Original Article

A comparison between the Supreme laryngeal mask airway and the laryngeal tube suction during spontaneous ventilation: A randomized prospective study

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Abstract

Background and Aims: The Supreme laryngeal mask airway (SLMA) and the laryngeal tube suction-disposable (LTS-D), both second-generation supraglottic airway devices, have a record of efficiency when used for airway management in mechanically ventilated patients, during general anesthesia. There is no published data comparing these two devices in patients breathing spontaneously during general anesthesia.

Material and Methods: Eighty patients with normal airways undergoing elective general anesthesia with spontaneous ventilation were randomized to airway management with a SLMA or LTS-D. Efficacy and adequacy of oxygenation and ventilation were compared.

Results: No cases of desaturation of oxygen saturation (SpO_2) values of less than 95% occurred with either device. The mean difference for SpO_2 between the two devices (0.7%) has no clinical significance. Slight hypercapnia was noted with both devices to acceptable values during spontaneous ventilation.

Conclusions: Both SLMA and LTS-D are suitable and effective for airway management in patients breathing spontaneously during general anesthesia for minor surgery of short duration.

Keywords: Laryngeal tube suction, spontaneous ventilation, Supreme laryngeal mask airway

Introduction

The Supreme laryngeal mask airway (SLMA) (Intavent Orthofix, Maidenhead, UK) [Figure 1] and laryngeal tube suction-disposable (LTS-D) (VBM Medizintechnik GmbH, Sulz, Germany) [Figure 2] are second-generation single-use supraglottic airway devices (SADs) with gastric access, for airway management during general anesthesia in spontaneously and mechanically ventilated patients.[1-4]

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The SLMA has been compared with the Proseal laryngeal mask airway (PLMA) during mechanical and spontaneous ventilation[5-7] and the LTS-II (multiple use version of the LTS-D) with the PLMA.[8-12] Recently, the LTS-D and SLMA have been compared when used by basic life support trained nurses[13] and during pressure controlled mechanical ventilation.[14]

To date, there is no published data comparing the SLMA with the LTS-D during spontaneous ventilation. We hypothesized that despite differences in their structural design, the SLMA and LTS-D have similar performances

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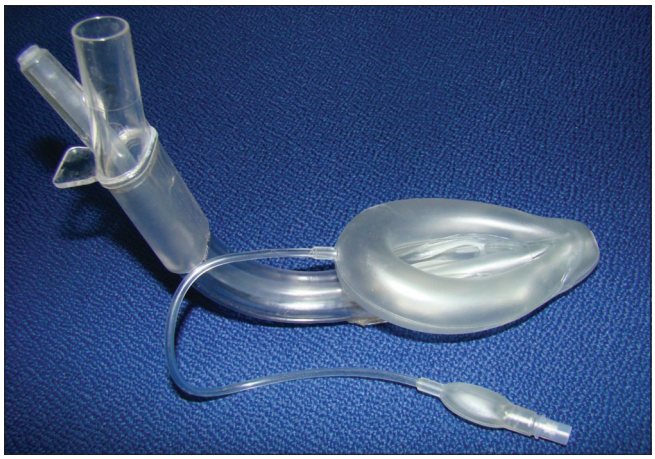

Figure 1: Supreme laryngeal mask airway

in patients breathing spontaneously during general anesthesia.

We compared the SLMA and the LTS-D with respect to oxygenation saturation (SpO_2) and end-tidal CO_2 ($ETCO_2$), time to achieve an effective airway, ease of insertion, need for interventions to optimize ventilation, cuff-leak pressure, ventilatory variables, fiberoptic score, and adverse perioperative events.

Material and Methods

Local Ethics Committee approved the study and written informed consent was obtained from all participating patients and the study was registered with Clinical Trial.gov [ID: NCT 02859922]. Eighty patients, American Society of Anesthesiologists physical status I and II, weighing 50–100 kg, with normal airways, undergoing elective general anesthesia in the supine position for minor surgical procedures of short duration were randomly assigned to have either a SLMA or a LTS-D for airway management. Randomization was done using a computer-generated randomization list. Exclusion criteria were age <18 years, weight <50 kg, body mass index (BMI) >35 kg/m^2, known difficult airway, limited neck movement, chronic obstructive lung disease, and active gastroesophageal reflux. The following data were collected: sex, age, height, weight, BMI, type of surgery, and duration of anesthesia.

On arrival in the operating rooms, standard monitors were applied and midazolam 0.05 mg/kg and fentanyl 2 mcg/kg intravenous (IV) were administered during the 3 min period of preoxygenation. General anesthesia was induced with propofol 2 mg/kg IV and maintained with end-tidal concentration of sevoflurane up to 1.5%. After 3 min of face mask ventilation, the SAD was inserted. Two attending anesthesiologists

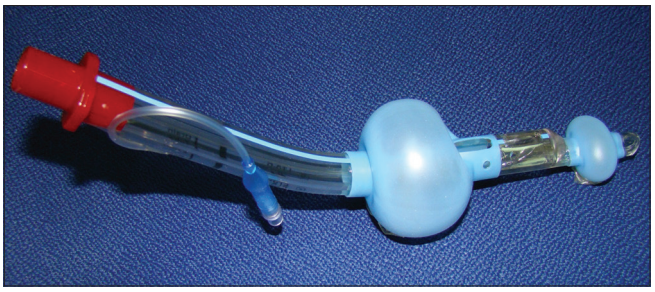

Figure 2: Laryngeal tube suction-disposable

experienced in using both SLMA and LTS-D inserted the SAD.

A size 4 or 5 of the SLMA and size 4 or 5 of the LTS-D were used following the manufacturer's recommendations and the cuffs were inflated to 60 cm H_2O using a manometer (VBM Medicine, Sulz, Germany). The airway was considered adequate if a minimum 6 mL/kg expiratory volume could be achieved during manual ventilation at a peak airway pressure of 15 cm of H_2O, a normal capnograph trace was obtained, and no leak was identified by auscultation over the neck.

The time to achieve an effective airway was measured from removing the facemask until the capnograph tracing was observed after insertion of the SAD. Two attempts to insert the SAD were allowed. Endotracheal intubation was planned if the SAD insertion was unsuccessful. Airway adjustment maneuvers were allowed to properly position the device, if necessary, and categorized as minor interventions (adjusting head/neck position, jaw thrust, changing depth of insertion) or major interventions (reinsertion of the device, changing the SAD size).

The anesthesiologist inserting the SAD was asked to evaluate the ease of insertion as easy, moderate difficult, very difficult, or impossible. After achieving an effective airway, oropharyngeal cuff-leak pressures were measured by noting the airway pressure at which equilibrium was obtained, at a gas flow rate of 3 L/min, after closing the expiratory valve of the anesthesia circuit. The maximum allowed airway pressure during the leak measurement was 40 cm H_2O.[15]

The fiberoptic position of the devices was determined by passing a flexible fiberoptic bronchoscope (Storz, Germany, 3.7 mm) through the ventilation channel of the SLMA/LTS-D to a position 1 cm proximal to the ventilation aperture. After reaching this position, the anesthesiologists were allowed to maneuver the tip of the fiberoptic scope to optimize the laryngeal view.

We used the scoring system described by Brimacombe and Berry to score the fiberoptic view: "4, only cords seen; 3, cords

plus posterior epiglottis seen; 2, cords plus anterior epiglottis seen; 1, cords not seen, but function adequate; 0, failure to function where cords not seen fiber-optically."[16] For the SLMA, the fiberoptic scope was passed on either side of the gastric tube to reach the ventilation aperture. The LTS-D has a separate gastric channel allowing fiberoptic bronchoscope insertion in the middle of the ventilation channel, so that the glottic view can be observed through the frontal apertures.

The largest allowed gastric tube (16-CH for the SLMA and 18 CH for the LTS-D) was inserted and proper placement was confirmed by aspiration of gastric contents. The SpO_2, $ETCO_2$, inspired and expired minute volumes (MVinsp, MVexp), and respiratory rate (RR) were recorded 5 min after resuming spontaneous ventilation until the removal of the SAD. The flow volume loops were continuously checked on the monitor in order to detect leaks.

At the end of the procedure, the SAD was removed and examined for presence of blood. Patients were interviewed when released from the postanesthesia care unit (PACU) and 24 h after surgery, to detect the incidence and severity of airway-related postoperative adverse events. A blinded research assistant conducted the interview by asking nonleading questions. Postoperative airway-related adverse events were graded as: mild (coughing or gagging on insertion, hiccups), moderate (bronchospasm, airway obstruction, blood staining of the device, oral pain, sore throat, hoarseness, dysphagia, and dysphonia), or severe (hypoxia, regurgitation, aspiration, dental trauma, soft tissue trauma, gross blood-staining of the device).

The primary outcomes studied were oxygenation and adequacy of ventilation. Secondary outcomes were time to achieve an effective airway, ease of insertion, airway intervention requirements, cuff seal leak pressure, respiratory variables, fiberoptic view, success of gastric drain insertion, and perioperative airway-related adverse events.

Statistical analysis

Sample size was determined by using the primary variables SpO_2 and $ETCO_2$ and assuming a standard deviation of 2% for SpO_2 and 6 mmHg for $ETCO_2$. A difference of 3% in SpO_2 or 5 mmHg in $ETCO_2$ was considered significant for this purpose. Assuming a two-sided test with a power of 95% and an α of 0.05, we determined that we would need 39 patients in each group. Repeated measures analysis of variance (ANOVA) were used to analyze continuous data over time. Wilcoxon test was used for ordinal data, and Fisher's exact test for categorical data. Due to the similarity of values in all variables across time and devices and the absence of interaction between time and devices, we analyzed the overall device effect using the arithmetic mean of all the measurements per variable in each patient, followed by *t*-test for equivalence using the two one-sided tests (TOST) method.[17] For the secondary variable, the following were considered significant: 0.5 L/min in expired minute ventilation, 5 s in insertion time, and 5 cm H_2O in leak pressure. According to the TOST method, there is equivalence between devices when the mean difference is significantly different from both the upper (mean difference < upper threshold) and lower threshold (mean difference > lower threshold). If the mean is different from both, then the overall test is significant and equivalence is proved.

Results

A total of 80 patients were recruited, 40 in each group. There were no significant differences between the two groups with respect to demographic data [Table 1]. First attempt insertion was successful in 38 patients with both devices, and all patients at the second attempt.

The SpO_2 values were very similar between groups at all time points. When analyzed using repeated measures ANOVA, the SpO_2 values were different across devices as shown in Table 2 ($F_{1,64} = 0.975$, $P < 0.015$), with no interaction with time. However, the differences are small and clinically not relevant. When tested for equivalence both devices were similar (specified difference threshold 3%, mean difference 0.54%, standard error (SE) difference 0.07, $P < 0.0001$). The overall mean SpO_2 for LTS-D was 98.5 ± 0.7 and 97.9 ± 0.8 for the SLMA.

Likewise, the $ETCO_2$ values were very similar between both devices across all time points. The overall mean values $ETCO_2$ for LTS-D was 42 ± 1.7 mmHg and for SLMA

Table 1: Demographic data

	LTS-D	SLMA
Age (years)	63±7	66.4±9
Male/female	31/9	31/9
ASA I/II	14/26	10/30
Weight (kg)	72±5	74±4
Height (cm)	174±6	173±4
Duration of surgery (min)	34±3	38±5

LTS-D=Laryngeal tube suction-disposable, SLMA=Supreme laryngeal mask airway, ASA=American Society of Anesthesiologists physical status I and II

Table 2: Oxygen saturation over time (%)

	0	5 min	10 min	15 min	20 min	25 min	30 min
LTS-D	98.2	98.1	98.1	98.1	97.9	97.9	97.9
SLMA	98.4	98.5	98.4	98.4	98.5	98.5	98.6

LTS-D=Laryngeal tube suction-disposable, SLMA=Supreme laryngeal mask airway

was 42.4 ± 1.7 mmHg. There were no differences between devices ($F_{1,48} = 0.005$, $P < 0.63$) [Table 3]. When tested for equivalence both devices were similar (specified difference threshold 5 mmHg, mean difference 0.38 mmHg, SE difference 0.22, $P < 0.0001$).

The mean time to achieve an effective airway was 16.1 ± 1.4 s when using an LTS-D and 16.6 ± 1.9 s when using the SLMA device. When tested for equivalence both devices were similar (specified difference threshold 5 s, mean difference 0.47 s, SE difference 0.37, $P < 0.0001$).

There were no differences in terms of ease of insertion. In the LTS-D group, 36 patients were graded easy and 4 as moderate difficult, as compared to 35 patients in the SLMA group graded easy and 5 as moderate difficult (Fisher's exact test, $P = 1$).

Hyperextension of the head (minor intervention) was needed in 19 patients in the LTS-D group and 17 patients in the SLMA group. This difference was not statistically significant (Fisher's exact test, $P = 0.822$).

However, jaw thrust maneuvers (minor intervention) were needed in 11 patients in the LTS-D group and 3 patients in the SLMA group. This difference was statistically significant (Fisher's exact test, $P < 0.037$).

The mean oropharyngeal leak pressure in the LTS-D group was 31.7 ± 3.1 cm H_2O, which was significantly higher than the 23.7 ± 2.6 cm H_2O measured in the SLMA group ($F_{1,78} = 153.7$, $P < 0.0001$). When tested for equivalence both devices were not equivalent (specified difference threshold 5 cm H_2O, mean difference 8 cm H_2O, SE difference 0.6, $P = 1$).

No statistical difference was found between groups in MVinsp, 3.8 ± 0.2 L/min and 3.9 ± 0.4 L/min for LTS-D and the SLMA, respectively. Interestingly, the SLMA device variance was larger (Levene's test for equal variances $F_{1,78} = 7.98$, $P < 0.006$), but the means were not different (Welch ANOVA testing means equal allowing unequal variances, $F_{1,64.95} = 0.5441$, $P = 0.46$). When tested for equivalence both devices were also equivalent (specified difference threshold 0.5 L/min, mean difference 0.05 L/min, SE difference 0.07, $P < 0.0001$).

Similarly, the MVexp was also very similar between both groups. The mean MVexp for LTS-D was 3.6 ± 0.2 L/min and for the SLMA was 3.63 ± 0.4 L/min. Also interestingly, the SLMA device variance was larger (Levene's test for equal variances $F_{1,78} = 8.55$, $P < 0.004$), but the means were not different (Welch ANOVA testing means equal allowing unequal variances, $F_{1,61.49} = 0.0001$, $P = 0.99$). Both devices were equivalent (specified difference threshold 0.5 L/min, mean difference 0 L/min, SE difference 0.07, $P < 0.0001$).

The fiberoptic score is presented in Table 4. In all patients for both devices, it was possible to insert a gastric tube. Blood stains were observed in 5 patients (12.5%) in the SLMA group and 6 patients (15%) in the LTS-D group.

Five patients in the SLMA (12.5%) group and 6 patients (15%) in the LTS-D group presented sore throat in the PACU. Five (12.5%) from the SLMA and 4 patients (10%) from the LTS-D group presented hoarseness in PACU ($P = 1.0$).

After 24 h, 4 patients (10%) from the SLMA group and 4 (10%) from the LTS-D group had sore throat. There is no significant difference between the groups in this respect (Fisher's exact test, $P = 1.0$) [Table 5].

Discussion

The SLMA and the LTS-D are equally effective for airway management, in patients breathing spontaneously during general anesthesia of short duration. The slight difference between the devices in the SpO_2 was statistically significant; however, it has no clinical significance. Further, no cases of desaturation to SpO_2 less than 95% occurred with either

Table 3: End-tidal CO_2 over time

	0	5 min	10 min	15 min	20 min	25 min	30 min
LTS-D	42.2	42.3	41.1	42.6	42.7	42.9	43.1
SLMA	42.0	41.6	42.0	42.1	42.4	42.1	42.8

LTS-D=Laryngeal tube suction-disposable, SLMA=Supreme laryngeal mask airway

Table 4: Fiberoptic view score

Fiberoptic view score	LTS-D	SLMA	P
4	4 (10%)	17 (42.2%)	0.002
3	14 (35%)	18 (45%)	0.49
2	16 (40%)	5 (16.5%)	0.010
1	6 (5%)	0	0.026

LTS-D=Laryngeal tube suction-disposable, SLMA=Supreme laryngeal mask airway (number of patients and percentage)

Table 5: Airway trauma

	LTS-D (*n*=40)	SLMA (*n*=40)	P
Blood	6 (15%)	5 (12.5%)	1.00
Hoarseness	4 (10%)	3 (7.5%)	1.00
Sore throat PACU	6 (15%)	5 (12.5%)	1.00
Sore throat 24 h	4 (10%)	4 (10%)	1.00

LTS-D=Laryngeal tube suction-disposable, SLMA=Supreme laryngeal mask airway, PACU=Postanesthetic care unit

SAD. The $ETCO_2$ concentrations were not different. The minimal hypercapnia that occurred with both SADs was within the acceptable values during spontaneous ventilation.

Similar times to achieve an effective airway were noted for both devices, in accordance to previous reported data for the SLMA and LTS-D.[2,3] Despite the fact that the insertion techniques are different, insertion of both the LTS-D and SLMA is simple and straightforward. However, the LTS-D required more jaw thrust maneuvers to achieve an effective airway.

Schalk *et al.*[18] suggested that pulling the tongue away from the dorsal pharyngeal wall by performing jaw thrust enhances the retropharyngeal space and increases the insertion success rate of the LTS-D from 49 to 100%.

We found a lower oropharyngeal leak pressure with the SLMA than reported by Zunder and Brimacombe[1] and Verghese and Ramaswamy[2] but similar to Cook *et al.*[19] The higher cuff seal pressure with the LTS-D is advantageous in mechanically ventilated patients, especially when ventilatory pressures must be limited to avoid gastric insufflation. As airway pressures are lower during spontaneous ventilation, cuff seal pressures of 10 cm H_2O of higher are sufficient to provide an effective seal during spontaneous ventilation.[20]

We did not find statistical difference between the two groups regarding the inspiratory and expiratory minute volume. However, the SLMA had MVinsp and MVexp values that presented with significantly larger variation in comparison with the LTS-D. This large variance is difficult to interpret as it may be due to a larger leak or a better anatomical fit, reflecting more accurately the expected changes in tidal volume during spontaneous ventilation.

Despite their different anatomical and structural design, the ventilatory performances of both devices were similar. The cuff of the SLMA surrounds the laryngeal inlet and forms a seal with the hypopharyngeal tissues. The inner cuff is strengthened and prevents airway obstruction from in-folding. The ventilation hole has epiglottic fins that prevent airway obstruction from epiglottis down-folding. The several ventilation apertures of the LTS-D help to prevent hypopharyngeal tissues from obstructing the ventilator inlet.

Even though the role of the epiglottic bars of the SLMA to prevent airway obstruction was questioned,[21] we believe that the obstruction protective mechanisms existing in both studied SADs are important design features that allow unimpaired ventilation. The anatomical position of the ventilation orifice was better for the SLMA as confirmed by fiberoptic visualization. Forty-five percent of the patients with the LTS-D had a suboptimal fiberoptic view (grades 2 and 1); however, ventilation was adequate in all these patients, similarly to the findings reported by Mihai *et al.*[22]

Similar to previous reports,[2,22,23] the gastric tube was easily placed in both devices with the LTS-D allowing passage of a larger gastric drain tube. This presents an advantage when it is necessary to evacuate large gastric contents.

No differences were found in the complication rate between the two groups in the incidence of device blood staining, hoarseness, and sore throat, suggesting that both SADs are similar regarding airway trauma. The rate of traumatic airway complications following the use of SADs is multifactorial and varies widely, depending on the induction agent, insertion technique, correct positioning of the SAD, cuff pressures, type of analgesia, etc.[24-26] Our relatively low incidence of postoperative sore throat could be explained by the fact that only two experienced anesthesiologists inserted the device while adhering to the manufacturer's recommendation to inflate the SADs to 60 cm H_2O. The incidence of pharyngeal trauma in our study was higher for the SLMA than that reported by Cook *et al.*[19] and Tan *et al.*[23] and lower for the LTS-D.[3]

Our study has a number of limitations. First, the intraoperative data were obtained by an unblinded observer may be a source of bias. Second, our results may not be applicable to patients who are mechanically ventilated. Third, we used both devices for short anesthetics.

Both devices presented similar times to achieve an effective airway and low complications rate. The LTS-D necessitated more jaw thrust maneuvers to achieve an effective airway. In conclusion, both the SLMA and the LTS-D are effective in airway management of spontaneously breathing patients undergoing general anesthesia for short duration of minor elective surgery. Both devices have low rate of complications. The LTS-D necessitated more jaw thrust maneuvers to achieve an effective airway and has a lower fiberoptic score.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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