A clinical comparison of disposable airway devices

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SAJAA 2008; 14(6): 31-36

ABSTRACT

Background: The re-usable Classic laryngeal mask airway (LMA®) is widely used. There are concerns regarding the transmission of pathogens. Disposable airway devices provide a cost-effective alternative. We performed a side by side clinical comparison of these devices applicable to the South African context.

Methods: Adult ASA 1-3 patients (30 – 100 kg) presenting for elective peripheral surgery in Tygerberg Academic Hospital were randomised to receive the gold standard Classic LMA®, or one of four disposable devices. They all received a standardised anaesthetic with propofol, fentanyl and isoflurane in 40% O_2/N_2O. Insertion technique, mask sizes and maximum cuff volumes were per manufacturer's instructions. The cuff was inflated to achieve an adequate airway seal (no audible leak at an airway pressure of 20cm H_2O), or to the maximum recommended volume. Cuff and airway pressures were measured continuously. A protocol was followed for repeated or failed attempts. 115 of the proposed 130 patients were recruited. Categorical data was analysed using Chi squared tests, and one-way ANOVA was performed on parametric data. An alpha level of 0.05 was accepted.

Results: The patients were of comparable age, weight, ASA grade and airway grading. There were no statistical differences in the number of times the airway device size had to be changed (p = 0.627), ease of insertion (p = 0.357) or insertion attempts (p = 0.909). Only the Cobra PLA™ was graded as "Grade 4: impossible to establish an airway" in 10% of cases, and the insertion time with this device was prolonged (p = 0.018). The Cobra PLA™ predictably differed from the other groups in cuff volumes (p = 0.001). Cuff pressures were significantly higher in the Ambu™ and LMA Unique™ (p = 0.001). Maximum airway pressure attainable after 5 minutes was significantly higher in the Ambu™ (p = 0.036). Airway trauma as graded by visible blood on the device was low, and similar between groups (p = 0.237). Secretions were negligible in 67.8% patients and there was no difference in the amount of suctioning required (p = 0.094). Patient comfort was exceptional and comparable, achieving similar visual analogue scores for sore throat (p = 0.742), dysphagia (p = 0.760) and hoarseness (p = 0.258). No complications were noted.

Conclusions: We found no difference in routine clinical practice between the Classic LMA®, LMA Unique™, Portex Soft Seal ™, Ambu™ and Cobra PLA™ in terms of ease of insertion, number of attempts, size changes, patient comfort or airway trauma. The Ambu device allowed an airway seal at higher pressures. The Cobra devices had a prolonged average insertion time. The Cobra devices were the only ones found impossible to achieve a satisfactory airway after 3 attempts in 10% of cases, although this did not reach statistical significance.

Background

Since its introduction in 1988 the re-usable Classic laryngeal mask airway (LMA®; Laryngeal Mask Company, Heneley-on-Thames, UK) has been used widely, with an estimated 20 million uses per annum worldwide.[1] With the use of supraglottic airway devices additional interventions such as muscle relaxation and laryngoscopy are circumvented. In addition, anaesthesiologists may secure the airway even in patients in whom tracheal intubation or conventional mask ventilation is difficult or impossible. However, there are some concerns regarding the use of the Classic LMA®, in particular its high acquisition cost and the potential risk of cross contamination between patients due to the incomplete removal of biological debris.[2,3,4,5,6]

Creutzfeldt-Jakob disease, first recognised in humans in 1996,[7] is caused by an infectious protein (prion).[8] A number of studies showed residual protein deposits or prions on reuasable devices, despite cleaning and sterilisation processes in accordance with the manufacturers instructions.[2,3,4] Guided scrubbing, ultrasonic cleaning,[5] immersion in potassium permanganate 2mg/L[9] as well as repeated autoclaving does not remove protein deposits from the Classic LMA®.[1,4]

Disposable airway devices accommodate the concerns regarding the risk of disease transmission and the costs of cleaning and sterilisation of reusable laryngeal masks, and provide a cost effective alternative to reusable airway devices (Classic LMA®). There are currently a wide variety of disposable airway devices available on the South African market, with significant differences in anatomical design and the material used.

This study was designed to evaluate the available disposable airway devices in routine clinical practice applicable to the South African context. Although there are numerous studies comparing the reusable Classic LMA® with disposable laryngeal airway devices, to date there has been no side by side comparison of these devices. We performed a side by side clinical comparison of disposable airway devices and compared them with the gold standard Classic LMA® with regards to insertion time, insertion difficulty, sealing properties, oropharyngeal irritation and patient satisfaction.

Since the start of the study other alternatives, including the I-gel® supraglottic device has been introduced on the South African market and the Cobra PLA™ has been withdrawn.

Methods
This was a prospective randomised study, which was approved by the University of Stellenbosch ethics committee. Power analysis indicated that we needed 130 cases to achieve 80% power, if a 20% difference is considered significant.

Adult ASA 1-3 patients in Tygerberg Academic Hospital, weighing 30 – 100 kg who presented for elective peripheral surgery that did not require tracheal intubation, were recruited. Patients were excluded if morbidly obese (BMI > 35 kg m^{-2}), or if they were considered to have an increased risk of aspiration, as well as patients with limited inter-incisor distance (< 2.5 cm), Mallampati 4 or judged to have a high risk of a failed intubation.

Written informed consent was obtained from each patient. Patients were randomised by the drawing of sealed envelopes for either the control group (the reusable Classic LMA®), or one of four disposable airway device groups – Cobra PLA™, Portex Soft Seal™, LMA Unique™ or Ambu™. The investigators were unblinded as to which airway device was used.

The same investigators were used for all the patients. The investigators were allowed to familiarise themselves with the different techniques prescribed by the manufacturers. There were practice sessions on a manikin under the supervision of the representatives of the different manufacturers, as well as a minimum of five live insertions. The insertion technique, mask sizes as well as the cuff inflation volume were according to the manufacturers' recommendation.

Pre-medication, if necessary, comprised of oral diazepam 10 mg. The majority of patients underwent day case diagnostic procedures and did not receive any sedative pre-medication. Devices were tested for leaks before insertion, and lubricated as recommended by the manufacturer with water-soluble lubricant. Routine monitoring was established (ECG, non-invasive blood pressure, pulse oximetry, capnography and vapour analysis). All the patients received a standardised anaesthetic with intravenous fentanyl 1.5 μg/kg and propofol 2–2.5 mg/kg. Additional boluses of intravenous propofol 0.5mg/kg were given as required. Patients did not receive any muscle relaxants. Anaesthesia was maintained with the inhalation of isoflurane 1–2% in 40% O_2/ 60% N_2O at 1.5 litre per minute through a circle system and absorber. The airway device was inserted 60 seconds after induction. The patient's head was positioned in a neutral position and the airway device was inserted according to the manufacturers' instructions. Time to successful insertion was measured from removing the face mask and picking up the device (60 seconds after induction) until the first expiratory tidal volume > 200 ml.

A protocol was followed for the inability to establish an adequate airway. If an effective airway could not be achieved, reinsertion or repositioning was attempted. A different size device was tried if either unable to pass a device due to size, or if a poor seal was found at maximum cuff volume despite apparent adequate positioning. A failed attempt was defined as the inability to establish an adequate airway by these manoeuvres and the removal of the airway device from the mouth. Three attempts were allowed and if unsuccessful, an endotracheal tube was inserted. Patients were allowed to breath spontaneously or assisted where required to maintain arterial saturation > 94% and $EtCO_2$ < 5.5 kPa. Patients received fentanyl 50 μg boluses or morphine, as required.

Cuff inflation volume was according to the manufacturers' recommendation to achieve an adequate airway seal or the maximum recommended volume. An adequate seal was defined as no audible leak at the mouth @ 20 cm H_2O airway pressure. Cuff and airway pressures were measured. Cuff pressures were measured by averaging three measurements obtained using a manometric pressure gauge and a three way tap on the cuff port. The maximum airway sealing pressure was measured by closing of the APL valve and reading the pressure at which an audible leak occurred. This was done five min after establishing an acceptable airway to allow for settling of the device. At the end of the surgery, anaesthesia was discontinued, and the airway device was removed when the patient was able to open his or her mouth on command.

The experienced anaesthesiologist who inserted the airway device gave a subjective assessment of the insertion procedure that was rated as easy, possible, difficult or impossible. Patient comfort was assessed by measuring post-operative sore throat, dysphagia and hoarseness rated on a 10 cm visual analogue scale after recovery during a structured interview. Patients were unaware of the airway device or technique used.

Statistical analysis
The primary aim of the study was to compare clinical efficacy of disposable airway devices. Secondary outcome measures included time to establish airway, number of insertions required to establish an airway, change in size, cuff volumes, cuff pressure, maximum seal pressure, airway trauma and patient comfort. Data was captured on an Excel spreadsheet and analysed using NCSS 2004 (Number Cruncher Statistical Systems, Utah). Categorical data was analysed using Chi squared tests (Fisher exact test), and one-way ANOVA was performed on parametric data. Post hoc analysis of differences found with ANOVA was performed using the Tukey-Kramer Multiple-Comparison Test. 115 of the proposed 130 patients were recruited in the time available.

Results
Groups were comparable with regards to sex, body weight, ASA classification, predictors of a difficult airway and the duration of surgery. The procedures were mostly diagnostic urological interventions performed on an outpatient basis.

The demographic details of the patients are recorded in Table I.

Mask insertion details are recorded in Table II. There were no significant differences in the ease of insertion ($p = 0.357$) as well as the requirements for a size change ($p = 0.626$) between the study groups. Insertion was successful on first attempt in 79.1% of patients overall, and similar between groups ($p = 0.909$). With the Cobra PLA™ it was impossible to establish an airway in 10% of cases, although this was not statistically significant. The time to establish an airway was significantly longer in the Cobra PLA™ group ($p = 0.018$).

Cuff volume and cuff pressures are recorded in Table III. The cuff volume required to seal differed due to the difference in the design of the airway devices. Due to the design of the Cobra PLA™, it had significantly larger cuff volumes than the other groups ($p<0.001$). This did not translate to increased cuff pressures – in fact Cobra PLA™ cuff pressures were significantly lower ($p = 0.001$). The Ambu device required the highest average cuff pressure, but also allowed an airway seal up to the highest pressure ($p = 0.036$).

Differences in both surface area and material used may lead to varying stimuli for oropharyngeal secretions among these devices; anatomical differences could lead to an increased risk of insertion trauma. We found no significant differences in the incidence of secretions ($p = 0.094$) or blood, the latter being indicative of trauma ($p = 0.236$), on the airway devices. We expected a significant difference in the incidence of sore throats, dysphagia and hoarseness due to the higher cuff pressures and varying design adherence to normal airway anatomy. However, this was not found, and patients graded sore throats ($p = 0.742$), dysphagia ($p = 0.760$) and hoarseness ($p = 0.258$) remarkably low, and similar between groups. Subjective assessment of blood, secretions and patient comfort are recorded in Table IV.

Table I: Patient demographics

		LMA Classic	LMA Unique	Portex	Cobra	Ambu	p
	n	**25**	**21**	**25**	**20**	**24**	
Sex	**Male** **Female**	9 16	10 11	15 10	11 9	10 14	**0.453**[a]
ASA	**1** **2** **3** **4** **5**	16 5 4 0 0	14 5 2 0 0	17 5 3 0 0	13 6 1 0 0	18 5 1 0 0	**0.910**[a]
Weight	**kg**	65.6 (59.8–71.4)	67.0 (58.8–75.3)	71.5 (66.9–76.1)	78.5 (70.1–86.8)	69.5 (63.2–75.9)	**0.061**[b]
Mallampati Airway evaluation	***1*** ***2*** ***3*** ***4***	20 4 1 0	18 3 0 0	23 1 1 0	18 2 0 0	20 4 0 0	**0.747**[a]
Mouth opening	***Normal*** ***Restricted***	25 0	21 0	25 0	20 0	24 0	**0.430**[a]
Neck Mobility	***Normal*** ***Restricted***	25 0	21 0	25 0	20 0	23 0	**0.430**[a]
Dentition	***Normal*** ***No incisors*** ***Adentulous***	1 4 9	5 0 5	4 6 8	1 6 4	1 4 5	**0.219**[a]
Procedure time	**min**	48.6 (31.6–65.5)	61.6 (45.2–78.0)	63.1 (47.9–78.3)	50.5 (43.1–57.9)	50.0 (37.8–62.3)	**0.402**[b]

[a] χ_2 test (Fisher exact test) [b] Oneway ANOVA * Statistically significant difference
Data is given as absolute numbers, or mean (95% CI)

Table II: Mask insertion findings

		LMA Classic	LMA Unique	Portex	Cobra	Ambu	p
Size Change	**Y** **N**	1 24	0 21	2 23	2 18	1 23	**0.626**[a]
Insertion	**Easy** **Possible** **Difficult** **Impossible**	20 4 1 0	15 5 1 0	16 7 2 0	14 2 2 2	16 6 2 0	**0.357**[a]
Insertion attempts	**1** **2** **3**	21 3 1	16 4 1	19 5 1	15 3 2	20 4 0	**0.909**[a]
Insertion time	***seconds***	29.3 (20.2–38.4)	34.3 (19.6–48.9)	48.4 (24.1–72.6)	64.1 (31.9–96.3)	27.7 (20.3–35.0)	**0.018**[b]*

[a] χ2 test (Fisher exact test) [b] One-way ANOVA * Statistically significant difference
Data is given as absolute numbers, or mean (95% CI)

Table III: Cuff volume and pressure

	LMA Classic	LMA Unique	Portex	Cobra	Ambu	p
Cuff volume	26.6 (22.2–30.9)	27.9 (23.2–32.5)	28.1 (23.2–33.0)	56.6* (46.6–66.6)	25.8 (21.6–30.1)	**<0.001**
Cuff pressure	103.0 (82.6–123.3)	143.7 (112.2–175.1)	106.0 (77.6–134.3)	81.7* (42.4–101.0)	143.8 (121.3–166.3)	**0.001**
Maximum airway seal pressure	21.6 (19.2–24.0)	21.2 (19.3–23.1)	25.5 (20.9–30.1)	23.4 (20.6–26.6)	43.3* (18.4–68.1)	**0.036**

Analysis using one-way ANOVA. D * Statistically significant difference
Data is given as absolute numbers, or mean (95% CI)

Graph 1: Box plot of the average cuff pressures in the different airway devices. Boxes indicate 25th ,75th percentiles and mean. Range and outliers indicated.

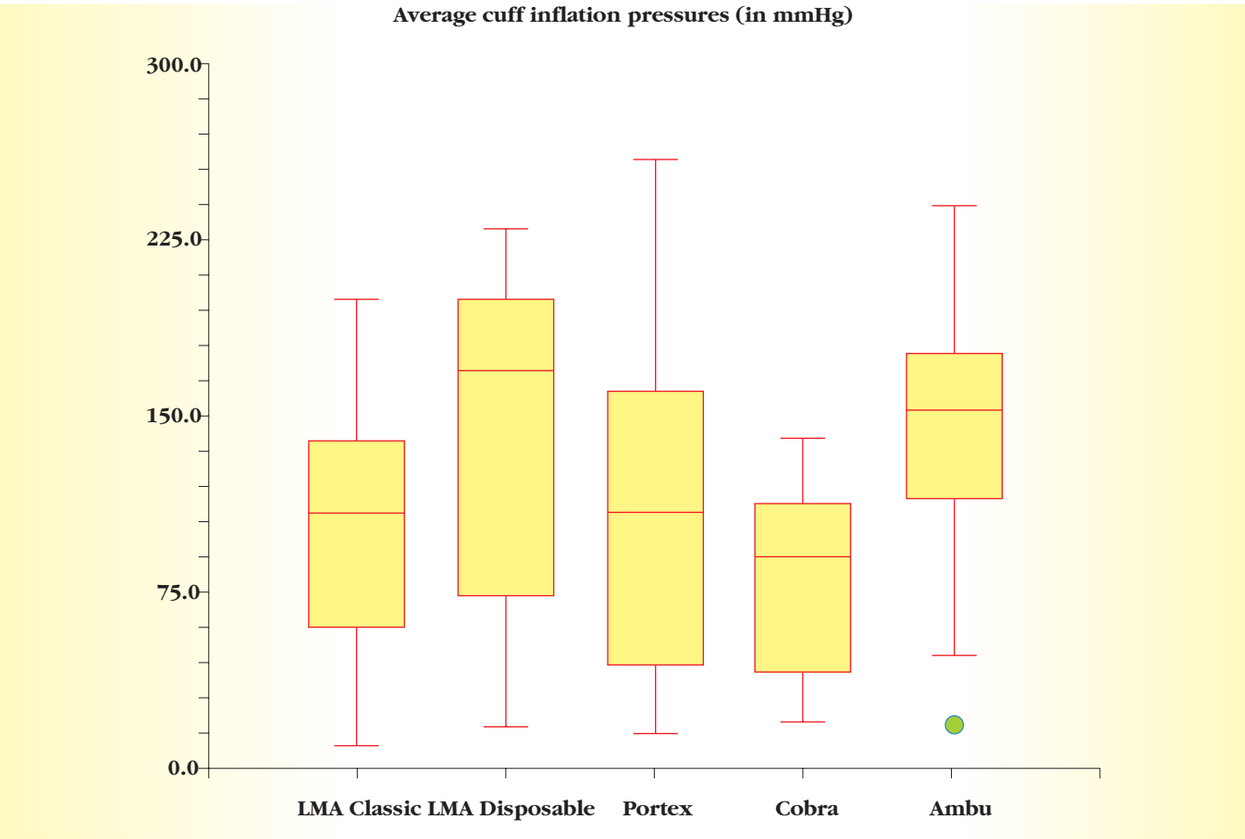

Table IV: Subjective assessment of blood, secretions and patient comfort

		LMA Classic	LMA Unique	Portex	Cobra	Ambu	p
Blood	***None***	21	18	19	11	20	
	Spots (<30%)	3	3	3	5	4	
	Soiled (>30%)	1	0	3	3	0	**0.236**[a]
Secretions	***Negligible***	13	18	19	10	18	
	Some	10	3	4	5	5	
	Copious	2	0	2	4	1	**0.094**[a]
Sore throat		0.4 (-0.1–0.9)	0.5 (-0.5–1.5)	0.8 (0–1.5)	0.8 (0.3–1.2)	0.3 (0–0.6)	**0.742**[b]
Disphagia		0.3 (-0.2–0.7)	0.0 (0–0)	0.3 (-0.3–0.9)	0.4 (0–0.8)	0.3 (-0.2–0.5)	**0.760**[b]
Hoarseness		0.0 (0–0)	0.0 (-0.1–0.1)	0.0 (0–0)	0.0 (0–0)	0.1 (0–0.2)	**0.258**[b]

[a] $\chi 2$ test (Fisher exact test) [b] One-way ANOVA * Statistically significant difference
Data is given as absolute numbers, or mean (95% CI)

Discussion

Dr Archie Brain first conceived the re-usable Classic LMA® in the early 1980's and it has been tremendously successful. Since 1997 several alternative laryngeal airway devices have been introduced. These devices are disposable and cost effective, and may reduce the risk of cross contamination between patients.[2]

Spongiform encephalopathies (e.g. Creutzfeldt-Jakob disease) are a group of slow onset neurodegenerative diseases that are fatal once symptoms appear.[8] Iatrogenic transmission may be increased with the use of the reusable Classic LMA®[10] due to the large concentration of prions in the tonsillar tissue.[11] However, the risk of prion disease transmission from

the reusable Classic LMA® is unknown. The frequency of prion disease is estimated as 1 per million.[12] There is no data on the frequency of Classic LMA® contamination from an infected patient nor on the infective inocculum size or the true efficacy of routine cleaning and sterilising.[4] The relevance of prion disease in sub-Sahara Africa has not been established.

We found no statistical difference in the operator's perceived ease of insertion between the Classic LMA®, and the disposable airway devices (p = 0.357). These findings are in keeping with Gaitini *et al* [13] who showed that the Cobra PLA™ was as easy to insert as the LMA Unique™. Similarly, Akca *et al* [14] showed that the Cobra PLA™ was as easy to insert as the Classic LMA®. However, Brimacombe *et al* [15] as well as Van Zundert *et al* [16] found that the LMA Unique™ was easier to insert than the Cobra PLA™. These different findings might be related to the use of muscle relaxants, which provide optimal insertion conditions. However, no muscle relaxants were use by Akca *et al* [14], Van Zundert *et al* [16] nor in this study.

The fact that we found no significance difference in the ease of insertion might be related to the same relative anatomical location of each airway device even though there are distinct differences in their design.

In our study 70.4% of insertions were regarded as easy. Our findings support that of Gaitini *et al* [17] who showed a small but statistical significant difference in the time to establish an effective airway. They found with the LMA Unique™ an effective airway was established faster (2.87 seconds) than with the Cobra PLA™.[17] In our study the Cobra device required 35 seconds longer than the LMA Classic and 29 seconds longer than the LMA Unique (endpoints may differ between studies). Still, none of our or Gaitini's patients experienced arterial desaturation < 90%.[17] In comparison with a recent multicentre evaluation[18], Francksen *et al* [19] showed major differences with respect to insertion times with the Ambu™(14 seconds versus 48 seconds). They felt that the large variability in insertion times may reflect different levels of training of the attending anaesthesiologists or differences in the patient population.[19] We used the same investigators repeatedly, and had a fairly homogeneous patient population, and thus consider the increased time to establish an airway a reflection of a functional difference of the device.

Despite the different techniques of insertion mandated by differences in design, the placement of each mask is relatively simple. Gaitini *et al* [17]showed a short learning curve when using the Cobra PLA™, as their experience with the LMA® and LMA Unique™ far exceeded that of the Cobra PLA™.

The first time insertion rate was comparable between devices (p = 0.909). Insertion was successful on first attempt in 79.13% of cases. The Classic LMA® had the highest success rate (84%) while the Cobra PLA™ had the highest failure rate; it was impossible to establish an adequate airway in 10% of cases. Francksen *et al* [19] reported the highest failure rate (5%) in the Portex Soft Seal™ group. Similar results were reported in an audit of the Portex Soft Seal™, where the failure rate was 3.8%.[20] In our study the Portex devices performed on par, but did require a longer time to establish the airway (comparable to the Cobra).

The cuff volume required to seal differed due to the difference in design. The Cobra PLA™ had significantly larger cuff volume than all the other groups (p < 0.001). This, however, did not lead to an increase in cuff pressure in the Cobra PLA™. The difference in the design and therefore the cuff volume may not necessarily predict the cuff pressure and thus the incidence of post-operative airway morbidity. We found alarmingly high cuff pressures overall, exceeding 120 cmH_2O and well above capillary perfusion pressure. In vivo cuff pressures measured by Francksen *et al* [19] were comparable to values reported by Keller and Brimacombe *et al* [21] in cadavers. The in vivo cuff pressures in cadavers were only moderate predictors of the applied mucosal pressures and may not reflect the pressure exerted on the mucosa. The reason for this is that the cuff is inflated in an environment where soft tissues gently expand away from the inflated cuff. In our study we found very high cuff pressures in the Portex Soft Seal™ and Ambu™ groups, but with no significant increase in airway morbidity.

The maximum airway pressure attained at 5 min without an audible leak differed between the groups (p = 0.03). Van Zundert *et al* [16] found that the airway pressure without a leak (seal pressure) was lower with the LMA Unique™ than with the Portex Soft Seal™ and the Cobra PLA™. This is different from the findings of Brimacombe *et al* [15] who showed that the seal pressure was similar with the LMA Unique™ and the Portex Soft Seal™. Gaitini *et al* [13] and Akca *et al* [14] showed that the seal pressure was higher with the Cobra PLA™ than with the LMA Unique™ or Classic LMA® respectively. Francksen *et al* [19] showed a higher seal pressure in the Portex Soft Seal™ group than in both the LMA Unique™ and Ambu™ groups. In our study we found significantly higher seal pressures in the Ambu™ (41.5 cmH_2O) group. The higher seal pressure with the Ambu™ is only a possible advantage when patients are mechanically ventilated, and even then the pressure must be limited to avoid gastric insufflation. During spontaneous ventilation high sealing pressures are unnecessary, as the airway pressure remains low.

As in the studies done by Van Zundert *et al* [16] and Gaitini *et al* [17] we found a lower seal pressure (20.2 cmH_2O) in the LMA Unique™ group. This may imply that the LMA Unique™ may be less suitable than the other disposable airway devices for positive pressure ventilation; however Brimacombe *et al* [15] showed no difference in the ventilatory capability between the LMA Unique™ and the Portex Soft Seal™.

We found blood staining/soiling more frequently in the Cobra PLA™ (15%) and the Portex Soft Seal™ (12%) groups. There was, however, no statistical difference between the different groups (p = 0.236). This is in keeping with findings of Van Zundert *et al* [16] who found blood staining to be more frequent with the Cobra PLA™ than with the LMA Unique™ and the Portex Soft Seal™. Brimacombe *et al* [15] and Gaitini *et al* [13] showed more blood staining with Portex Soft Seal™ than with the LMA Unique™.

The causes of postoperative airway morbidity after using supraglottic devices are multifactorial. The occurrence of postoperative sore throat, hoarseness and dysphagia may be related to the direct physical effects of insertion and the removal of the devices, insertion technique, number of insertion attempts, intra-cuff pressure, analgesia provided and the duration of the anaesthesia. However in our study there was no statistical significant difference in the incidence of postoperative sore throat, dysphagia and hoarseness, despite the more frequent blood staining in the Portex Soft Seal™ and Cobra PLA™ groups. We found no statistical difference in patient comfort as rated by the patients on a 10cm (visual analogue scale)VAS after recovery. No serious complications were noted.

Our study has several limitations. Firstly, although the investigators had practice sessions on a manikin under the supervision of the representatives of the different manufacturers as well as 5 live insertions, the level of experience with the Classic LMA® and therefore the identical LMA Unique™ were considerably more, and therefore a possible source of bias. Secondly the data was collected by unblinded investigators. Thirdly we only recruited 115 of the planned 130 patients due to time constraints. The group sizes differed due to the random allocation of patients and were too small to achieve 80% power. In addition we evaluated patient comfort as rated by patients on a 10 cm visual analogue scale post-recovery. Patients were not re-evaluated later and it was apparent from patients that presented for follow-up surgery that some had airway discomfort hours after discharge. It is therefore possible that there may

have been differences in the incidence of airway morbidity and patient discomfort after 24 hours, which may be ascribed to late oropharyngeal oedema or inflammation due to subclinical trauma. Finally the study investigators are experienced anaesthesiologists and therefore our results may not be applicable to less experienced clinicians who try these new devices for the first time.

In conclusion we found no difference in routine clinical practice between the Classic LMA®, LMA Unique™, Portex Soft Seal ™, Ambu™ and Cobra PLA™ in terms of ease of insertion, patient comfort or airway trauma. We did find an increased time to establish an airway with the Cobra PLA™ and ™, Portex Soft Seal™ devices, which may indicate more difficult placement. The Ambu device allowed an adequate seal at higher than required airway pressures, which may be an advantage during mechanical ventilation. We found high cuff pressures overall. However, this did not lead to an increase in airway morbidity. We believe this is an important study to facilitate an informed choice when considering a safe and cost effective alternative to the re-usable Classic LMA®. SAJAA

Declaration of interest
All masks were provided free of charge by the different manufacturers.

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