Comparison of the flexible and standard laryngeal mask airways

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Purpose: To determine mucosal pressures, ease of insertion, mask position and oropharyngeal leak pressures for the flexible (FLMA) and standard laryngeal mask airway (LMA).

Methods: Forty anesthetized, paralysed adult patients were randomly allocated to receive either the FLMA or LMA. Microchip sensors were attached to the LMA or FLMA at identical locations corresponding to the base of tongue, hypopharynx, lateral pharynx, oropharynx, posterior pharynx and pyriform fossa. Mucosal pressure, oropharyngeal leak pressure (OLP) and mask position (assessed fibreoptically) were recorded during inflation of the cuff from 0-40 ml in 10 ml increments.

Results: Ease of insertion and mask position were similar between devices. Mean OLP was higher for the LMA (22 *vs* 19 cm H_2O), but the maximum OLP was similar (25 *vs* 24 cm H_2O). Mean mucosal pressures were generally low (< 12 cm H_2O) for both devices, but were higher for the LMA in the lateral pharynx (4 *vs* 1 cm H_2O) and oropharynx (13 *vs* 3 cm H_2O) and higher in the posterior pharynx for the FLMA (4 *vs* 2 cm H_2O). The OLP for both devices increased with increasing intracuff volume from 0-10 ml and 10-20 ml, and from 20-30 ml for the FLMA.

Conclusions: We conclude that the LMA and FLMA perform similarly in terms of ease of insertion and mask position, but OLP and mucosal pressures are slightly higher for the LMA. Pharyngeal mucosal pressures for both devices are lower than those considered safe for the tracheal mucosa. The overall clinical performance between the two devices is similar.

Objectif : Déterminer les pressions exercées par la muqueuse, la facilité d'insertion, la position du masque et les pressions liées aux fuites oropharyngées concernant le masque laryngé flexible (MLF) et le masque laryngé standard (ML).

Méthode : Quarante patients adultes, sous anesthésie, ont été répartis au hasard et ont reçu soit le MLF soit le ML. Des détecteurs électroniques ont été attachés au ML ou au MLF à des endroits identiques correspondant à la base de la langue, à l'hypopharynx, au pharynx latéral, à l'oropharynx, au pharynx postérieur et à la fosse piriforme. La pression de la muqueuse, la pression de fuite oropharyngienne (PFO) et la position du masque (évaluée par fibroscopie) ont été notées pendant le gonflement du ballonnet de 0-40 ml en incréments de 10 ml.

Résultats : La facilité d'insertion et la position du masque ont été similaires pour les deux appareils. La PFO moyenne a été plus élevée avec le ML (22 *vs* 19 cm H_2O), mais la PFO maximale a été similaire (25 *vs* 24 cm H_2O). Les pressions muqueuses moyennes ont été généralement basses (< 12 cm H_2O) pour les deux masques, mais plus élevées pour le ML dans le pharynx latéral (4 *vs* 1 cm H_2O) et l'oropharynx (13 *vs* 3 cm H_2O) et plus élevées dans le pharynx postérieur pour le MLF (4 *vs* 2 cm H_2O). La PFO a augmenté avec le gonflement du ballonnet de 0-10 ml et de 10-20 ml pour les deux masques, et de 20-30 ml pour le MLF.

Conclusion : Nous concluons que le ML et le MLF sont similaires quant à la facilité d'insertion et à leur position, mais la PFO et les pressions muqueuses sont légèrement plus élevées avec le ML. Les pressions de la muqueuse pharyngée, pour les deux masques, ont été plus basses que celles qu'on considèrent habituellement sans risque pour la muqueuse trachéale. Le bilan général est similaire pour les deux appareils.

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THE flexible laryngeal mask airway (FLMA) was first described by Alexander in 1990[1] and was specifically designed to be used when the standard laryngeal mask airway (LMA) tube would interfere with the surgical field. It is a useful alternative to the tracheal tube for adenotonsillectomy,[2,3] laser pharyngoplasty[4] and dental surgery,[5] but there are no comparative data with the LMA. Although the cuff portion of the FLMA is identical to that of the LMA, the airway tubes are different: the FLMA has a long, narrow, non-rigid flexometallic tube; the LMA has a shorter, wider, semi-rigid tube. The semi-rigid LMA airway tube facilitates transmission of elastic recoil forces to the cuff, when it is fixed correctly, and force along the shaft during placement, but the non-rigid FLMA airway tube does not. We considered that these differences would influence insertion success rates and the way the cuff interacted with the pharyngeal tissues. In the following study, we test the hypothesis that mucosal pressures, ease of insertion, mask position and oropharyngeal leak pressure differ between the two devices.

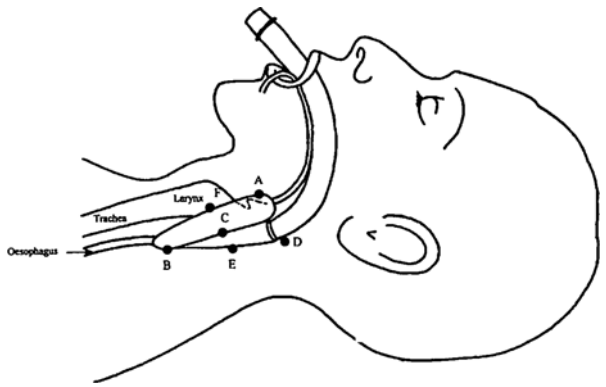

FIGURE Location of sensors on LMA and FLMA (corresponding anatomical area): A) anterior base of cuff (base of tongue); B) the posterior tip of cuff (hypopharynx); C) posterior middle part of cuff side (lateral pharynx); D) posterior tube (oropharynx); E) the backplate (posterior pharynx) and F) anterior middle part of the cuff side (pyriform fossa)

Methods

Twenty male and twenty female (ASA 1-2, aged 18-80 yr.) adult patients were randomly allocated to the size #5 FLMA or LMA for airway management. Ethical committee approval and informed consent were obtained. Patients were excluded from the trial if they were at risk of aspiration or considered otherwise unsuitable for the LMA. Mucosal pressures were measured using six strain gauge silicone microchip sensors (Codman® MicroSensor™, Bracknell, UK) attached to the external surface of the FLMA or LMA with clear adhesive dressing 45 μm thick.

The sensors had a diameter of 1.2 mm, a functional pressure range of −50 to 250 mm Hg, a temperature sensitivity of less than 0.1 mm Hg·°C^{-1}, a zero drift of < 3 mm Hg·24 hr^{-1}, a frequency response of 0-10 Hz and were accurate to ± 2%. The flat rectangular sensing element was located in a shallow groove 1 mm proximal to the tip. The cable had a diameter of 0.7 mm. Attachment of the sensors was performed manually by placing the sensor in the correct position on the FLMA or LMA and then overlaying it with the adhesive dressing. The sensing element was orientated such that it was facing the mucosa at 180 from the FLMA or LMA surface. The position and orientation of all the sensors were checked *in-vitro* over the entire inflation range before and after use in each patient by visual inspection. The sensors were zeroed after attachment to the FLMA or LMA. The accuracy of the measurement system was tested *in vitro* before and after use in each patient by submerging the cuff portion in water at 37°C to a depth of 13.6 cm (10 mm Hg) and 40.8 cm (30 mm Hg) and noting the pressure readings from each sensor. The sensors were attached with the microchip orientated away from the surface of the FLMA or LMA. The sensors were attached to the following locations on the LMA (corresponding mucosal area): A) anterior base of cuff (base of tongue); B) the posterior tip of cuff (hypopharynx); C) posterior middle part of cuff side (lateral pharynx); D) posterior tube (oropharynx); E) the backplate (posterior pharynx) and F) anterior middle part of the cuff side (pyriform fossa) (Figure 1). All sensors were zeroed in water 0.25 cm deep at 37°C prior to insertion.

A standard anesthesia protocol was followed and routine monitoring applied. Anesthesia was induced with 2.5 mg·kg^{-1} propofol and maintained with 100% O_2 and isoflurane 1-2%. Muscle relaxation was with 0.6 mg·kg^{-1} rocuronium. A single experienced FLMA/LMA user (> 1000 uses each device) inserted and fixed the FLMA/LMA according to the manufacturer's instructions.[6] The insertion technique was identical for both devices and included full deflation of the cuff, flattening it against the hard palate and pushing it along the posterior palato-pharyngeal curve using the index finger to provide centrifugal force. A size #5 device was used for all patients.[7] Measurements were made with the head and neck in the neutral position with the occiput resting on a firm

pillow 7 cm in height. The pilot balloon was attached via a three-way tap to a 10-ml syringe and a calibrated pressure transducer with an accuracy of ± 5%. The intracuff pressure was reduced to −55 cm H_2O *in vitro*. Mucosal pressures, intracuff pressures, oropharyngeal leak pressures and fibreoptic position were documented at zero volume and after each additional 10 ml up to 40 ml (maximum recommended cuff volume). The oropharyngeal leak pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 $L \cdot min^{-1}$, and noting the airway pressure at which the dial on the aneroid manometer reached equilibrium.[8] The fibreoptic position of the LMA or FLMA was determined using an established scoring system[9,10] and any displacement of the cuff from the periglottic tissues was noted. The circle system was disconnected during fibreoptic scoring and a self-sealing diaphragm was not used. The position of the hypopharyngeal sensor was verified at the end of the procedure by observation of a pressure spike during the application of gentle cricoid pressure. The number of attempts required for placement and the time taken to place the device determined the ease of insertion. A failed attempt was defined as removal of the device from the mouth. The insertion time was from first placement of the device in the mouth to cuff inflation. All observations were made by a second anesthesiologist.

Sample size was based on a pilot study of 10 patients in which mucosal pressures, oropharyngeal leak pressures and insertion time for the FLMA and LMA were measured for a type I error of 0.05 and a power of 0.9. The distribution of data was determined using Kolmogorov-Smirnov analysis. Statistical analysis of airway sealing and mucosal pressures was with paired t test (normally distributed data) and Friedman's two-way analysis of variance (non-normally distributed data). Chi squared test was used to compare fibreoptic scores. The relationship between mucosal pressure and oropharyngeal leak pressure was determined using Pearson product-moment correlation coefficient. Unless otherwise stated data are presented as mean (95% confidence intervals). Significance was taken as $P < 0.05$.

Results

There were no demographic differences between groups (Table I). All devices were inserted at the first attempt and the hypopharyngeal sensor was positioned correctly as judged the cricoid pressure spike. Time to successful placement was similar. The position and orientation of the sensors were identical and the pressures accurate before and after usage. There was no displacement of the cuff from the periglottic tissues. Oropharyngeal leak pressures were higher with the LMA at low intracuff volumes, but were similar at higher cuff volumes. Fibreoptic scores were similar. Mean mucosal pressure was higher for the LMA in the lateral pharynx (4 *vs* 1 cm H_2O) and oropharynx (13 *vs* 3 cm H_2O) and higher in the posterior pharynx for the FLMA (4 *vs* 2 cm H_2O) (Table I). The highest mucosal pressure was in the hypopharynx for the FLMA and in the oropharynx for the LMA. Mucosal pressures increased with increasing intracuff pressure and cuff volume for all locations with both devices, but the rate of increase varied between locations (Table II). There was no correlation between mucosal pressure and oropharyngeal leak pressure at any location for the LMA, but there was a correlation at one location for the FLMA (Table III). There was a correlation between mucosal pressure and cuff volume in 5/6 locations for the FLMA and 6/6 locations for the LMA. There was a correlation between mucosal pressure and intracuff pressure at all locations for both devices. Oropharyngeal leak pressure for the FLMA

TABLE I Demographic data, ease of insertion, mean oropharyngeal leak pressure, intracuff pressure, fibreoptic score (FOS) and mean mucosal pressures for the flexible laryngeal mask airway (FLMA) versus the standard laryngeal mask airway (LMA). Data are mean (95% confidence interval). Pressures are in cm H_2O. NS = Not significant.

	FLMA	*LMA*	*P*
Age; yr.	39 (32-45)	35 (30-41)	NS
Weight; kg	74 (64-82)	73 (68-77)	NS
Height; cm	173 (169-176)	172 (169-175)	NS
Male: Female; n	10:10	10:10	NS
Ease of insertion			
- Attempts 1/2/3; n	20/0/0	20/0/0	NS
- Time; sec	17 (9-25)	15 (8-24)	NS
Oropharyngeal leak pressure			
- Overall	19 (17-20)	22 (20-23)	0.0009
- Maximal	24 (22-25)	25 (22-28)	NS
Intracuff pressure	78 (62 - 94)	76 (60 - 92)	NS
FOS: 4/3/2/1; n	27/45/18/10	17/51/22/10	NS
Mucosal Pressures			
- A: Base of Tongue	9 (7-11)	12 (10-14)	NS
- B: Hypopharynx	9 (7-11)	11 (9-13)	NS
- C: Lateral pharynx	1 (1-2)	4 (3-5)	<0.0001
- D: Oropharynx	3 (2-3)	13 (11-16)	<0.0001
- E: Posterior pharynx	4 (2-6)	2 (1-2)	0.01
- F: Pyriform fossa	9 (7-11)	10 (9-12)	NS

Fibreoptic score 4=only vocal cords visible 3=vocal cords plus posterior epiglottis 2=vocal cords plus anterior epiglottic 1=vocal cords not seen[9]

TABLE II Oropharyngeal leak pressures (OLP), intracuff pressure (ICP), fibreoptic score (FOS) and mucosal pressures with increasing cuff volume (vol) for the flexible laryngeal mask (FLMA) and standard laryngeal mask airway (LMA). Data are mean (95% CI). Pressures are in cm H_2O.

	Vol (ml)	*OLP*	*ICP*	*FOS (n) 4/3/2/1*	*A*	*B*	*C*	*D*	*E*	*F*
FLMA	0	10 (8-12)	-29 (-32– -25)	5/8/4/3	3 (0-5)	3 (0-6)	1 (0-1)	1 (0-2)	1 (1-2)	2 (1-3)
	10	16 (14-19)	32 (21-43)	5/8/4/3	6 (3-8)	5 (3-8)	1 (0-2)	2 (1-3)	4 (1-9)	4 (2-5)
	20	21 (19-23)	70 (56-84)	5/10/3/2	9 (5-13)	9 (5-12)	2 (1-2)	3 (2-4)	4 (0-8)	10 (6-14)
	30	24 (22-25)	122 (104-140)	6/10/3/1	13 (7-18)	12 (8-17)	2 (1-3)	3 (2-5)	5 (2-8)	14 (9-19)
	40	23 (22-25)	197 (185-207)	6/9/4/1	15 (9-22)	17 (10-24)	2 (1-3)	4 (2-5)	5 (2-9)	17 (10-24)
LMA	0	14 (12-16)	-22 (-26– -19)	3/10/5/2	1 (0-2)	3 (1-5)	1 (0-2)	4 (2-7)	1 (0-1)	6 (3-8)
	10	19 (16-22)	27 (17-38)	3/10/5/2	8 (4-11)	5 (3-6)	3 (2-4)	7 (3-11)	2 (1-2)	8 (6-11)
	20	24 (21-27)	65 (53-77)	4/13/1/2	14 (9-20)	10 (7-13)	5 (3-6)	13 (8-18)	2 (1-2)	10 (7-13)
	30	25 (22-28)	113 (99-115)	4/8/6/2	15 (11-19)	14 (9-20)	5 (3-7)	17 (11-23)	2 (1-2)	13 (9-17)
	40	23 (20-27)	190 (179-205)	3/10/5/2	22 (16-28)	22 (15-30)	7 (5-9)	25 (17-33)	2 (2-3)	15 (10-19)

A: Base of Tongue. B: Hypopharynx. C: Lateral Pharynx. D: Oropharynx. E: Posterior Pharynx. F: Pyriform Fossa
Fibreoptic score 4=only vocal cords visible 3=vocal cords plus posterior epiglottis 2=vocal cords plus anterior epiglottis 1=vocal cords not seen.[9]

TABLE III The relationship between leak pressure, intracuff volume, intracuff pressure and mucosal pressure for the flexible laryngeal mask (FLMA) and the standard laryngeal mask airway (LMA). Pearson product-moment correlation coefficient (PPCC): +1 = perfect positive correlation; 0 = no correlation; -1 = perfect negative correlation. NS=not significant.

	Oropharyngeal leak pressure				*Cuff volume*				*Intracuff pressure*			
	FLMA		*LMA*		*FLMA*		*LMA*		*FLMA*		*LMA*	
Mucosal Location	*PPCC*	*P*	*PPCC*	*P*	*PPCC*	*P*	*PPCC*	*P*	*PPCC*	*P*	*PPCC*	*P*
A: Base of Tongue	0.092	NS	0.127	NS	0.437	<0.001	0.593	<0.001	0.385	<0.001	0.604	<0.001
B: Hypopharynx	0.228	0.02	0.121	NS	0.455	<0.001	0.603	<0.001	0.436	<0.001	0.575	<0.001
C: Lateral pharynx	0.033	NS	0.008	NS	0.320	0.001	0.510	<0.001	0.207	0.04	0.364	<0.001
D: Oropharynx	0.072	NS	0.027	NS	0.309	0.002	0.548	<0.001	0.363	<0.001	0.586	<0.001
E: Posterior pharynx	0.053	NS	0.014	NS	0.174	NS	0.347	<0.001	0.215	0.03	0.259	0.009
F: Pyriform fossa	0.166	NS	0.052	NS	0.531	<0.001	0.403	<0.001	0.499	<0.001	0.408	<0.001

increased with increasing intracuff volume from 0-10 ml ($P < 0.001$), 10-20 ml ($P < 0.001$) and from 20-30 ml ($P < 0.001$), and remained unchanged from 30 to 40 ml. Oropharyngeal leak pressure for the LMA increased with increasing intracuff volume from 0-10 ml ($P < 0.001$) and 10-20 ml ($P < 0.001$), and was unchanged from 20-30 ml and from 30 to 40 ml.

Discussion

The FLMA is identical to the LMA in all respects except that the semi-rigid airway tube has been replaced by a floppy flexometallic tube. This gives it flexibility and compression resistance, but force cannot be transmitted along the shaft and some authors consider it more difficult to insert than the LMA.[11] However, the insertion technique for the FLMA does not require use of the tube and can be accomplished by placing the index finger at the mask/tube junction and pressing the cuff into and pushing it along the posterior palatopharyngeal curve. Our data suggest that ease of insertion is similar between the LMA and FLMA using the above technique. It has been shown that the FLMA offers more resistance to gas flow and accommodates a smaller fibreoptic scope than the standard LMA, but gas flows and fibreoptic scope sizes are comparable to a similar sized TT.[12,13]

Mucosal pressures and oropharyngeal leak pressures were slightly higher for the LMA. These differences are probably related to the elastic recoil forces of the LMA airway tube pressing the cuff more firmly into the pharynx. The greatest difference for mucosal pressure was in the oropharynx. At this location, the curved LMA tube is adjacent to the vertebral body and is pressed posteriorly into it by its own elastic recoil. This does not occur with the floppy FLMA tube and the mucosal pressure is lower. This mecha-

nism may also explain the higher mucosal pressure in the lateral pharynx for the LMA, but not the higher pressure in the posterior pharynx for the FLMA. The differences in mucosal pressure between devices are probably unimportant since they are small and the overall values substantially lower than capillary perfusion pressure.[14] The greatest difference in oropharyngeal leak pressure between the devices was at low cuff volumes when it was 3-4 cm H_2O lower for the FLMA, but at higher cuff volumes it was similar. The differences in oropharyngeal leak pressure are probably unimportant since they are also small and can be eliminated by adding air to the FLMA cuff.

It is the conformity of the LMA cuff with the pharynx, rather than the pressure the cuff exerts on the mucosa, that determines the efficacy of the seal,[15,16] and oropharyngeal leak pressures are higher at low, rather than high, intracuff volumes and pressures.[15,17,18] Our data confirm these findings for the LMA and demonstrate that they also apply to the FLMA. Patients were managed with a size #5 LMA or FLM since using the size #5 in all adults is a better size selection strategy than the manufacturer's weight-based recommendations.[7] However, similar results (easy of insertion, mucosal pressures, mask position and pattern of changing oropharyngeal leak pressures) have been recently obtained when using the size #4 LMA in men and women.[19] We found a correlation between intracuff pressure and mucosal pressure, but intracuff pressures were considerably higher, other than at zero cuff volume. The cuff itself generates most of the intracuff pressure rather than the surrounding tissues. By subtracting *in-vivo* from *in-vitro* intracuff pressures, mucosal pressures can be calculated, but this technique has been shown to be imprecise since parts of the cuff press against the tube rather than the mucosa.[16,20]

We conclude that the LMA and FLMA perform similarly in terms of ease of insertion and mask position, but oropharyngeal leak pressure and mucosal pressures are slightly higher for the LMA. Pharyngeal mucosal pressures for both devices are lower than those considered safe for the tracheal mucosa. The overall clinical performance between the two devices is similar.

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