British Journal of Anaesthesia 1998; **80**: 677–679

Clinical assessment of the single use laryngeal mask airway—the LMA-Unique

C. VERGHESE, J. BERLET, A. KAPILA AND R. POLLARD

Summary

We conducted a clinical comparison of the laryngeal mask airway (LMA) and the new single use PVC LMA (LMA-Unique) in 100 fasted adult patients undergoing elective surgery. Patients were allocated to one of two groups: group 1 ($n=50$) was managed by two consultants and group 2 by two trainee anaesthetists. Airway management was randomized prospectively within each group, and cuff pressure in both devices was maintained at a maximum of 50 mm Hg with upward size substitution if leaks persisted during intermittent positive pressure ventilation (IPPV). Insertion with the recommended technique was successful in all patients (85 first attempt). One patient (group 1) required four attempts for insertion of the LMA-Unique and in one patient (group 2) the LMA-Unique was replaced by a tracheal tube because of persistent leaks during IPPV. In 99 patients IPPV was uneventful. The adjusted mean volume of air for cuff inflation in the LMA-Unique was significantly less in group 1 ($P=0.0013$). At fibreoptic laryngoscopic examination, the vocal cords or arytenoids, or both, could be seen in 92% of patients in group 1 and in 90% of patients in group 2. Immediate throat soreness was reported in four patients in group 1 and in seven in group 2. The results suggest that the LMA-Unique was similar in clinical performance to the LMA. (*Br. J. Anaesth*. 1998; **80**: 677–679)

Keywords: equipment masks anaesthesia; intubation tracheal; ventilation intermittent positive pressure

The laryngeal mask airway (LMA) has become an increasingly popular alternative to the face mask or tracheal tube for securing the airway in fasted patients undergoing elective surgery under general anaesthesia, for immediate airway support in cardiopulmonary resuscitation (CPR) by nurses trained in its use and is included in the European Resuscitation Council advanced airway management algorithm.[1–4] Calder and colleagues reported on its use in failed intubations[5] and Benumof recommended its use in the ASA difficult airway algorithm.[6]

The LMA may be re-used up to 40 times after recommended sterilization procedures.[2] However, for pre- and in-hospital CPR and in the high infection risk patient, a disposable LMA may be preferred.

The LMA-Unique was introduced in September 1997 as a "single use"/disposable device at approximately one-third of the cost of an LMA. The cuff, backplate, airway tube and pilot balloon of the LMA-Unique are manufactured from clear medical grade PVC (ISO 10993 biocompatibility standard). The airway tube is clear, semi-rigid and more curved than the softer silicone airway tube of the LMA, but is otherwise similar in appearance to the LMA (fig. 1). The LMA-Unique is supplied sterile and cannot withstand autoclaving.

In this study, we have compared the LMA-Unique with the LMA for ease of insertion, alignment with the laryngeal inlet (verified using fibreoptic laryngoscopy), IPPV and incidence of immediate sore throat.

Methods and results

After obtaining approval from the local Ethics Committee and written informed consent, we studied 100 fasted adult patients (ASA I–III) undergoing elective surgery requiring general anaesthesia with neuromuscular blocking agents and intermittent positive pressure ventilation (IPPV). Patients were allocated to one of two groups ($n=50$): group 1 was managed by two consultant anaesthetists and group 2 by two trainee anaesthetists. Pregnant, non-fasted and patients with symptomatic gastro-oesophageal reflux disease were excluded. Patients in each group were randomized prospectively for airway management with the LMA or LMA-Unique (adult sizes 4 and 5) using a randomized sealed envelope technique.

Perioperative monitoring included non-invasive arterial pressure, pulse oximetry, continuous ECG, end-tidal carbon dioxide and end-tidal MAC (Datex AS/3 ADU, Datex Corporation, Finland). General anaesthesia was induced with fentanyl 1–1.5 $\mu g\ kg^{-1}$ and propofol 2–3 $mg\ kg^{-1}$. Neuromuscular block was established with atracurium 0.5 $mg\ kg^{-1}$ and after loss of response to peripheral nerve stimulation, either the LMA or LMA-Unique was inserted. The insertion technique was standardized to that recommended for LMA insertion.[2] After insertion, cuff inflation of either device was to a "just-seal" pressure or up to a maximum of 50 mm Hg, measured with a simple hand-held aneroid manometer (Yamasa, Harvey Medic, Surrey). The volume of air used was recorded, and if leaks persisted on gentle manual ventilation, a larger sized device was substituted. Cuff pressure was monitored continuously and maintained at 50 mm Hg or less, by removal or addition of small volumes of air.

C. VERGHESE, FRCA, J. BERLET, MB, BS, A. KAPILA, FRCA, R. POLLARD, FRCA, LMA Research Centre, Department of Anaesthesia, Royal Berkshire Hospital, Reading RG1 5AN. Accepted for publication: January 6, 1998.

Correspondence to C. V.

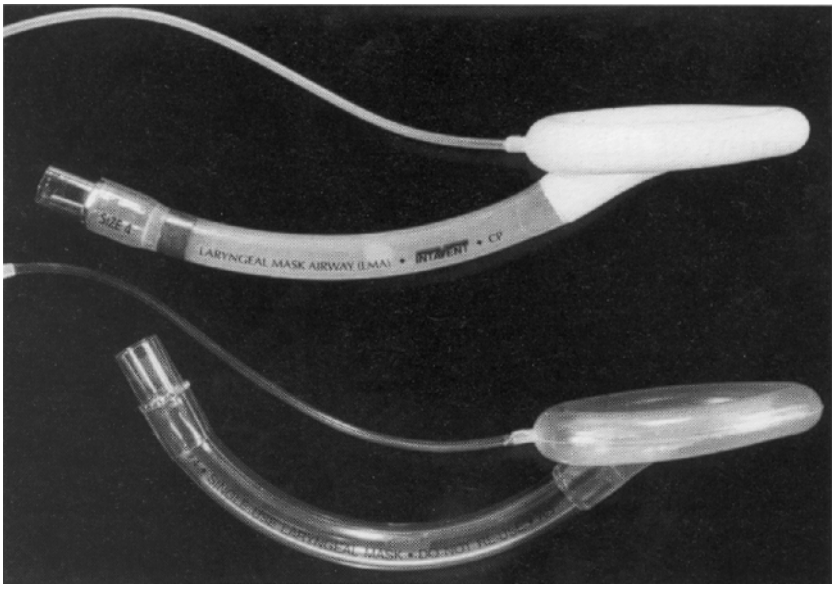

Figure 1 Comparison of the laryngeal mask airway (LMA) (top) with the new LMA-Unique (bottom), a "single use"/disposable device manufactured from clear PVC.

Anaesthesia was maintained with 1–2% isoflurane and nitrous oxide in oxygen. Atracurium was given to abolish responses to peripheral nerve stimulation. Mechanical ventilation was volume controlled and time cycled with tidal volumes (5–8 ml kg^{-1}) set to maintain peak inspiratory pressures of less than 20 cm H_2O and ventilatory frequency adjusted to maintain end-tidal carbon dioxide ($P_{E'CO_2}$) at 4.5–5.0 kPa. In the perioperative period, a fibreoptic laryngoscope (Olympus LF-2, Keymed, Essex) was passed through a swivel elbow (Intersurgical) into the device, so that the tip was just above the cuff tears. The view was scored as described previously.[7]

Neuromuscular block was antagonized with glycopyrrolate 0.5 mg and neostigmine 2.5 mg. Patients breathed spontaneously until protective reflexes returned and the device was then removed with the cuff inflated. The presence of blood was recorded.

On discharge from the recovery room, patients were asked if they had a sore throat and responses were recorded as nil, mild, moderate or severe (table 1). All data were recorded on a simple form and transferred onto a spreadsheet (Microsoft EXEL 7.0). Statistical analysis was with SAS 6.0.

There were no failures on inserting either device. One substitution upwards took place in the LMA group in group 1, and in one LMA and LMA-Unique in group 2. These three patients required only one attempt for re-insertion (table 1). The male patient in group 2 in whom a tracheal tube replaced the size 5 LMA-Unique was not included in the data analysis.

Chi-square analysis demonstrated that there was no association between use of the LMA or LMA-Unique, and experience of the user, incidence of sore throat or fibreoptic laryngoscopy score. Analysis of variance showed that the mean volume of air used to inflate the cuff of the LMA-Unique was significantly lower in group 1 ($P=0.0013$). None of the patients showed clinical signs of regurgitation or aspiration of gastric contents during the study.

Table 1 Patient characteristics (mean (SD) [range] or number) in the two groups. FOL = Fibreoptic laryngoscopy

	Group 1 (34 males)		Group 2 (18 males)	
	LMA	LMA-Unique	LMA	LMA-Unique
Weight (kg)	79.67 (11.50) [60–112]	78.08 (14.53) [50–105]	76.35 (19.95) [55–118]	74.03 (16.65) [54–122]
Insertion attempts				
1	23	22	20	20
2	1	3	5	3
3		0	1	1
4		1		
Mean volume of air in cuff (ml)	17.78	17.31	19.92	24.92
Duration of airway *in situ* (min)	75.20 (48.28)	84.80 (37.92)	62.46 (19.13)	80.52 (38.05)
FOB Score				
1 = only vocal cords seen	11	13	13	16
2 = cords and/or arytenoids	11	11	9	6
3 = only epiglottis seen	1	2	4	1
4 = other (e.g LMA cuff, pharynx, etc)	1	0	0	0
Blood seen on device	4	5	5	4
Sore throat				
No pain	21	25	24	18
Little pain	3	0	2	4
Moderate pain	0	1	0	1
Moderate to severe pain	0	0	0	0

Comment

Our initial impression of the LMA-Unique was that although it was similar in shape to the LMA, it was stiffer. We considered that the relative stiffness of the tubular portion combined with the hardness of the backplate tip might contribute to difficulty in insertion, a higher incidence of trauma during insertion and a greater incidence of sore throat. Brimacombe documented early and late learning curves in the use of the LMA, and therefore we used two groups to assess the new device.[8] Ease of insertion of both devices with the recommended insertion technique for the LMA was similar both within and between groups, and was successful in all patients. The only patient requiring four attempts for insertion of the LMA-Unique was a 48-yr-old female patient, 1.68 m tall, weighing 67 kg, with a fibreoptic laryngoscopy score of 1, who had blood present on the cuff with no immediate sore throat. $P_{E'CO_2}$ was maintained at 4.0–5.0 kPa in all 99 patients at ventilatory frequencies of 10–14 bpm. Chi-square analysis of fibreoptic laryngoscopy view scores showed no association with the type of device used, incidence of sore throat or experience of the user.

Direct questioning would increase the likelihood of complaints of sore throat. However, 92% of patients in group 1 and 85.7% in group 2 reported no throat soreness.[9] Duration of placement did not contribute to the incidence of sore throat. The low incidence of sore throat in both groups may have resulted from careful attention to the insertion and fixation technique, use of neuromuscular blocking agents and maintenance of cuff pressures at less than 50 mm Hg.[10] Lower volumes of air were required to achieve a seal in the LMA-Unique compared with the LMA in group 1 and may reflect the lower compliance of PVC and the experience of the users. At low cuff pressures the device moulds itself to laryngeal structures whereas at higher pressures the cuff imposes its contours on laryngeal structures. A larger study may establish if smaller volumes of air need to be used to inflate the cuff of the LMA-Unique compared with the LMA to achieve "just seal" pressures.

The presence of blood on the cuff after removal was used as an indicator of tissue trauma and our data showed a low incidence with both devices after removal, which was similar between and within groups.

In summary, this study suggests that the LMA-Unique was similar to the LMA for ease of insertion, alignment with the laryngeal inlet, ventilation of the lungs of paralysed patients requiring IPPV and incidence of immediate sore throat.

Acknowledgements

We thank the Laryngeal Mask Company Ltd for provision of the LMA-Unique, Dr S. Abeyasekera, Statistical Services Centre, University of Reading, for assistance with statistical analysis, and Mr N Garbutt, ODP, Royal Berkshire Hospital, for help during the trial.

References

1. Verghese C, Brimacombe J. Survey of laryngeal usage in 11,910 patients—safety and efficacy for conventional and unconventional usage. *Anesthesia and Analgesia* 1996; **82**: 129–133.
2. Brimacombe JR, Brain ALT, Berry AM. *The Laryngeal Mask Airway: A Review and Practical Guide*. London: WB Saunders, 1997; 70–85.
3. Stone BJ, Leach AB, Alexander CA, Ruffer DR, McBeth C, Warwick JP, Baskett PJF, Nicholls E, Prior-Willeard PFS, Verghese C, Jago R. The use of the laryngeal mask airway by nurses during cardiopulmonary resuscitation—results of a multicentre trial. *Anaesthesia* 1994; **49**: 3–7.
4. Guidelines for the advanced management of the airway and ventilation during resuscitation. A statement by the Airway and Ventilation Management Working Group of the European Resuscitation Council. *Resuscitation* 1996; **31**: 2201–2230.
5. Calder I, Ordman AJ, Jacowski A, Crockard HA. The Brain laryngeal mask airway. An alternative to emergency tracheal intubation. *Anaesthesia* 1990; **45**: 137–139.
6. Benumof J. The laryngeal mask airway and the ASA difficult airway algorithm. *Anesthesiology* 1996; **84**: 686–699.
7. Kapila A, Addy V, Verghese C, Brain AIJ. Intubating laryngeal mask airway: a preliminary assessment of performance. *British Journal of Anaesthesia* 1995; **75**: 228–229.
8. Brimacombe J. Analysis of 1500 laryngeal mask uses by one anaesthetist in adults undergoing routine anaesthesia. *Anaesthesia* 1996; **51**: 76–80.
9. Harding CJ, McVey FK. Interview method affects incidence of postoperative sore throat. *Anaesthesia* 1987; **42**: 1104–1107.
10. Burgard G, MollhoffT, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. *Journal of Clinical Anaesthesia* 1996; **8**: 198–201.