Original Article

Can a stapling device with bioabsorbable polyglycolic acid felt reduce intraoperative air leak?

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Background: Currently, it is unknown whether polyglycolic acid (PGA) felt staplers can reduce the occurrence of intraoperative air leaks. We investigated whether staplers with bioabsorbable PGA felt reduced intraoperative air leakage compared to the conventional stapler in patients undergoing lung resection.

Methods: From 2013 to 2021, 211 patients diagnosed with lung cancer or pulmonary metastasis underwent lung resection using only PGA felt (n=88) or conventional (n=123) staplers at Tokyo Rosai Hospital. One-to-one propensity score matching was used to compare intraoperative air leak rates, operation time, and intraoperative bleeding between the two groups.

Results: The PGA felt group required more staples than the conventional stapler group. The forced expiratory volume in one second percentage of predicted in the PGA felt stapler group was lower than that in the conventional stapler group. In the PGA felt stapler group, 56.8% of patients had undergone anatomic lung resection, whereas 29.3% of patients in the conventional stapler group had undergone wedge resection. In a propensity-matched analysis of 67 pairs, the occurrence of intraoperative air leaks was significantly lower in the PGA felt stapler group than in the conventional stapler group (16.4% *vs.* 56.7%, P<0.001). The operation time was significantly shorter and intraoperative bleeding was significantly lower in the PGA felt stapler group than in the conventional stapler group (P=0.001 and P=0.016, respectively).

Conclusions: Pulmonary resection using staplers with a PGA felt could reduce the occurrence of intraoperative air leaks among patients undergoing lung resection.

Keywords: Stapling device; bioabsorbable polyglycolic acid felt (bioabsorbable PGA felt); intraoperative air leak

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Introduction

The most common adverse event after lung resection is air leakage (1), which has been shown to impair pulmonary function and exercise capacity (2). Prolonged air leakage is linked to serious postoperative complications like pneumonia, atelectasis, and pyothorax (3). The presence of an air leak necessitates that a thoracic drain is left in place, which contributes to increased postoperative pain (4), and the occurrence of such complications following lung resection surgery is a risk factor for lung cancer recurrence (5). In a meta-analysis, Attaar *et al.* (6) reported that an air leak occurs not only in relation to lung resection and surgical technique but also in relation to wound healing factors. Forced expiratory volume in one second percentage of predicted (FEV_1% predicted), smoking history, major anatomic lung resection, and pleural adhesion are all risk

factors for a prolonged air leak (6).

Conventional staplers are used in lung resection, and the incidence of postoperative air leakage from the lung parenchyma has been reported to be 7–25% (1,7-15). A majority of air leaks are caused by staple needle holes or disruption of the visceral pleura close to the staple (16). Stapling the lung parenchyma with polyglycolic acid (PGA) felt attached to the cartridge has been shown to reduce the incidence of postoperative air leaks (17,18).

However, the utility of a stapler with PGA felt is unclear because postoperative air leakage is reduced through a variety of factors, including additional intraoperative procedures, such as fibrin glue application, simple suture closure, mattress suture closure using a pledget, absorbent felting with fibrin glue, thrombostatic sealant application, or low-pressure coagulation. It is currently unknown whether PGA felt staplers can reduce the occurrence of intraoperative air leaks.

Therefore, we designed a retrospective case-control study with propensity score matching and independent variables based on the meta-analysis by Attaar *et al.* (6) The purpose of this study was to assess whether staplers with PGA felt reduced intraoperative air leaks compared to conventional staplers in patients undergoing lung resection. This manuscript is written following the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1352/rc).

Highlight box

Key findings

- Polyglycolic acid (PGA) felt staples reportedly reduce the incidence of postoperative air leakage among patients undergoing lung resection.
- PGA felt staplers were associated with significantly lower intraoperative air leakage and prolonged air leak than conventional staplers. Furthermore, reducing intraoperative air leakage may eliminate the need for additional procedures, resulting in shorter operation times and reduced intraoperative bleeding.

What is known and what is new?

- It is currently unknown whether PGA felt staplers can reduce the occurrence of intraoperative air leaks.
- Pulmonary resection using PGA felt staplers could reduce the occurrence of intraoperative air leaks and prolonged air leaks among patients undergoing lung resection.

What is the implication, and what should change now?

- Staples with PGA felt should be actively used during lung resection in patients with risk factors, such as a lower forced expiratory volume in one second percentage of predicted, smoking history, major anatomic lung resection, and pleural adhesion.

Methods

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Tokyo Rosai Hospital (No. 02-15) and the requirement for individual consent for this retrospective analysis was waived.

Data and patient selection

This study included patients who underwent lung resection for lung cancer or pulmonary metastasis based on a preoperative diagnosis at Tokyo Rosai Hospital between January 2013 and September 2021. Data on patient age, sex, body mass index (BMI), smoking history, number of staples used for pulmonary resection, total pleural adhesion, right-sided resection, upper resection, FEV_1% predicted, chronic obstructive pulmonary disease (COPD), lung resection (wedge resection, segmentectomy, or lobectomy), intraoperative air leak, intraoperative bleeding, operation time, prolonged air leak, postoperative complications, drainage duration, and postoperative hospital stay were all included in the hospital database. Total adhesion was defined as the extensive adhesion of all lung lobes to the surrounding area. Prolonged air leak was defined as air leak lasting longer than 5 days, use of postoperative adhesive agents, and reoperation for pulmonary fistula. We compared the intraoperative air leak rate between patients with PGA felt staplers (PGA felt stapler group) and conventional staplers (conventional stapler group). Patients were excluded if staples were not used for lung resection; if both the conventional and PGA felt staplers were used; or if they had undergone a pneumonectomy, bilobectomy, bilateral simultaneous lung resection, or combined resection of the neighboring structures. We checked the intraoperative air leak using the operation reports and videos. Air leakage from the staple needle hole or disruption of the visceral pleura near the staple was defined as an intraoperative air leak (16).

Outcome measurements

The primary endpoint was the intraoperative air leak rate

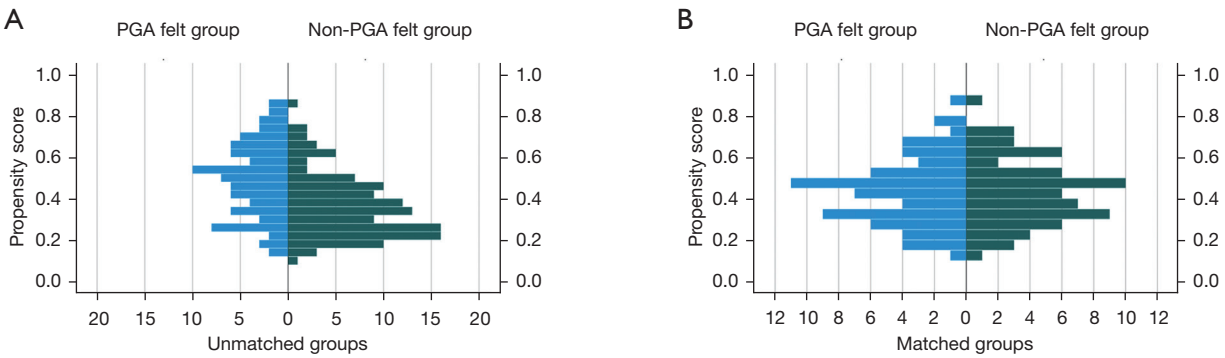

Figure 1 Distribution of propensity scores in the unmatched (A) and matched (B) groups. PGA, polyglycolic acid.

in the PGA felt and conventional stapler groups. The secondary endpoints were operation time, intraoperative bleeding, prolonged air leak rate, postoperative complication rate, drainage duration, and the length of postoperative hospital stay.

Surgical procedures

In May 2015, we started using staples with PGA felt (Endo GIA™ Reinforced Reload with Tri-Staple™ Technology; Medtronic, Minneapolis, MN, USA). The PGA felt was lubricated when the PGA felt staplers were used. The sealing test was performed by maintaining an airway pressure of 15–20 cm H_2O after the collapse was fully dilated. If an intraoperative air leak was observed, additional procedures, including fibrin glue application or spray, simple suture closure, mattress suture closure with a pledget, absorbent felting with fibrin glue, thrombostatic sealant application, or low-pressure coagulation, among others, were performed.

Statistical analysis

Based on the estimated propensity scores for each patient, we performed a one-to-one matching analysis between the PGA felt and conventional stapler groups. We compared the PGA felt and conventional stapler groups in terms of surgical procedure (major anatomic lung resection *vs.* wedge resection), age, sex, BMI, smoking history (non-smoker *vs.* current or previous smoker), FEV_1% predicted, number of sutures with cartridges used for pulmonary resection, total pleural adhesion, and COPD. A lobectomy or segmentectomy was defined as a major anatomical lung resection. We fitted a logistic regression model to these air leak factors to estimate the propensity score. The C-statistic was computed to evaluate the goodness of fit. Patients were matched 1:1 using nearest-neighbor matching (caliper width: 0.2) without replacement. Comparisons were made between the matched groups. Fisher's exact test was used to compare the intraoperative air leak rates, prolonged air leak rates, and postoperative complication rates between the PGA felt and conventional stapler groups. The Mann-Whitney *U* test was used to compare operation time, intraoperative bleeding, drainage duration, and postoperative hospital stay between the PGA felt and conventional stapler groups among the propensity-matched patients. The significance level was set at $P<0.05$. IBM SPSS version 28.0 was used for all statistical analyses (IBM SPSS, Armonk, NY, USA).

Results

Between 2013 and 2021, 211 patients [for whom only PGA felt staplers (n=88) and only the conventional staplers (n=123) were used] from the Tokyo Rosai Hospital database met the inclusion criteria and were included in the study. A total of 67 pairs from the PGA felt and conventional stapler groups were selected using one-to-one score matching. In the propensity score model, the C-statistic for the goodness of fit was 0.712. The distribution of propensity scores in the unmatched and matched groups is shown in *Figure 1*.

The demographics and clinical characteristics of all patients (n=211) are shown in *Table 1*. The PGA felt stapler group required more staples than the conventional stapler group [3.0 (IQR: 2.0–4.0) *vs.* 3.0 (IQR: 2.0–3.0), respectively; P=0.004]. The PGA felt group had a lower FEV_1% predicted [82.9% (IQR: 68.9–97.2%)] than the conventional stapler group [91.7% (IQR: 83.0–108.2%),

Table 1 Demographic and clinical characteristics of all patients

Variable	PGA felt stapler group (n=88)	Conventional stapler group (n=123)	P value
Age (years)	73.0 [68.0–76.0]	71.0 [65.0–77.0]	0.246
Sex (male)	61 (69.3)	83 (67.5)	0.881
BMI (kg/m^2)	22.1 [19.8–25.0]	22.9 [21.0–25.4]	0.220
Smoking history			
Nonsmoker	22 (25.0)	41 (33.3)	0.223
Current/former smoker	66 (75.0)	82 (66.7)	
Number of staples	3.0 [2.0–4.0]	3.0 [2.0–3.0]	0.004
Total pleural adhesion	2 (2.3)	3 (2.4)	>0.999
Right-side resection	56 (63.6)	78 (63.4)	>0.999
Upper resection	52 (59.1)	72 (58.5)	>0.999
COPD	34 (38.6)	26 (21.1)	0.008
FEV_1% predicted (%)	82.9 [68.9–97.2]	91.7 [83.0–108.2]	<0.001
Lung resection			
Major anatomic lung resection	50 (56.8)	87 (70.7)	0.041
Wedge resection	38 (43.2)	36 (29.3)	

Continuous data are presented as the median [interquartile range], and categorical data are presented as n (%). Major anatomic lung resection was defined as lobectomy or segmentectomy. PGA, polyglycolic acid; BMI, body mass index; COPD, chronic obstructive pulmonary disease; FEV_1%, forced expiratory volume in one second percentage.

P<0.001]. Overall, 56.8% of patients in the PGA felt group had undergone a major anatomical surgery, whereas 29.3% of patients in the conventional stapler group had undergone wedge resection.

The demographics and clinical characteristics of all propensity score-matched patients (n=134) are shown in *Table 2*. Patient distributions were the same between the PGA felt and conventional stapler groups after propensity score matching.

Table 3 depicts the intraoperative air leak rate, operation time, intraoperative bleeding, prolonged air leak rate, postoperative complication rate, drainage duration and postoperative hospital stay in the propensity-matched the PGA felt and conventional stapler groups. The PGA felt stapler group had a significantly lower intraoperative air leak rate than the conventional stapler group (16.4% *vs.* 56.7%, odds ratio: 0.150, 95% confidence interval: 0.067–0.336; P<0.001). The PGA felt stapler group had a significantly lower prolonged air leak rate than the conventional stapler group (7.5% *vs.* 20.9%, odds ratio: 0.625, 95% confidence interval: 0.448–0.873; P=0.045). The PGA felt stapler group had a significantly shorter operation time (P=0.001) and reduced intraoperative bleeding (P=0.016), and shorter drainage duration (P=0.005) than the conventional stapler group.

Discussion

Based on the results of an earlier meta-analysis, this study investigated whether staplers with PGA felt can reduce the incidence of intraoperative air leaks compared to conventional staplers after adjusting for patients' demographic and clinical characteristics. Herein, the incidence of intraoperative air leaks (P<0.001), prolonged air leak (P=0.045), operation time (P=0.001), intraoperative bleeding (P=0.016) and drainage duration (P=0.005) were lower in the PGA felt stapler group than in the conventional stapler group.

Application of appropriate preoperative surgical strategies requires identification of the risk factors for alveolar-pleural fistulas. The most common postoperative adverse event is prolonged air leakage, which is associated with serious complications such as pneumonia, atelectasis, and respiratory failure (3). Longer hospital stays result in higher

Table 2 Demographic and clinical characteristics of propensity-matched patients

Variable	PGA felt stapler group (n=67)	Conventional stapler group (n=67)	P value
Age (years)	72.0 [68.0–76.0]	71.0 [66.0–76.0]	0.632
Sex (male)	47 (70.1)	49 (73.1)	0.848
BMI (kg/m^2)	22.5 [19.8–25.8]	22.5 [20.2–25.5]	0.776
Smoking history			
Nonsmoker	20 (29.9)	17 (25.4)	0.699
Current/former smoker	47 (70.1)	50 (74.6)	
Number of staples	3.0 [2.0–4.0]	3.0 [2.0–4.0]	0.557
Total pleural adhesion	2 (3.0)	0 (0.0)	0.496
Right-side resection	43 (64.2)	41 (61.2)	0.858
Upper resection	41 (61.2)	42 (62.7)	>0.999
COPD	22 (32.8)	21 (31.3)	>0.999
FEV_1% predicted (%)	86.2 [75.9–104.5]	84.0 [72.0–102.8]	0.702
Lung resection			
Major anatomic lung resection	41 (61.2)	47 (70.1)	0.363
Wedge resection	26 (38.8)	20 (29.9)	

Continuous data are presented as the median [interquartile range], and categorical data are presented as n (%). Major anatomic lung resection was defined as lobectomy or segmentectomy. PGA, polyglycolic acid; BMI, body mass index; COPD, chronic obstructive pulmonary disease; FEV1%, forced expiratory volume in one second percentage.

Table 3 Comparison of outcomes between propensity score-case-matched patients in the PGA felt stapler group and conventional stapler group

Variable	PGA felt stapler group (n=67)	Conventional stapler group (n=67)	P value
Intraoperative air leak	11 (16.4)	38 (56.7)	<0.001
Operation time (min)	199 [119–246]	285 [140–350]	0.001
Intraoperative bleeding (mL)	0 [0–50]	50 [0–130]	0.016
Prolonged air leak	5 (7.5)	14 (20.9)	0.045
Postoperative complication	16 (23.9)	21 (31.3)	0.440
Drainage duration (days)	4 [2–6]	5 [4–6]	0.005
Postoperative hospital stay (days)	9 [7–15]	8 [7–11]	0.088

Continuous data are presented as the median [interquartile range], and categorical data are presented as n (%). PGA, polyglycolic acid.

hospital costs as a result of the prolonged air leakage (19). Previous research has linked prolonged intraoperative air leakage with patient-related risk factors such as increased age, smoking history, low BMI, low FEV_1% predicted, steroid use, COPD, dyspnea, Zubrod score >1, low FEV1/forced expiratory volume (FVC), low lung diffusion capacity for carbon monoxide, and low FVC% (6,20-23). Intraoperative risk factors include major lung resection, right-sided resection, upper resection, and pleural adhesions (6). In a meta-analysis, Attaar *et al.* found that FEV_1% predicted, previous smoking history, major anatomic lung resection and pleural adhesions had the strongest correlation with prolonged air leakage. These factors were used as confounding factors for intraoperative air leakages in this study.

Various surgical techniques can be used to manage

pulmonary fistulas intraoperatively. Suturing and stapling are common methods for treating intraoperative air leaks after lung resection. Fibrin glue (24-26), synthetic polyethylene glycol-based hydrogel sealants (27-29), topical application of human fibrinogen/thrombin-coated collagen patch (30), and staple line reinforcement (31-35) are some other approaches that have been reported.

The Endo GIA™ Tri-Staple™ Linforce cartridge was the conventional linear stapler in 2014, with the addition of PGA suture reinforcement. PGA felt is a bioabsorbable material that absorbs completely *in vivo* in about 15 weeks and loses strength in about 4 weeks. In an animal study, inflammatory changes were observed 12 weeks after PGA implantation (36). As a result, fibrosis caused by local inflammation around the PGA felt was thought to strengthen the staple line with PGA felt. The advantages of stapling with PGA have been demonstrated in a variety of other surgeries, including a reduced rate of suture failure in gastrectomy (37) and colorectal resection (38), and a reduced rate of pancreatic fluid leak during pancreatic resection (39). Recent studies have found that PGA staplers reduce postoperative air leaks in pulmonary resection (17,18). However, it was unclear whether the reduction in intraoperative air leakage was due to the use of PGA felt or due to additional intraoperative procedures and postoperative management strategies. As a result, we evaluated intraoperative air leaks after stapling with only PGA felt and only non-PGA felt in this study, and found that the staplers with PGA felt was associated with a significantly lower intraoperative air leakage rate and prolonged air leak rate than the conventional staplers. Furthermore, it was discovered that reducing intraoperative air leakage may eliminate the need for additional procedures, resulting in a shorter operation time and reduced intraoperative bleeding. However, it should be noted that PGA adhesion to the surrounding tissues can be harmful during reoperation and staplers with PGA felt should be used with caution if additional resection is planned in the future (36).

This study had several limitations. First, this was a retrospective, nonrandomized study involving a small number of patients from a single institution. The surgical technique and learning curve may have differed based on the surgeon's experience, which may have influenced our findings. Second, we had no data on the time of additional procedures due to the intraoperative air leaks. However, it is clear that there was a prolongation of operative time due to the additional procedures. Third, intraoperative blood loss is a complex outcome that is dependent on a variety of factors in addition to staples with PGA felt. Fourth, despite the shorter drainage duration, the lack of a difference in the length of hospital stay is suspected to be due to the extended length of hospital stay because of respiratory rehabilitation, which was started in 2019 at our institution. We believe that this point should be researched further in future studies. Nonetheless, after controlling for the potential causative factors of intraoperative air leakage, our findings remained unchanged.

Conclusions

Pulmonary resection with PGA felt staples could reduce the incidence of intraoperative air leak and prolonged air leak. The use of PGA felt staples may lead to shorter operation times and reduced intraoperative bleeding among patients undergoing lung resection. Accordingly, the proactive use of PGA felt staples is recommended during lung resection in patients with risk factors such as a lower FEV_1%, smoking history, major anatomic lung resection, and pleural adhesion. A prospective, multicenter, randomized controlled study is needed in the future to confirm the efficacy of this method.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1352/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1352/dss

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1352/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1352/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of Tokyo Rosai Hospital (No. 02-15) and the requirement for individual consent for this retrospective analysis was waived.

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