

A Randomized Controlled Trial Comparing the ProSeal™ Laryngeal Mask Airway with the Laryngeal Tube Suction in Mechanically Ventilated Patients

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Background: The ProSeal™ Laryngeal Mask Airway (PLMA) (Laryngeal Mask Company, Henley-on-Thames, United Kingdom) is a new laryngeal mask with a modified cuff designed to improve its seal and a drain tube for gastric tube placement. Similarly, the Laryngeal Tube Suction (LTS) (VBM Medizintechnik GmbH, Sulz a.N, Germany) is a new laryngeal tube that also has an additional channel for gastric tube placement. This study compared the placement and functions of these two devices.

Methods: One hundred fifty patients undergoing general anesthesia for elective surgery were randomly allocated to the PLMA (n = 75) or LTS (n = 75). Oxygenation and ventilation, ease of insertion, fiberoptic view, oropharyngeal leak pressure, ventilatory data, ease of gastric tube insertion, and postoperative airway morbidity were determined.

Results: After successful insertion of the devices in 96% of patients with the PLMA and in 94.4% with the LTS it was possible to maintain oxygenation, ventilation, and respiratory mechanics during the entire duration of surgery. Successful first and second attempt insertion rates were 57 patients (76%) and 15 patients (20%), respectively, for the PLMA and 60 patients (80%) and 11 patients (14.6%), respectively, for the LTS. Airway placement was unsuccessful with the PLMA in three patients and with the LTS in four patients. Time to achieve an effective airway was 36 ± 24 s with the PLMA versus 34 ± 25 s with the LTS. Gastric tube insertion was possible in 97.3% of patients with the PLMA and in 96% with the LTS.

Conclusions: With respect to both physiologic and clinical function, the PLMA and LTS are similar and either device can be used to establish a safe and effective airway in mechanically ventilated anesthetized adult patients.

THE ProSeal™ Laryngeal Mask Airway (PLMA) (Laryngeal Mask Company, Henley-on-Thames, United Kingdom) (fig. 1) is a new laryngeal mask airway (LMA) with a modified cuff designed to improve the seal around the glottis and with an added drain tube to provide a bypass channel for regurgitated fluid, prevent gastric insufflation, and allow gastric tube placement.¹⁻³

The newly introduced Laryngeal Tube Suction (LTS) (VBM Medizintechnik GmbH, Sulz a.N, Germany) (fig. 2) is a further development of the Laryngeal Tube (LT) that

allows separation of the respiratory and alimentary tracts. The LTS is a latex-free, double-lumen silicon tube wherein one lumen is used for ventilation and the other for gastric tube placement. The new device, like the original LT, is inserted blindly with the distal tip positioned in the hypopharynx/upper esophagus. The LTS has two low-pressure cuffs (proximal and distal), and two main oval ventilation apertures placed between them. Dorges et al.⁴ recently described the successful use of the LTS in mechanically ventilated patients. To date there are relatively few studies comparing the LMA to the LT⁵⁻⁷ and only three studies that have compared the PLMA to the LT.⁸⁻¹⁰ To our knowledge, no study has yet compared the PLMA with the LTS. We hypothesized that the LTS and the PLMA perform similarly, when measured by oxygenation and ventilation as primary study outcome variables. Secondary outcome measures used to examine the clinical performances of the devices were ease of insertion, fiberoptic view, oropharyngeal leak pressure, ventilatory data, ease of gastric tube insertion, and postoperative airway morbidity.

Materials and Methods

The study was approved by the hospital's human ethics committee (Bnai-Zion Medical Center, Haifa, Israel) and written, informed consent was obtained from all patients. One-hundred fifty American Society of Anesthesiologists physical status I-II, Mallampati I-II adult patients, aged 18-75 yr, undergoing routine general anesthesia for minor elective surgery were randomly allocated to receive either a PLMA (n = 75) or a LTS (n = 75) for airway management. Randomization was performed by opening a sealed envelope immediately before induction. Exclusion criteria included age <18 yr, pregnancy, esophageal pathology, pulmonary disease, and body mass index >35 kg/m².

The size of both devices was chosen according to the manufacturer's recommendations. Two attending anesthesiologists (LAG and SJV), who had each performed at least 10 PLMA or LTS insertions before the implementation of the study, placed either device.

All patients received premedication with oral diazepam (10-20 mg). After 3 min of preoxygenation with an inspired oxygen fraction of 100%, anesthesia was induced with up to 3 µg/kg fentanyl and 2-3 mg/kg propofol and maintained with 70% nitrous oxide/30% oxygen and isoflurane. Neuromuscular blockade was ob-

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Fig. 1. ProSeal™ laryngeal mask airway.

tained with vecuronium 0.1 mg/kg and maintained throughout surgery at 1 of 4 on train-of-four, as assessed by using a peripheral nerve stimulator with electrodes placed over the ulnar nerve. After confirmation of complete neuromuscular blockade, the PLMA or LTS was blindly inserted and the cuffs inflated according to the manufacturer recommendations. The digital insertion technique was used for placement of all PLMAs whereas the LTS was inserted blindly. All patients were positioned in the sniffing position for insertion of either device.

The cuffs of both devices were inflated with air using a manometer (Cuff Pressure Gauge, VBM Medizintechnik GmbH, Sulz, Germany) to an intracuff pressure of 60 cm H₂O and maintained at this value throughout the entire procedure.

The insertion time was noted from removal of the face mask to attachment of the breathing system to the PLMA or LTS after inflation of the cuffs. The number of attempts taken to insert the PLMA and the LTS was recorded. Two attempts were allowed before a failure of insertion was recorded. A failed insertion attempt was defined as the removal of the device from the mouth. If the PLMA or LTS could not achieve a satisfactory airway within two insertions, an endotracheal tube was inserted for airway management. The lungs were ventilated with



Fig. 2. Laryngeal tube suction.

volume-controlled mechanical ventilation using a ventilator of an AS/3™ anesthesia delivery unit (Datex-Ohmeda, Helsinki, Finland) with a semiclosed circuit incorporating a carbon dioxide absorber. Ventilatory settings included an inspiratory:expiratory time of 1:2 and set tidal volume of 12 ml/kg. The initial respiratory rate was 12 breath/min and adjusted to maintain an end-tidal carbon dioxide of 40 mmHg using a fresh gas flow of 3 l/min.

An effective airway was defined as bilateral chest movement and auscultation, normal value of partial pressure of end-tidal carbon dioxide, normal capnograph curve, and fiberoptic visualization of the glottic opening. In the case of an ineffective airway, interventions such as jaw lift, adjusting the head or neck position, and changing the depth of the device insertion were performed and recorded.

Position of the airway tube in relation with the glottic opening was assessed using a flexible fiberoptic bronchoscope passed to a position 1 cm proximal to the ventilation orifice of the device. The fiberoptic view was scored according to an established scoring system: 4 = only vocal cords, 3 = vocal cords plus posterior epiglottis, 2 = vocal cords plus anterior epiglottis, 1 = cords not seen but functions adequately, 0 = cords not seen and functions inadequately.¹¹

Once an effective airway was obtained, 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 obtained. The gas leak was also observed as a nonclosing flow-volume loop.

Gastric tube insertion (18-gauge for PLMA and 14-gauge for LTS) was performed through the special channel of both devices, and correct placement was assessed by suction of fluid or detection of injected air by epigastric auscultation.

Oxygen saturation and end-tidal carbon dioxide were measured and recorded automatically using the AS/3™ monitor.

Breath-by-breath spirometry data were obtained using a side-stream spirometry device (D-lite™ flow sensor; Datex-Ohmeda, Helsinki, Finland) attached between the proximal end of the PLMA™ or LTS and the Y-piece, which continuously computes flow and pressure readings derived *via* a pressure system. Data were noted at 5-min intervals after the introduction of the PLMA or LTS and included airway pressures (peak and positive-end-expiratory-pressure, lung volumes (minute and tidal volume), graphically displayed loops (pressure-volume and flow-volume) and curves (pressure and flow), the ratio of passively exhaled volume during the first second to the total expiratory tidal volume, and dynamic compliance.

Upper airway trauma was assessed by observing the devices for the presence of blood and inspection of the oropharynx after device removal. In addition, the pa-

Table 1. Patient Demographic Data

	PLMA	LTS
Age (years)	46 ± 14 (19–74)	52 ± 16 (20–75)
Height (cm)	171 ± 12 (159–180)	168 ± (160–181)
Weight (kg)	74 ± 11 (53–90)	74 ± 11 (52–92)
Body mass index (kg · m ⁻²)	26 ± 4 (19–32)	27 ± 5 (19–31)
Sex ratio M:F (n)	41:34	47:28
ASA I:II	45:30	40:35
Duration of surgery (min)	58 ± 22 (20–140)	55 ± 19 (15–130)

Data are presented as mean ± standard deviation and range.

ASA = American Society of Anesthesiologists; LTS = Laryngeal Tube Suction; PLMA = ProSeal™ Laryngeal Mask Airway.

tients were questioned 24 h after surgery regarding symptoms of airway irritation, such as sore throat, hoarseness, and pain in deglutition.

The study was terminated immediately if ventilation of the patient's lungs was clinically unacceptable, peak airway pressure exceeded 40 cm H₂O, or oxygen saturation decreased below 90%.

Statistical Analysis

The primary variables data, oxygenation (oxygen saturation) and ventilation (end-tidal carbon dioxide), were analyzed using independent sample Student *t* tests. A *P* value < 0.05 was considered as statistically significant. Sample size was calculated to detect a projected difference of 15% between the groups, for a type I error of 0.05 and a power of 0.9, according to Machin *et al.*¹² Because sample size was calculated separately for each of the variables, the highest calculated sample size was used to cover all the other tested variables.

Results

There were no differences between the two groups with respect to demographic or surgical data, as demonstrated in table 1.

Oxygen saturation and end-tidal carbon dioxide were 97.2 ± 2% and 40.1 ± 6 mmHg respectively for the PLMA and 97.1 ± 2 and 38.5 ± 4 mmHg respectively for the LTS.

First attempt and second attempt insertion rates were 76% (57 patients) and 20% (15 patients) for the PLMA

versus 80% (60 patients) and 14.6% (11 patients) for the LTS. Airway placement was unsuccessful with the PLMA in three patients and with the LTS in four patients. Time to achieve an effective airway was 36 ± 24 s with the PLMA versus 34 ± 25 s with the LTS.

After successful insertion of the device in 96% of patients with the PLMA and in 94% of patients with the LTS, it was possible to maintain oxygenation, ventilation, and respiratory mechanics (table 2) for the entire duration of surgery.

Oropharyngeal leak pressures at intracuff pressures of 60 cm H₂O were 28 ± 7 cm H₂O for the PLMA and 34 ± 6 cm H₂O for the LTS. Fiberoptic position (n = 4/3/2/1/0) was 24/33/12/1/2 for the PLMA and was 20/23/20/4/3/1 for the LTS. Airway interventions utilized are presented in table 3. Gastric tube insertion was possible in 97.3% of patients with the PLMA and in 96% with the LTS.

Complications with the PLMA included pulmonary aspiration (one patient) and airway obstruction (three patients). In the patient with pulmonary aspiration, an attempt to introduce a gastric tube was unsuccessful and concurrently gastric contents became evident in the oropharynx. The PLMA was removed and replaced with an endotracheal tube. On auscultation of the lungs crepitations were detected at the lower right lobe. The lung radiograph revealed an infiltrate at the apical segment of the right lower lobe. After antibiotic treatment the patient recovered and was discharged from the hospital 6 days later. Complications with the LTS included airway obstruction (four patients) and laryngospasm (one patient).

Blood was noted on the cuff after removal of the device in 12 cases involving the PLMA and in six cases with the LTS. Nine patients in the PLMA group and four patients in the LTS group complained of sore throat postoperatively. No hoarseness was noted in any patient. Pain at deglutition appeared in three cases with the PLMA and in four patients with LTS.

Discussion

This study demonstrates that the clinical performance of the PLMA and the LTS are similar with regard to oxygenation and ventilation and that both devices can

Table 2. Spirometry Data

	Inspiratory MV (l/min)	Expiratory MV (l/min)	V1.0% (l/min)	PEEP (cm H ₂ O)	Ppeak (cm H ₂ O)*	Dynamic compliance (ml/cm H ₂ O)
PLMA	5.8 ± 3 (4.9–10.5)	5.6 ± 2 (4.7–10.2)	63.1 ± 7 (31–78)	3.1 ± 0.6 (2–4)	19.4 ± 6 (14–34)	47.7 ± 13 (30–59)
LTS	5.9 ± 4 (4.6–8.6)	5.7 ± 2 (4.5–8.4)	60.4 ± 3 (38–68)	3.4 ± 0.3 (1–4)	27.5 ± 3 (20–35)	42.9 ± 12 (24–58)

Data are presented as mean ± standard deviation and range.

* Significant statistical difference.

LTS = Laryngeal Tube Suction; MV = minute volume; PEEP = positive end-expiratory pressure; PLMA = ProSeal™ Laryngeal Mask Airway; Ppeak = maximum airway pressure; V1.0% = ratio of passively exhaled volume during the first second to the total expiratory tidal volume.

Table 3. Incidence of Airway Interventions

	PLMA	LTS
Jaw thrust	16	19
Adjusting head position	4	6
Adjusting neck position	8	5
Changing depth of device insertion	4	5
Total	32	35

LTS = Laryngeal Tube Suction; PLMA = ProSeal™ Laryngeal Mask Airway.

be effectively and safely used in minor elective surgery in mechanically ventilated patients.

We also obtained an overall successful insertion rate of 96% PLMA and 94% for the LTS. Although these rates are lower than those previously reported,^{2,4,13} our study design only allowed a maximum of two insertion attempts, rather than three. Furthermore, the PLMA was introduced using the digital insertion technique, similar to the technique used for insertion of the LMA-Classic. Insertion of the PLMA has been reported to be easier when using the introducer guide,² which could explain our lower insertion success rate for the PLMA. We prefer to introduce the PLMA using the digital insertion technique, taking into account that the PLMA metallic introducer guide could enhance the hemodynamic response.³

Insertion times were similar for both devices but prolonged in comparison with LMA^{2,14} and LT,^{5,15} respectively, possibly because of their more complex design. Although more complex, the design of the PLMA and LTS allows additional functions, including the drainage of gastric contents, and a more effective seal (PLMA).¹⁴ By comparison, the PLMA has no back plate and a larger cuff than the LMA, whereas the additional channel of the LTS, located posterior to the ventilation channel, confers a larger and more rigid configuration than the LT.

Despite the different seal mechanisms of the devices, no significant differences in oropharyngeal leak pressures were found at 60 cm H₂O intracuff pressures. The PLMA confers a better seal in comparison with the LMA.¹⁶ Design changes that made this possible include a second cuff attached to the dorsal surface, which pushes the ventral cuff more firmly into the periglottic tissue,¹⁶ and a ventral cuff that is larger proximally to improve the seal by plugging potential gaps. The LTS has the same mechanism of providing an oropharyngeal seal as the LT by forming a plug in the upper pharynx.⁶

There were significantly higher peak airway pressures with the LTS, as compared to the PLMA. One of the explanations for the higher peak airway pressures could be the higher resistance to airflow because of the smaller ventilation outlets of the LTS, similar to those of LT.^{7,15}

When correctly placed, both devices should isolate the respiratory tree from the gastrointestinal tract and, thus, provide airway protection from regurgitated gastric fluid. It has already been proven that the PLMA provides better protection of the airway from passive regurgita-

tion than the LMA-Classic.¹⁷ The PLMA is capable of protecting the airway in the event of passive regurgitation intraoperatively by allowing the regurgitated fluid to pass up the drain tube and bypass the glottis.¹⁸

In our study, there was one case of pulmonary aspiration in a patient in which a PLMA was used. Most likely, the PLMA was improperly positioned, resulting in occlusion of the distal orifice of the drain tube secondary to folding of the tip of the cuff during insertion. A case of gastric insufflation has been reported with the PLMA, in which the tip of the cuff was folded posteriorly despite a good seal and a negative malposition test.¹⁹ Two additional cases of aspiration with the PLMA were recently described.^{20,21}

The LTS uses a different strategy in preventing regurgitation/aspiration. Its distal tip is placed in the hypopharynx/upper esophagus and inflation of the esophageal cuff may offer additional protection from regurgitation and aspiration of stomach contents.

Fiberoptic assessment of the anatomical position of the PLMA and LTS was only performed through the airway tube. Positioning of the drain tube was not directly assessed. Moreover, positioning may only be part of the issue regarding problems with the gastric tube. By expanding the hypopharynx, the PLMA may impair function of the upper esophageal sphincter.²² In two previous studies^{2,14} the upper esophageal sphincter was found open, as visible from the drain tube of the PLMA, in 9% of the cases. The clinical significance of this finding is unknown. Natalini *et al.*²³ found that despite the optimal airway seal of the PLMA, the patency of the drain tube should always be tested because it can be kinked without influencing the seal.

Upper airway trauma, as evaluated by the presence of blood on the devices after their removal, as well as the incidence of the sore throat, were higher with the PLMA *versus* the LTS; this could be explained by the combination of trauma on insertion and pressure exerted by the large balloon against the pharyngeal mucosa.¹⁴ The incidence of sore throat for the PLMA was similar to that seen in previous reports.^{3,14}

Our study has a number of limitations. First, we only determined the position of the airway tube and not the position of the gastric channel of the devices. This would possibly have helped in detecting misplacement of the PLMA, particularly in the case of gastric content aspiration. Nevertheless, fiberoptic assessment of the positioning of these devices is not commonly done in routine anesthesia practice. Recently, Brimacombe *et al.* suggested performing a simple air leak test to rule out malposition of the PLMA.¹⁹ Second, as there is only one published study on the LTS,⁴ more data are needed to validate our results. Third, our data may not be applicable to patients who are breathing spontaneously. Fourth, our intraoperative data collection was performed by an unblinded observer, which is a possible source of bias.

In conclusion, we believe that the PLMA and LTS, although fairly comparable in clinical utility, have the advantage of more complex functionality than their counterparts, the LMA-Classic and LT. In an attempt to improve the function of the LMA and the LT, the respective manufacturers have made significant progress in achieving a better seal for PLMA and better airway protection from gastric content aspiration for both devices.

With respect to both physiologic and clinical function, the PLMA and LTS are similar and either device can be used to establish a safe and effective airway in anesthetized adult patients.

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