

The ProSeal Laryngeal Mask Airway

A Randomized, Crossover Study with the Standard Laryngeal Mask Airway in Paralyzed, Anesthetized Patients

Joseph Brimacombe, M.B., Ch.B., F.R.C.A., M.D.,* Christian Keller, M.D.†

Background: The ProSeal laryngeal mask airway (PLMA) is a new laryngeal mask device with a modified cuff to improve seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement. In the present randomized, crossover study, the authors tested the hypothesis that ease of insertion, airway sealing pressure, and fiberoptic position differ between the PLMA and the standard laryngeal mask airway (LMA). For the PLMA, we also assess ease of gastric tube placement and the efficacy of an introducer tool.

Methods: Sixty paralyzed, anesthetized adult patients were studied. Both devices (only size 4) were inserted into each patient in random order. Airway sealing pressure and fiberoptic position were determined during cuff inflation from 0 to 40 ml in 10-ml increments. Gastric tube insertion was attempted with the PLMA if there was no gas leak from the drainage tube. In 60 additional patients, ease of insertion for the PLMA was compared with and without an introducer.

Results: First-time success rates were higher (60 of 60 vs. 52 of 60; $P = 0.003$) and the effective airway time shorter (9 ± 3 s vs 20 ± 18 s; $P < 0.0001$) for the LMA. There were no failed uses of either device within three attempts. Airway sealing pressure was 8–11 cm H₂O higher for the PLMA at all cuff volumes ($P < 0.00001$) and was higher in females for both devices. Fiberoptic position was better with the LMA at all cuff volumes ($P < 0.00001$), but vocal cord visibility was similar (LMA, 59 of 60; PLMA, 56 of 60). For the PLMA, gastric tube placement was successful in 58 of 58 patients and took 9 ± 5 s. First-time success rates were higher (59 of 60 vs 53/60; $P = 0.03$) and the

effective airway time shorter (15 ± 13 s vs 23 ± 18 s; $P = 0.008$) with the introducer.

Conclusion: The PLMA is capable of achieving a more effective seal than the LMA and facilitates gastric tube placement, but it is more difficult to insert unless an introducer tool is used. When correctly positioned, the PLMA isolates the glottis from the upper esophagus with possible implications for airway protection. (Key words: Aspiration; gastric tube; positive pressure ventilation; regurgitation.)

THE standard laryngeal mask airway (LMA) is not an ideal airway device because the low-pressure seal may be inadequate for positive pressure ventilation, and it does not protect the lungs from gastric contents regurgitated into the pharynx.¹ A new laryngeal mask device, the ProSeal LMA (PLMA; Laryngeal Mask Company, Henley-on-Thames, UK), has been developed with a modified cuff to improve the seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement. In the present randomized, crossover study, we tested the hypothesis that ease of insertion, airway sealing pressure, and fiberoptic position differ between the PLMA and the LMA in paralyzed, anesthetized patients. For the PLMA, we also assessed ease of gastric tube placement and compared ease of insertion with and without an introducer.

* Clinical Professor, University of Queensland, Department of Anaesthesia and Intensive Care, Cairns Base Hospital, Cairns, Australia.

† Consultant Anaesthetist, Department of Anaesthesia and Intensive Care Medicine, Leopold-Franzens University, Innsbruck, Austria.

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Address reprint requests to Dr. Brimacombe: Department of Anaesthesia and Intensive Care Medicine, University of Queensland, Cairns Base Hospital, Cairns 4870, Australia. Address electronic mail to: jbrimacombe@north.net.au

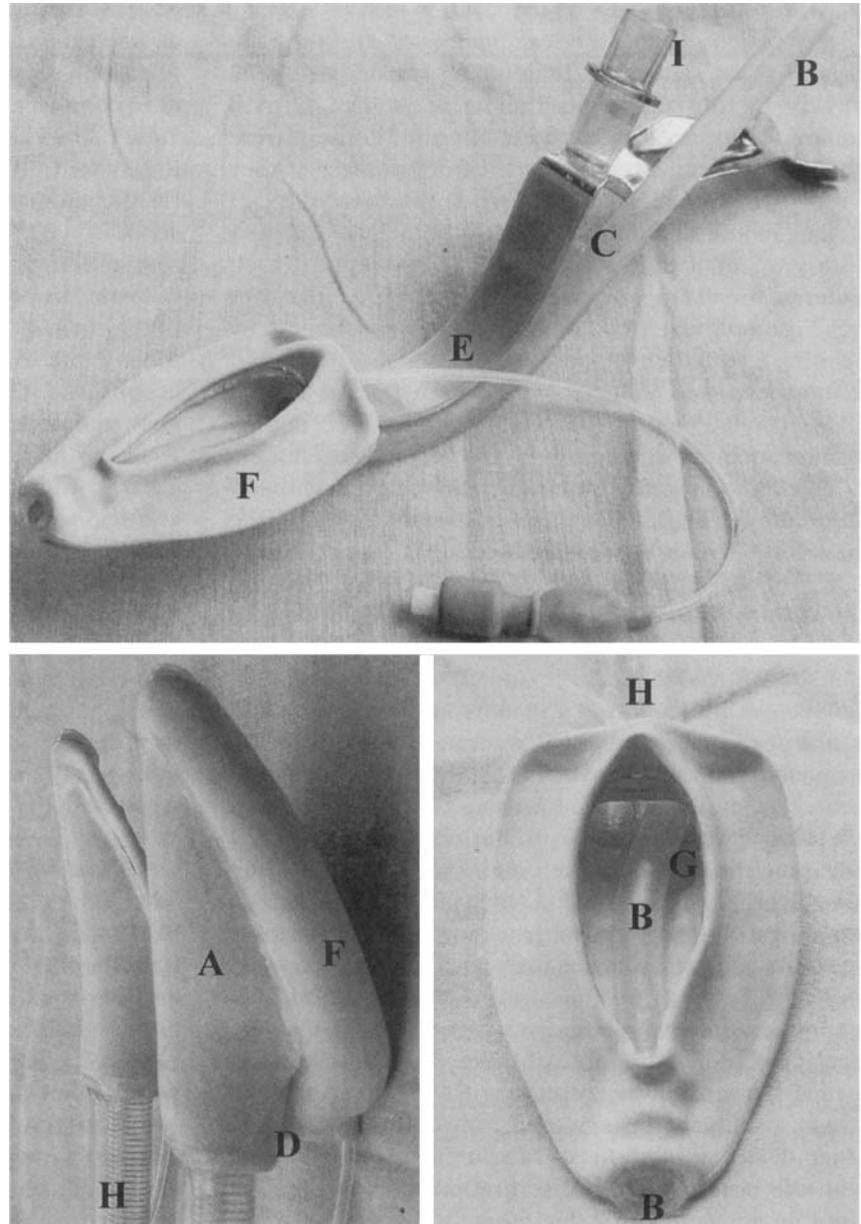
Methods

Device Description

The PLMA (fig. 1) is made from medical grade silicone and has the following new or modified features (intended purpose): (A) a dorsal cuff (pushes the ventral cuff into the periglottic tissues to improve the seal); (B) a drainage tube that travels from the tip through the bowl and alongside the airway tube (for passage of a ≤ 18 -French gauge gastric tube, for venting regurgitated fluid and to provide information about device position); (C) a built-in bite block; (D) a locating strap on the anterior

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Fig. 1. The ProSeal laryngeal mask airway with the introducer attached (*top*), with the cuff deflated and inflated (*bottom left*) and the drainage tube traveling through the bowl to the tip (*bottom right*). (A) Dorsal cuff; (B) drainage tube; (C) bite block; (D) locating strap; (E) introducer; (F) ventral cuff; (G) accessory vent; (H) double-tube configuration; (I) airway tube—wire enforced.



distal tube (prevents the finger or introducer slipping off the tube); (E) an introducer comprising a curved, malleable, silicone-coated, metal blade with a guiding handle (the distal end fits into the locating strap, and the proximal end fits into the airway tube); (F) a ventral cuff that is larger proximally (to improve seal by plugging gaps) and contained posteriorly by a bucket-shaped section of the distal tube; (G) an accessory vent under the drainage tube in the bowl (prevents pooling of secre-

tions and acts as an accessory ventilation port; (H) a double-tube configuration (increases stability); (I) a wire-reinforced airway tube (prevents the double-tube configuration from being too stiff); and (J) a deeper bowl than the standard LMA (facilitates a better fit in the pharynx; not depicted in fig. 1). The PLMA does not have a semirigid shield and does not have mask aperture bars, although the drainage tube functions as a mask aperture bar for the accessory vent.

Clinical Study 1

Sixty patients with American Society of Anesthesiologists physical status 1–2 undergoing minor peripheral surgery in the supine position were studied. Ethical committee approval and written, informed consent were obtained. Patients were excluded from the trial if they were < 18 yr of age, had a known or predicted difficult airway, mouth opening < 2.5 cm, a body mass index > 35 kg/m², or if they were at risk of aspiration. In 30 patients, the PLMA was inserted first and in 30 the LMA was inserted first. Randomization was performed by opening a sealed envelope.

Anesthesia was induced with fentanyl 1 µg/kg and midazolam 0.05 mg/kg followed by propofol 2.5 mg/kg. Maintenance was achieved with oxygen and sevoflurane 1–2%. Neuromuscular blockade was achieved with vecuronium 0.1 mg/kg. Patients were ventilated *via* a face mask for 3–5 min. Two experienced LMA users (J.B. and C.K., LMA > 1,500 uses; PLMA 30 uses) inserted the LMA/PLMA. The insertion technique for both devices was identical to the recommended technique for the LMA and included neck flexion, head extension, full deflation of the cuff, and a midline approach.² A slight lateral approach was used if resistance was felt in the oropharynx. A size 4 LMA/PLMA was used for all patients. The cuff was inflated with up to 40 ml air until an effective airway was obtained. Both devices were fixed by taping the tube over the chin. The number of insertion attempts was recorded. A failed attempt was defined as removal of the device from the mouth. Three attempts were allowed before device use was considered a failure. The time between picking up the LMA/PLMA and obtaining an effective airway was recorded. An effective airway was defined as normal thoraco-abdominal movement and a square wave capnograph trace. If an effective airway could not be achieved, one attempt with the other device was allowed. Measurements were made with the head/neck in the neutral position and the occiput on a firm pillow 7 cm in height.

Airway sealing pressure, the location of the airway gas leak at airway sealing pressure, and fiberoptic position were determined at 0–40-ml cuff volume in 10-ml increments. Airway sealing pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min and noting the airway pressure (maximum allowed, 40 cm H₂O) at which equilibrium was reached.³ The location of the airway gas leak at airway sealing pressure was determined as mouth (audible), stomach (epigastric auscultation), or drainage tube with the PLMA (bubbling of lubricant placed on the proximal

end of the drainage tube). Fiberoptic position of the airway tube (LMA/PLMA) was determined by passing a fiberoptic scope through the airway tube to a position 1 cm proximal to the end of the tube. The airway tube view (LMA/PLMA) was scored using an established scoring system.⁴ Fiberoptic position of the drainage tube (PLMA only) was determined by passing a fiberoptic scope down the drainage tube to a position just proximal to the end of the tube. The view was catalogued as follows: closed hypopharynx (mucosa blocking the end of the drainage tube); open hypopharynx (short conical tube of mucosa visible from drainage tube); open upper esophageal sphincter (a clear view down the esophagus); and other (glottis, epiglottis, arytenoids).

Gastric tube insertion was attempted if there was no gas leak from the drainage tube. The cuff volume was set at a standard value of 40 ml, and a lubricated 16-French gauge gastric tube was inserted. The time taken to pass the gastric tube was recorded, and placement was confirmed by synchronous injection of air and epigastric auscultation during apnea. The gastric tube was then removed. Airway sealing pressure was monitored during gastric tube placement and removal. The initial randomized device was then removed and the second device inserted. The observational assessments for each patient were made by the authors.

Clinical Study 2

In 60 additional patients, ease of insertion for the PLMA was compared with and without the introducer. Both the PLMA and PLMA plus introducer were inserted into each patient in random order. The insertion technique with the introducer was similar to the intubating LMA and comprised a one-handed rotational technique with the neck flexed and head extended. The introducer was removed immediately after insertion of the PLMA. Any airway problems at removal were documented.

Statistics

Sample size was selected to detect a projected difference of 20% between the groups with respect to airway sealing pressure for a type I error of 0.01 and a power of 0.9. The power analysis was based on data from a pilot study of 30 patients in which airway sealing pressure was measured with the PLMA and compared with published data for the LMA. Patients were excluded from the analysis of effective airway time if more than one attempt was required. The distribution of data were determined using Kolmogorov-Smirnov analysis.⁵ Statistical analysis was performed with a paired *t* test, Friedman's

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Table 1. Airway Sealing Pressure and Fiberoptic Position for the Laryngeal Mask Airway (LMA) and ProSeal Laryngeal Mask Airway (PLMA) with Increasing Cuff Volume

| Cuff volume | Airway sealing pressure* | | | Fiberoptic position of airway tube 4/3/2/1; n | | | |
|-------------|--------------------------|------------|----------|---|------------|----------|--|
| | LMA | PLMA | P | LMA | PLMA | P | |
| 0 | 7 (5-8) | 15 (14-17) | <0.00001 | 36/3/13/8 | 19/27/4/10 | <0.00001 | |
| 10 | 14 (12-15) | 22 (20-24) | <0.00001 | 38/3/14/5 | 19/28/5/8 | <0.00001 | |
| 20 | 16 (15-18) | 25 (23-28) | <0.00001 | 35/6/17/2 | 19/31/6/4 | <0.00001 | |
| 30 | 17 (15-19) | 27 (24-30) | <0.00001 | 35/5/19/1 | 19/28/9/4 | <0.00001 | |
| 40 | 16 (14-18) | 27 (24-30) | <0.00001 | 35/7/17/1 | 20/26/10/4 | <0.00001 | |

Data are mean (95% confidence interval) or numbers. Pressures are in cm H₂O.

* Airway sealing pressure > 40 cm H₂O in 5/60 with the LMA and 22/60 with the PLMA.

4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis; 2 = vocal cords plus anterior epiglottis; 1 = vocal cords not seen.

two-way analysis of variance, and chi-square test. Unless otherwise stated, data are presented as mean \pm SD. Significance was taken as $P < 0.05$.

Results

Clinical Study 1

The mean age, height, and weight were 39 yr (range, 18-77 yr), 171 cm (range, 150-193 cm), and 72 kg (range, 40-115 kg), respectively. The male:female ratio was 34:26. There were no failed uses of either device, but for the LMA, first-time success rates were higher (60 of 60 *vs* 52 of 60; $P = 0.003$) and the effective airway time shorter (9 ± 3 s *vs* 20 ± 18 s; $P < 0.0001$). With the PLMA, seven patients required two attempts, and one patient required three attempts. Repeat attempts were required because of difficulty sliding the cuff into the pharynx ($n = 5$) and an ineffective seal once in the pharynx ($n = 4$). A slight lateral approach was required more frequently with the PLMA (27 of 60 *vs* 3 of 60; $P < 0.00001$). An ineffective seal was always associated with air leakage up the drainage tube. Airway sealing pressure was 8-11 cm H₂O higher for the PLMA (all cuff volumes: $P < 0.00001$; table 1). For the LMA, airway sealing pressure increased significantly from 0- to 10-ml ($P < 0.00001$) and 10- to 20-ml ($P < 0.0001$) but remained unchanged from 20- to 30-ml and 30- to 40-ml cuff volume. For the PLMA, airway sealing pressure increased significantly from 0- to 10-ml ($P < 0.00001$), 10- to 20-ml ($P < 0.00001$), and 20- to 30-ml ($P = 0.03$) but remained unchanged from 30- to 40-ml cuff volume. Airway sealing pressure over the inflation range was higher for females than males for the LMA (17 ± 8 *vs* 12 ± 6 cm H₂O; $P < 0.0001$) and PLMA (27 ± 10 *vs* 23 ± 10 cm H₂O; $P = 0.005$). Fiberoptic position was better for the LMA (all

cuff volumes: $P < 0.0001$), but vocal cord visibility was similar (LMA, 59 of 60; PLMA, 56 of 60). A closed hypopharynx was observed from the drainage tube in 54 patients at zero cuff volume, decreasing progressively to 48 patients at 40-ml cuff volume. An open hypopharynx was observed in three patients at zero cuff volume, increasing progressively to seven patients at 40-ml cuff volume. An open upper esophageal sphincter was observed in 2 of 60 patients with the PLMA. In one patient, this occurred at all cuff volumes and in the other only at maximum cuff volume. In both of these patients, the PLMA had a good seal. Airway gas leakage at airway sealing pressure occurred from the mouth in 60 of 60 patients with the LMA and in 58 of 60 with the PLMA. Airway gas leakage occurred from the drainage tube in two patients: in one patient it occurred at 0-40-ml cuff volume and in one patient only at 40-ml cuff volume. In both of these patients, the arytenoids were visible from the drainage tube. Gastric insufflation was not detected with either device. Gastric tube placement was successful in 58 of 58 patients and took 9 ± 5 s. Airway sealing pressure did not change during gastric tube placement.

Clinical Study 2

The mean age, height, and weight for the additional 60 patients was 44 yr (range, 18-80 yr), 170 cm (range, 152-192 cm), and 69 kg (range, 46-108 kg), respectively. The male:female ratio was 38:22. With the introducer, first-time success rates were higher (59 of 60 *vs* 53 of 60; $P = 0.03$) and the effective airway time shorter (15 ± 13 s *vs* 23 ± 18 s; $P = 0.008$). Seven patients without the introducer required a second attempt, and insertion failed in one patient with and without the introducer. Airway sealing pressure and fiberoptic position were similar with and without the introducer. There

were no airway problems during removal of the introducer.

Discussion

ProSeal laryngeal mask airway insertion is more difficult than the LMA when used without the introducer. The larger cuff is more difficult to place in the mouth, leaves less room for the index finger, and is more likely to fold over. Insertion is easier with the introducer because it occupies less space than the finger, directs the cuff around the oropharyngeal inlet, and facilitates full depth of insertion. Although not tested, PLMA insertion should be feasible in nonparalyzed patients provided anesthesia depth is adequate.

The PLMA forms a better seal than the LMA, probably because the larger ventral cuff plugs gaps in the proximal pharynx and the dorsal cuff pushes the ventral cuff more firmly into the periglottic tissues. We used size 4 devices because the size 5 was unavailable. Airway sealing pressure for the LMA increases with mask size,⁶ which should also occur with the PLMA. Because we found that seal for the size 4 PLMA was better in females than males, a size 5 PLMA might be more appropriate for males. Although we only assessed airway sealing pressure as an index of airway/respiratory mechanics, the better seal suggests that the PLMA may be a better ventilatory device. Other pharyngeal airway devices where efficacy of seal has been compared with the LMA are the glottic seal airway⁷ (higher seal) and the cuffed oropharyngeal airway⁸ (lower seal).

The fiberoptic position of the airway tube was worse for the PLMA because of epiglottic downfolding. This may be related to the larger cuff catching the epiglottis during insertion. Epiglottic downfolding can increase work of breathing with the LMA,⁹ but this should not occur with the PLMA because of the accessory vent. Hypopharyngeal opening suggests that the PLMA tip can sit in the proximal hypopharynx or move into the proximal hypopharynx on cuff inflation. Upper esophageal sphincter opening may be related to reflex relaxation of the upper esophageal sphincter or a direct mechanical effect.

Gastric tube insertion was successful whenever attempted. Residual gastric fluid is commonly found in patients undergoing elective surgery.¹⁰ Routine gastric tube placement through the PLMA may have a role in gastric volume reduction, but further work is required before this can be recommended. Gastric tube place-

ment through the PLMA may be indicated if gastric insufflation has occurred after face mask ventilation.

When correctly positioned, the PLMA isolates the glottis from the esophagus. The PLMA may therefore provide some airway protection from regurgitated fluid. The LMA forms an effective plug above the upper esophageal sphincter in cadavers.¹¹ Preliminary cadaver work conducted by our group suggests that the PLMA allows fluid in the esophagus to bypass the oropharynx. The relative risks of draining regurgitated pharyngeal fluid (PLMA) to preventing pharyngeal regurgitation (LMA) are yet to be determined. We did not detect gastric insufflation, but the efficacy of epigastric stethoscopy for detection has not been formally validated. In theory, gastric insufflation is unlikely because any airway pressure exposed to the upper sphincter should be vented up the drainage tube. Further work using a more sensitive detection system such as an epigastric microphone is required. Interestingly, we found that the presence of an air leak up the drainage tube was always associated with malposition. The PLMA should be reinserted if it is malpositioned, and if this fails, an alternative airway device should be used.

Further research is required to determine the role of the PLMA in airway management, but the better seal suggests a role as an alternative to the LMA for positive pressure ventilation either as a backup (if the LMA fails) or as a replacement device (because overall success is likely to be higher). The PLMA may also be a safer option than the LMA or face mask in the "cannot intubate, cannot ventilate" scenario in which the patient is at risk of aspiration.

In conclusion, the PLMA is capable of achieving a more effective seal than the LMA and facilitates gastric tube placement, but it is more difficult to insert unless an introducer tool is used. When correctly positioned, the PLMA isolates the glottis from the upper esophagus with possible implications for airway protection.

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