

# The Laryngeal Mask Airway ProSeal™ as a Temporary Ventilatory Device in Grossly and Morbidly Obese Patients Before Laryngoscope-Guided Tracheal Intubation

Christian Keller, MD\*, Joseph Brimacombe, MB, ChB, FRCA, MD†, Axel Kleinsasser, MD\*, and Lawrence Brimacombe, MB, ChB, MRCP†

\*Department of Anaesthesia and Intensive Care Medicine, Leopold-Franzens University, Innsbruck, Austria; and

†Department of Anaesthesia and Intensive Care, Cairns Base Hospital, Cairns, Australia

We determined the efficacy of the laryngeal mask airway ProSeal™ (PLMA) as a temporary ventilatory device in morbidly obese patients before laryngoscope-guided tracheal intubation. Sixty patients (body mass index 35–60 kg/m<sup>2</sup>) scheduled for elective surgery, who preferred airway management under general anesthesia, were studied. The induction of anesthesia was with midazolam/fentanyl/propofol and maintenance was with sevoflurane 1%–3% in oxygen 100%. The PLMA was inserted and an effective airway established. Rocuronium was given IV for paralysis. Oropharyngeal leak pressure, ease of gastric tube placement, residual gastric volume, fiberoptic position of the airway/drainage tube, and ease of ventilation at a tidal volume of 8 mL/kg was determined. The PLMA was then removed and laryngoscope-guided tracheal intubation attempted. The number of insertion/intubation attempts (maximum two each) and time taken to establish an effective airway with each device were recorded. An effective airway was obtained at the first insertion attempt in 90% of patients (54/60) and at the second attempt in 10% (6/60). The time taken to provide an effective airway was 15 ± 7 s (7–42 s). Oropharyngeal

leak pressure was 32 ± 8 cm H<sub>2</sub>O (12–40 cm H<sub>2</sub>O). The residual gastric volume was 36 ± 46 mL (0–240 mL). Positive pressure ventilation without air leaks was possible in 95% of patients (57/60). The vocal cords were seen from the airway tube in 75% of patients (45/60), but the esophagus was not seen. The fiberoptic view from the drainage tube revealed mucosa in 93% of patients (56/60) and an open upper esophageal sphincter in 7% (4/60). Tracheal intubation was successful at the first attempt in 90% of patients (54/60), at the second attempt in 7% (4/60), and failed in 3% (2/60). In these latter two patients, the PLMA was reinserted and surgery performed uneventfully with the PLMA. The time taken to tracheally intubate the patient was 13 ± 10 s (8–51 s). There were no episodes of hypoxia (SpO<sub>2</sub> <90%) or other adverse events. There were no differences in insertion success rate, or the time to successful insertion between the PLMA and laryngoscope-guided intubation. We conclude that the PLMA is an effective temporary ventilatory device in grossly or morbidly obese patients before laryngoscope-guided tracheal intubation.

(Anesth Analg 2002;94:737–40)

**T**he laryngeal mask airway ProSeal™ (PLMA) is a new laryngeal mask device with a modified cuff to improve the seal and a drainage tube to provide access to the gastrointestinal tract (1). Studies performed in patients with a body mass index (BMI) <35 kg/m<sup>2</sup> have shown that the PLMA has a more effective seal than the classic laryngeal mask airway (LMA), facilitates gastric tube placement, and isolates the glottis from the esophagus when

correctly positioned (1–3). The LMA is contraindicated in grossly or morbidly obese patients, other than for airway rescue or as an aid to awake tracheal intubation, because of the increased risk of regurgitation and the requirements for high airway pressure ventilation (4). In the following descriptive study, we determined the effectiveness of the PLMA as a temporary ventilatory device used in grossly and morbidly obese patients before laryngoscope-guided tracheal intubation.

## Methods

With ethics committee approval and written informed consent, we studied 60 grossly (BMI ≥35–

Accepted for publication November 6, 2001.

Address correspondence and reprint requests to Professor Brimacombe, Department of Anaesthesia and Intensive Care, Cairns Base Hospital, The Esplanade, Cairns 4870, Australia. Address e-mail to jbrimacombe@austarnet.com.au.

50 kg/m<sup>2</sup>) or morbidly (BMI ≥50 kg/m<sup>2</sup>) obese patients scheduled for elective surgery, who preferred airway management under general anesthesia. Patients were excluded if they had more than 1 symptom of gastroesophageal reflux per week, mouth opening <2.5 cm, or had a known difficult airway. In our institutes, anesthesia management for these patients would normally comprise preoxygenation, induction of anesthesia, face mask ventilation, and intubation. In this feasibility study, the PLMA was used as an alternative to the face mask before tracheal intubation.

Patients were premedicated with ranitidine 150 mg *per os* 1.5 h preoperatively. Monitoring was applied before induction and included an electrocardiograph, pulse oximeter, gas analyzer, arterial line, tidal volume monitor, airway pressure monitor, and peripheral nerve stimulator. Anesthesia was given with the patient in the supine position with the patient's head on a standard pillow 8 cm in height. Midazolam 0.02 mg/kg and fentanyl 1 μg/kg were administered. Patients were preoxygenated for 5 min. Anesthesia was induced with propofol 2–3 mg/kg given over 30 s, and the PLMA inserted when there was no response to jaw thrust (5). Additional boluses of propofol 0.5 mg/kg were given as required until an adequate level of anesthesia was achieved for placement. Anesthesia was maintained with sevoflurane 1%–3% in oxygen 100%. Face mask ventilation was performed if conditions for insertion were not suitable within 30 s of completion of the induction dose.

The size 5 PLMA was inserted/fixed according to the manufacturer's instructions (6). The introducer tool was used. The PLMA was connected to a circle anesthesia breathing system and the cuff inflated with air until an effective airway was established or the maximal recommended inflation volume reached (40 mL). An effective airway was judged by a square wave capnograph trace and no audible leak with peak airway pressures ≥12 cm H<sub>2</sub>O during manual ventilation. The PLMA was removed and reinserted if air leaked up the drainage tube, or there was airway obstruction, or the bite block protruded from the teeth/gums. Once an effective airway was obtained, rocuronium 0.5 mg/kg IV was administered for paralysis. The intracuff pressure was set at 60 cm H<sub>2</sub>O, and the oropharyngeal leak pressure was determined (7). Any gastric insufflation was noted during oropharyngeal leak pressure testing by listening over the epigastrium with a stethoscope (8). A well-lubricated 14F gastric tube was inserted through the drainage tube if there was no air leak up the drainage tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy. The gastric tube was then aspirated, removed, and the volume of aspirate noted. A fiberoptic scope was passed down to the distal aperture of the

airway tube and the visibility of the vocal cords and/or esophagus noted. The fiberoptic position of the drainage tube 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 cataloged as hypopharynx (mucosa), open upper esophageal sphincter (a clear view down the esophagus), and others (glottis, epiglottis, arytenoids). Patients were ventilated for 3 min with the cuff fully inflated at an inspired tidal volume of 8 mL/kg (true weight), a respiratory rate of 12/min, and an inspiratory/expiratory ratio of 1:1.5. The presence/absence of oropharyngeal air leaks (detected by listening over the mouth (7)), gastric air leaks (detected by listening with a stethoscope over the epigastrium (8)), drainage tube air leaks (detected by placing lubricant over the proximal end of the drainage tube), or an end-tidal CO<sub>2</sub> >45 mm Hg was noted. Once these data were collected and the train-of-four count was zero, the PLMA was removed and laryngoscope-guided intubation attempted by using a MacIntosh laryngoscope blade (Parker Healthcare, Mansfield, Australia) and a size 8.0-mm tracheal tube. Conditions for intubation were optimized, as described by Benumof (9). If the vocal cords were not visible, a gum elastic bougie was used. The Cormack and Lehane (10) score was noted at laryngoscopy: grade 1, glottis visible including anterior and posterior commissures; grade 2, glottis visible, but anterior commissure not seen; grade 3, glottis not visible, but corniculate cartilages visible; grade 4, glottis and corniculate cartilages not visible. The number of insertion and intubation attempts was recorded. A maximum of two attempts was allowed before insertion or intubation was considered a failure. A failed attempt was defined as removal of the PLMA or laryngoscope from the mouth. If either technique failed, the alternative technique was used. The time between picking up the PLMA or laryngoscope and obtaining an effective airway was recorded. Any episodes of hypoxia (SpO<sub>2</sub> <90%) or other adverse events were documented.

All cases were conducted by anesthesiologists with more than 10 yr clinical experience of laryngoscope-guided tracheal intubation and more than 100 uses of the PLMA. Data were collected by unblinded observers. Statistical analysis was performed with paired *t*-test,  $\chi^2$  test, and Kendall's rank correlation. Data are mean ± SD (range) or numbers unless otherwise stated. Significance was taken as *P* < 0.05

## Results

The age, height, weight, and BMI were 37 ± 9 yr (21–65 yr), 170 ± 9 cm (155–189 cm), 124 ± 19 kg (95–180 kg), and 43 ± 6 kg/m<sup>2</sup> (35–60 kg/m<sup>2</sup>), respectively. The male/female ratio was 27:33. The ratio of

grossly to morbidly obese patients was 46:14. The distribution of modified Mallampati (11) grades was: 1/2/3/4,  $n = 14/12/17/17$ . The procedures being performed were: gastric banding ( $n = 18$ ), peripheral orthopedics ( $n = 21$ ), laparoscopic cholecystectomy ( $n = 8$ ), gynecologic laparotomy ( $n = 8$ ), umbilical/inguinal hernia repair ( $n = 4$ ), and mastectomy ( $n = 1$ ). Conditions were suitable for PLMA insertion in all patients within 30 s. An effective airway was obtained at the first insertion attempt in 90% of patients (54/60) and at the second attempt in 10% (6/60). The time taken to provide an effective airway was  $15 \pm 7$  s (7–42 s). Oropharyngeal leak pressure was  $32 \pm 8$  cm H<sub>2</sub>O (12–40 cm H<sub>2</sub>O). The vocal cords were seen from the airway tube in 75% of patients (45/60), but the esophagus was not seen. The fiberoptic view from the drainage tube revealed mucosa in 93% of patients (56/60) and an open upper esophageal sphincter in 7% (4/60). There were no air leaks from the drainage tube. Gastric insufflation was not detected in any patient. The gastric tube was inserted at the first attempt in all patients. The residual gastric volume was  $36 \pm 46$  mL (0–240 mL). Positive pressure ventilation at 8 mL/kg tidal volume was possible without oropharyngeal air leaks in 95% of patients (57/60), without gastric air leaks in 100% (60/60), without drainage tube air leaks in 100% (60/60), and without the end-tidal CO<sub>2</sub> >45 mm Hg in 98% (59/60). The distribution of Cormack and Lehane scores was: 1/2/3/4,  $n = 20/31/8/1$ . Tracheal intubation was successful at the first attempt in 90% of patients (54/60), at the second attempt in 7% (4/60), and failed in 3% (2/60). In these latter two patients, the PLMA was reinserted and the procedure completed with the PLMA as the airway device. The gum elastic bougie was used in nine patients. The time taken to intubate the patient (excluding the two failures) was  $13 \pm 10$  s (8–51 s). There were no adverse events. There were no differences in success rates or the time to successful insertion between the PLMA and laryngoscope-guided intubation. There were no differences between grossly and morbidly obese patients. There was no correlation between Mallampati or Cormack and Lehane scoring and any measured variable for the PLMA.

## Discussion

We found that the PLMA is an effective temporary ventilatory device in grossly or morbidly obese patients before laryngoscope-guided tracheal intubation. The insertion success rates, insertion time, fiberoptic position of the airway and drainage tube, and ease of gastric tube placement were similar to our previous study of nonobese patients. However, oropharyngeal leak pressure was higher in obese patients. This may be related to the use of the size 5 in the current study

versus the size 4 in the previous study (2). Interestingly, Brain et al. (1) found that there was a positive correlation between BMI and oropharyngeal leak pressure for the PLMA and LMA. Perhaps fat deposits in the neck allow the pharynx to better adapt to the shape of the cuff or reduce the pharyngeal volume.

We found that positive pressure ventilation with a tidal volume of 8 mL/kg was possible in 95%–98% of patients. This is comparable to the efficacy of the PLMA (12) and LMA<sup>1</sup> (13) as a ventilatory device for nonobese patients. We found that there were no air leaks up the drainage tube during oropharyngeal leak pressure testing, that gastric insufflation did not occur, and that gastric tube insertion was easy. This suggests that the respiratory tract was effectively isolated from the gastrointestinal tract. There is evidence from cadavers (14) and an anesthetized patient (15) that the PLMA will protect the lungs from regurgitated gastric contents if it is correctly placed. The frequency of the upper esophageal sphincter being open was similar to the previous study of nonobese patients (2). Assuming a binomial distribution for the incidence of adverse events, the upper limit for the probability of an adverse event occurring when no such events have been observed in 60 patients is 0.07 (16). Therefore, we can state with 95% confidence that the technique seems to be safe in at least 93% of grossly and morbidly obese patients.

We found that there was no relationship between Mallampati or Cormack and Lehane scoring and any measured variable for the PLMA. This suggests that the PLMA insertion is feasible in obese patients with predicted and unpredicted difficult airways. Similar findings have been obtained for the LMA for both Mallampati (17–19) and Cormack and Lehane<sup>2</sup> (20) scoring. Interestingly, in all six patients in the current study who required more than one intubation attempt, the PLMA formed an effective airway at the first insertion attempt. Insertion of the PLMA is more difficult than the LMA in nonobese patients with normal airways (2), but the implications of this for the difficult airway scenario in obese and nonobese patients is unknown.

Our study has a number of limitations. First, we only used the PLMA for a period of 5–10 minutes before the patient was intubated and our data must be interpreted cautiously regarding its use for longer periods. However, we consider it unlikely that airway quality would have deteriorated with time. There is evidence that airway quality does not change with time for the LMA (21,22) and the stability of the LMA

<sup>1</sup> Izuka T, Ishii N. The efficacy of the laryngeal mask airway during positive-pressure ventilation under general anesthesia [abstract]. *Anesth Analg* 1997;84:S240.

<sup>2</sup> Mahiou P, Narchi P, Veyrac P, et al. Is laryngeal mask easy to use in case of difficult intubation? [abstract] *Anesthesiology* 1992;77:A1228.

and PLMA are similar in different head and neck positions (23). Also, there was no change in airway quality in the two patients managed with the PLMA during the procedure after failed intubation. Second, airway management was performed by experienced users and our findings might not apply to less experienced users. Third, any comparisons with tracheal intubation must be interpreted cautiously because PLMA insertion always preceded intubation. We elected to intubate patients after PLMA insertion because this is the current "gold standard" for airway management of grossly and morbidly obese patients. We considered that using the PLMA for the entire procedure was not justified given the current lack of knowledge about the device in this high-risk population. However, based on our findings, we consider that the PLMA could be used as an alternative ventilatory device in grossly and morbidly obese patients. Fourth, data collection was unblinded. Fifth, we did not use a control group managed with the LMA.

We conclude that the PLMA is an effective temporary ventilatory device in grossly and morbidly obese patients before laryngoscope-guided tracheal intubation. Further investigations into the prolonged use of the PLMA in this population are justified.

## References

1. Brain AIJ, Verghese C, Strube PJ. The LMA 'ProSeal': a laryngeal mask with an oesophageal vent. *Br J Anaesth* 2000;84:650-4.
2. Brimacombe J, Keller C. The ProSeal laryngeal mask airway: a randomized, crossover study with the standard laryngeal mask airway in paralyzed, anesthetized patients. *Anesthesiology* 2000;93:104-9.
3. Keller C, Brimacombe J. Mucosal pressure and oropharyngeal leak pressure with the ProSeal versus the classic laryngeal mask airway. *Br J Anaesth* 2000;85:262-6.
4. Brimacombe J, Brain AIJ, Berry A. The laryngeal mask airway: review and practical guide. London: WB Saunders, 1997.
5. Drage MP, Nunez J, Vaughan RS, Asai T. Jaw thrusting as a clinical test to assess the adequate depth of anaesthesia for insertion of the laryngeal mask. *Anaesthesia* 1996;51:1167-70.
6. LMA ProSeal™ instruction manual. Henley-on-Thames: The Laryngeal Mask Company, Ltd., 2000.
7. Keller C, Brimacombe J, Keller K, Morris R. A comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *Br J Anaesth* 1999;82:286-7.
8. Brimacombe J, Keller C, Kurian S, Myles J. Reliability of epigastric auscultation to detect gastric insufflation. *Br J Anaesth*. In press.
9. Benumof JL. Management of the difficult adult airway: with special emphasis on awake tracheal intubation. *Anesthesiology* 1991;75:1087-110.
10. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. *Anaesthesia* 1984;39:1105-11.
11. Samssoon GLT, Young JRB. Difficult tracheal intubation: a retrospective study. *Anaesthesia* 1987;42:487-90.
12. Brimacombe J, Keller C, Boehler M, Puehringer F. Positive pressure ventilation with the ProSeal versus classic laryngeal mask airway: A randomized, crossover study of healthy female patients. *Anesth Analg* 2001;93:1351-3.
13. Van Damme E. The laryngeal mask in ambulatory anesthesia. An evaluation of 5,000 ambulatory anesthesia incidents. *Anesthesiol Intensivmed Notfallmed Schmerzth* 1994;29:284-6.
14. Keller C, Brimacombe J, Kleinsasser A, Loeckinger A. Does the ProSeal laryngeal mask airway prevent aspiration of regurgitated fluid? *Anesth Analg* 2000;91:1017-20.
15. Brimacombe J, Keller C. Airway protection with the ProSeal laryngeal mask airway: a case report. *Anaesth Intensive Care* 2001;29:288-91.
16. Pearson ES, Hartley HO, eds. Biometric tables for statisticians. Cambridge, UK: Cambridge University Press, 1970:228.
17. Brimacombe J, Berry A. Mallampati classification and laryngeal mask insertion. *Anaesthesia* 1993;48:347.
18. Brimacombe J. Analysis of 1500 laryngeal mask uses by one anaesthetist in adults undergoing routine anaesthesia. *Anaesthesia* 1996;51:76-80.
19. Berry AM, Brimacombe J, McManus KF, Goldblatt M. An evaluation of the factors influencing selection of the optimal size of laryngeal mask airway in normal adults. *Anaesthesia* 1998;53:565-70.
20. Walker RW. The laryngeal mask airway in the difficult paediatric airway: an assessment of positioning and use in fiberoptic intubation. *Paediatr Anaesth* 2000;10:53-8.
21. Brimacombe J, Keller C. Does efficacy of seal and anatomic position change during anaesthesia with the laryngeal mask airway: a comparison of oxygen and oxygen-nitrous oxide gas mixtures. *Acta Anaesthesiol Scand* 2000;44:1258-60.
22. Brimacombe J, Berry A. Laryngeal mask airway cuff pressure and position during anaesthesia lasting one to two hours. *Can J Anaesth* 1994;41:589-93.
23. Brimacombe J, Keller C. Stability of the ProSeal and standard laryngeal mask airway in different head and neck positions: a randomised crossover study. *Eur J Anaesthesiol*. In press.