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The Efficiency and Safety of Variable-Height Staple Technology in Pulmonary Resections

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Abstract

Objectives: Mechanical suturing devices are commonly used for resection of the pulmonary parenchyma. We evaluated a new variable-height staple, Tri-Staple, in a prospective single arm study.

Method: Sixty patients with lung tumor who underwent resection of the pulmonary parenchyma with the Tri-Staple between October 2011 and February 2012 were assessed for various outcomes, including the incidence of prolonged pulmonary fistula, incidence and severity of air leaks from the site of resection with the mechanical suturing device, and duration of drain placement. Patients who had preoperative imaging evidence of severe emphysema, pulmonary fibrosis, or adhesion and those who were expected to have pleural adhesion were excluded.

Results: A total of 172 cartridges were used: eight Tan (Camel) Reloads, 104 Purple Reloads, and 60 Black Reloads. The median number of cartridges used per patient was 2.87 (1 to 13). Prolonged pulmonary fistula occurred in 1.7% (1/60) of patients. Of all staple firings, 8.1% (14/172) were associated with intra operative air leaks. The location of the air leak was the staple holes in nine patients (64.3%, 9/14) and the visceral pleura outside of the staple line in five patients (35.7%, 5/14). No air leaks were observed at the stumps or staple line overlapping sites. The middle to the tip of the staple line was associated with more air leaks, but with no significant difference between the sections of the staple line. Analysis by cartridge size showed a trend toward a lower incidence of air leaks with the cartridge intended for thick tissues. No cartridge caused poor staple formation. The median time to the resolution of air leaks was 0 days (0 to 10 days), the duration of drain placement was 2.3 days (0 to 11), and the only adverse event observed during the study was reoperation for prolonged pulmonary fistula.

Conclusion: Pulmonary resection with the Tri-Staple was associated with a low incidence of prolonged pulmonary fistula and intra operative air leaks, demonstrating that it is feasible in terms of safety and efficiency. When it is difficult to decide which cartridge to use, selecting higher staple heights may reduce the risk of air leaks.

Keywords: Surgery; Operative procedures; Pulmonary resection; Mechanical suturing device

Abbreviation

CTCAE**:** Common Terminology Criteria for Adverse Events; POD: Postoperative Day; VATS: Video-Assisted Thoracoscopic Surgery

Introduction

Mechanical suturing devices are an alternative to conventional manual sutures by surgeons. Since the end of the 1950s and the beginning of the 1960s, they have been used in resection of the bronchus and pulmonary parenchyma, contributing to reducing surgery time and bleeding [1-4]. Currently, various types of devices with differing shapes and suture line lengths are available and constitute an integral part of many surgical procedures. Staples, which are directly placed in the tissue, are an important component of the device, and multiple types of replaceable cartridges incorporating staples have been developed to allow secure closure of tissue margins. In general staplers, the cartridge contains two or three rows of single-height staples. Staples with a pre-closure height of 4.8 mm (green cartridge) or 3.5 mm (blue cartridge) used to be selected depending on the thickness of the pulmonary parenchyma to be resected. In 2010, Covidien developed Tri-Staple Reloads, which incorporate, on each side, three rows of staples with heights increasing from the inner to the outer row.

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Table 1: Intraoperative air leak grading.

Air leak grading	Intraoperative physiologic definition
0	No leak
1	Minor leak
2	Moderate leak not detected by anesthetist but easily visible to surgeon
3	Major leak detected by anesthetist through loss of ventilation volume

A number of studies on air leaks after pulmonary resection have been reported [5-16], but very old, early models were used in most of the studies that evaluated mechanical suturing devices for various outcomes, such as the risk of air leaks or bleeding and usefulness [1-4]. We conducted a clinical study to prospectively evaluate the usefulness and safety of the new Tri-Staple technology by determining the location, incidence and severity of air leaks in the tissue around the fired staples.

Material and Method

Prior to the initiation of the study, the protocol was approved by the Institutional Review Board at Kanagawa Cancer Center. This prospective study was registered to UMIN, the number is UMIN000006462.

Study design and endpoints

The primary endpoint of this clinical study was the incidence of prolonged pulmonary fistula lasting more than 5 days postoperatively (defined by the Society for Thoracic Surgery). The secondary endpoints were: the incidence and severity of air leaks at the stapled resection site; incidence of pleural injury; staple formation; hemostasis in the staple line; use of a sealant for air leaks; placement of additional sutures; incidence of intra- and post-operative adverse events; duration of postoperative drain placement; and length of postoperative hospital stay. Patients were prospectively recruited and assessed for these endpoints.

Sample size calculation

On the assumption that ≤ 5% of patients would experience prolonged pulmonary fistula lasting more than 5 days postoperatively, a sample size of 59 patients would provide 95% power to detect at least one case of air leak. To allow for possible dropouts, 60 patients were to be enrolled in this study.

Patients

The study population consisted of 60 patients with lung tumor who were scheduled to undergo resection of the pulmonary parenchyma with the Tri-Staple in the Dept. of Thoracic Surgery, Kanagawa Cancer Center, between October 2011 and February 2012. Prior to surgery, written informed consent was obtained from each patient. Patients who had preoperative CT evidence of severe emphysema or pulmonary fibrosis and those who had previous ipsilateral thoracotomy or were expected to have significant pleural adhesion were excluded from the study.

Materials

The products used in this study were ENDO GIA Ultra Universal Staplers (Covidien Inc., Mansfield, MA) and Tri-Staple cartridges with three different staple heights (Tan [Camel] Reloads with a pre-closure staple height of 2.0mm to 3.0 mm and a post-closure staple height of 0.75 mm to 1.25 mm; Purple Reloads with 3.0 mm to 4.0 mm and 1.25 mm to 1.75 mm heights, respectively; and Black Reloads with 4.0 mm to 5.0 mm and 1.75 mm to 2.25 mm heights, respectively). The surgeon selected one of the three cartridge sizes based on subjective assessment of tissue thickness (thin, normal or thick).

Methods

The intraoperative air leak test was conducted after the completion of pulmonary resection but before chest closure. The thoracic cavity was filled with physiological saline to ensure that the stumps were immersed. With the entire residual lung inflated by the anesthetist, airway pressure of 20 cm H_2O was applied to assess air leaks. If an air leak occurred, the following were recorded: location (staple holes, visceral pleura, stumps, or staple line overlapping sites), severity of air leak, and section of the cartridge jaw (base, middle or tip). The severity of air leaks was graded from 1 to 3 using Macchiarini's scale [6] and recorded (Table 1). In addition, staple formation, pleural injury and other outcomes were visually examined and recorded.

Criteria for using a sealant or additional sutures

When the test revealed an air leak, the surgeon was allowed to use a sealant and/or additional sutures at his/her discretion to ensure that leakage was minimized before chest closure as per the standard

Table 2: Patient demographics.

Number of patients		60 patients
Gender		27 men and 33 women
Age		67.9 (34-86)
Smoking		30 patients Brinkman Index 334.85 (6–1920)
Surgical Procedure	Lobectomy	42
	Segmentectomy	7
	Partial resection	11
Concurrent conditions		
Respiratory	Emphysema	2
	Interstitial pneumonia	0
Cardio- and cerebro-vascular	Cerebrovascular disorder	2
	Ischemic heart disease	9
	Anticoagulant therapy	3
Metabolic disease, etc.	Diabetes	2
	Use of steroids	0

Table 3: Surgical Procedure and Number of Cartridges Used.

Surgical Procedure	Number of Patients	Number of Cartridges Used				
		Tan (Camel)	Purple	Black	Total	Mean (Range)
Lobectomy	42	7	83	20	110	2.62 (1–13)
Right upper	15	0	25	5	30	2.00 (1–4)
Right middle	6	1	10	11	22	3.67 (2–5)
Right lower	6	1	22	1	24	4.00 (1–13)
Left upper	6	3	8	1	12	2.00 (1–4)
Left lower	9	2	18	2	22	2.44 (1–4)
Segmentectomy	7	1	6	21	28	4.00 (3–6)
Partial resection	11	0	15	19	34	3.09 (2–5)
Total	60	8	104	60	172	2.87 (1–13)

procedure.

Grading of postoperative adverse events

Adverse events were graded using the Common Terminology Criteria for Adverse Events (CTCAE) ver 4.0: Grade 2 events were considered mild, Grade 3 moderate, and Grade 4 severe. The relationship of each event to the mechanical suturing device was graded as "not related," "possibly related," or "related."

Postoperative management

After surgery, patients were managed in a standardized manner guided by a clinical path. On the day of surgery, continuous suction was applied with a pressure of -10 cm H_2O. If evidence of an air leak was noted on postoperative day (POD) 1 and beyond, a water seal was used. Drains were removed when no air leaks were present, with a daily drainage volume of ≤ 250 mL.

Statistical analysis

Each variable was tested by the chi-square test, Fisher's exact test and Student's t test. Analysis was performed with SPSS, version 21. Significance was defined as $p<0.05$.

Results

Patient demographics are shown in Table 2. The surgical procedure was lobectomy in 42 patients, segmentectomy in 28 patients, and partial resection in 34 patients. The approach was via video-assisted thoracoscopic surgery (VATS) in 42 patients and thoracotomy in 18 patients. The cartridge providing a suture line length of 60 mm was primarily used for the stapler fired in the pulmonary parenchyma. The cartridges used in each procedure are shown in Table 3.

The primary endpoint of this study was the incidence of prolonged pulmonary fistula lasting more than 5 days postoperatively, which was observed in 1.7% (1/60) of patients. Intraoperative air leaks occurred in 36.7% (22/60) of patients, of whom 63.6% (14/22) had staple-related air leaks. Of all staple firings, 8.14% (14/172) were associated with air leaks. Analysis by cartridge size showed that air leaks occurred with 12.5% (1/8) of Tan Reloads, 12.5% (13/104) of Purple Reloads, and 1.7% (1/60) of Black Reloads, indicating that air leaks were significantly less common with the cartridge intended for thick tissues (Tan + Purple vs. Black, $p = 0.036$). The location of air leaks was the staple holes in nine patients and the visceral pleura in five patients; no air leaks were observed at the stumps or 65 sites where staple lines overlapped (Table 4).

The severity of air leaks was assessed as Grade 1 in ten patients (71.4%), Grade 2 in three patients (21.4%), and Grade 3 in one patient (7.1%). Mild air leaks were mostly through the staple holes (80%; 8/10), whereas the visceral pleura was the most common location of moderate to severe air leaks (75%; 3/4) (Table 5). Analysis by the section of the stapler jaw showed that the middle and tip sections were more commonly associated with air leaks. Grade 1 air leaks occurred equally in all sections of the jaw, whereas more severe air leaks were more common from the middle to the tip of the jaw (Table 6). All patients who were found to have air leaks were given staple line reinforcement, as shown in Table 7, to ensure that leakage was minimized before chest closure.

The results of postoperative evaluation were as follows: The median time to the resolution of air leaks was 0 days (0 to 10 days), the duration of drain placement was 2.3 days (0 to 11 days), and the length of hospital stay was 7.5 days (6 to 15 days). Only one patient who underwent reoperation for prolonged pulmonary fistula experienced a Grade 3 adverse event. In this patient, reoperation was considered necessary on POD 3, because a severe air leak persisted and worsened immediately after operation, resulting in increasing subcutaneous emphysema. Re-thoracotomy findings revealed pulmonary laceration at a site unrelated to the stapled pulmonary parenchyma. This event resulted from over inflation of the fragile lungs and was not considered related to the mechanical suturing device; however, it was considered possibly related, since the stapler might have contributed to the event in some way. No patient had poor staple formation.

Discussion

This was the first prospective study to evaluate the efficiency and safety of a mechanical suturing device introduced into the market in recent years. The primary endpoint of this study was the incidence of air leaks lasting more than 5 days postoperatively, which was 1.7% (1/60), considerably lower than that reported in the literature (approximately 7 to 15%) [5-7,17]. The high performance of the mechanical suturing device might have contributed to this favorable result, which, however, may also be attributable to the fact that patients susceptible to postoperative air leaks due to medical conditions such as severe emphysema and adhesion were excluded from the study. Prolonged air leaks after surgery increase the length of the hospital stay and the risk of pulmonary empyema and other complications, resulting in increased treatment costs [8-11]. Intraoperative air leaks from the pulmonary parenchyma occur mainly at the suture site of the pulmonary parenchyma and the interlobar fissures, with a reported incidence of 58 to 74% [8,12]. When an air leak occurs during surgery, it is usually sealed by suturing or using biological glues, fibrin, synthetic patches, etc. [13-16]. However, such procedures cause additional

Table 4: Cartridge Size (Location of Air Leak).

	Number of Cartridges Used (60/45 mm)	Location of Air Leak				
		Staple holes	Visceral pleura	Stumps	Staple line overlapping sites*	Total (%)
Tan (Camel)	8 (6/2)	0	0	0	0	0 (0.0)
Purple	104 (98/6)	8	5	0	0	13 (12.5)
Black	60 (53/7)	1	0	0	0	1 (1.7)
Total	172 (157/15)	9 (64.3%)	5 (35.7%)	0 (0%)	0 (0%)	14 (8.1)

*There were 65 sites where staple lines overlapped

Table 5: Severity of Air Leak (Location of Air Leak).

	Staple holes	Visceral pleura	Stumps	Staple line overlapping sites	Total (%)
Grade 1	8	2	0	0	10 (71.4)
Grade 2	1	2	0	0	3 (21.4)
Grade 3	0	1	0	0	1 (7.1)
Total	9	5	0	0	14

Table 6: Severity of Air Leak (Section of the Stapler).

	Tip	Middle	Base	Total
Grade 1	3	4	3	10
Grade 2	1	2	0	3
Grade 3	1	0	0	1
Total (%)	5 (35.7)	6 (42.9)	3 (21.4)	14

costs; thus, minimizing air leaks at the suture site would eliminate the need for such reinforcement and reduce costs. The pulmonary tissue is resected by compressing it and firing a staple line, but tissues vary in thickness and are often thicker at the tip. If the cartridge suitable for the tissue thickness at the tip is selected, the staple height at the base of the cartridge jaw will be too high to accommodate the tissue thickness there, resulting in insufficient compression and potentially leading to an air leak or bleeding. On the other hand, if the cartridge suitable for the peripheral region of the tissue is chosen, the central tissue region at the tip is compressed too much, potentially causing damage to the visceral pleura. In clinical practice, stapler cartridge selection often poses a challenge to surgeons.

Analysis by location showed that air leaks occurred through the staple holes and in the visceral pleura and were not observed at the stumps or staple line overlapping sites. The staple holes accounted for 64.3% (9/14) of air leaks. Analysis by the section of the cartridge jaw showed that the middle section was most frequently associated with air leaks, but the severity of air leaks was higher at the tip than in the middle. Air leaks from the pleura were also observed more frequently in the middle and tip sections (78.6%; 11/14) than at the base of the cartridge jaw, occurred close to the site where staples were fired, and became more severe from the middle to the tip. Only one patient experienced a Grade 3 air leak, which also occurred in the visceral pleura at the tip of the cartridge jaw.

These results indicate that air leaks were more common and more severe at the tip of the cartridge, suggesting that the optimal cartridge for the tissue thickness at the tip was not selected. However, selecting the cartridge suitable for the tissue thickness at the tip could potentially result in insufficient staple height and compression at the base of the cartridge, where the tissue is thicker. In fact, however, analysis by the staple leg length (i.e., cartridge size) showed that the Black Reload intended for thick tissues was associated with only one case of air leak, which occurred through the staple holes. This suggests that, when it is difficult to decide which cartridge to use, selecting longer staple legs may reduce the risk of postoperative air leaks. No air leaks were observed in any of the 65 staple line overlapping sites, although we had expected that air leaks would occur there, where tissue tension was caused more than once because the tissue was sutured with the staple lines overlapping, and then cut with a scalpel. It seems that various factors, such as the sharpness of the scalpel and material/fineness of the staples, combined to contribute to this, but the exact reason is unknown.

Conclusion

Resection of the pulmonary parenchyma with the Tri-Staple is useful and safe. Tissue thickness from the middle to the tip of the cartridge jaw should be considered when using the Tri-Staple. When it is difficult to decide which cartridge to use, selecting higher staple heights may be effective in reducing the risk of postoperative air leaks.

Ethics Approval and Consent to Participate

Prior to the initiation of the study, the protocol was approved by the Institutional Review Board at Kanagawa Cancer Center. This prospective study was registered to UMIN, the number is UMIN000006462.

Competing Interests

Dr. Ito and Dr. Nakayama have conducted an investigator-sponsored study (Medtronic, Japan) entitled 'The efficiency and safety of new variable-height staple technology in pulmonary resections; prospective single arm study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Authors' Contributions

Dr. Ito and Dr. Nakayama participated in the design of the study and performed the statistical analysis. Dr. Ito drafted the manuscript. Dr. Nakayama helped to draft the manuscript. All authors read and approved the final manuscript.

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