Review Article on Prolonged Air Leak after Lung Surgery: Prediction, Prevention and Management

The role of new staplers in reducing the incidence of air leak

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Contributions: (I) Conception and design: A Marra; (II) Administrative support: Both authors; (III) Provision of study materials or patients: None; (IV) Collection and assembly of data: Both authors; (V) Data analysis and interpretation: Both authors; (VI) Manuscript writing: Both authors; (VII) Final approval of manuscript: Both authors.

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Abstract: Surgical staplers play an important role in the contemporary minimally invasive thoracic surgery including resection of lung tissue. However, staple line failure resulting in postoperative air leaks is a common complication after lung surgery, that if persist more than five days are defined as prolonged air leaks (PALs). PALs are associated with increased length of stay, patient morbidity and mortality, and hospital costs. To reduce the incidence of PALs, stapler devices underwent in the last years ongoing development aimed at improving device-to-tissue interaction. This clinical practice review explores the most important aspects of the evolution of surgical staplers, based on the review of the available literature. Modern staple cartridges entail small bumps to engage tissue and minimize tissue movement during compression and firing. Staplers with graduated staple heights are advocated to generate less stress on tissue during compression and clamping, thus affording greater perfusion into the staple line. However, air leaks may occur from an appropriate staple line with complete pleural coverage and perfusion due to enlarged staple canals after lung inflation, particularly in case of emphysema. To buttress staple line, thus prevent air leaks in high-risk patients, several types of tissue coverage (bovine pericardium, polytetrafluoroethylene, knitted calcium alginate, bioabsorbable polyglycolic acid) have been successfully developed in the last years. Finally, the most advanced stapler technology is represented by the new energy powered staplers, able to eliminate the manual firing force, monitor tissue compression during firing, and making automatic adjustments to optimize the staple line.

Keywords: Lung surgery; pulmonary lobectomy; air leakage; linear stapler

Submitted Feb 14, 2022. Accepted for publication Jul 12, 2022. Published online Aug 19, 2022.
doi: 10.21037/jtd-22-192
View this article at: https://dx.doi.org/10.21037/jtd-22-192

Introduction

With the advent of modern video-assisted thoracoscopic surgery (VATS), mechanical stapling of lung tissue has become essential for both anatomical and atypical lung resections. Since the first successful use of stapler devices for lung surgery in the USSR in the 1950s as well in the USA in the 1960s, endoscopic instruments have been developed for minimally invasive surgery allowing precise, safe, and time saving transection and simultaneous sealing of lung tissue (1).

However, staple line failure resulting in postoperative air leaks is a common complication after lung surgery, that if persist more than five days are defined as prolonged air leaks (PALs) and have a reported incidence of 8%–26% (2,3). In the previous literature, PALs have been associated with increased patient morbidity and mortality, length of stay, and hospital costs (3,4).

Therefore, staple line integrity is critical to create a completely sealed transection line as well as to preserve the perfusion of tissue margins. These issues have been the focus of continuing innovation by surgical stapler manufacturers (5). Recent efforts have been aimed at improving device-to-tissue interaction by optimizing following components of stapler devices:

Figure 1 Signia™ Powered Stapling System with Tri-staple™ technology (6) (with permission of Medtronic Inc., Minneapolis, MN, USA).

Figure 2 ECHELON™+ Powered stapler with GST 45 mm green reload (7) (with permission of Ethicon Inc., Cincinnati, OH, USA).

- ❖ Surface of cartridge and length of staples,
- ❖ Buttress of staple lines with non-absorbable or absorbable material, and
- ❖ Mechanism of firing staples and cutting the tissue.

The present Clinical Practice Review is aimed to provide an overview of above-mentioned features of new staplers to reduce the incidence of air leaks, based on the review of available literature.

Evolution of staple and cartridge conformation

Traditional cartridges were flat-faced with single-height staples. To improve the fixation of the device to the tissues and—therefore—its stability during stapling, manufactures have developed different solutions with focus either on the length of staples or the surface of the cartridge.

The Tri-Staple™ reload (Medtronic, Minneapolis, MN) has a stepped cartridge face that delivers graduated compression and three rows of varied height staples. That design is advocated to generate less stress on tissue during compression and clamping (*Figure 1*) (6).

The Echelon™ stapler reloads (Ethicon Inc., Cincinnati, OH) feature Gripping Surface Technology (GST), which entails small bumps extending from the driver wells such that the cartridge face is not flat. These bumps are intended to engage tissue and minimize distal and lateral tissue movement during stapler compression and firing (*Figure 2*) (7).

To date, there is limited published information on the above-mentioned technologies. Imhoff and Monnet compared two graduated compression staples (Tri-Staple™, Covidien) and standard staples (Endo GIA™, Covidien) for lung biopsy in dogs. In this *ex vivo* experimental study graduated staples leaked at significantly lower airway pressures than standard staples, so the authors concluded that they may not be suitable for canine lung biopsy (8). On the other hand, a single paper reports the application of Tri-Staple™ on human lung tissue, with no complications noted in 56 uses for either wedge resection or bronchus closure (9).

In an *ex vivo* porcine lung model Eckert and coll. investigated differences in air leak occurrence and air leak rates between two different ventilation modalities: positive pressure ventilation (PPV), mimicking intraoperative ventilation, and negative pressure ventilation (NPV), mimicking natural breathing. In addition, they compared the rate of air leaks associated with staple-line configuration with uniform staple heights (UNI) versus graduated staple heights (GRD) under both ventilation modalities. The authors observed an increased occurrence of leaks as well as higher leak rates under NPV than under PPV, and by using graduated staple design than uniform staple design (10).

Another issue is the choice of the appropriate staple height to avoid a mismatch between staple height and tissue thickness, which may result in a leakage due to necrosis or poor apposition. Cartridges are available with different heights of closed, B-shaped staples, varying from 0.75 to 2.3 mm, and are color-coded according to the staple height. However, the staple reload selection is an empiric process based on surgeon's judgement, because there is no current method providing an objective intraoperative measurement of deflated tissue thickness prior to cartridge selection.

Reinforced stapler cartridges

The role of staplers as a protection against air leak was studied in a meta-analysis by Lu *et al.*, they compared the effect of staplers *vs.* electrocautery in patients undergoing segmental lung resection. Because of the high risk of leakage through the quite long tissue resection line uncovered by visceral pleura, this group of patients is most likely to suffer PALs. In the series of 385 patients the advantage of the mechanical staplers on reduction of PAL rate was reported with an OR of 3.91 (95% CI: 1.64–9.35; P=0.002) (11).

However, air leak may occur from an appropriate staple line with complete pleuralization either due to tissue ischaemia or enlarged staple canals. The latter mechanism plays an important role in patients with severe emphysema undergoing lung surgery, as reduced thickness of tissue layers in the staple line may offer less resistance against local pressure in the inflated lung, resulting in enlargement of staple canals or small lacerations of the surrounding visceral pleura.

To buttress staple line, thus prevent air leaks in patients with emphysema, several types of tissue coverage have been developed in the last years.

In the literature the most frequently studied covered line is with bovine pericardium. These reinforced staplers have been always compared with sealants regarding the effectiveness on PAL prevention. Buttresses have been shown in randomized trials to decrease the incidence and duration of air leaks, as well as the time chest tube is required in patients with severe emphysema undergoing atypical resection (12). Although the data are not clear for patients with severe emphysema undergoing anatomic lobectomy or segmentectomy, we assume that it is reasonable to use staple-line buttresses in this patient group as well.

Regarding liquid sealants, most studies have reported neither statistically nor clinically significant improvements in hospital stay or time to removal of chest tube. Although one might think it logical that sealants would demonstrate a clearer benefit in patients with substantial emphysema, this may not be the case, and only a single small study (albeit with positive results) has looked at this subgroup of patients (13). Also needed are studies that are large enough for stratification based on the size of the initial intraoperative air leaks, studies that look at prolonged or complicated air leak as an outcome measure, and studies that evaluate PAL-related costs (12).

Based on the mentioned study on patients undergoing lung volume reduction surgery (LVRS), there is evidence that covered stapler may prevent air leakage through stapler line. The mechanical explanation of the effect of covered staple line was also studied on cadaveric lung models from Murray *et al.* They confirmed that unreinforced staple lines began to leak air at an airway pressure of 20 mmHg, and >90% leaked at a pressure of 35 mmHg. Both bovine pericardium and expanded polytetrafluoroethylene (ePTFE) used in the study significantly reduced the incidence of air leak at these airway pressures. At higher airway pressures, ePTFE was superior to bovine pericardium (13). Similar results emerged from the study conducted by Downey *et al.*: on an experimental pig model, they compared reinforcement with four different materials with normal staplers under different pressure up to 75 mmHg. The conclusion was that commercially available reinforcements allow pulmonary staple lines to tolerate higher intrabronchial pressures without developing air leak. In addition, reinforcement with small intestinal submucosa afforded a significant advantage to the other reinforcements in terms of staple line leak rate. The main limitation of this study was that the authors compared in most of cases the staplers outside the physiologically applied pressure during the operation, as the pressure rarely overcome 30 mmHg (14).

The clinical implication of the above-mentioned studies has been confirmed in a randomized clinical trial performed in leading thoracic surgery centres in Europe (Vienna, Zurich, and Essen). The study group concluded that the median duration of air leaks after LVRS was shorter in the buttressed stapler group than in the control group (0 *vs.* 4 days; P<0.001), with a corresponding shorter median drainage time in this group (5 *vs.* 7.5 days; P=0.045). Hospital stay was similar in the two groups (median: 9.5 *vs.* 12.0 days; P=0.14) (15).

The need to reinforce staple line was also confirmed based on the experimental study of Bonnet *et al.*, in which they compared microscopic lung tissue changes of a porcine lung model after lung resection with and without stapler. They concluded that only perfect allocation of the stapler can prevent leakage through the lung parenchyma. This conclusion is quite important in the era of VATS resections, as stapler line allocation may be not always that perfect depending on the different thoracoscopic access (uniportal or multiportal). In order to prevent PALs, their conclusion indirectly stresses the need of staple line reinforcement in selected patients (16).

Different types of reinforcement material are available on the market. The most utilized ones are bovine pericardium (BP) and polytetrafluoroethylene (PTFE) patches, both not resorbable. In their study Vaughn *et al.* compared the tissue response after reinforcement of the staple line either with the pericardium or PTFE. Based

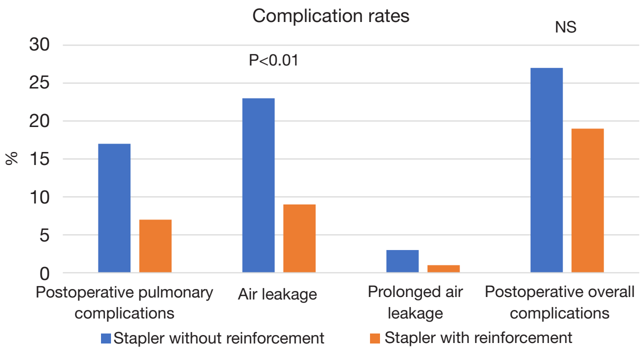

Figure 3 Staplers with polyglycol reinforcement *vs.* staplers without reinforcement: comparison according to postoperative complications. Results from a propensity score-matched analysis comparing patients undergoing pulmonary lobectomy with or without Reinforced Tri-Staple Technology (22). NS, no significant difference.

on their experimental dog model they observed that at 30 days, the BP specimens showed chronic inflammatory changes and thin tissue incorporation, whereas the PTFE specimens had no inflammation and was embedded by a thick tissue layer. At 3 and 6 months, the inflammation in the BP specimens had resolved, but tissue incorporation remained minimal, whereas in the PTFE specimens tissue coverage had increased (P<0.0001). No air leaks, staple-line failure, or infections were observed in both study groups. In conclusion, a more favourable tissue response was observed in the group with PTFE patches (17). Further, we could find some anecdotal papers concerning complications after application of bovine pericardium like metalloptysis (18,19).

There are many others reinforcement materials which are under investigation und can represent an alternative to the widely used ones. The most important characteristic of these materials should be easily application, high sealing power, and safety.

In a multicenter study from France the role of knitted calcium alginate (FOREseal™) sleeves for buttressing the staple line were investigated in different types of resections. Intraoperative air leakage was assessed at a mean ventilatory peak pressure of 30 cmH_2O, and rated as grade 1, 2, or 3. Persistent air leakage in the postoperative course, as well as any relevant event, were assessed daily. The study group concluded that FOREseal™ is an ergonomic, safe, and promising new material instead of nonabsorbable materials and xenomaterials for staple-line reinforcement (20).

Contrary to the results of the French Investigation was the conclusion regarding the efficacity of FOREseal™ in a randomized controlled trial conducted by Alifano *et al.* They have tested the efficacy of the mentioned buttress in preventing PAL in high-risk patients with emphysema undergoing anatomical lung resection (lobectomy or bilobectomy). Based on collected data of 380 randomized patients the authors concluded that buttressing has not advantages over standard fissure separation with linear stapler without reinforcement (21).

Another newly investigated agent for buttressing the staplers is bioabsorbable polyglycolic acid (PGA). Deguchi *et al.* conducted a propensity score matched analysis on two groups of 125 patients each. They results confirmed that using the stapler with PGA to divide the incomplete interlobar fissure for lobectomy reduced postoperative air leakage and decreased the need for additional intraoperative management using fibrin glue as compared with stapler without reinforcement (*Figure 3*) (22).

In their experimental investigation on a dog model, Hashimoto *et al.* have compared the efficacy of different stapler line buttressing, also including the combination form FOREseal™ plus PGA. They concluded that this alginate buttress may be more effective for preventing air leakage after lung surgery, because it has both sealant and bolster effects working in conjunction. Interestingly, in their study model the applied pressure for proving air tightness of stapled lung parenchyma was more than 50 mmHg—away from the more physiological pressures applied during intraoperative ventilation (23).

A quite new and scarce investigated material is the small intestinal submucosa (SIS). The report by Downey *et al.* has shown some advantages over commercially used bovine pericardium as well as PTFE. A possible explanation of his quality was that due to its bioabsorbable profile SIS may be a more suitable material for staple line reinforcement in selected patients requiring nonanatomic lung resection (14).

In conclusion, based on the evidence of the literature the role of the buttressed stapler seems to be important to reduce the rate of postoperative PALs, especially in the group of patients with predictive factors for this economically relevant surgical complication.

The new (energy) powered staplers

The evolution of the minimally invasive thoracic surgery needed the improvement of the stapler design to reduce not only the operation time but also postoperative complications such as PAL. The evolution of surgical staplers has been described previously; nowadays the most advanced stapler technology are the powered staplers. The powered stapling systems offers one-handed, push-button operations, which eliminate the manual firing force and possibly enable more precise resection.

Increased tension to reduce the costs of surgery despite of increasing material costs can be mostly compensated by reducing the length of patient's hospital stay. That's why it is important to prove if the newly designed staplers can reduce the overall costs of lung surgery by preventing postoperative complications such PAL.

Based on the analysis of 433 patients with the use of staplers in their VATS lobectomy for lung cancer, Gao *et al.* confirmed that the use of powered stapler afforded a significantly shorter operation time and postoperative hospital length of stay than using the manual stapler in a multivariable regression analysis adjusted by patient characteristics. However, no other significant differences, including the rates of PAL were observed for other clinical outcomes between the two stapler groups (24).

A confirmation of the above-mentioned results has emerged from the study conducted by Licht *et al.*, who investigated the clinical outcome after VATS using a new surgical stapling device in two different geographic regions (United States and Europe). Ten participating institutions enrolled a total of 226 subjects in this study. Primary endpoints were occurrence and duration of postoperative air leaks, including PALs. Regional differences were observed for cartridge selection relative to tissue type and intraoperative leak testing. Despite disparity in surgical technique between the two continents, no significant differences in air leak or other clinical outcome were observed (25).

These results have been confirmed in the similarly designed, retrospective study by Miller *et al.*, who compared hospital resource use, costs, and complications of VATS lobectomy procedures using powered versus manual endoscopic surgical staplers. Multivariate regression analysis adjusted for patients, institution, provider characteristics and hospital-level clustering was carried out to compare following factors: length of hospitalisation, operation time, total hospital costs, complications (bleeding and/or need for blood transfusion, PALs, pneumonia, and other infection), discharge status, and all-cause readmissions at 30, 60, and 90 days. The analysis included only VATS lobectomy procedures. As a result, powered staplers were associated with significant benefits in terms of hospital resource use, costs, and clinical outcomes when compared with manual staplers. Concerning the incidence of PALs, the study didn't show any advantage of powered staplers (26).

Because one of the most sensitive group of patients at risk for air leak as main postoperative complication are patients with emphysema undergoing LVRS, the randomized study by Akil *et al.* addressed the question if powered staplers may afford any form of clinical benefit. Patients with advanced emphysema were enrolled in a prospective randomized trial and underwent bilateral VATS-LVRS. Each patient was randomized for receiving lung resection with the powered iDrive™ or the mechanical Endo GIA™ stapler device (both manufactured by Medtronic Inc., Minneapolis, MN) on the right lung or left lung. Forty resections were performed with the iDrive™ and 40 with the Endo GIA™. Duration of surgery, air leakage after extubation and on postoperative day 1, as well as length of chest tube therapy, were recorded. The powered system led to comparable results to the conventional mechanical stapler without any disadvantages in patients undergoing bilateral VATS-LVRS (27).

No advantages of the powered staplers over the manual ones were confirmed also in the multicentric study performed by Qiu *et al.*, analysis was carried out on a heterogenous group of lung resections (anatomic and wedge ones). Post-operative data included air leak assessment, chest tube duration, length of hospital stay, and adverse events. Post-operative air leaks were observed in 5 (5.3%) patients undergoing lobectomy, whereas PALs in only 1 (1.1%) patient. The authors concluded that powered staplers make the VATS procedure easier for the surgeon and may achieve intra- and post-operative outcomes comparable to those previously reported using mechanical devices (28).

Another group of patients at risk of postoperative PAL are those with incomplete fissure. The role of new stapler devices in these patients was investigated by Shigeeda *et al.* Their study evaluated the effectiveness of powered staplers in reducing the need for intraoperative fibrin glue and the incidence of air leakage after radical pulmonary resection. The subjects of this retrospective study were 478 patients who underwent resection for lung cancer. Propensity score analysis generated two matched pairs of 177 patients each treated by using powered or manual staplers, respectively. There was significantly less intraoperative need for fibrin glue in the powered stapler group than in the manual stapler group (47.5% *vs.* 58.8%; P=0.033). The incidence of PAL was also significantly lower in the powered stapler group than in the manual stapler group (2.8% *vs.* 10.7%; P=0.003). The authors concluded that the use of a powered

Figure 4 The Intuitive Surgical Stapler SureForm™ is compatible with Xi or X da Vinci Surgical Systems. The device can be used with staple line or tissue buttressing material (30) (with permission of Intuitive Surgical, Inc., Sunnyvale, CA. ©2022 Intuitive Surgical Operations, Inc.).

stapler to divide an incomplete interlobar fissure decreased the need for additional intraoperative management using fibrin glue and reduced postoperative air leakage in radical pulmonary resection (29).

One of the most unclear questions is whether the higher costs of new powered staplers could be compensated by shortening of postoperative stay. Zervos *et al.* tried to answer on this question comparing the more expensive robotic staplers (*Figure 4*) with hand-held staplers. They compared perioperative outcomes and costs between robotic lobectomy cases that utilized robotic staplers versus hand-held staplers in real-world clinical practice with a propensity score matched analysis. In their multivariate regression analysis, robotic stapler was associated with a reduced risk for air leak (OR =0.70; 95% CI: 0.50–0.98) and overall complications (OR =0.76; 95% CI: 0.58–0.99). The total index hospitalization costs were comparable between the two groups (median: $21,667 in the robotic stapler group *vs.* $21,398 in the hand-held stapler group; P=0.22) (30).

Based on the cited studies is difficult to confirm any advantages of powered staplers regarding PAL. Concerning the cost analysis it is crucial to select patients, who based on preoperative and intraoperative findings are at higher risk for prolonged leakage from the resection surface (31,32); in those cases, the use of powered staplers could be cost effective and could propose some advantages over mechanical (or old generation) staplers.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (Roberto Crisci, Alessandro Brunelli, Florian Augustin, Francesco Zaraca) for the series "Prolonged Air Leak after Lung Surgery: Prediction, Prevention and Management" published in *Journal of Thoracic Disease*. The article has undergone external peer review.

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-192/prf

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-192/coif). The special series "Prolonged Air Leak after Lung Surgery: Prediction, Prevention and Management" was sponsored by Bard Limited. Bard Limited has no interference on the contents of the special series. 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.

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Cite this article as: Marra A, Yankulov A. The role of new staplers in reducing the incidence of air leak. J Thorac Dis 2023;15(2):893-900. doi: 10.21037/jtd-22-192

