의학석사 학위논문

Combined Effect of Thermosoftening with Dexamethasone on the Larygopharyngeal Injury following One Lung Anesthesia using Double Lumen Tube

Thermosoftening 과 dexamethasone 의 병용이 이중관 튜브를 사용하는 일측폐마취에 따르는 인후두 합병증에 미치는 영향

2015년 2월

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Abstracts

Combined Effect of Thermosoftening with Dexamethasone on the Larygopharyngeal Injury following One Lung Anesthesia using Double Lumen Tube

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Introduction

Hoarseness and sore throat are common layryngopharyngeal complications following endotracheal intubation. Thermosoftening method and intravenous administration of dexamethasone are known to be effective reducing the laryngopharyngeal complications. We combined two methods of thermosoftening of DLT and prophylactic dexamethasone administration 0.1mg/kg to minimize the larynopharyngeal injury during DLT intubation.

Methods

Patients (n=157) undergoing thoracic surgery using DLT were randomized into three groups. Group TD (thermosoftening + dexamethasone), whose DLT was thermosoftened with 40℃ normal saline bottle and received intravenous administration of dexamethasone 0.1mg/kg; Group D (no thermosoftening +

dexamethasone) whose DLT was not thermosoftened and received intravenous administration of dexamethasone 0.1 mg/kg; Group C (no thermosoftening + 0.9% saline) whose DLT was not thermosoftened and received a placebo of 0.9% saline. Hoarseness and sore throat were evaluated until second postoperative days.

Results

The incidence of hoarseness at had significant differences among the three groups (P=0.028). Group TD showed lower incidence of hoarseness at 24 hour compared with Group C (17% vs 42%, P=0.008). The incidence of sore throat was comparable between the three groups.

Conclusions

Combined treatment of thermosoftening and intravenous administration of dexamethasone 0.1 mg/kg can reduce the postoperative hoarseness at 24 hour following one lung anesthesia using double lumen tube.

Keywords : Intubation, Airway management, Anesthesia, General, Dexamethasone, Hoarseness

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Contents

List of Tables

List of Figures

Introduction

Hoarseness and sore throat are common laryngopharyngeal complications following endotracheal intubation.[1, 2] Double lumen tube (DLT) used for lung isolation is known to produce more laryngopharyngeal morbidities than single lumen tube does. [3, 4] DLTs increase the potential to increase the risk of laryngopharyngeal injury due to a larger external diameter, elliptical shape on cross-section view and a tip of the tracheal lumen as an obstacle during passage through glottis.[3, 5]

Dexamethasone is a widely used potent glucocorticoid with analgesic, anti-inflammatory properties. Single dose of intravenous dexamethasone has been used to reduce the incidence and severity of laryngopharyngeal complications with minimal side effects. Though its impact on hoarseness and sore throat remains unclear since the results from different studies used a variety of intravenous dexamethasone dose[6-10], 0.1 mg/kg of dexamethasone seems to be effective showing clinically improved outcomes.[11]

Kim et al.[12] reported that thermosoftening of nasotracheal tube with warm saline can reduce the complication of epistaxis or nasal damage. Because the DLT is made of polyvinyl chloride like nasotracheal tube, we can expect that thermosoftening of DLT will alleviate the laryngopharyngeal damage during endotracheal intubation (IRB H-1204-030-404, not yet published).

Therefore, we set a 3-group study adding thermosoftening method to intravenous administration of dexamethasone 0.1mg/kg. The purpose of this study was to determine combined treatment of thermosoftening and intravenous administration of dexamethasone can reduce the laryngopharyngeal complications following one lung anesthesia using DLT.

Methods

The study protocol was approved by Seoul National University Hospital Institutional Review Board (Ref. H-1311-088-536). After obtaining written informed consents, patients who were scheduled for elective thoracic surgery requiring the placement of a left-sided DLT and aged from 20 to 75 were enrolled in the study from May to October 2014. Any patients with a preexisting hoarseness or sore throat, laryngeal or upper airway disease, symptom of hoarseness or sore throat, allergy to dexamethasone, recent use of corticosteroid, active infection state, recent history of live vaccination were excluded from the study. We also excluded the patients suspected to have difficulties with airway management such as Mallampati score of 3 or 4, long anesthesia time over 6 hours. The patients were randomly assigned to one of the three groups using a computer generated randomization list.

Clinical Procedures

Before the induction of anesthesia, patients were randomly assigned to one of three groups: Group TD (thermosoftening + dexamethasone), whose DLT was thermosoftened at 40℃ normal saline and received dexamethasone 0.1mg/kg; Group D (dexamethasone + 0.9% saline) whose DLT was not thermosoftened and received dexamethasone 0.1 mg/kg; Group C (placebo + 0.9% saline) whose DLT was not thermosoftened and received a placebo of 0.9% saline.

The anesthesiology resident not participating in postoperative patient evaluation prepared the study drugs as a 3ml clear solution in identical syringes. The randomization group and the identity of the study drugs were all blinded from the patients, intubating or participating anesthesiologist during surgery, and the investigator who collected the postoperative data. In group C and group D, DLT was

prepared in a 1L saline bottle stored at room temperature. In group TD, DLT was prepared in a 1L saline bottle warmed to 40℃. Because warmed saline bottle's upper inner surface was vaporized and could be differentiated with cold saline bottle by eyes, external surface was wrapped with a cotton blanket and intubating anesthesiologist could not determine whether the DLT was warmed or not.

The DLT size was selected according to the gender and the height of patients.[13] We used a 39 Fr DLT for men taller than 178 cm; a 37 Fr DLT for men 160–178 cm tall and for women taller than 165 cm; a 35 Fr DLT for men shorter than 160 cm and for women 153–165 cm tall; and a 32 Fr DLT for women shorter than 153 cm.

Patient received no premedication and standard monitoring was established. General anesthesia was induced with total intravenous anesthesia with propofol (Fresofol MCT 2% Inj., Fresenius Kabi, Graz, Austria) and remifentanil (Ultiva®, GlaxoSmithKline, Parma, Italy) at 5 μg/ml and 5 ng/ml, respectively. After confirming the patient's loss of consciousness, rocuronium 0.8mg/kg with study drug (dexamethasone or 0.9% saline for each group) was injected. Tracheal intubation was performed with a disposable polyvinyl chloride left-sided DLT (Broncho-Cath®, Mallinckrodt Medical Ltd., Athlone, Ireland) by an experienced anesthesiologist. The DLTs were initially inserted into the glottis with the bronchial tip directing anterior under direct laryngoscopy using either a Macintosh 3 or 4 laryngoscope blade. After the bronchial tip passed the vocal cords, the stylet was removed and the DLT was rotated 90° counterclockwise and advanced until slight resistance was met. The DLT position was adjusted under direct vision of a fiberoptic bronchoscope (LF-DP or LF-GP, Olympus Optical Co., Tokyo, Japan) after removal of the headrest used during intubation.[14] After completing positional change, the DLT position was reassessed by fiberoptic bronchoscope. Subsequent anesthetic management was performed by the anesthesiologist who was unaware of

the group assignment and not involved in the study. Anesthesia was maintained with propofol and remifentanil and rocuronium was administered at intervals of 30–40 min to maintain neuromuscular block, but it was not given within 1 h of the end of surgery. Immediately after completion of surgery, the patient was repositioned to supine and pyridostigmine 0.3 mg/kg with glycopyrrolate 0.01 mg/kg were administered to reverse neuromuscular block. After gentle suctioning of oral secretions and the DLT was carefully extubated.

Intravenous patient controlled analgesia (IVPCA) or patient controlled epidural analgesia (PCEA) was used to manage postoperative pain. The IVPCA consisted of fentanyl 10~20 mcg/ml and morphine 0.4~0.7 mg/ml with total volume 100 ml at a continuous infusion rate of 0.5 ml/h and a bolus 1 ml with a lockout interval 10 min. The PCEA consisted of 0.12 % levobupivacaine and fentanyl 2 mcg/ml with total volume 500 ml at a continuous infusion rate of 6 ml/h and a bolus 0.5ml with a lockout interval 20 min. The IVPCA or PCEA was maintained until the 3rd postoperative day.

Measurements

During direct laryngoscopy, Cormack and Lehane's grading[15] was used to assess the glottis exposure. The resistance during an advance of DLTs through the glottis was subjectively evaluated as none, mild, moderate, or severe by the intubating anesthesiologist. Severe resistance was defined as the inability to advance DLTs without rotating 180° counterclockwise to direct the tracheal lumen anteriorly and then advanced until the tip of the tracheal lumen passed beyond the vocal cords.[5]

The severity of postoperative sore throat and hoarseness was the primary outcome of this study. A blinded investigator visited and assessed patients for sore throat and hoarseness in the recovery and first, second, third postoperative day. Sore throat was

defined as a continuous throat pain and hoarseness was defined an acoustic quality that was different from the preoperative voice quality of the patient. The examiner recorded the occurrence of sore throat and hoarseness or not.

Statistical analysis

In previous studies by Knoll et al.[3], 44% of patients complained of sore throat 24 hour after DLT intubation. We considered a 50% reduction in the incidence of sore throat to be clinically significant. Assuming a Type-I error protection of 0.05 and a power of 0.80, 46 patients were needed in each group. Considering the drop rate of 10%, we needed 156 patients to enroll. Data were expressed using mean (±standard deviation) for continuous variables as proportions for categorical data. Chi-square test or Fisher's exact test was used to analyze the difference in sex, DLT size, laryngoscopic grade, resistance during DLT advance, surgical side, the incidence of sore throat. Analysis of variance (ANOVA) test was used to analyze the difference in height, body weight, surgical time, anesthesia time with bonferroni correction for the post hoc analysis. For our primary endpoint (sore throat and hoarseness at operation day with the first and second postoperative day) we used a 2×3 chi-square test to compare three groups. SPSS software (version 18.0; SPSS, Inc., 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 278 patients (Fig. 1), seventy-six patients did not meet the inclusion criteria and 45 patients refused to participate. A total of 157 patients were randomized and 18 patients were excluded from analysis. One hundred and thirty-nine patients were finally analyzed; 47 patients were allocated to the group C and 46 patients were allocated to the group D and the group TD, respectively.

Demographic data for the 149 patients are shown in Table 1. There were no differences among the three groups with respect to age, height, weight, sex. Variables associated with tracheal intubation are listed in Table 2. Cormack and Lehane scores, DLT size, resistance, intubation time, type of surgery, surgical side and duration of anesthesia did not differ among the three study groups.

An incidence of postoperative laryngopharyngeal discomfort is listed in Table 3. The symptom of sore throat was maximal at 2 hour (Group C 26% and Group D 33%) or 24 hour (Group TD 28%). The incidence of sore throat at 2 hour, 24 hour, 48 hour after extubation showed no difference among three groups.

The symptom of hoarseness was maximal at 2 hour (Group D 37%) or 24 hour (Group D 42% and Group TD 24%). The incidence of postoperative hoarseness at 24 hour (Figure 2) had significant differences among the three groups (P=0.028). Group TD showed lower incidence of hoarseness at 24 hour compared with Group C (17% vs 42%, P=0.008) but showed little difference compared with Group D (17% vs 28%, P=0.214). Group D had little difference compared with Group C (28% vs 42%, P=0.150). The incidence of postoperative hoarseness at 2 hour and 48 hour showed no significant difference. No patient showed complications associated with the use of dexamethasone or thermosoftening.

Figure 1. CONSORT flow diagram.

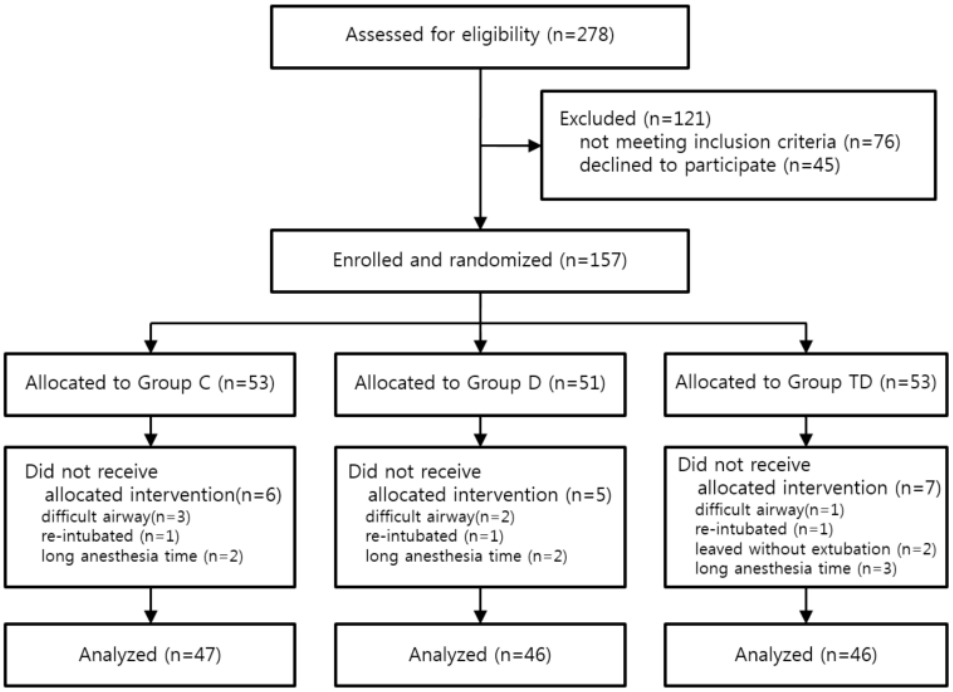


Table 1. Demographic data and patient characteristics.

	Group C (n= 47)	Group D (n= 46)	Group TD (n= 46)	All patients	*p* value
Age(yr)	59.6±12.6	53.9±15.7	56.8±13.2	56.8±14.0	0.144
Height(cm)	162.0±10.5	164.3±10.4	163.5±9.2	163.3±10.0	0.511
Weight(kg)	65.0±31.1	66.4±31.9	60.4±19.2	64.0±26.2	0.525
Sex(male/female)	20/27	25/21	28/18	73/66	0.200
Type of Surgery (VATS/thoracotomy)	41/6	44/2	40/6	125/14	0.311 *
Surgical side (left/right/both)	20/25/2	14/32/0	14/25/4	48/85/6	0.177

Values are expressed as the mean ± SD or number of patients.

Group C, control group (no thermosoftening + 0.9% saline); Group D, dexamethasone group (no thermosoftening + dexamethasone); Group TD, combined treatment group (thermosoftening + dexamethasone)

VATS, video-assisted thoracoscopic surgery.

* Fisher's exact test used instead of Chi-square test

Table 2. Variables associated with tracheal intubation.

	Group C (n= 47)	Group D (n= 46)	Group TD (n= 46)	All patients	*p* value
Laryngoscope grade (Cormack I / II)	34/13	29/17	35/11	98/41	0.343 *
DLT size(32/35/37/39)	3/25/11/8	6/17/14/9	2/19/19/6	11/61/44/23	0.331
Resistance(0/1/2/3)	6/22/17/2	6/27/10/3	15/21/9/1	27/70/36/6	0.100 *
Time to achieve intubation (sec)	28.3±12.3	26.3±10.1	26.2±11.3	27.0±11.3	0.617
Duration of anesthesia(min)	209.4±65.5	190.6±56.8	205.9±72.1	202.0±65.1	0.340

Values are expressed as the number of patients or mean ± SD.

Group C, control group (no thermosoftening + 0.9% saline); Group D, dexamethasone group (no thermosoftening + dexamethasone); Group TD, combined treatment group (thermosoftening + dexamethasone)

DLT, double-lumen endobronchial tube

* Fisher's exact test used instead of Chi-square test

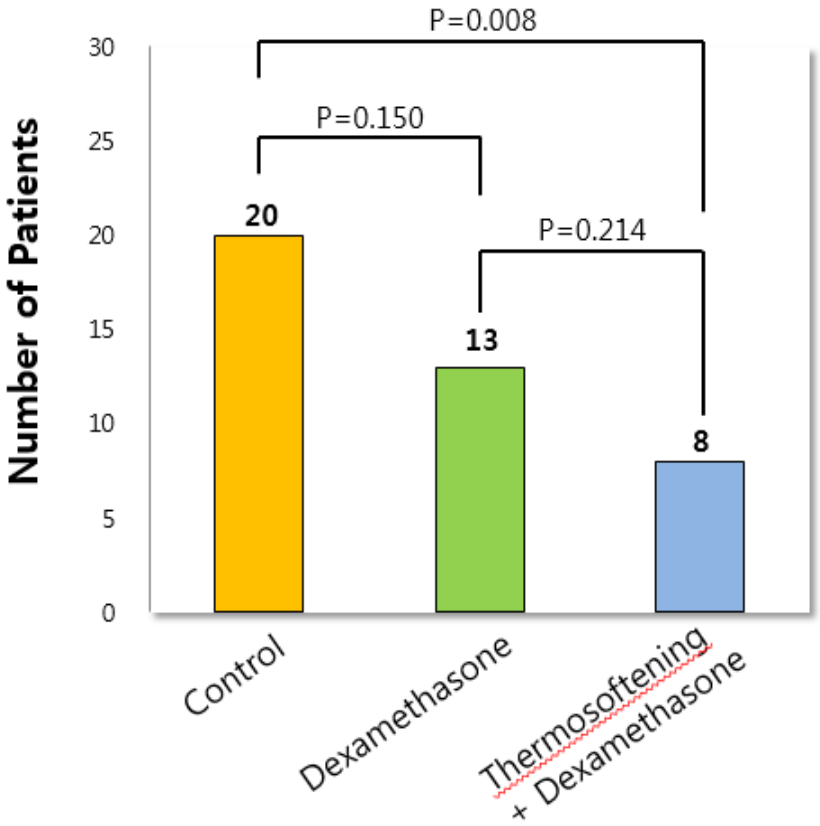
Table 3. Incidence of postoperative laryngopharyngeal complaints for each group.

	Group C (n= 47)	Group D (n= 46)	Group TD (n= 46)	*p* value for Group D vs Group C	*p* value for Group TD vs Group D	*p* value for Group TD vs Group C	Overall *p* value
2 h after extubation							
Sore throat	12(26%)	15(33%)	12(26%)	0.452	0.492	0.951	0.702
Hoarseness	16(34%)	17(37%)	11(24%)	0.769	0.174	0.282	0.369
24h after extubation							
Sore throat	11(23%)	13(28%)	13(28%)	0.593	1.000	0.593	0.829
Hoarseness	20(42%)	13(28%)	8(17%)	0.150	0.214	0.008	0.028
48h after extubation							
Sore throat	9(19%)	7(15%)	9(20%)	0.615	0.582	0.959	0.835
Hoarseness	16(33%)	11(24%)	8(17%)	0.282	0.613	0.115	0.262

Data are number of patients (%).

Group C, control group (no thermosoftening + 0.9% saline); Group D, dexamethasone group (no thermosoftening + dexamethasone); Group TD, combined treatment group (thermosoftening + dexamethasone)

Figure 2. Hoarseness at 24 hours after extubation



Overall *p* value = 0.028

Discussion

There had been no published investigation that evaluated the role of combined treatment of dexamethasone administration and thermosoftening of DLT to reduce the incidence and severity of laryngopharyngeal complications like hoarseness and sore throat after short-term intubation period. The results of this study showed that combined treatment of 0.1 mg/kg of dexamethasone given before tracheal intubation and thermosoftening of a DLT decreased the incidence of postoperative hoarseness 24 hour after endotracheal extubation of the DLT compared with placebo group.

In a previous study[8], 0.1 mg/kg dexamethasone was effective for reducing the sore throat and hoarseness 1 hour after DLT extubation compared with placebo group. In our study, 0.1 mg/kg dexamethasone monotreatment had a tendency to reduce hoarseness compared with placebo group at 24 hour (42% vs 28%, P=0.150) and 48 hour (33% vs 24%, p=0.282) but statistically not significant. The difference of two study results may have originated from the difference of intubation and manipulation technique of DLT, clinical procedural settings or proceduring anesthesiologist.

There is a large variation in the reported incidence (24~57%) of sore throat immediately after short term DLT intubation.[3, 5, 8, 16, 17] In our current study, the overall incidence of posteoperative sore throat was 26% in the group C (placebo). The reasons for the low incidence of postoperative sore throat in our study may be difference of induction protocol, intubation technique and a use of postoperative IVPCA, PCEA or additional analgesics, marginal effective dose of intravenous dexamethasone, but the practical reason for the different result from the previous studies could not be identified.

Thermosoftening of nasotracheal tube with warm saline can reduce the complication of epistaxis or nasal damage.[12] Thermosoftening is a simple method to apply in the clinical practice with no potential complication. Because the DLT is made of polyvinyl chloride like nasotracheal tube, we expect that the thermosoftend DLT will reduce direct physical damage to the vocal cords during endotracheal intubation. Considering the result that combined treatment of thermosoftening and dexamethasone 0.1 mg/kg decreases the hoarseness following DLT intubation compared with placebo group, thermosoftening may have benefit in reducing the damage during the intubation of DLT. Because the damage to the vocal cord can be a large contributing factor to the laryngopharyngeal complications like sore throat and hoarseness[5], softening of DLT by thermosoftening and anti-inflammatory effect of dexamethasone may act synergistically to minimize the vocal cord damage and following inflammatory reaction like edema.

In a previous single lumen tube study[18], the incidence and severity of postoperative sore throat and hoarseness after endotracheal intubation was reduced by the use of small tubes. The use of a DLT has been considered as a major risk factor for a higher frequency of postoperative hoarseness and sore throat compared with a single lumen tube due to its large outer diameter (13–14 mm for 37 French and 12–13 mm for 35 French DLTs versus 10 mm for ID 7.5mm and 9.3 mm for ID 7.0 mm of single lumen tubes). Additional investigated risk factors of the postoperative sore throat and hoarseness are sex[19, 20], duration or type of surgery[21, 22], tracheal tube size[18], intubating condition[23]. Risk factors known to contribute to vocal cord injuries were controlled in the current study. Additionally we excluded 6 patients with a laryngoscopic view grade 3 or more according to the Cormack and Lehane to avoid difficult airway interfere the results.

The word ‘sore throat’ is a simple description for broad spectrum of signs and symptoms. It seems to originate from oral mucositis, pharyngitis, laryngitis, tracheitis or dysphagia as a result of mucosal injury with resulting inflammation caused by the procedure of laryngoscopy, suctioning or irritating foreign object (endotracheal tube, LMA or oral airway).[24] Though sore throat is a frequently complained complications from multiple causes following general anesthesia, it has subjective portion in its nature. On the other hand, hoarseness is a more direct evidence of damage confined to larynx.[25] Furthermore, hoarseness can be evaluated obviously by an observer and pathologic changes in the larynx can be assessed via an endoscopy if needed. Considering the difference of characteristics between sore throat and hoarseness, it appears that hoarseness can be a more reliable marker than sore throat in evaluating the postoperative laryngopharyngeal injury following general anesthesia.

A total of three anesthesiologists participated in the process of intubation. About the half of intubation of performed by Chung YS (n=73, 52.5%) and Seo JH performed 46 intubations (33.1%) and Cho CW performed 20 intubations (14.4%). Although statistical analysis showed no difference on the primary outcome of hoarseness and sore throat between three anesthesiologists, these operator’s different intubation skill or subtle technical tendency could influence the outcome.

Dexamethasone is a steroidal agent used for decades and its pharmacological characteristics are relatively well known. The potential side effects of dexamethasone are hyperglycemia, peptic ulcer, susceptibility to infection, electrolyte imbalance. But those side effects are observed only in a long term use of high dose dexamethasone. We used minimal dose of dexamethasone (0.1mg/kg) to minimize the potential side effects. Although our study’s follow-up was only for 48 hour and we did not have large enough patient sample size, we could not observe

any complications associated with a single use of dexamethasone (0.1 mg/kg) in this study.

The study has several limitations. First, the primary endpoints were patient's reports of subjective hoarseness and sore throat. Secondly, our results had partially negative or statistically insignificant results of primary endpoint, we cannot exclude that the sample too small to discriminate the difference. Third, the use of analgesics may affect the incidence of sore throat because we did not compare the total dose of PCA or additional analgesics used for postoperative pain control.

Conclusion

In conclusion, combined treatment of thermosoftening and intravenous administration of dexamethasone 0.1 mg/kg can reduce the postoperative hoarseness at 24 hour following one lune anesthesia using double lumen tube. We recommend that anesthesiologist might consider using combined method of thermosoftening and minimal dose of intravenous dexamethasone during intubation of DLT.

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국문초록

배경

목쉼과 인후통은 기관내 삽관을 시행할 때 생기는 바람직하지 않은 인후두 합병증들이다. 기관내 삽관 튜브를 thermosoftening시키는 방법과 정맥내 dexamethasone을 투여하는 방법은 각각 인후두 합병증을 줄이는 데 효과가 있는 것으로 알려져 있다. 저자들은 이중관 튜브의 기관내 삽관시 생기는 후두 손상을 줄이기 위하여 이중관 튜브를 Thermosoftening시키는 방법과 0.1 mg/kg의 dexamethasone을 정주하는 방법을 동시에 시행하여 효과를 평가하였다.

방법

흉부 수술을 받는 DLT를 사용하는 157명의 환자를 대상으로 하여 세 그룹을 설정하였다. Group TD는40℃의 생리식염수에 DLT를 담궈놓아 thermosoftening을 하면서 intubation 전에 0.1 mg/kg의 dexamethasone을 투여하였으며, Group D는 상온의 생리식염수에 DLT를 담궈놓고 intubation 전에 0.1 mg/kg의 dexamethasone을 투여하였고 Group C는 상온의 생리식염수에 DLT를 담궈놓고 intubation 전에 생리식염수를 투여하였다. 수술후 2째날까지의 목쉼과 인후통을 평가하였다.

결과

발관 후 24시간째에 평가하였을 때 세 그룹간의 목쉼 증상은 유의한 차이를 보였다 (P=0.028). Group TD는 Group C에 비하여 낮은 목쉼 증상 발생률을 보였다 (17% vs 42%, P=0.008). 세 그룹간에 인후통의 발생은 유의

한 차이를 보이지 않았다.

결론

Thermosoftening과 dexamethasone 0.1 mg/kg정주법의 병용은 이중관 튜브를 이용하여 일측폐마취를 받은 환자에서의 술후 24시간째의 목쉼 증상을 줄인다.

주요어 : Intubation, Airway management, Anesthesia, General, Dexamethasone, Hoarseness

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