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Respiration and the Airway

RESPIRATION AND THE AIRWAY

The effects of thermal softening of double-lumen endobronchial tubes on postoperative sore throat, hoarseness and vocal cord injuries: a prospective double-blind randomized trial

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Abstract

Background: It is well known that thermal softening of polyvinyl chloride tracheal tubes reduces nasal damage during nasotracheal intubation. We hypothesized that thermal softening of double-lumen endobronchial tubes (DLTs) may be effective for reducing airway injury. This randomized double-blind study was performed to investigate whether thermal softening of DLTs decreased postoperative sore throat, hoarseness or vocal cord injuries.

Methods: Patients (n=140) undergoing one lung anaesthesia were randomized into two groups (n=70 each) depending on whether the DLT was softened by warming or not before tracheal intubation. The DLTs were placed in warm saline [40(1)°C] in the thermal softening group or in room temperature saline in the control group for 10 min. The vocal cords were examined by using flexible laryngoscopy immediately after extubation. Sore throat and hoarseness were evaluated for three postoperative days. The primary outcomes were the incidence of sore throat, hoarseness, and vocal cord injuries.

Results: Sore throat and vocal cord injuries occurred less frequently in the thermal softening group than in the control group [14/70 *vs* 27/70, risk ratio (95% CI): 0.52 (0.30–0.90), P=0.025 for sore throat; 15/70 *vs* 27/70, risk ratio (95% CI): 0.56 (0.32–0.95), P=0.042 for vocal cord injuries]. However, the incidence of hoarseness was comparable between the two groups.

Conclusions: Tracheal intubation with DLTs softened by warming decreased the postoperative incidence of sore throat and vocal cord injuries. Therefore, thermal softening of DLTs before intubation seems to be helpful in reducing airway injuries associated with DLT intubation.

Clinical trial registration.: NCT 01626365.

Key words: airway management; anesthesia, general; bronchi; intubation, intratracheal; one-lung ventilation

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Editor's key points

- Warming the tracheal tube reduces nasal injuries during nasotracheal intubation.
- This simple study compared the effect of warming the distal part of a double lumen endobronchial tube (DLT) on airway complications.
- Sore throat and vocal cord injuries were reduced but postoperative hoarseness was unaffected.
- Warming the distal part of a DLT seems to be an easy and effective way of reducing some airway complications.

For lung isolation, double-lumen endobronchial tubes (DLTs) are more commonly used than single-lumen tracheal tubes with bronchial blockers because the DLT facilitates faster positioning and lung deflation and enables separate ventilation of each lung.[1 2] However, tracheal intubation using DLTs is more likely to result in airway injuries or postoperative discomfort, such as sore throat and hoarseness as compared with single-lumen tracheal tubes[1–3] probably because DLTs are stiffer, have a larger external diameter, and are inserted deeply into the mainstem bronchus. Therefore, every care should be taken to minimize the potential airway injuries associated with intubation of DLTs.

Nasotracheal intubation is more traumatic than orotracheal intubation. For nasotracheal intubation, thermal softening of tracheal tubes made of polyvinyl chloride has been known to be effective to reduce nasal damage and epistaxis, because it makes the tube less stiff and increases flexibility of the tube during nasal passage.[4–6] Likewise, the thermal softening pretreatment of DLTs may be useful for preventing the airway injuries that are associated with the use of DLTs.

Therefore, we hypothesized that thermal softening of DLTs may reduce the airway injuries associated with DLT intubation. This study was performed to investigate whether the use of DLTs softened by warming decreased postoperative sore throat, hoarseness, and vocal cord injuries in patients undergoing one lung anaesthesia.

Methods

Study design

This prospective, double-blind, single-center, parallel-arm, randomized controlled trial was approved by the Institutional Review Board of Seoul National University Hospital (Seoul, Korea) and registered at ClinicalTrials.gov (NCT01626365). After obtaining written informed consents, we enrolled patients with ASA physical status I-III, aged 20–75 yr, and undergoing elective thoracic surgery under one-lung anaesthesia, using left-sided DLTs from May 2012 and April 2013. We excluded patients with pre-existing sore throat, hoarseness, upper respiratory tract infection, cervical spine diseases, presence of tracheostomy, and Mallampati score ≥3. Patients were randomly assigned to one of the two groups in a 1:1 ratio depending on whether the DLT was softened by warming or not before tracheal intubation. All patients were unaware of their group assignment. Group allocation was randomized using a computer-generated randomization code and the sealed envelope method by a clinician not involved in the study.

Thermal softening of double-lumen endobronchial tubes

According to random allocation, all DLTs were pretreated by an assistant who was unaware of the study protocol. After deflating the tracheal and bronchial cuffs, the distal portion of the DLT, from the bronchial tip to the proximal margin of the tracheal cuff, was immersed in sterile normal saline in a bottle for 10 min before tracheal intubation (Fig. 1). The temperature of the saline was manually maintained at 40 (1)°C for the softened group and at operating room temperature for the control group, which were measured via using an aseptic thermometer (Ewha Biomedics, Seoul, Korea). The saline bottle was covered with an opaque insulation blanket made of styrofoam and foil so as to minimize heat loss and to blind the pretreatment of the DLT (Fig. 1). The DLTs were withdrawn from the bottle immediately before tracheal intubation, and, without any lubrication to the cuffs, handed over to one of the two investigators (JHS and JHB) who were blinded to the group assignment.

Anaesthetic management

The DLT size was chosen depending on the sex and height of the patients as follows: 39-Fr for men >178 cm; 37-Fr for men 160–178 cm and women >165 cm; 35-Fr for men ≤160 cm and women 153–165 cm; and 32-Fr for women ≤153 cm.[7 8]

The patients were monitored with electrocardiography, non-invasive bp, pulse oximetry, acceleromyography (TOF-watch SX; MSD BV, Oss, the Netherlands), and a bispectral index monitor (A-2000 XP; Aspect Medical Systems, Newton, MA, USA). In the patients undergoing thoracotomy, epidural catheterization was performed at the level of T4–5 or T5–6 for postoperative pain management.

Fig 1 Treatment of a double-lumen tube before intubation. Only the distal part of the tube was immersed in sterile normal saline (left) and the bottle was covered with an opaque insulation blanket made of styrofoam and foil to minimize heat loss and to blind the pretreatment of the tube (right).

Without premedication, general anaesthesia was induced with target-controlled infusion of propofol and remifentanil; effect-site concentrations of the drugs were adjusted 4–5 mcg ml^{-1} for propofol and 4–5 ng ml^{-1} for remifentanil, respectively. Rocuronium 0.6–0.8 mg kg^{-1} was administered i.v. for neuromuscular block, and train-of-four counts were monitored with acceleromyography at the adductor pollicis muscle. Before tracheal intubation, an otorhinolaryngologist, who was blinded to the group allocation, examined the vocal cords under transnasal flexible laryngoscopy (LF-GP; Olympus Optical Co., Tokyo, Japan) and took the pictures for later comparison.

With the patient's head on a headrest, tracheal intubation was performed using a disposable polyvinyl chloride left-sided DLT (Mallinckrodt endobronchial tube; Covidien, Mansfield, MA, U.S.A.) via direct laryngoscopy using either a Macintosh 3 or 4 laryngoscope blade. After the bronchial tip was inserted through the glottis directing anteriorly, the stylet was removed and the DLT was rotated 90° counterclockwise, directing the bronchial tip to the left side, and then advanced until the pre-estimated depth of insertion.[9] If severe resistance was encountered at the glottis, the DLT was further rotated counterclockwise up to 180° directing the tracheal lumen anteriorly and its advancement through the glottis was attempted.[7] After removing the headrest,[8] the patient's head was placed in the neutral position, and the DLT position was correctly adjusted under fibreoptic bronchoscopy. If the DLT was misdirected into the right bronchus, it was repositioned into the left bronchus under fibreoptic bronchoscopic guidance.

After turning patients to the flexed lateral decubitus position, DLT position was rechecked using fibreoptic bronchoscopy. Tracheal and bronchial intra-cuff pressures were adjusted to less than 25 and 44 cm H_2O, respectively, via using a cuff pressure monitoring device (VBM Medizintechnik GmbH, Sulz am Neckar, Germany).[10 11] During one lung anaesthesia, mechanical ventilation was conducted with a tidal volume 6 ml kg^{-1} and a PEEP 5–10 cm H_2O. The respiratory rate and inspired oxygen fraction were adjusted to obtain arterial tensions of carbon dioxide and oxygen at 5.3–6 and >12 kPa, respectively. Anaesthetic depth was maintained at a bispectral index of 40–60 by adjusting the target effect-site concentrations of propofol and remifentanil. Rocuronium 0.2–0.3 mg kg^{-1} was intermittently administered i.v. at a train-of-four count of ≥1.

Thirty min before the end of surgery, either i.v. or epidural patient-controlled analgesia was initiated for postoperative pain management. The i.v. regimen for thoracoscopic surgery consisted of fentanyl at 10–20 mcg ml^{-1} and morphine at 0.4–0.7 mg ml^{-1}, with a total volume of 100 ml at a continuous infusion rate of 0.5 ml h^{-1} and 1-ml bolus with a lockout interval of 10 min. The epidural regimen for thoracotomy consisted of 0.12% levobupivacaine and fentanyl at 2 mcg ml^{-1}, with a total volume of 500 ml at a continuous infusion rate of 6 ml h^{-1} and 0.5-ml bolus with a lockout interval of 20 min.[7] The patient-controlled analgesia was continued until the third postoperative day.

After the end of surgery, patients were placed in the supine position, and pyridostigmine 0.3 mg kg^{-1} and glycopyrrolate 0.01 mg kg^{-1} were administered to antagonize residual neuromuscular block. Oral secretions were gently suctioned and the trachea was carefully extubated when the train-of-four ratio was >90% and adequate spontaneous breathing and response to verbal commands were confirmed.

Measurement of outcomes

The investigator performing tracheal intubation assessed the laryngoscopic views using the Cormack–Lehane grades and subjectively evaluated the resistance to advancement of the DLT through the glottis as none, mild, moderate, or severe. The intubation time was measured as the duration between inserting the laryngoscope blade into the patient's mouth and removing the blade from the mouth. The mean arterial pressure and heart rate were measured immediately before intubation, and two min after intubation. The number of intubation attempts and incidence of the right bronchial misplacement of DLTs were also recorded.

After tracheal extubation and nasal administration of topical lidocaine spray, the otorhinolaryngologist, who had conducted flexible laryngoscopy before intubation and blinded to the group allocation, re-examined the vocal cord lesions and took the pictures for the comparison with the finding before intubation. The lesions were classified with regard to the side and type as follows: petechiae, small red spots on the mucosa; oedema, swollen mucosa; haematoma, bleeding into the mucosa; granuloma, granulation tissue remained as localised and rounded tissue; and any other lesions.[1 12] If various lesions were observed, only the most predominant lesion was recorded.

At one, two, and three days after surgery, an investigator (CWC), unaware of the group assignment and the presence of vocal cord injuries, asked the patients specific questions about sore throat and hoarseness. Sore throat was defined as continuous throat pain and graded as follows: none, no sore throat; mild, pain with deglutition; moderate, pain constantly present and increasing with deglutition; severe, pain interfering with eating and requiring analgesic medication.[1 3 7] Hoarseness was defined as an acoustic quality differed from the preoperative voice and graded as follows: none, no hoarseness; mild, noticed by patient; moderate, obvious to observer; severe, aphonia.[1 3 7]

Because sore throat and hoarseness were reported to occur most commonly one day after using DLTs,[1 7 13] the primary outcomes of this study were the incidences of sore throat and hoarseness on the first postoperative day and vocal cord injuries after tracheal extubation. The secondary outcomes were the incidences of sore throat and hoarseness on the second and third postoperative days, the severity of these complaints, the type of vocal cord lesions, and intubating conditions such as resistance to advancement of DLTs, intubation time, haemodynamic responses, intubation attempts, and right bronchial misplacement.

Statistical analysis

In a previous study,[1] 44% of patients complained of sore throat on the first postoperative day. When a 50% reduction in the incidence of sore throat was considered to be clinically significant, 70 patients were required in each group with a power of 0.8 and a risk of 0.05 for a type-I error for two-tailed statistical analysis.

Continuous variables were tested for normal distribution using Kolmogorov–Smirnov test and expressed as mean (SD) or median (interquartile range). According to the analysis of distribution, independent Student's *t*-test or Mann–Whitney *U*-test were used to compare statistical differences in continuous variables. Categorical variables were shown as number of patients, and compared using Fisher's exact. For the primary outcomes, the risk ratio with 95% CI were also calculated. A SPSS software (version 19.0; SPSS Inc., IBM, Chicago, IL, USA) was used for the statistical analysis. All reported *P* values were two-sided, and $P<0.05$ was considered statistically significant.

Results

After screening 153 available patients, 13 patients were excluded, 140 eligible patients were randomized (70 patients in each group)

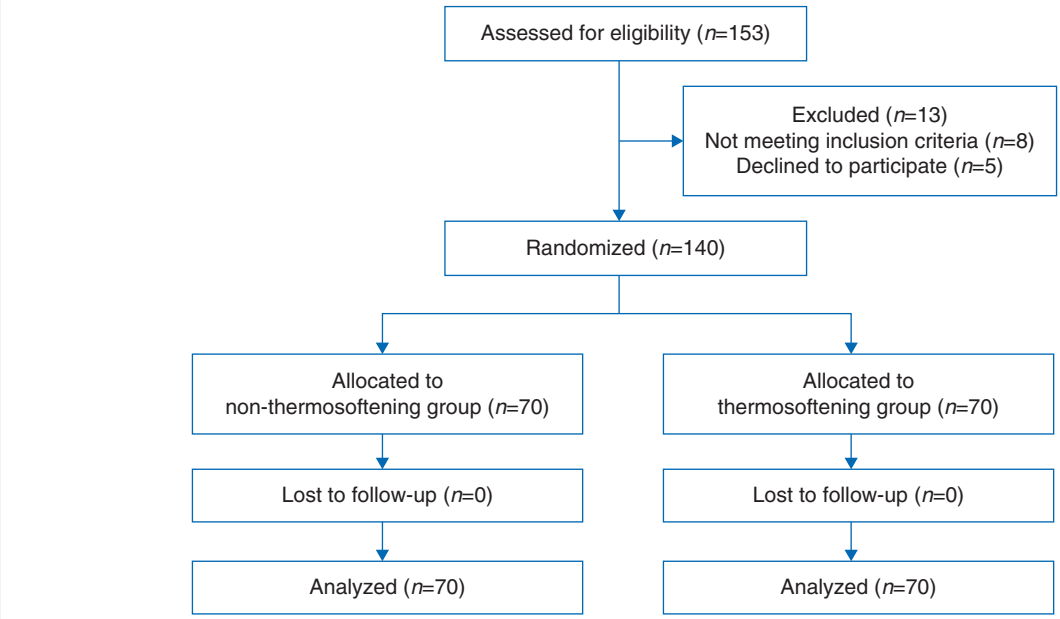

Fig 2 CONSORT diagram.

and completed the study (Fig. 2). There were no significant differences in the baseline characteristics of patients, types of surgery, and postoperative pain managements between the two groups (Table 1).

In all patients, tracheal intubation succeeded at the first attempt. The laryngoscopic view grades, incidence of right bronchial misplacement, intubation time, and haemodynamic responses to intubation were comparable in both groups (Table 2). However, the thermal softened DLTs passed the glottis more smoothly with lower resistance than the non-thermal softened DLTs ($P<0.001$; Table 2). In the five patients with severe resistance (Table 2), the DLT was further rotated 180° counterclockwise at the glottis, thereby advanced through the glottis with mild resistance in three patients and moderate resistance in two patients. In the five patients with right bronchial misplacement (Table 2), the DLT was successfully repositioned into the left mainstem bronchus under fibreoptic bronchoscopic guidance.

After extubation, fewer patients had vocal cord lesions in the thermal softening group than in the control group (15/70 *vs* 27/70, $P=0.042$; Table 3). Specifically, petechiae were observed less frequently in the thermal softening group than in the control group (6/70 *vs* 16/70, $P=0.035$), but the incidences of oedema and haematoma were comparable between both groups (Table 3).

The incidences of sore throat and hoarseness were highest on the first postoperative day and subsequently decreased (Table 4). No patients developed new symptoms on the second and third postoperative days (Table 4). On the first postoperative day, the incidence of sore throat was significantly lower in the thermal softening group than in the control group [14/70 *vs* 27/70, risk ratio (95% CI): 0.52 (0.30–0.90), $P=0.025$]), but did not differ on the second and third postoperative days (Table 4). Although there were no severe incidence in patients, sore throat was generally less severe in the thermal softening group than in the control group on the first postoperative day [56/11/3/0 *vs* 43/18/9/0 (none/mild/moderate/severe), $P=0.035$; Table 4]. The severity of sore throat was similar on the second and third postoperative days (Table 4). Moreover, there were no significant differences between the two groups in the incidence and severity of postoperative hoarseness (Table 4).

Table 1 Characteristics of patients, surgery, and postoperative pain management. Values are shown as mean (SD) or number of patients except age [mean (range)]

	Control (n=70)	Thermal softening (n=70)
Age (yr)	57 (20–74)	58 (23–75)
Sex (male/female)	37/33	40/30
Weight (kg)	62 (9)	60 (10)
Height (cm)	163 (9)	163 (9)
BMI (kg m^{-1})	23.2 (2.8)	22.8 (3.2)
Smoking history	47	44
ASA physical status (I/II/III)	24/33/13	27/36/7
Double-lumen tube size (32/35/37/39-Fr)	8/26/34/2	8/25/34/3
Side of surgery (left/right)	25/45	28/42
Duration of anaesthesia (min)	194 (66)	199 (67)
Patient-controlled analgesia (i.v./epidural/none)	59/10/1	56/12/2

Discussion

Postoperative sore throat is a common complaint associated with tracheal intubation and is more frequent after the use of DLTs rather than the use of single-lumen tubes.[1–3] This complication may reduce the satisfaction of patients immediately after surgery and even after hospital discharge.[10 14] This study showed that,

Table 2 Intubating conditions and haemodynamic responses to intubation of left-sided double-lumen tubes. Values are expressed as number of patients or mean (SD). *P<0.001 by Fisher's exact test

	Control (n=70)	Thermal softening (n=70)
Laryngoscopic view (1/2)	53/17	47/23
Intubation time (s)	29 (9)	29 (10)
Resistance to advance of double-lumen tubes through the glottis (None/mild/moderate/severe)*	29/22/15/4	58/9/2/1
Right bronchial misplacement	3	2
Mean arterial pressure (mm Hg)		
Before intubation	68 (13)	72 (15)
After intubation	85 (16)	84 (18)
Heart rate (beats min^{-1})		
Before intubation	61 (13)	61 (10)
After intubation	73 (14)	73 (12)

Table 3 Incidence and side of postoperative vocal cord lesions. Values are number of patients. If various lesions were observed, only the most predominant lesion was reported. *For the incidence of the lesion in the thermal softening group as compared with the control group. †P=0.035 for the incidence by Fisher's exact test. ‡P=0.042 by Fisher's exact test

	Control (n=70)	Thermal softening (n=70)	Risk ratio* (95% CI)
Petechiae (left/right/both)†	16 (4/6/6)	6 (0/2/4)	0.38 (0.16–0.90)
Oedema (left/right/both)	7 (2/2/3)	6 (1/2/3)	0.86 (0.30–2.42)
Haematoma (left/right/both)	4 (1/2/1)	3 (1/0/2)	0.75 (0.17–3.23)
Total incidence‡	27	15	0.56 (0.32–0.95)

Table 4 Incidence and severity of postoperative sore throat and hoarseness. Values are presented as number of patients. No patients complained newly developed symptoms on the second and third postoperative days. * For the incidence of sore throat or hoarseness in the thermal softening group as compared with the control group. †P=0.025 for the incidence of sore throat by Fisher's exact test. ‡P=0.035 for the severity of sore throat by Fisher's exact test

	Sore throat			Hoarseness		
	Control (n=70)	Thermal softening (n=70)	Risk ratio* (95% CI)	Control (n=70)	Thermal softening (n=70)	Risk ratio* (95% CI)
1st postoperative day†‡ (none/mild/moderate/severe)	27 (43/18/9/0)	14 (56/11/3/0)	0.52 (0.30–0.90)	19 (51/10/9/0)	18 (52/13/5/0)	0.95 (0.54–1.65)
2nd postoperative day (none/mild/moderate/severe)	14 (56/10/4/0)	10 (60/8/2/0)	0.7 (0.34–1.50)	10 (60/8/2/0)	9 (61/6/3/0)	0.90 (0.39–2.08)
3rd postoperative day (none/mild/moderate/severe)	8 (62/6/2/0)	3 (67/3/0/0)	0.38 (0.10–1.36)	6 (64/5/1/0)	6 (64/4/2/0)	1.00 (0.34–2.95)
Total incidence†	27	14	0.52 (0.30–0.90)	19	18	0.95 (0.54–1.65)

compared with non-softened DLTs, intubation with thermally softened DLTs decreased postoperative sore throat. Because thermal softening makes the DLT less stiff, it seems to attenuate airway trauma during intubation, thereby reducing postoperative sore throat. In a previous study,[15] use of silicone rather than PVC DLTs significantly decreased the incidence of postoperative sore throat, which seems to be because of softer characteristics of silicone.

A number of methods for reducing postoperative sore throat have been used for the single-lumen tracheal tubes,[10 16–25] whereas only a few studies have been conducted for DLTs,[7 13 15] despite the fact that intubation of DLTs is more traumatic to the airway. Compared with the known methods for attenuating postoperative sore throat, such as premedication with dexamethasone,[13] 180° rotation technique of DLTs,[7] and use of silicone DLTs,[15] thermal softening is a simple technique that carries no pharmacological side-effects and can be performed at the bedside.

Although any part of the airway can be damaged during intubation, the vocal cords are most vulnerable to trauma because the glottis is the narrowest portion in close contact with the tracheal tube.[26 27] In our study, the softened DLTs passed the glottis more smoothly with lower resistance, and produced fewer petechiae, suggesting less vocal cord trauma in this group. In order to ensure blinding of the intubator, the proximal part of the DLT normally handled was not warmed.

Postoperative sore throat and hoarseness associated with tracheal intubation can be influenced by many other factors, such as gender[28]; size,[29] cuff type,[30] and intra-cuff pressure[31] of tubes; and type[10] or duration[32] of surgery. Among these factors, sore throat may be more directly affected by the physical damage resulting from intubation itself,[7 15 17] whereas hoarseness seems to be more associated with other factors such as smoking history[33] or duration of intubation,[32] which were similar between the two groups. Therefore, thermal softening of DLTs seems to influence the incidence of postoperative sore throat but not hoarseness, which again suggests a reduction in laryngeal trauma.

There are some limitations in our study. First, several outcomes were subjective, such as sore throat, hoarseness, and resistance to DLT advancement through the glottis. Moreover, airway injuries could be caused by DLTs and by any other procedures related to airway management such as extubation, oral suctioning and adjustment of the DLT position. Second, the type of surgery and postoperative patient-controlled analgesia were not controlled during the study. Nevertheless, because of the double-blind randomized controlled study design, the bias caused by these factors could be minimized. Third, the vocal cord lesion was examined only immediately after extubation and its severity was not graded. Furthermore, sore throat and hoarseness were evaluated only for three postoperative days. Therefore, further studies could benefit from longer follow-up until resolution of these complications.

In conclusion, tracheal intubation with thermally softened DLTs decreased the postoperative incidence of sore throat and vocal cord injuries. Therefore, we may recommend the routine use of thermal softening when using DLTs.

Authors' contributions

Study design: J-H.S., Y.J., J-H.B.
Study conduct: C.W.C., D.M.H.
Data analysis: C.W.C., Y.J.
Writing paper: J-H.S., D.M.H.
Revising paper: all authors

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Declaration of interest

None declared.

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