Original Article

Comparison of standard weight-based and thenar eminence dimension-based selection of I-gel in pediatric patients – A randomized controlled study

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Abstract

Background and Aim: Supraglottic airway devices are increasingly being used for airway management. I-gel is being widely used even for pediatric patients. Although the weight-based selection of the size of the device seems to be the standard technique, this method may not be possible in all patients. The aim of the study was to compare the standard weight-based method with the thenar eminence dimension-based method for I-gel selection.

Material and Methods: A prospective randomized study was conducted on 74 pediatric patients of either sex, aged between 6 months and 15 years, belonging to American Society of Anesthesiologists (ASA) physical status I, II, and III and who were posted for various surgical procedures under general anesthesia. The study population was divided into two groups of 37 patients each. I-gel was inserted based on weight in group A patients and based on thenar eminence size in group B patients. Parameters like first attempt success rate, ease of insertion, and complications were compared between the two groups using Student's *t*-test and Chi-square test.

Results: The demographic values between the groups were comparable. The first attempt success rate was 97.4% in group A and 91.7% in group B ($P = 0.358$). Insertion of I-gel was unsuccessful in two patients in group B. Two patients of group B had blood staining of the device. None of the patients had complications related to insertion.

Conclusion: The thenar eminence dimension can be used instead of weight while choosing the size of I-gel in pediatric patients. None of the patients had complications related to device insertion.

Keywords: Airway, general anesthesia, intubation, laryngeal mask, pediatric anesthesia, supraglottic airway device

Introduction

Airway management is an indispensable skill in pediatric anesthesia. It involves evaluation, planning, and use of a variety of devices and techniques to obtain an effective pathway for oxygenation and ventilation. Although endotracheal tubes are gold standard for airway management, they have now paved the way for supraglottic airway devices (SGAD) in many clinical situations. They are increasingly being used for airway management. They fill the niche between the face mask and tracheal tube in terms of anatomical position, ease of insertion, and degree of invasiveness. These airway devices are handy in elective as well as emergency conditions.[1-3]

The I-gel™ (Intersurgical, Wokingham, UK) is a second-generation SGAD made of soft, gel-like, transparent, medical-grade, thermoplastic elastomer. I-gel seems to be a safe alternative airway device, even for pediatric patients.[4] The

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Access this article online

Quick Response Code:

Website: https://journals.lww.com/joacp

DOI: 10.4103/joacp.joacp_215_22

How to cite this article: Sachidananda R, Petkar LV, Mitragotri MV, Malipatil A. Comparison of standard weight-based and thenar eminence dimension-based selection of I-gel in pediatric patients – A randomized controlled study. J Anaesthesiol Clin Pharmacol 2023;39:642-7.

Submitted: 11-Jun-2022 **Revised:** 02-Aug-2022
Accepted: 20-Aug-2022 **Published:** 21-Feb-2023

successful placement of airway devices in pediatric patients largely depends on the selection of appropriate size, which is generally based on the weight of the child as per the manufacturer's recommendations.

However, when the patient's weight is not known (immobilized or unconscious patients) or when the clinician is unable to recollect the relationship between weight and I-gel size, an unconventional method is justified. The weight-based technique may not be applicable for overweight and underweight children. In patients whose body weight lies borderline between two sizes, choosing the correct size may be difficult. Owing to the structural variations of the upper airway as well as a wider range of body weight, the weight-based selection method for a given size of I-gel as per the manufacturer's recommendations may not be convenient to all patients.[5]

Hence, there is a need for an alternative method that may be simple and feasible and may be used in emergency situations.

Although I-gel was introduced for airway management, there have been only very few studies available in the literature to determine an alternative method for selecting the appropriate size of I-gel in pediatric patients. Hence, we felt there is a need to study this alternative method for I-gel insertion. The primary objective of the study was to compare the first attempt success rate of the standard weight-based method with thenar eminence dimension-based method for I-gel selection in pediatric patients.

The secondary objectives were to compare the insertion time of the device, ease of insertion of I-gel, ease of insertion of Ryle's tube and the complications associated with the device insertion.

In this study, it was hypothesized that the first attempt success rate of insertion of I-gel based on thenar eminence would be similar to the weight-based method in pediatric patients.

Material and Methods

After obtaining approval from the institutional ethical committee (ETHICS COMM-441 2019-2021 dated 11.19.2019), a prospective randomized controlled study was conducted on pediatric patients undergoing various surgical procedures under general anesthesia. Informed written consent was obtained from the parents or guardians of the patient and assent for children aged more than 7 years. The study was registered in Clinical Trials Registry of India (registration number- CTRI/2021/02/031494). The study included 74 pediatric patients aged between 6 months and 15 years and belonging to American Society of Anesthesiologists' physical status (ASA-PS) I, II, and III. Children with anticipated difficult airway or surgery involving airway, those with significant cardiovascular, pulmonary, or liver disease, those with hiatus hernia, full stomach, decreased pulmonary or chest wall compliance, risk of aspiration, a recent history of respiratory tract infection, or limb deformities were excluded from the study.

The study group was divided into two groups of 37 each [Figure 1]. Randomization was done according to computer-generated random numbers. In group A (n = 37), I-gel was inserted based on weight. I-gel size was chosen according to the patient's weight in accordance with the manufacturer's recommendations – size 1.5 (5–12 kg), size 2 (12–25 kg), size 2.5 (25–35 kg). In group B (n = 37), I-gel was inserted based on thenar eminence size.

The long and short axes of thenar eminence were measured with fingers in the neutral position [Figure 2]. The long axis corresponded to the intersection point of the thumb to wrist curl, while the short axis corresponded to the major portion of thenar eminence. The size of the I-gel, which closely correlated with the measurements taken, was inserted.

Allocation concealment of the two groups was done by the closed envelope technique. There were three observers in the study. The first observer performed the preanesthetic evaluation, noted the age and weight of the child, and measured the thenar eminence size, determined the size of the I-gel, and mentioned it in the file of the patient. The second observer, who was also the primary anesthesiologist, was an experienced anesthesiologist; he was unaware of the group allocated and

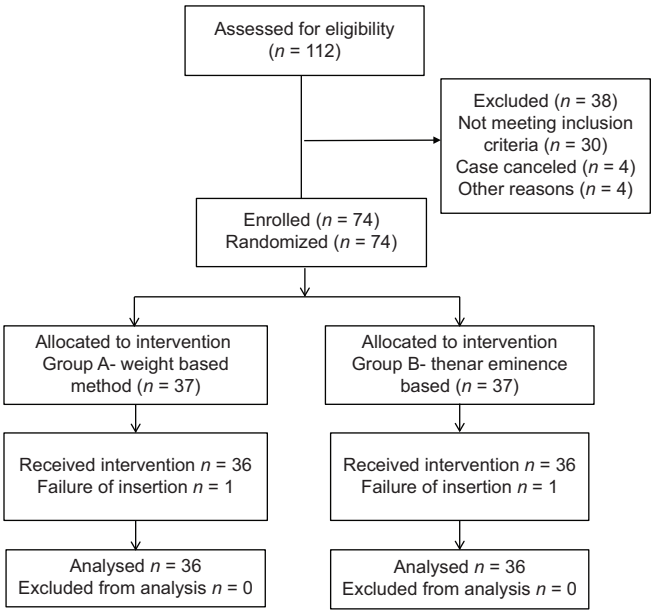

Figure 1: CONSORT flow chart

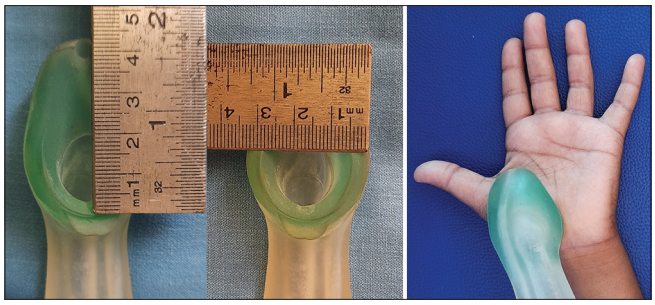

Figure 2: Measurement of thenar eminence dimensions and the corresponding size of the I-gel

inserted the I-gel handed over to him. The outcome was assessed by the primary anesthesiologist. The third observer handed over the I-gel to the primary anesthesiologist based on the group allocated.

All patients were evaluated the day before surgery. Routine investigations were done as per the institutional protocol. Patients were kept nil by mouth for solid food for 6 h and for clear fluids for 2 h before the surgical procedure. In the operation theater, an intravenous (IV) access was obtained and an infusion of Ringer's lactate was started. All patients were premedicated with intravenous glycopyrrolate 0.005 mg/kg and midazolam 0.05 mg/kg. Routine standard monitoring included pulse oximeter (SpO_2), noninvasive blood pressure (NIBP), capnography, and electrocardiogram (ECG). The patients were preoxygenated with 100% oxygen for 3 min via mask gently placed over the face using Jackson-Rees' circuit or Bain's circuit. Propofol 2 mg/kg was used for induction and atracurium 0.5 mg/kg was administered as a muscle relaxant to facilitate placement of I-gel. Fentanyl 2 μg/kg and paracetamol suppository were used as analgesic. Anesthesia was maintained with oxygen, nitrous oxide, and sevoflurane. With the head resting on the ring pillow, a lubricated I-gel was inserted by a standard technique.

Successful placement of I-gel was confirmed by observing chest heave on positive pressure ventilation, absence of audible leak with a peak airway pressure of 20 cmH_2O, auscultation of bilateral air entry, and a square wave end-tidal CO_2 waveform during ventilation. A leak pressure above 20 cmH_2O was considered malposition.[6] Time for successful insertion was recorded in seconds from the time of introduction of I-gel between the teeth to sustained appearance of capnography waveform. Failure was defined as the presence of an audible leak. In case of failure, insertion with a larger size I-gel was attempted. A maximum of two attempts were allowed; in case of failure despite two attempts, the trachea was intubated with an endotracheal tube. After insertion of the I-gel, appropriate-sized gastric tube was inserted. Ease of insertion of I-gel (very easy- device inserted without manipulation; easy- when insertion into the pharynx required any one of the maneuvers like chin lift, jaw thrust, head extension, and neck flexion; difficult- when more than one maneuver was required to insert) was noted.[7] After the completion of surgery, neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and glycopyrrolate 0.005 mg/kg. I-gel was removed when the patient fulfilled the criteria of I-gel removal (spontaneous eye opening, obeying verbal commands, sustained head lift). Complications such as laryngospasm, bronchospasm, fall in oxygen saturation to <90%, gagging, and blood staining of the device were recorded. Causes for insertion failure, such as a leak or incorrect placement, were also noted. The primary outcome was the successful placement of the device, and the secondary outcome was complications associated with the device placement.

Statistical analysis

The sample size was estimated based on the difference in the proportion of success rate in inserting the I-gel based on thenar eminence dimensions and based on weight. The success rate in the standard weight-based method was 90% and in the thenar eminence-based method was 60% in a pilot study conducted by us. With the power for the study being 80% and type I error being 5%, the sample size was estimated to be 33 in each group. Considering the dropouts, 37 patients were recruited in each group.

Data was entered in MS Excel and analyzed using Statistical Package for the Social Sciences (SPSS) 22 version software. Quantitative data were presented as mean and standard deviation (SD). Student's *t*-test was the test of significance for quantitative data, and Chi-square test was the test of significance for qualitative data. A P value <0.05 was considered as statistically significant.

Results

The demographic profile of the patients is shown in Table 1. The study groups were comparable with respect to age, gender, body mass, ASA-PS, type of surgery, and insertion time. They were also comparable with respect to the size of the I-gel used [Table 2].

There was no statistically significant difference between the study groups in relation to the success rate of I-gel insertion ($P = 0.358$) [Table 3]. In group A, insertion failed in one patient. In this case, there was an audible leak following the insertion of the I-gel; then, an I-gel of the next appropriate size was used, which also demonstrated an audible leak, and the patient was intubated with an appropriate-sized endotracheal tube. In group B, two patients (5.6%) required a second attempt for successful insertion of I-gel and insertion

failed in one patient (2.7%). In this patient, there was an audible leak on inserting the I-gel (I-gel was chosen based on thenar eminence size- size 2), and then there was an audible leak on inserting the I-gel of the next size (size- 2.5). Hence, the patient was intubated with an appropriate-sized endotracheal tube.

On comparing the ease of insertion of I-gel between the study groups [Figure 3], it was found that in group A, insertion of I-gel was very easy in 22 patients (61.1%) and easy in 14 patients (38.9%), whereas in group B, ease of insertion of I-gel was very easy in 23 patients (63.9%), easy in 11 patients (30.5%), and difficult in two patients (5.6%). The study groups were comparable ($P = 0.3$). The insertion of Ryle's tube was easy in 72 patients.

In group B, two patients (5.4%) had blood staining of the device. None of the patients from group A had blood staining on the device. There was no significant difference between the study groups, and the *P* value obtained was 0.151. None of the patients from group A or group B had complications such as laryngospasm, bronchospasm, fall in oxygen saturation to less than 90%, coughing, or gagging on removal of the I-gel.

Table 1: Comparison of demographic profile, insertion time, and type of surgeries between the study groups

Variables	Group A (*n*=37)		Group B (*n*=37)		*P*
	Mean	SD	Mean	SD	
Age (years)	8.2	3.4	7.4	3.4	0.315
Gender					
Male	26 (70.3%)	-	30 (81.1%)	-	0.278
Female	11 (29.7%)	-	7 (18.9%)	-	
ASA-PS					0.3
1	37 (100%)	-	35 (94.4%)	-	
2	0	-	1 (2.8%)	-	
3	0	-	1 (2.8%)	-	
Weight (kg)	20.8	9.3	18.0	6.7	0.141
Height (cm)	117.1	15.2	108.7	16.2	0.084
BMI (kg/m^2)	14.7	4.2	13.3	3.4	0.1
Insertion time (s)	8.9	2.0	10.3	3.9	0.07
Type of surgery					0.150
General surgery	18 (48.6%)	-	26 (70.3%)	-	
Orthopedic	16 (43.2%)	-	8 (21.6%)	-	
Urology	2 (5.4%)	-	3 (8.1%)	-	
Others	1 (2.7%)	-	-	-	

ASA-PS=American Society of Anesthesiologists' physical status, BMI=body mass index, SD=standard deviation. Data expressed as mean±SD. P<0.05 is considered significant

Table 2: Comparison of size of I-gel used across the study groups

Size of I-gel used	Group A (*n*=37)		Group B (*n*=37)		Total	*P*
	n	%	n	%		
1.5	12	32.4	18	48.7	30	0.310
2	15	40.6	13	35.1	28	
2.5	10	27.0	6	16.1	16	
Total	37	100.0	37	100.0	74	

P<0.05 is considered significant

Table 3: Comparison of success rate for I-gel insertion between the study groups

Success rate	Group A		Group B		Total	*P*
	n	%	*n*	%		
First attempt	36	97.4	34	91.7	70	0.358
Second attempt	0	-	2	5.6	2	
Failure	1	2.6	1	2.7	2	
Total	37	100.0	37	100.0	74	

P<0.05 was considered significant

Discussion

In our study, we compared the first attempt success rate of insertion of I-gel between the weight-based and thenar eminence dimension-based study groups. In our study, the success rate on the first attempt was 97.4% in group A and 91.7% in group B. There was no significant statistical difference in the first attempt success rate between the study groups.

To best of our knowledge, there are no such randomized controlled trials reported in literature comparing the I-gel insertion based on weight and thenar eminence measurements.

Apan *et al.*[8] conducted a prospective descriptive study in pediatric patients of age group 0–12 years, in which I-gel was inserted based on weight. They found statistically significant correlation between the measurements of thenar eminence and the I-gel which was inserted. They concluded that, while choosing the correct size of I-gel, the thenar eminence measurements can be used as an anatomical landmark in pediatric patients. In their study, the success rate of insertion in the first attempt was 95%. The first attempt success in various other studies in which I-gel was inserted based on weight was 90% and 94%.[9,10]

The width of the index, middle, and ring fingers was also used to determine the size of in the prospective randomized study

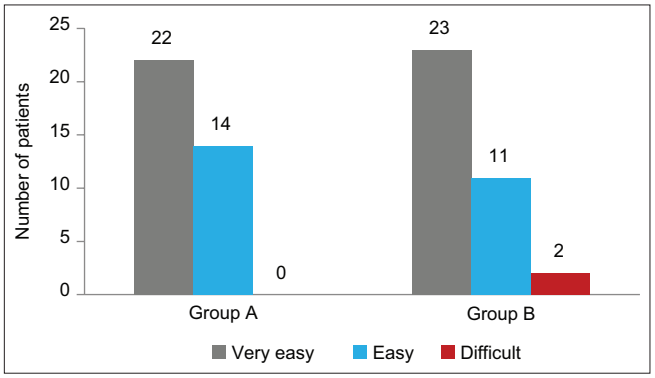

Figure 3: Comparison of ease of insertion of I-gel between the study groups

by Mathew *et al.*[11] in pediatric patients. They reported that the size of PLMA was the same in both methods in 66.66% of the children, but was inconsistent in 33.34%, with only one size in those whose weight was borderline.

In yet another study, the selection of PLMA in the pediatric age group based on the auricle size was considered more practical than the conventional method which is based on weight.[12] In a similar study by Ravi *et al.*[13] in a pediatric population, weight-based PLMA insertion was compared with pinna size-based insertion. They concluded that pinna-based size selection of PLMA can be used as an alternative method to weight-based selection for positive pressure ventilation. The insertion time in our study groups was comparable (*P* value 0.07), being 8.9 s in group A and 10.3 s in group B. Studies have postulated that the unique gel-like material, shape, contour, buccal stabilizer, and epiglottic blocker may facilitate easy insertion of the device.[14] The I-gel insertion time was 17 s and the insertion time of LMA Classic was 21 s ($P = 0.002$).[15] Tokgoz *et al.*[16] found the I-gel easier to insert compared to PLMA (mean 19 vs. 28 s, respectively; $P = 0.01$). However, the insertion time was longer when compared to LMA supreme (mean 13 vs. 11s, respectively; $P = 0.001$) and Ambu AuraOnce (median 26 vs. 24 s, respectively; $P = 0.02$). The authors concluded that the longer time could have been related to the inclusion of time required for securing the device.[15,17]

In our study, atracurium was used as a muscle relaxant to facilitate insertion. Low-dose succinylcholine or atracurium provided adequate jaw relaxation, thereby helping easy and smooth insertion of I-gel.[18] The shorter insertion time in our study could be related to the use of atracurium. Low-dose muscle relaxant reduces airway pressures, improves thoracic compliance, and inhibits patient–ventilator asynchrony and displacement of the device.[19]

The ease of insertion of the nasogastric tube was comparable between the study groups. The easy insertion of a nasogastric tube may be associated with good positioning of the device, and so, fiber-optic confirmation is not required.[20]

There was no significant statistical difference between the study groups regarding the complications with I-gel placement, such as blood staining of the device, coughing, gagging, and others. I-gel has a noninflatable soft cuff that prevents any compromise in the blood supply to the laryngeal or perilaryngeal tissues. In the SGAD with inflatable cuff, the cuff inflation can cause tissue injuries or ischemia.[21]

Limitations of the study

An analysis is also required to test the feasibility of this method (based on thenar eminence dimension) of I-gel insertion in infants under 6 months of age. None of these techniques of I-gel insertion may be applicable in patients with congenital abnormalities and patients with syndromes or disorders of bone or soft-tissue growth. Fiber-optic scope was not used to confirm correct placement of the device.

Conclusion

The thenar eminence dimension can be used as a proxy to weight while selecting the size of I-gel in pediatric patients when the weight of the child is not known. None of the patients had complications related to device insertion. The use of muscle relaxants could have reduced the insertion-related complications.

Acknowledgements

Dr. Madhuri S. Kurdi, Professor and Head of Department of Anesthesia, and Dr. Vikram Kemmannu Bhat, Professor and unit chief, Department of ENT, KIMS Hubli, Karnataka, are acknowledged.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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