Original Article

Clinical outcomes of pre-attached reinforced stapler reloads in thoracic surgery: a prospective case series

Eric Lim[1], Jean-Marc Baste[2], Michael Shackcloth[3]

[1]Imperial College and The Royal Brompton Hospital, London, UK; [2]Rouen University Hospital, Rouen, France; [3]Liverpool Heart & Chest Hospital, Liverpool, UK

Contributions: (I) Conception and design: All authors; (II) Administrative support: E Lim; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Professor Eric Lim, MD. Academic Department of Thoracic Surgery, Royal Brompton Hospital, Sydney Street, London SW3 6NP, UK. Email: e.lim@rbht.nhs.uk.

Background: Reinforced staple lines are less susceptible to leaks or bleeding and may consequently reduce morbidity and complications during or after surgery. However, their safety and benefits as well as the best form of reinforcement are still under debate. This study evaluates the safety of a stapler with pre-attached buttressing material based on adverse events (AEs) in thoracic surgery.

Methods: A multi-center prospective study was conducted to assess the use of stapler reloads with pre-attached staple line reinforcement material in thoracic surgery. The primary endpoint was the rate of device-related AEs reported within 30 days of lung cancer thoracic surgery. AEs, bleeding ≥50 mL, leaks, and 30-day readmissions were reported as additional outcomes.

Results: A total of 40 patients underwent lobectomy (n=22), wedge resection (n=10), or other thoracic surgery (n=8). Access was open (n=9) or by video-assisted thoracoscopic surgery (VATS, n=31). One patient was lost to follow-up. Intraoperatively, there were no cases of bleeding ≥50 mL requiring staple line intervention, and three cases (8%) experienced minor leaks that were treated conservatively. Bleeding unrelated to the staple line occurred in 20 patients intraoperatively (50%) and 21 patients postoperatively (54%). Three patients were readmitted (8%) for procedure-related causes and deemed unrelated to the investigational device. Of the AEs reported, one device-related event occurred intraoperatively, associated with minor bleeding. The other 33 AEs were related to infection (15%), bleeding (12%), or leak (9%). There were no deaths during the follow-up period.

Conclusions: This study demonstrates that AEs related to the use of reinforced reloads and occurring during or within 30 days of lung cancer surgery pose minimal safety concerns.

Keywords: Surgical stapler; staple line reinforcement; thoracic surgery; adverse events (AEs); prospective studies

Submitted Feb 24, 2022. Accepted for publication Jun 11, 2022.
doi: 10.21037/jtd-22-220
View this article at: https://dx.doi.org/10.21037/jtd-22-220

Introduction

The surgical resection of lung tissue related to cancer diagnosis or treatment can present a technical challenge for surgeons. Removal of malignant or suspect tissue may involve the dissection and closure of a wide variety of tissues including blood vessels, lung parenchyma and bronchi, each with different thicknesses and elastic properties (1). Managing these various tissues may cause surgical complications of varying severity, including bleeding and air leaks. Surgical techniques are under constant revision in efforts to reduce the occurrence of these complications. Minimally invasive video-assisted thoracoscopic surgery (VATS) versus open thoracotomy has been associated with

Figure 1 Endo GIA™ Tri-Staple™ technology with Reinforced Reload (Medtronic) with preloaded buttress material (*Used with the permission of Medtronic*).

lower rates of select complications (2,3).

Stapling is one method of closure for the different tissue types in the lung, with varying rates of associated complications (1,4). Among these complications, postoperative air leak is the most common complication after lung resection. Prolonged air leak (PAL) is a serious complication that can cause a range of outcomes up to severe pneumonia or pleural empyema. These outcomes may result in prolonged need for chest drains, longer hospital stays (5) and increased hospital mortality (6). One study identified the in-hospital phase (operating room and length of stay) as a major cost driver of VATS lobectomy (7). Efforts to reduce the in-hospital time burden may lessen the overall economic burden (7).

Staple line reinforcement has been explored as a method to reduce complications. Reinforcements in pulmonary surgery have included glue and buttressing materials, as either biological or synthetic materials (8-12). Different materials have different effects on complication rates; a meta-analysis of reinforcement methods found, for example, that of four materials compared, only fibrin glue and buttressing significantly reduced the odds of developing PAL, while synthetic glue and collagen patch yielded non-significant reductions (12). Buttressing reduces the incidence of air leaks at the staple lines, while it does not affect the duration of postoperative air leaks (12-17).

Synthetic buttressing currently requires manual application of the material to the stapler prior to firing the staples (14). Stapler cartridges preloaded with buttress material (*Figure 1*) can streamline the operating room procedures and reduce the risk of human errors while providing the benefits of reinforced staple lines.

Our study reports prospectively collected data on a cohort of patients in a post-market characterization of safety outcomes following the routine clinical use of stapler reloads with pre-attached reinforcement (reinforced reloads) in surgery for lung cancer via open and minimally invasive approaches. We present the following article in accordance with the TREND reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-220/rc).

Methods

Study design

This study was designed as a prospective, non-comparative trial on the safety of buttressing material integrated into the reload cartridge of a surgical stapler for submission to a regulatory body. The investigation was conducted at five European hospitals between May 2015 and May 2016. Its aim was to characterize the safety of the stapling device and the reinforced reloads by tracking adverse events (AEs) under varying circumstances and in the hands of different surgeons. All study patients provided informed consent, and the study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and approved by the Joint Research Compliance Office (No. 14SM2245), the Comité consultative sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS, No. 15.396), and the Ethikkomission der Medizinischen Universität Innsbruck (No.: AN2015-0129 349/4.16). The study was registered with clinicaltrials.gov (NCT02500537).

The primary study outcome was the incidence of device-related AEs, particularly concerning bleeding [defined as an estimated blood loss (EBL) of ≥50 mL per study protocol] and leaks. Secondary outcomes included intraoperative bleeding and leaks, the index hospital stay incidence, leak duration , the incidence of infections, reinterventions to address staple line failures, as well as hospital readmissions and complications within 30 days from surgery.

The initial protocol intended for patients to be divided into two groups: abdominal and thoracic procedures with enrollment targets of 60 and 40 patients at seven and five hospitals, respectively. To properly evaluate the outcomes for the two indications, the findings were reported separately for abdominal and thoracic procedures. This study presents the results of the thoracic group, while a companion report presents those of the abdominal (bariatric

surgery) grouping (18).

The definition of infection adopted in the protocol refers to infections linked to the staple line. The recorded data referred primarily to infections at the surgical incision site, with no link to the staple line discernible. The outcome is reported as surgical site infection (SSI).

Device

The device used in this study is a manual stapler using the Endo GIA™ Tri-Staple™ technology with Reinforced Reload (Covidien, Mansfield, MA). This Tri-Staple™ reload fires a triple-staggered row of titanium staples. It is preloaded with buttress material: a layer of NEOVEIL™ Reinforcement Staple Line Material, an absorbable polyglycolide (PGA) porous mesh developed by GUNZE (Osaka, Japan) that is attached to the anvil and cartridge of the stapler reloads with an anchoring suture. After staple firing, the buttressing material remains on the tissue, secured by staples on both sides of the cut line. Purple and black cartridges of 45 or 60 mm length were used as appropriate. The on-site surgeon determined the size and quantity of the cartridges during surgery. .

Study population

Consecutive consenting patients between 18–80 years of age, a forced expiratory volume in 1 second (FEV1) ≥40% and undergoing an indicated primary thoracic procedure (open or VATS) for lung cancer where the reinforced stapler device is used per its Instructions for Use were eligible for inclusion. Patients undergoing cardiac and vascular procedures, emergency procedures or revisions/reoperations for the same indication as well as anticoagulant treatment were excluded. Pregnancy, co-morbidities which, in the opinion of the Investigator, will not be appropriate for the study, life expectancy of less than 6 months, bleeding disorders and concurrent enrollment in other studies were further exclusion criteria.

Assessment of adverse events

AEs were assessed based on changes to the subject identified in physical examinations, laboratory tests, and/or signs and symptoms. Conditions that required preplanned procedures, and symptoms of preexisting conditions found during screening were not considered as AEs, unless either of these were exacerbated since the initial screening. Patients were monitored from the beginning of the procedure until the 30-day follow-up visit. The severity, duration, and association to the investigational device of all AEs was evaluated. A device-related AE was defined as being related to, or caused by, the investigational device. Encoding for the AE required the surgical team in attendance of the procedure to indicate the relationship of the AE separately to the procedure and to the device on a scale. For the most conservative presentation of results, all events with no other known etiologies are counted as related to the device or procedure.

Perioperative measures

The staple line was evaluated for bleeding, leakage, origin of the leak site in relation to buttressing, and need for interventions to treat staple line failure. Intraoperative air leak tests were performed by infusing saline buffer into the thoracic cavity, reinflating the lung, and checking for air bubbles. All air leaks irrespective of their duration were recorded; air leaks with a duration of more than 7 days were considered persistent air leaks. Total EBL and the occurrence of blood transfusions as well as device deficiencies and AEs were also recorded.

Postoperative measures

Prior to discharge, information on surgical site and infection assessment, vital signs, incidence of postoperative bleeding, EBL, requirement of blood transfusions, incidence and cause of reoperations, length of hospital stay, AEs, and treatment for AEs were collected. Postoperative drain management was performed according to local protocols at each institution.

During a 30-day follow-up examination, vital signs were collected, and a physical examination was performed. This included collecting the incidence and causes of hospital readmissions and staple line reinterventions, as well as AEs and their management.

Statistical analysis

The statistical power for the entire study was estimated at 86% to capture at least one subject with a device-related AE based on an assumed incidence rate of 2% for 100 subjects in both indications, with thoracic procedures having a 77% probability with a minimum of 30 subjects. Endpoints were collected for each participant. The endpoint analysis was

Table 1 Baseline demographics

Parameter	Overall (n=40)
Age, mean ± SD, years	65±10
Female, n (%)	20 (50.0)
FEV1, mean ± SD, %	82±20
BMI, mean ± SD	27.9±5.9
ASA class, n (%)	
Class 1	2 (5.0)
Class 2	15 (37.5)
Class 3	20 (50.0)
Unknown	3 (7.5)
Tobacco use, n (%)	
Current smoker	11 (27.5)
Former smoker	20 (50.0)
Non-smoker	9 (22.5)
Duration smoking†, years, median [IQR]	43 [29–52]
Duration since patient stopped smoking‡, years, median [IQR]	7 [1–10]
Co-morbidities, n (%)	38 (95.0)
Cardiovascular	5 (12.5)
Diabetes mellitus type II	3 (7.5)
Gastrointestinal	5 (12.5)
Hypertension	15 (37.5)
Musculoskeletal	4 (10.0)
Renal	1 (2.5)
Respiratory (lung)	26 (65.0)
Respiratory (other)	2 (5.0)
Other	22 (55.0)

†, duration of smoking only applies to former and current smokers for whom starting age and/or quitting age were available; ‡, duration since patient stopped smoking only applies to former smokers for whom quitting age was available. SD, standard deviation; FEV1, forced expiratory volume in 1 second; BMI, body mass index; ASA, American Society of Anesthesiologists; IQR, interquartile range.

summarized across all patients with descriptive statistics as counts and percentages, mean ± standard deviation [SD], and median with interquartile range (IQR), as appropriate. Comparative tests that yield p-values were not performed. All analyses were performed with the Statistical Analysis System (SAS® Version 8.0 or higher, SAS Inc., Cary, NC; RRID:SCR_008567).

Results

Patient demographics

Per protocol, 40 consecutive patients were recruited and had perioperative data for analysis. One patient was lost to follow-up, leaving 39 patients with data for the postoperative period of 30 days. Demographics are shown in *Table 1*. The subjects were evenly split, male and female, and most were smokers (current or former) with a median duration of 43 years [IQR: 29–52].

Intraoperative outcomes

Table 2 summarizes the perioperative data. Different procedures were performed, mostly for lung cancer treatment (wedge resection and/or lobectomy), but biopsies were also included. Most surgeries were lobectomies (22/40, 55%), and most were using VATS access (31/40, 78%). The procedures classed as "other" ranged from nodule biopsy to a lobectomy that was converted to thoracotomy, thus giving rise to large uncertainty intervals for some parameters. Most staplings (146/149 firings) were on parenchyma or fissure with few on bronchus (2/149) and one staple firing on parenchyma that also included vasculature (1/149).

Half of all patients (20/40, 50%) had a total EBL of ≥50 mL as a result of the operation, but none of these cases involved staple line intervention to resolve bleeding. Only two patients (5%) experienced bleeding at the staple line; one with an EBL of 30 mL, resolved with application of pressure, the other with an EBL of 300 mL, but the method of intervention to resolve it was not documented. The median intraoperative EBL was 40 [IQR: 0–212] mL. Two patients required intraoperative transfusion.

Leaks were detected in three patients (9%). All three leaks were minor and therefore managed conservatively.

Staple line interventions occurred for 5/40 patients (13%) including the minor bleed resolved with pressure, conservative management of a leak, and a resection of additional lung tissue to release a reinforced reload that could no longer be opened after firing (the only device-related AE). Two other interventions (for a leak and a bleed) occurred away from the buttressed staple line.

Staple line buttressing is generally considered most useful in patients with impaired lung function (with FEV1 <60%

Table 2 Perioperative data

Parameter	Unimpaired lung function (n=33)	Impaired lung function (n=7)	Overall (n=40)
Procedure, n (%)			
Lobectomy	19 (57.6)	3 (42.9)	22 (55.0)
Wedge resection	7 (21.2)	3 (42.9)	10 (25.0)
Combined lobectomy and wedge resection	2 (6.1)	1 (14.3)	3 (7.5)
Other[†]	5 (15.2)	0 (0.0)	5 (12.5)
Operative time, median [IQR], minutes	165 [105–190]	155 [85–171]	158 [100–184]
ICU stay, n (%)	13 (39.4)	3 (42.9)	16 (40.0)
SSI class, n (%)			
Class I[‡]	33 (100.0)	7 (100.0)	40 (100.0)
Hemostasis (intraoperative)			
Total EBL, median [IQR], mL	50 [0–225]	20 [0–330]	40 [0–212]
Total EBL ≥50 mL, n (%)	17 (51.5)	3 (42.9)	20 (50.0)
EBL ≥50 mL at staple line, n (%)	1 (3.0)	0 (0.0)	1 (2.5)
Bleeding with staple line intervention, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Transfusion required, n (%)	2 (6.1)	0 (0.0)	2 (5.0)
Leak, n (%)			
Leak test performed	26 (78.8)	7 (100.0)	33 (82.5)
Leak detected	3/26 (11.5)	0 (0.0)	3 (9.1)
Leak addressed before closure	2/3 (66.7)	n/a	2/3 (66.7)
Staple line, n (%)			
Staple line visualized	32 (97.0)	7 (100.0)	39 (97.5)
Buttress visualized in place	33 (100.0)	7 (100.0)	40 (100.0)
Any bleeding observed at staple line	2 (6.1)	0 (0.0)	2 (5.0)
Perioperative intervention[§]	5 (15.2)	0 (0.0)	5 (12.5)
Pre-discharge reintervention[¶]	2 (6.1)	0 (0.0)	2 (5.0)

[†], other procedures include combined pleural biopsy and wedge resection, combined lobectomy and lymphadenectomy, VATS biopsy, resection of posterior mediastinal mass, and lobectomy that was converted to thoracotomy; [‡], class I surgical site infections are defined as clean wounds (non-traumatic wound, noninflamed, no break in technique, no entry of the infection into the gastrointestinal, genitourinary or respiratory tract or oropharynx); [§], perioperative interventions include pressure to resolve a minor staple line bleeding, a drain for a leak, a resection of additional lung tissue to release a reinforced reload that got stuck and could no longer be opened (the only device-related adverse event), and two other interventions to address a leak and a bleed that occurred away from the buttressed staple line; [¶], pre-discharge reinterventions were the insertion of a drain to address the air leak that developed postoperatively and the exchange of the drain type. IQR, interquartile range; ICU, intensive care unit; SSI, surgical site infection; EBL, estimated blood loss; VATS, video-assisted thoracoscopic surgery.

and/or COPD). In an exploratory analysis, patients with impaired lung function (n=7) were more likely to receive wedge resections than other patients; otherwise, there were no discernable differences. Given the small sample available, however, no significance testing could be performed.

Postoperative outcomes

The median length of stay from surgery to discharge was 4 [IQR: 2–6] days, while patients with impaired lung function had a median hospital stay of 6 [IQR: 3–7] days (*Table 3*).

Table 3 Postoperative outcomes

Parameter	Unimpaired lung function (n=33)	Impaired lung function (n=6)	Overall (n=39)
Length of stay, median [IQR], days	4 [2–6]	6 [3–7]	4 [2–6]
Total postoperative EBL, median [IQR], mL	50 [0–120]	60 [45–125]	50 [0–135]
Postoperative EBL ≥50 mL, n (%)	17 (51.5)	4 (66.7)	21 (53.8)
Postoperative leak[†], n (%)	3 (9.1)	0 (0.0)	3 (7.7)
Drain			
Drain used, n (%)	31 (94%)	6 (100.0)	37 (94.9)
Volume, median [IQR], mL	400 [100–1,013]	400 [244–631]	400 [100–935]
Duration, median [IQR], days	3 [1–4]	3 [1–5]	3 [1–4]
Readmission (any)[‡], n (%)	3 (9.1)	0 (0.0)	3 (7.7)

[†], duration of postoperative leaks were 4, 5 and 14 days. Only the leak lasting 14 days was considered a prolonged air leak (i.e., lasting >7 days); [‡], reasons for readmission were mild (infection, n=1) or moderate (swelling n=1, pain n=1). IQR, interquartile range; EBL, estimated blood loss.

Twenty-one patients (53.8%) had an EBL of ≥50 mL after surgery. Two patients received pre-discharge interventions, one to change drain type and the other to add a drain to address a postoperative air leak that developed on day three which lasted for 4 days. Two other patients were noted to have air leaks, one lasting 5 days and the other 14 days, for an overall postoperative leak incidence of 3/39 patients not lost to follow-up (7.7%). The patient with impaired lung function lost to follow-up was excluded from the postoperative analyses, as the events recorded here were not limited to index hospitalization and could potentially have occurred after discharge. Drains were used for most patients (94.9%) with a median duration of 3 [IQR: 1–4] days.

Hospital readmission occurred for three patients (of 39 with follow-up data after discharge, 8%). Reasons for readmission were mild (infection, n=1) or moderate (swelling n=1, pain n=1) and all were managed with medication.

Aside from a longer hospital stay, patients with impaired lung function showed no other easily discernable difference in outcomes compared to other patients. Due to the small sample available, no significance testing could be performed.

Safety outcomes

In total, there were 34 AEs (*Table 4*) that occurred in 17 patients (17/40, 43%). Eight patients (20%) had more than one AE. No AEs were classified as severe. The majority of AEs were mild (21/34, 62%), occurred pre-discharge (25/34, 74%), and were associated with the procedure (20/34, 59%). One device-related event occurred intraoperatively in which the reinforcement material became stuck in the stapler and the lung. The event was considered to be of moderate severity and was resolved by additional dissection of lung tissue to remove the stapler cartridge (incidence 1/40 or 3% of patients, 1/149 or 0.7% of reloads). No deaths occurred in the follow-up period.

Discussion

This study was a prospective analysis of complications and AEs associated with the use of a stapler cartridge with pre-attached buttressing material in various lung cancer procedures across a variety of countries, institutions, and users. Complication rates in the present study are comparable to those reported elsewhere for pulmonary resection surgery. The 2017 French study by Alifano *et al.* compared an exogenously added absorbable buttressing material with non-reinforced stapling across 380 patients undergoing lobectomy for lung cancer, randomized to treatment arm (14). The air leak rate of 7% reported for buttressed staple lines is close to the 9% postoperative leak rate of the present study, and both are below the non-buttressed rate of 18% (14). The chest drain duration (4 days), length of stay (9 days), and incidence of at least one complication (46%) in that study also compare well with the present study results (median 3 days, median 4 days, and AE incidence 43%, respectively). Bleeding at the staple line in this study was observed in two patients (5%), which is

Table 4 Safety data

Parameter	Open	VATS	Overall
AEs, n	1	33	34
Classification, n (%)			
Mild[†]	1/1 (100)	20/33 (61)	21/34 (62)
Moderate[‡]	NA	13/33 (39)	13/34 (38)
Timing, n (%)			
In hospital	NA	25/33 (76)	25/34 (74)
Post-discharge	1/1 (100)	8/33 (24)	9/34 (26)
Procedure-related, n (%)	1/1 (100)	19/33 (58)	20/34 (59)
Possible device involvement, n (%)	0/1 (0)	1/33 (3)	1/34 (3)
Related to bleeding, n (%)	0/1 (0)	4/33 (12)	4/34 (12)
Related to leaks, n (%)	0/1 (0)	3/33 (9)	3/34 (9)
Related to infection, n (%)	1/1 (100)	4/33 (12)	5/34 (15)
AEs by patient, n (%)			
Any AE	1/9 (11)	16/31 (52)	17/40 (43)
More than 1 AE	0/9 (0)	8/31 (26)	8/40 (20)
AE in hospital	0/9 (0)	12/31 (39)	12/40 (30)
AE post-discharge[§]	1/9 (11)	5/30 (17)	6/39 (15)
Death	0/9 (0)	0/31 (0)	0/40 (0)

[†], awareness of event, but easily tolerated; [‡], discomfort enough to cause some interference with activities of daily living; [§], note post-discharge total number of patients is decreased due to loss of one patient to follow-up. VATS, video-assisted thoracoscopic surgery; AE, adverse event.

comparable, given the limited size of this study to reporting of 1% in larger series (19). Rates of total intraoperative bleeding ≥50 mL were relatively high at 50%, but such bleeding is typically associated with injury to the pulmonary vasculature (19), rather than parenchymal stapling as was primarily used in this study. A single device AE occurred in the cohort that was associated with only minor bleeding and was intraoperatively resolved, representing a patient incidence of 3% and device incidence of 0.7%. Given the limited size of the present study, the 0% 30-day mortality cannot be reliably compared with rates in the European setting that have been reported at 2% (20, 21).

One instance of PAL was reported in the present study with a leak spanning 14 days, while another lasted 5 days. Only one postoperative air leak developed on day 3, but it was not described as prolonged.

The present device uses pre-attached absorbable buttressing material, but typically, buttressing material is added manually to the cartridge during the operation, as in the study of Alifano *et al.* (14). In that study, no significant difference was noted in operative time, with the buttress group only slightly longer on average than the non-buttressed group. The issue of additional time has, however, been noted in bariatric surgeries, where the benefit of buttressing was thought to outweigh the longer operative time (22). Should a surgeon choose to use buttress material as reinforcement of the staple line in pulmonary resection, the present device would obviate this issue, but the impact of such potential time savings would need to be examined in a larger study of less diverse surgery types. The surgeons and nurses involved in the present study found the preloaded staplers easy to use and reported no technical difficulties with their handling. This impression is similar to what was reported in other studies, where staplers with preloaded buttressing were described as reducing the risk of handling errors and the effort of the surgeon and operating

room staff, as they require no additional preparation and time to apply (16).

The risk factors most strongly associated with the development of PAL are low FEV1, previous smoking history, major anatomic lung resection and pleural adhesions and, to a lesser degree, increased age, male sex and low BMI (23). Staple line reinforcement reduces the occurrence of PAL (12). Therefore, patients with an increased risk of developing PAL after pulmonary resection are most likely to benefit from the application of staple line buttressing.

While staple line buttressing may be safe and effective, it is also expensive. A study by Deguchi *et al.* (17) compared staplers with preloaded absorbable buttressing material with non-reinforced stapling in 125 propensity-matched cases of pulmonary lobectomy each. This study reported that despite being more expensive than regular staplers, reloads with preloaded buttressing did not significantly increase the total material costs, as the use of staple line reinforcement reduced the material costs associated with the intraoperative management of air leaks. As buttressed staple lines have been shown to reduce postoperative air leaks (14,17) and PAL (12), it can be speculated that reinforced reloads may even offer an economic benefit in a broader cost analysis. To our knowledge, such an analysis has not been undertaken.

Limitations

The main limitations of this study are the small size, the time between collection and publication of the data and the lack of comparative data. Conclusions may therefore not generalize to a broad population. The size limitation is partly addressed by the variety of settings, where operators following local practice guidelines demonstrated successful deployment of the device during surgery. Clinically-relevant differences in outcomes have been observed after lung cancer surgery even between hospitals in a single national setting, so the expansion to multiple countries represents a broader sampling of technique (21). Bleeding at other sites cannot be excluded if staple line bleeding was reported. In order to provide a conservative presentation of the results, all blood loss was therefore ascribed to staple line bleeding in these cases. With a follow-up period of 30 days, no statement can be made regarding potential long-term buttress-related foreign body reactions. The efficacy and safety of the stapling devices used depends on the experience of the operating surgeon. Some operational parameters are at the surgeon's discretion, such as whether to use a stapler and if so, whether reinforcement should be applied. These choices may have contributed to limiting the number of patients available for analysis. Future studies may seek increased enrollment in randomized trials or otherwise increase numbers for analysis through retrospective analyses of clinical databases, as in the study in the Netherlands reporting intra-hospital differences, which analyzed over 10,000 patients (21). The data of the present study still, however, serve as an illustration from a broad user base of low device-related complication rates and AEs, providing further evidence of safe deployment of the technology in lung cancer surgery.

Conclusions

Overall, our findings point toward minimal safety concerns in the use of preloaded reinforced reloads as measured by AEs studied in 39 VATS or thoracotomy procedures for a range of pulmonary resections within a 30-day period of the procedure. This finding held across multiple institutions with different local practices. Future studies might focus on larger cohorts in a randomized, comparative context to delineate differences more finely among closure and reinforcement methods to further reduce complication rates after pulmonary resections.

Acknowledgments

Medtronic owns the trial data. Data analyses were performed by Medtronic in partnership with the academic authors. The authors would like to thank Dr. Rex Stanbridge and Dr. Thomas Schmid for the enrollment of patients included in this dataset. The authors would also like to thank the following Medtronic employees for: biostatistical support by Sylvain Anselme, medical writing and editorial support by Gregory M Sindberg, PhD, and administrative support by Stephanie Herrmann-Stevenson. Manuscript writing and editorial support were provided by Dr. Juliane O. Hafermann (Coreva Scientific, Germany), funded by the study sponsor (Medtronic).

Funding: The study was sponsored and funded by Medtronic, which contributed to the study design, data collection and analysis, and manuscript writing. The authors (EL, JB, MS) had final responsibility for the decision to submit for publication. The authors were not paid to write this article by the sponsor or any other agency. The data interpretation presented in this manuscript was performed solely by the authors herein with medical writing support provided by Medtronic being performed in accordance with

Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).

Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-220/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-220/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-220/coif). All authors (or their institutions) received study sponsorship, support for data analysis, medical writing support, and research support provided by Covidien (now owned by Medtronic PLC; Mansfield, MA). EL reports grants from AstraZeneca, grants from Boehringer Ingelheim, grants and personal fees from Medela, grants from Lily Oncology, personal fees from Beigene, personal fees from Roche, personal fees from BMS, outside the submitted work; In addition, EL has a patent P52435GB pending to Imperial Innovations, and a patent P57988GB pending to Imperial Innovations and is the founder of My Cancer Companion, a mobile phone application with the aims of improving health, wellbeing and length of life with cancer. JMB reports other from Medtronic, other from Intuitive Surgery, outside the submitted work. The authors have no other 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 trial was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Written informed consent for participation and publication was obtained from all study patients, and the study was approved by the Joint Research Compliance Office (No.: 14SM2245), the Comité consultative sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS No.: 15.396), and the Ethikkomission der Medizinischen Universität Innsbruck (No.: AN2015-0129 349/4.16).

References

1. Chekan E, Whelan RL. Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes. Med Devices (Auckl) 2014;7:305-18.
2. Hennon M, Yendamuri S. Video assisted thoracoscopic surgery vs. thoracotomy for lobectomy: why are we still talking about this? J Thorac Dis 2019;11:S1284-5.
3. Long H, Tan Q, Luo Q, et al. Thoracoscopic Surgery Versus Thoracotomy for Lung Cancer: Short-Term Outcomes of a Randomized Trial. Ann Thorac Surg 2018;105:386-92.
4. Subotic D, Hojski A, Wiese M, et al. Use of staplers and adverse events in thoracic surgery. J Thorac Dis 2019;11:S1216-21.
5. Petrella F, Spaggiari L. Prolonged air leak after pulmonary lobectomy. J Thorac Dis 2019;11:S1976-8.
6. Geller AD, Zheng H, Mathisen DJ, et al. Relative incremental costs of complications of lobectomy for stage I non-small cell lung cancer. J Thorac Cardiovasc Surg 2018;155:1804-11.
7. Khullar OV, Fernandez FG, Perez S, et al. Time is Money: Hospital Costs Associated With Video-Assisted Thoracoscopic Surgery Lobectomies. Ann Thorac Surg 2016;102:940-7.
8. Cooper JD. Technique to reduce air leaks after resection of emphysematous lung. Ann Thorac Surg 1994;57:1038-9.
9. Fischel RJ, McKenna RJ Jr. Bovine pericardium versus bovine collagen to buttress staples for lung reduction operations. Ann Thorac Surg 1998;65:217-9.
10. Muramatsu T, Ohmori K, Shimamura M, et al. Staple line reinforcement with fleece-coated fibrin glue (TachoComb) after thoracoscopic bullectomy for the treatment of spontaneous pneumothorax. Surg Today 2007;37:745-9.
11. Vaughn CC, Wolner E, Dahan M, et al. Prevention of air leaks after pulmonary wedge resection. Ann Thorac Surg 1997;63:864-6.
12. Malapert G, Hanna HA, Pages PB, et al. Surgical sealant for the prevention of prolonged air leak after lung resection: meta-analysis. Ann Thorac Surg 2010;90:1779-85.

13. Miller JI Jr, Landreneau RJ, Wright CE, et al. A comparative study of buttressed versus nonbuttressed staple line in pulmonary resections. Ann Thorac Surg 2001;71:319-22; discussion 323.
14. Alifano M, Jayle C, Bertin F, et al. Medical and Economic Evaluation of FOREseal Bioabsorbable Reinforcement Sleeves Compared With Current Standard of Care for Reducing Air Leakage Duration After Lung Resection for Malignancy: A Randomized Trial. Ann Surg 2017;265:45-53.
15. Takamochi K, Oh S, Miyasaka Y, et al. Prospective randomized trial comparing buttressed versus nonbuttressed stapling in patients undergoing pulmonary lobectomy. Thorac Cardiovasc Surg 2014;62:696-704.
16. Shigeeda W, Deguchi H, Tomoyasu M, et al. The utility of the Stapler with PGA sheet for pulmonary wedge resection: a propensity score-matched analysis. J Thorac Dis 2019;11:1546-53.
17. Deguchi H, Tomoyasu M, Shigeeda W, et al. Reduction of air leakage using linear staple device with bioabsorbable polyglycolic acid felt for pulmonary lobectomy. Gen Thorac Cardiovasc Surg 2020;68:266-72.
18. Ahmed A, Morales-Conde S, Legrand M et al. Clinical outcomes of pre-attached reinforced stapler reloads in bariatric surgery: A prospective case series. Int J Surg Open 2021;32:100337.
19. Gonzalez-Rivas D, Stupnik T, Fernandez R, et al. Intraoperative bleeding control by uniportal video-assisted thoracoscopic surgery†. Eur J Cardiothorac Surg 2016;49 Suppl 1:i17-24.
20. Green A, Hauge J, Iachina M, et al. The mortality after surgery in primary lung cancer: results from the Danish Lung Cancer Registry. Eur J Cardiothorac Surg 2016;49:589-94.
21. von Meyenfeldt EM, Marres GMH, van Thiel E, et al. Variation in length of hospital stay after lung cancer surgery in the Netherlands. Eur J Cardiothorac Surg 2018;54:560-4.
22. Gayrel X, Loureiro M, Skalli EM, et al. Clinical and Economic Evaluation of Absorbable Staple Line Buttressing in Sleeve Gastrectomy in High-Risk Patients. Obes Surg 2016;26:1710-6.
23. Attaar A, Tam V, Nason KS. Risk Factors for Prolonged Air Leak After Pulmonary Resection: A Systematic Review and Meta-analysis. Ann Surg 2020;271:834-44.

Cite this article as: Lim E, Baste JM, Shackcloth M. Clinical outcomes of pre-attached reinforced stapler reloads in thoracic surgery: a prospective case series. J Thorac Dis 2022;14(8):2864-2873. doi: 10.21037/jtd-22-220