Original Article

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# Comparison of Actual Body Weight, Ideal Body Weight and Age for Selection of Appropriate I-gel Size in Paediatric Patients: A Randomised Controlled Study

Anaesthesia Section

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## ABSTRACT

**Introduction:** Manufacturer's guidelines for I-gel advocate size selection of the device based on patient's Actual Body Weight (ABW). However, this may not be suitable for children because of the wide range of weight for each device and the variation in individual anatomy due to difference in growth rate of paediatric patients.

**Aim:** To compare ABW, Ideal Body Weight (IBW) and age for selection of I-gel size in paediatric patients.

**Materials and Methods:** The present randomised controlled double-blinded study was carried out in the Department of Anaesthesiology and Critical care at Pt. B.D. Sharma PGIMS, Rohtak, Haryana, India. The study was conducted from February 2020 to November 2021. A total of 60 patients of age group 2 to 10 years (20 in each group) scheduled to undergo elective surgery under general anaesthesia using I-gel were enrolled and randomised into three groups: Group-I (IBW), Group-A (ABW) and Group-Ag (Age). A standard anaesthesia protocol was followed and I-gel size was selected as per the group criteria. The authors recorded the number of attempts, ease of insertion and Oropharyngeal Leak Pressures (OLP). The Wilcoxon's signed-rank test and Kruskal-Wallis test were used for quantitative data, while, Chi-square test was used for qualitative data. Level of significance was set at $p<0.05$.

**Results:** Demographic characteristics, i.e., age, gender, weight and height, were statistically similar in three groups. Mean age was 6.02±2.62, 5.40±3.23 and 6.65±2.43 years in groups Ag, A and I, respectively (p=0.37). First attempt success rate was highest in Group-I (90%), which was statistically significant between Group-Ag (55%) vs Group-I (p=0.01) and Group-A (75%) vs Group-I (p=0.02). I-gel insertion was easy in maximum patients (n=18) in Group-I, with difficulty in only two patients, leading to statistically significant difference between Group-Ag vs Group-I (p=0.04) and between Group-A vs Group-I (p=0.001). Mean OLPs ($cmH_2O$) were 21.6±7.46, 24.4±1.0 and 24.35±0.9 in Groups-Ag, Group-A and Group-I, respectively (p>0.05). Blood stains on I-gel after removal were observed in seven patients in Group-Ag, three patients in Group-A and only one patient in Group-I.

**Conclusion:** The IBW can be a better predictor of I-gel size estimation as compared to ABW and age in paediatric patients. In our study, selection of I-gel size on the basis of IBW resulted in better first attempt success rate and easier insertion with fewer complications than ABW and age.

**Keywords:** Airway, Paediatric anaesthesia, Supraglottic airway device

## INTRODUCTION

The I-gel airway is a novel and innovative Supraglottic Airway Device (SAD) made of a medical-grade thermoplastic elastomer, Styrene Ethylene Butadiene Styrene (SEBS), which is soft, gel-like and transparent. I-gel, being a device without an inflatable cuff, has many potential advantages, which include easier insertion, minimal risk of tissue compression and stability after insertion i.e., no position change with cuff inflation as noted with inflatable devices. It is not necessary to insert finger into mouth to achieve full insertion. The I-gel is designed as a latex-free, sterile, single-patient-use device [1,2].

Paediatric I-gel has been commercially available in sizes suitable for children since 2010. It is available in different sizes (1, 1.5, 2 and 2.5) according to the actual weight of the children. I-gel of size 1 is devoid of additional gastric lumen [1-3].

Optimal size selection of I-gel is important to ensure adequate placement and ventilation, to prevent trauma to periglottic structures and to prevent postoperative complications like sore throat. Manufacturer's guidelines for I-gel advocate size selection of the device based on patient's ABW. However, this may not be suitable for some patients becau se of the wide range of weight for each device and the variation in size and individual anatomy due to difference in growth rate of paediatric patients [1,3].

Laryngeal Mask Airway (LMA) manufacturers recommend size selection based on weight only, which may not be suitable for overweight and underweight children [4,5]. Individuals who have wide thyroid/cricoid cartilages or cylindrical necks might need a bigger size I-gel than is typically advised based on weight. On the other hand, individuals with a broad or stocky neck, or smaller thyroid/cricoids cartilage could need a smaller size I-gel than is often advised based on weight. In practice, patients with central obesity-where the majority of their weight is distributed around the hips and abdomen-may need an I-gel that is the appropriate size for their height and IBW, not their ABW [1]. Also, in children, height and weight varies for age and depends on various factors like growth rate, nutrition, genetics, endocrine factors and syndromic condition [6]. So, sizes recommended as per ABW only may not be appropriate for each and every child, increasing the chances of inadequate ventilation in case of smaller I-gel and increased chances of trauma or complications in case of a larger device [1,3,7]. Therefore, we need alternative criteria's for optimal size selection of I-gel in children.

It was hypothesised that the first attempt success rate of insertion of I-gel would be similar in all the three groups (IBW, ABW and age) in paediatric patients. Recently, various studies have been published using criterias other than ABW for size selection of

supraglottic devices [4,5,7]. However, the literature is scarce when it comes to evaluating age and IBW for recommendation of I-gel size in children. Therefore, we conducted a study to compare ABW, IBW and age for selection of I-gel size in paediatric patients. The primary outcome was first attempt success rate of I-gel. Secondary outcome measures included ease of insertion, OLPs and complications, if any.

## MATERIALS AND METHODS

The present randomised controlled double-blinded study was carried out in the Department of Anaesthesiology and Critical care at Pt. B.D. Sharma PGIMS, Rohtak, Haryana, India, after receiving approval from Institutional Ethics Committee (IEC/Th/19/Anst18) and obtaining written informed consent from the parents. The study was conducted from February 2020 to November 2021.

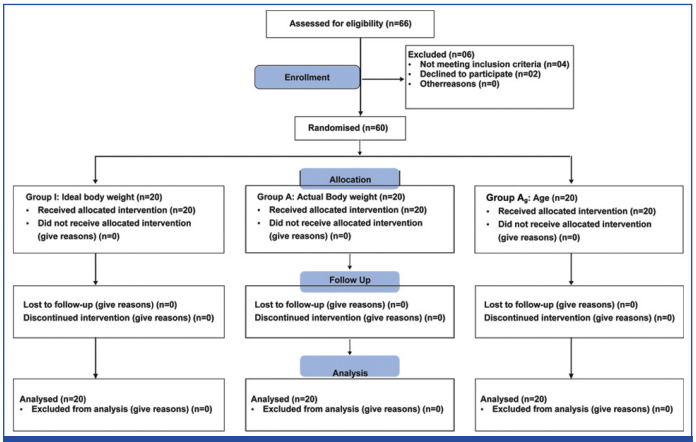
**Sample size calculation:** The study by Chinachoti T et al., observed that correlation between size of the Laryngeal Mask Airway (LMA) and body weight was 0.746, while the correlation between size of LMA and age was 0.606 [8]. Taking these values as reference and with a Standard Deviation (SD) of 0.15, the minimum required sample size with 80% power of study and 5% level of significance was 18 patients in each study group. To reduce margin of error, total sample size taken was atleast 60 (20 patients per group).

**Inclusion criteria:** A total of 60 patients of age group 2 to 10 years (20 in each group) of either sex, belonging to American Society of Anaesthesiologists (ASA) I-II, Body Mass Index (BMI) <25 kg/m$^2$ scheduled to undergo elective surgery under general anaesthesia using I-gel, were enrolled in the study.

**Exclusion criteria:** Patients (n=6) with an anticipated difficult airway or risk of aspiration, those undergoing laparoscopic surgeries, surgeries anticipated to last more than two hours and those who refused consent were excluded from the study.

### Study Procedure

**Patient preparation:** All the patients enrolled in the study were advised fasting for six hours for solids and cow's/formula milk, four hours for breast milk and two hours for clear liquids prior to the scheduled time of surgery. All the patients were premedicated with syrup Phenergan at a dosage of 0.1 mg/kg half an hour prior to the surgery. The patients were shifted to operating room. All routine monitors, such as Heart Rate (HR), Electrocardiography (ECG), Non Invasive Blood Pressure (NIBP) and Pulse Oximetry ($SpO_2$), were attached. Patients were enrolled and divided in three groups of 20 each by the consultant anaesthesiologist using computer-generated randomisation number table [Table/Fig-1]. The consultant who randomised the patients and selected the I gel size was not involved in the clinical management inside the operating room. The data was recorded by the postgraduate resident. The persons recording and analysing the data were blinded to the study groups.




**[Table/Fig-1]:** Consolidated Standards of Reporting Trials (CONSORT) diagram.

**Group-I (n=20):** IBW- It was calculated by Traub formula [9]. Length was measured in children aged 1 to 2 years [6]. Standard height was measured in children aged 2 to 10 years [6].

**Group-A (n=20):** ABW- it is the weight measured by weighing the child on a weighing machine.

**Group-Ag (n=20):** Age was used as the reference for proposed LMA sizes for age, which was followed for selection of I-gel for age in the present study [8].

**Anaesthesia technique:** A standard anaesthesia protocol was followed. An intravenous (IV) line was secured. Size of I-gel was decided according to the group allocated to the patient. Device was prepared by lubricating it with a water-soluble lubricant. After preoxygenation, patients were given an injection of glycopyrrolate at 0.005 mg/kg and an injection of fentanyl at 2 µg/kg. 2 µgkg$^{-1}$. Patient was induced with inj propofol (2-2.5 mg/kg) administered in titrated doses to induce anaesthesia. Check ventilation was done and inj. atracurium 0.5 mgkg$^{-1}$ was given to achieve neuromuscular blockade, following which patient were manually ventilated with oxygen in sevoflurane. After three minutes of manual ventilation, I-gel size was selected as per the group criteria and inserted by the standard technique as recommended by the manufacturer. After connecting the paediatric circuit to the I-gel, appropriate placement and ventilation was assessed by chest wall movement and a square wave capnograph. Anaesthesia was maintained with sevoflurane (MAC: 1), nitrous oxide in oxygen (50:50) and intermittent boluses of atracurium, as required. After return of spontaneous respiratory efforts, the remaining neuromuscular blockade was reversed by inj glycopyrrolate 0.01 mg/kg and inj neostigmine 0.05 mg/kg. The device was removed once the child was fully awake or easily arousable.

**Data recorded:** The primary outcome measure was first attempt success rate of I-gel. Secondary outcome measures included ease of insertion, OLPs and any complications that may arise.

**Number of attempts:** In the event of inadequate placement, reinsertion was attempted. However, in case of significant leak, the I-gel of higher size was tried. It was considered as a failure for the group, however was considered for statistical analysis. A maximum of three insertion attempts were allowed for the placement of device before considering it as a failure. In case of failure, alternative device was used as per discretion of anaesthesiologist to secure the airway.

**Ease of insertion:** It was graded on a subjective three-point scale [10]: Easy, difficult and failure. Insertion within the pharynx without resistance in a single manoeuvre was referred to as an easy insertion. A difficult insertion was noted if there was resistance to insertion or more than one manouvre was required for successful insertion of the device. Three insertion attempts were allowed before labelling it as a failure of insertion.

**Oropharyngeal Leak Pressure (OLP):** After successful I-gel insertion, the patient's head was placed in a neutral position and OLP was determined. The Adjustable Pressure-limiting (APL) valve of the anaesthesia circuit was fully closed and at a fixed gas flow of three litres per minute, the OLP was defined as the pressure at which the manometer reading stabilised for >10 seconds [11].

**Complications:** The I-gel was observed for any blood stains. Any other complication like sore throat, dysphonia, hoarseness of voice, were also noted and recorded in the postoperative period.

## STATISTICAL ANALYSIS

Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. Descriptive data was expressed as percentages, means and standard deviations. The Wilcoxon's signed-rank test (for quantitative data

to compare before and after observations) and Kruskal-Wallis test (for quantitative data within three groups) were used for quantitative data comparison of all clinical indicators Chi-square test was used for qualitative data whenever two or more than two groups were used to compare. The level of significance was set at p<0.05.

## RESULTS

Demographic characteristics were comparable among the groups [Table/Fig-2]. The shows number of attempts of insertion in the three groups is shown in [Table/Fig-3]. First attempt success rate was significant higher in Group-I as compared to Group-Ag (p=0.01) and Group-A (p=0.02). Ease of insertion of I-gel in the three groups is shown in [Table/Fig-4]. Maximum easy insertions (n=18) of I-gel was observed in Group-I, followed by Group-A (n=15) and Group-Ag (n=11). This difference was statistically significant between Group-Ag vs. Group-I (p=0.04) and Group-A vs. Group-I (p=0.001). Mean OLPs ($cmH_2O$) were 21.6±7.46, 24.4±1.0 and 24.35±0.9 in Group-Ag, Group-A and Group-I, respectively (p>0.05) [Table/Fig-5]. Blood stains on I-gel after removal were observed in seven patients in Group-Ag, three patients in Group-A and only one patient in Group-I. This difference in airway morbidity was statistically significant between Group-Ag vs. Group-I (p=0.01) and Group-Ag vs. Group-A (p=0.01) [Table/Fig-6]. No other complication was observed in either group.

| Parameters | Group-Ag | Group-A | Group-I | p-value |
|---|---|---|---|---|
| Age (years) | 6.02±2.62 (4.79-7.26) | 5.40±3.23 (3.89-6.91) | 6.65±2.43 (5.51-7.79) | 0.37# |
| Gender (M/F) | 16/4 | 19/1 | 16/4 | 0.30@ |
| ASA (I/II) | 15/5 | 18/2 | 17/3 | 0.43@ |
| Actual Body Weight (ABW) (kg) | 19.75±6.67 (16.62-22.88) | 19.47±8.60 (15.45-23.5) | 21.42±8.04 (17.66-25.19) | 0.69# |
| Ideal Body Weight (IBW) (kg) | 20.07±5.8 (17.36-22.79) | 17.82±6.95 (14.57-21.08) | 20.67±5.17 (18.25-23.1) | 0.29# |
| Height (cm) | 109.2±16.15 (101.64-116.76) | 102.85±18.67 (94.11-111.59) | 111.45±13.53 (105.12-117.78) | 0.23# |

**[Table/Fig-2]:** Demographic characteristics.
#Intergroup comparison (Kruskal-Wallis test)
@Intergroup comparison (Chi-square test)

| Number of attempts | Group-Ag n (%) | Group-A n (%) | Group-I n (%) | p-value | | |
|---|---|---|---|---|---|---|
| | | | | Ag vs A | Ag vs I | A vs I |
| 1 | 11 (55%) | 15 (75%) | 18 (90%) | 0.86 | 0.01* | 0.02* |
| 2 | 6 (30%) | 4 (20%) | 2 (10%) | | | |
| 3 | 0 | 1 (5%) | 0 | | | |
| Failure | 3 (15%) | 0 | 0 | | | |
| Total | 20 (100%) | 20 (100%) | 20 (100%) | | | |

**[Table/Fig-3]:** Number of attempts of insertion of I-gel.
*p-value significant; Chi-square test

| Ease of insertion | Group-Ag n (%) | Group-A n (%) | Group-I n (%) | p-value | | |
|---|---|---|---|---|---|---|
| Easy | 11 (55%) | 15 (75%) | 18 (90%) | Ag vs A 0.74 | Ag vs I 0.04* | A vs I 0.001* |
| Difficult | 6 (30%) | 5 (25%) | 2 (10%) | | | |
| Failure | 3 (15%) | 0 | 0 | | | |
| Total | 20 (100%) | 20 (100%) | 20 (100%) | | | |

**[Table/Fig-4]:** Ease of I-gel insertion.
*p-value significant; Chi-square test

| Groups | OLP Mean±SD ($cmH_2O$) | Minimum | Maximum | p-value |
|---|---|---|---|---|
| Group-Ag | 21.6±7.46 | 23.00 | 26.00 | 0.07 |
| Group-A | 24.4±1.0 | 23.00 | 27.00 | |
| Group-I | 24.35±0.9 | 23.00 | 27.00 | |

**[Table/Fig-5]:** Oropharyngeal Leak Pressure (OLP).
Kruskal-Wallis test

| Airway morbidity | Group-Ag | Group-A | Group-I | p-value | | |
|---|---|---|---|---|---|---|
| B | 7 (35%) | 3 (15%) | 1 (5%) | Ag vs A 0.01* | Ag vs I 0.01* | A vs I 0.06 |
| N | 13 (65%) | 17 (85%) | 19 (95%) | | | |
| Total | 20 (100%) | 20 (100%) | 20 (100%) | | | |

**[Table/Fig-6]:** Airway morbidity.
*p-value significant; B: Blood on device after removal; N: No other complication. Chi-square test

## DISCUSSION

The use of SADs is associated with more haemodynamic stability and lower incidence of complications like postoperative sore throat and cough as compared to endotracheal tubes [12]. Although initial clinical use was typically for anaesthetised patients breathing spontaneously, SADs are now increasingly being used intraoperatively in controlled ventilation. This is because newer devices provide higher seal pressures [13]. SADs are also included in difficult Airway Society guidelines for unanticipated difficult intubation [14].

The challenges in children in airway management compared with adults, are even more due to anatomical variations and physiologic considerations. Children are more prone to hypoxia than adults because of lower oxygen reserve and higher oxygen consumption [15]. Pharyngeal anatomy of paediatric patients is also different from adults. Infants have larger occiput, relatively large tongue, floppy epiglottis, higher and more anterior larynx and enlarged tonsils making endotracheal intubation sometimes difficult. As a result, SADs have become popular among anaesthesiologists seeking an alternative to endotracheal intubation [1].

The I-gel is a novel non inflatable SAD used routinely nowadays in paediatric patients. Selection of adequate size is very important to ensure the performance and safety of the SADs. In accordance with the manufacturer's guidelines, the determination of the size of SAD based on ABW is the most commonly used method, because it is easier. However, ABW may not predict the right device size for some patients as there is a wide range of weight for each size and individual anatomical variations [3]. Though various alternative strategies have been assessed for selecting the size of SADs, no particular criteria has been deemed strong enough in published research to predict optimal size of the device and change the weight-based guidelines [16]. Therefore, the present study was conducted to compare ABW, Ideal Body Weight (IBW) and age for selection of I-gel size in paediatric surgical patients.

**Number of Attempts:** In the present study, the authors observed that the first attempt success rate was highest in the IBW group. Arif SK et al., studied size selection of I-gel in obese adult patients and observed that first attempt for LMA insertion was successful in 54.54% and 81.81% patients in Group-ABW and Group-IBW, respectively (p=0.025) [16]. These findings are similar to those of the present study, that is, less number of attempts was required for device insertion in IBW group. Chinachoti T et al., conducted a study for selecting appropriate LMA size in paediatric patients and observed that correlation coefficient was 0.746 (p<0.001) for body weight, while it was 0.606 (p<0.001) for age. The authors concluded that weight is a good predictor for determination of LMA size. Also, age was found to be a predictor of LMA size, but it was less effective than body weight [8]. In the present study, also, success rate of device insertion was higher in the weight group, be it actual weight or ideal weight as compared to age.

Kim MS et al., conducted a trial to compare IBW and ABW while choosing the appropriate size of the cLMA in overweight adult patients. The success rate for insertion in first attempt was clinically higher, though statistically similar, in IBW group as compared to ABW group (96% vs. 82% patients; p=0.051). Overall success rate for insertion of cLMA was 100% and 98% in IBW and ABW group, respectively, which was also statistically insignificant (p=1.00) [17]. Solanki SL et al., compared IBW and ABW for PLMA size selection

in overweight and obese adult patients and observed that first attempt success rate was statistically similar between the two groups (87.1% vs. 74.2% patients; p=0.069) [18].

**Ease of Insertion:** In the present study, the authors observed that difference in ease of insertion was statistically significant between Group-Ag and Group-I (p=0.04) and Group-A vs Group-I (p=0.001). Maximum number of patients in Group-I had an easy insertion. In a previous study conducted by Arif SK et al., ease of insertion in the ABW group consisted of no resistance, mild resistance and severe resistance in 18.19%, 45.45% and 36.36% of patients, respectively. Whereas the ease of insertion in the IBW group consisted of no resistance and mild resistance in 72.73% and 27.27% patients, while severe resistance and failure of device insertion was not found in the IBW group. Thus the resistance to device insertion was observed in significantly lesser number of patients in IBW group as compared to ABW group (p=0.017) [16]. Kim MS et al., evaluated ease of insertion of LMA in overweight adult patients based on IBW and ABW. In IBW group, no resistance to insertion was observed in significantly higher number of patients in IBW group as compared to ABW group (80% vs. 44%; p<0.001) [17]. Solanki SL et al., studied ease of PLMA insertion in overweight adults and observed that there was no resistance to insertion of PLMA in 67.74% patients in Group ABW as compared to 86.9% patients in IBW group (p=0.027) [18]. These findings were similar to the present study, where ease of insertion was better in IBW group.

**Oropharyngeal Leak Pressure (OLP):** In the present study, the authors observed that OLPs were statistically similar among the three groups (p=0.07). The OLP values observed in the present study correlate with a previous study conducted in paediatric patients undergoing surgery with cLMA and I-gel as airway device [19]. The present findings are similar to various previous studies. In a study conducted by Arif SK et al., the mean OLPs with the I-gel were 28.36±1.629 $cmH_2O$ and 28.09±1.921 $cmH_2O$ in Group-ABW and IBW, respectively, which were statistically similar (p=0.723) [16]. In a study conducted by Kim MS et al., mean values of OLP with cLMA were 21.9±4.5 and 20.5±3.9 $cmH_2O$ in Group-ABW and IBW, respectively (p=0.116) [17]. Solanki SL et al., also observed that OLPs with PLMA were comparable in both the groups (p=1.00) [18].

Kim HJ et al., evaluated PLMA size selection in overweight and underweight children. Median OLPs observed in overweight children were 26.5 $cmH_2O$ and 15 $cmH_2O$ in Group-ABW and Group-IBW, respectively (p<0.01), while OLPs in underweight children were 18 $cmH_2O$ and 25.5 $cmH_2O$ in Group-ABW and Group-IBW, respectively (p<0.01) [20]. OLPs were significantly higher in ABW group in overweight children, whereas it was higher in IBW group in underweight children, indicating that up-sizing provides a better fit compared to a smaller-sized LMA [21]. These findings differ from the present study, as these authors included children with abnormal BMI.

## Limitation(s)

The present study had a limited age group of only 2-10 years. Further studies with large sample size are required including both younger and older children. The present study was done under controlled ventilation, though the ease of insertion would have been defined better in spontaneously breathing patients.

# CONCLUSION(S)

The IBW can be a better predictor of I-gel size estimation as compared to ABW and age in paediatric patients. In the present study, selection of I-gel size on the basis of IBW resulted in better first attempt success rate and easier insertion with fewer complications than ABW and age. However, in regards to airway morbidity, weight be it ideal or actual, is better as compared to age for size selection.

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