Introduction

Minimally invasive thoracic surgery is the recent trend and it may lead to postoperative pain reduction, shorter hospitalization, and quicker functional and social recovery. For minimally invasive thoracic surgery, staplers are considered essential. Stapling in the management of the lung parenchyma and bronchi was first reported in early 1960s.1,2) As the staplers became more sophisticated, the use of staplers has been widely accepted and regarded as a safe procedure.3,4) Now, the widespread use of video-assisted thoracic surgery (VATS) is supported by the frequent use of staplers. However, sometimes stapling failure or other adverse events (AEs) of stapling are experienced. Only a few papers have been published concerning stapling failure and other AEs of stapling.5–8) The aim of the present study is to analyze the intraoperative and postoperative AEs of stapling in thoracic surgery.

Purpose: The use of staplers for thoracic surgery has been widely accepted and regarded as a safe procedure. However, sometimes adverse events (AEs) of stapling are experienced. The aim of the present study was to retrospectively analyze AEs of stapling in thoracic surgery.

Methods: A retrospective multi-institutional review was conducted by the 27 institutions of the Central Japan Lung Cancer Surgery Study Group. Between January 2009 and December 2010, 4495 patients underwent thoracic surgery using mechanical stapling.

Results: Stapling of various tissues was performed 16403 times. Total number of AEs related to stapling was 126 (0.77%). One hundred and nine events occurred intraoperative and 17 events occurred postoperative. The AE rates ranged from 0% to 1.8%. No relationship was seen between the incidence of AE and a stapling volume of thoracic surgery.

Conclusion: We have investigated intraoperative and postoperative AEs of stapling. Generally, stapling in thoracic surgery was safe. An AE rate of stapling in thoracic surgery is not influenced by the numbers of stapling in institutions.

Keywords: adverse event, thoracic surgery, stapler
surgery and to determine the relation between the incidence of AEs and a surgical volume of thoracic surgery.

Materials and Methods

A retrospective institutional review was conducted by each of the 27 institutions which participated in the Central Japan Lung Cancer Surgery Study Group. The present study was approved by the Institutional Review Board (IRB) of Nagoya City University Hospital and other institutions. Between January 2009 and December 2010, 4495 patients underwent thoracic surgery using a mechanical stapler in these 27 institutions. In these thoracic operations for 4495 patients, 16403 staplings were performed for the various tissues.

The underlying diseases of the 4495 patients included lung cancer (n = 2508), pneumothorax (n = 923), metastatic lung tumor (n = 478), inflammatory pulmonary disease (n = 217), benign lung tumor (n = 134), mediastinal tumor (n = 89), and other diseases (n = 146). Cofactors which might have influenced AEs of stapling were preoperative chemotherapy (n = 121), preoperative radiotherapy (n = 31), diabetes (n = 291), and severe complications (n = 213).

As AEs of intraoperative stapling, stapling failure, oozing, air leakage, laceration, technical tissue injury at insertion, and rupture of the stamp were assumed and reported. Stapling failure was defined as incomplete stapling with incomplete fastening of staples by any cause, for example, stapler defect, inappropriate usage of staplers and so on. Oozing was defined as small bleeding from the stamps or splinter points of the staples. Only the cases with additional procedures of hemostasis, ligation, suturing or a use of an absorbable fibrin sealant patch were reported. Air leakage was defined as air leakage from the stamps or splinter points of the staples. Air leakage in the intraoperative AE was limited only in the cases with additional procedures of suturing or a use of an absorbable fibrin sealant with major air leakage. Air leakage in the postoperative AE was limited only in the cases with prolonged air leakage postoperatively. Such judgment was entrusted by reporters. Laceration was defined as an injury of tissues with bleeding or air leakage not from the stamps or splinter points of the staples. Laceration occurs during the stapling process from compression to release of the staplers. It was distinguished from tissue injury by a tip of a stapler at insertion which was caused by technical failure. Technical tissue injury was defined as tissue injury which occurred before the stapling process by technical failure. Rupture was defined as the open stamp after completion of stapling. As postoperative AEs, AEs which occurred within 30 days postoperatively were reported.

Statistical Analysis

The significance of differences between categorized groups was evaluated using a x² test and Fisher's direct method. The relations between the numbers of staplings and incidence of AEs were assessed by a simple regression method. Statistical significance was defined as p < 0.05.

Results

In the operation for 4495 patients, 16403 times of stapling were performed (mean, 3.6 staples per patient). Thirty-two kinds of staplers with various cartridge lengths and colors were used. All staplers were produced by Covidien (Mansfield, Massachusetts, USA) or Ethicon Endo-Surgery (Cincinnati, Ohio, USA). Among the 16403 staplings, 10908 (66.5%) staplings were for the lung, 2030 (12.4%) for the bronchus, 1580 (9.6%) for the pulmonary artery, and 1813 (11.1%) for the pulmonary vein (Table 1).

Total number of AEs related to stapling was 126 (0.77%). Of this, 109 events occurred intraoperative and 17 events occurred postoperative.

The intraoperative AEs were air leakage (n = 46), stapling failure (n = 28), laceration of the adjacent tissue (n = 24), oozing (n = 7), and others including an event of technical tissue injury at insertion (n = 4) (Fig. 1A). The postoperative AEs were prolonged air leakage (n = 9), bronchopleural fistula (BPF) (n = 4), bleeding from the chest wall (intercostal artery) (n = 2), suture line rupture (n = 2) (Fig. 1B).

There were significant differences of the incidence of total AEs, intraoperative AEs, stapling failure, and postoperative AEs (Table 1). Total AEs and intraoperative AEs occurred more frequently in the bronchus than other tissues. There was no significant difference of the incidence of postoperative AEs between the tissues.

The numbers of staplings and AE in institutions were plotted in Fig. 2. There was a positive correlation between the numbers of staplings and AE (p = 0.0035). The number of staplings and AE rates in institutions were plotted in Fig. 3. There was no correlation between the number of staplings and AE rate (p = 0.510). The AE
Table 1  Adverse events of stapling in thoracic surgery

<table>
<thead>
<tr>
<th>Tissues</th>
<th>Number of stapling</th>
<th>Number of intraoperative AEs</th>
<th>Number of postoperative AEs</th>
<th>Number of total AEs</th>
<th>Stapling AE rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary parenchyma</td>
<td>10908 (66.5%)</td>
<td>70</td>
<td>11</td>
<td>81</td>
<td>0.74</td>
</tr>
<tr>
<td>Bronchus</td>
<td>2030 (12.3%)</td>
<td>31</td>
<td>5</td>
<td>36</td>
<td>1.8</td>
</tr>
<tr>
<td>Pulmonary vessels</td>
<td>3393 (20.7%)</td>
<td>8</td>
<td>1</td>
<td>9</td>
<td>0.27</td>
</tr>
<tr>
<td>Others</td>
<td>72 (0.7%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>16403 (100%)</td>
<td>109 (0.66%)</td>
<td>17 (0.10%)</td>
<td>126 (0.77%)</td>
<td>0.77</td>
</tr>
</tbody>
</table>

Total AEs and differences of tissues: p < 0.0001; Intraoperative AEs and differences of tissues: p < 0.0001; Postoperative AEs and differences of tissues: p = 0.118; AE: adverse event.

Fig. 1  Intraoperative and postoperative adverse events (AE). (A) intraoperative adverse events, (B) postoperative adverse events.

Fig. 2  The relation between the numbers of stapling and AE. AE: adverse event.

Y = −.307 + .008 X; R² = .294

Fig. 3  The relation between the number of stapling and AE rate. AE: adverse event.

Y = .006 + 2.316E−6 X; R² = .018
rates ranged from 0% to 1.8%. There was no relation between the number of stapling and an incidence of AEs in institutions.

**Discussion**

Although stapling in thoracic surgery is a frequently performed procedure, AEs are sometimes encountered. It can be serious and even fatal. There have been no large scale reports of AEs of staplings in thoracic surgery. This is the first multi-institutional report of AEs in the stapling of pulmonary vasculatures in thoracic surgery. Till date, only a few institutional reports have been published concerning to AEs of stapling. Asamura, et al. reported the rate of the stapling misfire for pulmonary vasculatures as 0.1%. Szwerc, et al. also reported only one case of misfire in 2548 staplings for the pulmonary vasculatures and the rate of intraoperative AEs was 0.27%. The rate of AEs in stapling for pulmonary vessels seemed to be lower than for the pulmonary parenchyma or the bronchus. We planned the present study to determine the rates of AEs rates of stapling in usual clinical settings.

Over sixteen thousand staplings were performed and 125 AEs occurred (0.76%). Most of the staplings were for the lung parenchyma. The rate of the AEs was the highest for the bronchus. Pulmonary vessel stapling was safely performed. The stapling failure rate and AE rate were similar to other reports. In the present study, the incidence of AEs may be evaluated too few. Especially, the intraoperative air leakage from the pulmonary stamps or splinter points of the staples seems to be the most likely candidate. Minor intraoperative air leakage from the pulmonary stump or splinter points was not recorded in the surgical records. Therefore, the incidence of air leakage may mean only major air leakage in the present study. While the results of this study are encouraging, it is acknowledged that any conclusions should be tempered by the limitation of a retrospective study. It is also difficult to apply the same definition of AE or causes of AEs in all institutions.

There were mainly 5 patterns of AEs occurred intraoperatively, air leakage (42.2%), stapling failure (25.7%), laceration of the adjacent tissue (22.0%), oozing (6.4%) and others (3.7%). There were 4 patterns of AEs occurred postoperatively, air leakage prolongation (52.9%), bronchopleural fistula (23.5%), bleeding from chest wall (11.8%), suture line rupture (11.8%). In the 2 cases with postoperative AEs by Duet TRSTM, it was demonstrated at reoperation that buttress material of the Duet TRSTM induced bleeding from chest wall (intercostal arterial bleeding). The postoperative bleeding has been reported elsewhere in other cases using Duet TRSTM. In Japan, Duet TRSTM has been recalled by the company and its use was forbidden for thoracic surgery from 2012. Present study supports this prohibition as valid and proper.

We collected the data from 27 institutions. The number of staplings in each institution ranged from 61 to 1411. The AEs rates ranged 0% to 1.8% and were independent on the volume of stapling. This suggests that stapling in thoracic surgery is a safe procedure even in the institutions with small number of thoracic surgery.

In conclusion, we have investigated intraoperative and postoperative AEs of stapling in thoracic surgery. Generally, stapling in recent thoracic surgery was safe and the incidence of AEs was independent on the stapling volumes in institutions.

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**Disclosure Statement**

All authors have no conflict of interest in the present study. None of the contributors has to disclose interests...
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References