

Randomized Study Comparing Equal Height Staples With Graduated Height Staples in Bronchial Closure

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Background. There are two forms of staple cartridge available for lung cancer operations, the flat face with equal height staples and the stepped face with graduated height staples. The objective of the study was to evaluate their stapling ability in lobectomy.

Methods. A randomized prospective study was conducted to compare two types of stapling reloads for bronchial closure. Stapling ability was evaluated by the staple formation on the resected bronchial stump. The stumps were sliced along the staple line, and the shapes of the staples were recorded by roentgenogram. Then, the staple formation was scored as 0 to 4 points with 4 approximating a perfect B-shaped staple.

Results. A total of 61 patients were randomly assigned to the equal height staples ($n = 30$) or the graduated height staples ($n = 31$). From 61 patients, 183 staple lines, which included 1,144 staples, were evaluated. The case

scores were significantly lower in the equal height staples than in the graduated height staples (2.17 versus 2.88, $p = 0.0003$), respectively. The percentage of staples that formed a complete "B" shape was significantly higher in the graduated height staples than in the equal height staples (25.3% versus 10.0%, $p = 0.000$). No considerable difference was found between the two groups concerning postoperative complications. No bronchopleural fistula was observed.

Conclusions. The graduated height staples had significantly higher scores of the staple formation on the bronchia stump than the equal height staples. From the clinical point of view, both the equal height staples and the graduated height staples showed acceptable performance in the stapling ability.

(Ann Thorac Surg 2017;104:1012–9)

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Bronchial closure is a crucial step during lobectomy. The incomplete closure of the bronchial stump may develop into bronchopleural fistula (BPF), which is one of the main surgical complications associated with a longer hospital stay or operative deaths. According to published reports, BPF occurs 0.7% to 5.7% after anatomic pulmonary resection [1]. Therefore, to achieve a safe and reliable bronchial closure is a matter of primary concern for thoracic surgeons.

To close the lobar bronchus, surgical staplers are widely used. Among the several different types of staplers available, an articulating-jaw type is the principal choice because of the advantage of accessibility into the thoracic cavity through a small window [2]. Currently, two forms of staple cartridge reload are available for the articulating-jaw stapler, and both are widely used in clinical practice in various fields of operation [3, 4]. A

conventional form has a flat face with three rows of equal height staples (EHSs). In contrast, a new form of the reload, which is named Tri-Staple technology (Medtronic, North Haven, CT) and introduced into the market in 2010, is highlighted by a stepped face with three rows of graduated height staples (GHSs). According to the patent description [5], this technology results in graduated compression of the tissue, and the smaller staples at the cut line and the larger staples on the outer third row are designed to minimize tissue trauma.

Here, we conducted a single-center randomized study to test the stapling ability of the two different types of cartridge reload in lobectomy for primary lung cancer. To evaluate the stapling cartridges, we scored the staples by their shape on the resected bronchial stump as 0 to 4 points with 4 approximating a perfect B-shaped staple. We then compared staple formation scores and the clinical events between the two forms of cartridge reload.

Accepted for publication Feb 21, 2017.

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Drs Okami and Higashiyama disclose a financial relationship with Medtronic.

Patients and Methods

Participants, Design, and Objectives

This is a randomized, prospective, single-center study comparing two forms of cartridge reloads: the flat face with EHSs (the EHS group) and the stepped face with GHSs (the GHS group). The protocol was approved by the institutional review board and registered at University hospital Medical Information Network-Clinical Trials Registry (ID: 000009813) in January 2013. The study was performed between March 2013 and November 2013 at Osaka Medical Center for Cancer and Cardiovascular Diseases (Osaka, Japan). Written and informed consent were obtained from all participants.

Inclusion criteria were as follows: indication for upper or lower lobectomy for primary lung cancer, age 20 years or older, and an Eastern Cooperative Oncology Group performance status of 0 or 1. Exclusion criteria were as follows: centrally located tumor, severe comorbidity, and patients with history of ipsilateral thoracic operation. Enrolled patients were excluded intraoperatively when the primary tumor or lymph nodes were invaded or adjacent to the lobar bronchus or main bronchus. The allocation sequence was generated using a computerized block randomization. Primary end point was the performance of staple formation at the lobar bronchial stump. Secondary end points were clinical events during the operation and within the first 30 days. Postoperative complications were classified according to the Clavien-Dindo classification.

Staplers

The Endo GIA Ultra Universal staplers (EGIAUSHORT; Medtronic) were used for all patients. For the EHS group, the Endo GIA cartridge reload with a flat face and equal height staples was used for bronchial closure (Fig 1A). The selection of either the blue cartridge for medium tissue (no. 030455; Medtronic) or the green cartridge for thick tissue (no. 030456; Medtronic) was made at the discretion of each surgeon. The staple heights of the blue cartridge and the green cartridge are 3.5 mm and 4.8 mm for all rows, respectively. For the GHS group, the Endo GIA cartridge reload with a stepped face and graduated height staples (Tri-Staple technology) was used for bronchial closure (Fig 1B). The purple cartridge for medium/thick tissue (EGIA45AMT; Medtronic) was used for all patients in the GHS group. The staple heights of this reload were 3.0 mm for the inner row, 3.5 mm for the middle row, and 4.0 mm for the outer row.

Surgical Procedure

Surgical procedures were performed in the same way between the groups. The lobar bronchus was closed and divided with one of the two cartridge reloads depending on the 1:1 randomization assignment. Before lobar bronchial stapling, the circumference of the lobar bronchus was measured.

Evaluation of the Bronchial Stump on the Patient Side

Immediately after bronchial stapling, the bronchial stump on the patient side was evaluated in terms of staple

formation by gross appearance, bleeding or oozing, dehiscence, and air leak under pressure of 10 to 20 cm H₂O.

Evaluation of Staple Formation

After the operation, bronchial stumps were cut out from the resected lobe and fixed in buffered formalin. The stapled stumps were sliced along the staple line. All pieces were embedded in paraffin and photographed by roentgenogram. An example of an X-ray photograph of a staple line is shown in Figure 2A. The tissue thickness of the stapled stumps were measured with electronic calipers. Staple formation was evaluated and scored with points. If the stapler works properly, the two legs hit the corresponding grooves in the anvil and are bent at four locations (*a*, *b*, *c*, and *d* in Fig 2B) in each staple to hold the bronchial tissue closed. The ideal shape of a staple is a B-shape shown in Figure 2B. Staple formation was evaluated by the number of proper leg bendings of the four bending locations. Each closed staple was scored as 0, 1, 2, 3, or 4. Examples of each scoring pattern are shown in Figure 2C. Scoring was performed by five thoracic surgeons (J.O., T.T., T.K., D.I., and M.H.) independently under blinded conditions. Staple scores were given for each individual staple (range, 0 to 4) and averaged among the five surgeon scorers. Staple scores were then averaged for the staple-line score, and the case score was the average of all staple scores in each patient.

Statistical Analysis

It was estimated that this study required 30 patients in each group to detect at least a 0.3-point difference in the scores of the staple formation. The analysis of primary and secondary variables was performed on an intention-to-treat basis. Discrete score data are summarized as median with the 25th and the 75th percentiles in parentheses, because the distribution of some variables were skewed. The statistical significance of categorical variables was evaluated by Fisher's exact test, whereas either the Student *t* test or the Wilcoxon's rank sum test was selected, depending on the type of variables. Inter-observer agreement of the scoring system among five scorers was determined by calculating the weighted kappa coefficient [6].

Results

Study Population

A total of 69 patients were randomly assigned to either group for pulmonary lobectomy. The intention-to-treat population consisted of 61 patients (30 in the EHS group and 31 in the GHS group) (Fig 3). In all patients, primary lung cancer was pathologically diagnosed, and complete resection was performed. Operation time was 187.8 minutes (95% confidence interval [CI]: 177.8 to 197.8 minutes). No significant difference was found between the two groups concerning baseline characteristics (Table 1). Outer circumference of the lobar bronchus was 34.5 mm (95% CI: 32.8 to 36.2 mm). From the surgeons'

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