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A Multicenter Study Comparing the ProSeal™ *and* Classic™ *Laryngeal Mask Airway in Anesthetized, Nonparalyzed Patients*

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Background: **The laryngeal mask airway *ProSeal*™ (*PLMA*™), a new laryngeal mask device, was compared with the laryngeal mask airway *Classic*™ (*LMA*™) with respect to: (1) insertion success rates and times; (2) efficacy of seal; (3) fiberoptically determined anatomic position; (4) orogastric tube insertion success rates and times; (5) total intraoperative complications; and (6) postoperative sore throat in nonparalyzed adult patients undergoing general anesthesia, hypothesizing that these would be different.**

Methods: **Three hundred eighty-four nonparalyzed anesthetized adult patients (American Society of Anesthesiologists physical status I–II) were randomly allocated to the *PLMA*™ or *LMA*™ for airway management. In addition, 50% of patients were randomized for orogastric tube placement. Unblinded observers collected intraoperative data, and blinded observers collected postoperative data.**

Results: **First-attempt insertion success rates (91 *vs.* 82%, $P = 0.015$) were higher for the *LMA*™, but after three attempts success rates were similar (*LMA*™, 100%; *PLMA*™, 98%). Less time was required to achieve an effective airway with the *LMA*™ (31 ± 30 *vs.* 41 ± 49 s; $P = 0.02$). The *PLMA*™ formed a more effective seal (27 ± 7 *vs.* 22 ± 6 cm H_2O; $P < 0.0001$). Fiberoptically determined anatomic position was better with the *LMA*™ ($P < 0.0001$). Orogastric tube insertion was more successful after two attempts (88 *vs.* 55%; $P < 0.0001$) and quicker (22 ± 18 *vs.* 38 ± 56 s) with the *PLMA*™. During maintenance, the *PLMA*™ failed twice (leak, stridor) and the *LMA*™ failed once (laryngospasm). Total intraoperative complications were similar for both groups. The incidence of postoperative sore throat was similar.**

Conclusion: **In anesthetized, nonparalyzed patients, the *LMA*™ is easier and quicker to insert, but the *PLMA*™ forms a better seal and facilitates easier and quicker orogastric tube placement. The incidence of total intraoperative complications and postoperative sore throat are similar.**

A NEW laryngeal mask device, the laryngeal mask airway *ProSeal*™ (*PLMA*™), has been developed by Brain[1] with a modified cuff to improve the seal and a drainage tube to provide access to the gastrointestinal tract. Preliminary studies in anesthetized, paralyzed patients have shown that the *PLMA*™ is capable of achieving a more effective seal than the laryngeal mask airway *Classic*™ (*LMA*™), facilitates orogastric tube placement, isolates the glottis from the esophagus when correctly positioned, and exerts mucosal pressures similar to the *LMA*™.[1–3] However, there are no published data about its use in nonparalyzed patients, and the frequency of clinical problems is unknown. In the current multicenter study, we compared the *LMA*™ and *PLMA*™ with respect to: (1) insertion success rates and times; (2) efficacy of seal; (3) fiberoptically determined anatomic position; (4) orogastric tube insertion success rates and times; (5) total intraoperative complications; and (6) postoperative sore throat in nonparalyzed adult patients undergoing general anesthesia. We hypothesized that the devices were different in these areas.

Methods

Three hundred eighty-four adult patients (American Society of Anesthesiologists physical status I–II) undergoing general anesthesia for routine minor procedures were randomly assigned to have either the *PLMA*™ or *LMA*™ used for airway management. In addition, 50% of patients in each group were randomly assigned to have a gastric tube inserted orally. Eight study sites from seven countries (one each in Australia, Austria, France, Germany, Italy, and Spain, and two in the United States) participated in the study. Each study site conducted 48 cases with even randomization for the type of airway device and use of the orogastric tube. Randomization was performed by opening a sealed envelope immedi-

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Part of the data from the German study site has been published previously (Anasthesiol Intensivmed Notfallmed Schmerzther 2001; 36:213–8). Dr. Brimacombe has previously worked as a consultant for the Laryngeal Mask Company and Mallincrodt Medical. Dr. Keller has previously worked as a consultant for the Laryngeal Mask Company. This project was sponsored by the Laryngeal Mask Company, which manufactures the *ProSeal*™ and *Classic*™ laryngeal mask airway devices. Neither the Laryngeal Mask Company nor Dr. Brain (the inventor) were involved in the design of the study, data analysis, or manuscript preparation.

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ately before induction. Ethics committee approval was obtained from each individual study site, and written consent was obtained from all patients. All participating anesthesiologists were experienced *LMA*™ users (> 200 uses) and had some experience with the *PLMA*™ (> 20 uses). Exclusion criteria were body mass index greater than 35 kg/m^2, cervical spine disease, a known difficult airway, mouth opening less than 2.5 cm, upper respiratory tract symptoms in the previous 10 days, surgery to be performed to the head–neck or thoracoabdominal cavities or in the lateral–prone positions, or if the patient was considered at risk of aspiration (nonfasted, gastrosophageal reflux disease). The conduct of anesthesia was divided into four phases: (1) placement phase (commencement of propofol induction to establishment of an effective airway); (2) positive pressure ventilation phase (effective airway to commencement of spontaneous breathing); (3) spontaneous breathing phase (commencement of spontaneous breathing to discontinuation of anesthesia); and (4) emergence phase (discontinuation of anesthesia until removal of the device). Unblinded trained observers collected data during the four phases of anesthesia, and blinded trained observers collected the data in the postanesthesia care unit and the following day.

Premedication with 5–15 mg oral midazolam 1 h preoperatively was permitted, if required. Anesthetic management was standardized according to the following protocol: Monitoring was applied before anesthetic induction and included an electrocardiograph, pulse oximeter, gas analyzer, noninvasive blood pressure monitor, tidal volume monitor, and airway pressure monitor. Anesthesia was administered with the patient in the supine position, with the patient's head on a standard pillow 8 cm in height. Intravenous sedation (0.02–0.03 mg/kg midazolam and 5–10 μg/kg alfentanil) and oxygen *via* a face mask were administered. Two minutes later, anesthesia was induced using 2–3 mg/kg intravenous propofol mixed with 25 mg lidocaine given over 30 s. The patient remained anesthetized with 1–3% end-tidal sevoflurane in 33% oxygen and nitrous oxide. Face mask ventilation was commenced and continued for at least 30 s until conditions were suitable for *PLMA*™–*LMA*™ insertion (loss of eyelash reflex, jaw relaxation, absence of movement, and apnea). Additional boluses of 0.5 mg/kg intravenous propofol were given as required until an adequate level of anesthesia was achieved for placement. The following cardiorespiratory and anesthesia depth data were recorded every 5 min, commencing at the start of each new phase until the device was removed: heart rate, mean blood pressure, minimal oxygen saturation (Spo_2), expired tidal volume, respiratory rate, peak airway pressure (positive pressure ventilation phase only), fraction of inspired oxygen, end-tidal carbon dioxide concentration, and end-tidal sevoflurane concentration.

A size 4 was used for women and a size 5 for men. A clear, water-based gel without local anesthesia was used for lubrication. Both devices were inserted and fixed according to the manufacturer's instructions.[4,5] The *PLMA*™–*LMA*™ was connected to a circle breathing system, and the cuff was inflated with air until an effective airway was established or the maximum recommended inflation volume reached (size 4, 30 ml; size 5, 40 ml). The number of insertion attempts was recorded. A failed attempt was defined as removal of the device from the mouth. Three attempts were allowed before device use was considered a failure. If the randomized device failed, three attempts were permitted with the alternative device. The time between picking up the *PLMA*™–*LMA*™ and obtaining an effective airway was recorded. An effective airway was judged by a square wave capnograph trace and no audible leak with peak airway pressures 12 cm H_2O or greater during gentle manual ventilation. The introducer tool was not used for the first insertion attempt with the *PLMA*™ but could be used for the second and third attempt. If both randomized airway devices failed during the placement phase, or if the airway device failed after the placement phase, the anesthesiologist was free to manage the airway as clinically indicated.

Once an effective airway was obtained, intracuff pressure was set at 60 cm H_2O, and the oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min, noting the airway pressure (maximum allowed = 40 cm H_2O) at which equilibrium was reached.[6] Any air entering the stomach was noted when measuring oropharyngeal leak pressure by listening over the epigastrium with a stethoscope. Orogastric tube insertion was performed manually through the drainage tube for the *PLMA*™ and behind the cuff for the *LMA*™. A 14- and 16-French size lubricated orogastric tube was used for the size 4 and 5 *PLMA*™–*LMA*™, respectively, as recommended by the manufacturer. Orogastric tube placement was not attempted with the *PLMA*™ if there was an air leak up the drainage tube. Correct orogastric tube placement was assessed by suction of fluid or detection of injected air by epigastric auscultation. The time taken for correct placement was recorded (picking up the orogastric tube until confirmation of placement). The number of insertion attempts was recorded. A failed attempt was defined as failure to advance the orogastric tube. Two attempts were allowed before orogastric tube insertion was considered a failure. The orogastric tube was removed immediately after insertion. Anatomic position was determined by passing a fiberoptic scope to a position just proximal to the end of the airway tube and scoring the view.[7] Anatomic position of the drainage tube (*PLMA*™ only) was determined by passing a fiberoptic scope to the end of the drainage tube and scoring the position, as

previously described[2] Adjustments to the position of the *PLMA*™–*LMA*™ were not based on the fiberoptic view.

Patients underwent positive pressure ventilation until spontaneous breathing resumed. Intraoperative analgesia was with intravenous alfentanil, intravenous morphine, ketoralac, or infiltration of local anesthesia. Anesthesia was not discontinued until the surgery was complete to standardize conditions for the emergence phase. Patients were given 100% O_2 during emergence, and the airway device was removed when the patient was awake. The following intraoperative complications were documented: failed use, aspiration–regurgitation, hypoxia ($Spo_2 < 90\%$), bronchospasm, airway obstruction, gastric insufflation, coughing–gagging–retching, hiccup, cough during removal, blood staining of the airway device, and tongue–lip–dental trauma. If a complication occurred, an explanation was given and the minimal Spo_2 documented. Heart rate, mean blood pressure, Spo_2, and respiratory rate were recorded 5 min after *PLMA*™–*LMA*™ removal with the patients breathing oxygen at 4 l/min *via* a Hudson mask. Analgesia in the postanesthesia care unit was with morphine or ketoralac.

Patients underwent two structured interviews: (1) before leaving the postanesthesia care unit; and (2) 18–24 h after surgery (by phone or ward interview). Patients were asked about sore throat (constant pain, independent of swallowing), sore neck, sore jaw, dysphonia (difficulty–pain on speaking), and dysphagia (difficulty–pain on swallowing). Symptoms were graded by the patient as mild, moderate, or severe. Patients were also asked if they were satisfied with the anesthetic (yes–no). Patients were unaware of the airway device used.

Statistics

The primary variables tested were *LMA*™ device insertion success rates and times, efficacy of seal, fiberoptically determined anatomic position, orogastric tube insertion success rates and times, total intraoperative respiratory complications, and postoperative sore throat. Secondary variables tested were the individual intraoperative complications (other than insertion failure) and individual postoperative complications (other than sore throat). Sample size was based on data from previous studies on the *LMA*™–*PLMA*™,[2,3,8,9] a pilot study of sore throat with the *PLMA*™ (found to be 14%), and the need to allow even distribution of the four randomized groups between eight study sites. The sample size allowed a projected difference of 10% or less to be detected between the groups for all of the primary variables for a type I error of 0.05 and a power of 0.95. The variable requiring the largest sample size was sore throat. If the randomized device failed and the alternative device succeeded, all variables were assigned to the initial randomized device (intention to treat). The distribution of data was determined using Kolmogorov-Smirnov analysis. Statistical analysis was with paired *t* test (parametric data), and Kruskal-Wallis test, Mann–Whitney rank sum test, and chi-square test (nonparametric data). $P < 0.05$ was considered significant.

Table 1. Demographic and surgical details

	PLMA™	*LMA*™
	n = 192	n = 192
Age (yr)	47 ± 16 (18–84)	45 ± 17 (18–81)
Height (cm)	172 ± 10 (147–206)	172 ± 10 (145–196)
Weight (kg)	78 ± 15 (39–120)	75 ± 15 (38–130)
Body mass index ($kg \cdot m^{-2}$)	23 ± 4 (14–34)	22 ± 4 (13–34)
Male:female ratio (n)	107:85	105:87
Smokers (n)	70	63
Dentition—own/partial/edentulous (n)	129/42/18	140/35/16

Data are mean ± SD (range) or numbers.

PLMA™ = laryngeal mask airway *ProSeal*™; *LMA*™ = laryngeal mask airway *Classic*™.

Results

Intraoperative data were 99% and postoperative data were 97% complete. Incomplete intraoperative data were a result of failure to attempt gastric tube placement (*LMA*™, n = 23), failure to document the anatomic position of airway tube (*LMA*™, n = 2), and failure to document the anatomic position of the drainage tube (*PLMA*™, n = 78). Incomplete postoperative data were a result of failure to interview the patient postoperatively. There were 53 protocol deviations: desflurane was used instead of sevoflurane in six patients (*PLMA*™, n = 3; *LMA*™, n = 3), minor intraabdominal laparoscopic surgery was performed in six patients (*PLMA*™, n = 3; *LMA*™, n = 3), a nondepolarizing muscle relaxant was given to one patient (*LMA*™, n = 1), and adjustments in intracuff pressure were made in 40 patients (*PLMA*™, n = 19; *LMA*™, n = 21). These patients were included in the analysis because the protocol deviations were minor and evenly distributed between groups. The French study site only completed 16 cases, and the shortfall of 32 cases was completed by the Australian site. All other sites completed their quota of 48 cases.

There were no differences between devices with respect to demographic and surgical details (table 1). There were no differences between devices with respect to doses of coinduction–induction agents and intraoperative–postoperative analgesics. First-attempt insertion success rates (*LMA*™, 91%; *PLMA*™, 82%, $P = 0.015$) were higher for the LMA, but after three attempts success rates were similar (*LMA*™, 100%; *PLMA*™, 98%; table 2). Less time was required to achieve an effective airway with the *LMA*™ (*LMA*™, 31 ± 30 s; *PLMA*™, 41 ± 49 s; $P = 0.02$). In all patients in whom the *PLMA*™ failed, the *LMA*™ was successfully inserted at the first attempt.

Table 2. Insertion Success Rates for the Airway Device and Orogastric Tube, Oropharyngeal Leak Pressure, and Fiberoptic Position

	PLMA™	*LMA*™	*P* Value
Device insertion	n = 192	n = 192	
Number of insertion attempts required			
1	159 (83)	174 (91)	0.015
2	26 (14)	14 (7)	NS
3	5 (3)	4 (2)	NS
Fail	3 (2)	0 (0)	NS
Size changes	31 (16)	19 (10)	NS
Device failures after placement phase	2 (1)	1 (1)	NS
Total failures	5 (3)	1 (1)	NS
Effective airway time (s)	41 ± 49 (8–408)	31 ± 30 (6–280)	0.02
Orogastric tube insertion	n = 95*	n = 73†	
Number of insertion attempts required			
1	74 (78)	38 (52)	<0.001
2	10 (11)	2 (3)	NS
Fail	11 (12)	33 (45)	<0.0001
Insertion time (s)	22 ± 18 (5–120)	38 ± 56 (9–420)	0.02
Oropharyngeal leak pressure (cm H_2O)	27 ± 7 (10–40)	22 ± 6 (8–40)	<0.0001
Fiberoptic view airway tube	n = 189‡	n = 190§	
Fiberoptic view grade			
4, Only vocal cords visible	25 (13)	65 (34)	
3, Vocal cords plus posterior epiglottis visible	69 (37)	78 (41)	<0.0001
2, Vocal cords plus anterior epiglottis visible	75 (40)	35 (18)	
1, Vocal cords not seen	20 (11)	12 (6)	
Esophagus visible	4 (2)	5 (3)	NS
Fiberoptic view drainage tube	n = 114#		
Hypopharynx (mucosa)	89 (78)		
UES open (clear view down the esophagus)	10 (9)		
Others (glottis, epiglottis, arytenoids)	15 (13)		

* Not attempted in 1 patient because of air leak from drainage tube; † not attempted in 23 patients because of failure to follow protocol; ‡ *PLMA* failed to form an effective airway in 3 patients; § problem with fiberoptic scope in 2 patients and data not collected; # investigators failed to collect data in 78 patients.

Data are mean ± SD (range) or numbers (%).

PLMA™ = laryngeal mask airway *ProSeal*™; *LMA*™ = laryngeal mask airway *Classic*™; NS = not significant; UES = upper esophageal sphincter.

There were three device failures after the placement phase. The *PLMA*™ failed in one patient 15 min into the positive pressure ventilation phase because of excessive oropharyngeal leak, and in one patient 30 min into the spontaneous breathing phase because of persistent stridor. The *LMA*™ failed in one patient 20 min into the spontaneous breathing phase because of severe laryngospasm. These patients were successfully managed by laryngoscope-guided tracheal intubation (n = 2) or a cuffed oropharyngeal airway (n = 1). The *PLMA*™ formed a more effective seal (*PLMA*™, 27 ± 7 cm H_2O; *LMA*™, 22 ± 6 cm H_2O; $P < 0.0001$). Fiberoptically determined anatomic position was better with the *LMA*™ ($P < 0.0001$; table 2). The fiberoptic view from the drainage tube revealed an open upper esophageal sphincter in 9% of patients (table 2). Orogastric tube insertion was more successful (*PLMA*™, 88%; *LMA*™, 55%; $P < 0.0001$) and quicker (*PLMA*™, 22 ± 18 s; *LMA*™, 38 ± 56 s) with the PLMA (table 2). Cardiorespiratory tolerance and anesthesia depth data were similar for both groups during all phases of anesthesia and in the postanesthesia care unit. Total intraoperative complications were similar for both groups, but the incidence of minor tongue–lip–dental trauma ($P = 0.02$) was higher for the *PLMA*™, and the incidence of hiccup ($P = 0.03$) was higher for the *LMA*™ (table 3). Minor dental trauma (a chipped tooth) occurred in one patient during *LMA*™ insertion. Postoperative sore throat and other postoperative secondary variables were similar (table 4). Five patients said that they were not satisfied with their anesthesia management (*PLMA*™, n = 4; *LMA*™, n = 1). Oropharyngeal leak pressure was higher in women for both the *PLMA*™ (29 ± 7 *vs.* 26 ± 7 cm H_2O; $P = 0.02$) and *LMA*™ (23 ± 5 *vs.* 21 ± 6 cm H_2O; $P = 0.03$), but otherwise there were no differences in performance between men and women. Postoperative morbidity was unaffected by use of an orogastric tube. There were no statistical differences in the results among the study sites that completed their quota and no differences with the French site.

Table 3. The Incidence of Intraoperative Complications by Patient

	PLMA™	*LMA™*	*P*
Airway and respiratory complications			
Failed use	5	1	NS
Regurgitation/aspiration	0	0	NS
Hypoxia (<90%)	3	4	NS
Bronchospasm	1	0	NS
Airway obstruction	1	3	NS
Gastric insufflation	1	3	NS
Cough/gagging/retching	6	1	NS
Hiccup	3	11	0.03
Cough during removal	13	18	NS
Blood staining following removal	34	27	NS
Minor tongue/lip/dental trauma	17	6	0.02
Total	84	74	NS

Data are numbers.

PLMA™ = laryngeal mask airway *ProSeal*™; *LMA*™ = laryngeal mask airway *Classic*™; NS = not significant.

Discussion

The *LMA*™ was easier and quicker to insert at the first attempt than the *PLMA*™. This confirms data from a crossover study of 60 anesthetized, paralyzed patients.[2] The increased difficulty with *PLMA*™ insertion probably reflects the larger cuff (impeding digital intraoral positioning and propulsion into the pharynx), the lack of a backplate (making the cuff more likely to fold over at the back of the mouth), and the need for precise tip positioning (to prevent air leaks up the drainage tube). It is possible that increased experience or initial use of the introducer tool may have improved first-time success rates.[2] Despite the increased difficulty with insertion, success rates after three attempts for the *PLMA*™ were high (98%) and similar to the *LMA*™ (100%), suggesting that both are clinically effective airway devices.

The efficacy of seal was 5 cm H_2O higher for the *PLMA*™, confirming the findings of two preliminary crossover studies.[1,2] The improved seal is probably a result of: (1) the broader proximal cuff plugging the oropharynx more effectively; (2) the second ventral cuff pressing the dorsal cuff more firmly into the periglottic tissues; and (3) the parallel, narrower tubing allowing the base of the tongue to cover the proximal cuff more effectively. The improvement in seal may be an advantage in situations in which higher airway pressures are required for positive pressure ventilation, such as in obese patients, the lithotomy–head down position, or in patients with restrictive pulmonary pathology. The better seal probably offers no advantage in the spontaneously breathing patient.

Fiberoptically determined anatomic position was better with the *LMA*™, confirming the findings of two preliminary crossover studies.[1,2] This was primarily related to increased epiglottic downfolding and is probably caused by the broader proximal cuff catching the epiglottis during insertion. It has been shown in adults and children that work of breathing with the *LMA*™ is increased by epiglottic downfolding.[10] Because we found that respiratory variables were similar to the *LMA*™ during spontaneous and positive pressure ventilation, we speculate that a downfolded epiglottis does not significantly impede airflow with *PLMA*™, perhaps because of the accessory vent. The incidence of an open upper esophageal sphincter being visible from the drainage tube of the *PLMA*™ was 9% and similar to a preliminary study.[2] The clinical importance of this finding is unknown.

Orogastric tube placement was easier and quicker with the *PLMA*™. This is not surprising because the drainage tube aligns the orogastric tube with the upper esophageal sphincter. However, the success rate for orogastric tube placement *via* the *PLMA*™ was lower than in the preliminary crossover studies.[1,2] This may reflect a lack of appropriate lubrication, selection of too

Table 4. Incidence of Postoperative Complications by Patient before Leaving the Postanesthesia Care Unit (PACU) and 18–24 hr Postoperatively

	Laryngeal Mask Airway *ProSeal*™				Laryngeal Mask Airway *Classic*™				
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total	*P*
Before leaving PACU		n = 191				n = 190			
Sore throat	25	7	0	32 (16)	39	3	1	44 (23)	NS
Dysphagia	21	3	2	26 (14)	26	2	1	29 (15)	NS
Dysphonia	3	2	0	5 (3)	3	2	0	5 (3)	NS
Sore neck	3	0	0	3 (2)	3	0	0	3 (2)	NS
Sore jaw	3	0	0	3 (2)	3	0	0	3 (2)	NS
18–24 hr postoperatively		n = 187				n = 188			
Sore throat	37	8	1	46 (25)	35	6	1	42 (22)	NS
Dysphagia	22	4	1	27 (15)	16	5	0	21 (11)	NS
Dysphonia	7	1	0	8 (5)	8	2	1	11 (6)	NS
Sore neck	5	1	1	7 (4)	8	0	0	8 (4)	NS
Sore jaw	4	0	1	5 (3)	2	0	0	2 (1)	NS

Data are numbers (%).

NS = not significant.

large an orogastric tube, or folding over of the drainage tube.[11] The latter phenomenon was identified in three patients and may have occurred in a number of others since passage of the fiberoptic scope also failed. The danger of a folded drainage tube is that the standard test for malpositon—air leaking up the drainage tube during positive pressure ventilation—will not detect it. This may indirectly put the patient at increased risk of gastric insufflation and aspiration by giving the anesthesiologist a false sense of security.

A simple, noninvasive method to exclude this malposition would be to pass an orogastric tube down to the end of the *PLMA*™ tip to verify that the drainage tube is patent. We recommend that this drainage tube test be performed if there is any tactile resistance to *PLMA*™ placement. It is possible that use of a larger, stiffer orogastric tube would increase success rates for the *LMA*™. Residual gastric fluid is commonly found in patients undergoing elective surgery.[12] Routine gastric tube placement through the *PLMA*™ may have a role in gastric volume reduction, but further work is required before this can be recommended. Gastric tube placement through the *PLMA*™ may be indicated if gastric insufflation has occurred after face mask ventilation.

We found no differences in total intraoperative complications, but there was a higher incidence of minor tongue–lip–teeth trauma for the *PLMA*™ and a higher incidence of hiccup for the *LMA*™. The increased incidence of minor tongue–lip–teeth trauma may be related to the increased difficulty with insertion. A possible explanation for the increased incidence of hiccup is that the *LMA*™ may stretch the hypopharynx more vigorously than the *PLMA*™ since the tube is more rigid, allowing more force to be transmitted. Hiccup is known to be associated with lower esophageal reflux with the *LMA*™[13] and endotracheal tube.[14] There were no episodes of clinically detected regurgitation or aspiration. In principle, if the drainage tube of the *PLMA*™ is correctly positioned, it should provide protection from fluid regurgitation, and this is supported by a recent cadaver study.[15] However, the *PLMA*™ is contraindicated in nonfasted patients, in whom the endotracheal tube remains the airway device of choice.

The safety and efficacy of the *PLMA*™ in patients with gastroesophageal reflux, obesity, and those undergoing intraabdominal surgery is unknown. However, the classic *LMA*™ has been widely used in these situations,[16–18] and the *PLMA*™ should be a safer alternative.

The incidence of postoperative sore throat was similar. Postoperative sore throat is probably caused by a combination of trauma on insertion and pressure exerted by the cuff against the pharyngeal mucosa. Although the number of insertion attempts was higher with the *PLMA*™, the incidence of blood detected on removal was similar to the *LMA*™, suggesting that the incidence of mucosal trauma may have been similar. It is also likely that mucosal pressures were similar because it has been shown that the *PLMA*™ and *LMA*™ exert similarly low pressures against the pharyngeal mucosa for a given cuff volume.[3] Interestingly, it has been suggested that the incidence of sore throat with the *PLMA*™ might be less than the *LMA*™ if cuff volume is reduced to the minimal required to form an effective seal since the *PLMA*™ exerts lower mucosal pressures for a given oropharyngeal leak pressure.[3] The incidence of intraoperative complications and postoperative sore throat was similar to previous studies in anesthetized, nonparalyzed patients for the *LMA*™.[9,19]

A limitation of our study is that it was conducted by experienced *LMA*™ users who had some experience with the *PLMA*™. The relative lack of experience suggests that performance might improve with the *PLMA*™. It has been shown that performance with the *LMA*™ improves over the first 75[20] and 1,500 uses.[21] The implications of our findings for the novice *PLMA*™ user are unknown.

We conclude that, in anesthetized, nonparalyzed patients, the *LMA*™ is easier and quicker to insert, but the *PLMA*™ forms a better seal and facilitates easier and quicker orogastric tube placement. The incidence of total intraoperative complications and postoperative sore throat is similar.

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