Comparing the performance of the laryngeal tube suction with cuffed endotracheal tube during general anesthesia with controlled ventilation in elective surgeries: A prospective, block-randomized, single-blinded, parallel group trial

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Abstract

Introduction: Maintaining a safe airway in patients who are candidates for surgery and who are required to undergo general anesthesia is one of the most important duties of the anesthesiologist. This study was conducted to compare the performance of laryngeal tube suction (LTS) and endotracheal tube (ETT) in terms of leak and peak pressures, intubation time, peripheral capillary oxygen saturation (SPO2), End-tidal CO2 (ETCO2) and perioperative complications.

Methods: The prospective, block-randomized, single-blinded, parallel group trial was conducted on the 100 patients with ASA class 1 and 2 who were scheduled for the elective surgery under general anesthesia and volume-controlled ventilation. The convenience sampling and then, blocked randomization, were used to randomly assign the patients to two groups of LTS and ETT. Outcomes variables were intubation rate, ventilation quality, leak and peak pressures and complications. Data were analyzed using independent sample t-test and Chi-square test by SPSS-19.

Results: The mean age of LTS and ETT group was 35.94±5.96 and 34.76±4.20 years, respectively, (P=0.25). The mean peak pressure in the LTS group (28.54±1.55 CmH2O) was significantly higher than in the ETT group (25.76±1.93 CmH2O), (P<0.001). The mean leak pressure in the LTS and ETT groups was 20.84±3.59 cmH2O and 18.16±2.5 CmH2O, respectively, (P<0.001). The time required for placement of LTS and ETT devices was 25.66±2.09 and 28.28±2.17 seconds (P<0.001). Both devices exhibited a good performance, and the difference between the two groups in terms of dysphonia and sore throat incidence rate was low and insignificant (P>0.05).

Conclusion: LTS and ETT are highly effective devices for airway management and protection. Although peak and leak pressures were significantly higher in the LTS group, there was no significant difference between the two devices in terms of complications.

Key words: Cuffed endotracheal tube, General anesthesia, laryngeal tube suction

Discussion

Maintaining a safe airway in patients who are candidates for surgery and are required to undergo general anesthesia is one of the most important duties of the anesthesiologist. In emergency cases or when intubation is made difficult by patients' anatomic shape of the oral cavity, head and neck, apart from the cuffed endotracheal tube, supraglottic devices such as laryngeal tube suction can also be used for intubation (1).

LTS is an advanced version of the Laryngeal Tube (LT) that has an esophageal drainage tube, which facilitates the insertion of the gastric tube and gastric emptying. Therefore, this device plays a notable role in airway management during airway restoration and anesthesia, and is a suitable device for managing airway in pre-hospital emergencies (2).

Endotracheal tubes (ETT) are designed to provide a safe airway. Suitable cuff pressure prevents massive pulmonary aspiration (3).

In the last three decades, many anesthesia airway care units have become significantly safer. According to a report published by American Society of Anesthesiologists (A.S.A), the number of accidents related to airway management declined from 37% in 1910 to 14% in 1990. However, there has been a more than 2-fold increase in the contribution of characteristics attributable to difficult intubation, which is probably due to the excessive use of monitoring (4).

Prolonged intubation leads to complications such as hypoxia and hypercarbia, increased risk of aspiration, cardiovascular responses (hypertension, tachycardia, artiman), respiratory responses (bronchospasm, laryngospasm) and cerebral complications (increased ICP) (5). On the other hand, post intubation complications include sore throat (with laryngeal or pharyngeal origin), or caused by the tube size (contact with the tracheal cuff), hoarseness, laryngeal edema, stridor caused by obstruction along with general wheezing, vocal cord edema and paralysis, dislocation of the vocal cord and vocal cord granulomas (6).

Tracheal intubation during anesthesia is considered as a standard and safe method used for airway management and lung ventilation. Also, the cuffed endotracheal tube can be used in people over 8 years of age (7, 8).

LT seems to be a good alternative for ETT in cases of difficult intubation or during cardiopulmonary resuscitation (CPR) because it is easier to place and the esophageal cuff can prevent aspiration of gastric contents (9). LT was licensed for use in cardiopulmonary resuscitation in Japan in 2002 and was approved by the U.S. Food and Drug Administration in 2003 (10).

Prescribed and non-prescribed use of LT is similar to the laryngeal mask, and it can be utilized for general anesthesia during minor surgeries (11). Doubled-lumen suction tube, which allows insertion of nasogastric tube, has more advantages than the standard LT and is recommended as a first-line device for maintaining airway in emergency situations, especially when the direct laryngoscopy fails in newborns and infants (12).

In a study in Germany in 2009, Cavus et al. compared Easy Tube (EZT), ProSeal laryngeal mask airway (PLMA), LTS and ETT. They determined the overall intubation success rate, cuff pressure, and airway leak pressure. Overall, the intubation success rate of EZT, PLMA, LTS and ETT was 14 out of 22 patients (64%), 20 out of 22 patients (91%) and 21 out of 22 (96%), respectively. The time for first successful ventilation in EZT was significantly longer than PLMA, LTS, and ETT. (56, 25, 24 and 20 seconds respectively). The lowest and highest airway leak pressure was observed in EZT (19 cmH2O) and LTS (40 cmH2O). In contrast to EZT, both PLMA and LTS are considered as appropriate devices for airway management by anesthesiologists (13).

In a study in Germany, Russo et al. (2012) compared i-gel ™, LMA-S and LTS-D in terms of their performance in airway management. The leak pressure was somehow the same (i-gel ™: 25.9cmH2o, LTS-D: 27.1 cmH2o and LMA-S: 24 cmH2o). Moreover, the placement time was as follows: i-gel ™: 10, LMA-S: 11 and LTS-D: 14 seconds. The leak pressure in LMA-S was significantly higher than LTS-D in low cuff pressures. The intubation success rate was significantly different (I-gel ™ 95%, LMA-S 95%, LTS-D 70%). The highest and the lowest airway compliance was observed in -gel ™ and LTS-D, respectively. At the end, the performance of all devices in lung ventilation under anesthesia for surgery was described as adequate (14).

Considering that LTS is a new device that is still under study and given the conflicting results reported in the previous studies, the study was designed and carried out to compare the performance of laryngeal tube suction (LTS) and endotracheal tube (ETT) in terms of leak and peak pressures, intubation time, peripheral capillary oxygen saturation (SPO2), End-tidal CO2 (ETCO2), and perioperative complications during general anesthesia with controlled ventilation in elective surgeries as the researchers hypothesized the LTS has acceptable and better performance than ETT.

Methods

A prospective, block-randomized, single-blinded, parallel group trial was conducted in Ali-Ibn-Abitalib hospital in Zahedan, Iran from January 2014 to December2015 to compare the performance of the laryngeal tube suction with cuffed endotracheal tube during general anesthesia with controlled ventilation in elective surgeries. The hospital was a general, referral, and governmental hospital with 200 beds. The hospital had different wards, including medical, surgical, neurological, pediatric, and neonatal ICUs, with different general adult and pediatric medical and surgical wards.

All parts of the study were reviewed according to the consolidated Standards for reporting trials (CONSORT)

statement (Hopewell et al., 2008). In the first step, a convenience sampling method was used. All patients who met the inclusion criteria were recruited. The inclusion criteria were (1) patients aged 18 to 45 years, and (2) ASA I & II. The exclusion criteria were (1) an underlying systemic disease such as heart disease, lung disease, hypertension, neurological disease, diabetes; (2) patients with full stomach; (3) neck condition and diseases affecting upper part of the digestive tract; (4) patients with gastroesophageal reflux; (5) patients who had a difficult airway; (6) lack of consent to participate in the study; (7) body mass index less than 15 or greater than 30.

According to the formula and similar studies (15, 16), a sample size of 50 patients was selected for each group.

Considering a confidence level of 95% and a power of 80%, a required sample size of at least 45 cases was determined. In order to prevent patient attrition from affecting the results of the study, a total of 50 qualified patients were asked to participate. The major reason for patient attrition was failure to meet the inclusion criteria. Then, ASA I or II class patients who underwent elective surgery performed in the supine position, were randomized into two groups of 50 people. Random allocation was conducted using Random Allocation Software® to place 50 patients in the LTS group and 50 in the ETT group. For the allocation of the patients, a computer-generated list of random numbers was used. Patients were randomly assigned to one of two treatment groups following simple randomization procedures (computerized random numbers). Block randomization was done by a computer-generated random number list prepared by an expert statistician who had no clinical involvement in the trial.

The approval of the Institutional Review Board of the Research Committee of Zahedan University of Medical Sciences (Zahedan, Iran) was obtained with the code of ethics (IR.ZAUMS.REC.1392.6043), and the study was conducted according to the Declaration of Helsinki principles (Association, 2014). The ethical considerations of this study were related to the patients' autonomy, confidentiality, and anonymity during the study period and the study's publication. The purpose of the study was explained to all patients, and they were also informed that they were free to participate, decline participation, or withdraw from the study at any time. A written informed consent form to participate in the study was obtained from each patient's next of kin.

All standard pre-anesthetic monitoring was done for patients in both groups. The protective padding was used to maintain the patient's head and neck. Then, the patients first underwent pre-oxygenation and then 0.03 mg/kg midazolam, 1-2 µ/kg fentanyl and 2-2.5 mg/kg propofol were all injected intravenously in order to induce anesthesia. Also, 0.15 mg/kg of cis-atracurium was used to relax the muscles before airway manipulation. To maintain anesthesia, 5-8 mg/kg/h of propofol and N2O+ O2 mixture (50% each) were used. After achieving effective airway, the intubated device LTS (VBM Medizin technik, sulus, GERMANY) (Figure 1) was used.

According to the manufacturer's recommendations with regard to the patient's height (size 3 for patient's height of 122-255 cm, size 4 for those height of 155-180 cm, and size 5 for patients taller than 180 cm and suitable ETT offered for the patient by two anesthesiologists) was attached to the respiratory system (Fabius, Drager, Lubek, Germany). The cuffs were inflated to the maximum allowable volume before starting ventilation.

The lungs were first ventilated at the tidal volume of 8 ml/kg, RR=12bpm and I/E= 1/2 in the volume mode. Five minutes after tightening the device and ensuring the airway safety, maximum airway pressure and SPO2 and ETCO2 were recorded (Siemens sc7000 Monitor made by China). The leak pressure was later recorded and measured by closing the exhalation valve of the respiratory circle and using constant flow of 3 lit/min and by considering the leak pressure (maximum 40 cm H2O).

The placement time of the device was measured and recorded from the time it was taken by hand to the time the cuff was filed.

Following the controlled ventilation with above specifications, if ETCO2 remains constant at the normal level, there will be no need to change the device settings, but respiratory rate can be adjusted, if needed. In case of normal chest movements, attempts were made to ensure adequate oxygenation and Square waves on SPO2 in the capnograph; moreover, lack of audible leaks and gastric expansion were considered as reasons indicating adequate ventilation.

Patients were followed up for 24 hours after the surgery, and their sore throat and dysphonia, if any, were recorded in their information forms. Also, the follow-up was done in the form of a phone call up to 24 hours later in case of patient discharge.

All analyses were performed using SPSS 19.0 (SPSS Inc., Chicago, IL). Frequency (percent) and mean (standard deviation) were presented for qualitative and quantitative variables, respectively. The normality of the study variables was tested by the Kolmogorov-Smirnov one-sample test. Normality was confirmed for all variables. For comparing outcomes variables in the two groups, independent-sample t-test and chi-square test were used. P values < 0.05 were considered significant.

Results

this study, a total of 100 patients who were hospitalized in Ali Ibn AbiTalib Hospital of Zahedan to undergo elective surgery, were randomly divided into two groups: LTS and ETT. The mean age of patients in the LTS and ETT groups was 35.94±5.96 and 34.76±4.20 years, respectively. There was no statistically significant difference between the two groups (P=0.25), Independent samples t-test).

There were a total of 49 male patients (49%) and 51 female patients (51%) in the study. There was no statistically significant difference between the two groups (Table 1).

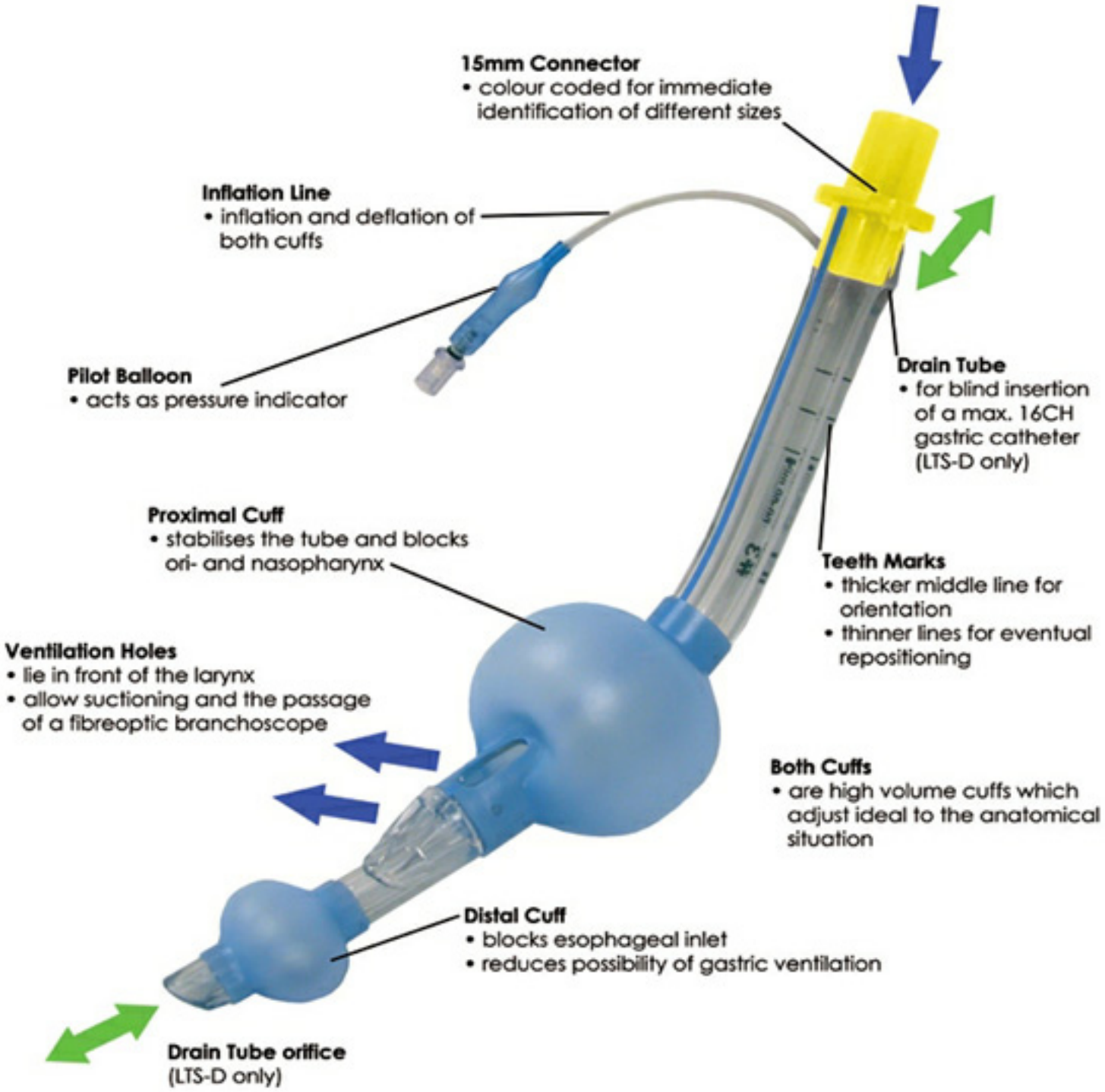

Figure 1: Laryngeal tube and its components (http://medtree.co.UK/vbm-it-d-laryngeal-tube)

Gender	LTS	ETT	P-Value
	Frequency (%)	Frequency (%)	
Male	22 (44%)	27 (54%)	0.42
Female	28 (56%)	23 (46%)	

Table 1: Frequency of patients in the two groups based on gender

After inserting the device, the leak pressure was measured in each group.
The mean leak pressure in the LTS group was significantly higher than that in the ETT group (P<0.001). The mean leak pressure in LTS and ETT groups was 20.84± 3.59 and 18.16± 2.5 mmHg, respectively, which was statistically significant (P<0.001) (Table 2).

Table 2: Mean and peak pressures, ETCO2, PO2, and the intubation time in two groups

Variables	LTS (Mean ± SD)	ETT (Mean ± SD)	t	df	P-Value*
Leak Pressure (CmH_2O)	1.55 ± 28.54	0.93 ± 25.76	7.92	98	<0.001
Peak Pressure (CmH_2O)	3.59 ± 20.84	2.5 ± 18.16	8.92	87.39	<0.001
$ETCO_2$ (CmH_2O)	1.10 ± 39.08	1.16 ± 38.72	1.58	98	0.11
SPO_2 (%)	1.17 ± 98.04	1.34 ± 97.56	1.9	98	0.06
Required time for placement (s)	2.09 ± 25.66	2.17 ± 28.28	6.92	98	<0.001

* Independent sample t-test

There was no statistically significant difference between the two groups in terms of ETCo2, the mean value of which in LTS and ETT groups was respectively 39.08±1.10 and 38.72±1.16 mmHg. Also, there was no significant difference between the two groups in terms of SPo2, the mean value of which was respectively 98.04±1.17 and 97.56±1.34 mmHg in LTS and ETT groups (P=0.06).

In order to evaluate the intubation rate in this study, the intubation time variable was used. The intubation time was equal to 25.66±2.09 seconds in the LTS which was significantly less than the same time for ETT (28.28±2.17 seconds) (P<0.001).

These results reflect higher intubation rate for LTS (Table 2). There was no difference between the two groups in terms of incident rate of post-operative dysphonia and throat (Table 3).

Table 3: Frequency of risk of dysphonia and sore throat in the two groups

Variables	ETT Frequency (%)	LTS Frequency (%)	P-Value*
Dysphonia	6 (12%)	9 (18%)	0.57
Sore throat	15 (30%)	18 (36%)	067

* Chi-square test

Discussion

The results of this study showed that higher leak and peak pressures can be achieved using LTS. LTS was intubated more quickly than ETT, but there was no difference between the two devices in terms of side effects. Maintaining a safe airway in patients who are candidates for surgery and need to undergo general anesthesia is one of the most important duties of the anesthesiologist. Apart from the cuffed endotracheal tube, supraglottis devices such as laryngeal tube suction can be used in difficult intubation caused by patients' anatomic shape of the oral cavity, head and neck and in emergency cases (1).

LTS is a new type of LT, in which an additional channel for suction and emptying of the stomach and digestive system is embedded. LTS is also used in order to maintain the airway during general anesthesia. It is one of the supraglottic airway devices and can be inserted using blind intubation method (2).

In this study, 100 patients who underwent elective surgery in Ali Ibn Abi Talib Hospital in Zahedan, were randomly divided into two groups, including LTS and ETT. After the device was inserted, the leak pressure was measured in each group. The mean leak pressure in the LTS group was significantly higher than in the ETT group. The mean peak pressure in LTS was higher than the ETT group, which was not statistically significant.

Although there were no similar studies comparing the two devices, several studies have addressed the LTS, including Cavus's study (2009), the results of which are consistent with the results obtained in the present study (13). In a study, Russo (2012) also reported a leak pressure that was equal to the one obtained in the present study (14).

Yet in another study on LT and LMA, Cook (2003) reported that leak and peak pressures were respectively 71.12 and 44.45 CMH2o in the LT group which is consistent with the findings obtained in the present study (17).

In a study conducted by Esa et al. in Malaysia in 2011, 54 patients were randomly divided into two groups to receive LTS and PLMA.

Both devices provided a safe airway even when the intra-abdominal pressure was increased to 17 mm Hg. In this study, there was no difference between LTS and PLMA regarding their ease of placement, hemodynamic changes, airway quality, oxygenation and ventilation parameters and complications (18).

Scheller et al. (2010) published the results of their study on 8 patients who underwent surgery using LTS. The results showed that LTS was successfully intubated in all cases. The placement was performed at the first attempt, which was classified as ''easy''. The tracheotomy surgery was performed in 6 of 8 patients, while the LTS was used for oxygenation and ventilation. LTS enables rapid oxygenation in patients with emergency difficult airway (15).

In a prospective study conducted by Wiese et al. in 2008, 50 volunteers underwent the standard treatment for cardiac arrest simulated on a mannequin. The volunteers were assigned to two groups using LST and ETT. The duration of lack of air flow during the cardiac arrest in mannequins, was significantly reduced in the LST group, compared with the ETT group (109.3 vs. 190.4 sec). The LST can be inserted much faster than ETT (13 vs.52 seconds). Also, its success intubation rate in the first attempt was 98% compared with 72% obtained for the ETT (19).

In a study, Thierbach et al also showed that LTS is a fast and reliable method to maintain an open airway and to achieve better ventilation results in the mannequin model. The success rate, time of placement and participants' views indicated that the LTS is an important alternative to ETT. LTS offers special benefits for less experienced users (20).

In a study of 2001 on CPR cases, Ganz Walker et al. concluded that the stomach expansion issue was observed in all alternatives to ETT, except for the LST., The maximum airway pressure in the ETT group was 28CMH2O and reached 32 CMH2O when LST device was used during ventilation (21).

In another article by Ganz Walker et al., LST was introduced as an effective device during difficult intubation. The significant difference calculated between the airway resistance and dynamic compliance confirms the fact that the total airway resistance in the LT was higher than that of ETT and the dynamic compliance of the LT is lower than the ETT, which indicates that routine use of LTS in patients' high airway resistance, whether admitted to the intensive care unit or for anesthesia, seems inappropriate because its resistance is added to the airway resistance thereby leading to barotrauma (16).

The time required for LTS placement is 25.66±2.09 seconds, which is significantly less than the same time in ETT (28.28±2.17 seconds). These results reflect higher intubation rate for LTS.

In another study, Cook (2003) reported a peak pressure of 17.9 cmH2O and an intubation time of about 22 seconds for LT which is almost similar to the findings obtained in the current study (22). Another similar study was conducted by Wiese (2008) who reported a LT intubation rate that was consistent to the same intubation rate obtained in the present study (19).

With regard to the adequacy of ventilation between LTS and ETT, the mean SPo2 and ETCo2 was higher in the LTS group than the ETT group; but since this difference is not significant, all patients enjoyed the desirable and acceptable ventilation. In terms of complications, the incidence rate of postoperative dysphonia and sore throat in the LTS and ETT groups was 18%, 36% and 12%, and 30%, respectively, which of course was not statistically significant. So, none of these devices were preferred over the other from this point of view. Both LTS and ETT can be safely used in airway management in elective surgery.

Higher peak and leak pressures can be achieved using LTS. LTS can be inserted more quickly than ETT, but there was no significant difference between the two devices in terms of the side effects. Since the LTS is much easier to implement compared with ETT and does not require great skill, especially in difficult intubation cases, it can save a patient's life.

Conclusion

Airway management provides gas exchange, protects the lungs from injury and permits treatment. This requires safe, effective and reliable use of equipment, often in combination. A management plan with backup plans is essential, but a sequence of logical plans forming an airway management strategy is better. Correct equipment use needs correct knowledge, skill and attitudes.
In the present study, despite the statistically significant results of this study and also considering that few studies have been conducted with the same purpose, it is recommended to conduct further studies to evaluate the efficacy of LTS in obese patients and patients with difficult airway and high risk for aspiration and patients with underlying lung disease.

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