Correlations Between Controlled Endotracheal Tube Cuff Pressure and Postprocedural Complications: A Multicenter Study

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BACKGROUND: Postoperative respiratory complications related to endotracheal intubation usually present as cough, sore throat, hoarseness, and blood-streaked expectorant. In this study, we investigated the short-term (hours) impact of measuring and controlling endotracheal tube cuff (ETTc) pressure on postprocedural complications.

METHODS: Five hundred nine patients from 4 tertiary care university hospitals in Shanghai, China, scheduled for elective surgery under general anesthesia were assigned to a control group without measuring ETTc pressure, and a study group with ETTc pressure measured and adjusted. The duration of the procedure and duration of endotracheal intubation were recorded. Twenty patients whose duration of endotracheal intubation was between 120 and 180 minutes were selected from each group and examined by fiberoptic bronchoscopy immediately after removing the endotracheal tube. Endotracheal intubation–related complications including cough, sore throat, hoarseness, and blood-streaked expectorant were recorded at 24 hours postextubation.

RESULTS: There was no significant difference in sex, age, height, weight, procedure duration, and duration of endotracheal intubation between the 2 groups. The mean ETTc pressure measured after estimation by palpation of the pilot balloon of the study group was 43 ± 23.3 mm Hg before adjustment (the highest was 210 mm Hg), and 20 ± 3.1 mm Hg after adjustment (P < 0.001). The incidence of postprocedural sore throat, hoarseness, and blood-streaked expectoration in the control group was significantly higher than in the study group. As the duration of endotracheal intubation increased, the incidence of sore throat and blood-streaked expectoration in the control group increased. The incidence of sore throat in the study group also increased with increasing duration of endotracheal intubation. Fiberoptic bronchoscopy in the 20 patients showed that the tracheal mucosa was injured in varying degrees in both groups, but the injury was more severe in the control group than in the study group.

CONCLUSIONS: ETTc pressure estimated by palpation with personal experience is often much higher than measured or what may be optimal. Proper control of ETTc pressure by a manometer helped reduce ETT-related postprocedural respiratory complications such as cough, sore throat, hoarseness, and blood-streaked expectoration even in procedures of short duration (1–3 hours). (Anesth Analg 2010;111:1133–7)

The purpose of cuff inflation after endotracheal intubation is to prevent air leakage, thus ensuring the effect of ventilation and reducing the leakage of inhalation anesthetics. However, severe overinflation of the endotracheal tube cuff (ETTc) imparts risk for serious or even fatal injury1 and affects blood flow supply to the tracheal mucosa, resulting in tracheal mucosal ischemia, ulceration, necrosis, tracheoesophageal fistula,2,3 or tracheal rupture.4,5 This has been shown primarily for patients with prolonged (days) endotracheal intubation.1–8 For brief procedures lasting only a few hours, most clinicians give little attention to inflation pressure of the ETTc and simply determine the pressure by pilot bulb palpation according to their experience. Studies by faculty anesthesiologists, anesthesia residents,9 and critical care unit staff10–12 have demonstrated a prevalent inability of these clinicians to accurately determine ETTc pressure by pilot balloon palpation. No large prospective study assessing short-term benefits of measuring ETTc pressure has been reported. In this multicenter study, we studied the importance of monitoring and controlling ETTc pressure in reducing endotracheal intubation–related respiratory complications including cough, sore throat, hoarseness, and blood-streaked expectoration on a short-term basis.

METHODS

Subjects

This was a randomized, prospective, and observational study of the correlation between ETTc pressure control and postprocedural complications. This study was approved by

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the Local Ethics Committee of Tongji University and Jiaotong University in Shanghai, China. Informed consent was obtained from all patients who participated in the study. Subjects were 18 years or older (ASA physical status I–II) from 4 tertiary university hospitals in Shanghai, China and scheduled for general anesthesia. Exclusion criteria included patients who had cough and sore throat before operation, those who experienced double-lumen endobronchial intubation, difficult endotracheal intubation and repeated endotracheal intubation, and those who were scheduled to undergo oral and laryngopharyngeal surgery.

Anesthesia Methods

All patients were scheduled for general anesthesia. Patients were intubated after anesthesia induction with midazolam 3 to 5 mg, etomidate 0.3 mg/kg, vecuronium 0.1 to 0.15 mg/kg, and fentanyl 4 µg/kg. The ETT (inner diameter 7.0–8.0 mm, RUSCH sterile ETT with a high-volume low-pressure cuff, Malaysia) was selected individually (male 7.5–8.0, female 7.0–7.5). After endotracheal intubation, mechanical ventilation was provided by connecting the tube to the anesthesia machine (S/5 Aespire; Datex-Ohmeda, Madison, WI). Anesthesia was maintained by an IV infusion of propofol 2 to 4 mg/kg/h and inhalation of Ohmeda, Madison, WI). Anesthesia was maintained by an IV infusion of propofol 2 to 4 mg/kg/h and inhalation of nitrous oxide was not allowed during the operation.

Electrocardiography, noninvasive arterial blood pressure, and peripheral oxygen saturation were measured during anesthesia. End-tidal PCO2 was detected after endotracheal intubation and adjusted to 30 to 35 mm Hg during the operation.

Protocols

Patients were randomized by means of individually prepared envelopes to either the control or study group. The researcher was not blinded to the group assignment; however, all of the other participants including anesthesiologists, follow-up resident physicians, and fiberoptic bronchoscopists were not aware of the assignment. The ETTC in the control group was inflated by the anesthesiologist according to his/her personal experience using the pilot balloon palpation method without any assistance of instrumentation, whereas that in the study group was inflated first by the anesthesiologist and then adjusted once by the researcher with a sensitive and accurate manometer (XB-11B; Shanghai Medical Instruments Co., Ltd., Shanghai, China) within the range of 15 to 25 mm Hg. Air leakage around the ETT was monitored with a stethoscope. Operation duration and duration of endotracheal intubation were recorded in both groups. ETTC pressure was measured soon after initial inflation of the cuff and again after adjustment in the study group. A resident physician was assigned to follow up the patients with a structured questionnaire and record endotracheal intubation-related respiratory complications including cough, sore throat, hoarseness, and blood-streaked expectoration 24 hours postextubation.

Twenty patients whose duration of endotracheal intubation was between 120 and 180 minutes were selected randomly from each group and examined by fiberoptic bronchoscopy (Pentax FB-15RBS; Asahi Optical Corp., Tokyo, Japan) immediately after removal of the tube to observe the degree of injury to the tracheal mucosa.

Data Analysis

The analysis was performed using SPSS 14.0 (Tongji University, Shanghai, China). The data obtained were entered into the databank and checked for use. Data are expressed as mean ± SD. The t test or single-factor analysis of variance was used to compare continuous variables. The χ2 test was applied for categorical data. P < 0.05 was considered statistically significant.

RESULTS

Study Population

Of 509 patients evaluated, 273 (male/female 112/161) were in the control group and 236 (male/female 81/155) were in the study group. The male-to-female ratio within the group was imbalanced; there were significantly more female patients than male patients in both groups. There was no significant difference in age, sex, body height, body weight, operation duration, and duration of endotracheal intubation between the 2 groups (Table 1). In the study group, the mean measured ETTC pressure when estimated by pilot balloon palpation was 43 ± 23.3 mm Hg before adjustment (the highest was 210 mm Hg) and 20 ± 3.1 mm Hg after adjustment (P < 0.001).

Complication Incidence

There was no significant difference in the incidence of coughing 24 hours postextubation between the 2 groups. The incidences of sore throat, hoarseness, and blood-streaked expectoration 24 hours after extubation in the study group were 34%, 3%, and 4%, respectively, which were significantly lower than 44%, 11%, and 11% in the
The incidence of cough, sore throat, and blood-streaked expectoration increased with the increasing duration of endotracheal intubation in both groups. When the duration of endotracheal intubation was longer than 180 minutes, the incidence of sore throat and blood-streaked expectoration in the control group increased significantly ($P < 0.005$), and the incidence of sore throat in the study group also increased ($P < 0.001$). Correlations between the duration of endotracheal intubation and complication incidence in the 2 groups are shown in Table 3.

**Fiberoptic Bronchoscopic Examination**

Different changes of injury to the tracheal mucosa were observed by fiberoptic bronchoscopy in both groups (Figs. 1–3), but the injury in the study group was less severe than in the control group ($P = 0.043$). Based on the findings by fiberoptic bronchoscopy, we define solitary, diffuse, and pinpoint congestion as sporadic spots of congestion, and nonsolitary and fused congestion as local patchy congestion. Sporadic spots of congestion in the tracheal mucosa were observed in 8 patients of the control group and 15 patients of the study group (Fig. 1). When only this pattern of injury was present, the patients did not complain of cough, sore throat, hoarseness, and blood-streaked expectoration 24 hours after removing the ETT. Local patchy congestion of the tracheal mucosa was observed in 9 patients of the control group and 5 patients of the study group (Fig. 2). These patients complained of sore throat 24 hours after removing the ETT. Formation of patchy hemorrhagic ulceration was observed in 3 patients of the control group and none in the study group (Fig. 3). These patients complained of sore throat and blood-streaked expectoration 24 hours after removing the ETT.

**Table 3. Correlations Between the Duration of Endotracheal Intubation and the Incidence of Complications Between the Two Groups**

<table>
<thead>
<tr>
<th>Duration of endotracheal intubation (min)</th>
<th>Control group</th>
<th>Study group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤180</td>
<td>&gt;180</td>
</tr>
<tr>
<td>Cases</td>
<td>181</td>
<td>92</td>
</tr>
<tr>
<td>Cough (%)</td>
<td>26 (14)</td>
<td>11 (12)</td>
</tr>
<tr>
<td>Sore throat (%)</td>
<td>68 (38)</td>
<td>51 (55)*</td>
</tr>
<tr>
<td>Hoarseness (%)</td>
<td>16 (8)</td>
<td>14 (15)</td>
</tr>
<tr>
<td>BSE (%)</td>
<td>13 (7)</td>
<td>17 (18)*</td>
</tr>
</tbody>
</table>

Intragroup comparison. * $P < 0.05$.

BSE = blood-streaked expectoration.
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DISCUSSION
Cough and sore throat are common complaints after endotracheal intubation under general anesthesia, and the incidence of sore throat is as high as 30% to 55%. In this study, the incidences of sore throat and blood-streaked expectoration 24 hours after extubation were 34% and 4%, respectively, in the study group and 44% and 11%, respectively, in the control group. The probable causes could include mechanical compression by the cuff, the tube itself, and physiochemical stimulation by tube additives. Clinical symptoms are most prominent 24 hours after removing the tube. It has been reported that excessive inflation of the ETTc would produce high pressure on the tracheal wall, thus affecting blood perfusion of the tracheal mucosa resulting in ischemic necrosis of the tracheal mucosa. When the pressure in the ETTc exceeds 22 mm Hg, blood flow in the tracheal mucosa begins decreasing and reduces markedly when the pressure reaches 30 mm Hg. When the pressure in the cuff reaches 50 mm Hg for 15 minutes, ischemic injury to the tracheal mucosa would occur. During prospective evaluation of postoperative tracheal pain and its relationship to ETTc pressure, we found a correlation between excessive ETTc pressure and the presence of tracheal pain 1 hour and 24 hours after extubation. However, it is uncertain whether there is a good correlation between the degree of mucosal damage and the severity of patient symptomatology because symptoms are always subjective. In addition, the incidence of hoarseness in the control group was significantly higher than that in the study group. Previous studies also reported that hoarseness was related to increased cuff pressure. The actual reason for this needs to be determined because the ETTc is below the glottis, and thus should not affect voice changes significantly. The main cause of hoarseness is edema of the vocal cords from endotracheal intubation, mechanical contact, and abrasion of the tube in the glottal area.

It was our hypothesis that an appropriate ETTc pressure even in short procedures would reduce endotracheal intubation–related morbidity. At present, the recommended ETTc pressure is 15 to 25 mm Hg. The volume of cuff inflation should preferably not be fixed. To allow effective ventilation, the cuff should be inflated just until it prevents an air leak, so, in this study, we controlled the ETTc pressure to no more than 25 mm Hg in the study group without noticeable air leakage.

Although it is recommended that ETTc pressure should be measured routinely after endotracheal intubation, it is not done in most hospitals. Instead, the pressure is usually estimated by the anesthesiologist according to his/her personal experience using the pilot balloon palpation method. Sole et al. reported that personal experience could ensure ETTc pressure within the recommended range of 15 to 25 mm Hg in only 54% of patients. Svenson et al. reported that ETTc pressure was by far higher than 30 mm Hg in 58% of patients. In the control group of this study, ETTc pressure was determined by the anesthesiologist according to his/her experience using palpation of the pilot balloon. In the study group, the mean ETTc pressure estimated by pilot balloon palpation was 43 ± 33.3 mm Hg (the highest was 210 mm Hg) before adjustment, confirming that cuff inflation according to personal experience is significantly higher than the normal limitation. The ETTc pressure after adjustment of the study group was 20 ± 3.1 mm Hg (<25 mm Hg), and the incidences of sore throat, hoarseness, and blood-streaked expectoration 24 hours postextubation were 34%, 3%, and 4%, respectively, which were significantly lower than 44%, 11%, and 11% of the control group. Fiberoptic bronchoscopic examination also showed that injury to the tracheal mucosa was more severe in the control group than in the study group (P = 0.043), indicating that routine monitoring of ETTc pressure after endotracheal intubation even during brief surgical procedures is helpful in reducing postoperative intubation–related respiratory complications.

The results of this study also suggest that the incidence of sore throat and blood-streaked expectoration 24 hours after removing the ETT increased with increasing duration of endotracheal intubation in the control group, and the incidence of sore throat also increased in the study group, especially when the duration of endotracheal intubation was longer than 180 minutes. This observation may mean pressure and time are both important variables in producing morbidity after endotracheal intubation. This is presumably attributable to prolonged time of compression on the trachea and worsening of local ischemia. Based on the findings of this study, it seems prudent to use a manometer to establish and maintain ETTc pressure.

This study has some limitations. No histological study was performed because of ethical considerations in patients with tracheal mucosal injuries as observed by fiberoptic bronchoscopy to confirm the severity of injury. Also, it would have been valuable to measure ETTc pressure in the control group before extubation and compare this value with that in the study group. In addition, these patients were followed up for only 24 hours without a longer follow-up plan to observe their full recovery time and long-term complications.

In conclusion, ETTc pressure estimated by clinical judgment is often much higher than the optimal values to prevent tracheal injury. This study also demonstrated that proper control of ETTc pressure by a manometer even in procedures lasting only a few hours helps to reduce postprocedural endotracheal intubation–related complications.

AUTHOR CONTRIBUTIONS
JL helped conduct the study and write the manuscript. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript. XZ helped design the study. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript. SF helped design the study and conduct the study. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript. FW helped conduct the study. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript. WG helped conduct the study. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript. MZ helped conduct the study. This author has seen the original study data, reviewed the analysis of the data.
and approved the final manuscript. YH helped design the study. This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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REFERENCES