

APPARATUS

A comparison of the disposable Ambu[®] AuraOnce[™] Laryngeal Mask with the reusable LMA Classic[™] laryngeal mask airway[★]

G. Sudhir,¹ D. Redfern,² J. E. Hall,³ A. R. Wilkes⁴ and C. Cann⁵

1 Locum Consultant Anaesthetist, 2 Specialist Registrar, 3 Reader, 4 Senior Research Fellow and 5 Research Co-ordinator, Department of Anaesthetics and Intensive Care Medicine, Wales College of Medicine, Cardiff University, Heath Park, Cardiff CF14 4XN, UK

Summary

Single-use supraglottic airway devices are now available and are intended to be comparable with the reusable LMA Classic[™] laryngeal mask airway. We performed a randomised cross-over study comparing the Ambu[®] AuraOnce[™] Laryngeal Mask with the LMA Classic. Fifty patients participated in the trial. Success rates for insertion at the first attempt were similar (92% with the Ambu and 84% with the LMA Classic; $p = 0.22$). The volumes of air required to inflate the cuff to produce a seal were similar, but the cuff pressure was lower for the Ambu Laryngeal Mask (median (IQR [range]) 18 (10–31 [0–100] cmH₂O) than the LMA Classic 27 (17–50 [4–90] cmH₂O; $p = 0.007$). Visual analogue scores for ease of insertion were 87 (73–93 [26–97]) mm for the Ambu and 84 (60–89 [18–96]) for the LMA Classic ($p = 0.017$). Complications were similar in both groups. We suggest that the disposable Ambu Laryngeal Mask is an acceptable alternative to the reusable LMA Classic.

Correspondence to: Dr G. Sudhir

E-mail: sudhirg@cf.ac.uk

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The laryngeal mask airway has been available since 1988 and is widely used. The LMA Classic[™] laryngeal mask airway (Intavent Orthofix, Maidenhead, UK) is made from silicone; it is reusable and is sterilised by autoclaving. Autoclaving and other methods of sterilising surgical and anaesthetic equipment are effective in preventing bacterial and viral transmission between patients, but there remains a potential threat from prion diseases such as variant Creutzfeldt–Jakob disease (vCJD). Prions demonstrate a profound resistance to standard sterilisation methods used in surgical practice [1]. Proteinaceous material has been found in a majority of autoclaved laryngeal masks and cleaned laryngoscope blades [2]. This may have implications for the safety of multiple-use surgical and anaesthetic instruments. Prediction of the risk of transmission of vCJD is difficult because of the many uncertainties and

variables [3]. A pessimistic model has suggested that cross-infections may occur in 1 : 1000–100 000 anaesthetics [4]. The use of single-use (disposable) laryngeal mask airways would eliminate this potential risk. Disposable devices would also be safer for patients with malignant hyperpyrexia because normal decontamination procedures for rubber and silicone products only reduce, rather than eliminate, volatile anaesthetic agents [5].

The patent for the LMA Classic expired in 2003 and since then a number of disposable devices have become available. Studies comparing the LMA-Unique[™] and the Portex Soft Seal[™] with the LMA Classic have demonstrated that these single-use devices have similar clinical effectiveness and may be acceptable alternatives [6–8]. The Ambu[®] AuraOnce[™] Laryngeal Mask (Ambu A/S, Ballerup, Denmark) is claimed to have advantages over

competitors. It features an in-built curve in the airway tube designed to allow the head to remain in a more natural position and to reduce stress on the upper jaw, and lacks epiglottic bars. The risk of breakage is claimed to be limited as it has a one-piece construction. It also has a soft cuff made of 0.4-mm-thick polyvinyl chloride. The manufacturer claims that this allows improved conformation to the shape of the airway. A multicentre study involving 118 patients demonstrated that the Ambu Laryngeal Mask is easy and quick to insert, providing a safe and efficient seal during positive pressure ventilation in non-paralysed patients undergoing elective surgery [9]. However, the study was limited by being non-comparative in design.

This study is a randomised cross-over trial comparing the first attempt insertion success rate of the single-use Ambu Laryngeal Mask to that with the reusable LMA Classic. Also investigated were the volume of air required to achieve a good seal, the sealing pressure at this point, and any airway complications associated with the insertion such as cough, laryngospasm or loss of airway.

Methods

Following South Wales Local Research Ethics Committee approval and written informed consent, 50 adults of ASA physical status 1 or 2, undergoing elective general anaesthesia in which the LMA was considered appropriate, were enrolled into the study. All patients had Mallampati scores of I–III and breathed spontaneously during surgery. Patients were not included if they presented with neck pathology, upper respiratory tract pathology (including pre-operative sore throat), known history of lung pathology, upper gastro-intestinal pathology, increased risk of pulmonary aspiration of gastric contents, body mass index $> 35 \text{ kg.m}^{-2}$ or planned surgery in the non-supine position.

All patients underwent pre-operative fasting according to hospital guidelines. Routine pre-use leak tests were performed and the appropriate size of airway was selected according to the manufacturers' instructions. Both airways were prepared for insertion (lubricated with Aquagel™ (Adams Healthcare, Leeds, England) with the cuff deflated). In this cross-over trial, the airways were inserted one after the other in random order, each device being used first on 25 occasions. The randomisation code was generated using a custom-made Microsoft EXCEL (Redmond, WA) spreadsheet. Baseline levels of heart rate, blood pressure and oxygen saturation were recorded. After pre-induction monitoring and intravenous access, anaesthesia was induced and maintained using a total intravenous anaesthesia technique. All patients received $1.5 \text{ }\mu\text{g.kg}^{-1}$ fentanyl before propofol was started using a target control infusion

(TCI) pump. An Alaris Asena™ PK Mark III TCI pump (Alaris Medical Systems Inc., San Diego, CA) based on the Marsh pharmacokinetic model [10] was used for the study. The initial target was set at $7 \text{ }\mu\text{g.kg}^{-1}$. The depth of anaesthesia was assessed by good jaw relaxation and the target level of propofol was adjusted if required to achieve this [11].

Once an adequate depth of anaesthesia was achieved, one of the airways was inserted according to the manufacturer's instructions. After insertion, 5-ml increments of air were introduced into the cuff until a good seal was achieved. This was checked by gently squeezing the breathing bag after connecting the breathing system through a breathing system filter. An attempt at insertion was considered unsuccessful if the airway had to be re-adjusted after inflation of the cuff or had to be taken out and re-inserted. A circle system was used and the adjustable pressure limiting valve was set at a pressure of $10 \text{ cmH}_2\text{O}$. Absence of any audible leak and a square wave pattern on capnography was taken to indicate a good seal and good tidal ventilation. The pressure inside the cuff of the laryngeal mask was then measured with a calibrated aneroid cuff pressure gauge (Mallinckrodt Medical, Ireland) and recorded. A maximum of three insertion attempts was allowed for each device.

The first airway was removed after 5 min of use and replaced with the second one, after checking the depth of anaesthesia as previously described. The second airway was then inserted and similar procedures and measurements were performed. This airway was left in place for the duration of the operation. All were inserted by the same anaesthetist (GS) who is very experienced in the use of the LMA Classic and who had successfully inserted the Ambu Laryngeal Mask on 10 occasions before the start of the study. The ease of insertion was scored using a visual analogue scale (0 mm = impossible; 100 mm = easy). Any adverse event such as cough, laryngospasm or loss of airway during insertion and the first 5 min after insertion was recorded.

Anaesthesia was maintained using TCI propofol. The patients breathed a mixture of air and oxygen spontaneously. Manual ventilation was provided until adequate spontaneous ventilation restarted. Heart rate, blood pressure and oxygen saturation were recorded every 5 min. At the end of the procedure the patient remained in the supine position and was transferred to the recovery room with the cuff inflated. The device was removed by either the anaesthetist or the recovery nurse. The presence of any blood on the laryngeal mask was noted and recorded on removal. Two hours after recovery from anaesthesia, all patients were asked whether they had a sore throat.

The study design was that of a 'non-inferiority' trial. The first-time success rate with the LMA Classic is high:

the calculated sample size required for the study was based on a success rate for the first attempt at insertion of 97% [12]. The aim was to demonstrate that the success rate with the Ambu Laryngeal Mask was no more than 15% less than that of the LMA Classic, which we considered to be the limit of clinical acceptability. With a type I error of 0.05 and a power of 90%, the sample size required was 23 in each group, or 46 in total, based on a parallel group study design [13]. The present study was a cross-over study and therefore this sample size was conservative; furthermore, we actually recruited 50 patients for this study. The 95% confidence interval was used to determine the range within which the true difference in first time insertion success rates between the two differences would lie [14]. The secondary outcomes measured were ease of insertion, cuff volume and pressure required to achieve a good seal, incidence of adverse airway events and presence of blood on the device on removal. These were analysed using the Wilcoxon signed-rank test and

McNemar’s test. Data were entered on to an EXCEL spreadsheet and statistical analysis was performed using SPSS software (version 14, SPSS Inc., Chicago, IL). The significance level was set at 0.05.

Results

Fifty patients were recruited, of whom 22 were males. The mean (SD) age and body mass index were 44 (16) years and 25 (4) kg.m⁻², respectively. The success rates for insertion at the first attempt were not statistically different (Table 1). The ease of insertion was statistically significantly better with the Ambu Laryngeal Mask than with the LMA Classic (Table 2). The ease of insertion of the Ambu Laryngeal Mask was rated better on 28 occasions and the LMA Classic was rated better on 18 occasions; insertion was similar on four occasions. Which device was inserted first had no effect on success rate or ease of insertion. The volume of air required to inflate the cuff to achieve a good seal for either laryngeal mask was similar (Table 2). The pressure required to provide a good seal was lower with the Ambu Laryngeal Mask on 34 occasions, whereas it was lower with the LMA Classic on 14 occasions and the same for both devices on two occasions. The pressure in the cuff required to achieve a good seal was lower for the Ambu Laryngeal Mask than for the LMA Classic (Table 2). The incidence of adverse airway events on insertion was similar with both airways (Table 3). In one patient, who weighed 100 kg and was 192 cm tall, a size-5 LMA Classic was used (the second in the sequence) and ~ 15 min after insertion there was loss of airway as the result of a blood clot inside the bowl of the device. The laryngeal mask airway was taken out and

Table 1 Success rates for insertion of the Ambu AuraOnce Laryngeal Mask and LMA Classic laryngeal mask airway at the first attempt in 50 patients. Values are number (proportion).

	Ambu Laryngeal Mask		Total
	Success	Failure	
LMA Classic			
Success	41	1	42 (84%)*
Failure	5	3	8 (16%)
Total	46 (92%)*	4 (8%)	50

*Difference 8% (95% CI - 3 to 20%; p = 0.22).

Table 2 Ease of insertion and cuff volume and pressure for the Ambu AuraOnce Laryngeal Mask and LMA Classic laryngeal mask airway in 50 patients. Values are median (IQR [range]).

	Ambu Laryngeal Mask	LMA Classic	p-value
Ease of insertion VAS*	86.5 (73–93 [26–97])	84 (60–89 [18–96])	0.017
Cuff volume; ml	10 (5–10 [5–20])	10 (5–10 [5–25])	0.48
Cuff pressure; cmH ₂ O	18 (10–31 [0–100])	27 (17–50 [4–90])	0.007

*VAS, visual analogue scale: 0 mm = impossible; 100 mm = easy.

Table 3 Complications following insertion of the Ambu AuraOnce Laryngeal Mask and LMA Classic laryngeal mask airway in 50 patients. Values are numbers.

	Ambu Laryngeal Mask							
	Cough		Laryngospasm		Loss of airway		Blood on airway	
	Yes	No	Yes	No	Yes	No	Yes	No
LMA Classic								
Yes	1	1	0	0	1	1	4	0
No	1	47	0	50	0	48	5	41

the clot removed before successful re-insertion, and the procedure completed without any untoward events. Because of the blood on the device, it was expected that the patient might experience a sore throat due to possible pharyngeal trauma, but he denied any sore throat when questioned postoperatively. Two patients had mild sore throat postoperatively, which subsided within 12 h without treatment. This study was a cross-over trial and hence sore throat could not be attributed to either of the laryngeal masks.

Discussion

This study demonstrates that the success rates for insertion at first attempt of the Ambu Laryngeal Mask and LMA Classic are similar. The 95% CI for the difference, –3 to 20%, indicates that the success rate on first attempt with the Ambu Laryngeal Mask is unlikely to be >3% less than with the LMA Classic. A previous study by Cao et al. [15] showed success rates of 84% and 79% with the LMA Classic and disposable laryngeal mask airways, respectively. However, other studies have shown higher first-attempt success rates for the LMA Classic. In this study, we followed Ambu's recommendations for sizing the device, using a size 3 Laryngeal Mask for patients weighing 30–50 kg, a size 4 for 51–70 kg and a size 5 for >70 kg. The investigator inserting the laryngeal mask airways (GS) felt that a smaller mouth in three patients contributed to initial failure in these patients. A review of cuff volume and sizing of laryngeal mask airways has recommended the use of larger-sized devices to provide a better seal without affecting ease of insertion [16]. However, a larger device may be difficult to insert if the mouth opening is small.

Overall, ease of insertion was better with the Ambu Laryngeal Mask than with the LMA Classic. This may be attributable to the difference in their materials. The median volume of air required to produce a clinically acceptable mask seal was 10 ml with both devices, reflecting current recommendations for cuff inflation [15]. The median cuff pressure when the seal was good was lower for the Ambu Laryngeal Mask than for the LMA Classic, suggesting that the current common practice of inflating the cuff with the maximum recommended volume of air is perhaps undesirable in the absence of cuff pressure gauges. We suggest inflating the cuff with 10 ml air followed by checking the adequacy of the seal. If a good seal is not achieved, 5-ml increments of air may be added until a good seal is achieved, but the total volume should not exceed the maximum recommended inflation volume for that device.

In summary, the Ambu Laryngeal Mask is similar to the LMA Classic but it requires a lower cuff pressure to

produce a good seal and is therefore a worthy alternative to the LMA Classic.

References

- 1 Frosh A. Prions and the ENT surgeon. *Journal of Laryngology and Otology* 1999; **113**: 1064–7.
- 2 Miller DM, Youkhana I, Karunaratne WU, Pearce A. Presence of protein deposits on 'cleaned' re-usable anaesthetic equipment. *Anaesthesia* 2001; **56**: 1069–72.
- 3 Anonymous. Risk Assessment for Transmission of vCJD via Surgical Instruments. www.dh.gov.uk [accessed on 1 January 2007].
- 4 Blunt MC, Burchett KR. Variant Creutzfeldt-Jakob disease and disposable anaesthetic equipment – balancing the risks. *British Journal of Anaesthesia* 2003; **90**: 1–3.
- 5 Danbury CM, Torlot K. Malignant hyperpyrexia and the laryngeal mask airway. *Anaesthesia* 2001; **56**: 802.
- 6 Brimacombe J, Keller C, Morris R, Mecklem D. A comparison of the disposable versus the reusable laryngeal mask airway in paralyzed adult patients. *Anesthesia and Analgesia* 1998; **87**: 921–4.
- 7 Shafik MT, Bahlman BU, Hall JE, Ali MS. A comparison of the Soft Seal disposable and the Classic re-usable laryngeal mask airway. *Anaesthesia* 2006; **61**: 178–81.
- 8 Van Zundert AA, Fonck K, Al-Shaikh B, Mortier E. Comparison of the LMA-classic with the new disposable soft seal laryngeal mask in spontaneously breathing adult patients. *Anesthesiology* 2003; **99**: 1066–71.
- 9 Hagberg CA, Jensen FS, Genzwuerker HV, et al. A multi-center study of the Ambu laryngeal mask in nonparalyzed, anesthetized patients. *Anesthesia and Analgesia* 2005; **101**: 1862–6.
- 10 <http://www.alarimed.co.uk/products> [accessed 15 February 2007].
- 11 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.
- 12 Brimacombe JR, Brimacombe JC, Berry AM, et al. A comparison of the laryngeal mask airway and cuffed oropharyngeal airway in anesthetized adult patients. *Anesthesia and Analgesia* 1998; **87**: 147–52.
- 13 Jones B, Jarvis P, Lewis JA, Ebbutt AF. Trials to assess equivalence: the importance of rigorous methods. *British Medical Journal* 1996; **313**: 36–9.
- 14 Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ. Reporting of noninferiority and equivalence randomized trials. an extension of the CONSORT statement. *Journal of American Medical Association* 2006; **295**: 1152–60.
- 15 Cao MM, Webb T, Bjorksten AR. Comparison of disposable and reusable laryngeal mask airways in spontaneously ventilating adult patients. *Anaesthesia and Intensive Care* 2004; **32**: 530–4.
- 16 Asai T, Brimacombe J. Cuff volume and size selection with the laryngeal mask. *Anaesthesia* 2000; **55**: 1179–84.