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Original Research Article

Evaluation of auricle size based method for sizing of ProSeal LMA in paediatric population: A prospective observational study

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Abstract

Background and Aims: The weight-based method is the most commonly used approach for sizing the ProSeal laryngeal mask airway (PLMA) in paediatric patients. However, this method may not always be practical or reliable, particularly in situations where a patient's weight is unknown. This study aimed to evaluate the effectiveness of an auricle size-based method for PLMA sizing in children and its agreement with the conventional weight-based method. Additionally, we explored the association between Body Mass Index (BMI) and PLMA sizing using both methods.

Materials and Methods: This prospective observational study included 56 paediatric patients aged 2–12 years, classified as ASA I/II, undergoing elective surgeries under general anaesthesia. The auricle size-based method involved selecting a fully inflated PLMA that visually approximated the patient's auricle size. The first attempt at insertion was performed using the auricle size-based method, and if unsuccessful, the weight-based method was employed. The agreement between the two methods was assessed using Cohen's Kappa coefficient, and qualitative variables were analysed using the Chi-square test.

Results: Successful first-attempt PLMA insertion and effective ventilation were achieved in 40 out of 56 patients (71.43%) using the auricle size-based method. Among younger children (aged 2–7 years), the success rate was notably higher at 91.18% (31/34 patients). The agreement between the auricle size-based and weight-based methods was minimal ($\kappa = 0.21$). However, for patients aged ≤7 years, the agreement improved to fair ($\kappa = 0.39$, $p = 0.001$). There was no significant association between BMI and PLMA size determined by either the auricle size-based method (χ^2, $p = 0.379$) or the weight-based method (χ^2, $p = 0.128$).

Conclusions: The auricle size-based method can serve as a viable alternative for PLMA sizing in paediatric patients, particularly in scenarios where weight-based estimation is not feasible.

Keywords: ProSeal laryngeal mask airway, Pediatrics; Airway management; Supraglottic airway device.

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1. Introduction

Supraglottic Airway Devices (SADs), particularly the ProSeal Laryngeal Mask Airway (PLMA), are widely utilized in operating rooms, pre-hospital settings, emergency care, and as part of the ASA difficult airway algorithm across all age groups.[1,2] Selecting the appropriate LMA size in paediatric patients is crucial, as an improper fit can lead to complications such as difficult insertion, multiple attempts, mucosal injury, improper sealing, inadequate ventilation, gastric insufflation, high ventilatory pressures, and the need for repositioning.[3]

Since SAD insertion is a blind technique, its sizing should ideally be based on indirect anatomical measurements that correlate with the patient's hypopharyngeal anatomy.[4] The gold standard for PLMA sizing is the manufacturer's weight-based recommendations; however, this method may be unreliable in cases of overweight, underweight, or borderline-weight children, as well as in emergency

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situations where the child's weight is unknown (e.g., bedridden patients).[5]

To address these limitations, alternative methods such as the auricle size-based method and the three-finger width method have been proposed. These approaches are simple, quick to perform, reliable, and applicable at the bedside, making them practical options for paediatric airway management.[5] This study aimed to evaluate the effectiveness of the auricle size-based method for determining the appropriate PLMA size and to assess the association between Body Mass Index (BMI) and PLMA size as determined by both the auricle size-based and weight-based methods in normal BMI paediatric patients for better clinical outcome during patient care.

2. Materials and Methods

This prospective, observational study was conducted following approval from the Institutional Ethical Committee and registered with CTRI, India (CTRI/2018/05/013690). Paediatric patients aged 2–12 years, classified as ASA I and II, of either sex, undergoing elective surgeries under general anaesthesia, were enrolled. Patients requiring tracheal intubation, those with restricted mouth opening, risk of aspiration, upper airway abnormalities, or weight and height beyond the 5th–95th percentile were excluded. During the preoperative visit, written informed consent was obtained from parents or guardians, and demographic data, including age, sex, height, weight, and BMI, were recorded. ASA standard NPO guidelines were followed.

A fully inflated PLMA (with the maximum standard suggested volume), closely approximating the size of the auricle on visual inspection, was selected using the auricle size-based method. If the auricle size corresponded to an intermediate size between two standard PLMA sizes, the larger size was chosen to ensure an adequate seal (**Figure 1**).

Figure 1: Sizing of PLMA (fully inflated) by auricle-based method

A standard anaesthesia protocol was followed for all patients. On arrival in the operating room, intravenous access was established, and standard non-invasive monitoring was initiated. General anaesthesia was induced using injection fentanyl (2 µg/kg), injection propofol (1–2.5 mg/kg), and injection vecuronium (0.1 mg/kg) for neuromuscular blockade. After three minutes of bag-mask ventilation with 100% oxygen and 2% sevoflurane, a pre-lubricated PLMA sized according to the auricle size-based method was inserted by an experienced anaesthesiologist. The anaesthesiologist performing the insertion had successfully placed at least 20 PLMAs in mannequins and 10 in patients. The insertion was performed using the bougie method, and the cuff was inflated to a pressure of 60 cm H_2O using a cuff pressure monitor.

Successful PLMA insertion was confirmed by outward movement of the PLMA tube upon full cuff inflation, bilateral visible chest rise, a square wave capnograph, and successful passage of a Ryle's tube through the drain tube. If mechanical ventilation failed on the first attempt due to inadequate chest rise, improper capnograph, or an audible leak, a second attempt was made using the conventional weight-based method. If insertion failed after two attempts, tracheal intubation was performed using an appropriate-sized endotracheal tube (ETT). In cases where the PLMA size selected by the auricle size-based method matched the size determined by the weight-based method, the PLMA was inserted, and adequacy was assessed. If insertion failed, the PLMA was removed, and the patient was intubated with an endotracheal tube.

For borderline-weight patients, the first attempt was made using the auricle size-based method. If unsuccessful, the second attempt was made with a larger PLMA selected by the weight-based method. If both attempts failed, the patient was intubated with an ETT and excluded from the study (**Figure 2**).

Figure 2: Bougie method of PLMA insertion

Based on a study by Murat et al., assuming a 93.9% success rate and a β-error of 5%, a sample size of 56 patients was calculated using the formula: $n= [(Z_{\alpha/2})^2 pq]/ d^2$ where, p represents the observed success rate, q is 1 – p, and d is the margin of error. Qualitative variables were expressed as frequencies and percentages and were compared using the

Chi-square test. The agreement between techniques was measured using Cohen's Kappa coefficient, with a significance level set at $p < 0.05$, indicating statistical significance.[5]

3. Results

The study population consisted of paediatric patients aged 2–12 years, with the majority being ≤7 years old. The mean age of the participants was 6.38 ± 2.94 years, and 64% (36 patients) were males. Most patients had a normal BMI, with a mean BMI of 15.2 ± 2.28 (**Table 1**).

Successful PLMA insertion on the first attempt using the auricle size-based method was achieved in 40 patients (71.43%), while 16 patients (28.57%) required a second attempt using the weight-based method (**Table 1**).

Among children aged 2–5 years, 100% had successful PLMA insertion on the first attempt with the auricle size-based method, with no need for a second attempt. In the 2–7 years age group, 31 out of 34 patients (91.18%) had successful insertion. However, in the 8–12 years age group, the success rate dropped to 9 out of 22 patients (40.90%). A significantly higher success rate was observed in children aged ≤7 years compared to those >7 years ($p < 0.001$) (**Table 2**).

Minimal agreement was observed between the PLMA size determined by the auricle size-based method and the weight-based method in patients aged ≤7 years ($\kappa = 0.39$; $p = 0.001$) and in the overall 2–12 years age group ($\kappa = 0.21$; $p = 0.005$), both of which were statistically significant (**Table 3**, **Table 4**). However, no significant agreement was found in patients aged >7 years ($\kappa = 0.017$; $p = 0.829$).

No significant association was found between BMI and PLMA size determined by the auricle size-based method (χ^2, $p = 0.379$) or by the weight-based method (χ^2, $p = 0.128$).

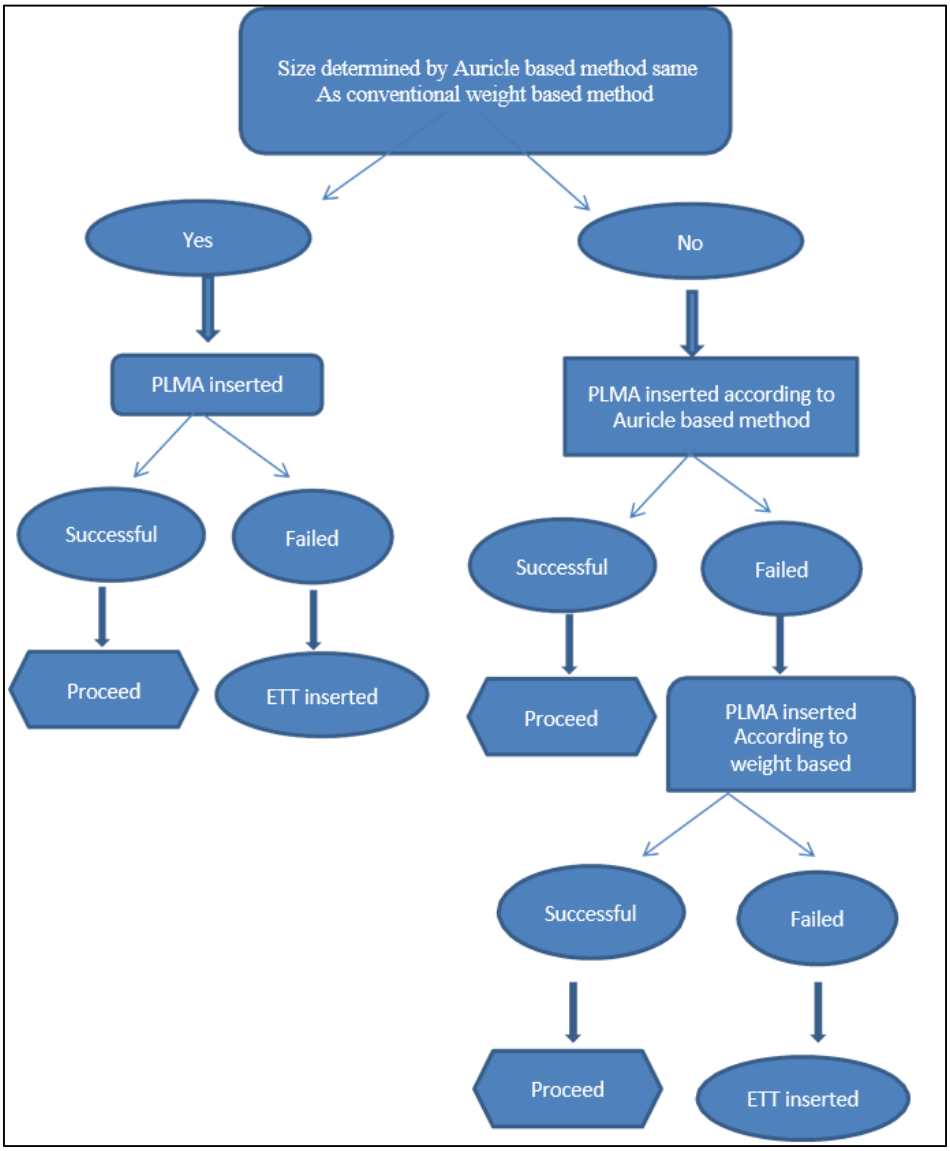

Figure 3: Flow chart for selection of PLMA size

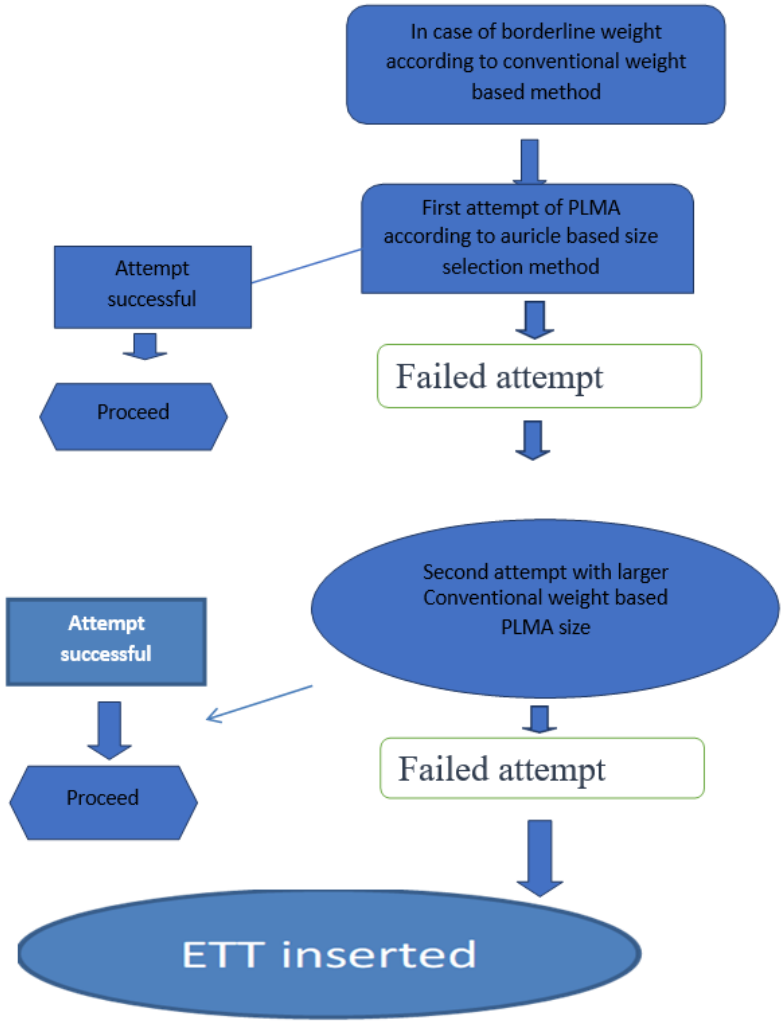

Figure 4: PLMA size selection in patients with borderline weight

Table 1: Demographic profile of study population and anaesthetic property

Demographic data and anaesthetic property	**Mean ± SD or number (%)**
Age(years)	6.38±2.94
Sex (females/males)	20(35.71%)/36 (64.29%)
Weight(kg)	20.25±6.49
Height(cms)	114.41±16.69
BMI (kg/m^2)	15.2±2.28
Success rate of placement–at first attempt auricle size-based method	40 (71.43%)
Success rate of placement–at second attempt auricle size-based method	16 (28.57%)

Table 2: Comparison of percentage of patients with successful PLMA insertion by using auricle method in patients aged ≤7 years and above 7 years

	≤7years	**>7years**	**Chi-square (p-value)**
Successful PLMA insertion (auricle based)	91.18%	40.90%	<0.001

Table 3: Agreement of PLMA size determined by auricle-based method and that by weight-based method in patients aged ≤ 7 years

PLMA as per Weight		PLMA Auricle			Chi-square (p-value)	Kappa (p-value)
		1.5	2	2.5		
	1.5	3	0	0		
	2	3	21	0	34.436	0.390
Weight						
					(<0.001)	(0.001)
	2.5	0	5	1		
	3	0	0	1		

Table 4: In study population 2-12 years, agreement of PLMA size determined by auricle-based method and that by weight-based method

PLMA asper Weight		PLMA Auricle			Chi-square (p-value)	"Kappa (p-value)"
		1.5	2	2.5		
Weight	1.5	3	0	0	48.364 (<0.001)	0.216 (0.005)
	2	3	24	0		
	2.5	0	20	4		
	3	0	0	2		

4. Discussion

This prospective, observational study was conducted on 56 paediatric patients aged 2–12 years to evaluate the effectiveness of the auricle size-based method for PLMA sizing in paediatric patients. The study demonstrated that 71.43% of patients had successful first-attempt insertion when the auricle size-based method was used. The success rate was significantly higher in younger children (2–7 years: 91.18%) compared to older children (8–12 years: 40.90%), highlighting that auricle size may be a more reliable predictor of PLMA size in younger age groups. A fair agreement was observed between the auricle size-based and weight-based methods, but no significant association was found between BMI and PLMA size determined by either method.

The selection of the correct PLMA size in paediatric patients remains challenging, primarily due to the lack of standardization in weight-based and age-based sizing method.[4] Various studies have attempted to determine the optimal PLMA size to ensure an adequate airway seal and reduce complications.[6-8] Proper PLMA sizing is crucial as it directly influences airway seal adequacy and is linked to postoperative sore throat incidence.[1,9-11]

Although the weight-based method is the most commonly used approach, manufacturer recommendations are not based on robust paediatric studies.[12] Furthermore, the first-attempt success rate of PLMA insertion in children is lower than in adults, suggesting a need for alternative sizing methods to improve airway management.[7]

Alternative methods, including the auricle size-based approach, have been investigated to enhance first-attempt success rates.[13,14] Auricle size has been explored as a potential predictor for PLMA sizing due to its correlation with hypopharyngeal growth and soft tissue development of the head and neck. Since craniofacial dimensions may not always align with weight, auricle size could serve as a more reliable predictor of PLMA size, particularly in younger children.[5,8]

In our study, we evaluated the auricle size-based method as an alternative approach for PLMA sizing in the paediatric population. To eliminate confounding variables related to insertion techniques, the bougie-guided method of PLMA insertion was chosen, as it has been reported to achieve a 100% success rate on the first attempt.[15,16]

The first-attempt success rate of PLMA insertion using the auricle size-based method was 71.43%, which is lower than that reported in previous studies (93.9% and 93.07%, respectively).[5,7] The probable reasons for these differences could be anthropometric variations across different study populations, such as Asian, Oriental, and Caucasian cohorts.

A statistically significant but minimal agreement ($\kappa = 0.21$; $p < 0.05$) was found between PLMA sizes determined by the auricle size-based method and the weight-based method. This contrasts with previous studies that reported good agreement ($\kappa = 0.62$; $p < 0.05$) and moderate agreement ($\kappa = 0.50$, $\kappa = 0.52$).[5-7]

An intriguing observation was made regarding PLMA size selection in children over 7 years of age. In 25 out of 56 cases, the auricle size-based method resulted in the selection of a PLMA size smaller than that recommended by the weight-based method. This could be attributed to the minimal growth in auricle width after the age of 7, which may limit its

reliability as a predictor of PLMA size in older paediatric patients.

In 20 cases within our study, a size 2 PLMA was selected based on the auricle size-based method, despite the weight-based method recommending a size 2.5 in patients over 7 years old. This contrasts with previous studies, where the auricle size-based method predominantly favoured size 2.5.[6,7] The discrepancy may be explained due to differences in interpretation, where previous studies may have chosen the larger size (2.5) when auricle size appeared slightly larger than size 2, even if it seemed disproportionate. Our study also adhered to a similar principle, where if the auricle size fell between two standard PLMA sizes, the larger size was chosen. This approach was intended to account for natural variations in auricle size and ensure an adequate airway seal. However, the observed disparity in size selection between our study and previous research could be attributed to observer bias or differences in PLMA models used. Notably, our study employed fully inflated PLMA models, whereas previous studies used fully deflated or partially inflated models with room air. [6,7] Minimal growth in auricle size occurs after the age of 7, which may limit the reliability of the auricle size-based method in older paediatric patients. This finding highlights the complexity of PLMA size selection in children over 7 years and highlights the need for standardization and careful consideration when using the auricle size-based method in this age group.

The percentage of successful PLMA insertion using the auricle size-based method was significantly higher in the 2–7 years age group (91.18%) compared to 8–12 years (40.90%). Several factors may explain this difference: (a) Ear size is more dependent on age rather than body size, making age-based PLMA prediction more reliable. (b) In children older than 7 years, auricle size may no longer correlate well with PLMA size, as auricular growth plateaus. (c) After 7 years of age, pinna growth is predominantly in length rather than width, whereas in younger children (<7 years), growth occurs in both dimensions, making it a better predictor for PLMA sizing. (d) There are inter-individual subjective variations in visualizing auricle size, which may contribute to discrepancies. (e) The older age group (>7 years) constituted 39.29% of our sample size, whereas in a previous study, only 15.73% (31 out of 197) of the study population fell into this category, potentially influencing results.[5,8,17,18]

The lack of significant agreement between the auricle size-based and weight-based methods in children older than 7 years ($p > 0.05$), although clinically relevant, was likely influenced by the small sample size in this subgroup.

Since BMI is highly dependent on height, it was hypothesized that PLMA size determined by the auricle size-based method might be associated with BMI. Therefore, we examined any correlation between BMI and PLMA size using both the auricle size-based and weight-based methods. However, no significant association was found between BMI and PLMA size determined by the auricle size-based method ($p = 0.379$) or the weight-based method ($p = 0.128$). This could be due to the higher representation of a particular BMI group in our study or the limited sample size. Another possible explanation is that patient demographics and hypopharyngeal geometry vary significantly, making BMI an inconsistent predictor of PLMA size.[19]

This study also had certain limitations. The exclusion of children younger than 2 years and underweight or overweight children (below the 5th percentile and above the 95th percentile) restricts the generalizability of findings to paediatric patients with atypical growth patterns and congenital anomalies. Additionally, the small sample size limits the statistical power of the study, emphasizing the need for further research with larger and more diverse populations to validate the findings. Future studies should also explore the applicability of the auricle size-based method in emergency scenarios, where weight measurements may not be feasible.

5. Conclusion

The auricle size-based method for PLMA sizing is a practical and effective alternative to the weight-based method, especially in younger children and situations where weight is unknown. This method could serve as a reliable bedside tool for airway management. However, further studies are required to validate these findings in broader paediatric populations, including those with atypical growth patterns and in emergency settings.

6. Source of Funding

None.

7. Conflict of Interest

None.

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