Comparison of laryngeal mask airway (LMA)-ProSeal™ and the LMA-Classic™ in ventilated children receiving neuromuscular blockade

[Comparaison entre les masques laryngés (LMA)-ProSeal™ et LMA-Classic™ chez les enfants ventilés lors d'un bloc neuromusculaire]

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Purpose: To determine whether a functional difference exists between the size 2 laryngeal mask airway (LMA)-Classic™ (CLMA) and LMA-ProSeal™ (PLMA) in anesthetized children who have received neuromuscular blockade. Airway leak during intermittent positive pressure ventilation (IPPV) and adequacy of fiberoptic laryngeal view were the primary study outcomes.

Methods: A randomized, controlled, single-blinded study of 51 ASA I or II children weighing 10–20 kg was undertaken. The anesthetic technique was standardized. Following insertion of the LMA and cuff inflation to 60 cm H₂O, we measured oropharyngeal leak pressure and gastric insufflation and leak fraction during IPPV, and evaluated the adequacy of fiberoptic view.

Results: Oropharyngeal leak pressure measured by neck auscultation was higher for the PLMA compared to the CLMA (23.7 vs 16.5 cm H₂O, $P = 0.009$) but, when measured by the inspiratory hold maneuver was not significantly different (24.8 vs 20.3 cm H₂O, respectively, $P = 0.217$). Leak fraction values were similar for the CLMA and the PLMA (21.2% vs 13.3%, respectively, $P = 0.473$). A satisfactory view of the larynx was obtained more frequently in the PLMA group (21/25 vs 10/25, $P = 0.003$). Gastric insufflation during leak determination was more common with the CLMA (12/26 vs 2/25 CLMA vs PLMA, respectively, $P = 0.006$).

Conclusion: In children undergoing IPPV with neuromuscular blockade, the size 2 PLMA is associated with a higher leak pressure by auscultation and less gastric insufflation compared to the CLMA. Leak pressures assessed by manometric stability are similar with these two devices. The improved fiberoptic view of the larynx through the PLMA may be advantageous for bronchoscopy.

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Objectif : Déterminer s'il existe une différence fonctionnelle entre les masques laryngés (LMA)-Classic™ (CLMA) et LMA-ProSeal™ (PLMA) de taille 2 chez les enfants anesthésiés lors d'un bloc neuromusculaire. Les fuites du masque pendant la ventilation à pression positive intermittente (VPPi) et une bonne vision laryngée par fibre optique constituaient les résultats principaux recherchés par cette étude.

Méthode : Une étude randomisée contrôlée en aveugle portant sur 51 enfants ASA I ou II et pesant entre 10 et 20 kg a été menée. La technique anesthésique utilisée a été standardisée. Après avoir inséré le LMA et gonflé le ballonnet à 60 cm H₂O, nous avons mesuré la pression de fuite oropharyngienne, l'insufflation gastrique et la fraction de fuite pendant la VPPi, et avons évalué la qualité de la vision par fibre optique.

Résultats : La pression de fuite oropharyngienne mesurée par auscultation du cou était plus élevée lors de l'utilisation du PLMA que du CLMA (23,7 vs 16,5 cm H₂O, $P = 0,009$) ; toutefois, lorsque celle-ci a été mesurée par manœuvre de retenue respiratoire, il n'y a pas eu de différence significative (24,8 vs 20,3 cm H₂O, respectivement, $P = 0,217$). Les valeurs de fraction de fuite étaient semblables avec le CLMA et le PLMA (21,2 % vs 13,3 %, respectivement, $P = 0,473$). Une vision satisfaisante du larynx a été plus fréquemment obtenue dans le groupe PLMA (21/25 vs 10/25, $P = 0,003$). L'insufflation gastrique pendant la détermination de la fuite a été plus fréquemment observée dans le groupe CLMA (12/26 vs 2/25 CLMA vs PLMA, respectivement, $P = 0,006$).

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Conclusion : Chez les enfants subissant une VPPI lors d'un bloc neuromusculaire, le PLMA de taille 2 est associé à une pression de fuite plus élevée par auscultation et moins d'insufflation gastrique par rapport à une utilisation du CLMA. Les pressions de fuite évaluées par stabilité manométrique sont semblables avec les deux appareils. Une vision par fibre optique améliorée du larynx avec le PLMA pourrait s'avérer utile pour la bronchoscopie.

THE laryngeal mask airway (LMA) is widely used in children both as an airway and as a conduit to facilitate fiberoptic bronchoscopy.¹ In children, use of the LMA-Classic™ (CLMA) for intermittent positive pressure ventilation (IPPV) is limited by gastric insufflation and airway leak.² The size 2 LMA-Proseal™ (PLMA) was recently introduced. In adults, the PLMA has both a higher oropharyngeal leak pressure (OPL)^{3,4} and a lower leak fraction (F_L) during IPPV than the CLMA.³ For both PLMA and CLMA, the incidence of airway complications in adults is similar.^{5,6} Thus, in adults, the PLMA may be the better device for IPPV. In adults, the fiberoptic view of the larynx is comparable through either the PLMA or the CLMA.^{4,3} Airway patency, however, is not necessarily an accurate predictor of an unobstructed fiberoptic laryngeal view.⁷ In children especially, down folding of the epiglottis, obscuring, but not obstructing the glottis, is a common finding on a fibrescope view through the LMA.^{8,9}

The size 2 PLMA differs from the adult PLMA not only in size but in design. It has an esophageal drain tube, an integrated bite block and a detachable metal introducer, but lacks the dorsal cuff extension which is thought to be important in maintaining pharyngeal seal during IPPV.¹⁰ These features, and the unique airway anatomy and lung mechanics of children, preclude the assumption that the size 2 PLMA will have a higher leak pressure and similar fiberoptic view of the larynx compared with the size 2 CLMA. In a prospective, randomized, single-blinded study we compared the size 2 PLMA with the size 2 CLMA in children undergoing general anesthesia with neuromuscular blockade. We hypothesized that there are no significant differences between the size 2 PLMA and CLMA with respect to the primary outcome of leak pressures and secondary outcomes of leak during IPPV, adequacy of fiberoptic laryngeal view or gastric insufflation.

Methods

This study was approved by the Conjoint Health Research Ethics Board of the University of Calgary. Written informed parental/guardian consent was obtained. A convenience sample of patients presenting for day surgery was used. Patients were recruited until 25 patients per group had been enrolled. Subjects were ASA physical status I and II, children weighing 10–20 kg. All subjects were scheduled for elective surgery requiring general anesthesia less than two hours duration, where an LMA would normally be indicated. Patients were excluded for any of the following reasons: lack of informed consent; at risk for aspiration; emergency surgery; asthma or reduced respiratory system compliance; active upper respiratory tract infection; known or suspected difficult airway; opioid administration; or for any contraindication to the anesthetic technique or drugs described below.

Using a computer-generated random number sequence; patients were randomly assigned to receive either a size 2 PLMA or a size 2 CLMA for airway management. The laryngeal masks were new and reserved exclusively for this study. Personnel who were not involved in the study completed randomization tasks.

Patients were not premedicated. After application of routine monitors, anesthesia was induced with 8% sevoflurane in N_2O/O_2 delivered *via* a Datex S/5 anesthetic delivery unit (Datex-Ohmeda Inc., Madison, WI, USA) and a pediatric circle system with a CO_2 absorber. A fresh gas flow (FGF) of $> 200 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ was used during induction. Following induction of anesthesia, we secured intravenous access and administered mivacurium $0.2\text{--}0.25 \text{ mg} \cdot \text{kg}^{-1}$ *iv*. Nitrous oxide was discontinued following induction. Prior to LMA insertion, bag-mask IPPV was limited to a peak inspiratory pressure of 20 cm H_2O . After confirming disappearance of the motor response to peripheral nerve stimulation, patients were randomized to one of the study groups. The patient's occiput was then supported by a small pillow which slightly flexed the neck and extended the head at the atlanto-occipital joint, a position maintained throughout the study. Water-soluble lubricating gel was applied to the leading edges of the assigned LMA. The PLMA was inserted with a metal introducer according to the manufacturer's recommended technique^A with the mask aperture facing anteriorly and the cuff deflated. Each LMA cuff was inflated to 60 cm H_2O (Hi-

A The Intavent Laryngeal Mask Instruction Manual, 2nd ed. Intavent Ltd.; 1993.

Lo™ Hand Pressure Gauge, Mallinckrodt Medical, Germany). To confirm airway patency, two or three positive pressure breaths at 20 cm H₂O were administered, whilst observing the patient's chest movements and expired CO₂ values. The LMA was then secured in a standardized manner with tape. Following LMA insertion, the primary and secondary outcomes were determined in a standard order.

A regional anesthetic, chosen by the attending anesthesiologist, was performed after the completion of all measures. Anesthesia was maintained with isoflurane 1.8%–2.5% in air and O₂ (F_IO₂ 0.5) according to clinical signs of adequacy of anesthesia. The patient's lungs were ventilated via a circle-CO₂ absorber system using a Datex ADU ventilator (Datex Ohmeda, Helsinki, Finland) in pressure mode with a FGF of 150 mL·kg⁻¹ and inspiratory pressures ≤ 20 cmH₂O. Normocarbica (end-tidal CO₂ 35–45 mmHg) was maintained by adjustment of respiratory rate. After data collection, and full spontaneous recovery of the twitch response, patients were allowed to resume spontaneous ventilation. At the end of surgery, LMAs were removed at a deep level of anesthesia and patients were awakened while breathing 100% O₂ via facemask.

Oropharyngeal leak pressure was determined by two different methods during a prolonged inspiratory pressure hold.¹¹ With the adjustable pressure limiting (APL) valve of the anesthesia circle system closed, at a FGF 300 mL·kg⁻¹·min⁻¹, an observer, blinded to the LMA type by a towel screen, auscultated the neck of each patient lateral to the thyroid cartilage. The airway pressure at which an audible leak occurred (OPL_{ausc}) was measured manometrically by the Datex AS/5. Next, gastric insufflation was assessed by auscultation of the epigastrium by the blinded observer. A second OPL measurement (OPL_{hold}) was made at the same FGF by closing the APL and observing the manometer until a stable plateau of pressure had been reached. Inspiratory pressure during these maneuvers was limited to a maximum of 40 cm H₂O. Following these measurements, the FGF was reduced to 150 mL·kg⁻¹·min⁻¹.

Leak fraction was determined using a P-100 BICORE neonatal pulmonary function monitor (Bicore, Irvine, CA, USA).¹² This comprises a disposable, low dead space variable orifice pneumotachograph. The device samples flow and pressure at 100 Hz and displays respiratory rate, inspired and expired tidal volumes and F_L for either ventilator or spontaneous breaths. Although this monitor was designed primarily for use in neonates, the device has been extensively tested at higher flows *in vitro* and the accuracy was found to be within 5% at flow rates from

400 mL·sec⁻¹ (expiratory) to 450 mL (inspiratory).¹³ The transducer was positioned between the LMA connector, with which it is compatible, and the Y-piece of the ventilator circuit. The F_L was calculated as the ratio of expiratory to inspiratory tidal volume (V_T) over 20 respiratory cycles at an inspired pressure of 20 cm H₂O, whilst the capnometer sampling port was temporarily excluded from the circuit by a stopcock.

A 5.3-mm video fiberoptic bronchoscope (Pentax EB-1530T3, Pentax Precision Instrument Co., Orangeburg, NY, USA) was passed through the airway tube of the LMA to a distance of 14.5 cm. The tip of the bronchoscope at this distance can view both the larynx and the aperture bars of the CLMA without impinging on the bowl of LMA. The view of the larynx was graded (by DRRL, AE or RGC) according to the following scale:²

1. Trachea in line with distal lumen of LMA and clear view of glottis
2. Glottis and posterior epiglottis visualized
3. Glottis and anterior epiglottis with < 50% glottis obscured
4. Glottis and anterior epiglottis with > 50% glottis obscured
5. Glottis not seen

Views rated 1, 2 or 3 were defined as satisfactory, and views rated 4 and 5 were considered unsatisfactory (as determined by their putative impact on fiberoptic guided tracheal intubation). As blinding of the fiberoptic view was not possible, a photograph of the best view obtained was printed and labelled on the reverse, for later determination of inter- and intra-rater reliability. Photographs were placed in random order in a photo sleeve without visible identifiers. The three investigators listed above scored all photographs.

Additional measures included LMA insertion time, recorded as time from removal of the facemask to confirmation of the second breath appearing on the capnograph. The number of attempts was recorded, and ease of insertion was graded by the investigator as easy, difficult or failed. Insertion complications were present if coughing, obstruction, or bleeding occurred. Intraoperative complications were present if obstruction, coughing occurred or if repositioning of the device was required. Following surgery, gastric distension was determined to be present if there was hyperinflation on inspection or hyperresonance on percussion of the epigastrium. Presence or absence of blood on the LMA was noted following removal. Removal complications were present if coughing, laryngospasm or airway obstruction occurred. In the postanesthesia care unit (PACU) complications were

FIGURE 1 OPL ausc = oropharyngeal leak pressure by auscultation; OPL hold = oropharyngeal leak pressure with inspiratory hold maneuver. Leak fraction of tidal volume over 20 respiratory cycles. The boxplot shows the 25th-75th percentile in the box. The median is marked as a line across the box. The vertical lines extend to the maximum and minimum values. Outliers ($> 1.5 \times$ interquartile range) are identified by a circle.

defined as presence of coughing, laryngospasm, stridor, airway obstruction or throat pain. The incidence of arterial oxygen desaturation ($\text{SpO}_2 < 90\%$) was also recorded.

We contacted parents/guardians by telephone the day following surgery to determine the presence or absence of signs or symptoms of sore throat, dysphonia, stridor or croup.

Statistical analyses

Standard deviations from a previous comparison of OPL in adults³ of the CLMA (6 cm H₂O) and PLMA (3 cm H₂O) were used as a basis for as measure of variability of the primary outcome for sample size calculations. Based on a clinically significant difference of 5 cm H₂O in OPL between groups with an α -error of 0.01 and a power of 0.8, a two-tailed test required 25 subjects per group. For the adequacy of fiberoptic laryngeal view, we predicted a "satisfactory" view (glottis and the posterior aspect of the epiglottis visible) in 50% of children.¹⁴ A sample size of 25 allowed the detection of a difference of 40 percentage points (to 10% or 90%, respectively) in the proportion

TABLE I Demographic data

	CLMA group (n = 26)	PLMA group (n = 25)
Age (months)	35.1 $\pm$ 2.5	33.5 $\pm$ 2.5
Weight (kg)	14.6 $\pm$ 0.48	14.1 $\pm$ 0.38
Duration anesthesia (min)	57 $\pm$ 0.04	54 $\pm$ 0.04
Duration surgery (min)	35 $\pm$ 0.03	33 $\pm$ 0.02
Time in PACU (min)	36 $\pm$ 0.02	40 $\pm$ 0.03
Circumcision/hypospadias (n)	5	5
Inguinal hernia/hydrocele/ orchidopexy (n)	11	13
Umbilical/epigastric hernia (n)	7	6
Orthopedic procedure (n)	3	1

CLMA = Laryngeal Mask Airway ClassicTM; PLMA = Laryngeal Mask Airway ProsealTM. Age, weight and time presented as mean $\pm$ standard error of mean, procedure as number of patients. PACU = postanesthesia care unit.

of satisfactory laryngeal views, with an α -error of 0.05 and a power of 0.8.

Statistical analyses were performed using SPSS 14.1 for Windows (SPSS Inc., Chicago, IL, USA). Proportions were compared using a Chi-squared test or Fisher's exact test. Continuous variables were compared by unpaired *t* test or the Wilcoxon exact test. Intra-rater reliability for fiberoptic laryngeal view was determined using Kappa statistic and inter-rater reliability by intra-class correlation coefficient. A Bonferroni correction was used to account for multiple comparisons. To achieve an overall α of 0.05 for the five primary and secondary outcomes a *P* value of 0.01 was considered statistically significant. Means (standard error of mean) are reported for continuous variables as are 95% confidence intervals for the difference in means.

Results

Fifty one patients were screened and subsequently randomized, and there were no withdrawals from the study. One patient (CLMA group) could not be ventilated adequately after induction of anesthesia. The patient had marked gastric distension and arterial oxygen desaturation necessitating withdrawal of the LMA and tracheal intubation. Data for this patient were collected for OPL and complications, but not for F_L or laryngeal view. Leak fraction could not be determined in another patient in the CLMA group for technical reasons. Postoperative follow-up data were available for all 25 patients in the PLMA group, and for 22 patients in the CLMA group. Demographic data are presented in Table I.

The results are presented in Table II. Data for OPL and F_L were not normally distributed. With respect to the fiberoptic view, the intra-rater reliability by Kappa

TABLE II Primary and secondary outcomes

	CLMA group	PLMA group	P value	95% Confidence interval of the difference
OPL _{ausc} (cm H ₂ O)	16.5 (1.0)	23.7 (1.9)	0.009	-2.69 to -11.58
OPL _{hold} (cm H ₂ O)	20.3 (1.4)	24.8 (1.9)	0.217	-8.93 to 0.50
F _L (%)	21.2 (5.4)	13.3 (3.3)	0.473	-4.83 to 20.69
Gastric insufflation (<i>n</i>)	12/26(46.1)	2/25(8.0)	0.006	12.3% to 63.9%
Satisfactory view (<i>n</i>)	21/25(84)	10/25(40)	0.003	16% to 71.9%

CLMA = Laryngeal Mask Airway Classic™; PLMA = Laryngeal Mask Airway Proseal™. Mean (SEM) for continuous variables and *n* (%) presented. OPL_{ausc} = oropharyngeal leak pressure by auscultation; OPL_{hold} = oropharyngeal leak pressure with inspiratory hold maneuver; F_L = leak fraction.

TABLE III Secondary outcomes

	CLMA group	PLMA group	95% Confidence interval of the difference
Time to insert (sec)	45.5 (3.8)	45.7 (3.5)	-10.6 to 10.2
Number of attempts:	1 attempt 24	1 attempt 24	N/A
1 vs 2	2 attempts 2	2 attempts 1	
Insertion grade:	Easy 23	Easy 24	N/A
Easy vs difficult	Difficult 3	Difficult 1	
Volume of air in cuff (mL)	4.4 (0.3)	4.7 (0.2)	-1.0 to 0.4
Time to return of spontaneous ventilation (min)	14 (0.01)	30 (0.04)	-0.25 to -0.06
V _T inspired (mL·kg ⁻¹)	14.8 (1.2)	18.4 (1.4)	-7.3 to 1.6
V _T expired (mL·kg ⁻¹)	11.8 (1.2)	15.8 (1.1)	-7.2 to -0.7

CLMA = Laryngeal Mask Airway Classic™; PLMA = Laryngeal Mask Airway Proseal™. Mean (SEM) presented for continuous variables. Number of patients in each category for number of attempts and ease of insertion. V_T = tidal volume; NA = not applicable.

statistic for the three investigators was 0.783–0.834; inter-rater reliability using the intra-class correlation coefficient was 0.78. Additional data are presented in Table III.

ADVERSE EVENTS

In addition to the one patient who required tracheal intubation, two patients in the CLMA group required gastric decompression by an orogastric tube after the leak tests. Intraoperatively, four patients per group had complications including stridor/obstruction (CLMA, *n* = 2; PLMA, *n* = 3) and repositioning of the LMA (CLMA, *n* = 2; PLMA, *n* = 1).

Gastric distension at the end of the procedure was observed in six and four patients of the CLMA and PLMA groups, respectively. Upon removal of the LMA, two patients in each group had blood on the LMA, and five patients in each group experienced minor complications (CLMA: cough, *n* = 2; stridor/obstruction, *n* = 2; laryngospasm, *n* = 1; PLMA: cough and stridor, *n* = 1; stridor/obstruction, *n* = 2; laryngospasm, *n* = 1). In the PACU, seven patients in the CLMA group experienced nine complications (cough, *n* = 4; stridor/obstruction, *n* = 4; sore throat, *n* = 1) and three patients experienced brief oxygen desaturation (SpO₂ < 90%) requiring no intervention. No patient in the PLMA group had complications in the PACU.

At follow-up, complications were as follows: CLMA (4/22: cough *n* = 1, sore throat *n* = 2, change in voice *n* = 1) and PLMA (5/25: cough *n* = 1, sore throat *n* = 1, change in voice *n* = 3).

Discussion

The main finding of our study is that, in children undergoing IPPV with neuromuscular blockade, the size 2 PLMA is associated with a higher leak pressure by auscultation and less gastric insufflation compared to the CLMA. Leak pressures assessed by manometric stability are similar with these two devices.

Randomized crossover studies of the PLMA vs CLMA sizes 1 ½,¹⁵ 2¹⁶ and 2 ½¹⁷ have been published by Goldmann *et al.*^{15–17} In these studies, with the patient's head in the neutral position, the OPL by auscultation was higher for the PLMA (size 2 PLMA - 18.8 cm H₂O; size 2 CLMA - 15.0 cm H₂O). Gastric insufflation was more common for the CLMA and was absent for the PLMA. The fiberoptic view was better for the PLMA for sizes 1 ½ and 2 ½. The view was better for the size 2 PLMA, but this did not reach statistical significance. In these studies, neuromuscular blockade was not used and, although the pressure was not visible to the observer, the observer was not blinded to which airway device was used. Shimbori *et al.*¹⁸ performed a randomized, non-blinded study in

60 children comparing size 2 PLMAs and CLMAs. Leak pressure was determined using manometric stability (similar to OPL_{hold}) at a fresh gas flow rate of $3\text{ L}\cdot\text{min}^{-1}$ without neuromuscular blockade. Leak pressures were $19\text{ cm H}_2\text{O}$ and $18\text{ cm H}_2\text{O}$ for the PLMA and CLMA, respectively. There was no difference in fiberoptic view between their groups. A randomized non-blinded study of 240 children, also without neuromuscular blockade, comparing sizes 2, $2\frac{1}{2}$ and 3 CLMA and PLMA¹⁹ showed a difference in leak pressure between groups (PLMA $33\text{ cm H}_2\text{O}$; CLMA $26\text{ cm H}_2\text{O}$), as well as a higher incidence of gastric insufflation with the CLMA, with no difference in fiberoptic view. These mean leak pressures far exceed those observed in the studies previously described^{15–18} as well as the current investigation. The inclusion of the size 3 PLMA, which has a posterior cuff, may account for the higher mean leak pressures observed, as well as compromise of the fiberoptic view as seen in adult studies.

The distinguishing feature of our study is the presence of confirmed neuromuscular blockade. Pharyngeal tone influences leak around endotracheal tubes.²⁰ Neuromuscular blockade may also affect leak characteristics of the LMA.²¹ In 10% of adults in whom a PLMA is used, onset of neuromuscular blockade can result in decreases in leak pressure of $>10\%$. Similar data are not available in children. Given the premise that the PLMA may be better for IPPV, it is important to determine leak in the presence of neuromuscular blockade. We also took care to ensure that measurements of leak pressure and gastric insufflation were blinded. Additionally, by performing inter-rater and intra-rater reliability scores we attempted to control for individual bias when scoring fiberoptic view.

In our study, we did not compare leak before and after initiation of blockade. However, observed leak pressures were similar to those observed in previous studies where neuromuscular block was not used. This suggests there may be little difference in leak pressures of the PLMA in patients with and without neuromuscular blockade.

We have shown that, in children undergoing IPPV with neuromuscular blockade, the OPL_{ausc} is higher and the incidence of gastric insufflation is lower with the size 2 PLMA compared to the CLMA. This mirrors the results shown by Goldmann¹⁶ for the size 2 LMA when using a similar technique. However, the OPL_{hold} was not significantly different between these two devices. This observation is similar to the results of Shimbori *et al.*¹⁸ who also used manometric stability to determine leak with the size 2 PLMA. With the CLMA in children, manometric stability and auscultation produce

similar leak pressure results.²² It is possible that this may not apply to the PLMA. In adults, manometric stability produces higher leak pressures than does auscultation for the CLMA.¹¹ The mean OPL for the size 2 PLMA was lower than that found in adult studies.³

In adults, the CLMA provides improved fiberoptic laryngeal visualization compared to the PLMA.^{3,6,23} In children we have found the opposite, as did Goldmann.^{15–17} This observation reinforces our belief that results from adult studies should not be extrapolated to children. A better view of the larynx through the PLMA than the CLMA may be a compelling reason to favour the PLMA as a conduit for a fiberoptic bronchoscope. However, the diameter of the airway tube of the PLMA is 0.6 mm smaller than that of the CLMA.^B Thus, the clinical utility of the PLMA as a conduit for diagnostic bronchoscopy or fiberoptic intubation in children requires further study. Ease of insertion was similar for the two devices, although we observed a higher rate of minor postoperative complications in the CLMA group.

This study has several limitations. Although the F_L was higher for the CLMA, this did not achieve significant significance. The sample size was inadequate to detect differences (type II error) for the outcome of F_L had they existed. We observed that the V_T expired was greater, and time to return of spontaneous ventilation was longer in the PLMA group. This was not part of our hypothesis testing, and may have been a coincidental observation. The tidal volume achieved with an inspired pressure of $20\text{ cm H}_2\text{O}$ was somewhat greater than would be used in routine clinical practice.

Other studies use a fixed FGF rate of $3\text{ L}\cdot\text{min}^{-1}$ regardless of size of the patient when performing leak tests. We chose to base FGF rates on body weight ($300\text{ mL}\cdot\text{kg}^{-1}$) during OPL measurements in an effort to standardize the rate of rise of airway pressure ($\Delta P/\Delta t$) during these maneuvers. The LMA-pharyngeal interface is a dynamic one, and the occurrence of a gas leak during IPPV is likely to depend on the interplay of several factors, including $\Delta P/\Delta t$, FGF, pharyngeal tone, head position and respiratory system compliance. The impact of FGF on OPL has not been studied with LMAs in children, but results from a study of tracheal tubes in children suggest that varying FGF rate within a clinically acceptable range is likely to have only a small effect on leak pressures.²⁰ Furthermore, data from the same study suggest that the head position and the degree of neuromuscular blockade are

B LMA™ Airway Instruction Manual, The Laryngeal Mask Company Ltd.; 2005.

significantly greater determinants of leak pressures around airway devices.

We conclude that, in children weighing 10–20 kg, undergoing IPPV with neuromuscular blockade, the size 2 PLMA has a higher auscultation leak pressure and a similar leak on manometric stability when compared to the CLMA. Gastric insufflation is less common with the PLMA. Because the fiberoptic laryngeal view through the PLMA is superior to that of the CLMA, the PLMA may be a better conduit for fiberoptic bronchoscopy in children.

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