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A Clinical comparison of the Laryngeal Tube^{TM} and the Laryngeal Mask^{TM} in spontaneously breathing anesthetized patients

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Abstract: Background: The laryngeal mask airway (LMA) can be used in general anaesthesia without neuromuscular block. The laryngeal tube (LT) is a new airway device with similar airway features as LMA. LT is provided with a distal cuff to prevent regurgitation. In this study we compared the LMA and LT concerning patient and user aspects.

Methods: Sixty patients with ASA (American Society of Anestesiologists) score 1-2 scheduled for minor surgery were randomized to be ventilated either through LMA or LT. After insertion, the number of insertion attempts, and "positioning" and "airway-assessment" was evaluated. The patients reported on "sore throat" after 30 and 60 minutes and the day after anaesthesia.

Results: Gender and mean age were equal in both groups. The first insertion attempt was successful in 25 of 28 patients randomised to LMA and in 23 of 27 patients randomised to LT. LMA was evaluated to be easier in "positioning" whereas no difference in "sore throat" was reported.

Conclusion: We found no difference between the LMA and the LT in terms user and patient friendliness and safety.

Keywords: Laryngeal tube, laryngeal mask, spontaneous breathing

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1 Introduction

The laryngeal mask airway (LMA Classic. Laryngeal Mask Company, Henley-on-Thames, UK ™) is a well-establish (for more than ten years) airway device in general anaesthesia for some types of operating procedures. Nevertheless, simple handling of the LMA is limited by the potential risk of aspiration [1, 2]. The laryngeal tube (LT™VMB, Meizintechnik, Germany) is a new airway device, with similar airway features as the LMA, It consists of an airway tube with a small cuff attached at the distal tip (distal cuff) and a larger cuff in the middle of the tube (proximal cuff). The distal cuff prevents the risk of regurgitation by blocking the esophagus. The cuffs are inflated through a single pilot tube balloon through which the cuff pressure can be monitored. There are two distal apertures in the tube between the two cuffs through which gas movement may take place. When the device is inserted, it lies along the length of the tongue, and the distal tip is positioned in the hypopharynx. The proximal cuff provides a seal by forming a plug in the upper pharynx and the distal cuff seals the esophagus inlet. Since its introduction into clinical practice, the design of the laryngeal tube has been modified on a few occasions [3, 4]. With increasing use of LMA, it is important to identify and quantify the incidence of minor pharyngolaryngeal morbidity associated with its use. Previous publications have noted a sore throat (constant pain, independent of swallowing), incidence ranging from 0 to 29% with LMA use [10]. Although it has been previously shown that the LT is safe and efficient [3, 5, 6], there is no clear data how this airway device compares with the LMA concerning patient comfort. The purpose of the present prospective, randomized study was to assess the discomfort to spontaneously breathing, anaesthetized patients undergoing routine minor surgical procedures and user aspects for the LT and LMA.

2 Methods

After approval of Local Ethics Committee and informed consent obtained, 60 adult patients ASA (American Society of Anestesiologists) physical status I-II scheduled for knee arthroscopy, hernia or breast surgery under general anaesthesia were included in our study. Patients were enrolled in the study into one of two groups, LT or LMA, in a prospective, operator unblinded study randomized by ballot in a sealed envelope. Patients with any abnormality of neck, upper respiratory tract, upper alimentary tract or risk of regurgitation of gastric contents were excluded.

In the anaesthesia room, an electrocardiograph, a pulse oximeter and blood pressure cuff were attached, and an intravenous cannula was inserted. After the patients had breathed oxygen through a face mask for 3 minutes, the induction of anaesthesia was initiated with 100 μg fentanyl given intravenously, followed by intravenous Propofol 2-3 mg/kg. Anaesthesia was maintained with sevoflurne in oxygen/air. In case of apnea after induction, patients were ventilated manually.

The size of LT was chosen according to patients' height. A size 4, LT 4 for patients measuring 155-180 cm and LT 5 when >180 cm. LMA was chosen according to patients'

weight: LMA 3 when weighing 50 kg or less, LM 4 when weighing 50-70 kg and LM 5 when weighing 70-100 kg [12]. LT and LM insertion was performed by two anaesthesia nurses with more than 5 years experience with the LM, and 3 months experience with the LT prior to the study.

The laryngeal tube was inserted into the oropharynx by the method where the cuffs were deflated and water-soluble lubricant was applied to them before insertion. The patients' neck was extended to "sniffing position". The tip of the LT was placed against the hard palate behind the upper incisors, and the device was slid down the centre of the mouth until a resistance was felt or the second bold black line on the tube passed between the upper and lower teeth. Care was taken not to push the tongue towards the posterior pharynx to minimize possible obstruction of the airway. The cuffs were inflatedusing a cuff inflator (VBM, Germany) until the intra-cuff pressure reached approximately 60-80 cm H_20. The laryngeal mask was inserted using the technique described in the manufacturer's instruction manual, and its cuff was inflated with a volume of air which gave an intra-cuff pressure of approximately 60-70 cm H_2O, (for size 4 with 30 ml, size 5 with 40 ml) [11].

The adequacy of ventilation was assessed by gently squeezing the reservoir bag, observing the presence of end-tidal carbon dioxide waveforms and chest movement. If there were any problems with ventilation, the following adjustments were allowed: lifting the angle of the mandible upwards, further extension of the patient's neck and head, turning the patient's head to the side, or a gentle push or pull of the device. After adjustments of the device, if ventilation was not satisfactory, a second attempt to insert the device was allowed. If insertion failed after three attempts, the use of the device was abandoned. The number of attempts at insertion was recorded. The level of positioning problems and airway-assessment was evaluated on a scale of 1-4 (1=easy or very good, 2=good, 3=fair, 4=poor). If problems with air leakage occur when the ventilation pressure is allowed to rise to 30 cm H_20 the air leakage is evaluated on the same scale as above. The data obtained from pulsoximetry and expired carbon dioxide measurements were noted after 10 and 30 minutes following anaesthesia induction and just before the ventilatory device was removed at the and of anaesthesia. The devices were withdrawn when the patients were able to respond to spoken commands.

Paracetamol (1 gram) was used every six hours for postoperative anaelgesia. Patients were interviewed by anesthetic nurse to determine the incidence and severity of postoperative symptoms related to intraoperatively use of the ventilatory device. This was done 30 minutes, 60 minutes, and 24 hours after surgery in the postoperative ward or at home for patients discharged from hospital within 24 hours after surgery. All symptoms were globally evaluated on a visual rating scale (VAS-like scale) from 0–10. The interview included questions concerning pain, sore throat (constant pain, independent of swallowing), hoarseness, dysphasia, difficulty swallowing, nausea and vomiting. The severity of these variables was assessed using VAS-scale ranging from no symptoms (0) to the most severe symptoms imaginable [10]. Patients were blinded to the type of ventilatory device used intraoperatively.

3 Statistics

The Mann-Whitney test was used for comparison between the two airway devices. The Wilcoxon test was used to determine differences in patient characteristics. A value of $p<0.05$ was considered to be statistically significant.

4 Results

A total of five patients were excluded from the study, two from LMA group and tree from LT group, mainly because of protocol violations. Twenty-eight patients were studied in the LMA group and twenty-seven in the LT group. The demographic and clinical data of the patients (n=55) are shown in Table 1.

Table 1 Demographic and clinical data of the patients that were randomized to be ventilated by laryngeal mask airway (LMA) or laryngeal tube (LT).

	LMA	LT
No. of patients (female/male)	28 (15/13)	27 (15/12)
ASA physical status (I: II)	21:7	21:6
Mallapati score (I: II: III: IV)	14:12:2:2	13:11:2:1
No. of patients (female/male)	28 (15/13)	27 (15/12)
ASA physical status (I: II)	21:7	21:6
Mallapati score (I: II: III: IV)	14:12:2:2	13:11:2:1
Size of the device used (4: 5)	19:9	15:12
Age (years) (median, range)	47 (26-68)	47 (22-67)
Weight (kg) (median, range)	75 (53-108)	76 (54-100)
Duration of anaesthesia (min) (median, range)	67 (35-135)	62 (40-112)
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ASA, American Society of Anestesiologists

The two groups were comparable in age, body weight, sex, ASA grade, Mallapati score and anaesthesia time. Size LMA 4 was used in 19 patients (67.9%) and size LMA 5 in 9 patients (32.1%). Size LT 4 was used in 15 patients (55.6%) and size LT 5 in 12 patients (44.4%). In most cases, both airway devices were inserted successfully after the first attempt. Two attempts were required in two patients with the LMA and two attempts in three patients with LT. One patient in each group required three attempts of insertion, Fig. 1. LMA was evaluated to be easier to insert than LT, $p > 0.05$, (table 2), but there was no difference in the final "airway assessment", (table 3).

Ventilation was rated as excellent in 25 patients using the LMA and 22 using the LT. In two patients LMA group assessment of the airway was rated 3 and 4 (fair, poor).

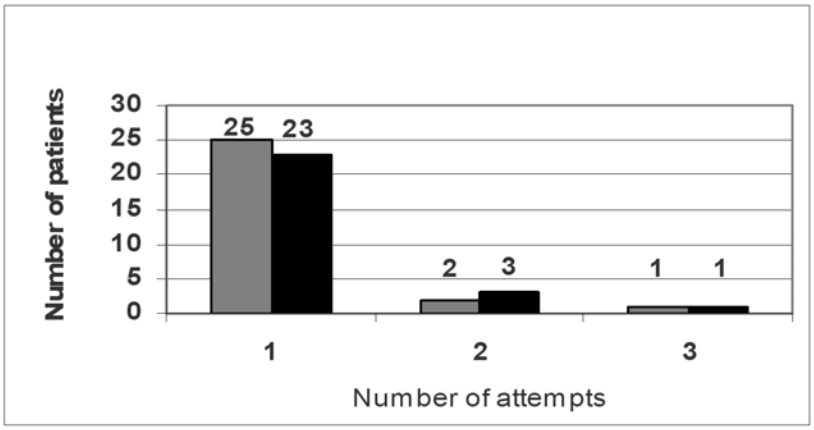

Fig. 1 Intubations attempts with Laryngeal mask Airway (LMA) and Laryngeal Tube (LT), grey = LMA , black =LT.

Table 2 Evaluation of the "positioning" of the two different devices; Laryngeal Mask Airway (LMA) and the Laryngeal Tube (LT).

Estimation	1	2	3	4
LMA	22/28	4/28	2/28	0/28
	78,6%	14,3%	7,1%	
LT	*14/27	*12/27	1/27	0/27
	(51,9%)	(44,4%)	(3,7%)	

1=easy, 2=good, 3=fair, 4=poor, *p<0.05.

Table 3 Evaluation of "airway-assessment" with use of the different devices; Laryngeal Mask Airway (LMA) and the Laryngeal Tube (LT).

Estimation	1	2	3	4
LMA	25/28	1/28	1/28	1/28
	89.3%	3.6%	3.6%	3.6%
LM	22/27	5/27	0/27	0/27
	85.5%	18.5%		

1=easy, 2=good, 3=fair, 4=poor.

There was no significant difference in efficacy of ventilation between the groups, both in individual operator evaluation and quality of spontaneous ventilation controlled by SaO_2 (oxygen saturation) (p=0.063) and $EtCO_2$ (endtidal CO_2), (p=0.82) measurements during anaesthesia, (table 4). $EtCO_2$ values increased significantly over the time of observation in both groups, p<0.05. The airways were equally well-tolerated during emergence from anaesthesia. One patient using LT developed laryngospasm. One patient

in each group developed mild airway obstruction with a short period of desaturation. On removal, blood was present on the device in 5 patients using LMA and 4 using the LT. Postoperative complications attributed to the airway device, evaluated with VAS-rating scale 30 and 60 minutes as well as 24 hours after anaesthesia, did not differ statistically. None of the patients from either group developed symptoms related to the inserted device in the postoperative period. Most patients in both groups were free of any symptoms related to either device in whole evaluated postoperative period at 30 and 60 minutes and 24 hours after the operation (75%, 68% and 82% respectively using LMA and 70%, 70% and 81% respectively using LT), (Figs. 2.a-2.c).

Table 4 Ventilatory data of the patients that were randomized to be ventilated by laryngeal mask airway (LMA) or laryngeal tube (LT).

	After10 min of ventilation	After 30 min of ventilation	Before removal of device
SaO_2 (%) LMA	97.06 ±1.47	97.46 ±1.73	97.89 ±1.42
SaO_2 (%) LT	97.96 ±0.99	97.27±1.16	97.69 ±0.97
$EtCO_2$ (kP) LMA	5.85 ±0.85	5.98 ±0.8	5.99 ±0.83
$EtCO_2$ (kP) LT	5.75 ±0.95	6.03 ±0.8	6.18 ±0.67

SaO_2, oxygen saturation(%); expired carbon dioxide, $EtC0_2$ (kP) measured 10 and 30 minutes after the induction of anaesthesia and just before ventilatory device was removed in spontaneously breathing patients with LMA or LT. Data are given as mean ± SD.

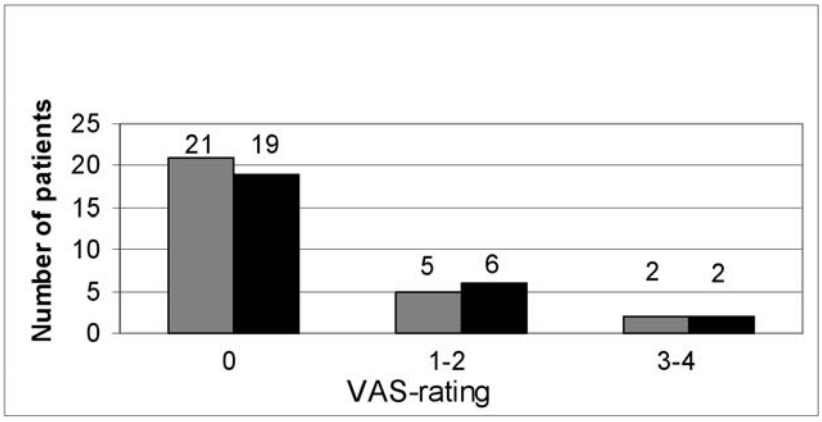

Fig. 2.a VAS-rating 30 minutes after removal of Laryngeal mask Airway (LMA) and Laryngeal Tube (LT), grey = LMA , black =LT.

5 Discussion

We could not find any difference in our study between the laryngeal tube or the classic LMA in maintaining a free airway in patients during spontaneous ventilation, both dur-

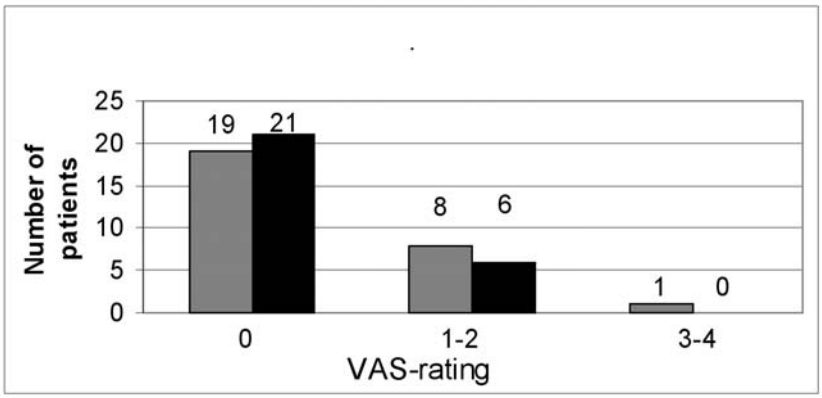

Fig. 2.b VAS-rating 60 minutes after removal of the Laryngeal mask Airway (LMA) and Laryngeal Tube (LT), grey = LMA , black =LT.

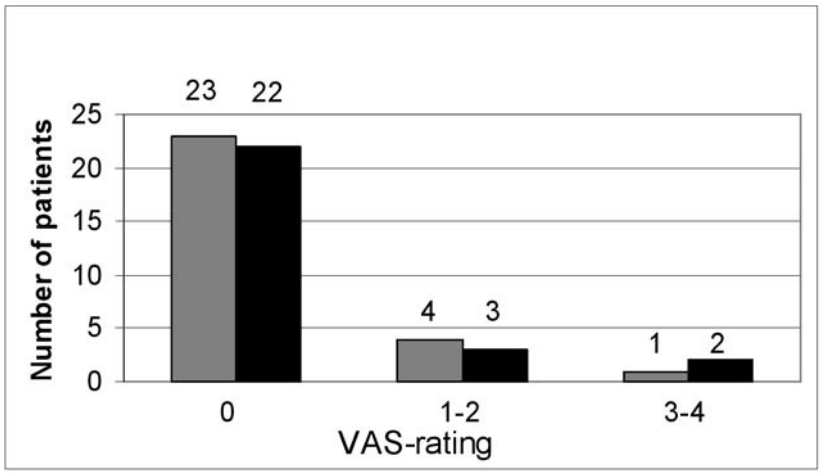

Fig. 2.c VAS rating 24 hours after removal of the Laryngeal mask Airway (LMA) and Laryngeal Tube (LT), grey = LMA , black =LT.

ing induction and administration of general anaesthesia. The success rate of obtaining a patient airway with either device was 100%. This result supports previous studies where the success rate of LT was 94-100%. Most of the studies have been done during controlled ventilation and with the use of different types of laryngeal masks. Since its introduction into clinical practice, the design of the laryngeal tube has been modified on a few occasions. Only one study found the laryngeal tube impossible to use. In this study 25 of 27 patients with the LT inserted, ventilation was not adequate. The explanation for the high failure rate is due to the use of one of the earliest prototype laryngeal mask. The first attempt of insertion was successful in most cases with LMA and LT, but LMA was found to be easier to position in our study. The difference between these results may be attributed to the fact that the investigators involved in our study had more previous experience with the classic LMA. We started to use the laryngeal tube three months prior to this study. Another known problem is that the laryngeal tube required more readjustments because of airway obstruction and required a greater airway peak pressure

during anaesthesia. The greater peak airway pressure with the laryngeal tube could be due to its smaller diameter and smaller distal apertures, which cause increased resistance [8]. After induction of anaesthesia, both the LMA and LT allowed immediate ventilation. "Airway assessment" after insertion of the devices was evaluated good or very good in most patients in both groups. These observations were in agreement with saturation and expired carbon dioxide data obtained from monitoring systems. They showed no difference between the groups in SaO_2 and $EtCO_2$, suggesting that the sufficient spontaneous ventilation and oxygenation could be achieved when using the LT similar to the LMA. Additionally, this data suggest that the smaller outlet diameter in the laryngeal tube compared to the classic LMA had no influence on quality of ventilation. Our observations are in agreement with Ocker et al. [1] who measured arterial blood samples before induction of anaesthesia and after 10 minutes of mechanical ventilation with the laryngeal tube and LMA, and did not find any difference in PaO_2, SaO_2 and $PaCO_2$ values. In our study $EtCO_2$ values suggest higher carbon dioxide retention in both groups, but patients were breathing spontaneously.

The devices were equally well-tolerated during emergence from anaesthesia. One patient in the LT group developed laryngospasm. One patient in each group developed mild airway obstruction and a short episode of desaturation. Upon removal, blood was present on the device in 5 patients using the LMA and in 4 patients using the LT which is a higher morbidity level comparing to other studies. The explanation for this can be due to a very restricted protocol where even a small amount of blood detected on the device counted as positive. The incidence of detecting blood on the LMA can be as high as 5-12%. In the study of Asai et al. 100 laryngeal tube insertions resulted in no patient blood detected on the devices after their removal [3].

In our study we attempted to evaluate the level of postoperative complications attributed to two different devices based on the patients' point of view of postoperative discomfort. The rated VAS-score was never worse than 4 in all patients in both groups. The interview included questions concerning pain, sore throat, hoarseness, dysphonia and difficulty swallowing. Additionally, nausea and vomiting were noted.

Postoperative complications that can be attributed to the airway devices used did not differ in either group. Both devices were well-tolerated, with low VAS-scores. In our study, we found that 25% of patients in both groups mentioned symptoms in early postoperative period. Symptoms related to the inserted device at 24 hours after anaesthesia were expressed by 15% of patients. We did not find any relation to size of device or duration of anaesthesia to symptoms of discomfort in either group. In one patient in the LMA group, anaesthesia time lasted for over 100 minutes. According to Grady et al. sore throat occurring at 24 hours after LMA insertion is produced by a different mechanism than that which occurs during the first hours after anaesthesia. Sore throat in the early postoperative period seems to be related to direct pharyngeal trauma, whereas sore throat at 24 hours is related to longer duration of anaesthesia. The presentation of a sore throat does not necessarily depend on the number of attempts of insertions but more to the size of the device used. We did not use muscle relaxation during induction of anaesthesia in

our study. Muscle relaxation leads to easier insertion of LMA or LT, due to a reduction in the tone of the pharyngeal musculature which allows the airway to accommodate a larger size of device.

We conclude that concerning user and patient aspects, there is no difference between the LMA^{TM}and the LT^{TM}. Both devices can be use safely in spontaneously breathing, anaesthetized patients undergoing routine minor surgical procedures.

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