Original article

Comparison of Laryngeal tube suction II (LTS II) and ProSeal laryngeal mask airway (PLMA) for controlled ventilation in anaesthetised and paralysed adult patients

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Abstract

Background: LTS II and PLMA are supraglottic devices that may be used for ventilation in patients with normal as well as difficult airways at risk of aspiration. **Aim**: Comparison of LTS II with PLMA during controlled ventilation in paralysed patients with respect to time to successful insertion, success rate of insertion, attempts at repositioning, airway leak pressure, ease of ventilation and Ryle's tube insertion, fibreoptic laryngeal view and complications. **Methods**: Thirty patients were studied using a prospective, randomised cross-over design. Ethical committee clearance and informed consent were obtained from all patients. Anaesthesia was induced with propofol and fentanyl and neuromuscular blockade achieved with vecuronium. Patients were divided into two groups: Group LTS and Group PLMA. In each group, the first airway device was inserted, various parameters observed and then removed. The second airway device was then inserted and the same parameters noted. Anaesthesia was continued with the second device in position. **Results**: Success with insertion at first attempt and time to insertion were comparable with both devices [LTS II 27/30 (17.5 s) and PLMA 29/30 (15.5 s) respectively]. PLMA required repositioning in fewer patients and provided better fibreoptic view than LTS II. Ryle's tube insertion failed in four patients with PLMA but in none with LTS II. No significant difference was found in the airway seal pressure [mean, PLMA (27 cm H_2O) and LTS II (26.4 cm H_2O)], ease of ventilation or overall complications. **Conclusion**: Insertion and ventilation are comparable with PLMA and LTS II. Ryle's tube insertion is easier with LTS II but requires more repositioning attempts and does not provide a good view of the larynx.

Keywords: Laryngeal tube, ProSeal LMA, controlled ventilation.

Introduction

The Classic Laryngeal Mask Airway (LMA), introduced in 1985, although well established for difficult airway management also has the potential risk of aspiration especially due to gastric insufflation. To avoid this, the ProSeal™ Laryngeal Mask Airway (PLMA, Laryngeal Mask Company, Henley-on-Thames, UK), featuring an extra lumen for gastric drainage and a modified cuff for better airway seal than the standard LMA, was introduced in 2000. The PLMA was found to be a more effective ventilating device when compared to the Classic LMA for positive pressure ventilation during laparoscopic procedures.[1]

Simultaneously, a new supraglottic device with a pharyngeal and an oesophageal cuff, the laryngeal tube (LT) (VBM Medizintechnik GmbH, Sulz am Neckar, Germany), was developed. In 2004, LTS II

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with an oesophageal drainage tube that isolates the respiratory and alimentary tracts and allows the passage of a gastric tube into the oesophagus was introduced. LTS II is envisioned as an alternative to the ProSeal™ in mechanically ventilated patients during general anaesthesia.

In the current study, we compared the LTS II and the PLMA with regard to their effectiveness, and stability in delivering positive pressure ventilation during controlled ventilation.

Patients and methods

Patients were enrolled in the study after getting approval from the departmental and hospital ethical committees and informed patient consent. It was a prospective, randomised, cross-over study. Adult patients, 18–60 years old, of either gender, belonging to ASA physical status I and II, height between 150 and 180 cm, body weight ranging between 50 and 70 kg and undergoing elective surgery under general anaesthesia and controlled ventilation were included. Patients with known or predicted difficult airway, upper airway obstruction or pharyngeal pathology, known oesophageal pathology, body mass index > 30 kg/m^2, and having conditions requiring rapid sequence induction were excluded.

The patients were evaluated the day before surgery and written informed consent was obtained from them. Patients were kept nil per oral for solids for six hours and for clear fluids for three hours prior to surgery. Oral diazepam (10 mg was given to patients weighing > 50 kg and 5 mg to patients weighing < 50 kg), ranitidine (150 mg) and metoclopramide (10 mg) were prescribed for the night before and approximately 3 hours prior to scheduled time of surgery.

In the operating room, intravenous access was secured and suitable infusion initiated. Patients were monitored using noninvasive blood pressure, electrocardiogram (lead II and V_5), pulse oximeter, capnograph ($EtCO_2$) and a peripheral nerve stimulator. The patients were made to lie supine with head supported by a pillow to achieve sniffing position.

The patients were preoxygenated with an appropriate sized face mask for 3 minutes with an O_2 flow of 6 L/min. At the end of preoxygenation, 2.0 μg/kg of fentanyl was administered. Anaesthesia was induced with propofol 2.5 mg/kg injected intravenously slowly over a period of 20 to 30 seconds. Once induced, ability to mask ventilate was checked and the patient paralysed with 0.1 mg/kg of vecuronium. Patients were manually ventilated and anaesthesia deepened with 1% isoflurane in O_2 to maintain a minimum alveolar concentration (MAC) of 1. After the train-of-four (TOF) count on peripheral nerve stimulator showed no twitches, the allotted airway device was inserted.

The patients were randomly allocated into two groups, Group PLMA and Group LTS. Randomisation was performed using a random number generator. Patients in Group PLMA were ventilated first using Laryngeal Tube Suction II and later with ProSeal Laryngeal Mask Airway. Patients in group LTS were ventilated first using ProSeal Laryngeal Mask Airway and later with Laryngeal Tube Suction II.

The LTS II was inserted in accordance with the manufacturer's instructions. Before insertion, the cuff was deflated and a water soluble lubricant applied. The patient's head was extended on the neck (sniffing position). The tip of the LTS II was placed against the hard palate behind the upper incisors and the device was advanced in the centre of the mouth until resistance was felt. If no resistance was felt the LTS II was positioned with the second bold line on the tube between the upper and the lower incisors. The cuff was then inflated with a cuff inflating syringe with a predetermined volume recommended and provided by the manufacturer. The cuff pressure was then reduced to 60 cm H_2O. A size 4 LTS II was used for patients of height 150 to 180 cm.

The PLMA was also inserted according to the manufacturer's instruction manual, but jaw thrust and a PLMA introducer were used to assist placement in all cases. The back of the cuff was lubricated with jelly. A size 4 PLMA was used. The cuff was then inflated to a cuff pressure of 60 cm H_2O.

As per the randomisation table, the first airway device was inserted and various parameters were observed. That instrument was then removed and the second airway device was inserted and the parameters were again noted. Anaesthesia was continued with the second airway device.

The following parameters were observed:

1. Time to successful insertion: Time from beginning of insertion of the instrument into the mouth to appearance of a satisfactory capnography trace.
2. Success rate of insertion: When the device was inserted and ventilation achieved with it was easy, it was considered a successful attempt.
3. Attempt at repositioning: If necessary, a single attempt at repositioning (such as up and down manoeuvre) was done with a view to improve ventilation.
4. Ease of ventilation: Subjective evaluation of ease of ventilation as easy, adequate but difficult or not able to ventilate.
5. Ease of passage of Ryle's tube: A Ryle's tube (14 F) was passed from the drainage tube of either device and its passage recorded as easy, difficult or not able to pass. Only one attempt was made to pass the Ryle's tube.
6. Fibreoptic view grade: The view obtained with the tip of the fibreoptic bronchoscope at the proximal and/or distal openings were graded as follows: Grade I - Vocal cords entirely seen; Grade II - Vocal cords partly seen; Grade III - Only epiglottis seen and Grade IV - No laryngeal structures visible. The device was considered satisfactorily aligned with the larynx if the fibreoptic view was Grade 1 or 2.
7. Airway leak pressure: A manometer was connected inline if not already in place. The fresh gas flow was set at 5 L/min and the airway pressure relief valve (APL) valve closed till 30 cm H_2O. Simultaneously the neck was auscultated for any leaks. The pressure at which a leak was first heard was recorded as the leak pressure.

Anaesthesia was maintained using 1% isoflurane in a mixture of 66% nitrous oxide and 34% oxygen. Neuromuscular relaxation was maintained by IV boluses of vecuronium. Patients were connected to a ventilator with appropriate settings. Intracuff pressure was continuously monitored and maintained at 60 cm H_2O. The airway device was removed at the end of the procedure when neuromuscular blockade was fully reversed and the patient was awake and co-operative.

After the procedure the oropharynx was examined for any visible signs of mucosal injury such as congestion and the airway device examined for blood staining. Patients were followed up for 18 - 24 h for evidence of any complications such as sore throat and hoarseness of voice.

Sore throat was graded as follows: None: no sore throat, mild: less severe than a cold, moderate: similar to that noted in a cold and severe: more severe than a cold. Hoarseness was recorded as present or absent.

Only one attempt at insertion and repositioning was made with each airway device. If any airway related problem occurred during the intraoperative period, the supraglottic airway device was removed and conventional laryngoscopy and endotracheal intubation was done.

Results

In this study, the primary outcome was to compare the airway seal pressure generated by the PLMA and the LTS II. Based on the results of previous studies, PLMA had a seal pressure of 29 cm H_2O. Power analysis determined that a sample size of 30 patients was required to provide an 80% power to the study to detect a difference of seal pressure of 5 cm H_2O between the two devices. The patient characteristics and their airway characteristics are given in *Table 1*.

The median time taken to insertion of PLMA was 15.5 s as against 17.5 s for LTS II. Although the p value showed a statistically significant difference, it was not significant clinically (*Table 2*). When the success rate of insertion was analysed, the PLMA could be inserted on the first attempt in 96.7% of cases whereas the LTS II could be inserted successfully in only 90% of patients. However, the

difference was not statistically or clinically different (*Table 2*). The LTS II required repositioning in 50% of the patients whereas only 16.7% of PLMA insertions required repositioning (*Table 3*).

Table 1: Patient characteristics (n = 30)

1	Males : Females (n)	5 : 25
2	Age (years)	39.8 (11.9)*
3	Weight (kg)	57.2 (6.1)*
4	Height (cm)	157 (3.9)*
5	BMI (kg/m^2)	23.2 (2)*
6	ASA I / II (n)	24 / 6
7	Mallampati class (I/II/III/IV)	9/20/1/0

* Indicates mean (± standard deviation)

Table 2: Time taken for insertion and rate of successful insertion

	PLMA (n=30)	LTS II (n=30)	p value
Time taken for insertion (s) [Median (25th – 75th percentile)]*	15.5 (12 – 19.3)	17.5 (15 – 20)	0.012
Successful insertion on the first attempt n (%)#	29 (96.7%)	27 (90%)	0.625

*Wilcoxon signed rank test;
p value < 0.05 = statistically significant
McNemar test;
p value > 0.05 = statistically not significant

Table 3: Attempt at repositioning

Attempts	PLMA n = 30	LTS II n = 30	p value
Nil	25 (83.3%)	15 (50%)	0.03
One	5 (16.7%)	15 (50%)	

McNemar test;
p value < 0.05 = statistically significant

The ease of ventilation and airway leak pressure were comparable between the two groups (*Tables 4* and *5*). Ryle's tube insertion was easier through the LTS II (96.7%) as compared to PLMA (65.5%) (*Table 6*).

The views obtained from the opening of both PLMA and LTS II were observed through a fibrescope whose tip was placed either at the outlet of the PLMA or at the proximal or distal opening of the LTS II. The PLMA offered Grade 1 view in 82.7%, Grade II in 6.8%, Grade III view in 6.8% and Grade IV view in only 3.4% of patients. The LTS II offered Grade 1 view in 3.3%, Grade II in 26.7%, Grade III view in 36.7% and Grade IV view in 33.3% of patients (*Table 7*). The difference between the two devices was statistically and clinically significant.

Table 4: Ease of ventilation

Ease of ventilation	PLMA n = 30	LTS II n = 30	p value
Easy	28 (93.3%)	27 (90%)	0.9
Adequate but difficult	1 (3.3%)	3* (10%)	
Not able to ventilate	1* (3.3%)	0	

Marginal Homogeneity test;
p value > 0.05 = statistically not significant
* Indicates - patients intubated

Table 5: Airway leak pressure

	PLMA n = 29	LTS II n = 30	p value
Leak pressure in cm H_2O Mean (± SD)	27.03 (± 5.02)	26.43 (± 4.46)	0. 52

Paired t test;
p value > 0.05 = Statistically not significant

Table 6: Ease of Ryle's tube insertion

	PLMA (n = 29)	LTS II (n = 30)	p value
Easy	19 (65.5%)	29 (96.7%)	0.002
Difficult	6 (20.7%)	1 (3.3%)	
Not able to pass	4 (13.8%)	0	

Marginal Homogeneity test
p value < 0.05 = Statistically significant

Table 7: Fibreoptic view grade

Grade	PLMA n = 29	LTS II n = 30	p value
I	24 (82.7%)	1 (3.3%)	< 0. 001
II	2 (6.8%)	8 (26.7%)	
III	2 (6.8%)	11 (36.7%)	
IV	1 (3.4%)	10 (33.3%)	

Marginal Homogeneity test ;
p value < 0.05 = Statistically significant

The complications seen after the study could not be attributed to any one device as it was a cross-over study. Complications such as blood staining of the instrument were seen in two instances. Oropharyngeal congestion was seen in three patients after the use of LTS II. Two patients in total had mild sore throat postoperatively. There were no patients who had moderate or severe sore throat or any hoarseness of voice.

Discussion

The ProSeal LMA and the LTS II are supraglottic airways that can be used as primary devices of airway control to maintain anaesthesia or as rescue devices to secure the airway in difficult airway situations. While the ProSeal LMA has evolved from the original standard LMA and incorporated a drain tube to be useful in full stomach situations, the LTS II bears more resemblance to the oesophagotracheal double lumen airway, commonly called the Combitube®.

The laryngeal mask airway scores over the Combitube® in that it is commonly used as an airway during routine anaesthesia and anaesthesiologists are much more familiar and comfortable with its use. The Combitube® has been mentioned as being more protective against aspiration of regurgitated gastric contents as compared to a laryngeal mask airway. This drawback of LMA being not so protective against aspiration of regurgitated gastric contents was at least partially overcome by the provision of a drain tube in the ProSeal LMA. A gastric tube can be inserted through this drain tube to empty the gastric contents. On the other hand, the LTS II is made of silicone and is easier than a Combitube® to insert. It may be used as a ventilating or rescue device.

The time to insertion and success rate of insertion of both devices were comparable and is consistent with the observations quoted in the literature.[2-8] The LTS II requires more repositioning attempts than the ProSeal LMA. Cook and Cranshaw compared PLMA and LTS in 32 patients and observed that to obtain a clinically adequate airway after insertion, the PLMA required significantly less manipulation than the LTS.[3] Similar observations were made by other investigators.[8-10] Cook *et al* compared PLMA and laryngeal tube (LT) in 32 patients and found that the PLMA gave a significantly better fibre optic view of the larynx than the LT. Part of the laryngeal inlet was visible in 29 of 32 cases with the PLMA and in 13 of 31 cases with LT.[11]

The airway leak pressure was similar with both PLMA and LTS II in the present study although this is variable in the literature.[2-4,7,8,10] Ryle's tube insertion was found to be easier with LTS II than the ProSeal LMA in the present study.

An attempt was made to view the cords through the distal opening of LTS II as well as that of PLMA with a possibility of being able to intubate using some exchange device such as a bougie. The LTS II is clearly meant to be only an airway and is unlikely to serve as a conduit for intubation even by exchange methods. This was suggested by the fibreoptic views obtained through each device. Grade 1 and 2 were acceptable as vocal cords were seen at least partially whereas Grade 3 and 4 offered no view of the vocal cords. Thus the PLMA offered Grade 1 or 2 views in 26 (89.5%) of patients whereas the LTS II had similar views only in 9 (30%) of the patients. This is a highly significant clinical difference between the two devices. Cook *et al* made similar observations in two of their studies on the LTS.[3,11]

This is attributable to the inherent design of the device where the distal opening of LTS II faces anteriorly whereas of the PLMA is at its tip and is situated directly above the larynx. The primary aim of the PLMA is to achieve ventilation and the mask sits snugly over the larynx. The posterior aperture provides access to the oesophagus to insert a gastric tube to empty it of its contents. The LTS II snugly occludes the oesophagus and ventilation occurs by the gas exiting between the inflated proximal and distal cuffs. Thus, the PLMA can serve not only as a ventilatory device but may permit endotracheal intubation subsequently using an exchange device whereas the likelihood of obtaining this with LTS II seems to be very low.

Conclusions

When LTS II and ProSeal LMA are compared, the

time to insertion, success rate, ease of ventilation and airway leak pressure are similar. Although insertion of Ryle's tube is easier with the LTS II, its satisfactory placement requires more repositioning attempts and it provides a less satisfactory view of the larynx than the ProSeal LMA.

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