Original Article

Comparison of weight-based and pinna size-based selection of ProSeal laryngeal mask airway in paediatric population – A prospective exploratory trial

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ABSTRACT

Background and Aims: Weight-based selection of ProSeal laryngeal mask airway (PLMA) size may be unreliable in some situations. The aim of this study was to compare the ventilation parameters using PLMA during controlled ventilation between weight-based size selection and pinna size–based selection in children. **Methods:** A total of 204 patients were randomised to receive either pinna size–based (Group P) or weight-based (Group W) size selection of PLMA. We tested the hypothesis that pinna size–based selection of PLMA was better than weight-based selection of PLMA in paediatric patients during controlled ventilation under general anaesthesia in terms of oropharyngeal sealing pressure (the primary end-point) and Brimacombe score. Cuff pressure was maintained at 60 cm of H_2O during the study. Secondary outcomes included the number of attempts for successful placement of PLMA, peak airway pressure, gastric tube placement, traumatic insertion, and complications were also compared. Parametric variables were analysed using unpaired *t*-test and categorical variables were analysed using Mann–Whitney and Chi-square test. **Results:** In all, 200 patients were analysed. The mean oropharyngeal sealing pressure in Group P was 25.4 ± 3.5 cmH_2O and 24.9 ± 3.8 cmH_2O in Group W, ($P = 0.34$). There was no significant difference between the two groups in any of the secondary outcomes. There were no traumatic insertion or complications reported in both the groups. **Conclusion:** Pinna-based size selection method can be used in PLMA placement in the paediatric population for positive pressure ventilation and it serves as an alternative method to weight-based selection.

Key words: Paediatric airway, pinna size, ProSeal laryngeal mask airway, size selection

INTRODUCTION

Optimal size selection of ProSeal laryngeal mask airway (PLMA) establishes its successful placement.[1,2] Inappropriate size selection leads to inadequate ventilation, trauma to the periglottic structure, and postoperative sore throat.[2,3] Sex-based and weight-based size calculation are commonly used in adults.[4] In children, weight-based selection is the most commonly used method. But when the weight of the patient is difficult to measure as in the case of emergency surgery, chronically bedridden child, and during resuscitation of an obese or undernourished child, weight-based calculation is not reliable.[5] Thus, an alternate method of size selection of laryngeal mask airway other than conventional weight-based method is warranted.[6-8] Pinna size had been tried for choosing laryngeal mask airway size as the upper respiratory tract growth correlates with the growth of soft tissue of head and neck.[9] This study was intended to compare the ventilatory parameters in pinna size–based selection and weight-based selection

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of PLMA in terms of oropharyngeal sealing pressure and Brimacombe score.

METHODS

The scientific approval for the conduct of the study was obtained on 7th October 2014 from the Institute Post Graduate Research Monitoring Committee (Reg. No.: PGMRC/ANAES/11/2014). The ethical approval for the study was obtained from Institute Ethics Committee (human studies) (Reg. No.: ECR/342/Inst/PY/2013) on 6th January 2015. The study carries minimal risk. Written informed consent was obtained from all the study participants before enrolment into the study. The trial was registered in Clinical Trials Registry – India. The registration number is as follows: CTRI/2015/09/006218. This study is a prospective exploratory study conducted between October 2015 and October 2017.

A total of 204 American Society of Anaesthesiologist (ASA) status 1 and 2 children between the age group of 6 months and 12 years were included in the study [Figure 1]. Parent/guardian was also provided with the information leaflet regarding the study on the previous day before the consent was taken. Assent was taken from the children between the age group of 8 and 12 years. Children with anticipated difficult airway, history of obstructive sleep apnoea, congenital anomalies involving ear, surgery involving the airway, risk of aspiration, and recent history of respiratory tract infection were excluded from the study.

Consented study participants were randomised using a computer-generated random numbers in varying block sizes on a 1:1 ratio. Randomisation was done using Random Allocation Software 2.0. Allocation results were concealed in sealed opaque envelopes.

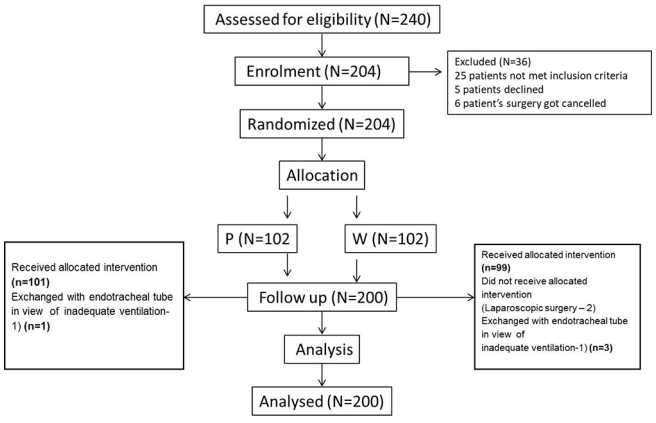

Figure 1: CONSORT flow diagram

The research coordinator handed one envelope per patient to the anaesthesiologist who chose the PLMA. The research coordinator who collected the outcome measures was blinded to the allocation results.

Study participants received the intervention according to their allocation group as follows:

1. Group P – received PLMA based on pinna size
2. Group W – received PLMA based on weight.

Age and weight of the patient were noted on the previous day of the study. On the day of the surgery, in the preoperative holding area, PLMA size was chosen by an anaesthesiologist not involved in the study or the case. If the child was randomised to group P, the anaesthesiolgist checked the PLMA size with pinna size and decided PLMA size compared with pinna size (outer margin of both); the cuff was inflated to atmospheric pressure by leaving the pilot balloon open and closing it once it filled spontaneously [Figure 2]. If pinna size fell between any two sizes, larger size PLMA was selected. If the study participant was in Group W, PLMA was selected based on the weight of the patient. The second anaesthesiologist doing the case inserted the PLMA chosen by the first person.

All participants received routine premedication 15 min before the surgery in the preoperative holding area as per the attending anaesthesiologist. Inside the operation theatre, monitors were connected to the patient (non-invasive blood pressure, electrocardiography and SpO_2). An intravenous line was secured after sevoflurane induction (up to 8%). Fentanyl (1–2 mcg/kg) and atracurium 0.5 mg/kg were given. After 3 min of mask ventilation, the selected PLMA was placed. PLMA

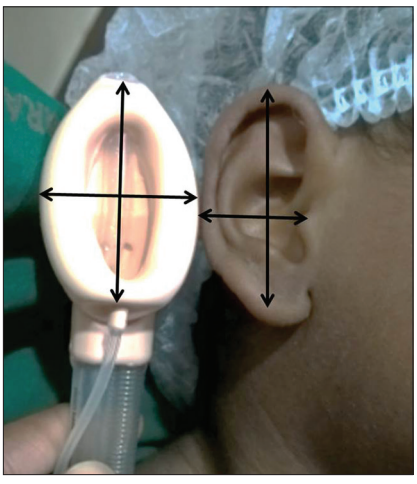

Figure 2: Depicts the size determination of PLMA based on pinna size by comparing the outer margin of the PLMA and the pinna of the child

insertion in both the groups was with the standard technique (index finger technique in midline approach and head in sniffing position). The cuff of the PLMA in both the groups was inflated up to 60 cm of H_2O and the cuff pressure was monitored using cuff pressure monitor. Successful insertion of PLMA was characterised by (1) slight upward movement of PLMA on inflation of cuff; (2) bilateral expansion of the chest; (3) presence of bilateral air entry; (4) absence of audible leak; and (5) appearance of square wave capnography.

The number of attempts in which successful insertion of PLMA was obtained was noted. (Three attempts were allowed). More than three attempts were as taken as failure, and it was followed by the conventional endotracheal tube insertion. Peak airway pressure (cmH_2O) was recorded when the patient was ventilated with the volume control ventilator mode at 10 mL/kg bodyweight of tidal volume. Oropharyngeal leak pressure (cmH_2O) (Datex-Ohmeda S/5 anaesthesia delivery system GE Model No. USE 1503A, USA.) was measured using aneroid manometer and ventilator pressure time scalar when the audible leak was present (measured by auscultation over the anterior part of neck) around the PLMA when the patient was put on to bag mode while the adjustable pressure limiting valve was fully closed with 3 L/min flow. Visualisation of glottis was determined by passing a fibreoptic bronchoscope through the airway tube to a position 1 cm proximal to the aperture of the PLMA airway tube. The airway tube view was scored using the Brimacombe scoring system which is graded as follows: 1: vocal cords not seen; 2: vocal cords plus anterior epiglottis seen; 3: vocal cords plus posterior epiglottis seen; 4: only vocal cords visible. Appropriate size gastric tube was placed in the drain tube according to the manufacturer's recommendation. Correct gastric tube placement was assessed by suction of fluid through the drain tube or detection of injected air by epigastric-stethoscopy. Ease of insertion of the PLMA was assessed by Likert scale (Easy/Difficult) by the attending anaesthesiologist. At the end of the procedure, neuromuscular blockade was reversed with 0.05 mg/kg of neostigmine and 0.01 mg/kg of glycopyrrolate. PLMA was removed once the child became fully awake. Traumatic insertion of PLMA was assessed by the presence of blood stain on it after its removal. Complications (if present) in the postoperative period were noted in both the groups. The primary outcomes of the study were oropharyngeal leak pressure and Brimacombe score. The secondary outcomes included (1) successful placement of PLMA, (2) number of attempts taken for successful placement of PLMA, (3) peak airway pressure, (4) traumatic insertion, and (5) complications.

SPSS for Windows statistical package (version 19; IBM, USA) was used for analysis. Sample size was taken as a minimum of 100 in each group as there were no previous studies comparing ventilator parameters between pinna size–based selection method and weight-based size selection method of PLMA. Considering the study period of 2 years and paediatric population undergoing surgery under general anaesthesia with PLMA placement, we arbitrarily took a minimum of 100 cases in each group. The sampling technique used was convenience sampling.

We performed our analysis under the assumptions that (1) the two groups were independent, (2) the source population of our data was normally distributed, and (3) variances within each group were equal. We presented our continuous data as mean (standard deviation) and categorical data as numbers and percentages. All parametric variables were analysed using unpaired *t*-test, Brimacombe score was analysed using Mann–Whitney *U*-test and other categorical data were analysed using Chi-square test. *P* value of less than 0.05 was considered as significant.

RESULTS

In all, 204 children were included in the study. One patient in Group P had inadequate sealing of PLMA after placement and the PLMA was replaced with an endotracheal tube. Two cases in Group W were planned to undergo laparoscopic procedure and the plan was changed to endotracheal tube placement, and one case in the same group had inadequate sealing after PLMA placement required replacement with endotracheal tube. These four cases were excluded from the statistical analysis. Thus, 101 cases in Group P and 99 cases in Group W (total = 200) completed the study protocol and their data were analysed [Figure 1].

Demographic details of the cases in Groups P and W which includes age, sex, weight, ASA classification and type of surgery were similar between the groups and found to have no significant statistical difference [Table 1]. The proportion of patients with a particular size of PLMA was similar between the groups [Table 2].

Successful placement of PLMA was achieved in the first attempt in 93.07% of patients in Group P and

90.91% of patient in Group W [Table 2]. The number of attempts taken by the anaesthesiologist for successful placement of PLMA and ease of insertion were similar in both the groups [Table 2].

Peak airway pressure and oropharyngeal sealing pressure were found to be similar between the groups [Table 3]. There was no significant difference between the two groups in terms of oropharyngeal sealing pressure in the age group less than or equal to 1 year [Table 3].

We also analysed the presence of oropharyngeal sealing pressure <20 cm of H_2O in both the groups [Table 2], and it was found to have no significant difference. Fibreoptic assessment of glottis view through the airway tube was also found to be similar in both the groups [Table 2]. There was no traumatic insertion in both the groups. Gastric tube was placed in all cases successfully by the anaesthesiologist without difficulty in both the groups. There were no complications reported in the study population in either of the groups in the study period.

Table 1: Demographic details

Parameters	Group P *n*=101	Group W *n*=99	*P*
Age (years) mean±SD	5.17±3.52	5.04±3.4	0.791
Gender (M/F)	89/12	86/13	0.789
Weight (kg) mean±SD	15.95±8.01	16.52±8.12	0.619

DISCUSSION

PLMA has been regularly used in paediatric patients undergoing surgery under general anaesthesia.[1] However, the success rate of insertion at first attempt is lower than in adults. One of the reasons suggested is the size selection of PLMA based on patient's body weight. Alternative methods of size calculation have been proposed.[6-8] Since airway growth correlates with the growth of the pinna, attempts have been made to use pinna size as a replacement for weight-based method to select PLMA size in paediatric population.[9]

This study demonstrates that there is no significant difference between the pinna-based size selection group and weight-based size selection group in terms of (1) first attempt success in PLMA placement, (2) number of attempts for successful placement, (3) peak airway pressure, (4) oropharyngeal sealing pressure, (5) Brimacombe score, (6) traumatic insertion, and (7) complications. It also demonstrated that pinna size–based method can be used as an alternative method to weight-based method.

Our study demonstrates that first attempt success in PLMA placement in pinna group is 93.07% which is similar to that found in a study conducted by Zahoor *et al.*[7] using classic laryngeal mask airway (93.31%). We did not find statistical difference between the groups in terms of the number of attempts taken

Table 2: Size distribution of PLMA and factors predicting successful placement of PLMA in study population

Parameter	Group P (*n*=101) % within group	Group W (*n*=99) % within group	Total *n*=200 (100%)	*P*
PLMA size				
1.5	24 (23.76%)	24 (24.24%)	48 (24%)	0.057
2	46 (45.54%)	50 (50.51%)	96 (48%)	
2.5	31 (30.69%)	20 (20.20%)	51 (25.50%)	
3	0 (0%)	5 (5.05%)	5 (2.50%)	
B) No .of. attempts				
1	94 (93.07%)	90 (90.91%)	184 (92%)	0.36
2	7 (6.93%)	7 (7.07%)	14 (7%)	
3	0 (0%)	2 (2.02%)	2 (1%)	
C) Ease of insertion				
Easy	94 (93.07%)	90 (90.91%)	184 (92%)	0.57
Difficult	7 (6.93%)	9 (9.09%)	16 (8%)	
D) Oropharyngeal sealing pressure (<20 cm of H_2O)	3 (2.9%)	7 (7.1%)	10 (5%)	0.19
E) Brimacombe score				
1	1 (0.99%)	3 (3.03%)	4 (2%)	0.98
2	28 (27.72%)	24 (24.24%)	52 (26%)	
3	53 (52.48%)	54 (54.55%)	107 (53.5%)	
4	19 (18.81%)	18 (18.18%)	37 (18.5%)	

Table 3 Peak airway pressure and Oropharyngeal sealing pressure

Parameter (Mean±SD)	Group P *n*=101 (cm of H_2O)	Group W *n*=99 (cm of H_2O)	*P*
A) Peak airway pressure	14.64±1.99	14.75±2.06	0.69
B) Oropharyngeal Sealing pressure	25.42±3.54	24.92±3.77	0.34
C) Oropharyngeal Sealing pressure (Age ≤1 year)	24.13±3.58	24.63±4.53	0.73

for successful placement though two cases of weight-based group (W) had three attempts for its successful placement unlike pinna-based group (P) which did not have any case requiring more than two attempts.

Cuff pressure was monitored in the study after PLMA placement, and the cuff had been filled with minimum volume of air required to maintain cuff pressure of 60 cm of H_2O. None of the cases in both the groups had traumatic insertion and postoperative complications including sore throat which is similar to the finding in previous studies conducted by Maino *et al.*[10] and Wong *et al.*[11] in which cuff pressure less than 60 cm of H_2O was associated with lesser incidence of sore throat. It also suggests that intraoperative monitoring of cuff pressure reduces pharyngolaryngeal morbidity.[12]

There is no significant difference between the mean oropharyngeal sealing pressure between the groups. The mean oropharyngeal pressure in the pinna group was 25.4 ± 3.5 cm of H_2O which is similar to optimal LMA size group in a study conducted by Berry *et al.*[4] in which the mean oropharyngeal sealing pressure was found to be 25 cm of H_2O. Thus, pinna-based size selection can be used as an alternative method of size selection for positive pressure ventilation. The mean oropharyngeal sealing pressure in PLMA group in study conducted by Brimacombe *et al.*[2] was 27 ± 7 cm of H_2O.

PLMA can be used as a conduit for fibreoptic intubation in a difficult airway scenario.[13] The ease of intubation through the airway tube in PLMA can be assessed by fibreoptic view of glottis through the airway tube.[13,14] Our study demonstrated that 71.28% cases in Group P had view more than score 3 which is similar to a previous study.[15]

There was no traumatic insertion in both the groups which was assessed by the inspection of PLMA for blood stain over it after its removal at the end of the procedure. Gastric tube was placed in all cases successfully by the anaesthesiologist without difficulty in both the groups. There were no complications reported in the study population in either of the groups in the study period.

We could not find a statistically significant difference between the two groups. The possible reason could be that the patient population in this study consisted of normal-sized patients, in whom we do not expect weight-based method to fail.

Our study confirms that pinna size can be used as an alternative for weight-based method in the study population. The weight-based method is expected to fail in undernourished or overweight children.

This study has few limitations. Our study did not include paediatric cases less than 6 months of age group in which placement of supraglottic device is crucial. We did not categorise them based on weight percentile. Since it was a prospective exploratory trial and only two hundred and four patients were included based on convenience sampling, further adequately powered trials are required.

CONCLUSION

Our study concludes that pinna based size selection of PLMA can be used as an alternative method to weight based size selection in age groups between 6 months and 12 years of age.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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