

Size 2.5 ProSeal™ LMA: Is it associated with increased attempts at insertion?

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ABSTRACT

Background: This randomized controlled study evaluated the success rate of insertion and the associated oropharyngeal morbidity for sizes 1.5, 2 and 2.5 of ProSeal™ laryngeal mask airway (PLMA) using an alternative digital technique (D) with conventional technique using the introducer tool (IT) technique. **Methods:** After approval from the hospital ethics committee, 250 healthy children, 6-months to 10 years of age, undergoing elective sub-umbilical surgeries, were included and randomly allocated to D and IT groups for PLMA insertion. The standard anaesthesia protocol was followed. The primary outcomes were success rate of insertion at first attempt and blood on device on removal and the secondary outcomes were oropharyngeal leak pressure and gastric tube placement. **Results:** The success rate of PLMA insertion at first attempt for sizes 1.5 and 2 did not differ between the two groups. However, for size 2.5, it was significantly lower than that for the other two sizes in both groups. The incidence of blood on device was higher with the 2.5 airway in both groups, reaching statistical significance only in group D. Other parameters did not differ between the two groups. **Conclusion:** We conclude that size 2.5 PLMA is associated with a lower success rate of insertion and a higher incidence of blood on device using both techniques. Insertion of PLMA sizes 1.5 and 2 by an alternative digital technique is comparable to the IT technique.

Key words: Size-2.5 ProSeal™ LMA, success rate, pediatric

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INTRODUCTION

Conventionally both, introducer tool (IT) and digital technique have been described to insert the ProSeal™ laryngeal mask airway (PLMA) in adults as well as in the paediatric population.

The smaller sizes of PLMA, i.e. 1.5, 2 and 2.5, are devoid of the dorsal cuff that is present in size 3 onwards. Despite the differences in the anatomy of different age groups, the same technique of insertion has been recommended by manufacturers for all sizes of PLMA.^[1-3] Some studies have reported a higher success rate of PLMA insertion in paediatric patients using non-conventional techniques.^[3-6] Moreover, only a single size IT is available for all the paediatric sizes, and use of IT involves additional cost.

In response to a questionnaire given to all the 36 consultants in our department, we found that even though all of them were aware of the standard digital technique recommended by the manufacturer, most did not use it. They favoured a non-conventional technique of holding the PLMA at midshaft position and gently slipping the device past the tongue and hard palate, continuously until resistance was felt [Figure 1]. We hypothesized that the success rate of the device placement varies with the size and that an alternative technique may be equally effective in inserting the PLMA in children thus obviating the need for an additional tool. This avoids inserting the fingers into the mouth and use of an additional aid for placement of the device. In this randomized controlled study, we compared the success rate of insertion and blood on the device on removal for sizes 1.5, 2 and 2.5 of PLMA using an alternate digital technique with the conventional technique using the IT.

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Figure 1: These pictures demonstrate a non-conventional Digital technique where the ProSeal™ Laryngeal Mask Airway has been held at between thumb and finger mid-shaft position, with the head of the patient in neutral position. Under direct vision the device is slipped over the tongue without applying excessive force, while gently opening the mouth with left hand until a definite resistance was experienced

METHODS

Hospital ethics committee approval was obtained for prospective collection of data from 250 children of American society of anaesthesiologist physical status I and II, age 6 months–10 years, scheduled for elective infraumbilical surgery, over a period of 2 years from October 2006 to September 2008. After written informed consent from the parents for this randomized prospective study, the patients were randomized using computer-generated numbers for PLMA insertion, using either the IT or D technique. The numbers were kept in sealed opaque envelopes that were opened immediately prior to surgery by an anaesthesia consultant not involved in the study.

Exclusion criteria included anticipated difficult airway, risk of regurgitation, morbid obesity and acute respiratory tract infection. The insertion of PLMA was carried out by anaesthesiologists with an experience of more than 500 PLMA insertions.

All children were fasted for 4–6 h depending on their age and hospital guidelines and were premedicated with oral midazolam syrup 0.2 mg/kg, 1 h prior to surgery.

Anaesthesia was induced with oxygen, nitrous oxide in 8% sevoflurane. Intravenous access and standard monitoring were carried out at appropriate times. Monitors included pulse oximeter, electrocardiography, non-invasive blood pressure, capnograph and

temperature. Caudal block was given for analgesia after PLMA placement.

Having achieved adequate depth as judged by jaw relaxation, a PLMA of appropriate size was selected in accordance to the manufacturer's instructions for weight. Owing to the smaller average weight of patients in our country, we included sizes 1.5, 2 and 2.5 only.

In the IT group, the device manufacturer's instructions were followed for using the IT, whereas in the D group, the device was held between the thumb and the fingers at the mid-shaft position [Figure 1], with the head of the patient in neutral position. Under direct vision, the device was slipped over the tongue without applying excessive force, while gently opening the mouth with the left hand until a definite resistance was experienced. No rotational movements were performed while inserting the PLMA. For both the groups, the device was fixed in accordance to manufacturer's instructions.

The PLMA cuff was inflated, and its pressure maintained thereafter at 60 cmH₂O using a cuff pressure monitor (Mallinckrodt Medical, Athlone, Ireland). Bilateral chest movements, square wave capnography and gel displacement test confirmed the PLMA position during manual ventilation. The gel displacement test was carried out by placing a blob of water-soluble jelly at the tip of the drain tube and noting its movement with gentle manual inflation of the reservoir bag. More than three attempts to place the PLMA and/or inability to ventilate the patient after device placement were considered a failure. In both these scenarios, it was replaced with a tracheal tube (TT), and these cases were excluded from the study. A gastric tube was passed through the drain tube of the PLMA and its placement was confirmed by air injection and epigastric auscultation. The gastric tube was left *in situ* and intermittently suctioned throughout the procedure.

The oropharyngeal leak pressure (OPL) was measured by closing the expiratory valve of the circle system at a fresh gas flow of 3 L/min and noting the airway pressure at which equilibrium was reached. The presence of a gas leak was detected as an audible sound escaping from the mouth and bubbling of lubricant placed on the proximal end of the drain tube. The position of the device in relation to the glottis was confirmed using a fiberoptic bronchoscope (Olympus LF-2). This was graded as fiberoptic grade (FOB): I – vocal cords not visible, II – vocal cords

and anterior epiglottis visible, III – vocal cords and posterior epiglottis visible and IV – only vocal cords visible. Maintenance of anaesthesia was with sevoflurane in nitrous oxide and oxygen using pressure control ventilation without muscle relaxants, aiming for minimal alveolar concentration of at least 1.5. Intra- and post-operative airway-related complications were documented, such as desaturation ($\text{SpO}_2 < 90\%$), bronchospasm, laryngospasm, airway obstruction or device malposition.

Evidence of blood on removal of the PLMA was considered as a sign of oropharyngeal trauma and was documented.

Statistics

Statistical analysis was performed using two-tailed Student's *t*-test and Chi square test. Non-parametric data was analyzed using the Mann–Whitney U/Wilcoxon tests.

P value of < 0.05 was considered statistically significant. Based on previous studies on adults and children, sample size was calculated for a projected difference of 20% in success rate of insertion at first attempt between the groups. It was calculated that a sample size of 125 in each group, with type 1 error of 0.05, would give a power of 90%.^[4-6] A Bonferroni correction was used to account for multiple comparisons. Statistical analyses were performed using SPSS 14.1 for Windows (SPSS Inc., Chicago, IL, USA).

The primary outcome of the study was success rate at first attempt and blood on device, and the secondary outcomes were overall success rate, OPL, gastric tube placements and cough.

RESULTS

The patient characteristics and device size-based distribution of PLMA did not differ between the two groups [Table 1].

The other overall details of PLMA between the two groups as in Table 2 show that the two groups did not differ in success rate, OPL and the position of the device in relation to the glottis, as shown by FOB grades. The success rate of device placement was 100% for both groups, and a third attempt was not required in any patient [Table 2]. The gastric tube placement was 100% successful for all patients in the two groups.

Table 1: Characteristics and size based distribution of pediatric patients randomized to ProSeal™ laryngeal mask airway insertion using either introducer tool or digital technique

Variable	IT (n=125)	D (n=125)	P value
Age (year)	3.7±2.9	3.9±2.7	0.573
Weight (kg)	15.6±7.3	16.8±8.9	0.245
Gender (F/M)	12/113	8/117	0.350
Sizes (n) 1.5/2/2.5	42/49/34	44/41/40	0.537

Values are number of patients (n) or mean±standard deviation. M: Male; F: Female; $P > 0.05$ not significant IT vs. D; IT - Introducer tool; D - Digital technique

Table 2: Comparative evaluation of introducer tool and digital techniques of insertion

	IT (n=125)	D (n=125)	P value
Insertion success rate (n) 1 st /2 nd attempt	110/15	117/8	0.188
Blood on device (n)	8/125	10/125	0.882
OPL (cm H ₂ O)	27.3±2.9	27.5±2.8	0.583
FOB grade (I/II/III/IV)	0/8/67/50	0/11/65/49	0.773

Values are number of patients (n) or mean±standard deviation. OPL: Oropharyngeal leak pressure; FOB: Fiberoptic grade; I: Vocal cords not seen; II: Vocal cords anterior epiglottis seen; III: Vocal cords+posterior epiglottis; IV: Vocal cords only. $P > 0.05$ not significant IT vs. D; IT - Introducer tool; D - Digital technique

Within both the IT group and the D group, the success rate of insertion at first attempt was significantly higher for sizes 1.5 and 2 when compared with size 2.5 [Table 3].

The overall incidence of blood on the device did not differ between the groups [8/125 (11.8%) and 10/125 (17.5%) in IT and D groups, respectively]. The incidence of blood on device was higher for PLMA 2.5 in both groups; however, this reached statistical significance only in group D ($P = 0.013$) [Table 3]. The incidence of cough did not differ between the groups. No other adverse events were encountered in any patient.

DISCUSSION

Our study demonstrates that size 2.5 PLMA differs from sizes 1.5 and 2 and is associated with a lower success rate of insertion at first attempt and higher incidence of blood on the device.

The success rates of PLMA insertion have been shown to vary from 67-100% in different age groups and with different techniques.^[3,7-12] Size-based analysis of paediatric sizes of PLMA for success rate and its comparative evaluation is lacking in most previous studies. A recent study has shown that previous experience with adult PLMA is not a prerequisite for achieving a high success rate at inserting paediatric

Table 3: Size based comparison of pediatric ProSeal laryngeal mask airway within introducer tool and digital groups

Number of attempts			P value
IT group			
Size	1.5	2.5	
1 st /2 nd attempt (n)	40/2	23/11	0.002*
Sizes	2	2.5	
1 st /2 nd attempt (n)	47/2	23/11	0.001*
Sizes	1.5	2	
1 st /2 nd attempt (n)	40/2	47/2	0.875
D group			
Size	1.5	2.5	
1 st /2 nd attempt (n)	44/0	22/18	0.000*
Sizes	2	2.5	
1 st /2 nd attempt (n)	39/2	22/18	0.000*
Sizes	1.5	2	
1 st /2 nd attempt (n)	44/0	39/2	0.228
Blood on device			P value
IT group			
Size	1.5	2.5	
Blood on device (n)	02/42	04/34	0.408
Size	2	2.5	
Blood on device (n)	02/49	04/34	0.395
Size	1.5	2	
Blood on device (n)	02/42	02/49	0.880
D group			
Size	1.5	2.5	
Blood on device (n)	00/44	07/40	0.013*
Size	2	2.5	
Blood on device (n)	03/41	07/40	0.318
Size	1.5	2	
Blood on device (n)	00/44	03/41	0.241

Values are expressed as absolute number (n). *P value <0.05 is significant within IT or within D groups; IT - Introducer tool; D - Digital technique

PLMA. All insertions in this study were carried out by experienced anaesthesiologists.^[2,4,8-12] We found that sizes 1.5 and 2 of the PLMA had a significantly higher rate of success than size 2.5, irrespective of use of the IT.

Although the size 2.5 PLMA is similar to sizes 1.5 and 2, it has been shown to have a lower success rate of insertion. The possible causes for this difference have not been evaluated till date. This could possibly be because of the higher degree of oropharyngeal impaction.^[13-16]

The overall incidence of second attempt at insertion in our study was significantly higher for size 2.5 PLMA, which is in agreement with previous reports.^[2,13] This was seen with both IT and D groups. This might explain the higher incidence of pharyngeal trauma (blood on device) with size 2.5 PLMA with both techniques. The OPL with both techniques for all sizes is in agreement with previous studies.^[2,14-22]

The 100% success rate of gastric tube placement in both groups rules out posterior folding of the mask in any patient.

There have been a few reports of unanticipated difficult airway in patients with lingual tonsils.^[16,23] The higher incidence of adenoid and tonsillar hypertrophy in children between the ages of 2 and 10 years should be kept in mind while choosing this device. This could account for a higher degree of failure on first attempt at insertion and blood on mask for size 2.5 PLMA with both the techniques.

The overall incidence of adverse events in our study was found to be comparable with previous studies.^[1,3,18] The majority were seen in the form of blood on the mask, which is indicative of pharyngeal trauma. It has been reported that the incidence of blood on mask can be significantly reduced by avoiding contact of the device with the palate and pharyngeal wall.^[18] We observed that the incidence of trauma, which is otherwise higher with size 2.5, is further increased when IT is not used.

The incidence of pharyngolaryngeal morbidity in other studies has been variedly reported, but size-based comparisons are lacking. Unlike the classical LMA, the paediatric PLMA is not simply a scaled-down version of the adult counterpart. The differences in anatomy of the paediatric airway and features of the PLMA, such as absence of dorsal cuff in size 1.5, 2 and 2.5 and a relatively larger ventral cuff in comparison with classic LMA, may require the anaesthesiologist to deal with them differently so as to minimize the number of attempts, the associated pharyngolaryngeal morbidity and any chances of airway obstruction.

Our study had some limitations; the incidence of sore throat could not be evaluated as many of our patients were in the pre-verbal age group, and the patients in whom we encountered difficult insertion were not subjected to direct laryngoscopy to ascertain the exact cause. None of our patients were evaluated pre-operatively for any supraglottic pathology.

It may be beneficial to perform direct laryngoscopy prior to inserting size 2.5 PLMA to improve the success rate of insertion and possibly decrease the accompanying pharyngolaryngeal morbidity.

CONCLUSION

We conclude that size 2.5 PLMA is associated with

a lower success rate and higher incidence of blood on device using both techniques. Insertion of PLMA sizes 1.5 and 2 by an alternative digital technique is comparable to the IT in terms of success rate of insertion, blood on device and oropharyngeal leak pressure.

REFERENCES

- Brain AI, Verghese C, Strube PJ. The LMA 'ProSeal'-a laryngeal mask with an esophageal vent. *Br J Anaesth* 2000;84:650-4.
- Kelly F, Sale S, Bayley G, Cook T, Stoddart P, White MA. Cohort evaluation of ProSeal laryngeal mask airway in 100 children. *PediatrAnesth* 2008;18:947-51.
- Brimacombe J, Keller C, Boehler M, Puringer F. Positive pressure ventilation with ProSeal versus classic laryngeal mask airway: A randomized crossover study of healthy female patients. *AnesthAnalg* 2001;93:1351-3.
- Teoh CY, Lim FS. ProSeal laryngeal mask airway in children: A comparison between two insertion techniques. *PediatrAnesth* 2008;18:119-24.
- Lopez-Gil M, Brimacombe J, Barragan J, Keller C. Bougie-guided insertion of ProSeal™ has higher first attempt success rate than the digital technique in children. *Br J Anaesth* 2006;96:238-41.
- Brimacombe J, Keller C, Vasoba Judd D. Gum elastic bougie guided insertion of the ProSeal™ laryngeal mask airway is superior to introducer tool technique. *Anesthesiology* 2004;100:25-9.
- Brain AI. The laryngeal mask-a new concept in airway management. *Br J Anaesth* 1983;55:801-5.
- Brimacombe J, Keller C. The ProSeal™ laryngeal mask airway: A randomized, crossover study with the standard laryngeal mask airway in paralysed, anesthetized patients. *Anesthesiology* 2000;93:104-9.
- Pennant JH, White PF. The laryngeal mask airway: Its uses in anesthesiology. *Anesthesiology* 1993;79:144-63.
- Cook TM, Mc Kinstry C, Hardy R, Twigg S. Randomized crossover comparison of the ProSeal laryngeal mask airway with the laryngeal tube during anaesthesia with controlled ventilation. *Br J Anaesth* 2003;91:678-83.
- Brimacombe J, Keller C, Fullekrug B, Agro F, Rosenblatt W, Dierdorf SF, *et al.* A multicentre study comparing ProSeal and Classic laryngeal mask airway in anesthetized, nonparalysed patients. *Anesthesiology* 2002;96:289-95.
- Goldmann K, Roettger C, Wulf H. The size 1.5 ProSeal laryngeal mask airway in infants. *AnesthAnalg* 2006;102:405-10.
- Goldmann K, Jacob C. A randomised crossover comparison of the size 2.5 laryngeal mask airway ProSeal™ versus Laryngeal mask airway-classic TM in Pediatric patients. *AnesthAnalg* 2005;100:1605-10.
- Brimacombe J, Richardson C, Keller C, Donald S. Mechanical closure of the vocal cords with the laryngeal mask airway. *ProSeal*. *Br J Anaesth* 2002;88:296-7.
- Stix MS, O'Conner CJ. Maximum minute ventilation test for the ProSeal laryngeal mask airway. *AnesthAnalg* 2002;95:1782-7.
- Nakazawa K, Ikeda D, Ishikawa S. A case of difficult airway due to lingual tonsillar hypertrophy in a patient with Down's syndrome. *AnesthAnalg* 2003;97:704-5.
- Lardner DR, Cox RC, Ewen A, Dickinson D. ProSeal and the LMA-Classic in ventilated children receiving neuromuscular blockade. *Can J Anaesth* 2008;55:29-35.
- Dingley J, Asai T. Insertion methods of the laryngeal mask airway: A survey of current practice in Wales. *Anaesthesia* 1996;51:596-9.
- Von Goedecke M, Brimacombe J, Hormann C, Jeske CH, Kleinsasser A, Keller C. Pressure support ventilation versus continuous positive airway pressure ventilation with the ProSeal laryngeal mask airway: A randomized crossover study of anesthetized pediatric patients. *AnesthAnalg* 2005;100:357-60.
- Sinha A, Sharma B, Sood J. ProSeal as an alternative to endotracheal intubation in pediatric laparoscopy. *PediatrAnesth* 2007;17:327-32.
- Wheeler M. ProSeal laryngeal mask airway in 120 pediatric surgical patients: A prospective evaluation of characteristics and performance. *PediatrAnesth* 2006;16:297-301.
- Lopez-Gil M, Brimacombe J. The ProSeal laryngeal mask airway in children. *PediatrAnesth* 2005;15:229-34.
- Ojeda A, Lopez AM, Borrat X. Failed tracheal intubation with the LMA-C Trach™ in two patients with lingual tonsil hyperplasia. *AnesthAnalg* 2008;107:601-2.

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