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Staple Line Reinforcement for Thoracic Surgery: A Retrospective Study of Memorial Thoracic Patients from 2009-2012

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Introduction

Description of the Problem

Linear staplers have long been used in thoracic surgery. However, the challenge associated with successfully treating air leakage from the staple line is still a concern for thoracic surgeons. The linear stapler does not consistently obtain an airtight closure; consequently, leading to postoperative air leaks that can significantly prolong a patient's recovery and hospitalization time. Air leaks from thoracic linear staplers can be caused by several factors such as tissue fragility, surgical techniques, and excessive tissue tension. Linear staplers also contribute to the high incidence of intraoperative bleeding. While management of bleeding can be rectified with conservative management, regaining control of air leaks is usually more difficult and contributes to one of the most common sources of morbidity for thoracic surgery (Murray, Ho, Hisia, & Little, 2002).

Linear staplers are used in abdominal surgery, thoracic surgery, gynecology, and pediatric surgery. These staplers are used for anastomosing of organs and tissues. The linear stapler is loaded with titanium staples and is easily operated by the complete squeeze of the trigger handle. Appropriate cartridges can be utilized with the linear stapler to ensure cost-effective, single patient use of the product (Haida Medical, 2012).

The success of thoracic surgery procedures is dependent on the closure of staple lines to prevent air leakage. Reinforcement of the staple line with various stapling devices is recommended to help solve the air leakage problem. While there are significant benefits to decreased operating time and tissue handling with surgical staplers, there are also complications, which typically include leakage and bleeding. In gastric bypass surgeries, leakage failure has been reported to be between 0.5-6% (Knapps, Ghanem, & Merchant, 2013).

Because complications compromise the success of thoracic procedures, staple line reinforcement has gained significant interest. Several techniques have been used to prevent and minimize air leaks, including buttress materials such as bovine pericardium, poly-terafluoroethylene (PTFE), Teflon, polyglycolic acid and gel foam. These materials provide a supporting buttress that can minimize the incidence of leakage and bleeding, as well as reinforce tissue edges that have become frail due to disease. This reinforcement occurs by placing a thin piece of material between the tissue and the stapler. After the stapler is fired, the material can reduce the tension in the staple line, seal the staple holes, and reduce the distance between the staples, which decreases leakage, bleeding, and tearing (Cook, 2014). A retrospective study will be conducted to examine patients who have undergone thoracic surgery involving a new staple line reinforcement material made from porcine small intestinal submucosa.

Definitions of terms

The Biodesign *Staple Line Reinforcement* (SLR) is part of a family of devices whose base material is composed of small intestinal submucosa (SIS), a naturally-derived biomaterial. The SIS biomaterial is minimally processed to maintain the natural three-dimensional, collagen-rich extracellular matrix (ECM), while removing all cells and nuclear matter. No chemical cross-linking is performed. Unlike synthetic or cross-linked meshes, products made from SIS are engineered to facilitate tissue remodeling while being slowly incorporated into the body (Cook, 2014).

Laparoscopic sleeve gastrectomy involves a bariatric surgeon resecting the stomach longitudinally on the greater curvature from the antrum starting opposite of the nerve of Latarjet up to the angle of His. This procedure is performed on patients who are morbidly obese (Iannelli et al., 2008).

Prolonged air leaks in thoracic surgery are defined as air leaks lasting more than 7 to 10 days. Pulmonary air leaks are often associated with pain owing to the chest tubes and immobilization; this causes a major limiting factor for discharge from the hospital (Moser et al., 2008).

Lung volume reduction surgery (LVRS) reduces dyspnea and ameliorates lung function and quality of life for individuals suffering from severe pulmonary emphysema (Moser et al., 2008).

Expanded polyetrafluorethylene (ePTFE) is a type of stapling line reinforcement material that is very strong, and microporous. This material allows for the release of gases without letting liquid penetrate the venting membrane (Gore, 2013).

Background Information

The SIS material is not a merely passive mechanical structure, but contains a complete and complex ECM that includes growth factors and cytokines that modulate cell behavior and aid in the healing process. During the remodeling process, the SLR is infiltrated by patient cells, tissues and blood vessels. SLR is slowly reabsorbed into the body, metabolized, and then excreted. SLR is not a long-term foreign body; therefore, the problems associated with permanent implant materials (erosion, chronic inflammation, and infection) are mitigated. Moreover, the SLR device provides a stronger seal than other materials by being completely remodeled into fully vascularized tissue. Surgeons find the SLR device easier to apply because its thin profile is string free and pre-coated with water-soluble adhesive. Other advantages of the SLR device is that it strengthens the staple line, offers a thin, uniform surface, resists migration and erosion, and it's available in sizes for most staplers. The SIS material embodying the SLR device is used frequently in gastric surgery with good outcomes not limited to reduced bleeding

and leaks. Consequently, this prompted our research in investigating patient outcomes with the SLR device in thoracic surgery (Cook, 2014).

Research Question

Population: In patients undergoing thoracic surgery (lobectomy, wedge resection, and/or blebectomy),

Intervention: Does using the Biodesign Staple Line Reinforcement device

Comparison: Compared to patients who did not receive the Biodesign Staple Line Reinforcement device listed in the Society of Thoracic Surgeons General Thoracic Surgery Database

Outcomes: Lead to better patient outcomes (decreased bleeding and air leakage from staples requiring chest tube insertion).

Theoretical Framework

In researching the various surgical closure options available for surgical procedures that yield optimal patient outcomes, the theoretical framework that seems to assess all aspects of the patient is Betty Neuman's Systems Model. In Neuman's model assessment, it states a person as being a layered multidimensional being. Each layer consists of a five-person variable or subsystems. The first variable refers to the physiological component, which relates to the physical aspects of the patient (for example, a patient presenting with lung cancer requiring a thoracotomy – patient may present with substantial weight loss, dyspnea on exertion, hemoptysis, etc.). The second variable is psychological that pertains to the emotional and mental processes. A patient undergoing thoracic surgery most likely is undergoing stress and experiencing some anxiety about his/her prognosis and recovery. The third component refers to the relationships and expectations society can impose on the person during a difficult time in

his/her life. This aspect of Neuman's model would involve the patient's support system (intermediate/extended family members; church family). The last two variables of Newman's Systems Model embody the importance of spiritual and development beliefs over time. The developmental factors of this patient population might include how the patient perceives how he/she will adjust to his/her lifestyle after the procedure. The spiritual factor would include what religious practice does the patient implement into his/her life (Nursing Theories, 2012).

Review of Literature

Introduction

The general topic of the review of literature being investigated involves examining the benefits of utilizing a stapling line reinforcement material in lieu of traditional closure devices in surgical procedures. The database resources include: CINAHL, Medline, Google Scholar, and the McKee Library. The key words used for the literature search include: staple line reinforcement, lobectomy, blebectomy, and buttress. A total of six citations that met specific criteria (primary sources, peer-reviewed, etc.) were included in this review.

Description of Studies

Stamou et al. (2011) conducted a prospective comparative study in order to determine if staple-line reinforcement with bovine pericardial strip reduces surgical complications for the 187 patients undergoing a laparoscopic sleeve surgery, with a median preoperative body mass index (BMI) of 45.3 kg/2. Ninety-six patients (group A) received the bovine pericardial strip staple-line reinforcement, and 91 (group B) did not; the two groups were similar in their various characteristics and they were not randomized. (Stamou et al., 2011).

Preoperative and postoperative collection tools were used to evaluate patient data in this study. Preoperative collection tools consisted of an evaluation of cardiopulmonary function,

measurement of weight and height using a standard electronic scale, and upper gastrointestinal endoscopy. Postoperative collection tools consisted of each patient having a CT scan to determine if there was a staple-line leak postoperatively. Any patient with septic signs underwent a CT scan to determine if there was an abdominal abscess. Bleeding was recorded as a surgical complication if a packed red cell blood transfusion was required. The experiment involved dividing the stomach of each patient along the lesser curvature, using the Echelon stapling device, Echelon Compact Linear Cutter (60mm), loaded with ECR60D cartridges that deliver six rows of stapling clips. Patients in group A (sample) had their staple line reinforced with bovine pericardium strips and patients in group B (control) did not have the staple line reinforcement (Stamou et al., 2011).

The significant results that these studies revealed were that in group A (SLR device utilized) there were significantly fewer occurrences of bleeding from the staple line and intraabdominal abscesses (p = 0.012 and 0.026) in contrast to group B (control group who did not receive SLR). Hence, patients in group A had overall fewer surgical complications (p = 0.007) than patients in group B when assessing post-operative leaks, abscesses, bleeding, reoperation, and death. A limitation of this study is that the postoperative outcomes of the patients could have been influenced by the patients' age, comorbidities, smoking, etc. In addition to this limitation, the sample size was small (Stamou et al., 2011).

Salgado, Roasa, Nonino-Borges, & Ceneviva (2011) conducted a prospective randomized study from August 2009 to April 2010 comparing extraluminal suture and a nonpermanent buttressing material (Seamguard) for staple line reinforcement on 40 random patients subjected to open-banded Roux-en-Y gastric bypass for the treatment of morbid obesity at a Brazilian University hospital by two surgeons. After intraoperative reinforcement, each patient's staple

line was tested by infusion of methylene blue. All 40 patients left the operating room wearing an abdominal drain to measure leakage. Salgado et al. (2011) found that no staple line dehiscence and no leakage occurred for both the Seamgurad and extraluminal suture groups. In addition, no mortality occurred for either group. Although not reaching statistical significance, the surgical time was lower for the Seamguard group (3hr and 45 minutes) versus the suture group (4 hours and 8 minutes) (p=0.2482). A limitation of this group is there is not a control group representing no staple line reinforcement and the sample size is small (Salgado et al., 2011).

Albanopoulos et al. (2012) conducted a prospective randomized clinical study from July 2009 to July 2010 comparing two different techniques in laparoscopic sleeve gastrectomy (LSG): buttressing the stapling line at the gastroesophageal junction (angle of Hiss) with Gore Seamguard versus staple-line suturing Polydioxanone (PDS) II sutures in a hospital setting in order to assess major surgical complications and cost analysis of both techniques. The sample group (group A) consisted of 48 patients who received the Gore Seamguard SLR device and the control group (group B) consisted of 42 patients who had continuous suture (PDS II). Total operative time ranged from 45-75 minutes for group A and 60 to 93 minutes for group B. The results concluded that total operative time and stomach sectioning time were significantly increased in group B (55.3 vs 69.4 and 13.2 vs 27.2, p<0.001). Although not reaching statistical significance, staple-line leak rates were 0% in group A and 4.2% in group B (p = 0.28) and bleeding rates were 0% in group A and 2% in group B (p = 0.53) There was no statistical significance for overall postoperative complications between the sample and control group (p=0.1) (Albanopoulos et al., 2012).

Dapri, Cadière, & Himpens (2010) conducted a prospective randomized clinical study to randomly compare three techniques in laparoscopic sleeve gastrectomy: no staple line

reinforcement (group 1), buttressing of the staple line with Gore Seamguard (group 2), and staple line suturing (group 3) between January 2008 and February 2009 on 75 similar patients. The three groups were assigned based on the type of their closure surgical intervention: 25 patients who had no staple line reinforcement (group 1), 25 patients with the buttressing technique at the staple line with Gore Seamguard (group 2), and 25 patients who had staple line suturing (group 3). Each patient of the three groups underwent laparoscopic sleeve gastrectomy by the same surgeon. The significant results found by Dapri et al. (2010) were that the mean blood loss during stomach sectioning was statistically different between the three groups ($p<0.001$) as evidenced by group 2 (SLR with Seamguard) having less bleeding time. Additionally, mean total blood loss was statistically significantly lower for group 2 versus the group 1 and group 3 ($p=0.03$). An interesting finding was that the mean hospital stay for patients in group 2 was significantly lower ($p=0.01$) than group 1 or group 3. No significant difference was found regarding postoperative leaks between the three different techniques of staple line reinforcement (Dapri et al., 2010).

Moser et al. (2008) performed a prospective randomized blinded study on 25 patients with severe emphysema who underwent bilateral lung volume reduction surgery (LVRS) by video-assisted thoracoscopy between June 2005 and October 2006 by the same surgeon to evaluate the effect of reinforcing the stapler lines with an autologous fibrin sealant (Vivostat) in a series of patients undergoing LVRS and examine the incidence of prolonged air leak and duration of chest tube drainage. The experiment consisted of randomly assigning each patient to the control or the treatment group (Vivostat group) at the end of each LVRS on the first side. In patients who were assigned to the control group on the first side, they were assigned to the treatment group on the second side; therefore, each patient was their own control. At the end of

the operation, two 24F apical chest tubes were inserted on each side and were systematically set at 10cm H_2O suction. Air leaks were assessed using the chest tube, with a severity score ranging from 0 (no leak) to 4 (severe continuous air leak with stream of bubbles or coalesced bubbles) that was interpreted by two independent observers blinded to the treatment in the intensive care unit. The total severity score was significantly lower in the Vivostat group ($p<0.01$) than the control group. Prolonged air leaks were found in only one (4.5%) of 22 treated sides as compared with seven (31.8%) of 22 control sides ($p = 0.031$). The mean duration of chest tube drainage was also significantly reduced in the treatment group (2.83 +/- 1.96days vs. 5.88 +/- 2.96 days; $p < 0.001$) as compared to the control group. The in-hospital mortality rate was 12% (3/25). Two died of a pulmonary embolism one day after surgery; the third patient died of pneumonia 10 days after surgery (Moser et al., 2008).

Murray et al. (2002) compared the effect of a range of airway pressures on pulmonary air leaks from closure techniques, using ten fresh frozen human cadaver thoraxes without gross evidence of significant pulmonary disease in three groups: simple staples (group 1), staple line reinforcement with either bovine pericardium (group 2) or ePTFE (group 3). The experiment consisted of the researcher performing a sternotomy and using a GIA™ surgical stapler from the same manufacturer to obtain 25 staple lines in each of the three groups. An air leak was identified by the escape of air through the staple line; a staple line without an air leak was considered a survivor. Murray et al. (2002) found that unreinforced versus bovine pericardium ($p<0.0001$), unreinforced versus ePTFE ($p<0.0001$), and ePTFE versus bovine pericardium ($p=0.001$). Lower airway pressures portend fewer air leaks due to less tension on the staple line. Airway pressures up to 25cm H_2O for both ePTFE and bovine pericardium reinforcement demonstrate the same degree of protection from the development of staple line air leaks.

However, if the airway pressure was greater than 50 cm H_2O, 48% of bovine pericardium-reinforced staples leaked air versus 12% of the ePTFE-reinforcement group (Murray et al., 2002).

Methods

Research Design

The purpose of this retrospective study is to examine medical records of all patients undergoing thoracic surgical procedures who received the SLR device between 2009 and 2012 at Memorial Hospital. The findings of these patients will then be compared to patients who meet the same inclusion/exclusion criteria, but did not receive the SLR device retrieved from the Society of Thoracic Surgeons General Thoracic Surgery Database. Outcomes will be measured by assessing clinically-relevant outcome measures of air leak duration, drainage volume, and time to drain removal, average days to chest tube removal, and average hospital stay duration. This is an ongoing retrospective study by Dr. Headrick and Cook Medical team to examine medical records of all patients undergoing thoracic surgical procedures (blebectomy, wedge resection, lobectomy, etc.) who received the SRL device at Memorial Hospital between 2009-2012. Waiver of informed consent was granted for this retrospective data collection due to it being a retrospective study and no patient involvement. Charts were reviewed for patient demographics, comorbidities, diagnosis, and previous surgeries. Operative notes were examined for the type of surgical procedure recorded. Clinically relevant outcome measures of air leakage duration, drainage volume and time to drain removal, average days to chest tube removal, and average hospital stay duration were evaluated.

Population

A total of 225 patients were identified who had undergone thoracic surgery procedures using the porcine SLR to bolster the staple lines. The mean age of the patient population was 64.7. Patients' ages ranged from 17-88 years of age with a mean BMI of 26.7 +/- 5.6kg/m^2 (range: 16 to 45). There were 127 (56.7%) women and 98 (43.3%) men. Seventy-one (31.7%) patients currently smoked at the time of the procedure, while 118 (52.7%) were former smokers and 35 (15.6%) had no smoking history. A diagnosis of malignancy was present in 190 (84.4%) patients. Procedures performed included lobectomy, wedge resection, and blebectomy; many patients had more than a single type of procedure performed. A total of 225 patients, who did not receive the SLR device, from the Thoracic Surgery database will be retrieved at a later time and findings will be reported.

Variables

Preoperative and operative variables for this research evaluated the following: gender, age, BMI, comorbidities (diabetes, hypertension, hypercholesterolemia), smoking status, concomitant diagnoses (malignancy, COPD, benign mass, pneumonia, pulmonary fibrosis, and sleep apnea), and type of resection (blebectomy, lobectomy, and wedge resection). Post-operative variables for this study included post-operative complications: pneumothorax, pneumothorax requiring surgical intervention, excessive bleeding, severe subcutaneous air in the chest, face, and/or scrotum requiring a second chest tube placement and intensive care unit admission, death due to a myocardial infarction, myocardial infarction, urinary tract infection, urinary retention, atrial fibrillation, arrhythmia, infection at the IV site, wound infection, pneumonia, atelectasis requiring bronchoscopy, histoplasmosis requiring mechanical ventilation,

and pulmonary embolism. All of these variables were compiled to evaluate the success of the SLR intervention for patients undergoing thoracic surgery.

Measurements/Surgical Intervention and Application of the SLR

All thoracic procedures were performed under general anesthesia with a double lumen endotracheal tube and sequential single lung ventilation. Surgical access was gained via thoracotomy or thoracoscopy. Areas targeted for resection were identified based on a preoperative computed tomography scan and palpation of the lung parenchyma. The pleural cavity was entered after single lung ventilation had been instituted. According to their diagnosis, patients underwent various procedures, including lobectomy, wedge resection, or blebectomy. During resection, the pulmonary arterial branches were identified and transected with a vascular stapler. The bronchus was identified and then transected with a GIA 80 stapler (Auto suture, Tyco Healthcare, Norwalk, CT). The fissure was divided with multiple firings of the GIA stapler with Biodesign Staple Line Reinforcement. A specimen was placed within a specimen bag and withdrawn to the anterior trocar site. After completing the resection and ensuring pneumostasis, a 24-French chest tube was inserted. The lung was gently re-inflated and the site was closed with running Vicryl sutures. Chest tubes were connected to seal drainage systems and left without suction. They were removed following cessation of the air leak and confirmation of full expansion of the lung. This was achieved in most patients within five days. However, if there was a persistent air leak or the lung failed to expand after five days, the patient was discharged home with a drain, which was removed during a subsequent office visit.

Results and Discussions

How Role Evolved

I was first made aware about this research opportunity when speaking to Jeremy Smith ANP who works with Dr. James Headrick (Alliance of Cardiac Thoracic & Vascular Surgeons) at Memorial Hospital. I discussed with him my desire to participate in a clinical research project and Dr. Headrick suggested my involvement in this research opportunity.

Role as Research Assistant

My main roles as a research assistant have been the write up and submission of an institutional review board (IRB) proposal to Memorial Hospital in Chattanooga, TN and a thorough review of the literature. Additionally, I am helping with compiling data (pre-operative, operative, and post-operative variables) into an Excel spreadsheet. I performed over 60 hours working on an IRB submitted to Southern Adventist University and Memorial Hospital, working on the literature review, and compiling data into Excel. Please see Appendix A and B for proof of the Excel data entry.

Findings

This study is still ongoing; however, most of the data retrieval from Memorial Hospital has been completed. From the chart reviews, one patient experienced intraoperative bleeding with inflammatory changes along the staple line. Otherwise, minimal intraoperative bleeding was noted. Three patients experienced air leakage lasting greater than five days that resolved without intervention, while one patient experience air leakage of less than five days duration and was subsequently returned to the operating room. A total of 30 patients experienced post-operative complications unrelated to staple line reinforcement (see Appendix B). The time to chest tube removal was 3.15+/- 3.45 days, and the average hospital stay was 3.35+/- 2.96 days.

A total of 88 (39.1%) patients had their chest tube removed within a day of surgery and 59 (26.2%) patients were discharged the day following their surgical procedure.

Evaluation

Overall, I have learned a tremendous amount from this research project experience. I have never worked on an IRB and/or submitted one. Every detail of our research was incorporated into our protocol to deliver a concise synopsis of our research study. I did not anticipate that the IRB would take so long to complete; it took me over 20 hours to complete and submit two IRBs (Southern & Memorial Hospital). Therefore, I now have a profound appreciation for the process of gaining IRB approval. I had to look up some foreign thoracic terminology when examining charts and performing my literature review. This process has taught me how time-consuming and challenging it is to conduct a research study, particularly outside one's area of expertise. However, the IRB committee has to be thorough in order to ensure quality research. Moreover, in completing the literature review, I have found few current articles that involve the SLR device with thoracic surgery. Therefore, it's vital that we examine this device with thoracic patients to provide optimal surgical outcomes as evidenced by the success of SLR devices in bariatric surgery. It is our hope that this retrospective study will be published and add to the sparse literature available on this topic.

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APPENDIX A

Table 1. Pre-operative and Operative Variables (Memorial Hospital)

Age	64.7 ± 12.6
Gender (M:F)	98:127
BMI	26.7 ± 5.6 kg/m^2
Diabetes, Type II (n, %)	40 (17.8)
Hypertension (n, %)	126 (56.0)
Hypercholesterolemia (n, %)	65 (28.9)
Smoking Status (n, %)	
Current Smoker	71 (31.6)
Past Smoker	118 (52.4)
Never smoked	35 (15.6)
Concomitant Diagnoses (n, %)	
Malignancy	190 (84.4)
COPD	128 (56.9)
Benign Mass	9 (4.0)
Pneumonia	7 (3.1)
Pulmonary Fibrosis	14 (6.2)
Sleep Apnea	5 (2.2)
Type of resection (n, %)	
Blebectomy	11 (4.9)
Lobectomy	127 (56.7)
Wedge Resection	111 (49.6)

APPENDIX B

Table 2. Post-operative Variables and Complications (Memorial Hospital)

Post-operative Complications	# of patients
Pneumothorax	6
Pneumothorax requiring surgical intervention	1
Excessive Bleeding	1
Severe subcutaneous air in the chest, face, and scrotum requiring 2nd chest tube and ICU admit	1
Death due to Myocardial Infarction	1
Myocardial Infarction	1
UTI	2
Urinary Retention	1
Atrial Fibrillation	3
Arrythmia	4
Infection at IV site	2
Wound infection	1
Pneumonia	3
Atelectasis requiring bronchoscopy	1
Histoplasmosis requiring mechanical ventilation	1
Pulmonary Embolus	1