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Original Research Article

Comparison of two insertion techniques for I-Gel placement in paediatric patients: standard vs rotational methods

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ABSTRACT

Background: I-Gel has found increasing favour amongst anaesthesiologists for securing and maintaining a patent airway during routine as well as emergency surgeries in the paediatric population. The present prospective randomized study was conducted to compare the two techniques (standard and rotational methods) for I-Gel insertion in children; by assessing the first attempt success rate, insertion time and ease of insertion.

Materials and Methods: ASA I and II paediatric patients (1-6 years old) scheduled for brief elective surgical procedures lasting less than one hour were randomly allocated into two groups viz. Group A (n= 30) employing the standard technique, and Group B (n= 30) utilizing the rotational technique for I-Gel placement.

Result: Group B subjects depicted a significantly higher first-attempt success rate vis a vis Group A subjects (P=0.040). The mean insertion time during the first attempt was longer in Group A (standard technique) as compared to Group B (rotational technique), but the difference was not statistically significant.

Conclusion: This study lends credence to the fact that the placement of I-Gel by employing the rotational method culminates in an increase in the first attempt success rate, suggestive of its potential superiority to the standard method

1. Introduction

The I-Gel™ (Intersurgical, Wokingham, UK) is a second generation supraglottic airway device (SAD) with a moldable, non-inflatable anatomical cuff that greatly aids in maintaining the airway by providing a good seal over the larynx and adjoining structures.[1] This device is increasingly being employed for providing ventilation during elective and emergency surgeries. I-Gel has been validated for emergency airway management in the pre-hospital setting too.[2–4]

A standard technique similar to LMA insertion is basically used to insert I-Gel. However, it becomes difficult at times to insert I-Gel by the standard technique in children. There are some alternative methods such as rotation of varying degree, inflating the cuff partially, and lateral approaches which have previously been utilized to facilitate the insertion and correct placement of LMA in children.[5] In a recent case report, Sen et al have suggested that it may be

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fruitful to employ the reverse technique for I-Gel insertion, once the standard technique for insertion has failed.[6]

The benefit of the rotational technique in ensuring a better first attempt success rate for the placement of the ProSeal laryngeal mask airway (LMA) without causing clinically significant hypopharyngeal mucosal trauma has been demonstrated in a number of studies.[7–9] Therefore, we hypothesized that in comparison to the standard technique, the rotational technique would prove to be more beneficial to ensure the correct placement of I-Gel in the posterior hypopharynx, in an early and smooth manner.

2. Materials and Methods

After securing approval of the Institutional Ethical Committee and obtaining written informed consent from parents; this prospective randomized clinical study was conducted in ASA I and II children, aged between 1and 6 years, undergoing brief elective surgical procedures lasting less than 60 minutes including abdominal (e.g. undescended testis), inguinal (e.g. herniotomy, circumcision), and orthopaedic procedures (e.g. surgeries involving upper and lower extremities). The patients were randomly distributed into two groups (using computer-based block randomization) i.e. Group A (n= 30) employing the standard method, and Group B (n= 30) utilizing the rotational method for placement of I-Gel. Patients with symptoms suggestive of recent/ongoing upper respiratory tract infection, children at increased risk of regurgitation, and children with anticipated difficult airway such as retrognathia, restricted mouth opening, trismus, facial trauma, or occluding mass in the pharyngeal space were excluded from the study.

In the operating theatre standard monitoring (pulse oximetry, NIBP, ECG, capnography and temperature) was connected to the child. After premedication with 0.1mg/kg midazolam and 1μg/kg fentanyl intravenously 10 min before induction, anaesthesia was induced with Propofol (3mg/kg) intravenously and maintained with sevoflurane, oxygen, spontaneous ventilation with regional blocks as indicated. The actual size of the I-Gel was accounted for based on the patients' bodyweight (size 1.5 for those weighing 5-12 kg, size 2 for those weighing 10–25 kg). In the standard group, the I-Gel was advanced along the hard palate and soft palate into the posterior pharyngeal space. In the rotational group, the I-Gel was rotated 90° in the anticlockwise direction after being introduced into the oral cavity and advanced downwards into the hypopharynx. It was then rotated clockwise to the original alignment, returning it to the standard position in the midline.

Successful I-Gel insertion was confirmed clinically by the ability of the attending anaesthesiologist to insufflate the lungs as indicated by adequate chest lift, no significant resistance or leakage to ventilation, and prompt refilling of the reservoir bag with confirmation on capnography.

Insertion time was recorded as the time from the opening of the patient's mouth at the start of insertion to confirmation of the proper placement of I-Gel with capnography. The ease of insertion was adjudged by the time taken to complete I-Gel insertion, the number of attempts before proper placement was accomplished, and the resultant complications (if any). An insertion was graded as easy when the anaesthesiologist could ensure the correct placement of I-Gel in the posterior pharyngeal space without encountering resistance in a single manoeuvre. On the contrary, a difficult insertion was one in which appreciable resistance was encountered during insertion or where additional manipulation had to be undertaken to place the device within the hypopharynx. Ease of I-Gel insertion as experienced by the attending anaesthesiologist was subjectively graded on a scale from 1 to 3 (Table 1).

Table 1: Ease of insertion and insertion score

Ease of insertion	Insertion score
Very Easy	1
Easy	2
Difficult	3

The incidence of complications such as cough, laryngospasm, strain (resistance against I-Gel insertion) and haemodynamic parameters such as blood pressure, heart rate and oxygen saturation were recorded. Once the child achieved full wakefulness with easy arousability, the supraglottic airway was removed. The I-Gel was observed for blood staining or sign(s) of any other trauma to the airway. The postoperative visit for each child was scheduled in the evening to record the incidence of sore throat (if any).

2.1. Statistical analysis

Based on a 95% confidence interval, a total sample size of 60 (30 in each group) was considered adequate for 80% statistical power and 5% level of significance. Results were expressed as frequency or mean ± SD. All data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 16. Unpaired t-test was utilized to compare the means between the two groups related to various parameters. Chi-square test was employed to find out the association between categorical variables. A p-value of < 0.05 was considered significant.

3. Results

The demographic profiles of patients such as age and gender were similar and comparable in the two groups (Table 2). The mean age of children in group A was 3.88±1.379 years whereas in group B it was 3.97±1.076years

The success rate of insertion at the first attempt was significantly greater in Group B (P = 0.040). However, the overall success rate of I-Gel placement was similar between

Table 2: Demographic data

	Group A (n=30)	Group B (n=30)	P value
Gender			
Male	17 (56.6)	15 (50)	0.611
Female	13 (43.3)	15 (50)	
Mean Age	3.88±1.379	3.97±1.076	0.774

Table 3: I-Gel insertion parameters

Parameters	Group A (n=30)	Group B (n=30)	p-valve
Insertion Attempts: 1 / 2 / 3	24 / 6 / 0	29 / 1 / 0	0.040*
Ease of Insertion: Very Easy / Easy / Difficult	24 / 4 / 2	27/ 2 / 1	0.454
Insertion Time (in seconds)	12.35±1.170	12.17±1.085	0.518

Table 4: Haemodynamic and ventilation parameters (mean)

Parameter	Group A (n=30)	Group B (n=30)	p value
Heart rate (before insertion)	101.35±5.289	102.23±6.966	.580
Heart rate (1 minute after insertion)	118.03±4.956	120.67±8.576	.146
MAP (before insertion)	65.52±8.970	61.77±9.793	.124
MAP (after insertion)	68.58 ± 9.124	66.07±10.596	.324
SpO2	100.00±.000	100.00±.000	-
Respiratory rate	19.19±1.778	19.93±3.129	.259
Air leak pressure (cm H2O)	19.32±1.514	19.10±1.583	.577
SBP before insertion (mmHg)	89.84±8.494	86.62±10.133	.187
DBP before insertion (mmHg)	51.87±9.204	48.14±11.498	.169
SBP after insertion (mmHg)	93.68±8.757	89.90±10.016	.124
DBP after insertion (mmHg)	54.45±11.036	50.83±12.441	.237

the two groups. The time taken for proper placement at the first attempt in Group A (standard technique) was longer vis-a-vis Group B (rotational technique); however, this difference was not statistically significant (Table 3).

The haemodynamic parameters in the two groups i.e. heart rate, mean arterial pressure (MAP), systolic blood pressure (SBP), and diastolic blood pressure (DBP) increased after I-Gel insertion but the same was not statistically significant (Table 4). Likewise, no significant difference in respiratory rate was observed in the two techniques of I-Gel insertion.

Blood staining of the tip of the device after its removal was recorded in both groups and it was found that 3 (10%) subjects in Group A and 2(6.6%) subjects in group B had evidence of blood staining. This was neither clinically nor statistically significant. There were no episodes of bucking, coughing, laryngospasm, sore throat or hoarse cry in both groups.

4. Discussion

The I-Gel is a novel, single-use, cuffless SAD manufactured using elastomer gel (styrene-ethylene butadiene styrene). Its shape partially resembles the inflated PLMA. Its design includes a central wide diameter airway tube, a stem that is elliptical in shape, an 'anatomically' shaped non-inflatable cuff, an integral bite block and a gastric drain tube.[1] These features provide low resistance to gas flow, stability, improved perilaryngeal and pharyngeal seal, and possibly decreased risks of airway occlusion or aspiration.

Beylacq L et al. studied the efficacy of I-Gel in the paediatric population (50 children above 30 kg undergoing short-duration surgery were enrolled).[10] The researchers evaluated the I-Gel on various parameters including ease of insertion, airway leak pressure, intraoperative ventilatory parameters and incidence of postoperative complications. The initial attempt success rate for insertion and proper placement was 100%. The authors observed that I-Gel insertion is a relatively easy procedure and appears to be safe for paediatric airway management. Hughes C et al evaluated 154 children managed with I-Gel (size ranging from 1 to 2.5) over a period of 12 months to assess the device efficacy based on certain parameters like successful rate of insertion, seal pressure, confirmation of proper placement by fiberoptic laryngoscopy, ease in placing the gastric tube, manipulations required, and complications during insertion and removal.[11] The success in the initial attempt at insertion was 93.5%, whereas complications were observed in 20% of cases. Most of the complications were minor, however, there were few cases of I-Gel displacement leading to a compromised airway. Contrary to the above, none of

the subjects in our study experienced any complication whatsoever.

Kim et al. compared two techniques i.e., standard and rotational techniques for I-Gel insertion in 180 anaesthetized adult patients.[12] The success rate of proper placement, insertion time, seal pressure and occurrence of complications were assessed. They inferred that the rotational method facilitated a greater success rate of proper I-Gel placement at the initial attempt than the standard method. In addition, the rotational method conferred other advantages over the standard method including an abridged I-Gel placement time, better airway patency and lesser perioperative complications involving the airway. In our study, the success rate of I-Gel insertion at the first attempt was significantly higher while employing the rotational technique (Group B). Our findings suggest that the rotational technique is the better alternative amongst the two methods to ensure rapid and smooth insertion of I-Gel in the paediatric population.

Our study has various limitations. The attending anaesthesiologist was not blinded to the insertion technique. At the same time, it was ensured that the observers entrusted with recording the various parameters were blinded to the grouping of the subjects. A single trained anaesthesiologist went ahead with all insertions in our study and hence it might not be very appropriate to extrapolate the findings to other anaesthesiologists not well versed with the rotational technique. However, it has been validated in two previous studies that even novices enjoy a high success rate in I-Gel insertion.[13,14] We are highly optimistic that our results are suitable for generalization since the success rate at the initial attempt, I-Gel placement time, and airway leak pressure recorded in the standard group (Group A) of our study are comparable to the observations of other researchers.[13,15,16]

5. Conclusion

This study demonstrates that I-Gel placement employing the rotational method results in an increase in the success rate at the initial attempt, evidently suggestive of the fact that the rotational technique is a better alternative to the standard method. We recommend the use of the rotational technique for ensuring rapid and smooth placement of I-Gel in anaesthetized paediatric patients.

6. Source of Funding

None.

7. Conflict of Interest

None.

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