Clinical Study

Randomised Comparison of the AMBU AuraOnce Laryngeal Mask and the LMA Unique Laryngeal Mask Airway in Spontaneously Breathing Adults

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We conducted a randomised single-blind controlled trial comparing the LMA-Unique (LMAU) and the AMBU AuraOnce (AMBU) disposable laryngeal mask in spontaneously breathing adult patients undergoing general anaesthesia. Eighty-two adult patients (ASA status I–IV) were randomly allocated to receive the LMAU or AMBU and were blinded to device selection. Patients received a standardized anesthetic and all airway devices were inserted by trained anaesthetists. Size selection was guided by manufacturer recommendations. All data were collected by a single, unblinded observer. When compared with the LMAU, the AMBU produced significantly higher airway sealing pressures (AMBU 20 ± 6; LMAU 15 ± 7 cm H_2O; $P = 0.001$). There was no statistical difference between the two devices for overall success rate, insertion time, number of adjustments, laryngeal alignment, blood-staining, and sore throat ($P \geq 0.05$). The AMBU AuraOnce disposable laryngeal mask provided a higher oropharyngeal leak pressure compared to the LMA Unique in spontaneously breathing adult patients.

1. Introduction

In 1988, Dr. Archie Brain introduced a reusable supraglottic airway device, the Laryngeal Mask Airway Classic (LMAC), a proven safe and effective device in airway management. There are several single-use disposable alternatives to the LMAC. They differ in shape, stiffness, and cuff properties to the LMAC [1]. We conducted a randomized comparison of two disposable supraglottic airways and their seal efficacy: the Laryngeal Mask Airway-Unique (LMAU; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) and the AMBU AuraOnce Disposable Laryngeal Mask (AMBU; AMBU A/S, Denmark). The LMAU is made from a medical grade PVC compound and is similar in design to the LMAC. The AMBU is constructed from a single piece PVC mould and is available in a full range of paediatric and adult sizes. It incorporates a 90-degree preformed curvature designed to better approximate airway anatomy [2] and lacks the aperture bars of the LMAU.

2. Materials and Methods

After receiving institutional review board approval (Royal Melbourne Hospital), written informed consent was obtained during the preanaesthetic assessment on 82 consecutive patients aged above 18 years (ASA I–IV) [3] undergoing spontaneous ventilating general anaesthesia. Patients undergoing peripheral surgery in orthopaedics and plastic surgery and patients undergoing breast (general) or urological surgery were deemed suitable for recruitment. Patients were excluded if they had contraindications to the use of a supraglottic airway (BMI > 40, interincisor distance <2.5 cm, or aspiration risk) or had a contraindication to our anaesthetic protocol. Patients were allocated to either the LMAU or AMBU groups by a pregenerated random number sequence concealed in a sealed opaque envelope. This was opened after informed consent and patients remained blinded to their group allocation. Weight-based sizing of the airway devices was used based on manufacturer

recommendations (size 3: 30–50 kg; size 4: 50–70 kg; size 5 > 70 kg). All participating consultant anaesthetists had >200 previous clinical attempts with an LMAU equivalent device (LMAC). To ensure adequate familiarity with the AMBU device, all anaesthetists completed an AMBU education program consisting of interactive tutorial and successful completion of 10 insertions with the AMBU on a manufacturer recommended part-task airway trainer. Routine preinsertion tests were performed according to the manufacturers' protocols [2, 4]. No premedication was given. Patients were preoxygenated and anaesthesia was induced with propofol (1-2 mg/kg), fentanyl (1–3 μg/kg), $\pm$ midazolam (0.025–0.05 mg/kg) at the discretion of the anaesthetist. Routine anaesthetic monitoring was instituted as per Australian and New Zealand College of Anaesthetists guidelines for general anaesthesia [5].

Following induction of anaesthesia patients underwent assisted bag-mask ventilation with 100% oxygen and sevoflurane. After loss of lash reflex and loss of jaw tone, the airway device was inserted and fixed according to manufacturer instruction [2, 4]. The cuff was filled with air to the maximum manufacturers recommended volume (size 3, 20 mls; size 4, 30 mls; size 5, 40 mls), and the intracuff pressure was measured using a three-way stopcock and calibrated aneroid manometer. Three attempts at insertion were allowed. During spontaneous ventilation, anaesthesia was maintained using sevoflurane (1–3%) and an oxygen-air mixture to achieve an inspired oxygen concentration of 70–80%. Metaraminol was administered for any systemic arterial hypotension. Analgesia was provided by titrated boluses of fentanyl. Following conclusion of surgery, the anaesthetic gases were replaced by 100% oxygen and the patient transferred to recovery room. The device was removed with the return of airway reflexes.

All data were collected by a single, unblinded, independent observer. The patient's age, sex, height and weight, American Society of Anesthesiologists-Physical Status (ASA) [3], device size and type, and duration of surgery were recorded. An effective airway was defined by resistance to further downward motion, chest wall movement, presence of end tidal side-stream CO_2 waveform, and movement of the reservoir bag during spontaneous ventilation. A failed insertion attempt was defined as complete withdrawal from the mouth following an unsuccessful placement. The number of insertion attempts was recorded, and after three attempts, the device was regarded as failed and a cLMA was then inserted without further data collection. The total time of insertion was defined by the moment the device was picked up to the first end tidal side-stream CO_2 trace.

Our primary endpoint of oropharyngeal leak pressure (OLP) was determined using the manometric stability test with a fresh gas flow of 3 L/min against a closed pressure-limiting valve of the anaesthetic circuit. The airway pressure (maximum of 30 cm H_2O) was recorded when equilibrium was obtained. After insertion, laryngeal alignment was assessed with fibreoptic bronchoscope (Olympus LF-GP, Olympus Optical Company, Japan) inserted to the aperture of the device via a self-sealing diaphragm. The fibreoptic view was graded according to an established scoring system

TABLE 1: Patient demographics, surgery type, and airway sizing.

	LMAU (n = 38)	AMBU (n = 41)	P-value
Age (Years)	46 20 (19–80)	45 16 (19–80)	0.707
Weight (kg)	72 13	75 16	0.421
Height (cm)	172 11	168 12	0.114
BMI (kg/m^2)	24 4	26 5	0.054
Male Gender	19 (50)	18 (44)	0.746
ASA (I/II/III/IV)	11/22/5/0	16/20/4/1	0.635
Surgery Type			0.875
General	14 (37)	21 (51)	
Plastics	12 (32)	13 (32)	
Orthopaedics	8 (21)	5 (12)	
Urology	4 (10)	2 (5)	
Airway Size (3/4/5)	14/19/5	19/16/6	0.738
Duration Surgery (mins)	37 22 (15–110)	46 20 (10–130)	0.375

All data are presented as mean standard deviation (range) or numbers (%). LMAU: LMA Unique laryngeal mask, AMBU: AMBU AuraOnce laryngeal mask, BMI: body mass index, ASA: American Society of Anesthesiologists physical status score.

for direct laryngoscopy [6]. Respiratory complications such as desaturations (pulse oximetry <95%), hiccups or stridor were noted. Cuff pressure was recorded at 5-minute intervals. The device was inspected for blood on removal and patients were directly questioned for sore throat using a dichotomous rating (present or absent) on discharge from the recovery room.

Sample size was obtained by performing a prospective power analysis with oropharyngeal leak pressure as the primary endpoint. The sample size was calculated to project a change of 20% in the primary outcome variable based on a previous peer-reviewed trial result for the LMAU of 25 ± 6 mmHg (mean $\pm$ S.D) [7], with a type I error 0.05 and a power of 95% to reject the null hypothesis. All quantitative data were found to be parametric and were examined by two-sided Student's t-tests for single comparisons and ANOVA for multiple comparisons. Cuff pressure changes were analysed by repeated measures ANOVA (SYSTAT v.7, SPSS Inc. Chicago). Qualitative data were assessed by Chi-square or Fisher exact test where appropriate. All data are presented as mean standard deviation (range) or numbers (%). $P < 0.05$ was considered statistically significant.

3. Results

Ninety-nine patients were identified as eligible for the study, eight patients declined consent, two patients had their surgery postponed, and seven patients were excluded by the treating anaesthetist, leaving eighty-two consecutive patients who were consented for the study. In three patients, equipment (fibreoptic bronchoscope) was unavailable, resulting in seventy-nine patients being randomised. At baseline, groups were similar (Table 1). The primary endpoint of oropharyngeal leak pressure (OLP) was completed in all

TABLE 2: Results.

	LMAU ($n = 38$)	AMBU ($n = 41$)	P-value
Insertion success			
First time	31 (82)	35 (85)	0.738
Overall	38 (100)	40 (98)	0.519
Insertion time (s)	32 16 (11–95)	27 10 (13–51)	0.111
OLP (cm H_2O)	15 7 (4–30)	20 6 (5–30)	0.001
Laryngeal Alignment	$n = 38$	$n = 40$	
I	21 (55)	21 (54)	
II	9 (24)	9 (23)	
III	7 (18)	7 (18)	
IV	1 (3)	2 (5)	0.613
Blood Staining	3 (8)	4 (10)	0.543
Sore Throat PACU	4 (11)	3 (8)	0.457

All data are presented as mean $\pm$ standard deviation (range) or numbers (%). LMAU: LMA Unique laryngeal mask, AMBU: AMBU AuraOnce laryngeal mask, OLP: oropharyngeal leakage pressure, laryngeal alignment (I: visualise entire vocal cords, II: posterior component of cords visible, III: epiglottis but no cords visible, IV: no vocal cords or epiglottis visible).

patients except one in the AMBU group, where an airway could not be established after three insertion attempts. This was recorded as a failed airway in the AMBU group; however postoperative data were analysed on an intention-to-treat basis. The OLP for the AMBU (20 ± 6 cm H_2O) was higher than for the LMAU (15 ± 7 cm H_2O; $P = 0.001$) (Table 2). Of the secondary endpoints, a successful airway was established in all patients of the LMAU group. One patient had a failed airway in the AMBU group. Time to insertion, successful insertions, laryngeal alignment, blood staining, and sore throat were similar between groups (Table 2). Cuff pressures were similar for both devices (LMAU 84 ± 39 mmHg; AMBU 98 ± 36 mmHg; $P = 0.473$). Cuff pressure in the LMAU changed slightly over time whilst the AMBU remained stable (LMAU -7 ± 8 mmHg, AMBU 0 ± 3 mmHg, $P = 0.01$). Respiratory complications such as hiccups (LMAU $n = 1$, AMBU $n = 1$; $P = 0.766$), stridor (LMAU $n = 3$, AMBU $n = 4$; $P = 0.529$), and oxygen desaturations below 95% (LMAU $n = 0$, AMBU $n = 1$; $P = 0.513$) were similar between groups.

4. Discussion

Our study demonstrated higher oropharyngeal leak pressures in the AMBU compared to the LMAU. This may be due to the 90-degree angulation of the tube as described by Vaida [8] and is consistent with other recently published results of Shariffuddin and Wang [10] and Francksen et al. [9]. The mean oropharyngeal leakage pressure achieved in the AMBU group (20 ± 6 cm H_2O) was similar to that of Shariffuddin (19 ± 7.5 cm H_2O) but was lower than that of Lopez, Francksen, Gernoth and Hagberg (32.2 ± 6.8; 21 (13–40); 25.6 ± 5.2; 24 ± 5.5 cm H_2O) [9, 11–13]. Our LMAU sealing pressure was also lower than that of other studies [7, 11, 14, 15]. These differences may be accounted for by a variety of mechanisms. We only allowed a maximum airway pressure of 30 cm H_2O when performing the manometric

stability test. Also, the injection of a maximum volume into the cuff (and subsequent higher cuff pressures) may have increased oropharyngeal leak due to cuff overinflation [14, 16]. Size selection may also play a role in oropharyngeal leakage pressure [17–19]. We use weight-based sizing as per manufacturer's recommendations, which resulted in 23 patients (29%) receiving size 3 masks, which is known to be associated with lower OLPs [17–19]. The differences may also be due to our large cohort of anaesthetists rather than a single experienced anaesthetist for insertion of the device [14].

Both devices performed similarly in establishing an adequate airway with first insertion (success rates AMBU 85%, LMAU 82%) and this is similar to other recent studies [10, 11, 13, 20]. There was a single failure within the AMBU group when there was easy insertion but inability to ventilate [10, 20]. Ng and Shariffuddin have hypothesized that these failures may be due to epiglottic downfolding on insertion of the AMBU [10, 20]. This is further supported effective ventilation following insertion with an LMAC, which has epiglottic aperture bars to prevent such an occurrence. This failure may be of consequence in the emergency setting where early establishment of ventilation is critical and other devices are not available (this aspect was not examined for directly in our study).

It has been previously suggested that the AMBU may be easier to insert in neck-immobilised patients [12], and the LMAUs PVC material may be more adherent to airway mucosa [21]. These factors may allow easier insertion in the AMBU. We found a trend toward faster insertion in the AMBU (LMAU 32 ± 16 s; AMBU 27 ± 10 s; $P = 0.111$) but this was not statistically significant, however our study was not powered to detect this, and further large-scale studies are needed.

The rate of vocal cord visualisation was similar in both groups (LMAU 79%; AMBU 78%; $P = 0.613$). This result is comparable to previous AMBU [10, 13] and LMAU [15, 22] studies.

Good anatomical alignment has been suggested to improve airway patency [23, 24] but other studies have shown no effect on device function [25]. The absence of aperture bars does not seem to alter the laryngeal alignment; however the absence of bars may aid insertion of instruments in the airway tube [13] such as assisted endotracheal intubation [26].

Both devices maintained stable cuff pressures. This finding is expected, given that we did not use N_2O, and is similar to the results of Maino et al. [27]. Although our initial cuff pressures were higher (LMAU 84 ± 39 mmHg; AMBU 98 ± 36 mmHg; $P = 0.473$) than other studies [7, 10, 13–15, 22, 25, 28–31] due to injection of a maximal volume of air, we did not observe a greater incidence of airway trauma or sore throat. There is considerable debate in the literature about whether higher intracuff pressures actually equate to higher airway mucosal pressures and higher incidences of postoperative sore throat [32–36].

Our study has several limitations. The anaesthetists at our institution were significantly more experienced with LMAC and the LMAU compared with the AMBU. We attempted to minimise this effect by instituting a targeted

education program; however there still may have been a learning curve with the AMBU. Second, our anaesthetists could not be blinded to the airway intervention. Bias was minimised by using a standard insertion technique for each device and an independent observer to collect data. Finally, our study was conducted only on adult patients in the operative setting and is not applicable to paediatric patients or emergency airway scenarios.

5. Conclusion

Our study found the AMBU to provide higher oropharyngeal leakage pressure than the LMAU in spontaneously breathing patients undergoing general anaesthesia. Overall success rates, insertion times, laryngeal alignment, and postoperative sore throat were statistically similar between both devices.

Acknowledgment

References

[1] T. M. Cook, "The classic laryngeal mask airway: a tried and tested airway. What now?" *British Journal of Anaesthesia*, vol. 96, no. 2, pp. 149–152, 2006.

[2] Directions for Use: Ambu Laryngeal Mask. Denmark: Ambu A/S, 2004.

[3] American Society of Anesthesiologists, "New classification of physical status," *Anesthesiol*, vol. 24, article 111, 1963.

[4] Intavent-Orthofix, *LMA(TM) Airway Instruction Manual*, Laryngeal Mask, Maidenhead, UK, 2005.

[5] Australian New Zealand College, *Recommendations on Monitoring During Anaesthesia. Professional Document PS18*, Australian and New Zealand College of Anaesthetists, 2006.

[6] R. S. Cormack and J. Lehane, "Difficult tracheal intubation in obstetrics," *Anaesthesia*, vol. 39, no. 11, pp. 1105–1111, 1984.

[7] A. van Zundert, B. Al-Shaikh, J. Brimacombe, J. Koster, D. Koning, and E. P. Mortier, "Comparison of three disposable extraglottic airway devices in spontaneously breathing adults: the LMA-unique, the soft seal laryngeal mask, and the cobra perilaryngeal airway," *Anesthesiology*, vol. 104, no. 6, pp. 1165–1169, 2006.

[8] S. J. Vaida and U. A. Yodfat, "Angulation of the airway tube in the AMBU laryngeal mask could be responsible for improved insertion success," *Anesthesia and Analgesia*, vol. 103, no. 1, p. 264, 2006.

[9] H. Francksen, B. Bein, E. Cavus et al., "Comparison of LMA Unique, Ambu laryngeal mask and Soft Seal laryngeal mask during routine surgical procedures," *European Journal of Anaesthesiology*, vol. 24, no. 2, pp. 134–140, 2007.

[10] I. I. Shariffuddin and C. Y. Wang, "Randomised crossover comparison of the Ambu AuraOnce Laryngeal Mask with the LMA Classic laryngeal mask airway in paralysed anaesthetised patients," *Anaesthesia*, vol. 63, no. 1, pp. 82–85, 2008.

[11] A. M. López, R. Valero, P. Bovaira, M. Pons, X. Sala-Blanch, and T. Anglada, "A clinical evaluation of four disposable laryngeal masks in adult patients," *Journal of Clinical Anesthesia*, vol. 20, no. 7, pp. 514–520, 2008.

[12] C. Gernoth, O. Jandewerth, M. Contzen, J. Hinkelbein, and H. Genzwürker, "Vergleich von zwei larynxmaskenmodellen zur atemwegssicherung bei patienten mit immobilisation der halswirbelsäule," *Der Anaesthesist*, vol. 55, no. 3, pp. 263–269, 2006.

[13] C. A. Hagberg, F. S. Jensen, H. V. Genzwuerker et al., "A multicenter study of the Ambu laryngeal mask in nonparalyzed, anesthetized patients," *Anesthesia and Analgesia*, vol. 101, no. 6, pp. 1862–1866, 2005.

[14] J. Brimacombe, A. von Goedecke, C. Keller, L. Brimacombe, and M. Brimacombe, "The laryngeal mask airway unique versus the soft seal laryngeal mask: a randomized, crossover study in paralyzed, anesthetized patients," *Anesthesia and Analgesia*, vol. 99, no. 5, pp. 1560–1563, 2004.

[15] L. Gaitini, B. Yanovski, M. Somri, S. Vaida, T. Riad, and D. Alfery, "A comparison between the PLA Cobra and the Laryngeal Mask Airway Unique during spontaneous ventilation: a randomized prospective study," *Anesthesia and Analgesia*, vol. 102, no. 2, pp. 631–636, 2006.

[16] G. Keller, F. Pühringer, and J. R. Brimacombe, "Influence of cuff volume on oropharyngeal leak pressure and fibreoptic position with the laryngeal mask airway," *British Journal of Anaesthesia*, vol. 81, no. 2, pp. 186–187, 1998.

[17] J. Brimacombe and C. Keller, "Laryngeal mask airway size selection in males and females: ease of insertion, oropharyngeal leak pressure, pharyngeal mucosal pressures and anatomical position," *British Journal of Anaesthesia*, vol. 82, no. 5, pp. 703–707, 1999.

[18] A. M. Berry, J. R. Brimacombe, K. F. McManus, and M. Goldblatt, "An evaluation of the factors influencing selection of the optimal size of laryngeal mask airway in normal adults," *Anaesthesia*, vol. 53, no. 6, pp. 565–570, 1998.

[19] T. Asai, T. K. Howell, K. Koga, and S. Morris, "Appropriate size and inflation of the laryngeal mask airway," *British Journal of Anaesthesia*, vol. 80, no. 4, pp. 470–474, 1998.

[20] S. Y. Ng, "Comparison of the AMBU laryngeal mask and the LMA classic in anaesthetised, spontaneously breathing patients," *Anaesthesia and Intensive Care*, vol. 35, no. 1, pp. 57–61, 2007.

[21] S. Platt, M. Aldory, T. Meek, and D. Cooper, "Single-use laryngeal masks for the management of unexpected failed intubation," *Anaesthesia*, vol. 60, no. 11, p. 1153, 2005.

[22] M. J. Paech, O. Tweedie, K. Stannard et al., "Randomised, crossover comparison of the single-use SoftSeal and the LMA Unique laryngeal mask airways," *Anaesthesia*, vol. 60, no. 4, pp. 354–359, 2005.

[23] S. Joshi, R. R. Sciacca, D. R. Solanki, W. L. Young, and M. M. Mathru, "A prospective evaluation of clinical tests for placement of laryngeal mask airways," *Anesthesiology*, vol. 89, no. 5, pp. 1141–1146, 1998.

[24] C. J. O'Connor Jr., M. S. Stix, and D. R. Valade, "Glottic insertion of the ProSeal LMA occurs in 6% of cases: a review of 627 patients," *Canadian Journal of Anesthesia*, vol. 52, no. 2, pp. 199–204, 2005.

[25] J. R. Brimacombe, *Laryngeal Mask Anaesthesia: Principles and Practice*, Saunders, Philadelphia, Pa, USA, 2nd edition, 2003.

[26] I. P. Osborn and R. Soper, "It's a disposable LMA, just cut it shorter—for fiberoptic intubation," *Anesthesia and Analgesia*, vol. 97, no. 1, pp. 299–300, 2003.

[27] P. Maino, A. Dullenkopf, V. Bernet, and M. Weiss, "Nitrous oxide diffusion into the cuffs of disposable laryngeal mask airways," *Anaesthesia*, vol. 60, no. 3, pp. 278–282, 2005.

[28] C. Verghese, J. Berlet, A. Kapila, and R. Pollard, "Clinical assessment of the single use laryngeal mask airway—the LMA-Unique," *British Journal of Anaesthesia*, vol. 80, no. 5, pp. 677–679, 1998.

[29] M. G. E. Tan, E. R. C. Chin, C. S. Kong, Y. H. Chan, and P. C. Ip-Yam, "Comparison of the re-usable LMA classic and two single-use laryngeal masks (LMA unique and softseal) in airway management by novice personnel," *Anaesthesia and Intensive Care*, vol. 33, no. 6, pp. 739–743, 2005.

[30] T. M. Cook, P. Trümpelmann, R. Beringer, and J. Stedeford, "A randomised comparison of the Portex Softseal laryngeal mask airway with the LMA-Unique during anaesthesia," *Anaesthesia*, vol. 60, no. 12, pp. 1218–1225, 2005.

[31] A. A. J. van Zundert, K. Fonck, B. Al-Shaikh, and E. Mortier, "Comparison of the LMA-classic with the new disposable soft seal laryngeal mask in spontaneously breathing adult patients," *Anesthesiology*, vol. 99, no. 5, pp. 1066–1071, 2003.

[32] R. Marjot, "Pressure exerted by the laryngeal mask airway cuff upon the pharyngeal mucosa," *British Journal of Anaesthesia*, vol. 70, no. 1, pp. 25–29, 1993.

[33] J. Brimacombe, C. Keller, and F. Pühringer, "Pharyngeal mucosal pressure and perfusion: a fiberoptic evaluation of the posterior pharynx in anesthetized adult patients with a modified cuffed oropharyngeal airway," *Anesthesiology*, vol. 91, no. 6, pp. 1661–1665, 1999.

[34] J. Brimacombe, L. Holyoake, C. Keller et al., "Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and females," *Anesthesiology*, vol. 93, no. 1, pp. 26–31, 2000.

[35] J. Brimacombe, L. Holyoake, C. Keller et al., "Emergence characteristics and postoperative laryngopharyngeal morbidity with the laryngeal mask airway: a comparison of high versus low initial cuff volume," *Anaesthesia*, vol. 55, no. 4, pp. 338–343, 2000.

[36] T. Hamakawa, S. Nakamura, and S. Kawasaki, "Intracuff pressure of the laryngeal mask and pressure on the pharynx," *Journal of Clinical Anesthesia*, vol. 17, pp. 1165–1167, 1993.