Section: Anaesthesiology

Original Research Article

COMPARATIVE STUDY ON SELECTION OF PROSEAL LARYNGEAL MASK AIRWAY SIZE USING PINNA SIZE AND WEIGHT OF THE PAEDIATRIC POPULATION – RANDOMISED CONTROLLED TRIAL

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Abstract

Background: The ProSeal laryngeal mask airway is crucial in preventing airway trauma, inadequate ventilation, and postoperative sore throat. Weight-based selection is often impractical in emergencies, especially in obese, undernourished, and bedridden children. This study aimed to compare the size selection of the ProSeal laryngeal mask airway by measuring the vertical and horizontal dimensions of the pinna with the standard weight-based technique among the paediatric population. **Materials and Methods:** This was a prospective, interventional, randomized controlled study conducted at the Department of Anesthesia, ESIC Medical College & Hospital, Chennai. A total of 128 paediatric patients between 1 year and 15 years of age of both sexes with ASA status I and II scheduled for elective surgeries under general anaesthesia satisfying the inclusion criteria were randomly selected and allocated into groups P and W by the closed envelope method. **Result:** There was no significant difference between the two groups, with an average age of 9.6 ± 4 years (51.6% females and 48.4% males). Most PLMAs were effective on the first attempt (93.8% in group P and 92.2% in group W, p = 1.000), and the insertion times were comparable (group P: 75.8 ± 3.1 seconds, group W: 75.1 ± 3.1 seconds, p = 0.224). Vital signs, including heart rate and blood pressure, remained stable with no significant differences between the groups. In addition, the peak airway and cuff pressures showed no significant variation (p = 0.083). **Conclusion:** Pinna size-based selection is a practical and workable substitute for the conventional weight-based selection of the ProSeal laryngeal mask airway.

INTRODUCTION

The ProSeal laryngeal mask airway's (PLMA) ideal size selection determines where it was placed successfully.[1,2] Improper size selection leads to airway trauma, inadequate ventilation, and sore throat post-operatively.[2,3] The most commonly used method is based on the patient's weight.[4] weight-based selection is not possible to measure in case of emergency surgery, during resuscitation of an obese and undernourished child, or chronically bedridden child.[5] Studies have shown that airway growth correlates well with pinna growth.[6] This study compared size selection based on weight and pinna size to determine the appropriate size for a better seal, and evaluated the time taken for PLMA insertion, ease of insertion, and ease of gastric tube placement.

Aim

This study aimed to compare the size selection of the ProSeal laryngeal mask airway by measuring the vertical and horizontal dimensions of the pinna with the standard weight-based technique among the pediatric population.

MATERIALS AND METHODS

This prospective, interventional, double-blinded, randomized controlled trial included 128 children scheduled for surgeries at the ESIC Medical College and Hospital, K.K. Nagar, Chennai, fulfilling the inclusion criteria from March 1, 2023, to August 31, 2024. This study was approved by the Institutional Ethics Committee (IEC/2023/1/28) before initiation, and informed consent was obtained from all patients.

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Inclusion criteria

The study included children aged 1–15 years of either sex, with American Society of Anesthesiologists (ASA) physical status I or II, whose parents/guardians provided written informed consent and were scheduled for short-duration surgeries under general anaesthesia with PLMA insertion, including circumcision, herniotomies, anal or urethral dilatation, appendectomy, hernia repair, orchidopexy, lymph node excision, hypospadias repair, abscess drainage, and cyst excision.

Exclusion criteria

Patients with anticipated difficult airways, refusal by patients or parents/attenders, history of obstructive sleep apnea, congenital ear anomalies, surgeries involving the airway, risk of aspiration, recent respiratory tract infections, mental retardation, congenital heart disease, asthma, and syndromic congenital conditions were excluded from the study.

Methods

Patients were randomised into two groups using a random number table, with 128 non-repeating numbers divided equally into group P (PLMA based on pinna size) and group W (PLMA based on weight). Numbers are written in envelopes by a team member, with group assignments placed on cards inside sealed envelopes arranged in ascending order. Each participant selected a sealed envelope to ensure equal chances of assigning and blinding to their group. The age and weight of the patients were recorded on the day before the study. On the day of surgery, an anesthesiologist not involved in the study determined PLMA size based on pinna size; for groups P and W, PLMA size was determined based on weight.

A pre-anesthetic check and routine investigation were performed. All patients were kept nil per oral as per the protocol. In the operating theatre, monitors (non-invasive blood pressure, ECG, SpO_2, HR) were connected, an IV line secured, and fluids were started using the 4-2-1 rule. Pre-medication included Injection of Glycopyrrolate (5 mcg/kg IV for >5 years) or Injection of Atropine (10 mcg/kg IV for <5 years), Injection of Midazolam (0.05 mg/kg IV), and Injection of Fentanyl (2 mcg/kg IV). After ensuring adequate oxygen saturation, children were pre-oxygenated and induced with an Injection of Propofol (2–3 mg/kg IV) and Atracurium (0.5 mg/kg IV).

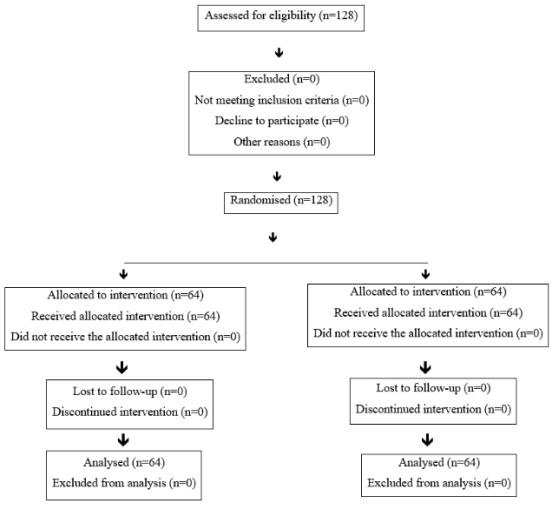
The PLMA was inserted using a standard technique after 3 min of mask ventilation, with cuff inflation monitored by a pressure monitor. Correct placement was confirmed by bilateral air entry, the absence of audible leaks, and square-wave capnography. Placement effectiveness was scored (3 = effective sealing; <3 = ineffective sealing). Once sealed, ventilation begins with a tidal volume of 7–10 ml/kg and a respiratory rate adjusted to maintain $EtCO_2$ at 35–40 mmHg.

The ease of PLMA insertion and the time to placement (introduction to normal capnogram) were recorded and graded: one, no resistance, two for mild resistance, three for moderate resistance, or four, inability to place. Ease of gastric tube placement was also assessed. Practical placement was confirmed by aspirating the gastric contents or by epigastric auscultation. Failed PLMA attempts result in intubation using conventional laryngoscopy.

Anesthesia was maintained using oxygen (50%), nitrous oxide (50%), and sevoflurane (MAC 0.6–1.6). Hemodynamic parameters (SBP, DBP, MAP, HR, SpO_2, and ECG), ventilator peak airway pressure, and cuff pressure were recorded before induction, at induction (0 min), and 1, 3, 5, 10, 15, 30, 45, and 60 min after PLMA placement. At the end of the procedure, residual neuromuscular blockade was reversed with an Injection of Neostigmine (50 mcg/kg IV) and either Injection of Glycopyrrolate (10 mcg/kg IV for >5 years) or Injection of Atropine (20 mcg/kg IV for <5 years). Once fully awake, the PLMA was removed, and hemodynamic parameters were monitored at 1, 3, 5, and 10 min, followed by monitoring in the PACU for 30 min before transfer to the postoperative ward.

Statistical analysis

Data are presented as mean, standard deviation, frequency, and percentage. Continuous variables were compared using the independent sample t-test and repeated-measures measures ANOVA. Categorical variables were compared using Pearson's chi-square test. Significance was defined as $p < 0.05$, using a two-tailed test. Data analysis was performed using IBM-SPSS version 21.0 (IBM-SPSS Corp., Armonk, NY, USA).



RESULTS

The majority of patients in both groups were aged 11–15 years, with 32 patients (50%) in Group P and 26 patients (40.6%) in Group W. In the 6–10 years age group, Group W had 28 patients (43.8%) compared to 21 patients (32.8%) in Group P. The 1–5 year age group was smaller in both groups, with 11 patients (17.2%) in Group P and 10 patients (15.6%) in Group W, with no significant difference ($p = 0.434$).

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The gender distribution was identical in both groups, with 33 females (51.6%) and 31 males (48.4%) in each group (p = 1.000).

The proportion of patients with ASA class I was slightly higher in Group W (33 patients, 51.6%) than in Group P (32 patients, 50%). The ASA class II included 32 patients (50%) in Group P and 31 patients (48.4%) in Group W, with no significant difference (p = 0.860).

MMS I was noted in 32 patients (50%) in Group P and 30 patients (46.9%) in Group W, whereas MMS II was present in 32 patients (50%) in Group P and 34 patients (53.1%) in Group W, with no significant difference (p = 0.724).

Bilateral air entry was slightly more common in Group P (63 patients, 98.4%) than in Group W (61 patients, 95.3%), while its absence was observed in one participant (1.6%) in Group P and three patients (4.7%) in Group W, with no significant difference (p = 0.619).

None of the patients in either group showed the presence of an audible leak, with all patients in Groups P and W (64 patients, 100%) exhibiting an absence of an audible leak.

Square-wave capnograph appearance was noted in 61 patients (95.3%) in Group P and 62 patients (96.9%) in Group W, with three patients (4.7%) in Group P and two patients (3.1%) in Group W, with no significant difference (p = 1.000).

Successful insertion on the first attempt was slightly higher in Group P (60 patients, 93.8%) than in Group W (59 patients, 92.2%). A second attempt was required in 4 patients (6.3%) in Group P and 5 patients (7.8%) in Group W, with no significant difference (p = 1.000).

Most patients in both groups had Grade I ease of insertion, with 60 patients (93.8%) in Group P and 59 patients (92.2%) in Group W. Grade II ease was noted in three patients (4.7%) in Group P and four patients (6.3%) in Group W, while Grade III ease was observed in one participant (1.6%) in both groups, with no significant difference (p = 0.927).

Both groups demonstrated identical results, with 59 patients (92.2%) achieving Grade I ease of gastric tube insertion and five patients (7.8%) requiring Grade II ease in both Group P and Group W (p = 1.000) [Table 1].

The mean weight of the patients was similar between groups P (27.5±8.9 kg) and W (27.5±8.2 kg), with no significant difference (p=0.984). The average height of patients was also almost identical, with group P at 130.5±24.9 cm and group W at 131.0±21.0 cm (p=0.89). The duration of surgery was similar for both groups, with group P at 33.9±5.9 minutes and group W at 33.5±5.2 minutes, showing no significant difference (p=0.692). The average PLMA size used was the same for both groups (2.6±0.5 in group P and 2.6±0.4 in group W), and no significant difference was found (p=0.695).

The time taken for placement of the PLMA was also similar between the two groups, with group P taking 75.8±3.1 seconds and group W taking 75.1±3.1 seconds (p=0.224). The peak airway pressure was slightly lower in group P (26.4±1.6 cm H2O) compared to group W (26.9±1.7 cm H2O), but this difference was not significant (p=0.083). The cuff pressure was very similar in both groups, with group P at 56.7±1.2 cm H2O and group W at 56.8±1.0 cm H2O, showing no significant difference (p=0.758) [Table 2].

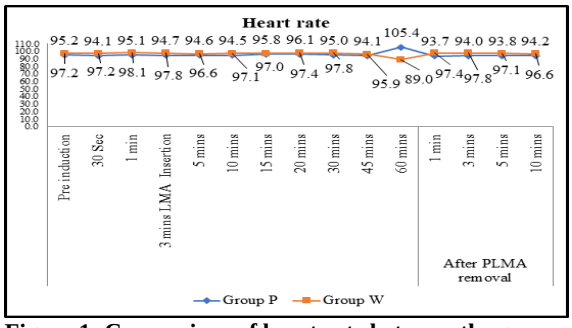

Figure 1: Comparison of heart rate between the groups

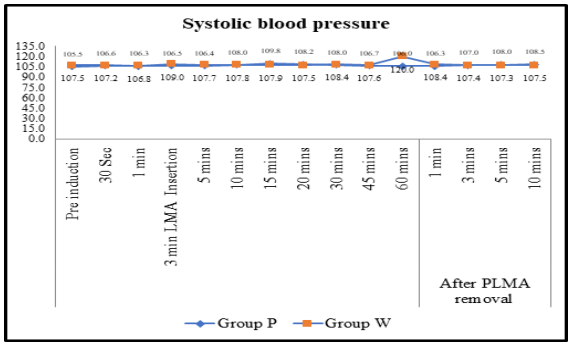

Figure 2: Comparison of SBP between the groups

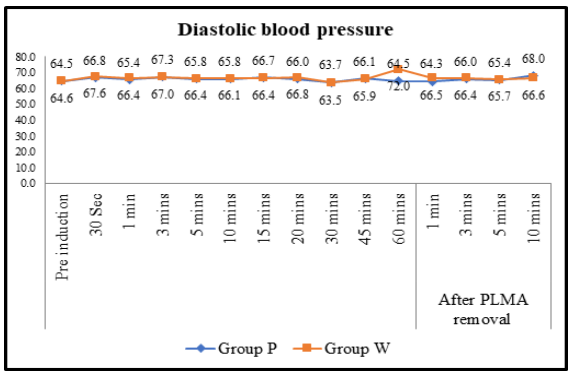

Figure 3: Comparison of DBP between the groups

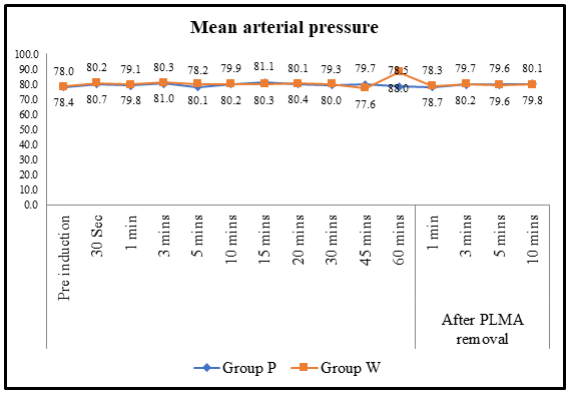

Figure 4: Comparison of MAP between the groups

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The comparison of heart rate between groups at all time durations showed no significant difference ($p > 0.05$) [Figure 1].

The comparison of SBP between groups at all time durations showed no difference ($p > 0.05$) [Figure 2].

The comparison of DBP between groups at all time durations showed no significant difference ($p > 0.05$) [Figure 3].

The comparison of MAP between groups at all time durations showed no significant difference ($p > 0.05$) [Figure 4].

Table 1: Comparison of characteristics and outcomes between groups.

		Count (%)		P-value
		Group P	Group W	
Age (in years)	1-5	11 (17.2%)	10 (15.6%)	0.434
	6-10	21 (32.8%)	28 (43.8%)	
	11-15	32 (50%)	26 (40.6%)	
Gender	Female	33 (51.6%)	33 (51.6%)	1.000
	Male	31 (48.4%)	31 (48.4%)	
ASA	I	32 (50%)	33 (51.6%)	0.860
	II	32 (50%)	31 (48.4%)	
MMS	I	32 (50%)	30 (46.9%)	0.724
	II	32 (50%)	34 (53.1%)	
Presence of bilateral air entry	0	1 (1.6%)	3 (4.7%)	0.619
	1	63 (98.4%)	61 (95.3%)	
Absence of audible leak	1	64 (100%)	64 (100%)	NA
Appearance of square wave capnograph	0	3 (4.7%)	2 (3.1%)	1.000
	1	61 (95.3%)	62 (96.9%)	
Insertion attempts	1	60 (93.8%)	59 (92.2%)	1.000
	2	4 (6.3%)	5 (7.8%)	
Ease of PLMA insertion	I	60 (93.8%)	59 (92.2%)	0.927
	II	3 (4.7%)	4 (6.3%)	
	III	1 (1.6%)	1 (1.6%)	
Ease of insertion of gastric tube	I	59 (92.2%)	59 (92.2%)	1.000
	II	5 (7.8%)	5 (7.8%)	

Table 2: Comparison of mean ± SD between groups

	Mean±SD		P-value
	Group P	Group W	
Weight (kg)	27.5±8.9	27.5±8.2	0.984
Height (cm)	130.5±24.9	131.0±21.0	0.89
Duration of surgery (mins)	33.9±5.9	33.5±5.2	0.692
PLMA size	2.6±0.5	2.6±0.4	0.695
Time taken for placement (sec)	75.8±3.1	75.1±3.1	0.224
Peak airway pressure (cm H2o)	26.4±1.6	26.9±1.7	0.083
Cuff pressure (cm H2o)	56.7±1.2	56.8±1.0	0.758

DISCUSSION

In our study, there was no significant difference between the two groups in terms of the measured parameters. The findings align with those of Mishra et al. and show comparable PLMA placement between the groups, which concluded that Pinna size–based estimation of LMA size is an effective alternative to weight-based selection.[7]

In our study, a comparison of insertion attempts between groups using Pearson's chi-square test showed no significant difference. Another relevant study by Haliloglu et al. concluded that Auricle-based PLMA size selection is a valid and practical alternative that is instrumental in situations where patient weight is unknown, such as emergencies.[8]

Our study excluded paediatric cases under one year of age, where the placement of a supraglottic device is crucial. As a prospective trial, only 128 patients were included using convenience sampling; further adequately powered trials are required.

CONCLUSION

Pinna size-based selection is a practical and workable substitute for the conventional weight-based selection of the ProSeal laryngeal mask airway.

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