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Randomized Prospective Study Comparing the Laryngeal Tube Suction II with the ProSeal™ *Laryngeal Mask Airway in Anesthetized and Paralyzed Patients*

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Background: **The Laryngeal Tube Suction II (LTSII; VBM, Medizintechnik, Sulz, Germany) is a recent revision of the Laryngeal Tube Suction. This study compared insertion and ventilation profiles of the LTSII and the *ProSeal*™ Laryngeal Mask Airway (PLMA™; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) in anesthetized and paralyzed patients.**

Methods: **One hundred adult male patients were randomly allocated to an LTSII or PLMA™ group. The rate of successful insertion, insertion time, airway leak pressure at a cuff pressure of 60 cm H_2O, tidal volume during pressure-controlled ventilation, incidence of gas leakage with cuff pressure reduced and with the shaft inclined, position of LTSII under fluoroscopic observation, and postoperative airway morbidity were determined.**

Results: **Insertion was successful in 37 and 48 of 50 patients with LTSII and PLMA™, respectively ($P = 0.002$), with similar insertion times. Tidal volume was lower with LTSII than with PLMA™. Median airway leak pressures of LTSII and PLMA™ were 16 and 21 cm H_2O, respectively ($P = 0.006$). Gas leakage around the cuff was observed more frequently with LTSII than with PLMA™ when the cuff pressure was reduced or the shaft of the device inclined. The position of LTSII varied significantly and did not statistically correlate with patient height. Postoperative airway-related morbidity was not significantly different. Finally, tracheal misplacement of LTSII occurred in 5 of 50 patients (10%), but ventilation was possible in 4 of them, and misplacement was identified only after fluoroscopic examination was performed.**

Conclusion: **Airway management with LTSII is inferior to that with PLMA™.**

THE Laryngeal Tube Suction II (LTSII; VBM, Medizintechnik, Sulz, Germany) is the most recent version of the Laryngeal Tube (LT) family of supraglottic airway devices originally intended for emergency airway management including out-of-hospital use, but which are currently also used during general anesthesia.[1–3] The original LT consists of an airway tube made of silicone and two cuffs. The distal and proximal cuff blocks the esophageal inlet and the pharyngeal space above the larynx, respectively, while the holes in the shaft between the cuffs allow ventilation. The Laryngeal Tube Suction (LTS), introduced in 2002, is the dual-lumen version of the LT. The LTS has an esophageal drainage tube that isolates the respiratory and alimentary tracts and allows passage of a gastric tube into the esophagus.[4] In 2004, the LTS was modified into the LTSII.[1,5] The major modifications include (1) a longer shaft, (2) a more pointed tip, and (3) an oval-shaped distal cuff to better fit the esophageal inlet (fig. 1). LTS and LTSII were initially envisioned as alternatives to the *ProSeal*™ Laryngeal Mask Airway (PLMA™; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) in mechanically ventilated patients during general anesthesia. However, the LTS was removed from the market, and we have insufficient knowledge as to the performance of the LTSII during general anesthesia.[6,7]

In the current study, we tested the hypothesis that the LTSII and the PLMA™ would be different with regard to their ease of insertion, effectiveness, and stability in delivering positive-pressure ventilation during controlled ventilation and general anesthesia.

This article is featured in "This Month in Anesthesiology." Please see this issue of ANESTHESIOLOGY, page 9A.

Materials and Methods

Participants and Anesthesia

The study was approved by the institutional human ethics committee (Yokohama City University Hospital, Yokohama, Japan), and written informed consent was obtained from all patients. One hundred consecutive male patients (American Society of Anesthesiologists physical status I or II) scheduled to undergo prostate brachytherapy were enrolled in the study. Patient exclusion criteria included (1) presence of any disease of the neck, upper respiratory tract, or upper gastrointestinal tract; (2) an increased risk of aspiration; (3) body mass index greater than 30 kg/m^2; and (4) mouth opening less than 3 cm. Before anesthesia, the view of the oropharynx on mouth opening was rated according to the classification of Mallampati *et al.*[8,9]

Patients were randomly allocated to an LTSII or PLMA™ group (n = 50 per group), randomization being performed by opening a sealed envelope.

Standard monitoring devices were attached before induction of anesthesia. Patients lay supine with their heads in the sniffing position. After preoxygenation by breathing oxygen through a facemask for 3 min, anes-

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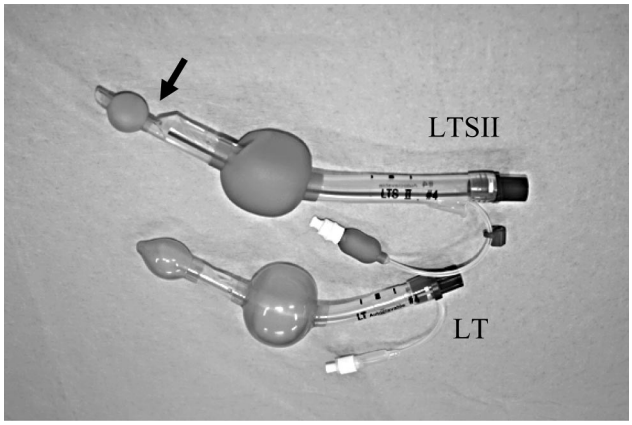

Fig. 1. The entire view of the Laryngeal Tube Suction II (LTSII) and the "classic" Laryngeal Tube (LT). The LTSII consists of tubes of different diameters. A *black arrow* shows where the two coaxial tubes join.

thesia was induced using 3 μg/kg fentanyl and 1–2 mg/kg propofol and maintained with 1–2% sevoflurane in 40–60% oxygen and air. After neuromuscular blockade, produced with 0.1 mg/kg vecuronium, a train-of-four count of 0 was confirmed using a peripheral nerve stimulator before airway manipulation was attempted, neuromuscular blockade being maintained with additional doses of vecuronium if required until all measurements were performed.

Insertion of the Device

Thirty-five anesthetists (including residents) with a wide range of experience in anesthesia practice performed device placement. Regardless of the airway device assigned, residents were given a short training on insertion techniques, practicing insertion on a manikin several times before the study. Staff anesthesiologists were familiar with the PLMA™, but because they had little experience with the LTSII, they were given instructions and the opportunity to practice on a manikin only when the LTSII was assigned.

Size selection criteria and insertion techniques used for the LTSII were as described by the manufacturer. Tube size selection was based on the height of each patient. Size 3 was used for patients shorter than 155 cm, size 4 was used for those between 155 and 180 cm, and size 5 was used for those taller than 180 cm. Before insertion, the cuff was deflated and a water-soluble lubricant was applied. Holding the LTSII like a pen in the area of the black lines, the anesthetist pushed the tip of the LTSII against the hard palate behind the upper incisors and then advanced the device into the pharynx, keeping it in the midline, until the second bold black line on the tube lay between the upper and lower incisors. The cuffs were inflated with air, the amount of air depending on tube size (60 ml for size 3, 80 ml for size 4, and 90 ml for size 5) initially. The LTSII was fixed in place using adhesive tape if effective ventilation was assessed as being possible.

Size selection of the PLMA™ depended on patient weight, as recommended by the manufacturer's instructions. Size 3 was used for patients less than 50 kg, size 4 was used for those between 50 and 70 kg, and size 5 was used for those over 70 kg in weight. Before insertion, a small amount of water-soluble lubricant was applied on the posterior surface of the deflated cuff. With the index finger placed in the retaining strap, the anesthetist pressed the cuff of the PLMA™ against the hard palate and advanced it into the pharynx until resistance was felt. The initially inflated cuff volumes were 20, 30, and 40 ml for sizes 3, 4, and 5, respectively. The PLMA™ was fixed in place after assessment of adequate ventilation.

Insertion time was recorded from the time of removal of the facemask to delivery of the first breath through the assigned airway device. A square capnography waveform was considered proof of adequate ventilation. After insertion, no adjustment of the position of the airway device was allowed. If the device could not be inserted or the lung could not be ventilated properly, the device was removed, and another attempt at insertion was made after a few breaths. The number of attempts needed to properly place the device was recorded. After three failed attempts, device insertion was recorded as a failure and the airway was secured in the most suitable manner determined by the assigned anesthetist. In such cases, further measurements were not performed. In some cases, after adequate ventilation was established, fluoroscopic observation (see next section) demonstrated misplacement of the LTSII in the trachea. These cases were also classified as failures. After three cases of tracheal misplacement, we slightly modified the protocol and inserted the LTSII under fluoroscopic observation to elucidate how this misplacement occurred. The anesthetist inserting the LTSII was blinded to the fluoroscopic image.

Anatomical Position of the LTSII

The manufacturer recommends that the size 4 LTSII be inserted by a fixed length, *i.e.*, until the center black line is level with the upper incisors, for patients in a wide height range (155–180 cm). Because a majority of Japanese males fall in this range, we predicted that the position of the ventilatory orifice of the LTSII relative to the cervical vertebral body would correlate with the patient's height (*i.e.*, the taller the person, the more cephalad the ventilatory orifice on the tube). To test this prediction, we obtained a lateral fluoroscopic view of the neck of patients with successfully placed LTSIIs. Because the LTSII has a radiopaque marker line all the way to the distal orifice, the position (vertebral body level) of the distal end of this radiopaque marker was recorded as the position of the ventilatory orifice. We did not evaluate the position of the PLMA™ because previous studies with fiberscopic observation have al-

ready demonstrated that the cuff of the properly placed PLMA™ is always located at the level of the larynx.[10]

Efficacy of the Airway Seal

The effectiveness of the airway seal with the LTSII and PLMA™ were compared in several different ways. First, while the cuff pressure of the airway device was maintained at 60 cm H_2O using a cuff pressure gauge and the fresh gas inflow to the breathing system was kept at 3 l/min, the pressure-limiting valve of the breathing system was closed and airway pressure was allowed to increase (but not permitted to exceed 40 cm H_2O) until it reached equilibrium, *i.e.*, until the leak around the cuff reached 3 l/min. The equilibrating airway pressure was recorded as the airway leak pressure.[11] Patients were then put on pressure-controlled ventilation at an inspiratory pressure of 15 cm H_2O, a respiratory rate of 10 beats/min, and an inspiratory-to-expiratory ratio of 1:2 (Fabius-Tiro Ventilator; Drager, Lubeck, Germany), and the following three measurements were performed. Pressure-controlled ventilation was chosen to limit gastric insufflation by limiting the amount of positive pressure applied, while still ensuring comparability of air leak by application of the same amount of positive pressure throughout. Expired tidal volume was recorded while the cuff pressure was maintained at 60 cm H_2O. Next, the threshold cuff pressure that just allowed gas leakage was measured by decreasing the cuff pressure in 5-cm H_2O decrements from 60 cm H_2O and maintaining each cuff pressure for 30 s. Gas leakage was judged to be present when any of the following three criteria was met: (1) audible leak from the mouth; (2) outflow of air through the esophageal drainage tube during inspiration, as detected by ejection of gel placed on the proximal end of the drainage tube; or (3) expired volume less than 90% of the inspired volume. The same measurement was repeated three more times while the shaft of the airway device was inclined at an angle of 30° relative to the neutral position in the cephalad, caudal, and right lateral directions. After all these measurements were completed, a 14-French gastric catheter was advanced into the esophagus through the drainage tube of the device.

Maintenance of Anesthesia

Anesthesia was maintained with 1–2% sevoflurane in 40–50% oxygen with air, and additional doses of fentanyl or remifentanil were administered as required. Inspiratory pressure and respiratory rate were adjusted to achieve an end-tidal carbon dioxide concentration between 35 and 45 mmHg. Cuff pressure was maintained at 60 cm H_2O.

Removal of the Device

At the end of the operation, anesthetic agents were discontinued and neuromuscular paralysis was reversed. After the patient regained consciousness and opened his mouth on command, the cuff was deflated and the device was removed. The presence or absence of blood on the device was recorded. Three and 24 h after removal of the device, patients were questioned for sore throat or dysphagia by another anesthetist who was blinded to the airway device used.

Table 1. Patient Demographic Data

	LTSII (n = 50)	PLMA™ (n = 50)	*P* Value
Age, yr	70 (59–78)	71 (53–79)	—
Height, cm	162 (145–174)	164 (153–176)	—
Weight, kg	64 (43–84)	64 (49–82)	—
Body mass index, kg/m^2	24 (17–29)	24 (20–30)	—
Mallampati class, I/II/III	33/16/1	28/22/0	—
Size, 3/4/5	1/49/0	2/38/10	—
Successful insertion, success/fail	37/13	48/2	0.002

Data are presented as median (range) or number of patients.

LTSII = Laryngeal Tube Suction II; PLMA™ = *ProSeal*™ Laryngeal Mask Airway.

Statistical Analysis

The primary aim of this study was to compare the seal pressures of the PLMA™ and LTSII, a difference of pressure of 5 cm H_2O being considered clinically significant. To estimate appropriate group size, we referred to SDs of leak pressure of the PLMA™ and LTS obtained in previous reports and found them to be within 7 cm H_2O.[2,10,12,13] With an α error of 0.05 and a power of 0.9, a group size of 43 patients would be required to provide accurate results; hence, the sample size was increased to 50 patients each to allow for possible failed insertions.

Between-group comparisons of numerical data were performed using the Mann–Whitney U test. Between-group comparisons for distributions were analyzed using Fisher exact test for data with two categories and chi-square test for data with more than two categories. Correlation coefficients (ρ) were assessed with Spearman rank correlation for patient height and position of the LTSII. Kaplan-Meier statistics and a log-rank test were used to compare the LTSII and PLMA™ with regard to the percentage of patients who could be ventilated without gas leakage when the intracuff pressure was reduced. A *P* value less than 0.05 was considered significant.

Results

Demographic data did not differ between the two groups (table 1). With respect to anesthetists who performed insertion, 16 residents and 9 staff anesthesiologists placed the LTSII, whereas 18 residents and 10 staff anesthesiologists inserted the PLMA™. The median number of years of anesthesia experience for both airways was 3 yr (range, 0.1–13 yr; $P = 0.963$).

Table 2. Patient Data Based on Successful Device Insertion

	LTSII (n = 37)	PLMA™ (n = 48)	*P* Value
Number of attempts, 1/2/3	30/6/1	29/12/7	0.075
Time to successful ventilation, s	40 (24–107)	39 (17–120)	0.81
Airway leak pressure, cm H_2O	16 (7–35)	21 (12–38)	0.006
Tidal volume, ml	710 (370–1,030)	880 (470–1,000)	0.003
Frequency of gas leakage			
30° right, leak +/−	11/26	1/47	<0.001
30° cephalad, leak +/−	20/17	1/47	<0.001
30° caudal, leak +/−	15/22	1/47	<0.001
Morbidity after removal			
Blood on device after removal, +/−	7/30	8/40	0.787
Sore throat 3 h after removal, +/−	4/33	9/39	0.313
Sore throat 24 h after removal, +/−	0/37	1/47	0.377
Dysphagia 3 h after removal, +/−	5/32	4/44	0.442
Dysphagia 24 h after removal, +/−	2/35	0/48	0.103

Data are presented as median (range) or number of patients.

LTSII = Laryngeal Tube Suction II; PLMA™ = *ProSeal*™ Laryngeal Mask Airway.

Insertion of the Device

The success rate of insertion was significantly higher with the PLMA™ than with the LTSII (table 1). Insertion times for successful cases in both groups were similar (table 2). Subsequent fluoroscopic examination revealed that in 5 of 13 failed cases of LTSII placement, the LTSII bent ventrally at the junction of the two coaxial tubes such that the distal end of the drainage tube was at the tracheal inlet (figs. 2A and B).

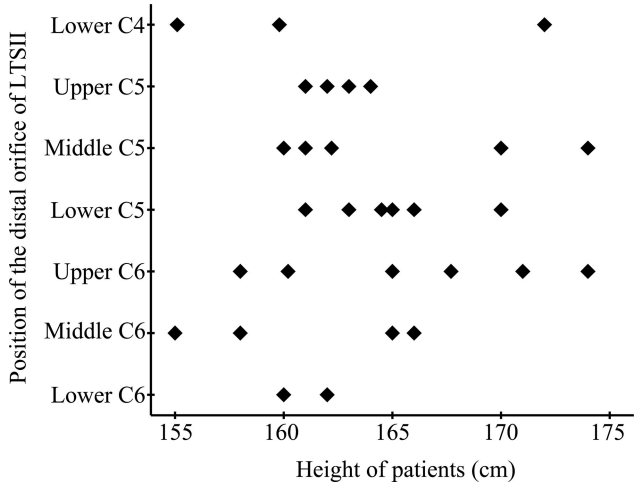

Fig. 3. Patients' height and the position of the distal orifice of the Laryngeal Tube Suction II (LTSII).

Anatomical Position of the LTSII

There was no statistically significant correlation between patient height and the position of the distal orifice of the LTSII (Spearman Rho = 0.093, $P = 0.591$; fig. 3).

Efficacy of the Airway Seal

The median leak pressure at a cuff pressure of 60 cm H_2O was significantly lower with the LTSII (16 cm H_2O; range, 7–35 cm H_2O) than with the PLMA™ (21 cm H_2O; range, 12–38 cm H_2O) (table 2). Tidal volume during pressure-controlled ventilation was also less with the LTSII than with the PLMA™ (table 2).

Figure 4 shows the percentage of patients without gas leakage at different cuff pressures when the cuff pressure was reduced from 60 cm H_2O. With the LTSII, a slight decrease of the cuff pressure resulted in gas leakage in more than half of the patients, whereas the PLMA™ provided good airway seal in 79% of cases, even when the cuff pressure was reduced to 15 cm H_2O ($P < 0.001$, log rank).

With the shaft of the device inclined in three directions, air leak occurred in 11–20 of 37 patients in the

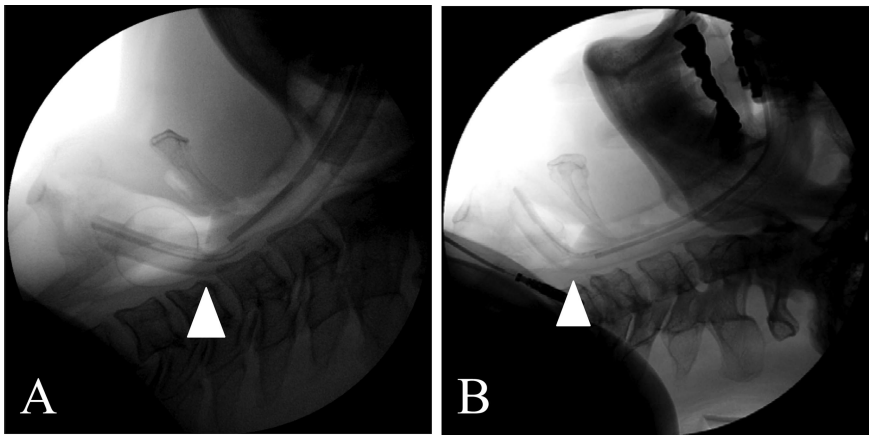

Fig. 2. (*A*) The typical cervical fluoroscopic image of the tracheal misplacement of the Laryngeal Tube Suction II. The Laryngeal Tube Suction II bent ventrally at the junction of the two coaxial tubes (*white arrowheads*), and the distal end of the drainage tube was at the tracheal inlet. Ventilation could be provided. (*B*) Ventilation was impossible in this case.

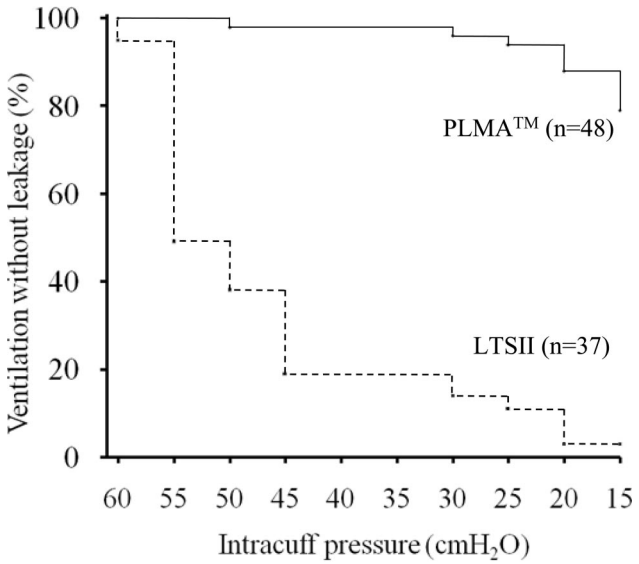

Fig. 4. Kaplan-Meier curves of the percentage of patients who could be ventilated without leakage when the intracuff pressure was reduced. The Laryngeal Tube Suction II (LTSII; *dotted line*) and the *ProSeal*™ Laryngeal Mask Airway (PLMA™; *solid line*) differed significantly ($P < 0.001$, logrank).

LTSII group, whereas only 1 of 47 patients in the PLMA™ group had an air leak (table 2).

Gastric catheter placement was successful in all patients in whom the assigned airway device was placed successfully.

Removal of the Device

There was no difference in the incidence of traumatic insertion, as indicated by the presence of blood on the device, and postoperative complications between groups (table 2).

Discussion

We have demonstrated that the LTSII is more difficult to insert and provides less reliable airway sealing when compared with the PLMA™. In this regard, LTSII is very different from the LTS (a predecessor of LTSII) because many studies (except Cook *et al.*[10]) have reported similar clinical utility for the LTS and the PLMA™.[2,12–14]

One obvious reason for the lower successful insertion rate of the LTSII in this study is that the LTSII entered the tracheal inlet instead of the esophagus in 5 of 50 patients (10%). To our knowledge, such tracheal misplacement has never been reported with the classic LT or original LTS. Fluoroscopic examination of the process of LTSII insertion revealed that when the LTSII was introduced into the pharyngeal space and the distal end of the drainage tube hit the posterior wall of the pharynx, the LTSII bent ventrally at the junction of the two coaxial tubes (figs. 5A and B). As the LTSII was advanced further, this ventral bending was maintained so that the tip moved toward the tracheal inlet (fig. 5C). We inserted

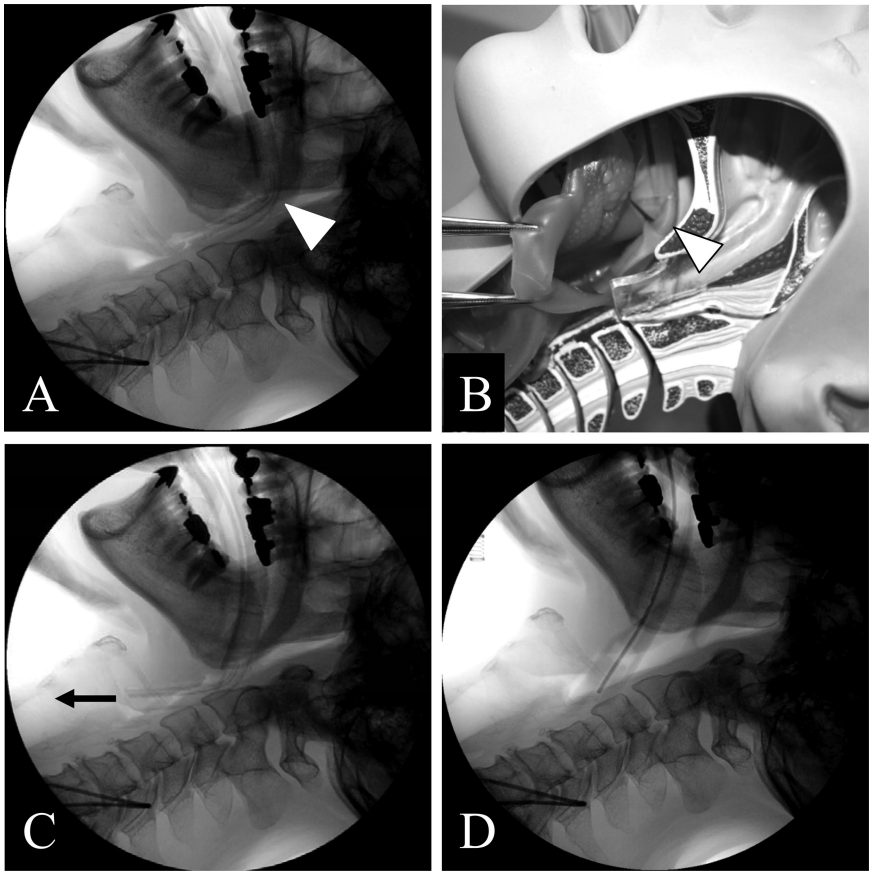

Fig. 5. *A* through *C* show how the misplacement of the Laryngeal Tube Suction II occurred. (*A* and *B*) When the Laryngeal Tube Suction II was introduced into the pharyngeal space, its tip contacted the posterior wall of the pharynx and was bent upward at the junction of two coaxial tubes (*white arrowheads*). (*C*) While the Laryngeal Tube Suction II was advanced further, the tip moved toward the vocal cords and entered the trachea (*black arrow*). (*D*) When the "classic" Laryngeal Tube was used, such bending did not occur.

the "classic" LT after misplacement of the LTSII in the fifth case, but such bending of the tip did not occur (fig. 5D) and the LT entered the esophagus smoothly. In our opinion, the slimmer and more pointed distal end of the LTSII, compared with the original LT or LTS, makes the LTSII more prone to bending when pushed against the posterior pharyngeal wall. Surprisingly, we could still provide ventilation in four of the five cases of tracheal misplacement, although the distal cuff should have blocked airflow into the trachea when the tip of the LTS was at the tracheal inlet.[4] This is probably because the distal cuff, being flat to better fit the cross-sectional shape of the esophagus, left some room for air movement when the cuff was inflated inside the trachea. When extra resistance is felt during insertion of the LTSII, the possibility of tracheal misplacement should be considered. In contrast to our results, a recent randomized controlled study comparing the LTSII and the PLMA™[7] has demonstrated a similarly high success rate of insertion for both the LTSII and the PLMA™. The reason for this discrepancy is unclear, but may be related to the fact that the anesthetists who inserted the device in the other study had performed at least 10 LTS insertions (despite no experience with LTSII), whereas our anesthetists had almost no experience with the LTS or classic LT. Another reason may be that we did not permit any airway manipulations after insertion of the LTSII, whereas they accepted the "up-and-down" maneuver as part of the insertion attempt.

Our results demonstrate that airway seal is better with the PLMA™ than with the LTSII. The airway leak pressure of the LTSII was significantly lower than that of the PLMA™. In addition, a slight decrease in the cuff pressure from 60 cm H_2O produced a leak around the cuff when the LTSII was used, whereas the PLMA™ continued to seal the airway adequately until the cuff pressure was reduced to relatively low levels. Further, the airway seal with the LTSII was less stable than that with the PLMA™ because the leak was easily produced by inclining the shaft. These results may be attributable to the difference in the function of the cuff; the cuff of the PLMA™ covers the cartilaginous larynx, whereas the cuffs of the LTSII are pushed against the soft tissue wall of the upper pharyngeal space and the esophageal inlet. Because high pressures exerted by the cuff may traumatize the pharyngeal mucosa,[15] the PLMA™ may be more appropriate for prolonged use than the LTSII.

The airway leak pressures we obtained for the PLMA™ and LTSII were considerably lower than those reported in the literature.[2,10,13,16] Although our study was not designed to formally elucidate the reason for this, we speculate that this may be because of differences in ethnicity. For example, the airway leak pressure of the PLMA™ is reported to be around 30 cm H_2O in many studies conducted in white subjects,[10,17] whereas some results with Asian subjects demonstrated lower pressures, similar to our results.[18–20]

The tidal volume produced by pressure-controlled ventilation was significantly lower with the LTSII than with the PLMA™. Our study design allowed comparisons between some variables that might have influenced the tidal volumes generated by the two devices, including patient physique and the level of anesthesia and muscle relaxation. Resistance to airflow is one factor that might have contributed to the results, because previous studies have demonstrated that the LTS is associated with significantly higher peak inspiratory pressures than the PLMA™ during volume-controlled ventilation.[2,10] The high airflow resistance of the LTS and the LTSII may be due to their small ventilation holes. Axial rotation of the device relative to the larynx might also be responsible for these lower tidal volumes,[6,10] as is the possibility that the shaft of the LTSII sometimes bends above the pharyngeal cuff, causing narrowing of the ventilatory lumen, as revealed by fluoroscopy in this study. We observed that chin lift sometimes ameliorated this bending and increased the expired tidal volume.

Our fluoroscopic observation also revealed that the position of the end of the radiopaque marker of the LTSII (corresponding to the distal ventilatory orifice) varied between the fourth through the sixth cervical vertebral levels, although the orifices are designed to be positioned at the level of the vocal cords.[4] Furthermore, there was no statistically significant correlation between the position of the distal orifice and the patients' height. The LTSII provided adequate ventilation despite this large and unpredictable variation in the position of the orifice, probably because the two cuffs are more than 5 cm apart. Our results are consistent with a recent study that demonstrates that the glottis is visible by fiberscopic inspection *via* the breathing tube of the LTSII in only 51% of patients, but that anatomical position of the tube and airway seal are not significantly related.[6]

The incidence of postoperative dysphagia and sore throat was not significantly different between the two groups. However, these results were obtained when the cuff pressure was maintained at 60 cm H_2O in both devices. This cuff pressure was necessary with the LTSII to prevent gas leakage, but lower pressures were sufficient with the PLMA™. It is unknown whether the incidence of pharyngeal trauma in association with PLMA™ use would be reduced by decreasing the cuff pressure to a level that just prevented air leak.

A number of limitations of our study should be noted. First, our protocol, prohibiting any maneuvering of the airway device after insertion, may have biased the results in favor of the PLMA™ because the LTS requires manipulations after insertion more frequently than the PLMA™, to obtain a clinically adequate airway.[10] However, lack of need for manipulation after insertion is a desirable characteristic for tubes of both the Laryngeal

Mask Airway and the LT families, because they are often used for prehospital airway management[21] and in patients with an unanticipated difficult airway[22] by operators with variable degrees of experience. Second, we enrolled only males in our study because we selected patients who were to undergo prostatic brachytherapy. Whether our results are applicable without any modifications to females is unclear. Third, we followed the manufacturer's instructions while selecting the size of the airway device for each patient, although there is no evidence that these are the best criteria for size selection. In fact, size selection of the PLMA™ by a sex-based formula causes air leakage less frequently than by the manufacturer's weight-based formula.[18] Fourth, many anesthetists who participated in this study were less familiar with the LTSII than with the PLMA™ because LTSIIs are new whereas PLMAs™ are used routinely in our anesthesia practice. This may have biased our results in favor of the PLMA™.

In conclusion, our data suggest that the LTSII is less reliable than the PLMA™ with regard to successful rate of insertion and airway seal. Furthermore, tracheal misplacement of the LTSII occurred in 5 of the 50 patients in our study in whom it was used. We recommend that all clinicians should keep this possibility in mind when they select the LTSII as their airway device of choice.

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