Original Article

Comparison of weight-based and pinna size method for ProSeal laryngeal mask airway size selection in children receiving general anesthesia: A randomized clinical study

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Abstract

Background and Aims: Several methods are in use for LMA ProSeal™ size selection in pediatric patients. Weight-based method is most commonly used. Pinna size–based method is a promising new technique for accurate size selection.

Material and Methods: A total of 146 children aged between 6 months and 12 years undergoing surgery under general surgery were included. They were randomized into either pinna-based group (group X) or weight-based group (group Y). Both groups were compared for accurate placement of ProSeal™ laryngeal mask airway (PLMA), ease of insertion, number of attempts needed, and peak airway pressures.

Results: A Comparable number of patients had a Brimacombe score of 3 and above, indicating correct placement in both groups ($P = 0.407$). PLMA was easily inserted in 79.5% and 87.7% of patients of groups X and Y, respectively ($P = 0.180$). Insertion was found to be difficult in 20.5% of patients in group X, whereas it was difficult in only 12.3% of patients of group Y ($P = 0.180$). The two groups were comparable as per the number of attempts needed for insertion ($P = 0.161$). Mean peak airway pressures too were comparable between both groups. Ease of insertion too, was statistically insignificant between both groups.

Conclusions: Pinna size–based estimation of LMA size is an effective alternative method to weight-based selection.

Keywords: Airway, ear pinna, laryngeal mask airway

Introduction

ProSeal™ laryngeal mask airway (PLMA), introduced by Dr. Archie Brain in 2000, is a modified generation of classic LMA. The presence of a gastric drainage tube allows regurgitated gastric contents to easily pass through the epiglottis and prevents pulmonary aspiration. Optimal size of PLMA is important for safe and effective use. Inappropriate placement of PLMA may result in inadequate ventilation, trauma to the periglottic structure, and in postoperative sore throat.[1–3] The most common method to estimate the size of PLMA is weight-based method. But this may prove to be unreliable in certain situations like overweight or underweight children, bedridden, paralyzed patients when weight of patient is unknown.[4] Some studies have suggested pinna size–based placement of PLMA as an alternative method to weight-based method placement in children during controlled ventilation under general anesthesia. Few Indian studies have compared the weight-based and pinna size-based placement of PLMA in children during controlled ventilation under general anesthesia till date. There is a need for more studies

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to throw light upon the feasibility of pinna–based method for PLMA size estimation in children undergoing surgery under general anesthesia.

The aim of the study was to compare weight-based and pinna size–based placement of PLMA in children during controlled ventilation under general anesthesia.

The primary objective of the study was to compare the correct placement of PLMA in children between weight-based and pinna size–based method using the Brimacombe score. The secondary objective was to find ease of insertion of PLMA, evaluate the peak airway pressure and number of attempts required for successful placement of PLMA

Material and Methods

This randomized, controlled study was conducted after obtaining approval from the Institutional Ethical Committee from November 2019 to March 2021. The trial was registered with Clinical Trials Registry India (CTRI/2020/06/026065). A total of 146 American Society of Anesthesiologists (ASA) physical status 1 and 2 children aged between 6 months and 12 years, undergoing elective surgery under general anesthesia were included in the study.

Patients with anticipated difficult airway, history of obstructive sleep apnea, anomalies involving the ear, surgeries involving the airway or previous esophageal surgery, increased risk of aspiration, and other oropharyngeal comorbidities were excluded from the study.

With reference to the previous study by Ravi *et al.*,[5] the Brimacombe score of 3 and 4 indicating a correct placement of PLMA was 71.29% and 72.73% in the pinna group (group X) and weight-based group (group Y), respectively. For the sample size calculation, the assumed difference of 10% was considered clinically significant. Thus, the sample size of 73 calculated with a power of 80%, at an α of 0.05 to detect the significant difference amongst the two groups was considered. Thus, a sample size of 146 was taken.

Randomization was performed using a computer-generated random number table. The lower limit was 1 and upper limit was 2. If 1 was generated, group X (pinna based PLMA) was allocated and if 2 was generated, group Y (weight based PLMA) was allocated. The allocated numbers were concealed using sealed envelopes. For group X, the pinna size was measured by using paper ruler [Figure 1]. Vertical length was measured from the most dependent portion of the lobule to farthest portion of the pinna. Horizontal length (width) was the length measured horizontally from the tragus to the farthest

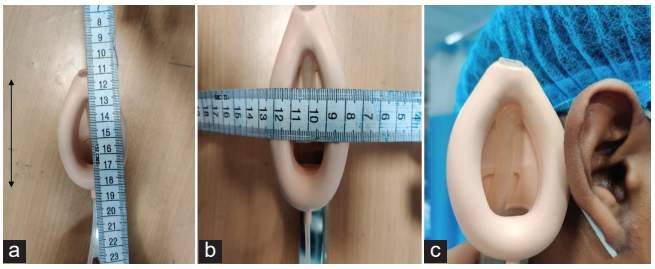

Figure 1: a) Measurement of vertical height in PLMA; b) Measurement of horizontal width of the PLMA; c) Size determination of PLMA on pinna size by comparing outer margin of PLMA and pinna

part of the helix. Based on these ear measurements, if the pinna size was between any two sizes, the larger sized PLMA was selected. Prior information regarding the procedure and study was provided to the parents and guardians, and informed consent was taken from parents and older children. Age and weight of the patient were recorded one day prior to surgery. On the day of the surgery in the preoperative holding area, the size of PLMA was decided by an experienced anesthesiologist not involved in the perioperative care of the patient. If the child was randomized to group X, the anesthesiologist analyzed PLMA size with pinna size and decided the size of PLMA (outer margin of both). The cuff was inflated to atmospheric pressure (1 mmHg) by leaving the pilot balloon open and then closing it once it was filled spontaneously. If the study participant was of group Y, PLMA was based upon weight of the patient. Another anesthesiologist involved in the perioperative care but unaware of the group allocation inserted the PLMA selected by the first anesthesiologist.

All the participants received routine premedication using syrup midazolam (0.5 mg/kg) 20–30 minutes before the surgery. In the operation theatre, all American Society of Anesthesiologists (ASA) standard monitors were connected and inhalational induction using sevoflurane (up to 8%) was performed followed by insertion of an intravenous cannula. Inj. fentanyl (1–2 mcg/kg) and inj. atracurium (0.5 mg/kg) were given. After 3 minutes of preoxygenation with 100% oxygen, the selected PLMA was inserted. A standard technique (index finger technique in midline approach and head in the sniffing position) was used for PLMA insertion in both groups. Following insertion, the cuff of PLMA was inflated up to 60 cm H2O and the cuff pressure was monitored using a cuff pressure monitor. A pediatric fiberoptic bronchoscope was used to assess correct placement of PLMA by visualizing the glottis to obtain the Brimacombe score. The fiberoscope was positioned 1 cm proximal to the PLMA airway tube and the glottic view was graded from 1 to 4, as shown in Table 1.[6] Successful placement was also determined by slight upward movement of PLMA on inflation of cuff,

bilateral expansion of chest, presence of bilateral air entry, absence of audible leak, and appearance of square wave capnography.[7] An appropriately sized gastric tube was then placed, and correct placement was assessed by the suction of fluid through drain tube. Ease of insertion of the PLMA was assessed using the Likert scale (easy/difficult) by the attending anesthesiologist. The number of attempts needed for successful insertion was noted. Three attempts were allowed for successful insertion of PLMA. Beyond three failed attempts, endotracheal intubation was performed. Patients were ventilated with tidal volume of 6–8 ml.kg^{-1}. Peak airway pressure was recorded.

At the end of the surgery, neuromuscular blockade was reversed with inj. 0.05 mg.kg^{-1} of neostigmine and inj. glycopyrrolate 0.01 mg.kg^{-1}. Once the child was fully awake, PLMA was removed. Presence of any trauma was noted by presence or absence of blood stains on the PLMA.

Statistical testing was performed with the Statistical Package for the Social Sciences (SPSS) version 17.0. Continuous variables were presented as mean ± SD or median (IQR) for the non-normally distributed data. The categorical variables were expressed as percentages and frequencies, respectively. Student's *t* test was used to compare the normally distributed continuous variables between the groups. The Chi-squared test or Fisher's exact test was used to compare the nominal data between the two groups whereas Mann–Whitney *U* test was used for the comparison of non-normal distribution. For all statistical tests in the study, a *P* value of less than 0.05 indicated a significant difference.

Results

A total of 146 children were included in the study. There were no dropouts [Figure 2]. Patients included in both groups were comparable as regards to demographic data like age, gender, weight, height, and BMI [Table 2]. PLMA insertion sizes utilized in both groups X and Y are depicted in Table 2.

A comparison of successful placement of PLMA as per Brimacombe score is shown in Table 3. A comparable number of patients had a Brimacombe score of 3 and above, indicating correct placement in both groups ($P = 0.407$). PLMA could be easily inserted in 79.5% and 87.7% of patients of groups X and Y, respectively. Insertion was found to be difficult in 20.5% of patients in group X, whereas it was difficult in only 12.3% of patients in group Y ($P = 0.180$) [Table 3]. There was no significant difference in distribution according to ease of insertion when compared between the two groups. The two groups were comparable as per the number of attempts needed for insertion ($P = 0.161$). Mean peak airway pressures, too, were comparable between both groups. [Table 3]

Table 1: Brimacombe score for correct placement of laryngeal mask airway

Brimacombe score for correct placement of laryngeal mask airway	
Score	**Fiberoptic view**
4	Only cords seen
3	Cords plus posterior epiglottis seen
2	Cords plus anterior epiglottis seen
1	Cords not seen, but function adequate
0	Failure to function where cords not seen fiberoptically

Table 2: Demographic data

Parameters	Group X	Group Y	*P*
Age (years) mean±SD	5.51±3.10	5.76±3.64	0.721
Gender (M/F)	57/16	54/19	0.561
Weight (in kg) mean±SD	21.22±8.52	21.80±9.47	0.757
Height (in cm) mean±SD	104.86±20.58	107.31±23.04	0.442
BMI mean±SD	18.64±2.38	18.00±2.71	0.08

Discussion

The development of the ProSeal™ laryngeal mask airway (PLMA) revolutionized the practice of anesthesia. The use of PLMA is a safe alternative to intubation in children.[7–10] Successful placement of PLMA is determined by the optimal size selection.[9,11] Commonly used methods for size selection in adults are gender-based and weight-based methods.[7,12] When a patient's weight is difficult to determine, like in case of bedridden children, in an emergency or in obese or malnourished children, the weight-based approach is rendered unreliable.[13,14] Inappropriate size selection may result in trauma to the periglottic structures and postoperative sore throat.[2,3,8,15] Other alternative methods like tongue width–based method, combined width of index, middle and ring fingers have been studied.[16,17] Gallart *et al.* found the combined widths of index, middle, and ring fingers to be a useful approach for LMA size selection, especially in situations of emergency or when weight is unknown. Wong *et al.* evaluated the thyromental size selection in comparison to weight-based method and concluded that weight-based method often overestimated the LMA size in overweight patients.[15] There has thus been a persistent need for a reliable alternative to the weight-based method.

Our study evaluated a new method for LMA size selection that is ear pinna–based method. Only a few studies have till date assessed this method.[16–18] It holds promise as an alternative method for LMA size selection since airway growth is closely associated with pinna growth. The method can be

Table 3: Comparison of number of attempts at insertion, PLMA size distribution, ease of insertion, successful insertion, and peak airway pressures

	Group X		Group Y		*P*
	Frequency	**%**	**Frequency**	**%**	
Number of attempts					
Attempts					
1	57	78.1%	65	89.0%	0.161
2	15	20.5%	8	11.0%	
3	1	1.4%	0	0.0%	
Total	73	100%	73	100%	
LMA size distribution					
Insertion Size					
1.5	10	13.7%	14	19.2%	0.362
2	41	56.2%	33	45.2%	
2.5	13	17.8%	11	15.1%	
3	9	12.3%	15	20.5%	
Total	73	100%	73	100%	
Ease of insertion					
Difficult	15	20.5%	9	12.3%	0.180
Easy	58	79.5%	64	87.7%	
Total	73	100%	73	100%	
Successful insertion					
Brimacombe score					
1	3	4.1%	4	5.5%	0.407
2	23	12.3	2	2.7%	
3	31	42.5	37	50.7%	
4	33	45.2	34	46.6%	
Total	73	100	73	100%	
Comparison of peak airway pressures					
Peak airway pressure	13.23±2.63		12.49±3.32		0.139

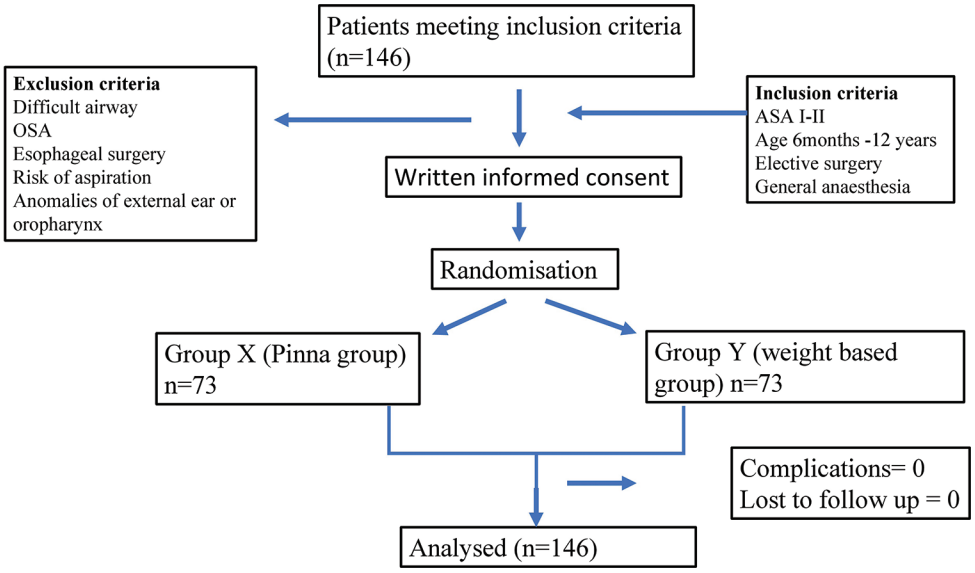

Figure 2: CONSORT diagram

easily understood and applied without the need to memorize a table as for weight–based method.[4,19,20]

Ravi *et al.* compared ventilation parameters for weight-based and pinna-based methods of ProSeal size selection in 204 paediatric patients. Successful insertion in the first attempt was seen in 93% of patients in the pinna group. The difference between the groups as regards to the number of attempts was statistically insignificant ($P = 0.36$) which was similar to that observed in our study. Ease of LMA insertion was also found

to be similar in both weight-based and pinna-based group, which, too, was similar to our study. Peak airway pressures as observed by the authors were comparable (14.64 ± 1.99 versus 14.75 ± 2.06; $P = 0.69$) in both groups, and that too was in accordance with results of our study.[5]

In another study by Zahoor *et al.*,[18] weight-based and ear-based technique of mask selection were compared in 210 children. Successful insertion in the first attempt was achieved in 196 patients (93.9%) while second attempt was required in 14 patients (6.7%) due to audible leak. Pinna size–based method was therefore concluded to be an effective method in determining the size of LMA in children. Similarly, Jha *et al.*[21] too observed the auricle method to be a promising alternative to weight-based LMA size calculation. Maximum number of insertions in the pinna group could be performed in a single attempt (96.07%) similar to the weight-based group (94.12%). These results are similar to our study too, where the PLMA could be successfully inserted in the first attempt in 78.1% of patients of the pinna group ($P = 0.161$)

Successful placement of PLMA using Brimacombe score was similar in both groups as seen in our study. This agrees with the results of previous studies.[5] Jha *et al.* also observed a Brimacombe score of 3 and 4 in 54.9% and 17.65% of the auricle group, respectively. This was comparable to the weight-based group. Our study is therefore one of the few studies conducted with the aim to find an alternative to weight-based LMA size prediction. But it is not free of limitations. Our study had a small sample size and was limited to a single center. We did not include patients who were below 6 months of age. It cannot be performed in patients with congenital anomalies of the external ear.

Conclusion

With pinna size–based method, the selected PLMA size can be placed with similar accuracy as with weight-based method and with similar ease of insertion and number of attempts. It can therefore be concluded that pinna size–based method is a reliable and effective alternative to weight-based method for LMA size selection in pediatric patients.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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