

Comparison of Three Disposable Extraglottic Airway Devices in Spontaneously Breathing Adults

The LMA-Unique™, the Soft Seal Laryngeal Mask, and the Cobra Perilaryngeal Airway

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Background: The authors compared three disposable extraglottic airway devices in spontaneously breathing anesthetized adults: the *LMA-Unique™* (LMA-U; The Laryngeal Mask Company, San Diego, CA), the Soft Seal® laryngeal mask (SS-LM; Portex Ltd., Hythe, United Kingdom), and the Cobra perilaryngeal airway (Cobra-PLA™; Engineered Medical Systems, Inc. Indianapolis, IN).

Methods: Three hundred twenty consecutive adults (American Society of Anesthesiologists physical status I-III; aged 18-80 yr) were randomly allocated for airway management with one of the three devices. Anesthesia was with fentanyl-propofol for induction and a sevoflurane-nitrous oxide-oxygen-fentanyl mixture for maintenance. Intraoperative data were collected by an unblinded observer about ease of insertion, effective airway time, oropharyngeal leak pressure, anatomical position (determined with a rigid endoscope), intracuff pressure changes, and airway trauma. Data were collected by a blinded observer about sore throat, dysphagia, and dysphonia 2 h after surgery.

Results: Insertion was easier with the LMA-U and SS-LM than with the Cobra-PLA ($P < 0.02$), but the overall failure rates were similar. Effective airway times were similar among groups. Oropharyngeal leak pressure was lower with the LMA-U than with the SS-LM and Cobra-PLA ($P < 0.001$). Intracuff pressure increased during surgery with all extraglottic airway devices. Anatomical position was better with the Cobra-PLA than with the SS-LMA ($P < 0.001$) and better with the SS-LM than with LMA-U ($P < 0.001$). Blood staining was detected more frequently with the Cobra-PLA than with the LMA-U and SS-LM ($P < 0.001$), but there were no differences in airway morbidity.

Conclusion: The LMA-U and SS-LM are easier to insert and cause less trauma than the Cobra-PLA, but the Cobra-PLA has a more effective seal than the LMA-U and better endoscopically determined anatomical position than the LMA-U and SS-LM.

TO accommodate concerns about disease transmission and the costs of cleaning and sterilization of reusable

laryngeal masks,¹ a wide variety of extraglottic airway devices (EADs) have recently become available.² Most of these devices are classified as orally inserted hypopharyngeal airways: Some form a seal around the glottic inlet, like the laryngeal mask airway (LMA), whereas others form a seal in the proximal pharynx, like the laryngeal tube airway; some are close copies of reusable devices, such as the *LMA-Unique™* (LMA-U; The Laryngeal Mask Company, San Diego, CA) and Soft Seal® laryngeal mask (SS-LM; Portex Ltd., Hythe, United Kingdom), whereas others are completely new designs, such as the Cobra perilaryngeal airway (Cobra-PLA™; Engineered Medical Systems, Inc., Indianapolis, IN).³ Although there are numerous studies comparing reusable EADs, or reusable with disposable EADs,² there are only two studies comparing disposable EADs: one comparing the LMA-U and SS-LM⁴ and another comparing the LMA-U and Cobra-PLA™.⁵ In the following study, we compare the LMA-U, SS-LM, and Cobra-PLA™ in terms of ease of insertion, effective airway time, oropharyngeal leak pressure, anatomical position, intracuff pressure changes, airway trauma, and early postoperative morbidity.

Materials and Methods

After institutional review board approval (Catharina Hospital-Brabant Medical School, Eindhoven, The Netherlands) and written informed consent, we studied 320 consecutive patients (American Society of Anesthesiologists physical status I-III; aged 18-80 yr) who were recruited at the Catharina Hospital, scheduled to undergo elective surgery, and did not require tracheal intubation. Patients were excluded from the trial if they had a known difficult airway, had a Mallampati grade III or IV,⁶ had a mouth opening less than 2.5 cm, were at risk of aspiration of gastric contents, required surgery in a nonsupine position, or had to undergo surgery to the head or neck. Patients were randomly allocated, using computer-generated tables of random numbers, to one of the three disposable EADs devices. The randomization assignment was maintained in an opaque, sealed envelope, which was opened immediately before induction of anesthesia.

Patients were premedicated with 10 mg diazepam 1 h before induction. The state of dentition and the inter-

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dental (or intergum) distance in the midline were noted. A standard anesthesia protocol was followed, and routine monitoring was applied. Check tests of the EADs were performed before use. The EADs were lubricated with a water-based lidocaine gel (Instillagel; FarcoPharma, Cologne, Germany). Anesthesia was in the supine position with the patient's head on a standard pillow, 7 cm in height. After preoxygenation for 3 min, induction of anesthesia was with 1 $\mu\text{g}/\text{kg}$ intravenous fentanyl and 3 mg/kg propofol. The lungs were manually inflated *via* a facemask using 2–3% sevoflurane in oxygen. A Guedel airway was not used. The EAD was inserted at least 1 min after completion of induction, and only when the jaw was relaxed and there was no lash reflex. Additional boluses of 0.5 mg/kg intravenous propofol were given, as required, until an adequate level of anesthesia was achieved for placement. A single anesthesiologist, who had used each EAD 50 times, inserted all of the devices. The Cobra-PLA™ and SS-LM were inserted according to the manufacturer's instructions. The LMA-U and SS-LM were inserted with the cuff partially inflated, and the Cobra-PLA™ was inserted with the cuff fully deflated. The manufacturer's weight-based recommendations were used for size selection (LMA-U and SS-LM: size 3, > 30–50 kg; size 4, > 50–70 kg; size 5, > 70 kg; Cobra-PLA™: size 3, > 35–70 kg; size 4, > 70–100 kg; size 5, >100 kg). Ease of insertion was graded using a four-point scoring system: 3 = insertion at the first attempt without tactile resistance; 2 = insertion at the first attempt with tactile resistance; 1 = insertion successful at the second attempt; and 0 = insertion failed at the second attempt. After the EAD was inserted into the pharynx, the cuff was inflated with air until an effective airway was established or the maximum recommended inflation volume was reached. Fixation was according to the manufacturer's instructions.

Two attempts were allowed before insertion was considered a failure. An insertion attempt was defined as placement of the EAD in the mouth. A failed attempt was defined as removal of the EAD from the mouth. An effective airway was defined as three square-wave capnograph traces during manual ventilation. The time between picking up the EAD and obtaining an effective airway was recorded. If an effective airway could not be achieved, an alternative airway device or a different size was used, but no further data were collected. When insertion was successful, the intracuff pressure was set at 60 cm H₂O using a handheld pressure gauge (Endotest; Rüschi, Kern, Germany) and then monitored using a pressure transducer (S/5 AM; Datex-Ohmeda, GE Healthcare, Helsinki, Finland). Oropharyngeal leak 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 was 40 cm H₂O) at which equilibrium was reached.⁷ Anatomical position of the airway tube as determined by passing a rigid endo-

scope⁸ through the airway tube to a position 1 cm proximal to the end of the tube and scoring the view.⁹ The technique involves disconnecting the EAD from the anesthesia breathing system, adopting the sniffing position to align the glottis and mouth, and advancing a 30° rigid endoscope (Hopkins II Forward-Oblique Telescope; Karl Storz, Tuttingen, Germany) to the distal end of the airway tube. The high-resolution images are then viewed on an external monitor.

Maintenance of anesthesia was with 1.5–2% sevoflurane in nitrous oxide and oxygen 33% using a circle system with fresh gas flows of 3 l/min. Analgesia was with 50- μg fentanyl boluses, as required. Patients underwent manually assisted ventilation until spontaneous ventilation resumed. Intracuff pressures were recorded at the start and end of surgery. At the end of surgery, anesthesia was discontinued, and the EAD was removed when the patient was able to open his or her mouth to command. The EAD cuff was deflated as the EAD was being removed. The following complications were documented: aspiration or regurgitation; hypoxia (peripheral oxygen saturation, oxygen saturation measured by pulse oximetry < 90%); bronchospasm; airway obstruction; gastric insufflation; coughing, gagging, or retching; hiccup; blood staining of the EAD; and tongue, lip, or dental trauma. If a complication occurred, an explanation was given and the minimal peripheral oxygen saturation was documented.

Patients underwent a structured interview 2 h after surgery. Patients were asked about sore throat (constant pain, independent of swallowing), dysphonia (difficulty or pain on speaking), and dysphagia (difficulty or pain on swallowing). Symptoms were graded by the patient as mild, moderate, or severe. Patients were unaware of the insertion technique used. Unblinded trained observers collected the data during anesthesia, and a blinded trained observer collected the data after removal of the EAD.

Sample size (106 for each group) was based on previous studies of the laryngeal mask and was selected to detect a medium effect size with respect to all the primary variables for a type I error of 0.05 and a power of 0.95. A medium effect size is defined as a ratio of between-group variance and within-group variance of 0.2. The groups were analyzed separately.

The primary outcome was ease of insertion. Secondary outcomes were effective airway time, oropharyngeal leak pressure, anatomical position, intracuff pressure changes, and airway trauma. Sample size was based on previous studies of the laryngeal mask. Power calculation required 300 patients to detect a 0.2 difference in the primary outcome with 95% power and 5% β error. We chose to study 300 patients to also allow us a 95% power to detect a 20% difference in our secondary outcomes.

Statistical analysis was with Kruskal-Wallis and chi-

Table 1. Patient Characteristics, Type of Surgery, Duration of Anesthesia, and Device Size for the LMA-U, the SS-LM, and the Cobra-PLA™

	LMA-U	SS-LM	Cobra-PLA™
Patient characteristics			
Sex, male/female ratio	20/83	18/84	22/83
Age, yr	43 ± 15	45 ± 15	45 ± 15
Weight, kg	72 ± 12	70 ± 12	74 ± 16
Height, cm	169 ± 8	167 ± 14	169 ± 9
Maximal mouth opening, cm	4.3 ± 0.8	4.4 ± 0.6	4.4 ± 0.7
Own teeth/single denture/double denture, n	85/8/10	72/12/18	89/5/11
Type of surgery, n			
General surgery	31	36	35
Gynecology	36	27	32
Orthopedics	5	8	3
Plastic and reconstructive	21	27	26
Urology	10	4	9
Duration of anesthesia, min	58 ± 32	64 ± 32	67 ± 43
EAD size 3/4/5, n	1/67/35	3/64/35	48/44/13*

* Smaller sizes used more frequently with the Cobra perilyngeal airway (Cobra-PLA™) ($P < 0.001$).

EAD = extraglottic airway device; LMA-U = LMA-Unique™; SS-LM = Soft Seal® laryngeal mask.

square test. Data are presented as mean ± SD unless otherwise stated. Significance was taken as $P < 0.05$. Statistical analysis was performed with SPSS version 9.0 (SPSS Inc., Chicago, IL).

Results

There were 107 patients in the LMA-U group, 103 in the SS-LM group, and 110 in the Cobra-PLA™ group. The Cobra-PLA™ did not provide an effective airway in 5 patients, the LMA-U did not provide an effective airway in 4 patients, and the SS-LM did not provide an effective airway in 1 patient. Data from these cases were excluded from the analysis, other than for ease of insertion. Demographic data, the type of surgical procedure, and the duration of anesthesia were similar among groups, but smaller sizes were used of Cobra-PLA™ than of the LMA-U and SS-LM (table 1).

In table 2, anesthesia data are provided regarding ease of insertion, effective airway time, oropharyngeal leak pressure, endoscopic score, and intracuff pressure increase. Insertion was easier with the LMA-U and SS-LM than with the Cobra-PLA™ ($P < 0.02$), but the overall failure rate was well below 5% for all devices. Effective airway time was similar among groups. Oropharyngeal leak pressure was lower with the LMA-U than with the SS-LM and Cobra-PLA™ ($P < 0.001$). Intracuff pressure increased during surgery with all EADs, but the increases were lower with the Cobra-PLA™ than with LMA-U and SS-LM ($P < 0.01$). All EADs passed the pre-use check tests; however, in six patients in the Cobra-PLA™ group, intracuff pressures gradually decreased to zero during maintenance of anesthesia. This had no effect on clinical

Table 2. Anesthesia Data for the LMA-U, the SS-LM, and the Cobra-PLA™

	LMA-U	SS-LM	Cobra-PLA™
Ease of insertion 3/2/1/0, n*†	101/2/0/4	101/1/0/1	95/10/0/5
Effective airway time, s	40 ± 12	38 ± 7	42 ± 11
Oropharyngeal leak pressure, cm H ₂ O‡	25 ± 6	31 ± 5	30 ± 6
Endoscopic score, 4/3/2/1§	27/64/1/11	45/55/1/1	58/36/0/11
Intracuff pressure increase, mmHg#	9.7 ± 9.2	9.6 ± 8.6	6.4 ± 6.4

* 3 = Insertion at the first attempt without tactile resistance; 2 = insertion at the first attempt with tactile resistance; 1 = insertion successful at the second attempt; 0 = insertion failed at the second attempt. † Insertion was easier with LMA-Unique™ (LMA-U) and Soft Seal® laryngeal mask (SS-LM) than with Cobra perilyngeal airway (Cobra-PLA™) ($P < 0.02$). ‡ Oropharyngeal leak pressure was lower with LMA-U than with SS-LM and Cobra-PLA™ ($P < 0.001$). § 4 = Only vocal cords seen; 3 = vocal cords and posterior epiglottis seen; 2 = vocal cords and anterior epiglottis seen; 1 = vocal cords not seen. || Endoscopic score was better with Cobra-PLA™ than with SS-LMA ($P < 0.001$) and better with SS-LM than with LMA-U ($P < 0.001$). # Intracuff pressure increases were lower with Cobra-LM than with LMA-U and SS-LM ($P < 0.01$). Data from the six patients with defective valves were excluded.

performance, oropharyngeal leak pressure measurements, or endoscopic score and was subsequently shown to be due to a defective valve. Data from these cases were excluded from the intracuff pressure analysis. Anatomical position was better with the Cobra-PLA™ than with the SS-LMA ($P < 0.001$) and better with the SS-LM than with the LMA-U ($P < 0.001$). Blood staining was detected more frequently with the Cobra-PLA™ than with the LMA-U and SS-LM ($P < 0.001$), but there were no differences in airway morbidity (table 3). There were no episodes of hypoxia or other complications.

Discussion

We found that the Cobra-PLA™ was more difficult to insert than the LMA-U or SS-LM, which were similarly easy. These findings contrast with those of Gaitini *et al.*,⁵ who showed that the Cobra-PLA™ was as easy to insert as the LMA-U, and Brimacombe *et al.*,⁴ who showed that

Table 3. Trauma and Airway Morbidity Data for the LMA-U, the SS-LM, and the Cobra-PLA™

	LMA-U	SS-LM	Cobra-PLA™
Trauma			
Mouth, lip, or tongue injury, yes/no	1/102	0/102	0/105
Blood staining, yes/no, n*	10/93	9/93	37/68
Airway morbidity, nil/mild/moderate/severe, n			
Sore throat	95/6/1/1	97/4/1/0	94/10/1/0
Dysphagia	101/2/0/0	97/4/1/0	96/8/1/0
Dysphonia	96/5/2/0	97/4/1/0	97/8/0/0

* Blood staining detected more frequently with the Cobra perilyngeal airway (Cobra-PLA™) than with the LMA-Unique™ (LMA-U) and Soft Seal® laryngeal mask (SS-LM) ($P < 0.001$).

the LMA-U was easier to insert than the SS-LM. Akca *et al.*¹¹ showed that the Cobra-PLA™ was as easy to insert as the classic LMA. Some of these differences may be related to the use of muscle relaxants,^{4,10} which provide perfect insertion conditions. However, as in the current study, the patients of Akca *et al.*¹¹ were not paralyzed.

It is our practice to insert the laryngeal mask with a partially inflated cuff despite the LMA-U manufacturer's recommendation. Insertion of a laryngeal mask with a partially inflated cuff has been shown to cause less morbidity than one that is completely deflated.¹² This might have potential bias against the LMA-U.

We found that oropharyngeal leak pressure was lower with the LMA-U than with the SS-LM and Cobra-PLA™. This contrasts with the finding of Brimacombe *et al.*,⁴ who showed that oropharyngeal leak pressure was similar with the LMA-U and SS-LM, but is in agreement with the finding of Gaitini *et al.*,⁵ who showed that oropharyngeal leak pressure was higher with the Cobra-PLA™ than with the LMA-U. Akca *et al.*¹¹ showed that oropharyngeal leak pressure was higher with the Cobra-PLA™ than with the classic LMA. In principle, the lower seal of the LMA-U may make it less suitable than the SS-LM and Cobra-PLA™ for positive-pressure ventilation; however, Brimacombe *et al.*⁴ noted no differences in ventilatory capability between the LMA-U and SS-LM.

Our results offer the possibility that the Cobra-PLA™ may perform better than the other devices during controlled ventilation. Although not studied, in principle, the better anatomical position of the Cobra-PLA™ may offer the possibility that it may be useful as a conduit for tracheal intubation; however, many other factors contribute to ease of intubation through an EAD. Further studies are warranted.

The increased use of smaller sizes with the Cobra-PLA™ was related to differences in the size selection criteria: For example, the size 3 was used in patients weighing less than 70 kg with the Cobra-PLA™ and less than 50 kg with the LMA-U and SS-LM.

We found that intracuff pressure increased for all EADs by a small (10–20%) but significant amount after 1 h. This finding contrasts with all previous studies, which show no increase in intracuff pressure for disposable EADs during nitrous oxide anesthesia,¹³ including a recent study by our group, which showed a nonsignificant increase of 1.5 mmHg with the SS-LM.¹⁴ This was thought to be related to the thick cuffs of disposable EADs making them relatively impermeable to nitrous oxide. Our finding suggests that some nitrous oxide crosses into the cuff. Unfortunately, we did not test the intracuff gases for the presence of nitrous oxide. We found that the increase in intracuff pressure was higher with the LMA-U and SS-LM than with the Cobra-PLA™. This may be related to the cuff being less permeable or to small leaks in the valves. In six patients who were subsequently excluded from the analysis of intracuff

pressure changes, there were large valve leaks caused by a manufacturing defect, which resulted in cuff deflation.¹⁵ These defects have since been rectified (personal verbal communication, Brad Quinn, B.S., Vice-President, Engineered Medical Systems, Inc., January 19, 2005).

We found that the endoscopically determined anatomical position was better with the Cobra-PLA™ than with the SS-LM and LMA-U. This supports the finding of Gaitini *et al.*,⁵ who showed that fiberoptic score was slightly better with the Cobra-PLA™ than with the LMA-U, but contrasts with the finding of Brimacombe *et al.*,⁴ who showed that fiberoptic score was higher with the LMA-U than with the SS-LM. These differences may, in part, be related to the use of a rigid endoscope rather than a fiberoptic scope for deriving the positional scores, because the anatomical position for assessment was the sniffing position for the rigid endoscope, whereas the neutral position is usually used for fiberoptic assessment. In principle, the better anatomical position of the Cobra-PLA™ may make it a more suitable airway intubator than the SS-LM or LMA-U; however, many other factors contribute to ease of intubation through an EAD.

We found that blood staining occurred more frequently with the Cobra-LM than with the LMA-U and SS-LMA, but the frequency of airway morbidity was similar. This contrasts with the finding of Brimacombe *et al.*,⁴ who showed there was more blood staining with the SS-LM than with the LMA-U, but is similar to the finding of Gaitini *et al.*,⁵ who showed that airway morbidity was similar with the Cobra-PLA™ and LMA-U. Van Zundert *et al.*¹⁶ showed that there was less sore throat with the SS-LM than with the classic LMA. There were no episodes of regurgitation or aspiration. A recent evaluation of the Cobra-PLA™ was halted when 2 of the first 29 patients aspirated.¹⁷

Our study has several limitations. First, although the level of experience with the study devices was similar, the user had considerable experience with the classic LMA, which is virtually identical to the LMA-U and similar to the SS-LM, a possible source of bias against the Cobra-PLA™. However, there was no evidence of a skill acquisition with the Cobra-PLA™ when comparing the first and second 50 uses. Second, all insertions were performed by an experienced anesthesiologist, and our findings may not be applicable to less experienced users. Third, the intraoperative data were collected by unblinded observers, a possible source of bias. Fourth, we only collected data about airway morbidity within 2 h of surgery, and it is possible that there may have been differences in the frequency of airway morbidity after 24 h. Fifth, there were differences in group size; these were due to the random allocation of patients and were too small to invalidate the power analysis. Sixth, because we studied only adult patients, we used a suitably sized rigid endoscope to fit through the different airway devices to determine the anatomical position of the device.

The size chosen was to ensure that no or minimal displacement of the device was caused. Seventh, because the majority of the patients studied were females, reflecting the workload at the study site, further studies in males might be useful to confirm our results in that group.

We conclude that the LMA-U and SS-LM are easier to insert and cause less trauma than the Cobra-PLA™, but the Cobra-PLA™ has a more effective seal than the LMA-U and better endoscopically determined anatomical position than the LMA-U and SS-LM. This suggests that the LMA-U and SS-LM would be more suitable in spontaneously breathing anesthetized patients. The suitability of the three devices for positive pressure ventilation might be the subject of a further study.

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