

A Comparison of the Disposable Versus the Reusable Laryngeal Mask Airway in Paralyzed Adult Patients

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A disposable (polyvinyl chloride) laryngeal mask airway (LMA) with dimensions identical to, but physical properties different from (stiffer tube/thicker cuff), the reusable (silicone) LMA has recently become available. We performed a randomized, cross-over study of 60 paralyzed, anesthetized patients to test the hypothesis that the use of these devices was different in terms of ease of insertion, airway sealing pressure, fiberoptic position, and changes in intracuff pressure during N₂O anesthesia. We also tested the hypothesis that the airway sealing pressure of the LMA is suboptimal if the cuff is inflated to a high intracuff pressure. Both the devices were inserted into each patient in random order, and their performance was assessed at two intracuff pressures (60 and 180 cm H₂O) by a blind observer. Subsequently, intracuff pressures were measured during N₂O anesthesia for the second device. Ease of insertion was similar: there was no difference in first attempt success rates (97% vs 98%) and insertion times (15 vs 13 s) for the disposable and reusable LMA, respectively. There were no differences in airway sealing

pressure or fiberoptic position. Airway sealing pressure was significantly higher at 60 cm H₂O intracuff pressure compared with the airway sealing pressure at 180 cm H₂O for both devices ($P < 0.02$). During N₂O anesthesia, the intracuff pressure remained stable for the disposable LMA but increased significantly for the reusable LMA. We conclude that the disposable and reusable LMAs perform similarly in paralyzed adult patients, but that the disposable LMA has more stable intracuff pressures during N₂O anesthesia. Inflation of the LMA to high intracuff pressures produces a suboptimal seal. **Implications:** This randomized, single-blind, within-patient study of 60 adult patients shows that the disposable (polyvinyl chloride) and reusable (silicone) laryngeal mask airways perform similarly, but that the disposable laryngeal mask airway has more stable intracuff pressures during N₂O anesthesia. Inflation of either device to high intracuff pressures produces a suboptimal seal.

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The laryngeal mask airway (LMA) is widely used as a routine airway for elective surgery (1), for difficult airway management (2), and, in some centers, as the initial airway device for cardiopulmonary resuscitation (3). The LMA is constructed from medical grade silicone and is reusable after steam autoclaving. A disposable LMA (LMA-UNIQUE™; Gensia Automedics, San Diego, CA), which is constructed from clear medical grade polyvinyl chloride, has recently been introduced. Although the dimensions of the disposable and reusable LMAs are identical, the disposable LMA tube is more rigid and the cuff

thicker than the reusable LMA. We postulated that because of these physical differences, the disposable LMA may be more difficult to insert, have a less effective seal with the airway, have an increased incidence of fiberoptic malposition, and be less permeable to nitrous oxide. In addition, it is common practice to inflate the LMA cuff to the maximal recommended volume, as illustrated in several trials (4-6), but in our clinical practice, we have noted that this often results in a suboptimal seal. In this randomized, cross-over study, we tested the hypothesis that the performance of the two devices is different in terms of ease of insertion, airway sealing pressure, fiberoptic position, and changes in intracuff pressure during N₂O anesthesia. We also tested the hypothesis that the airway sealing pressure is suboptimal if the LMA cuff is inflated to a high intracuff pressure.

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Methods

In vitro compliance curves were obtained for the size 4 and 5 reusable and disposable LMAs: four LMAs for each size and type were inflated with air in 5-mL increments using a syringe on 10 occasions. Intracuff pressures were measured using a calibrated pressure transducer. The reusable LMAs used in the trial were in routine clinical use, had been through at least 20 autoclave cycles, and had passed the preuse check tests (7). The same eight reusable LMAs tested *in vitro* were used in the clinical trial.

A randomized, single-blind, within-patient comparison of the silicone versus the disposable LMA was performed on 60 ASA physical status I or II patients undergoing minor peripheral surgery. Ethical committee approval and written, informed consent were obtained. Patients were excluded from the trial if they were <18 yr old; required surgery in nonsupine/nolithotomy positions; had a known or predicted difficult airway, respiratory tract pathology, a body mass index >35 kg/m²; were at risk of aspiration, or were considered otherwise unsuitable for the LMA.

In 30 patients, the reusable LMA was inserted first; in the remaining 30 patients, the disposable LMA was inserted first. Patients were assigned to treatment groups by opening a sealed randomized envelope 30 min preoperatively. Anesthetic management was standardized according to the following protocol. The head and neck were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height. Standard monitoring was used. The patients breathed oxygen, and anesthesia was induced with fentanyl 1 µg/kg and midazolam 0.05 mg/kg followed 2 min later by propofol 2.5 mg/kg. Anesthesia was maintained with O₂ and isoflurane 1%–2%, and neuromuscular blockade was accomplished with vecuronium 0.1 mg/kg. Patients were ventilated via a face mask for 3–5 min. The randomized device (size 4 for women, size 5 for men) (8) was inserted according to the manufacturer's recommendations (7) by a single experienced LMA user (>1500 uses). When the cuff had passed into the laryngopharynx, it was inflated with air (10 mL for size 4, 15 mL for size 5), and the tube was fixed to the circle anesthetic breathing system below the chin to ensure that the natural caudal curve of the LMA was maintained (9). A failed attempt was defined as removal of the device from the mouth.

Airway sealing pressure and fiberoptic position were recorded at two intracuff pressures (60 and 180 cm H₂O) for each device. The cuff pressure was adjusted to 60 cm H₂O using a Digital Cuff Pressure Monitor (Mallinckrodt Medical, Athlone, Ireland). Airway sealing pressure was determined by closing the expiratory valve at a fixed gas flow of 3 L/min and noting the airway pressure (measured from the proximal end of the airway device) at which value reached equilibrium. A single blind data collector made the assessments. Blinding was

accomplished by keeping the observer outside the operating room whenever the device was exposed and covering the device with a paper drape during data collection. The fiberoptic position of the airway device was recorded on videotape using a fiberoptic scope (Olympus Australia, Melbourne, Australia) passed to the level of the mask aperture bars. These tests were repeated with the intracuff pressure adjusted to 180 cm H₂O. The initial randomized device was removed and inspected for traces of blood. The second device was then inserted and all the measurements repeated. The cuff pressure of the second randomized device was then reduced to 60 cm H₂O, and 66% N₂O was added to the anesthesia mixture. Intracuff pressures were recorded every 5 min for 20 min during positive pressure ventilation with tidal volumes of 6–8 mL/kg.

The insertion sequence was recorded using a video camera and subsequently analyzed by an anesthesiologist not involved in the clinical trial to determine the insertion time and the number of attempts required for placement. The insertion time was measured from placement of the device in the mouth to cuff inflation. The video recordings of the fiberoptic view were transferred onto photographic plates and coded. All evidence of the airway device used was blocked with a marker pen. Three independent blind observers scored the fiberoptic position using an established scoring system (10).

Sample size was selected to detect a projected difference of 20% between the groups with respect to airway sealing pressure for a type I error of 0.01 and a power of 0.9. The power analysis was based on data from an unpublished pilot study of 10 patients in which airway sealing pressure and first attempt success rates were measured with the disposable LMA. This was compared with established values for first attempt success rates and the airway sealing pressure with the reusable device (11). A difference of <20% was considered clinically insignificant. Statistical analysis was performed by using Student's *t*-tests and χ^2 test. Unless otherwise stated, data are presented as mean \pm SD. Significance was taken as $P < 0.05$.

Results

The reusable LMA was more compliant *in vitro* than the disposable LMA (Figure 1). The variation in compliance between tested devices was less with the disposable LMA.

All patients enrolled in the study were included in the analysis. The age, weight, and height of our patients were 37 \pm 15 yr, 73 \pm 15 kg, and 173 \pm 9 cm, respectively. The male to female ratio was 31:29. The reusable LMA was successfully inserted at the first attempt in 59 of 60 (98%) patients, and the disposable

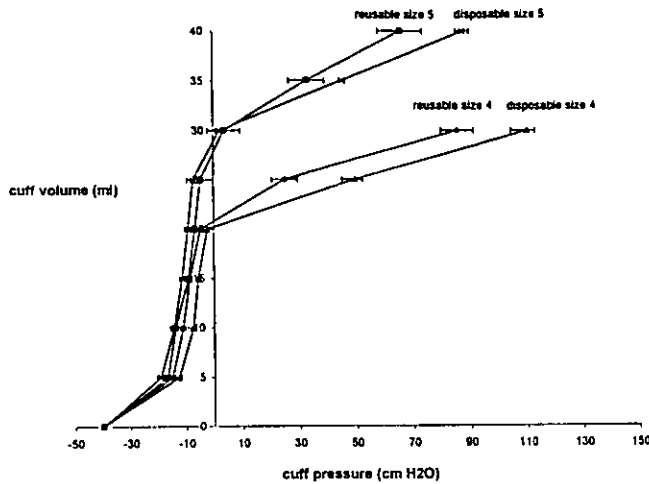


Figure 1. *In vitro* compliance curves for the disposable and reusable laryngeal mask airway.

LMA was successfully inserted at the first attempt in 58 of 60 (98%) patients. In one patient, the disposable LMA was the first randomized device and required a second attempt at insertion; subsequently, the reusable LMA was successfully inserted at the first attempt. In a second patient, both the reusable and the disposable LMA required two attempts. The insertion time was similar for both devices (disposable LMA 14.7 ± 5.1 s versus reusable LMA 12.9 ± 5.4 s). There were no differences in airway sealing pressure or fiberoptic position between devices (Table 1). The airway sealing pressure was significantly higher at 60 cm H₂O intracuff pressure compared with 180 cm H₂O intracuff pressure for the reusable LMA ($P = 0.00001$) and disposable LMA ($P = 0.014$). During N₂O anesthesia, the intracuff pressure remained stable for the disposable LMA, but increased significantly during every 5-min epoch for the reusable LMA (each epoch, $P < 0.000001$) (Figure 2). Blood staining was detected in two patients when the reusable LMA was used first and in one patient when the disposable LMA was used first. Airway sealing pressure, fiberoptic position, and insertion time were unaffected by the order of the devices.

Discussion

The reusable and disposable LMAs perform similarly in terms of first attempt success rates, time to placement, airway sealing pressure, and fiberoptic position in paralyzed adult patients. However, during N₂O anesthesia, intracuff pressures for the disposable LMA remain stable, whereas those for the reusable device increase. The cuff of the reusable LMA is highly permeable to N₂O, and intracuff pressures increase during N₂O anesthesia (12). This suggests that the polyvinyl chloride cuff of the disposable LMA is relatively

Table 1. Airway Sealing Pressure (ASP) and Fiberoptic Score (FOS) at Different Intracuff Pressures

	Disposable LMA		Reusable LMA	
	Intracuff pressure (cm H ₂ O)		Intracuff pressure (cm H ₂ O)	
	60	180	60	180
ASP (cm H ₂ O)	18.0 ± 5.8	15.6 ± 4.6	18.8 ± 5.1	16.5 ± 4.0
FOS (n) ^a				
4	22	22	16	21
3	17	15	24	13
2	15	20	16	22
1	6	3	4	4

^a 4 = only vocal cords visible, 3 = vocal cords plus posterior epiglottis visible, 2 = vocal cords plus anterior epiglottic visible, 1 = vocal cords not seen (10).

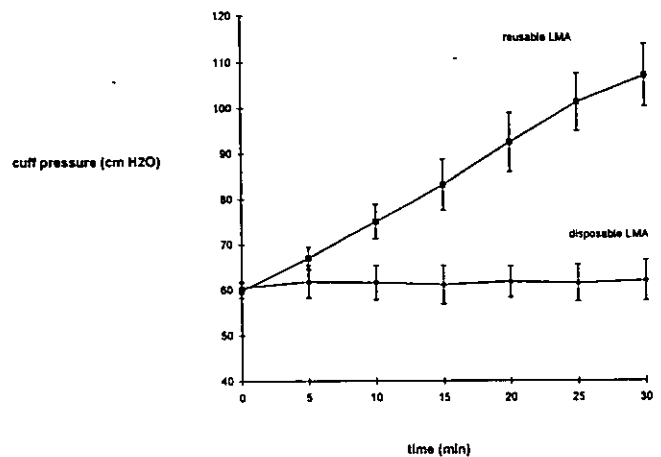


Figure 2. Change in intracuff pressure during nitrous oxide anesthesia (66%) for the disposable and reusable laryngeal mask airway.

impermeable to N₂O. Because polyvinyl chloride is permeable to N₂O, this relative impermeability is probably related to the thickness of the cuff. This increased thickness also explains the lower compliance of the disposable cuff. It has been suggested that maintenance of low intracuff pressures may facilitate a better seal, less sore throat, and a smoother emergence (13). To accomplish this with the reusable device requires intermittent withdrawal of air. In this respect, the disposable device offers an advantage over the reusable device.

Our data suggest that the LMA has a better seal at low, rather than high, intracuff pressures. In theory, the efficacy of the seal depends on the fit between the oval-shaped groove surrounding the glottis and the oval-shaped cuff of the LMA. It seems likely that the soft low-pressure cuff better fits into the variable contours of the periglottic groove than the tense high-pressure cuff. Researchers assessing the efficacy of the seal may underestimate these values if the cuff is inflated to the maximal recommended volume.

This study was conducted on paralyzed patients, but muscle relaxation does not improve ease of insertion of the LMA, provided anesthesia depth is adequate (14). Postoperative pharyngeal morbidity was not assessed because both devices were used in each patient, but there was a low incidence of blood detected, which suggests that the incidence of oropharyngeal trauma was low. A trial comparing the reusable with the disposable LMA has suggested that the incidence of sore throat is similar (15).

We conclude that disposable and reusable LMAs perform similarly in paralyzed adult patients, but that the disposable LMA has more stable intracuff pressures during N₂O. Inflation of the LMA to high intracuff pressures produces a suboptimal seal.

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