Mucosal pressure and oropharyngeal leak pressure with the ProSeal *versus* laryngeal mask airway in anaesthetized paralysed patients

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The ProSeal laryngeal mask airway (PLMA) is a new laryngeal mask device with a larger, wedge-shaped cuff and a drainage tube. We tested the hypothesis that directly measured mucosal pressure and oropharyngeal leak pressure (OLP) are higher for the PLMA compared with the laryngeal mask airway (LMA†). We also assess the mechanism of seal, and the reliability of cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure (*in vivo* minus *in vitro* intracuff pressure) to predict directly measured mucosal pressure. Thirty-two anaesthetized, paralysed adult patients were randomly allocated to receive either a size 4 LMA or PLMA. Microchip sensors were attached at locations corresponding to: (a) base of tongue; (b) distal oropharynx; (c) hypopharynx; (d) lateral pharynx; (e) posterior pharynx; and (f) pyriform fossa. *In vitro* and *in vivo* intracuff pressures, OLP and directly measured mucosal pressure were documented at zero volume and after each 10 ml up to 40 ml. Directly measured mucosal pressure was similar between devices for a given cuff volume, but was lower for the PLMA for a given OLP. Directly measured mucosal pressure was highest in the distal oropharynx for both devices, but rarely (<5%) exceeded 35 cm H_2O. OLP was higher for the PLMA at all cuff volumes. Directly measured mucosal pressure was usually lower than OLP for both devices, and there was a positive correlation between directly measured mucosal pressure and OLP. Cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure were poor to moderate predictors of directly measured mucosal pressure for the LMA and PLMA. We conclude that the PLMA forms a better seal than the LMA without an increase in directly measured mucosal pressure.

Br J Anaesth 2000; **85**: 262–6

Keywords: equipment; mask anaesthetic; airway; complications

Accepted for publication: March 1, 2000

The ProSeal laryngeal mask airway (PLMA) is a new laryngeal mask device with a larger cuff and a drainage tube. The cuff has a flat dorsal component designed to press the ventral elliptical cuff more firmly into the periglottic tissues and a wedge-shaped proximal component designed to plug gaps in the proximal pharynx (Fig. 1). We considered that these structural differences would influence the way the cuff interacted with the pharyngeal tissues. In this study, we test the hypothesis that directly measured mucosal pressure and oropharyngeal leak pressure (OLP) are higher for the PLMA compared with the classic laryngeal mask airway (LMA†) in anaesthetized, paralysed patients. We also assess the mechanism of seal, and the reliability of cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure to predict directly measured mucosal pressure.

Methods

Thirty-two ASA 1–2 adult patients were randomly allocated by opening a sealed envelope to receive either the LMA (eight male; eight female) or PLMA (eight male; eight female) for airway management. Ethical committee approval and informed consent were obtained. Patients were excluded if they were at risk of aspiration. Directly measured mucosal pressure was measured using six 1.2-mm-diameter strain gauge silicone microchip sensors (Codman® MicroSensor™, Johnson and Johnson Medical, Bracknell, UK) attached to the external surface of the

†LMA® is the property of Intavent Limited.

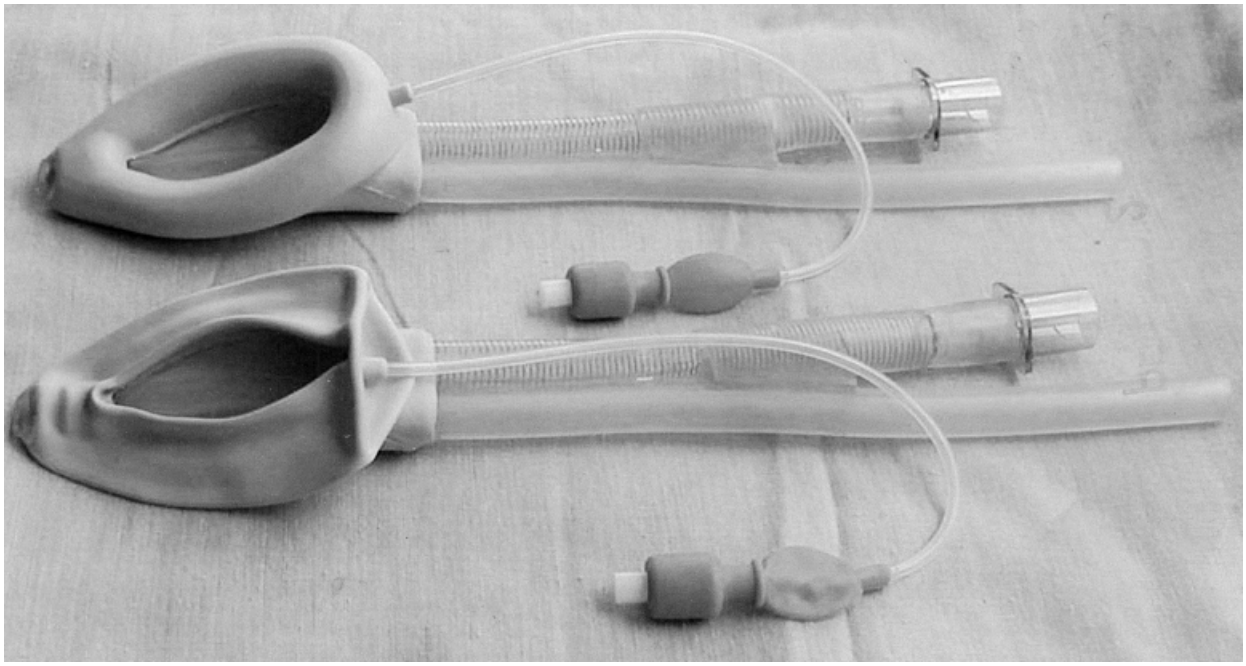

Fig 1 The PMA with the cuff inflated and deflated.

LMA/PLMA with clear adhesive dressing 0.45 mm thick (Tegaderm™, 3M, Ontario, Canada), as previously described.[1 2] The sensors were attached to the following locations (corresponding mucosal areas): (a) anterior base of cuff (base of tongue); (b) posterior tube (distal oropharynx); (c) posterior tip of cuff (hypopharynx); (d) posterior middle part of the cuff side (lateral pharynx); (e) middle of the backplate or dorsal cuff (posterior pharynx); and (f) anterior middle part of the cuff side (pyriform fossa) (Fig. 2A,B). The sensing element of the sensor was orientated towards the mucosal surface and was accurate to ±2%. The position/orientation/accuracy of all the sensors were checked over the entire inflation range *in vitro* before and after use in each patient.[1 2] Four LMAs and four PLMAs were used during the study. All LMA devices had passed the pre-use check tests.[3]

Anaesthesia was induced with propofol 2.5 mg kg^{-1} and maintained with 100% oxygen and 1–2% sevoflurane. Muscle relaxation was achieved with atracurium 0.5 mg kg^{-1}. An experienced LMA user inserted/fixed the LMA/PLMA using the technique recommended for the LMA.[3] Both devices were fixed by taping the tube over the chin. The numbers of attempts taken to place the device were recorded. A failed attempt was defined as removal of the device from the mouth. A size #4 LMA/PLMA was used for all patients. The pilot balloon was attached via a three-way tap to a 10-ml syringe and a calibrated pressure transducer accurate to ±5%. The intracuff pressure was reduced to –40 cm H_2O *in vitro*. *In vitro* and *in vivo* intracuff pressures, OLP and directly measured mucosal pressure were documented at zero volume and after each additional 10 ml up to 40 ml.

When measurements were complete, fibreoptic position was determined at 20 ml cuff volume to provide general information about anatomical position. OLP was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 litre min^{-1}, and noting the airway pressure at which the dial on the anaeroid manometer reached equilibrium.[4] Fibreoptic position was determined using an established scoring system (4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis; 2 = vocal cords plus anterior epiglottis; 1 = vocal cords not seen. [5 6] The position of the anterior tip sensor was verified at the end of the procedure by observation of a pressure spike during the application of cricoid pressure. An unblinded observer made measurements with the head–neck in the neutral position with the occiput resting on a firm pillow 7 cm in height.

Calculated mucosal pressure was determined by subtracting the *in vivo* intracuff pressure measurements from the *in vitro* intracuff pressure measurements, as previously described.[7] The mechanism of seal was determined by analysing the relationship between cuff volume, OLP and directly measured mucosal pressure. It was assumed that if OLP was greater than directly measured mucosal pressure, the mechanism of seal was related to the matching shape of the cuff and pharynx; and if there was a positive correlation between OLP and directly measured mucosal pressure, the mechanism of seal was related to the pressure exerted by the cuff against the pharyngeal mucosa.

Statistics

Sample size was selected to detect a projected difference of 25% between the groups with respect to directly measured

mucosal pressure for a type I error of 0.05 and a power of 0.9. The power analysis was based on data from a pilot study of 10 patients in which directly measured mucosal pressure was measured with the PLMA and a previous study of directly measured mucosal pressure with the LMA.[1] The distribution of data was determined using Kolmogorov–Smirnov analysis.[8] Statistical analysis was with paired *t*-test (normally distributed data), chi-squared test (non-parametric data), Friedman's two-way analysis of variance (non-normally distributed data) and regression analysis. The relationship between directly measured mucosal pressure and other variables was determined using Pearson product-moment correlation coefficient. The reliability of *in vivo* intracuff and calculated mucosal pressure to predict directly measured mucosal pressure was analysed using the intraclass correlation coefficient (ICC).[9 10] Significance was taken as $P<0.05$. Statistical analysis was performed on an IBM computer using SYSTAT version 7.0.

Results

The mean (range) for age, height and weight was 35 (19–65) yr, 169 (150–192) cm and 67 (40–95) kg, respectively. The physical characteristics of the patients in the two groups were similar. The first time success rate for the LMA and PLMA was 16/16 and 14/16. One patient with the PLMA required two attempts due to malposition (tip in the glottic inlet), and one patient required two attempts due to resistance when manoeuvring the cuff from the mouth to the pharynx. The pressure from the anterior tip probe increased to >100 cm H_2O when cricoid pressure was applied in all patients. The position/orientation/accuracy of the sensors were identical before and after usage. Directly measured mucosal pressure at specific locations was generally similar for the LMA and PLMA (Table 1). The lowest directly measured mucosal pressure for both devices was in the lateral pharynx, and the highest in the posterior pharynx and distal oropharynx. OLP was higher for the PLMA compared with the LMA at all cuff volumes (Table 1). OLP for both devices increased with increasing intracuff volume from 0 to 10 ml, but did not change from 10 to 20 ml, 20 to 30 ml or 30 to 40 ml. When comparing directly measured mucosal pressure with OLP at all cuff volumes and locations, directly measured mucosal pressure was significantly lower than OLP on 19/30 occasions for the LMA and 25/30 occasions for the PLMA, and directly measured mucosal pressure was never significantly higher than OLP for either device. There was a positive correlation between directly measured mucosal pressure and OLP at 3/6 locations with the LMA, at 4/6 locations with the PLMA, and a negative correlation at 1/6 locations with the PLMA (Table 2). There was a positive correlation between directly measured mucosal pressure and OLP at all cuff volumes for both the LMA and PLMA (all $P<0.001$, Table 2). Fibreoptic position (*n*: 4/3/2/1) for the LMA was 11/2/2/1 and for the PLMA was 5/7/3/2. There was a significant increase in directly measured mucosal pressure with increasing cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure at all locations for both devices; apart from the PLMA in the distal oropharynx which had a significant decrease (Table 3).

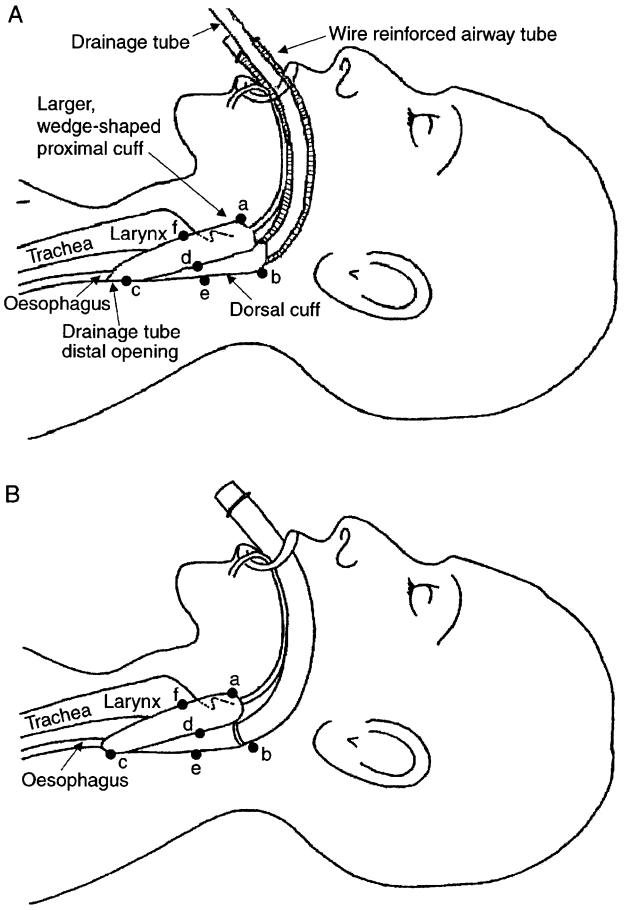

Fig 2 Schematic diagram showing the location of sensors (corresponding mucosal area) on the PMA (A) and Classic (B) LMA. (a) Anterior base of cuff (base of tongue); (b) posterior tube (distal oropharynx); (c) the posterior tip of cuff (hypopharynx); (d) posterior middle part of the cuff side (lateral pharynx); (e) the middle of the backplate or dorsal cuff (posterior pharynx); and (f) anterior middle part of the cuff side (pyriform fossa).

Discussion

Directly measured mucosal pressure was similar for both devices (Table 1) and lower than the upper limit considered safe for the tracheal mucosa during prolonged intubation (41 cm H_2O).[11] We recently showed that pharyngeal mucosal perfusion is progressively reduced when directly measured mucosal pressure is increased from 34 to 80 cm H_2O.[12] Directly measured mucosal pressure in the current study rarely exceeded 34 cm H_2O, suggesting that mucosal ischaemic injury will be uncommon with either device. However, the manufacturer recommends that LMA cuff volume is reduced to the minimal required to form an

Table 1 OLP, *in vivo*, *in vitro* and calculated intracuff pressure and directly measured pharyngeal mucosal pressures with increasing cuff volume for the standard LMA and PLMA. Data are mean (95% CI). Pressures are in cm H_2O. Interdevice statistics: LMA *versus* PLMA. Location B: [a]P=0.02; [b]P=0.04. Location C: [c]P=0.04. Location F: [d]P=0.04; [e]P=0.04

	Vol. (ml)	OLP	Intracuff pressures		Mucosal pressures					
			In vitro (n = 40)	*In vivo*	Calculated	Directly measured				
						A (base of tongue)	B (distal oropharynx)	C (hypopharynx)	D (lateral pharynx)	E (posterior pharynx)	F (pyriform fossa)
LMA	0	6 (4–9)	–40	–30 (–33–27)	10 (8–12)	4 (1–7)	2 (1–4)[a]	1 (0–3)	1 (0–2)	2 (1–3)	6 (4–8)[d]
	10	15 (11–19)	–8 (–9–7)	20 (16–23)	25 (21–29)	5 (1–10)	8 (4–13)	5 (2–8)	1 (1–2)	3 (2–5)	7 (5–9)[e]
	20	17 (13–20)	–3 (–4–2)	87 (75–99)	77 (64–90)	11 (6–16)	15 (6–24)	9 (5–13)	2 (1–4)	4 (2–5)	7 (5–9)
	30	17 (13–20)	126 (124–128)	223 (211–236)	87 (72–101)	14 (9–19)	14 (7–20)	12 (6–17)	2 (1–4)	7 (3–12)	10 (5–9)
	40	16 (12–19)	243 (240–246)	320 (308–333)	71 (55–87)	15 (10–21)	17 (9–26)[b]	15 (10–21)[c]	4 (2–6)	12 (6–17)	11 (7–16)
PLMA	0	18 (14–22)	–40	–34 (–37–31)	6 (4–8)	5 (–3–13)	22 (6–35)[a]	2 (0–5)	4 (0–7)	2 (0–4)	1 (0–3)[d]
	10	24 (20–28)	–12 (–11–3)	22 (19–26)	30 (26–35)	5 (–2–12)	20 (6–35)	6 (2–10)	5 (1–10)	8 (-2–19)	2 (0–4)[e]
	20	25 (21–29)	–7 (–7–6)	49 (42–56)	46 (38–53)	9 (2–16)	16 (5–26)	8 (4–12)	6 (2–10)	16 (–2–35)	5 (1–9)
	30	26 (21–31)	5 (4–5)	93 (83–102)	79 (66–92)	11 (4–19)	11 (–3–18)	7 (4–11)	6 (2–11)	18 (3–32)	7 (–1–15)
	40	27 (21–32)	40 (39–41)	139 (128–151)	93 (76–110)	16 (8–25)	6 (1–12)[b]	7 (3–11)[c]	6 (2–11)	20 (3–38)	8 (–1–17)

Table 2 PPCC and ICC for directly measured mucosal pressures with oropharyngeal leak pressure for the LMA and PLMA by location and volume. PPCC: +1 = perfect positive correlation; 0 = no correlation; –1 = perfect negative correlation. ICC: ⩾0.75 = excellent reliability; 0.41–0.74 = moderate reliability; <0.40 = poor.[10] NS, not significant

	LMA			PLMA		
	PPCC	*P*	ICC	PPCC	*P*	ICC
(a) Base of tongue	0.210	NS	0.33	0.415	0.01	0.38
(b) Distal oropharynx	0.302	NS	0.39	–0.519	0.001	0.54
(c) Hypopharynx	0.450	0.01	0.46	0.221	NS	0.33
(d) Lateral pharynx	0.301	NS	0.40	0.290	NS	0.35
(e) Posterior pharynx	0.402	0.01	0.44	0.410	0.01	0.49
(f) Pyriform fossa	0.402	0.01	0.45	0.383	0.04	0.45
Cuff volume						
0 ml	0.586	0.001	0.52	0.410	0.001	0.49
10 ml	0.600	0.001	0.54	0.421	0.001	0.48
20 ml	0.602	0.001	0.55	0.424	0.001	0.47
30 ml	0.599	0.001	0.52	0.410	0.001	0.47
40 ml	0.596	0.001	0.51	0.402	0.001	0.45

effective seal.[3] Because the PLMA forms a more effective seal than the LMA at all cuff volumes, directly measured mucosal pressure would be lower for the PLMA if this recommendation was applied. This may have implications for the incidence of pharynolaryngeal morbidity between devices.

The PLMA forms a more effective seal with the upper airway than the LMA. The PLMA was designed so that the larger, wedge-shaped cuff would plug gaps in the proximal pharynx and the flat dorsal cuff would push the ventral cuff more firmly into the periglottic tissues. We found no evidence (in terms of directly measured mucosal pressure change) that the ventral cuff was being pushed more firmly into the periglottic tissues, and we consider that the wedge-shaped proximal cuff is the more important new design feature with respect to improved seal. This latter concept is supported by the fact that OLP was higher at zero cuff volume when the dorsal cuff is deflated. Directly measured mucosal pressure increased with cuff volume at all locations except in the distal oropharynx with the PLMA where it decreased (Table 1). A possible explanation is that the distal posterior tube of the PLMA moves proximally during cuff inflation from the relatively narrow proximal laryngopharynx to the broader oropharynx.

The pattern of change of OLP with increasing cuff volume was similar for both devices suggesting that the mechanism of seal is similar. Directly measured mucosal pressure was generally lower than OLP, and there was a positive correlation between directly measured mucosal pressure and OLP. This suggests that the mechanism of seal is not only related to the matching shape of the cuff and pharynx, but also to the pressure exerted by the cuff against the mucosa. In a previous study,[13] we suggested that the mechanism of seal was related to the matching shape of the

Table 3 PPCC and ICC for directly measured mucosal pressures with cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure for the LMA and PLMA. PPCC: +1 = perfect positive correlation; 0 = no correlation; –1 = perfect negative correlation. ICC: ⩾0.75 = excellent reliability; 0.41–0.74 moderate reliability; <0.40 = poor.[10] NS, not significant

		Cuff volume			***In vivo* intracuff pressure**		**Calculated mucosal pressure**			
Device	**Location**	**PPCC**	***P*-value**	**ICC**	**PPCC**	***P*-value**	**ICC**	**PPCC**	***P*-value**	**ICC**
LMA	(a) Base of tongue	0.627	<0.001	0.49	0.650	<0.001	0.48	0.609	<0.001	0.45
	(b) Distal oropharynx	0.539	<0.001	0.48	0.573	<0.001	0.37	0.525	<0.001	0.43
	(c) Hypopharynx	0.566	<0.001	0.39	0.597	<0.001	0.45	0.564	<0.001	0.43
	(d) Lateral pharynx	0.510	<0.001	0.37	0.559	<0.001	0.42	0.569	<0.001	0.40
	(e) Posterior pharynx	0.548	<0.001	0.43	0.553	<0.001	0.41	0.497	<0.001	0.40
	(f) Pyriform fossa	0.639	<0.001	0.42	0.628	<0.001	0.39	0.514	<0.001	0.42
PLMA	(a) Base of tongue	0.469	<0.001	0.45	0.488	<0.001	0.45	0.462	<0.001	0.40
	(b) Distal oropharynx	–0.459	<0.001	0.43	–0.435	<0.001	0.39	–0.409	<0.001	0.39
	(c) Hypopharynx	0.540	<0.001	0.38	0.556	<0.001	0.48	0.529	<0.001	0.42
	(d) Lateral pharynx	0.468	<0.001	0.39	0.488	<0.001	0.41	0.458	<0.001	0.42
	(e) Posterior pharynx	0.413	<0.001	0.36	0.353	<0.001	0.37	0.388	<0.001	0.32
	(f) Pyriform fossa	0.327	0.003	0.50	0.349	<0.001	0.37	0.359	<0.001	0.37

cuff, but found no relationship between directly measured mucosal pressure and OLP. In the earlier study we did not analyse the relationship between directly measured mucosal pressure and OLP by cuff volume, but only by mucosal location and we used a size 5 LMA. We speculate that the relative contribution of the two sealing mechanisms may vary between patients and mask sizes.

Cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure are poor to moderate predictors of directly measured mucosal pressure for both devices. This suggests that these measurements are not useful in determining absolute values for directly measured mucosal pressure even though there is a significant correlation. Our data confirm the findings of a previous study[14] that calculated mucosal pressure is an imprecise method of determining localized directly measured mucosal pressure.

We conclude that the PLMA forms a better seal with the pharynx than the LMA in anaesthetized, paralysed patients, but without an increase in directly measured mucosal pressure. The mechanism of seal for both devices is related to cuff conformity with the pharynx and mucosal pressure. Cuff volume, *in vivo* intracuff pressure and calculated mucosal pressure are imprecise predictors of directly measured mucosal pressure.

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