/kg was given intravenously. Once an appropriate depth of anaesthesia was obtained, the i-gelTM was inserted using either a conventional or reverse technique. Size of i-gelTM was selected as size 1.5 for 5-12kg, 2 for 10-25 kg and 2.5 for 25-35kg children.[8]

Group C (Conventional, n = 45) had undergone the conventional technique of insertion. The lubricated i-gelTM was tightly held along the bite block site with the concavity of the device facing the mandible. The device was then inserted by sliding downwards and backwards along the hard palate with a continuous, but gentle push until it fit over the larynx. This was carried out using a pen holding grip. In Group R (Reverse, n=45), the device was introduced into the oral cavity with the concavity facing the hard palate. When tip of the device reached the oropharynx, it was rotated 180 degrees similar to Guedel airway insertion and introduced further into the laryngopharynx until it was able to cover the larynx.

The successful placement of i-gelTM was verified by the ability to insufflate the lungs, as evidenced by an adequate chest lift, no substantial resistance to ventilation, and an adequate refilling of the reservoir bag, as confirmed by capnography. In both the groups, the time taken for i-gelTM insertion was taken as the time from the opening of patient's mouth at the start of insertion to the appearance of a square wave pattern on capnography.[9] The device was removed, and two additional attempts were allowed before reporting insertion failure if an effective airway could not be achieved. If all three attempts failed, a different device or tracheal intubation was used and recorded. The ease of insertion was graded as follows: 1- No resistance and no maneuvers, 2- mild resistance and one manoeuvre (neck flexion, head extension or jaw thrust), 3- moderate resistance and more than one manoeuvre.[10]

For assessing oropharyngeal leak pressure, flow was kept at 3 litre/ minute in manual mode with expiratory valve closed and the pressure at which audible leak heard from the mouth was recorded.[11]

Before starting the surgery, caudal epidural block was given in lateral position for intra and postoperative analgesia. Any displacement of i-gelTMduring caudal block positioning was noticed by capnogram pattern and auscultation of breath sounds. Intraoperative heart rate, NIBP, SpO2 and EtCO2have been recorded before induction and at 1min and 5min after i-gelTMinsertion and monitoring was continued throughout the surgery. I-gelTM was removed under deep sedation and oxygen mask held on face immediately theresfter. The device was inspected for any blood staining, trauma to lips and teeth after its removal. Parents were asked about any complaints like hoarse cry or sore throat postoperatively upto 24 hours.

All airway interventions and intra operative monitoring were done by an anaesthetist of more than 5 years of experience.

SPSS 22.0 and the R environment version are the statistical software. The data was analyzed using 3.2.2. The mean ± standard deviation was used to present the results of quantitative measures, while categorical measurements were represented as percentages and numbers. The significance of study parameters on a continuous scale between two groups was determined using an independent t-test (intergroup analysis). Chi-square / Fisher. The significance of categorical parameters has been determined using the exact test.

Results

The study had a total of 90 students who all completed the same.
Demographic factors like age, weight and genderwere comparable in both the groups.

Table 1 : Comparison of demographic datas between the groups

Demographic factor	Group C (n = 45)	Group R (n = 45)	P value
Age (years)*	4.91±2.54	5.22±2.39	0.49
Weight (Kg)*	15.51±5.61	15.71±4.03	0.83
Gender (M:FM)	30:15	30:15	

Both groups underwent infra umbilical surgeries and most of them had duration of anaesthesia less than 30 minutes.

Mean time required for securing the airway for Group R was 20.77 ± 2.77 seconds as compared to 23.07 ± 3.82 seconds in Group C, which was statistically significant (p value = 0.001). I-gelTMcould be inserted in less than 20 seconds in 40% of cases in Group R, as compared to none in Group C. Time taken for insertion was prolonged (more than 30 seconds) for one patient in Group C and took two attempts.

Table 2: Time taken for insertion in both the groups

Time taken for insertion (Seconds)	Group C (n=45)	Group R (n=45)	Total (n=90)
< 20	0 (0%)	18 (40%)	18 (20%)
20 – 30	44 (97.8%)	27 (60%)	71 (78.9%)
> 30	1 (2.2%)	0 (0%)	1 (1.1%)
Total	45 (100%)	45 (100%)	90 (100%)
mean±SD	23.07 ± 3.82	20.77 ± 2.77	P value 0.001

Overall, Group R had better first attempt success rate compared to Group C.

(95.6% versus 84.4%%; p= 0.157) though it was statistically insignificant.

Table 3: number of i-gel insertion attempts in both groups

Number of attempts	Group C (n=45)	Group R (n=45)	Total (n=90)
1	38(84.4%)	43 (95.6%)	81 (90.0%)
2	7 (15.6%)	2 (4.4%)	9 (10.0%)
Total	45 (100%)	45 (100%)	90 (100%)

Regarding ease of insertion, three cases in Group C had mild resistance on i-gelTM insertion and needed one of the manoeuvres, while in Group R, no one experienced any resistance (p= 0.242).

Table 4: Ease of i-gel insertion in both the groups

Ease of insertion	Group C	Group R	Total
No resistance, no manoeuvers	42 (93.3%)	45 (100%)	87 (96.7%)
Mild resistance, one manoeuvre	3 (6.7%)	0 (0%)	3 (3.3%)
Total	45 (100%)	45 (100%)	90 (100%)

Mean oropharyngeal leak pressure measured after placing i-gelTMwas 22.42 ±3.94cmH in Group C and 23.82 ±3.56 cmH2O in Group R, which was statistically insignificant (p=0.077).

Blood staining of the device and trauma to lips or teeth were not seen in either of the groups. No incidence of postoperative hoarseness or sore throat was observed within the first 24 hours following surgery.

Discussion

The i-gelTM, a new supraglottic airway device has gained increasing popularity for maintaining airway for short procedures, especially in the pediatric age group. It consists of an elastomer gel, features an effectively shaped non-inflatable cuff, includes an integral bite block, and includes a stomach drain tube. These attributes enable low resistance to gas flow, enhance stability, enable peri-laryngeal and pharyngeal sealing, and might reduce the risk of airway obstruction or aspiration. In pediatric patients, the success rate of i-gel™ insertion is comparable to that of laryngeal mask airway (LMA), with oropharyngeal leak pressures exceeding those of the classic LMA and approximating those achieved with the ProSeal LMA. Tongue folding was a problem noticed during conventional i-gelTM insertionin children.[4] The cuff carried the tongue along with it posteriorly, making further movement of the i-gel™ impossible. So the present study compared the conventional and reverse technique of insertion and the later was found to be useful when the conventional technique proved unsuccessful due to tongue folding.[5]

Bhardwaj et alcompared conventional, reverse (1800) and rotation (900) techniques in 135 adults undergoing elective surgery under general anaesthesia.[9]Time taken for insertion was shortest and significantly lower (p= 0.048) for reverse (1800) technique comparing conventional technique.[9] The overall success rate in groups were 91.1%, 95.6%, or 93.3% correspondingly (p= 0.7). The first attempt success rate was 82.2%, 89%, or 84.4% (p= 0.07). In children, the present study was able to achieve a higher first attempt success rate with the reverse technique (95.6%) and conventional technique (84.4%) compared to the above study.

In current study, mean time required for i-gelTM insertion was 20.77 ± 2.77 seconds in Group R and 23.07±3.82 seconds in Group C (p=0.001). I-gelTM could be inserted in less than 20 seconds in 40% of Group R ,while in Group C, all insertions took longer than 20 seconds.Similarly, Sharda M et alcompared reverse and standard insertion techniques in 100 adult patients. They also noted lesser mean insertion time in reverse group (R: 17.5±6.9; C: 20.8±5.9) with statistical significance. The success rate for the first try was 86% in the conventional group and 96% in the reverse group (p= 0.08). The probability of sore throat and blood staining of the device was higher in the conventional method group compared to the reverse technique group.[4] Compared to the present study, they could insert i-gel at lesser time with reverse technique. This current study also has similar first attempt success rate, but complications were less.

Three patients in conventional group of this study required minor manipulation for i-gelTM insertion compared to none in reverse group. The oropharyngeal leak pressure though slightly higher in reverse group, was statistically insignificant. No blood staining was observed in either group and could have been due to operator experience and higher ease of insertion in children.

Park et al. performed a systematic review and meta-analysis of prospective randomized controlled trials (RCTs) that evaluated standard vs 90- or 180-degree rotation strategies for the placement of supraglottic airways under general anesthesia in adults and children. Devices such as LMA Classic, LMA Proseal, SoftSeal, and i-gel were incorporated.[5] Overall, the rotating procedures gave greater first-attempt rates, faster insertion, reduced number of attempts, and a decreased frequency of blood stain on the removed device. But it was unable to demonstrate better oropharyngeal leak pressure, fiberoptic view, and postoperative sore throat.[8] The present study suggests that the reverse technique is the more effective alternative to the traditional technique, ensuring quick and smooth insertion of i-gel TM in the paediatric population.

Soh et al concluded that reverse insertion of classic LMA in children had better success rate compared to standard technique (100% versus 90.3%).[6] While Tiwari et al observed that rotational (900) insertion of i-gelTM in children had higher 1st attempt success rate and less difficultiesthan standard technique (p=0.040).[7]

The strength of this study lies in the fact that there are no studies comparing conventional and reverse technique of i-gelTM insertion in children. We were able to do i-gelTM insertion in all children without any complications in both techniques.

The limitations of the present study is that the i-gelTM insertion was carried out by a single experienced anaesthesiologist and blinding could not be done due to nature of the procedure. Therefore, the findings may have limited generalizability to researchers who are not familiar with the reverse insertion technique. Nevertheless, we hope that the reverse technique can be used for i-gelTM insertion by more anaesthesiologists in future. We also did not carry out a fiberoptic examination of the larynx after placement of the device.

Conclusion

Reverse technique is a better alternative to conventional method of i-gelTM insertion in children in terms of time taken for securing the device.

Source of funding

None

Conflict of interest

None

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