Rana, Rashmeen, Impact of Endoscopic Vacuum-Assisted Closure on Quality of Life in Patients After Treatment of Gastrointestinal Leaks. Master of Science (Clinical Research Management), May, 2023, 56 pp., 5 tables, 1 figure, references, 37 titles.

Endoscopic Vacuum Assisted Wound Closure (EVAC) is an effective therapeutic option to treat Gastrointestinal (GI) leaks after the surgery. Prior to EVAC, conventional approaches to treat leaks included surgical intervention or endoscopic stents. Even though EVAC has been in use for more than a decade and has proven to be successful in treating GI leaks, the long-term quality of life impact of this treatment is uncertain. With the use of a short form (SF-36) survey, a validated questionnaire to assess both physical and mental health, the long-term impact of EVAC on the quality of life was evaluated. When assessing the long-term quality of life for patients who are at least 2 years out from their sentinel surgery, the EVAC group scored higher in all 8 quality of life domains with 4 domains reaching statistical significance as compared with conventional therapy group which received other treatments for leak management.

IMPACT OF ENDOSCOPIC VACUUM-ASSISTED CLOSURE ON QUALITY OF LIFE IN PATIENTS AFTER TREATMENT OF GASTROINTESTINAL LEAKS.

Rashmeen Rana, BS

APPROVED:

DocuSigned by:
Joseph Malaer 4/7/2023
41D5DA3895E4425...
Joseph Malaer, Ph.D, Major Professor

DocuSigned by:
John Preskitt
D49413C7FEB048F...
John T. Preskitt, MD, Committee Member

DocuSigned by:
George Farmer
8095BA47992C40F...
George Farmer, Ph.D, Committee Member

DocuSigned by:
Bruce Bunnell
868BC6F5892B4E9...
Bruce Bunnell, Ph.D, Chair, Department of Microbiology, Immunology and Genetics

DocuSigned by:
J. Michael Mathis 4/6/2023
3BD49482F06549B...
J. Michael Mathis, Ph.D, Dean, School of Biomedical Sciences

IMPACT OF ENDOSCOPIC VACUUM-ASSISTED CLOSURE ON QUALITY OF LIFE IN PATIENTS AFTER TREATMENT OF GASTROINTESTINAL LEAKS.

INTERNSHIP PRACTICUM REPORT

Presented to the Education Council of the
School of Biomedical Sciences
University of North Texas
Health Science Center at Fort Worth
In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By

Rashmeen Rana

Fort Worth, Texas

May 2023

ACKNOWLEDGEMENTS

I would like to present my deepest appreciation and gratitude to my committee members. First, I would like to thank my site mentor John. T Preskitt, MD, Division Director of Surgical Oncology for his continuous support, guidance, valuable time, and mentorship throughout my internship period. I am thankful to Dr. Preskitt for providing me with an outstanding learning environment and for always motivating me to succeed. Next, I would like to thank my major professor, Joseph Malaer, PhD who has provided me with maximum support, guidance, and moral support. My committee member George Farmer, PhD, for reviewing my drafts and giving me his valuable feedback that has helped me a lot in making my project better. I would also like to thank my program director, Stephen Mathew, PhD, for his guidance, wisdom and being so encouraging throughout my time at UNT.

I would like to present special thanks to Steven Leeds, MD, Division Director of Minimally Invasive Surgeries Program, and the Principal Investigator of my thesis project for giving me an opportunity to take part in this project, providing me with his valuable feedback, guidance, reviewing my research proposal, my practicum report drafts, and helping me understand the surgical procedure. I would also like to extend my gratitude to Lucas Fair, MD, Surgical Resident and EVAC project coordinator for putting together this project so well, adding me to this project, providing me guidance and reviewing my practicum report. I would like to thank Gerald Ogola, PhD, Biostatistician at BUMC for his assistance for the data analysis part of this project. A special thanks to non-committee member Rehma Shabbir, Supervisor of Surgical Research Department

for enlightening me with various aspects of the field of clinical research during my internship period.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Endoscopic Vacuum Assisted Closure (EVAC) or Endoluminal Vacuum Therapy (EVT) has been in use for more than a decade and is a successful treatment modality for the management of post-surgical complication of gastrointestinal (GI) leaks. Traditional approaches to treat GI leaks include surgical intervention, which is costly, more invasive and considered to have poor long-term quality of life due to the involvement of organ resection as part of the leak management. Considering poor quality of life outcomes from surgical repair of leaks, endoscopic treatments, such as stents and EVAC are more widely used. EVAC is a recently invented minimally invasive technique for the treatment of GI leaks and has proven to have higher rate of successful leak management when compared to other treatment modalities. Even though EVAC is a validated treatment approach with high clinical success to manage leaks, the long-term impact on quality of life of this procedure is uncertain. Through this study, we aim to quantify long-term quality of life outcomes of patients undergoing EVAC procedure while comparing them to patients undergoing other GI leak management modalities.

This practicum report includes the previously published literature on the various components of the GI leak management modalities to further strengthen the understanding of the topic. Significance and aims of the project are stated separately to provide an in-depth knowledge of the purpose of this report. Results sections include the findings of the project, whereas summary and conclusion section provide the comprehensive explanation of the study findings.

CHAPTER II

RESEARCH PROJECT

BACKGROUND AND LITERATURE REVIEW

History of Endoscopic Vacuum Assisted Closure Procedure

The esophagus and stomach make up the foregut, which is the first part of the GI tract. There are several indications for the surgery on the foregut with the two most common being Gastroesophageal Reflux Disease (GERD) and morbid obesity. GERD is one of the most common diseases in the world with the prevalence around 30% in North America, and adult obesity is increasing from 13.4% in 1962 to 42.4% in 2018 (Clapp et al., 2022; Slater et al., 2022; Sandhu & Fass, 2018). Due to the rising incidence of these diseases, foregut surgery has been increasingly prevalent. Foregut surgery has a risk of post-operative complication, such as an infection at the surgical site, delayed wound healing, or leakage at the site of an anastomosis. Of these potential complications, anastomotic leak tends to cause the most morbidity and mortality (Taleb et al., 2021). An anastomosis is the surgical term where a portion of the GI tract has been transected or connected to another piece of the GI tract. An anastomotic leak is a complication that occurs when two ends of GI tract that have been connected surgically do not seal completely. As a result, contents from inside the GI tract leak out into the abdominal cavity. This can be a devastating complication that can result in infection, further invasive surgeries, and potentially death (Griffiths et al., 2020; Gujjuri et al., 2021; Taleb et al., 2021). This complication most commonly occurs 3-5 days after surgery but can take up to three weeks to manifest in some patients (Kähler, 2017).

Due to the rising prevalence of GERD and obesity, common types of foregut surgery performed include weight loss surgery and anti-reflux surgery. The risk of a postoperative leak after weight loss surgery is less than 1%, and probably even lower for an anti-reflux surgery (Clapp et al., 2022; Leeds et al., 2023). Even though the risk of a leak is very low in both anti-reflux and weight loss surgery, these surgeries still pose a major concern given the number of procedures performed annually. In 2020, the number of weight loss surgeries almost reached 200,000 cases in the United States alone, and there are nearly 40,000 anti-reflux surgeries done on an annual basis (Clapp et al., 2022; Leeds et al., 2023). The number of leaks resulting from these two categories of surgery represent a significant need for improvement and innovation in the area of leak management. In addition, leaks also remains a significant concern in other types of foregut surgery, such procedures involving the esophagus. Anastomotic leak following surgical removal of the esophagus, esophagectomy, remains a major complication ranging up to 30% of the cases (Cereatti et al., 2020; Griffiths et al., 2020).

Historically, surgical intervention has been the hallmark of therapeutic options to treat GI leaks (Krishnan et al., 2019). Traditional surgical procedures involve partially or completely removing the organ at the site of the anastomotic leak. This is a highly morbid operation, and these procedures should only be selected as a salvage therapy when a patient has no other option, such as when are they are hemodynamically unstable or there are signs of sepsis and the patient is at risk for potential death (Chouillard et al., 2014; Gonzalez et al., 2004). In these scenarios, surgical intervention may be selected as sepsis complications are the primary cause of mortality with GI leaks (de Moura et al., 2018). Due to the morbidity associated with traditional surgical procedures, the clinician managing leak patients should evaluate other options that can achieve organ preservation (Leeds et al., 2023).

The advancement in surgical and endoscopic technology has allowed for new interventional procedures to flourish. Minimally invasive procedures use techniques that require very small or no incisions to treat underlying diseases that once required a large open surgery (Zhao & Gu, 2022). When compared to traditional surgeries, minimally invasive procedures have faster recovery, shorter hospital stay, and less pain (Baltayiannis et al., 2015). An area of minimally invasive surgery that has had recent advances is endoscopy, which is the use of an endoscope to see and perform procedures inside of the GI tract. Over the last few decades, endoscopic management of GI leaks has increased tremendously, and it has become an important part of the treatment algorithm. In recent studies, this advancement has demonstrated significantly lower morbidity and mortality rates compared to the surgical approach (Cereatti et al., 2020; Rausa et al., 2018). Endoscopic therapies that are used to treat GI leaks include stents and clips. Stents are tubular devices that are placed temporarily inside the GI tract at the site of the leak to aid healing, while clips are devices placed at the site of the leak to close the defect. Placement of covered self-expanding metal stents (CSEMS) and cap mounted clips are the most used endoscopic therapies in the treatment of upper GI leaks, and evidently, patients treated by stents have better quality of life as compared to surgical intervention (de Moura et al., 2018; Leeds et al., 2023; Rausa et al., 2018). However, stents can have poor efficacy due to the risk of migration which occurs in 20.8% of the cases. (de Moura et al., 2018; Krishnan et al., 2019; Rogalski et al., 2015). Due to the limitations of these endoscopic therapies, innovation is necessary to discover improved, alternative treatments.

Endoscopic Vacuum Assisted Wound Closure (EVAC) is a minimally invasive endoscopic procedure which was originated in Europe by Weidenhagen et al. (2007) with the use in rectum and Wedemeyer et al. (2008) with the use in foregut. Since then, EVAC has gained worldwide

recognition due to its minimally invasive nature and efficacy for the treatment of GI leaks. The first published report of EVAC therapy in the United States was in 2016 at Baylor University Medical Center in Dallas, Texas (Smallwood et al., 2015). When compared to stents, this procedure is more feasible, has shorter treatment duration, and has a lower in-hospital mortality rate (Rausa et al., 2018). Moreover, the EVAC procedure has a high success rate reported in the literature of around 80% in most of the publications but there are some instances where there was success of 100% (Ward et al., 2019).

Over the last 30 years, mortality rates after foregut surgery, such as esophagectomy, have decreased, but anastomotic leaks still occur and have significant morbidity (Wu et al., 2022). Although surgical treatments and stents can be effective at healing leaks, EVAC has been developed to provide an improved minimally invasive technique. Overall, EVAC seems to be safe and effective with a recent meta-analysis reporting a clinical success rate of 87.2% (Intriago et al., 2022). When compared to surgical intervention, EVAC appears to be the superior therapy. In a recent study, the treatment of leaks by surgical intervention has longer recovery time and is costly as compared to the EVAC procedure (Borejsza-Wysocki et al., 2015). It was important to develop techniques that were more feasible with shorter recovery time. According to Ward et al, the EVAC procedure is cost effective, time efficient and highly successful at healing leaks (Ward et al., 2019). Furthermore, there appears to be a survival benefit when using EVAC therapy. The largest comparison study to date has compared EVAC to stent placement and surgical intervention. The study reported the overall survival rate of patients undergoing EVAC therapy was around 88% as compared to surgical intervention and stents which was 50% and 32% respectively (Schniewind et al., 2013). In addition to treating foregut leaks, EVAC has successfully treated leaks in various parts of the GI tract with a closure rate of 86% and low rate of adverse events (Mencio et al., 2018).

Finally, when compared to stents, recent studies have demonstrated that EVAC is a more effective treatment (Brangewitz et al., 2013; Tachezy et al., 2021). Altogether, the literature available to date suggests that EVAC is an effective therapy for GI leaks and can offer advantages to other prominent treatment modalities. To further elaborate on the components of EVAC therapy and our research, we will discuss the EVAC technique, its mechanism of action, and the focus of our research problem in the following sections.

EVAC Procedure Technique

To start the procedure, the patient must undergo general endotracheal anesthesia for safe management of airway during the passage of the endoscope (Leeds et al., 2019). The EVAC procedure consists of a sponge that is joined and secured to the tip of nasogastric tube with a suture on a straight needle and guided via an endoscope to the site of the leak (Leeds et al., 2019; Smallwood et al., 2015). Once the sponge is at the leak site, the endoscope is retracted, the sponge remains, and negative pressure is applied by an external tube connected to the sponge. The sponge stays in the cavity depending on the clinical severity of the patient and the procedure is repeated to exchange the sponge every 3-7 days as per the surgeon to completely treat the leak (Smallwood et al., 2015). Once the cavity has closed and the wound is healed, the sponge is removed (Leeds et al., 2019).

EVAC aids in the healing of leaks of the GI tract in a few ways. First, it is able to obtain and maintain source control of the infected tissue by allowing continuous drainage of infected fluid through the nasogastric tube, removes the damaged tissue from the wound during therapy and promotes the formation of healthy, decontaminated tissue (Vignali & Nardi, 2022). Lastly, it

improves blood flow to the site of injury, encouraging healing of the leak. These components of EVAC provide advantages for this therapy when compared to other endoscopic tools.

Problem

The surgical resection to treat GI leaks is associated with higher morbidity and mortality than less invasive procedures. For instance, mortality rate can be around 13% despite using aggressive surgical techniques to treat the esophageal perforations (Biancari et al. 2013). Due to the issues with previous therapies, EVAC has been developed to treat post-surgical complication of GI leaks. However, since the EVAC procedure is relatively new and has only flourished in the past decade, there is limited data assessing long-term quality of life following this therapy. Fortunately, Baylor University Medical Center has a long history of its use and has the longest follow up for these procedures in the world.

HYPOTHESIS AND SPECIFIC AIMS

The advancement in endoscopic technology has transformed and circumvented many surgical procedures that once were only possible by invasive surgical interventions. EVAC procedure was developed to treat GI leaks with an improved minimally invasive and organ preserving approach. Although, numerous studies have been published that explains the technique as well as the successful outcomes of the EVAC, the long-term quality of life following this treatment is uncertain.

Hypothesis

EVAC provides better quality of life in the long term as compared to surgical intervention and other endoscopic treatment modalities to treat GI leaks.

Specific Aims

Aim 1: To assess long term quality of life using a validated questionnaire (Short Form-36).

Aim 2: To compare the quality of life (physical and mental health) of patients treated with EVAC therapy to patients who were treated by surgical intervention or other endoscopic procedures.

SIGNIFICANCE

Since the advancement in minimally invasive procedures, EVAC therapy is increasingly being used to heal the anastomotic leaks following GI surgery. Previously, many techniques have been used to take care of the leaks including non-operative management, percutaneous or operative drainage, primary surgical repair, tube drainage, or complete surgical diversion (Famiglietti et al., 2020). However, with the advancement in technology, endoscopic procedures which are minimally invasive are now more frequently used, with EVAC being the most recently invented minimally invasive procedure.

In comparison to other techniques for wound closure, EVAC therapy shows comparable, and in some cases better results regarding successful closure of leaks for anastomotic disruption and esophageal perforations (Heits et al., 2018; Rubicondo et al., 2020). To discuss the significance of this emerging procedure and the considerable long-term impact of GI leaks on a patient's life, it is important to carry out a quality-of-life study. Although it is evident through numerous studies that EVAC can be chosen over traditional surgical procedures as well as other endoscopic treatments for leak management, there is limited research on the impact EVAC procedure has on a patient's long-term quality of life. Recent studies have performed short-term quality of life assessments in patients following successful EVAC therapy (Dhayat et al., 2019; Heits et al., 2018). However, there are no studies comparing the long-term quality of life between patients who underwent EVAC and other treatment modalities. The purpose of this study is to fill this

knowledge gap by investigating the long-term impact of EVAC therapy on the quality of life of patients who underwent this procedure. Moreover, comparisons of EVAC therapy to other treatments, such as surgical intervention, could further validate the importance of organ preservation during the treatment of leaks (Leeds et al., 2023).

MATERIALS AND METHODS

Subject Selection

A retrospective review of an institutional review board approved GI leak database for all patients that underwent EVAC therapy from June 2012 to July 2022 was conducted. In addition, a control group was created using the same database and time frame for all patients that underwent surgical intervention or endoscopic intervention other than EVAC therapy. Patients under the age of 18 or who did not undergo endoscopic therapy to treat GI leaks were excluded from this study. For participating subjects, a retrospective chart review was conducted to gather patient data including age, gender, ethnicity/race, medical co-morbidities, body mass index (BMI) and American Society of Anesthesiologists (ASA) classification. Once subjects were screened, a phone call was conducted, and subjects were given complete information about the study and asked if they would like to participate. Once patients agreed to participate in the study, a 36- question short form (SF-36) survey was sent electronically.

Patients were split into two groups based on how their leak was treated: successful EVAC group and conventional treatment (CT) group. The EVAC group included patients whose leaks were primarily and successfully treated by EVAC therapy without the need for surgical repair. Patients were placed in the CT group if they required surgical repair in addition to EVAC, failed EVAC therapy and required definitive surgical intervention, or if they were treated with alternative endoscopic therapies besides EVAC.

Survey Description

Once subjects verbally agreed to participate in the study, the 36- question short form (SF-36) survey was sent via email to determine long term quality of life. The survey was developed by RAND corporation in 1992 consisting of a basic quality of life questionnaire, and is a reliable tool validated to assess quality of life (Farivar et al., 2007). The survey evaluates 8 key health domains relating to physical and mental health. The physical health domain includes physical functioning, pain, general health, and role limitations due to physical health. Mental health domain includes social functioning, emotional well-being, energy/fatigue, and role limitations due to emotional health. In addition, the survey also includes two summary scores: physical component summary (PCS) score and mental component summary (MCS) score. These component scores summarize the 4 domain scores in each physical and mental health. Each item is scored on a scale of 0 to 100, where higher number indicates better quality of life.

Sample Size

A total of 218 subjects were identified from the GI leak database who had undergone endoscopic therapy to treat GI leaks. Out of those 218 patients, 21 patients had died by the time of survey administration. Of the remaining 197 patients, 77 patients agreed to participate in the study, and 53 patients ultimately completed the survey which gave a response rate of 68.8%. Out of 53 patients who completed the survey, the patients who did not meet the inclusion criterion (n=4), and patients who had undergone endoscopic therapy for lower GI leaks (n=4) were excluded from the study. To create a more homogenous group, only foregut leaks were included in the study. After removing these 8 patients, the data was then analyzed by remaining 45 subjects. Out of those 45 patients, 28 were included in conventional treatment (CT) group and 17 were included in EVAC group. The subjects included in (CT) group had the undermentioned treatments: combined EVAC

therapy with surgical repair (n=13), failed EVAC therapy requiring definitive surgery (n=11), surgical interventions combined with endoscopic stents (n=3), and endoscopic stent placement alone (n=1). All the 17 patients in EVAC group had successful leak management by EVAC therapy without the need for surgical repair.

Statistical Analysis

Continuous variables were presented as mean and standard deviation, while categorical variables as frequency and percent of cases. SF-36 component domains were derived from the 36-survey items. Student's t-test was used to compare differences between continuous variables, while Chi-square or Fisher's exact test was used to compare categorical variables. Multivariable linear regression analysis was used to investigate the important predictors of PCS and MCS quality-of-life outcomes. Questions that are left blank are not considered while calculating the scale scores. P values less than 0.05 were determined to be significant.

RESULTS

Table 1 demonstrates the comparison between demographics and medical co-morbidities between EVAC and conventional therapy group. The EVAC group includes 17 subjects and CT group contains 28 subjects that gives a total of 45 patients who were included in the study. No significant differences in sex (p=0.28), race (p=0.53), age (p=0.30), BMI (p=0.70), ASA class (p=1), prior surgeries (p=0.19) and medical co-morbidities was noted between the two groups. The mean number of years from the sentinel operation was 3.8 for EVAC group and 4.8 for the CT group (p= 0.21). As previously mentioned, all the leaks included in the study were upper GI or foregut leaks. The common sentinel surgery was sleeve gastrectomy (n=20). There were two spontaneous esophageal perforations secondary to Boerhaave's syndrome (n=1) and food

impaction (n=1) that were included. Other sentinel surgeries were anti reflux surgery or revisional bariatric surgery (n=15), fundoplication and or/ hiatal hernia repair (n=5), endoscopic retrograde cholangiopancreatography (n=1) and duodenal switch (n=2).

Table 1. Demographics and Comorbidities comparison of EVAC vs CT patients

	EVAC (N=17)	CT (N=28)	p value
Age, years – mean (SD)	48.1 (11.7)	51.9 (11.7)	0.30
Sex			0.28
Female	11 (64.7%)	23 (82.1%)	
Male	6 (35.3%)	5 (17.9%)	
Race			0.53
White	10 (58.8%)	20 (71.4%)	
Black	4 (23.5%)	3 (10.7%)	
Other	3 (17.6%)	5 (17.9%)	
BMI – mean (SD)	35.4 (11.5)	36.6 (8.5)	0.70
ASA			1.00
2	3 (17.6%)	6 (21.4%)	
3	14 (82.4%)	21 (75.0%)	
4	0 (0.0%)	1 (3.6%)	
Hypertension	8 (47.1%)	14 (50.0%)	1.00
Diabetes	4 (23.5%)	3 (10.7%)	0.40
COPD	3 (17.6%)	8 (28.6%)	0.49
CAD	4 (23.5%)	3 (10.7%)	0.40
GERD	5 (29.4%)	10 (35.7%)	0.75
Anxiety/depression	4 (23.5%)	12 (42.9%)	0.22
Prior abdominal surgery	10 (58.8%)	22 (78.6%)	0.19
Years from sentinel operation – mean (SD)	3.8 (2.6)	4.8 (2.5)	0.21

Table 2 depicts the comparison of quality-of-life outcomes between the two groups with scores within each domain. The EVAC group scored higher in all the 8 domains that assess physical and mental health with role limitation due to physical health (73.5 vs 41.3, p= 0.02), reaching a statistically significant difference between the two groups. Moreover, EVAC group also scored higher in PCS (44.9 vs 38.3, p= 0.09) and MCS (49.5 to 44.0, p= 0.18) category as compared to conventional therapy group without reaching statistical significance.

Table 2. SF-36 Quality of Life Outcomes for EVAC Patients in Our Study (Overall)

	EVAC (N=17)	CT (N=28)	p value
Physical functioning	78.5 (23.6)	62.2 (29.7)	0.06
Role limitations due to physical health	73.5 (42.8)	41.3 (44.7)	0.02
Role limitations due to emotional problems	79.2 (38.2)	61.5 (43.9)	0.19
Energy/fatigue	51.6 (26.0)	38.7 (22.7)	0.10
Emotional well-being	76.5 (22.1)	65.5 (22.2)	0.13
Social functioning	75.8 (28.3)	58.7 (32.2)	0.09
Pain	67.8 (26.4)	54.9 (28.8)	0.15
General health	57.6 (19.0)	47.7 (26.1)	0.18
PCS	44.9 (11.6)	38.3 (12.4)	0.09
MCS	49.5 (12.7)	44.0 (12.9)	0.18

Table 3 compares the long-term quality of life measures of subjects who are at least 2 years out from their sentinel operation. The EVAC group scored significantly higher in the domains of physical functioning (87.3 vs 66.9, p= 0.03), role limitations due to physical health (84.1 vs 44.8, p= 0.02), energy/fatigue (60.0 vs 40.2, p= 0.03) and social functioning (86.2 vs 62.0, p= 0.03). Although not statistically significant, EVAC group scored higher in the remaining domains which includes role limitations due to emotional problems (90.0 vs 62.5, p= 0.08), emotional well-being (82.0 vs 65.8, p= 0.06), pain (75.0 vs 54.8, p= 0.06) and general health (60.5 vs 49.0, p= 0.21). In addition, EVAC group scored higher in both PCS (48.0 vs 39.3, p= 0.06) and MCS (53.0 vs 44.3, p= 0.08) categories.

Table 3. Long Term SF-36 Quality of Life Outcomes (≥ 2 years from sentinel operation)

	EVAC (N=11)	CT (N=24)	p value
Physical functioning	87.3 (13.7)	66.9 (27.4)	0.03
Role limitations due to physical health	84.1 (35.8)	44.8 (44.8)	0.02
Role limitations due to emotional problems	90.0 (31.6)	62.5 (43.2)	0.08
Energy/fatigue	60.0 (22.9)	40.2 (22.8)	0.03
Emotional well-being	82.0 (21.2)	65.8 (21.8)	0.06
Social functioning	86.2 (16.1)	62.0 (31.2)	0.03
Pain	75.0 (23.5)	54.8 (29.3)	0.06
General health	60.5 (16.3)	49.0 (27.7)	0.21
PCS	48.0 (10.4)	39.3 (12.4)	0.06
MCS	53.0 (11.9)	44.3 (12.9)	0.08

A subset analysis was performed to compare the groups who had organ preservation to those who did not, regardless of the treatment they received. This is depicted in Table 4. Patients who had their organ preserved scored higher in all 8 quality of life domains as well as in PCS and MCS category. Notably, general health (55.7 vs 38.2, p=0.03) and role limitations due to physical health (62.1 vs 27.5, p= 0.04) showed statistically significant difference between the two groups.

Table 4. Comparison of SF-36 Quality of Life Outcomes by Organ Preservation Status

	Not preserved (N=11)	Organ preserved (N=34)	p value
Physical functioning	67.5 (18.7)	68.8(30.8)	0.90
Role limitations due to physical health	27.5 (41.6)	62.1(45.1)	0.04
Role limitations due to emotional problems	66.7 (41.6)	68.8(43.1)	0.89
Energy/fatigue	41.0 (23.1)	44.4(25.3)	0.71
Emotional well-being	60.8 (26.9)	72.(20.7)	0.15
Social functioning	56.2 (24.5)	68.0(33.3)	0.31
Pain	47.2 (26.0)	63.8(28.2)	0.11
General health	38.2 (26.3)	55.7(21.9)	0.03
PCS	35.8 (11.2)	42.4(12.5)	0.15
MCS	43.8 (15.2)	46.8(12.4)	0.53

Table 5 reports a multivariate regression analysis to compare SF-36 quality of life summary scores (PCS and MCS) to patient characteristics. Patient characteristics including age, gender, BMI, diabetes, hypertension, ASA class, GERD, history of depression/anxiety, and number of endoscopic interventions did not show any significant association with either PCS or MCS scores. However, history of prior abdominal surgery at the time of the sentinel operation did have a significant negative association with MCS scores (RE = -11, 95% CI, -21, -0.38, p=0.05).

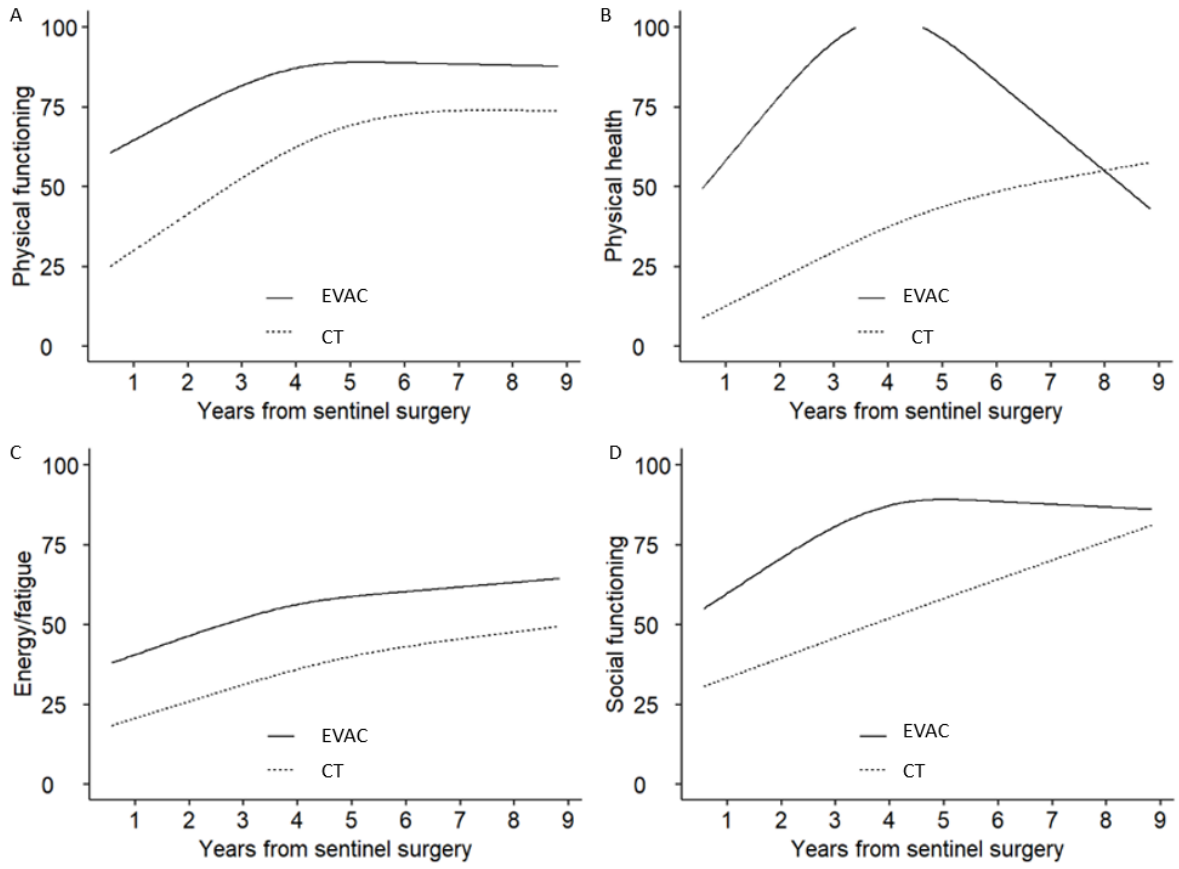
Table 5. Multivariable regression analysis assessing relationship between patient characteristics and SF-36 QoL (PCS and MCS) outcomes

	PCS			MCS		
Characteristic	Regression estimate	95% CI[1]	p-value	Regression estimate	95% CI[1]	p-value
Age	-0.38	-0.75, 0.00	0.057	0.19	-0.20, 0.58	0.35
Sex						
Female	0.00	—		0.00	—	
Male	-5.3	-17, 6.4	0.38	4.7	-7.6, 17	0.46
BMI	-0.04	-0.55, 0.47	0.88	-0.07	-0.60, 0.47	0.81
ASA						
2 or less	0.00	—		0.00	—	
3 or more	12	-14, 38	0.38	-1.6	-29, 26	0.91
Hypertension	3.7	-5.9, 13	0.46	-9.6	-20, 0.51	0.07
GERD	-3.4	-12, 5.4	0.46	2.8	-6.4, 12	0.56
Diabetes	3.1	-8.8, 15	0.62	-2.5	-15, 9.9	0.70
Anxiety/depression	2.3	-6.7, 11	0.62	-1.2	-11, 8.2	0.80
Prior abdominal surgery	-5.1	-15, 4.6	0.31	-11	-21, -0.38	0.05
Number of endoscopic interventions	-0.10	-1.3, 1.1	0.88	-0.26	-1.6, 1.0	0.69

[1]CI = Confidence Interval

Figure 1 graphically illustrates the SF-36 quality of life domains that showed statistically significant differences between the EVAC group and conventional therapy group. As evident from this graph, EVAC group scored higher in the domains of physical functioning, physical health, energy/fatigue, and social functioning as compared to conventional therapy group.

Figure 1. Relationship between SF-36 and years from sentinel surgery by type of procedure for EVAC vs CT patients.



SUMMARY AND CONCLUSIONS

Previously, the complications of leaks after GI surgeries were primarily treated by either surgical intervention or endoscopically with the use of stents. However, surgical intervention to treat leaks has a high rate of mortality and morbidity, whereas stents have a risk of migration, which could slow the healing process (Chung et al., 2021). In the past decade, the EVAC procedure started gaining widespread use because of its high clinical success. A recent meta-analysis reports that EVAC is safe and effective treatment option with around 85% success rate (Intriago et al., 2022). Since this is a new technique, there is limited data analyzing how this procedure impacts

the long-term quality of life in patients undergoing this therapy. Fortunately, Baylor University Medical Center (BUMC) has extensively used EVAC therapy to treat GI leaks and hence this is the ideal setting to evaluate quality of life measures after GI leaks complication. To our knowledge, this is the only study comparing quality of life outcomes between successful EVAC therapy and other treatment modalities. Furthermore, BUMC has the largest cohort of EVAC patients with the longest follow-up time when compared to the available literature on quality of life (Dhayat et al., 2019; Heits et al., 2018). The subjects were divided into two groups, the patients who were successfully treated with EVAC therapy were in the "EVAC" group and ones who had undergone other conventional interventions were in "CT" group.

According to the study findings, the EVAC group scored significantly higher in four out of eight domains measuring quality of life outcomes in the group that were at least 2 years out from their sentinel surgery (Table 3). This indicates better overall quality of life of patients who undergo EVAC therapy for their leaks management as compared to CT group. Further, as depicted in Figure 1, in physical functioning domain, the EVAC group score increased as the years from the sentinel surgery increased and trended higher as compared to CT group. The domains of energy/fatigue and social functioning both demonstrated a similar pattern. In role limitations due to physical health domain, the EVAC group initially had a higher score as the years increased from the sentinel operation. However, the line starts to fall after year 5. Since patients who are doing well clinically can be lost to follow-up, this may be due to a response bias regarding which patients were able to complete survey. In the remaining four domains including emotional well-being, role limitations due to mental health, general health and pain, the EVAC group scored higher, but the numbers were not statistically significant. Altogether, these findings suggest that EVAC therapy

is associated with an improved quality of life when compared to other treatment modalities, providing another advantage for this endoscopic tool.

A subset analysis was performed, and the subjects were divided into two groups; organ preservation group and organ not preserved group (Table 4). It was found out that patients in organ preservation group scored higher in all the quality-of-life domains, with role limitations due to physical health (62.1 vs 27.5, p= 0.04) and general health (55.7 vs 38.2, p=0.03) reaching statistical significance with p values less than 0.05. As mentioned earlier in the report, surgical intervention included organ resection as part of leak management, and it was theorized that organ preservation or saving the organ would lead to better overall quality of life as compared to if the organ was not saved and surgically resected. Also, organ preservation is a top priority and one of the reasons why the treatment paradigm has shifted from surgical to endoscopic management. This indicates that organ preservation does impact long term quality of life, and patients who had to undergo organ resection for leak management had worse long-term quality of life outcomes.

Another important finding of this study is that, according to the regression analysis to assess the relationship between component summary scores and patient characteristics that included age, gender, BMI, ASA class, medical co-morbidities, and number of endoscopic interventions (Table 5), a history of prior abdominal surgery at the time of the sentinel operation had a negative impact on MCS scores. This finding suggests having a prior abdominal surgical history at the time of the leaks complications has a negative impact on quality-of-life scores. The prior abdominal surgery was also negatively associated with the PCS score, but the value was not statistically significant. Additionally, since the EVAC procedure requires serial changes of the endosponge within the interval of 3 to 7 days until the leak is healed, it could be argued that the repeated interventions could negatively impact quality of life. Although this is theorized, our

analysis did not reveal it to be a significant factor. This suggests that the nuances of endoscopic therapy, such as prolonged length of stay due to multiple procedures, did not have a major impact on the long-term quality of life outcomes of the treated patients in this study.

To summarize, as evident by numerous studies mentioned, EVAC procedure has proven to be a safe and effective therapeutic option for GI leaks management. Considering the results this study evaluating long-term quality of life outcomes following successful management with EVAC procedure, it appears to outperform current invasive and endoscopic modalities commonly used.

LIMITATIONS

This study is subject to limitations. The retrospective nature of the study design could increase the risk of selection bias. Another limitation is that, since the data is collected from one institution, this can limit generalizability of our study findings. In addition, this study has a small sample size of 45 subjects who were included in data analysis, reducing the power of the study, and hence increasing the margin of error in the results. Lastly, as patients who are doing well clinically are commonly lost to follow-up, there could have been a response bias regarding which patients completed the survey at the extreme end of our follow-up period.

FUTURE RESEARCH

One of the limitations of this project is small sample size. Future studies should be conducted with larger sample size to get a more statistically significant result. Moreover, comparative, and prospective studies should be conducted comparing the long-term quality-of-life outcomes with different treatment modalities to further strengthen our study findings.

CHAPTER III

INTERNSHIP EXPERIENCE

Internship Site

My thesis project was completed during a six-month internship period at Baylor University Medical Center (BUMC) Dallas, Sammons Cancer Center. My site mentor is John. T Preskitt, MD, Division Director of Surgical Oncology. My project falls under the umbrella of the Division of Minimally Invasive Surgery at BUMC. Steven Leeds, MD, the Division Chief of Minimally Invasive Surgery and is the principal investigator of this project. The minimally invasive surgical department includes the procedures for general surgery, bariatrics, hernia repairs, forgut surgery, and many robotic surgery cases.

BUMC is a part of Baylor Scott and White hospital. Founded in 1903, today the hospital is a quaternary care center, level 1 trauma center, tertiary referral center and the largest of the hospitals in the Baylor Scott and White Network, which includes 52 hospitals in Texas. BUMC has 85 beds in its emergency department, 914 staffed beds and sees about 300,000 patients annually. The hospital holds 50 operating rooms, and about 25000 surgical procedures are performed each year (*Teaching hospitals*).

Journal Summary

Throughout my six months internship period, I was involved in different projects with different roles and responsibilities for each project. Dr. Preskitt is my site mentor and I closely worked with

his division. My tasks included manuscript writing, data collection, department meetings, and assisting with continuing review submissions. I also shadowed clinical research coordinator and clinical research nurse for monitor visit and attended site initiation visits.

a) Research Projects

I was involved in various projects during my internship period. EVAC long term quality of life is my thesis project. I worked on collecting data for its database, obtained verbal consent from patients via phone interviews and sent the surveys electronically using SurveyMonkey, which is a software to create, send and analyze surveys. EVAC was accepted for poster presentation at North Texas American College of Surgeons Conference, Austin TX, in Feb 2023 and as a podium presentation at Society of American Gastrointestinal and Endoscopic Surgeons, Montreal Canada, April 2023.

Prehabilitation Breast Cancer study was another project that I had a chance to work on. This project also involved surveys, but the surveys were not sent out electronically, rather I filled out the survey as I talked on phone with the patient. Prehab also got accepted for a poster presentation at American Society of Breast Surgeons Conference Boston, Massachusetts, April 2023.

I worked as a second author on Patient Health Questionnaire (PHQ) validation study manuscript.

I was also involved in data collection for a large Tumor Board database that included pancreatic, esophagus, and rectal cancer.

I worked on collecting data for multi-disciplinary pancreatic database (MDT).

b) Departmental Meetings

Every week I attended Division of Surgical Oncology meetings with Dr. Preskitt. These meetings were also attended by his research staff. During the meeting, I provided him my weekly updates of the projects I was working on.

I also attended Minimally Invasive Surgery Program Meetings. These meetings were primarily attended by gastrointestinal surgeons from the division of Minimally Invasive Surgery, surgical residents, and research staff. EVAC project was under this division, and I would get weekly updates on my project as well as other projects of this group.

I attended Surgical Research department meetings held by Rehma Shabbir, supervisor of surgical research department. I worked closely with this department because most of my projects were regulated by surgical research department. These meetings were also attended by surgical research staff.

There were surgical research monthly staff meetings that I attended which were mandatory to attend. I also attended monthly focus on research meetings.

c) Shadowing

During my internship period, I was provided Operating Room (OR) training and then I was able to observe surgical procedures in the OR. I observed Dr. Preskitt when he performed parathyroidectomy with reconstruction.

I also observed Dr. Steven Leeds preforming EVAC procedure and followed the same patient twice in the OR for endosponge exchange to understand the procedure.

I shadowed clinical research nurse for a consenting visit for vascular surgery research.

I shadowed clinical research coordinator for Crohn's and Colitis Foundation Study named SPARC for a consenting visit as well as a follow up visit.

I shadowed research analyst II for the learning experience of clinical data entry and to learn about investigated initiated trials data collection as well as regulatory aspects of these studies.

d) Outside Courses

During my internship period, I was introduced to a course in clinical research management through Coursera, provided by Vanderbilt University. To expand my clinical research knowledge and to learn about Redcap database, I completed this 5-week course through Coursera. Redcap is an electronic data capture software that stores clinical data, allows any kind of data collection and surveys collection. This course helped me get an understanding of how to build a database and survey in redcap. After completion of the course, I was given a project on gastroesophageal reflux disease (GERD) registry to collect patient data and build a survey in redcap that will be sent out to patients longitudinally for 10 years.

REFERENCES

Baltayiannis, N., Michail, C., Lazaridis, G., Anagnostopoulos, D., Baka, S., Mpoukovinas, I., Karavasilis, V., Lampaki, S., Papaiwannou, A., Karavergou, A., Kioumis, I., Pitsiou, G., Katsikogiannis, N., Tsakiridis, K., Rapti, A., Trakada, G., Zissimopoulos, A., Zarogoulidis, K., & Zarogoulidis, P. (2015). Minimally invasive procedures. *Ann Transl Med*, *3*(4), 55. https://doi.org/10.3978/j.issn.2305-5839.2015.03.24

Biancari, F., D'Andrea, V., Paone, R., Di Marco, C., Savino, G., Koivukangas, V., Saarnio, J., & Lucenteforte, E. (2013). Current Treatment and Outcome of Esophageal Perforations in Adults: Systematic Review and Meta-Analysis of 75 Studies. *World Journal of Surgery*, *37*(5), 1051-1059. https://doi.org/10.1007/s00268-013-1951-7

Borejsza-Wysocki, M., Szmyt, K., Bobkiewicz, A., Malinger, S., Swirkowicz, J., Hermann, J., Drews, M., & Banasiewicz, T. (2015). Endoscopic vacuum-assisted closure system (E-VAC): case report and review of the literature. *Wideochir Inne Tech Maloinwazyjne*, *10*(2), 299-310. https://doi.org/10.5114/wiitm.2015.52080

Brangewitz, M., Voigtlander, T., Helfritz, F. A., Lankisch, T. O., Winkler, M., Klempnauer, J., Manns, M. P., Schneider, A. S., & Wedemeyer, J. (2013). Endoscopic closure of esophageal intrathoracic leaks: stent versus endoscopic vacuum-assisted closure, a retrospective analysis. *Endoscopy*, *45*(6), 433-438. https://doi.org/10.1055/s-0032-1326435

Cereatti, F., Grassia, R., Drago, A., Conti, C. B., & Donatelli, G. (2020). Endoscopic management of gastrointestinal leaks and fistulae: What option do we have? *World Journal of Gastroenterology*, *26*(29), 4198-4217. https://doi.org/10.3748/wjg.v26.i29.4198

Chouillard, E., Chahine, E., Schoucair, N., Younan, A., Jarallah, M. A., Fajardy, A., Vitte, R.-L., & Biagini, J. (2014). Roux-En-Y Fistulo-Jejunostomy as a salvage procedure in patients with post–sleeve gastrectomy fistula. *Surgical Endoscopy*, *28*(6), 1954-1960. https://doi.org/10.1007/s00464-014-3424-y

Chung, Y., Park, D. G., & Kim, Y. J. (2021). Endoscopic Management of Staple Line Leak after Bariatric Surgery: Surgeon's Perspective. *Clin Endosc*, *54*(6), 805-809. https://doi.org/10.5946/ce.2020.298

Clapp, B., Ponce, J., DeMaria, E., Ghanem, O., Hutter, M., Kothari, S., LaMasters, T., Kurian, M., & English, W. (2022). American Society for Metabolic and Bariatric Surgery 2020 estimate of metabolic and bariatric procedures performed in the United States. *Surgery for Obesity and Related Diseases*, *18*(9), 1134-1140. https://doi.org/10.1016/j.soard.2022.06.284

de Moura, D. T. H., Sachdev, A. H., & Thompson, C. C. (2018). Endoscopic Full-Thickness Defects and Closure Techniques. *Current Treatment Options in Gastroenterology*, *16*(4), 386-405. https://doi.org/10.1007/s11938-018-0199-6

Dhayat, S. A., Schacht, R., Mennigen, R., Palmes, D., Vogel, T., Vowinkel, T., Senninger, N., & Laukoetter, M. G. (2019). Long-Term Quality of Life Assessment After Successful Endoscopic Vacuum Therapy of Defects in the Upper Gastrointestinal Tract Quality of Life After EVT. *J Gastrointest Surg*, *23*(2), 280-287. https://doi.org/10.1007/s11605-018-4038-9

Famiglietti, A., Lazar, J. F., Henderson, H., Hamm, M., Malouf, S., Margolis, M., Watson, T. J., & Khaitan, P. G. (2020). Management of anastomotic leaks after esophagectomy and gastric pull-up. *J Thorac Dis*, *12*(3), 1022-1030. https://doi.org/10.21037/jtd.2020.01.15

Farivar, S. S., Cunningham, W. E., & Hays, R. D. (2007). Correlated physical and mental health summary scores for the SF-36 and SF-12 Health Survey, V.1. *Health and quality of life outcomes*, *5*(1). https://doi.org/10.1186/1477-7525-5-54

Gonzalez, R., Nelson, L. G., Gallagher, S. F., & Murr, M. M. (2004). Anastomotic Leaks after Laparoscopic Gastric Bypass. *Obesity Surgery*, *14*(10), 1299-1307. https://doi.org/10.1381/0960892042583978

Griffiths, E. A., Singh, P., Evans, R. P. T., Nepogodiev, D., Bundred, J. R., Bharwada, Y., Tharmaraja, T., Lin, A., & Kamarajah, S. K. (2020). Risk factors and outcomes associated with anastomotic leaks following esophagectomy: a systematic review and meta-analysis. *Diseases of the Esophagus*, *33*(3). https://doi.org/10.1093/dote/doz089

Gujjuri, R. R., Kamarajah, S. K., & Markar, S. R. (2021). Effect of anastomotic leaks on long-term survival after oesophagectomy for oesophageal cancer: systematic review and meta-analysis. *Diseases of the Esophagus*, *34*(3). https://doi.org/10.1093/dote/doaa085

Heits, N., Bernsmeier, A., Reichert, B., Hauser, C., Hendricks, A., Seifert, D., Richter, F., Schafmayer, C., Ellrichmann, M., Schniewind, B., Hampe, J., Becker, T., & Egberts, J. H. (2018). Long-term quality of life after endovac-therapy in anastomotic leakages after esophagectomy. *J Thorac Dis*, *10*(1), 228-240. https://doi.org/10.21037/jtd.2017.12.31

Intriago, J. M. V., de Moura, D. T. H., do Monte Junior, E. S., Proenca, I. M., Ribeiro, I. B., Sanchez-Luna, S. A., Bernardo, W. M., & de Moura, E. G. H. (2022). Endoscopic Vacuum Therapy (EVT)

for the Treatment of Post-Bariatric Surgery Leaks and Fistulas: a Systematic Review and Meta-analysis. *Obes Surg*, *32*(10), 3435-3451. https://doi.org/10.1007/s11695-022-06228-0

Krishnan, V., Hutchings, K., Godwin, A., Wong, J. T., & Teixeira, J. (2019). Long-term outcomes following endoscopic stenting in the management of leaks after foregut and bariatric surgery. *Surgical Endoscopy*, *33*(8), 2691-2695. https://doi.org/10.1007/s00464-018-06632-7

Kahler, G. (2017). Anastomotic Leakage after Upper Gastrointestinal Surgery: Endoscopic Treatment. *Visc Med*, *33*(3), 202-206. https://doi.org/10.1159/000475783

Leeds, S. G., Kerlee, K. R., Fair, L., Tran, D., Davis, D. G., Ogola, G. O., & Ward, M. A. (2023). Esophagojejunostomy or Fistulojejunostomy are Safe Salvage Operations for Bariatric Surgery Leaks. *Foregut: The Journal of the American Foregut Society*. https://doi.org/10.1177/26345161221145918

Leeds, S. G., Mencio, M., Ontiveros, E., & Ward, M. A. (2019). Endoluminal Vacuum Therapy: How I Do It. *J Gastrointest Surg*, *23*(5), 1037-1043. https://doi.org/10.1007/s11605-018-04082-z

Mencio, M. A., Ontiveros, E., Burdick, J. S., & Leeds, S. G. (2018). Use of a novel technique to manage gastrointestinal leaks with endoluminal negative pressure: a single institution experience. *Surg Endosc*, *32*(7), 3349-3356. https://doi.org/10.1007/s00464-018-6055-x

Rausa, E., Asti, E., Aiolfi, A., Bianco, F., Bonitta, G., & Bonavina, L. (2018). Comparison of endoscopic vacuum therapy versus endoscopic stenting for esophageal leaks: systematic review and meta-analysis. *Diseases of the Esophagus*, *31*(11). https://doi.org/10.1093/dote/doy060

Rogalski, P., Daniluk, J., Baniukiewicz, A., Wroblewski, E., & Dabrowski, A. (2015). Endoscopic management of gastrointestinal perforations, leaks and fistulas. *World J Gastroenterol*, *21*(37), 10542-10552. https://doi.org/10.3748/wjg.v21.i37.10542

Rubicondo, C., Lovece, A., Pinelli, D., Indriolo, A., Lucianetti, A., & Colledan, M. (2020). Endoluminal vacuum-assisted closure (E-Vac) therapy for postoperative esophageal fistula: successful case series and literature review. *World Journal of Surgical Oncology*, *18*(1). https://doi.org/10.1186/s12957-020-02073-6

Sandhu, D. S., & Fass, R. (2018). Current Trends in the Management of Gastroesophageal Reflux Disease. *Gut Liver*, *12*(1), 7-16. https://doi.org/10.5009/gnl16615

Schniewind, B., Schafmayer, C., Voehrs, G., Egberts, J., von Schoenfels, W., Rose, T., Kurdow, R., Arlt, A., Ellrichmann, M., Jurgensen, C., Schreiber, S., Becker, T., & Hampe, J. (2013). Endoscopic endoluminal vacuum therapy is superior to other regimens in managing anastomotic leakage after esophagectomy: a comparative retrospective study. *Surg Endosc*, *27*(10), 3883-3890. https://doi.org/10.1007/s00464-013-2998-0

Slater, B. J., Collings, A., Dirks, R., Gould, J. C., Qureshi, A. P., Juza, R., Rodríguez-Luna, M. R., Wunker, C., Kohn, G. P., Kothari, S., Carslon, E., Worrell, S., Abou-Setta, A. M., Ansari, M. T., Athanasiadis, D. I., Daly, S., Dimou, F., Haskins, I. N., Hong, J., . . . Marks, J. M. (2022). Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). *Surgical Endoscopy*, *37*(2), 781-806. https://doi.org/10.1007/s00464-022-09817-3

Smallwood, N. R., Fleshman, J. W., Leeds, S. G., & Burdick, J. S. (2015). The use of endoluminal vacuum (E-Vac) therapy in the management of upper gastrointestinal leaks and perforations. *Surgical Endoscopy*, *30*(6), 2473-2480. https://doi.org/10.1007/s00464-015-4501-6

Tachezy, M., Chon, S. H., Rieck, I., Kantowski, M., Christ, H., Karstens, K., Gebauer, F., Goeser, T., Rosch, T., Izbicki, J. R., & Bruns, C. J. (2021). Endoscopic vacuum therapy versus stent treatment of esophageal anastomotic leaks (ESOLEAK): study protocol for a prospective randomized phase 2 trial. *Trials*, *22*(1), 377. https://doi.org/10.1186/s13063-021-05315-4

Taleb, S., Nedelcu, M., Skalli, M., Loureiro, M., Nedelcu, A., & Nocca, D. (2021). The evolution of surgical treatment for chronic leak following sleeve. *Surgery for Obesity and Related Diseases*, *17*(2), 278-283. https://doi.org/10.1016/j.soard.2020.10.008

Teaching hospitals. BUMC Surgery. (n.d.). Retrieved March 16, 2023, from https://www.baylordallasgensurgres.com/teaching-hospitals

Vignali, A., & De Nardi, P. (2022). Endoluminal vacuum-assisted therapy to treat rectal anastomotic leakage: A critical analysis. *World J Gastroenterol*, *28*(14),1394-1404. https://doi.org/10.3748/wjg.v28.i14.1394

Ward, M. A., Hassan, T., Burdick, J. S., & Leeds, S. G. (2019). Endoscopic vacuum assisted wound closure (EVAC) device to treat esophageal and gastric leaks: assessing time to proficiency and cost. *Surg Endosc*, *33*(12), 3970-3975. https://doi.org/10.1007/s00464-019-06685-2

Wedemeyer, J., Schneider, A., Manns, M. P., & Jackobs, S. (2008). Endoscopic vacuum-assisted closure of upper intestinal anastomotic leaks. *Gastrointest Endosc*, *67*(4), 708-711. https://doi.org/10.1016/j.gie.2007.10.064

Weidenhagen, R., Gruetzner, K. U., Wiecken, T., Spelsberg, F., & Jauch, K.-W. (2007). Endoscopic vacuum-assisted closure of anastomotic leakage following anterior resection

of the rectum: a new method. *Surgical Endoscopy*, *22*(8), 1818-1825. https://doi.org/10.1007/s00464-007-9706-x

Wu, J., Putnam, L. R., Silva, J. P., Houghton, C., Bildzukewicz, N., & Lipham, J. C. (2022). Impact of Robotic Approach on Post-Anastomotic Leaks After Esophagectomy for Esophageal Cancer. *The American Surgeon*, *88*(10), 2499-2507. https://doi.org/10.1177/00031348221101515

Zhao, Z., & Gu, J. (2022). Open surgery in the era of minimally invasive surgery. *Chinese Journal of Cancer Research*, *34*(1), 63-65. https://doi.org/10.21147/j.issn.1000-9604.2022.01.06

Baylor University Medical Center- Surgical Oncology

CRM Internship Journal

Week 1: (8/22/2022- 8/26/2022)

Day1: Meeting with Dr. Preskitt
Introduction- onboarding process
CITI training

Day 2: Meeting with Dr. Preskitt- His lecture about writing a thesis.
Project discussion with Dr. Preskitt
Training with Ala (PHD student) of using pancreatic data base and MDT data entry
Joined Division of Surgical Oncology Research Interns meeting with Dr. Preskitt.
Meeting with Dr. Katalin- tour of the hospital
Parking services visit to get badge

Day 3: Attended SPARC team meeting- Learned about SPARC and their goals and objectives
Worked on pancreatic database patients list assigned by Ala

Day 4: Meeting with Dr. Katalin regarding the selection of my project, basic overview of Baylor research center and responsibilities of an Intern.
Shadowed SPARC research coordinator, got some insight into patient enrollment process
Worked on pancreatic database patients list.

Day 5: Division of Surgical Oncology meeting
Surgical Research Studies Review meeting
Minimally Invasive Surgeries meeting

Site Mentor: KMC

Week 2: (8/29/2022 to 9/2/2022)

Day 1: Meeting with Dr. Preskitt to discuss the project
Meeting with Dr. Katalin
Project finalized with Dr. Fair and discussed with Dr. Katalin

Day 2: Worked on gathering information for the first committee meeting Presentation
Worked on pancreatic database MDT patient entry

Day 3: Meeting with Faculty advisor

Day 4: Worked on pancreatic database
Discusses the project details with Dr. Fair
Day 5: Division of Surgical Oncology meeting with Dr. Preskitt
Surgical Research Studies Review meeting
Minimally Invasive Surgeries Group meeting
Weekly Check-in with Dr. Katalin

Site Mentor: KMC

Week 3: (9/6/2022 to 9/9/2022)

Day 1: Labor day
Day 2: Presentation preparation
Day 3: Shadow Brittney (Research Nurse) at Texas Vascular Associates
Day 4: First Committee Meeting
Day 5: Division of Surgical Oncology meeting with Dr. Preskitt
Minimally Invasive Surgeries Group meeting
Meeting with Dr. Leads (PI of my thesis project)
Weekly checkin with Dr. Katalin

Site Mentor: KMC

Week 4: (9/12/2022 to 9/16/2022)

Day 1: Research on proposal writing
Day 2: Worked on writing my proposal
Active shooter training
Day 3: IRIS overview with Dr. Katalin
Day 4: Training with Anella
Tour of GI clinic and GI lab
OR training
Day 5: Division of Surgical Oncology Meeting
Weekly Checkin with Dr. Katalin

Site Mentor: KMC

Week 5: (9/20/2022- 9/23/2022)

Day 1: Proposal Writing
Meeting with Ala- discussed pancreatic database entry
Worked on patient data entry for Breast Cancer Prehab study
Day 2: CTO Lab Visit
Finished submitting first draft of proposal
Day 3: Continuing Review Overview by Dr. Katalin
Day 4: Weekly Checkin with Dr. Katalin
Working on proposal writing
Day 5: Attended Interprofessional Workshop at TCU

Site Mentor: KMC

Week 6: (9/26/2022 to 9/30/2022)

Day 1: Breast Cancer Prehab Study Data Collection
Proposal Writing
Meeting with Dr. Waddimba
Day 2: CRC Orientation Day 1
Day 3: CRC Orientation Day 2
Budget Overview with Dr. Katalin
Day 4: Final Proposal submission
Day 5: Division of Surgical Oncology Meeting with Dr. Preskitt
Surgical Research group meeting
Weekly Checkin with Dr. Katalin

Site Mentor: KMC

Week 7: (10/3/2022 to 10/7/2022)

Day 1: EVAC study data entry
Day 2: Meeting with EVAC study co-investigator.
Division of Surgical Oncology Research Interns Meeting
EVAC study data collection
Day 3: Revisions/Amendments Overview by Dr. Katalin
EVAC study data collection

Day 4: Observed Dr. Preskitt performing surgery
EVAC study data collection
Weekly Checkin with Dr. Katalin
Day 5: Rashmeen Time off

Site Mentor: KMC

Week 8 and 9 (10/10/2022 to 10/21/2022)
Out of Office

Site Mentor: KMC

Week 10: (10/24/2022 to 10/28/2022)
Day 1: EVAC study and Breast Cancer Study patient calls
Day 2: EVAC and Breast Cancer study patient calls
Day 3: EVAC and breast cancer study patient calls
Day 4: EVAC study patient calls
Day 5: Division of Surgical Oncology group Meeting
Minimally Invasive Surgeries Group meeting

Site Mentor: JTP

Week 11: (10/31/2022 to 11/4/2022)
Day 1: EVAC data collection
Day 2: EVAC study patient calls
Surgical Research department meeting
Day 3: EVAC study patient calls
Meeting with Rehma Shabbir
DAY 4: EVAC data collection
Redcap training course
Day 5: Division of Surgical Oncology meeting
Minimally Invaise Surgeries Group meeting
Meeting with Dr. Waddimba
EVAC data collection

Site Mentor: JTP

Week 12: (11/7/2022 to 11/11/2022)
Day 1: EVAC patient calls
Data entry for EVAC
Day 2: EVAC calls
Day 3: EVAC data entry and calls
Review articles sent by Dr. Waddimba for upcoming project
Day 4: EVAC data entry
Day 5: Division of Surgical Oncology meeting with Dr. Preskitt

Site Mentor: JTP

Week 13: (11/14/2022 to 11/18/2022)
Day 1: EVAC patient data collection
Day 2: EVAC data collection
Observed Monitor Visit
Redcap training
Day 3: EVAC data collection
Redcap training modules
Day 4: EVAC patient calls
Potluck
Meeting with Dr. Waddimba
Day 5: Division of Surgical Oncology meeting for a new project
Minimally Invasive Surgeries group meeting

Site Mentor: JTP

Week 14: (11/21/2022 to 11/25/2022)
Day 1: Redcap training
Literary research for PHQ validation study
Day 2: EVAC data entry
Redcap training modules
Day 3: Observed a resection surgery/ Ethicon stapler study
Meeting with Dr. Waddimba

Day 4: Thanksgiving Holiday
Day 5: Thanksgiving Holiday

Site Mentor: JTP

Week 15: (11/28/2022 to 12/02/2022)
Day 1: Redcap training
PHQ validation study literature research
Day 2: EVAC study data entry
Day 3: PHQ study manuscript writing
Redcap training
Day 4: PHQ writing
Literature research
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: JTP

Week 16: (12/5/2022 to 12/9/2022)
Day 1: EVAC data collection
PHQ study writing
Day 2: Redcap training
Day 3: Meeting with Dr. Davis for tumor board project
Day 4: Tumor project project data collection
Meeting with Dr. Waddimba
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting
Meeting with Dr. Davis

Site Mentor: JTP

Week 17: (12/12/2022 to 12/16/2022)
Day 1: Tumor board project data collection
Redcap training
Surgical research group team huddle

Meeting with Rehma to update on Redcap course
Day 2: EVAC data entry
Manuscript writing for PHQ study
Day 3: Tumor board project data collection
Redcap training
Day 4: Meeting with Dr. Waddimba
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp

Week 18: (12/19/2022 to 12/23/2022)
Day 1: Manuscript writing for PHQ study
Day 2: Meeting with Dr. Davis regarding Tumor board project
Day 3: PHQ study manuscript editing
Day 4: EVAC data collection
Day 5: Meetings cancelled

Site Mentor: jtp

Week 19: (12/26/2022 to 12/30/2022)
Day 1: Christmas Holiday
Day 2: Manuscript writing for PHQ study
Day 3: Tumor Board project data collection
Day 4: Manuscript writing
Day 5: Division of Surgical Oncology meeting

Site Mentor: jtp

Week 20: (01/02/2023 to 01/06/2023)
Day 1: Tumor board project data collection
Day 2: EVAC study data collection
Day 3: Tumor board project data collection
Day 4: Tumor board project data collection
Day 5: EVAC study data collection

Site Mentor: jtp

Week 21: (01/09/2023 to 01/13/2023)
Day 1: Worked on PHQ writing project
Day 2: Staff meeting
EVAC data collection
Day 3: Meeting with Rehma regarding Redcap project
Redcap training modules for the account setup
Day 4: PHQ study writing
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp

Week 22: (01/16/2023 to 01/20/2023)
Day 1: Tumor board project data collection
Day 2: PHQ study writing
Day 3: Tumor board project meeting
Neuros study revision with Rehma
Day 4: Site Initiation Visit for Roadster 3 study
Tumor board project rectal cancer data collection
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp

Week 23: (1/23/2023 to 1/27/2023)
Day 1: Surgical Research team huddle
Thesis draft writing
Redcap account activated
Day 2: Tumor board project data collection
Day 3: Tumor board project meeting
Redcap project- working on creating surveys for GERD project
Day 4: Tumor board project data collection

Redcap project creation
Day 5: Division of Surgical Oncology meeting
Meeting with Rehma regarding Redcap project

Site Mentor: jtp

Week 24: (1/30/2023 to 2/3/2023)
Day 1: Tumor board project data collection
Thesis writing
Day 2: Working from home due to weather conditions
Redcap project creation
Day 3: Working from home
Tumor board project meeting
Day 4: Tumor board project data collection
Thesis writing
Redcap project creation
Day 5: Division of Surgical Oncology meeting
Meeting with Rehma regarding Redcap project updates
Minimally Invasive Surgical group meeting

Site Mentor: jtp

Week 25: (2/6/2023 to 2/10/2023)
Day 1: Worked on building Redcap project
Day 2: Tumor board project data collection
Working on thesis writing
Day 3: Redcap project meeting with Rehma/ Discussed further steps of the redcap project
Tumor board project data collection
Day 4: Tumor board project meeting
Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp

Week 26: (2/13/2023 to 2/17/2023)
Day 1: Tumor board project data collection
Day 2: Observed EVAC procedure
Redcap project meeting
Day 3: Rad pad study case in OR
Day 4: Meeting with Dr. Davis for Tumor board project
Day 5: Observed EVAC procedure
Observed Parahiatal hernia repair case
Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp

Week 27: (2/20/2023 to 2/24/2023)
Day 1: Tumor board project data collection
Day 2: Meeting with Rehma regarding Redcap project
Day 3: Neuros study meeting
Day 4: Meeting with DR. Preskitt
Worked on Redcap project
Meeting with Dr. Davis
Day 5: Attended North and South Texas- American College of Surgeons Conference in Austin

Site Mentor: jtp

Week 28: (2/27/2023 to 3/3/2023)
Day 1: Tumor board project data collection
Surgical Research department team huddle
Day 2: Thesis writing
Tumor board project data collection
Day 3: Worked on Tumor board project
Day 4: Meeting with Rehma/ Redcap project
Day 5: Redcap project
Prolon study protocol review

Site Mentor: jtp

Week 29: (03/06/2023 to 03/10/2023)

Day 1: Redcap project
Meeting with Dr. Fair (surgical resident)
Meeting with Dr. Leeds regarding EVAC

Day 2: Meeting with Amy (research data coordinator) regarding redcap project
Surgical research department team huddle

Day 3: Tumor board project data collection
Redcap project meeting

Day 4: Meeting with Rehma to discuss new prospective projects

Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting
Meeting with Dr. Fair, surgical resident and MIS coordinator

Site Mentor: jtp

Week 30: (3/12/2023 to 3/17/2023)

Day 1: Surgical research team huddle

Day 2: Meeting with surgical research staff

Day 3: EVAC thesis writing
Staff meeting

Day 4: EVAC thesis

Day 5: Division of Surgical Oncology meeting
Minimally Invasive Surgeries group meeting

Site Mentor: jtp