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Outcomes Experienced by Patients Presenting With Ventral Hernias and Morbid Obesity in a Surgical Clinic

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Final Practice Inquiry Project:

Outcomes Experienced by Patients Presenting With Ventral Hernias and Morbid Obesity Seen in a Surgical Clinic

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Final Practice Inquiry Project Introduction

Hernias result from defects in the abdominal wall. A number of types of ventral hernias exist and ventral hernias are typically repaired surgically by means of an open approach or a less invasive laparoscopic approach. The average age of adults requiring hernia repair surgery is 50 years with approximately equal proportions of males and females. Frequently, adults with hernias have one or more comorbid conditions which can complicate repair.

Hernias are a significant and costly problem in healthcare today:

- Although mesh-based repairs have improved the durability of repair, as many as 350,000 hernia repairs are performed in the U.S. annually (Poulose et al., 2012),
- Incisional hernias are reported to occur in as many as 20 percent of patients that have had past abdominal operations (Cengiz & Israelsson, 1998),
- Postoperative complications and hospital readmissions occur in a substantial proportion of patients that undergo ventral hernia repair surgery. Depending on type of procedure and type of complication, estimates of the readmission rate following ventral hernia repair range from 5% to 11% (Baltodano et al., 2015; Brooke, Stone, Cronenwett, & et al., 2014; Kassin et al., 2012; Lovecchio et al., 2014; Merkow, Ju, Chung, & et al., 2015),
- Recurrence of hernia is a considerable problem due to the increased complexity of the surgical intervention, and increased likelihood of wound and other complications (Holihan, 2015).

The incidence of obesity, defined as body mass index (BMI) greater than or equal to 30 kg/m^2, in patients with ventral hernias is reported to be as high as 60%. This rate of obesity is nearly twice that of the estimated 34.9% of the United States adult population (Ogden, Carroll,

Kit, & Flegal, 2014). Evidence of the impact of patient preoperative clinical characteristics, including obesity, on hernia repair outcomes has increased over the last decade. While obesity has been linked to prediction of increased risk of surgical site infection after open repair of ventral hernias, and weight reduction to a BMI no greater than 40 kg/m^2 is recommended (Berger et al., 2013), little information is available concerning recommendations to achieve weight loss prior to hernia repair surgery. Surgeons generally agree that morbid obesity is a contraindication to hernia repair surgery due to the increased risk of adverse outcomes.

The purpose of this Practice Inquiry Project was to provide an overview of the incidence of morbid obesity (defined as BMI greater than or equal to 40 kg/m^2) in the ventral hernia patient population, the impact of morbid obesity on surgical providers' recommendations and on outcomes from ventral hernia repair surgery. An integrative literature review of the subject matter is followed by a hospital cost analysis of the clinically relevant predictors of hospital costs associated with ventral hernia repair. The third and final manuscript reports the findings from a retrospective review with a prospective component of a consecutive cohort of patients with ventral hernias complicated by morbid obesity that presented to a surgical practice devoted to care of patients with hernias over a two and a half year period of time. The events that ensued for the patients that presented to the outpatient office were detailed and categorized, including the outcomes of patients that underwent hernia repair, the amount of weight loss achieved or not achieved in the patients' efforts to become candidates for surgery, and anecdotal findings based on a telephone interview of the subset of patients that failed to return to the outpatient office following initial surgical consultation.

Manuscript 1

Ventral Hernia Repair Surgery and Morbid Obesity:

An Integrative Literature Review

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Abstract

Patients with ventral hernias are more likely to be morbidly obese than the U.S. population as a whole. Patient clinical outcomes following ventral hernia repair are generally assessed in terms of postoperative surgical site infection and hernia recurrence, and surgeons generally agree that morbid obesity is a contraindication to hernia repair surgery due to the increased risk of postoperative complications. The aim of this paper is to review literature concerning obesity and ventral hernia in order to provide the background to a descriptive study of the experience of a large cohort of patients. Depending on type of procedure and type of complication, the readmission rate following ventral hernia repair is significant with estimates ranging from 5% to 11%. Laparoscopic hernia repair has been shown to be a safe intervention for obese patients with ventral hernias; however, the recurrence rate is thought to be higher for these patients. Additionally, many ventral incisional hernias are not amenable to laparoscopic repair, leaving those patients no alternative other than open hernia repair. Bariatric surgery prior to definitive hernia repair is an effective means of weight loss, but is not available to all patients. Concomitant bariatric surgery and hernia repair is showing promise as an effective strategy to deal with both obesity and ventral hernia, but long-term data is not available. Surgeons are faced with difficult decisions in caring for this challenging patient population, and methods to assist patients to reach goal body mass index in order to improve chance of favorable outcomes are scarce.

Keywords: ventral hernia, morbid obesity, bariatric surgery, weight loss, postoperative complications, hernia recurrence

Introduction

Hernias result from defects in the abdominal wall and are typically classified by etiology and location. Inguinal hernias are the most frequently occurring type of hernia and were described by ancient Egyptians (Sachs, Damm, & Encke, 1997). Surgical treatment of inguinal hernia based on anatomical landmarks first was documented in the 16th century (Sachs et al., 1997). It was not until the mid to late 19th century that incisional hernias, hernias that occur at the site of a previous abdominal incision, were first described (Sanders & Kingsnorth, 2012).

Hernias are a significant and costly problem in healthcare today. Incisional hernias are reported to occur in as many as 20 percent of patients that have had past abdominal operations (Cengiz & Israelsson, 1998), and despite the fact that mesh implantation as a reinforcement has improved the durability of repair, as many as 350,000 hernia repairs are performed in the U.S. annually (Poulose et al., 2012). Hernia repair is accomplished either via an open or laparoscopic approach. In order to perform laparoscopic surgery, a camera is situated at the end of a laparoscope which is inserted into the patient's abdominal cavity and provides the internal view, the means by which the surgeon visualizes the operative field and is able to perform the necessary surgical procedure. In an open approach, the abdominal wall defect is approached generally through either a midline or transverse incision and the peritoneal cavity is or is not entered in order to repair the hernia defect and implant mesh again to reinforce the repair. Preoperatively, patients with complex ventral hernias may have open wounds due to presence of infected mesh and/or enterocutaneous fistulae, compromised physical functioning due to size of hernia and/or instability of the abdominal wall, and pain associated with the hernia, all of which can impair quality of life.

Obesity is estimated in the United States to affect greater than one-third of the adult population (34.9%) (Ogden, Carroll, Kit, & Flegal, 2014). The relationship between obesity and

surgical complications including surgical site infections (SSIs) has been presented in literature concerning colorectal abdominal surgery (Wick, Hirose, Shore, & et al., 2011), and more recently the association has been related specifically to ventral hernia repair (Berger et al., 2013). Body mass index (BMI) is considered a significant predictor for SSI when analyzed as a continuous variable, suggesting that risk increases with increasing BMI and optimization of comorbidities prior to surgical intervention is recommended (Berger et al., 2013). Frequently, patients that present with large ventral hernias, initial or recurrent, are overweight. Surgeons generally agree that morbid obesity is a contraindication to hernia repair surgery (Evans, Chim, Patel, Salgado, & Mardini, 2012; Goldberg et al., 2012).

The policy of the Minimally Invasive Surgery (MIS) Service at the University of Kentucky (UK) is that patients desiring ventral hernia repair surgery in the absence of exacerbating symptomatology, urgency or emergency must reach a goal BMI less than 40 kg/m^2 in order to decrease operative risk, to decrease risk of post-operative complications, and to decrease risk of hernia recurrence, in other words to increase the likelihood of favorable outcomes. Although this is the policy, the rate of adherence to the policy, the surgical outcomes of patients based solely on body mass index at time of repair, and the rate of success of patients who are recommended to lose weight are not known. Prior to describing the experience of morbidly obese, ventral hernia patients of the MIS service, a literature review is needed to guide the next steps in care of this unique patient population.

The purpose of this paper is to provide an integrative review of recent literature concerning evidence-based practice for care of patients with abdominal wall hernias, particularly for patients with ventral hernias and morbid obesity, to review evidence concerning:

- Ventral hernia repair and associated postoperative complications,

- Incidence of obesity and impact of obesity on postoperative complications,
- Laparoscopic vs. open ventral hernia repair and associated patient outcomes,
- Bariatric surgery and combined bariatric surgery and ventral hernia repair, and
- Evidence-based means of assisting patient to reach weight loss goals other than bariatric surgery.

The aim of this review is to present the current state of evidence as to the best methods to improve hernia patient outcomes and quality of life as they relate to morbidly obese patients. Additionally, gaps in knowledge concerning best practices for treatment of morbidly obese adults with hernias will be presented.

Methods

In order to qualify for inclusion into this review paper, studies were considered from 2002 to present. Papers written in English from nursing and medicine journals were sought. Meta-analyses, randomized controlled trials (RCTs), and prospective and retrospective cohort studies were included. Searches of PubMed, CIHAHL and the Cochrane Library were conducted using the keywords: "hernia repair postoperative outcomes," "hernia surgery outcomes," "laparoscopic vs. open hernia repair outcomes," "morbid obesity and surgical outcomes," "hernia repair and morbid obesity," "bariatric surgery and hernia repair," "weight loss programs," "effective weight loss strategies," and "weight loss and surgical outcomes." The primary review was of articles demonstrating comparisons of efficacy of differing hernia repair methods and weight loss parameters. Additionally, articles were sought that demonstrated benefit in terms of outcomes related to weight loss preoperatively. The Strength of Recommendation Taxonomy (SORT) (Table 1) was used to guide decision-making about level of evidence of the sources used in this literature review (Ebell et al., 2004).

Findings

A total of 40 articles from peer-reviewed journals were included in the final review. Table 2 presents the subtopic category of the articles with the study design by category and level of evidence per the SORT guidelines.

Ventral Hernia Repair / Risk of Postoperative Complications

Hernias result from defects in the abdominal wall and are typically classified by etiology and location. There are several types of hernias, but this paper will focus primarily on ventral incisional hernias, which are hernias that occur at the site of a previous abdominal incision, and were first described mid to late 19th century (Sanders & Kingsnorth, 2012). Ventral incisional hernias are a significant and costly problem in the United States today. Because hernias can be symptomatic and have a potential risk of strangulation and therefore have potential to become a surgical emergency, repair is recommended to many if not most patients with this problem. Numerous techniques of hernia repair have been described, and a variety of types of mesh have been used to reinforce the repairs. Mesh-based repairs have been shown to decrease recurrence rates (Flum, Horvath, & Koepsell, 2003). Initial uncomplicated ventral incisional hernias frequently are amenable to laparoscopic repair with mesh reinforcement. However, complex abdominal wall hernias may likely require open repair and may or may not additionally require repair utilizing a method of component separation technique, which involves separating the external and internal oblique muscles and releasing the posterior rectus sheath to enable medial mobilization of the fascia (Butler, Baumann, Janis, & Rosen, 2013). These are major abdominal operations and patients will expect a four to ten-day hospitalization post-operatively and a six to 12-week recovery period.

Postoperative complications and hospital readmissions plague ventral hernia repair surgery. Patient comorbidities, wound class, and operative factors are thought to contribute to the increased risk associated with this commonly-performed procedure. Depending on type of procedure and type of complication, the readmission rate following ventral hernia repair is significant with estimates ranging from 5% to 11% (Baltodano et al., 2015; Brooke, Stone, Cronenwett, & et al., 2014; Kassin et al., 2012; Lovecchio et al., 2014; Merkow, Ju, Chung, & et al., 2015). Surgical site infection is thought to be the most common complication and the most common reason for unplanned 30 day hospital readmission following ventral hernia repair (Lovecchio et al., 2014; Merkow et al., 2015; Nguyen et al., 2013).

The incidence of SSI following ventral hernia repair is reported to be as high as 19 to 25% for open repairs (Holihan et al., 2015; Liang, Goodenough, Martindale, Roth, & Kao, 2015). Despite advances in infection control procedures such as pre-operative antimicrobial prophylaxis, SSIs are a substantial cause of morbidity and mortality among hospitalized patients (Mangram et al., 1999). In addition to the impact of SSIs on hospitalized patients, it has been estimated that somewhere between 12% and 84% of SSIs are detected after patients are discharged from the hospital (Mangram et al, 1999). Surgical site infections are classified by the Centers for Disease Control and Prevention (CDC) as: superficial, deep incisional and organ/space, and are the most common type of nosocomial infection among surgical patients (Mangram et al, 1999). Other reasons for unplanned 30-day readmission following ventral hernia repair surgery are ileus or obstruction, bleeding, pulmonary issues, and venous thromboembolism (VTE) (Merkow, Ju, Chung, & et al., 2015). Further complicating the postoperative outcomes of VHR, SSI has been demonstrated to increase risk of hernia

recurrences (Holihan et al., 2015) which in the long-term also contributes to increased burden to patients, hospital and society.

As described previously, the wound problems that patients that have undergone complex ventral hernia repair experience may be as minor as cellulitis requiring oral antibiotics, but often are associated with an abdominal wall abscess and may require opening of a small or large segment of the patient's surgical incision, which then will require routine dressing changes or negative pressure wound therapy, either of which can take weeks to months to resolve. Hospital readmissions are not uncommon with this type of complication and lengthy need for home health care services ensue after discharge.

Another challenging issue is repair of recurrent ventral hernias in the context of infected mesh. Repair in the presence of contamination requires altered surgical decision-making and is associated with higher rates of wound complications than clean cases. A recent retrospective review of 128 patients that underwent complex ventral hernia repair each within a contaminated field, identified a 48% rate of wound complications (Rosen, Krpata, Ermlich, & Blatnik, 2013).

Although the majority of patients do not experience a wound complication following open repair of complex ventral hernias and variations in the severity of wound complications exist, the patients that experience significant wound complications are likely to incur substantial costs, in terms of decreased quality of life, loss of productivity, and financial burden which may include the costs of re-hospitalization, repeated office visits, and home health care costs. The costs to the healthcare system of these complications are also great (Reynolds, Davenport, Korosec, & Roth, 2013).

Incidence of Obesity and the Impact of Obesity on Postoperative Outcomes

Morbidly obese patients are believed to be at a higher risk for the development of abdominal wall defects and progression of the defect in size due to increased intra-abdominal pressure and poor wound healing potential (Sugerman et al.). The relationship between obesity and surgical complications including SSIs has been presented in literature concerning colorectal abdominal surgery (Wick et al., 2011), and more recently the association has been specifically related to ventral hernia repair (Berger et al., 2013). Authors found BMI to be a significant predictor for surgical site occurrence when BMI was analyzed as a continuous variable, suggesting that risk increases with increasing BMI. These authors recommend optimization of comorbidities such as morbid obesity prior to surgical intervention (Berger et al., 2013). Increased BMI also has been found to be associated with increased likelihood of dehiscence of the surgical wound (Shanmugam et al., 2015).

Because of the known increased risk of complications, surgeons generally agree that morbid obesity is a contraindication for repair of abdominal wall hernias due to the increased risk of complications in this patient population (Evans et al., 2012). However, with the increasing incidence of obesity in the adult population, surgeons are evaluating the outcomes of this patient subset in order to better understand feasibility of hernia repair. One recent study reviewed the care of patients with BMI as high as 50 kg/m^2 in association with other patient characteristics that were deemed to be favorable for laparoscopic repair (gynecoid body habitus, reducible hernias found in a central location, abdominal wall thickness less than 4 cm, and the defect's largest diameter not exceeding 8cm). These authors' findings were that with minimum of two years' follow up there was minimal hernia recurrence (Eid et al., 2003).

Laparoscopic vs. Open Repair of Ventral Hernia: Patient Outcomes

Several recent studies have compared patient clinical outcomes following laparoscopic vs. open repair of ventral hernias. One of these papers reported a retrospective review of a national database that included 18,223 cases and a second paper was a single-center review of 532 consecutive cases over a 10-year period (P. D. Colavita et al., 2013; M. K. Liang et al., 2013). Based on the national database, the authors found that laparoscopic repair was performed in 27.6% of the cases of ventral hernia repair (P. D. Colavita et al., 2013). Although many variables are associated with type of repair needed for an individual patient, the authors suggested that their analyses showed that the differences in percentage of type of repair performed by size of county of residence indicated that the differences may be impacted by access to surgeons with laparoscopic expertise (P. D. Colavita et al., 2013). Patient outcomes in terms of wound complications for both studies were better for patients undergoing laparoscopic repair. Recurrence rates were similar between the two groups. The larger study reported shorter length of stay, lower hospital charges and decreased mortality for patients who received laparoscopic repair compared to patients with open repair (P. D. Colavita et al., 2013).

Comparisons of quality of life (QOL) outcomes for patients for laparoscopic vs. open ventral hernia repair with patient self-administered QOL measures have utilized the Short Form-36 (Itani, Hur, Kim, & et al., 2010; Mussack et al., 2006), the Carolinas Comfort Scale (CCS) and a Visual Analog Scale (VAS) for pain (P. Colavita et al., 2013), and the Short Form-36 and CCS (Hope et al., 2008). Colavita, et al found that patients having undergone laparoscopic repair of ventral hernia were more symptomatic than open repair patients at one month post-operatively; however at 6 months and 12 months no differences were found in quality of life

scores. The QOL findings are favorable for laparoscopic repairs after the early postoperative period of time.

Several studies have reported comparison between laparoscopic and open surgery in terms of post-operative complications. A recent retrospective review of 827 hernia repairs performed in Finland over a seven-year time period focused on severe postoperative complications in a comparison of outcomes based on surgical approach. These authors found that the laparoscopic hernia repair patients had lower overall complication rate compared to open hernia repairs, however the difference was not statistically significant (Ahonen-Siirtola et al., 2015). Of concern, however, was that the laparoscopic group had a higher rate of enterotomy compared to the open group, four of which were left unnoticed and led to major, life-threatening complications. On the other hand, the open group had a statistically significantly higher incidence of SSI than patients that underwent laparoscopic repair of ventral hernia (8.6% vs. 3.2%, $p = .001$) (Ahonen-Siirtola et al., 2015). A retrospective review of 186 patients with BMI greater than 30 kg/m^2 also reported an increased rate of SSI for open repairs (15.8%) as compared to laparoscopic repairs (5.7%) ($p = .09$). (Froylich et al., 2015). A randomized-controlled study comparing approaches concluded that laparoscopic repair was associated with fewer but more severe complications (Itani et al., 2010).

Authors of a meta-analysis that reviewed short-term outcomes across 8 studies concluded that lower complication rates are associated with laparoscopic hernia repairs when compared to open repairs, and length of hospital stay and operative time are shorter with laparoscopic repairs (Goodney et al., 2002). Another recent study focused on the incidence of SSI comparing laparoscopic and open repair outcomes across a variety of abdominal operations. The authors of this meta-analysis of 44 studies, which included eight randomized controlled trials and 36

retrospective reviews, found that laparoscopic surgery had significantly reduced rates of surgical site infection. (Shabanzadeh & Sørensen, 2012).

Based on several studies, laparoscopic surgery appears to offer a safe means of hernia repair and may have decreased complication rates compared to open repairs, it is important to understand that not all hernias are amenable to laparoscopic repair and the hernia recurrence rate is not fully understood due to scarce long-term data.

Recent studies have aimed to assess clinical outcomes of obese patients that have undergone laparoscopic ventral hernia repair. A retrospective review of a prospectively-maintained database of four hernia surgeons focused on patients with BMI greater than or equal to 40 kg/m^2 compared to patients with BMI less than 40kg/m^2. The authors found that operative duration, length of hospital stay, and recurrence rate for a mean follow up time of 19 months each were significantly greater in the morbidly obese group than for patients with BMI less than 40 kg/m^2 (Tsereteli et al., 2007). Other studies have found the approach to offer a safe alternative for obese patients, but with apparent increased risk of recurrence of hernia for this subset of patients (Froylich et al., 2015; Lee et al., 2013; Regner, Mrdutt, & Munoz-Maldonado, 2015).

Bariatric Surgery / Concomitant Bariatric Surgery and Hernia Repair

Weight loss surgery is one method shown to be effective for losing weight, and recent literature reports that ventral hernia repair can be safely combined with weight loss procedures such as Roux-en-Y gastric bypass and sleeve gastrectomy or performed in stages (Newcomb et al., 2008; Praveen Raj et al., 2012; Raziel, Sakran, Szold, & Goitein, 2013). Recent literature has provided evidence of the effectiveness of medical weight loss programs (Lih et al., 2015), and the effectiveness of weight loss surgery (Abbas et al., 2015). However, in a recent

randomized controlled trial reported by Schauer, et al., weight loss surgery was shown to be far superior to medical management in weight reduction and diabetes control (Schauer et al., 2014). A large national database study showed that patients that underwent ventral hernia repair in conjunction with either laparoscopic Roux-en-Y gastric bypass or sleeve gastrectomy had increased incidence of surgical site infection but not overall morbidity in the 30-day postoperative time period, again providing evidence of the seeming appropriateness of the combination of these procedures (Spaniolas et al., 2015).

Other Methods of Weight Loss Prior to Ventral Hernia Repair

Best practices for weight loss in a morbidly obese population are not fully understood, and despite an abundance of recent journal articles that review methods of weight loss, little information is available in peer-reviewed journals over recent years concerning effective methods that resulted in more than minimal weight loss. Primary care providers would seem to have a stake in helping patients achieve ideal body weight, but it is not clear how these providers carry out that goal. A recent telephone survey of 548 obese patients reported in 2016 explored the relationship between a health care providers' advice to lose weight and consumption of key energy and nutrient-rich foods. The authors hypothesized that health care providers' advice to lose weight and attempts to lose weight would be strongly related. Interestingly, these authors reported that no relationship was found between health care providers' advice and attempts to lose weight; however, most interesting was the fact that 48% of the respondents stated that although they had seen a health care provider, they had not been advised to lose weight (Lorts & Ohri-Vachaspati, 2016).

A report of a promising strategy, the Medifast meal replacement program, showed that for the 185 patients that remained with the program for 12 weeks, there was a mean weight

reduction of 10.9 kg, and for patients that remained on the program for 24 weeks, a mean weight loss of greater than or equal to 5% of baseline body weight (Coleman et al., 2015). This commercial program included meal replacements, conventional food choices, and customizable levels of support for weight loss and maintenance (Coleman et al., 2015). It is not clear, however, the cost to the individual patient for the program, and it is important to consider that many patients will find commercial programs cost-prohibitive. In contrast, a recent study reported a low-cost, nonprofit program of weight reduction with a reported mean 5.9- 7.1% of body weight lost in one to three years (Mitchell, Dickinson, Kempe, & Tsai, 2011). The TOPS program plan provides members with information about healthy eating, exercise and behavior modification. The members also receive a six-week lesson plan booklet, a one-year subscription to a newsletter and membership in a local chapter through which weekly meetings are held (Mitchell et al., 2011).

A recent meta-analysis aimed to understand the effectiveness of self-weighing for weight loss. The authors concluded that evidence is lacking to understand if advising patients to weigh themselves without other interventions involved is effective (Madigan, Daley, Lewis, Aveyard, & Jolly, 2015).

While many general efforts have been reported, recent literature contains very little information concerning strategies for weight loss in order to optimize surgical outcomes. However, a study from 2015 provided promising weight reduction efforts concerning a multidisciplinary program for patients with complex ventral hernias being seen at a comprehensive hernia center (Rosen et al., 2015). The key players involved included a weight loss specialist, surgeon, the patient with the focus on the surgeon/patient relationship and the full "buy-in" and responsibility of the patient (Rosen et al., 2015). The patients were instructed to

use a preoperative modified protein sparing fast with mean preoperative weight loss of 24kg. Other than bariatric surgery recommendations, this study stood alone as weight loss advice specifically from a hernia standpoint.

Gaps in Knowledge

The most evident gap in knowledge related to morbidly obese patients in need of ventral hernia repair surgery is an effective means of weight loss other than bariatric surgery. Because bariatric surgery is not available to all patients and many patients do not desire to undergo bariatric surgery, an effective means to lose weight in the preoperative time frame has been eluded to in several studies, but is not well understood. The burden to society demands further research be conducted to determine effective strategies that can be used by willing patients to achieve weight loss goals in order to undergo safe and effective hernia repair surgery.

The full benefit of laparoscopic repair of ventral hernia for morbidly obese patients in terms of risk of hernia recurrence also is not fully understood due to scarcity of long-term data. In part because funding for hernia repair research is difficult to establish, the majority of hernia research is conducted in a retrospective nature by individual programs based on experience of former patients. However, more recently, multi-institutional cohort studies have been reported that lend a greater number of subjects; albeit still completed with a retrospective review of data. Randomized-controlled trials are lacking to understand the best practices associated with hernia repair in general and specifically for the morbidly obese population.

Conclusions

Ventral hernia repair surgery for morbidly obese patients is considered to be contraindicated due to increased risk of postoperative complications; however, there is growing evidence that laparoscopic repair is feasible and somewhat durable in this patient population.

Further research is needed to understand the long-term outcomes. Bariatric surgery is more effective than medical weight loss; however, it is not available nor desired by all potential candidates. Further research is needed to understand the best practice for concomitant weight loss surgery and ventral hernia repair. One medical weight loss program designed specifically for ventral hernia patients has been shown in a pilot study to have promising results.

Research funding that is not provided by industry due to concern for bias is needed in order for rigorous multi-institutional randomized controlled trials to be conducted to help answer many gaps in knowledge for care of morbidly obese patients with ventral hernias.

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Table 1. Grading Level of Evidence Based on: Strength of Recommendation Taxonomy (SORT) (Ebell et al., 2004)

A	Recommendation based on consistent and good quality patient-oriented evidence.
B	Recommendation based on inconsistent or limited quality patient–oriented evidence.
C	Recommendation based on consensus, usual practice, opinion, disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening.

Study Quality	**Diagnosis**	**Treatment/Prevention/Screening**	**Prognosis**
Level 1: good-quality, patient-oriented evidence	Validated clinical decision rule SR/meta-analysis of high quality studies High-quality diagnostic cohort study	SR/meta-analysis or RCTs with consistent findings High-quality individual RCT All-or-none study	SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up
Level 2: limited quality patient oriented evidence	Unvalidated clinical decision rule SR/meta-analysis of lower quality studies or studies with inconsistent findings Lower quality diagnostic cohort study or diagnostic case-control study	SR/meta-analysis of lower quality clinical trials or of studies with inconsistent findings Lower quality clinical trial Cohort study Case control study	SR/meta-analysis of lower quality cohort studies or with inconsistent results Retrospective cohort study or prospective cohort study with poor follow-up Case-control study Case series
Level 3: Other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only) , or case series for studies of diagnosis, treatment, prevention, or screening		

Table 2. Categories of Papers Reviewed with Study Type and Grading Level of Evidence

Sub Topic	Number of Papers	Types of Studies	Grading Level of Evidence
Ventral Hernia Repair/ Risk of Complications	11	Large national database retrospective cohort study: 6	A2
		Multi-institutional retrospective cohort study: 1	A2
		Single institution retrospective cohort study: 4	A2
Incidence of Obesity and the Impact of Obesity on Postoperative Outcomes	5	Large national database retrospective reviews: 2	A2
		Single institution retrospective cohort study: 2	A2
		Survey research: 1	A3
Bariatric Surgery / Concomitant Bariatric Surgery and Hernia Repair	6	Randomized Controlled Trial: 1	A1
		Large national database retrospective review: 1	A2
		Single institution retrospective review: 4	A2
		Systematic Review and Meta-Analysis: 1	A1
		Randomized-Controlled Trial: 1	A1
		Meta-analysis: 1	A1
Laparoscopic vs Open Hernia Repair: Patient Outcomes	12	Large national database retrospective cohort study: 4	A2
		Multi-institutional retrospective cohort study: 1	A2
		Single institution retrospective cohort study: 4	A2
		Meta-analysis: 1	A1
Other Methods of Weight Loss Prior to Ventral Hernia Repair	6	Large national database retrospective cohort study: 2	A2
		Single institution retrospective cohort study: 2	A2
		Survey research: 1	A3

Manuscript 2

Ventral Hernia: The Cost of Comorbidities and Complications

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Abstract

Ventral hernia repair (VHR) is among most frequently performed abdominal operations with a significant incidence of postoperative complications and readmissions. Payers are targeting increased "value" of care through both improved outcomes and reduced costs. Cost data in clinically relevant terms is still rare. This study aims to identify hospital costs associated with clinically relevant factors in order to facilitate strategies by surgeons to enhance the value of VHR.

An IRB-approved retrospective review of VHRs performed from April 2009 through September 2013 was conducted. NSQIP clinical data and hospital cost data were matched. Operating room (ORC), total encounter (TEC), and 90-day post discharge (90PDC) hospital costs were analyzed relative to the clinical variables using non-parametric tests. 385 patients that underwent VHR were included in the analyses. Considering all cases, median (interquartile range (IQR)) ORC was $6,900 TEC was $10,700 and 90PDC was $0, ASA Class ≥ 3 was associated with increased ORC and TEC ($p < .001$), and 90PDC ($p < .01$) compared to all VHRs. Wound Class >1 was associated with increased ORC and TEC ($p < .001$) and 90PDC ($p < .01$). Inpatient occurrence of any complication was associated with increased TEC and 90PDC ($p < .001$).

Although the hospital encounter represents the majority of the cost associated with VHR, additional costs are incurred during the 90 day postoperative period. An appreciation of global costs is essential in developing alternative payment models for hernia in order to provide the greatest value in hernia care.

Key Words: ventral hernia, hospital costs, comorbidities, outcomes, readmissions

Introduction

Postoperative complications and hospital readmissions plague ventral and incisional hernia repair (VHR) surgery. Patient comorbidities, wound class, and operative factors are thought to contribute to the increased risk associated with this commonly performed procedure. Depending on type of procedure and type of complication, the readmission rate following ventral hernia repair is significant with estimates ranging from 5% to 11% (Baltodano et al., 2015; Brooke, Stone, Cronenwett, & et al., 2014; Kassin et al., 2012; Lovecchio et al., 2014; Merkow, Ju, Chung, & et al., 2015). Surgical site infection (SSI) is thought to be the most common complication and the most common reason for unplanned 30-day hospital readmission following VHR (Lovecchio et al., 2014; Merkow, Ju, Chung, & et al., 2015; Nguyen et al., 2013). The incidence of SSI following VHR is reported to be as high as 19 to 25% for open repairs. (Holihan et al., 2015; Liang, Goodenough, Martindale, Roth, & Kao, 2015) Other reasons for unplanned 30-day readmission following VHR are ileus or obstruction, bleeding, pulmonary issues, and venous thromboembolism (VTE) (Merkow, Ju, Chung, & et al., 2015). Further complicating the postoperative outcomes of VHR, SSI has been demonstrated to increase recurrences (Holihan et al., 2015), which in the long-term also contributes to increased health care costs.

Evidence of the impact of patient preoperative clinical characteristics on hernia repair outcomes has increased over the last decade. The externally-validated Ventral Hernia Risk Score (VHRS), which allows a prediction of risk for SSI after VHR, utilizes wound class, body mass index (BMI), raising of skins flaps, American Society of Anesthesiologists (ASA) Class, and performance of a concomitant procedure with VHR to calculate the degree of risk (Liang, Goodenough, Martindale, Roth, & Kao, 2015). While improved prediction of outcomes based

on patient characteristics is valuable, the economic implications must still be inferred. The relationship of cost data with patient comorbidities, operative details, and postoperative complications that allows the cost data to be presented in clinically relevant terms is scarce.

Costs associated with VHR were more than $3 billion in 2006 in the United States alone with escalating costs over time (Poulose et al., 2012). Federal and private insurers are targeting increased "value" of care through both improved outcomes and reduced costs. Value of care is considered to consist of high quality care, acceptable outcomes, and avoidance of waste. In an effort to coordinate care and improve quality and cost-efficiency, the Medicare Payment Advisory Commission (MedPAC) has recommended broader bundling of payments for surgical episodes, lumping reimbursements to hospitals, physicians and other providers involved in care around a surgical episode into a single payment (Hackbarth, Reischauer, & Mutt, 2008). The Merit-based Payment System (MIPS) and the Alternative Payment Models (APMs) are the two methods of payment mandated by the United States Congress in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The purpose of the MACRA was to modernize Medicare provider payment by promoting better care over more care (Centers for Medicare and Medicaid Services, 2016). With the rapid shift toward bundled and value-based payment strategies, the need to understand the economic impact of ventral hernia repair surgery has taken on a greater sense of urgency. In order to enhance the value of VHR, it is important that health care providers understand how patient clinical characteristics, operative details, and postoperative complications influence the financial burden of VHR. Furthermore, an appreciation of the drivers of increased costs will assist providers in making informed decisions to provide more cost-efficient care while ensuring quality outcomes.

The purpose of this study was to identify hospital costs associated with clinically relevant factors in order to facilitate strategies by surgeons to enhance the value of VHR.

Methods

This retrospective review of clinical and cost data was approved by the University of Kentucky Institutional Review Board. The local American College of Surgeons National Surgery Quality Improvement Program (ACS NSQIP) database was queried for cases of ventral hernia repair performed during the four and a half year time period of April 1, 2009, to September 30, 2013. Prior to 2011, approximately one-third of all ventral hernia repair cases performed at the University of Kentucky were captured by the ACS NSQIP review; after January 1, 2011, all cases of VHR were included. Suture only VHR were excluded. Preoperative patient characteristics included in analyses were demographics and over thirty clinical variables including comorbid conditions and laboratory values. Perioperative detail included the primary procedure Current Procedure Terminology (CPT©) code, the Centers for Disease Control and Prevention (CDC) Wound Class, mesh type and size, admission status, operative approach, concomitant procedure(s), emergent or elective status, transfusion status, and the duration of the procedure. Postoperative clinical outcomes data included wound occurrences, respiratory occurrences, sepsis, urinary tract infection, VTE, cardiac and cerebrovascular occurrences, and discharge destination.

Hospital cost data was obtained from the hospital cost accounting system (Allscripts EPSi Version 7.5 FP2, Chicago, IL) and matched to the cases identified via the NSQIP query. Total hospital costs were analyzed in three groups: 1) operating room services and supplies (includes the holding room, operating room and post-anesthesia care), 2) total encounter (total admission for inpatient cases, outpatient surgery center for outpatient surgery), and 3) post discharge

hospital encounters within 90 days (including emergency room, readmission, or outpatient labs or imaging) of the surgical encounter. Total hospital costs included both direct (supplies, nursing, OR and ICU equipment) and indirect costs (administration, facility and other overhead) but did not include professional fees.

Non-parametric tests were used for the bivariate analyses of costs: the Mann-Whitney U test for binary variables, the Kruskal-Wallis test for non-ordered categorical variables, and the Jonckheere-Terpstra test for ordinal variables. Significance was set at $p < .01$ due to the number of comparisons. Backward stepwise multivariable regression with a removal probability of 0.05 was used to assess the independent contribution to cost of the preoperative, perioperative, and postoperative factors. Statistical analysis was performed using SPSS™ version 22 (IBM™ Corp., Armonk, NY).

Results

Three-hundred and eighty-five cases of ventral hernia repair were included in the analyses. Of the total cases, the majority were female (59%), and the mean age was 51.3 years (SD = 13.3 years). More than half of the patients (57%) were categorized as American Society of Anesthesiologists physical status class 3 (ASA class). The body mass index (BMI) of approximately one-fifth of the patients (18%) was > 40 kg/m^2. Of all VHRs included in the analyses, 133 cases involved recurrent ventral hernia (laparoscopic or open) with open repair of initial, reducible incisional hernia being the most frequently performed procedure (n = 69). Across all ventral hernia repair types, the median costs (interquartile range [IQR]) were as follows: Operating room (ORC): $6,900 ($5,600 - $10,000); total encounter (TEC): $10,700 ($7,500 - $18,600); and 90-day post discharge (90PDC): $0 ($0 - $800).

Patient preoperative factors associated with increased costs

ASA class was predictive of increased costs across all 3 cost groups (ORC, TEC, 90PDC). Female gender, increasing age, treated hypertension, and the presence of a preoperative open wound were associated with increased ORC and TEC. COPD and diabetes were predictive of increased TEC. Steroid use for a chronic condition was predictive of increased 90PDC (Table 1). (Only cost comparisons that reached the level of statistical significance are reported in the tables due to the large number of cost comparisons that were not significant.) Several comorbidities, including renal failure and dialysis were rare in this cohort so were not analyzable. The following preoperative factors were not significantly associated with any of the 3 cost groups: BMI group, smoking status, transfer status, and none of the routine lab values including elevated white blood cell count, elevated creatinine or reduced hematocrit.

Perioperative factors associated with increased costs

Open repair of initial reducible incisional hernia was most commonly performed procedure; however, open repair of recurrent incarcerated incisional hernia was associated with highest median (IQR) costs (Figure 1). Perioperative variables and the associated hospital costs are presented in Table 2. Nearly nine in 10 VHR were performed for CDC class 1 wounds, and the ratio of laparoscopic to open cases was nearly equal (4.8:5.2). Approximately one-third of cases were for recurrent ventral hernia and two-thirds required inpatient admission. The median duration of operative procedure was between 2.5 and 3.5 hours. Most cases used synthetic mesh (79%) and one-fifth of cases utilized two or more pieces of mesh. More than 90% of the cases were for ventral hernia repair alone.

All perioperative factors were associated with increased ORC and TEC except for incarcerated vs. reducible hernia (all $p < .01$, Table 2). Wound Class 3 patients incurred

increased ORC, TEC, and 90PDC compared to wound class <3. The Diagnosis Related Grouping (DRG) of the VHR admission reflected concomitant surgery and was predictive of increased ORC and TEC costs ($p < .001$, Table 3).

Post-operative predictors of costs

A total of 2.1% of patients developed an inpatient postoperative wound complication which were associated with more than a tripling of TEC. Other inpatient ACS NSQIP complications such as sepsis resulted in even larger increases in TEC (Table 4). After discharge, 6.2% of patients experienced a wound complication which was associated with a $6,700 increase in PDC on average ($P < .001$, Table 4). Post-discharge sepsis was diagnosed in 1% of patients resulting in even larger PDC increases, while other ACS NSQIP complications were rarely diagnosed post-discharge in this cohort.

A total of 62 patients (16.1%) were readmitted to the hospital during the 90 day postoperative time period with associated median 90PDC of $7,700 (IQR: $4,700, $19,200) compared to $0 ($0, $800) for all patients. 90 day post discharge hospital costs were increased due to readmission, emergency room visits and diagnostic testing (Table 5).

Multivariable Analysis

The preoperative variables independently associated with increased ORC and TEC based on the regression analysis were identified to be: female gender, increased age, and presence of an open wound preoperatively. All the perioperative variables that were associated with increased costs from the univariate analysis remained independent predictors in the multivariable analysis of log transformed ORC and TEC. Because of lack of new information, we do not show the results here.

Discussion

This study aimed to identify the specific clinical factors associated with increased hospital costs as related to ventral and incisional hernia repair. This study is unique in that hospital costs were captured as opposed to charges. Charges are frequently artificially elevated and do not reflect the cost of providing care. The hospital cost data presented in this study highlights the increased costs associated with the complex care of multiply comorbid, older patients with large ventral hernias requiring lengthy, complex repairs. Also, the data calls attention to the significantly increased costs associated with any postoperative complication. A previous hospital cost analysis from our institution that focused on 415 consecutive open VIHRs showed that the majority of cases were performed at a financial loss (Reynolds, Davenport, Korosec, & Roth, 2013). This challenging patient population requiring complex care demands a cost-efficient strategy. While achieving cost-efficient care has been an elusive goal, the data generated by the current study identifies areas for specific focus for cost containment with VHR .

The negative financial impact of increased ASA Class was clearly exposed by our cost data. Risk reduction has been recommended as a means to enhance outcomes and reduce costs (Davenport, Henderson, Khuri, & Mentzer, 2005), but cost associated with risk reduction is not understood. Several VHR risk score models have been developed to help surgeons predict readmission (Baltodano et al., 2015), surgical site infection (Liang et al., 2015), and wound morbidity and hernia recurrence (Petro et al., 2015). Factors shown to be associated with increased risk with VHR are numerous and include diabetes (Baltodano et al., 2015; Fischer et al., 2014; Liang et al., 2015), increased ASA Class (Baltodano et al., 2015; Fischer et al., 2014; Liang et al., 2015), and increased wound class (Liang et al., 2015; Petro et al., 2015), all of which mirror our cost data. While this study did not show evidence of a negative financial

impact of morbid obesity or cigarette smoking, weight reduction and smoking cessation have been shown to enhance clinical outcomes postoperatively (Berger et al., 2013; Sørensen, 2012). Although not an independent predictor, patients that are obese or smoke may be more likely to have other conditions which increase risk and cost. Suggested actions to reduce risk prior to VHR include weight reduction to body mass index no greater than 35 kg/m^2 (Berger et al., 2013), smoking cessation (Sørensen, 2012), and diabetes control (Liang, et al., 2015). Pulmonary and cardiac optimization and physical pre-habilitation are also optimization considerations. Additionally, poignant and repeated patient counseling concerning risk reduction is critical to success in risk optimization.

In addition to optimization of modifiable risks, quality improvement provides an opportunity to enhance outcomes and reduce costs. Standardized quality improvement efforts such as Enhanced Recovery (ER) protocols with colorectal surgery have been reported to be associated with improved patient satisfaction, decreased length of hospital stay, reduced complication rate, and reduced costs (Stone et al., 2016; Thiele et al., 2015). These evidence-based pathways provide the opportunity to standardize any number of aspects of patient care. Recently, a pilot study of an evidence-based approach to care of patients undergoing abdominal wall reconstruction which addresses optimal pain control and acceleration of intestinal recovery has been reported (Fayezizadeh, Petro, Rosen, & Novitsky, 2014).

Another quality improvement effort, the 19-item World Health Organization (WHO) Surgical Safety Checklist, has been shown to be associated with significantly decreased complication rates (11.0% to 7.0%, $p < 0.001$) and decreased mortality in the 30-day postoperative period (Haynes, et al., 2009). While some form of this perioperative checklist may be in place in many facilities, the concept could be expanded to the other portions of surgical

care via the Electronic Health Record (EHR). Confirming information about risk optimization, such as BMI, smoking cessation, A1c level, and discharge planning, such as timely follow up with the surgeon, post discharge care, PCP follow up for high risk patients, and contact information, would allow the many participants across the continuum of care to be informed of the status of quality efforts. While this type of quality checklist currently is not in place at our facility, it could be helpful for communication and care coordination.

In an effort to determine the financial impact of quality improvement, Scally et al, reviewed inpatient Medicare claims data for all Medicare beneficiaries that underwent 11 general and vascular procedures for two time periods several years apart (Scally, Thumma, Birkmeyer, & Dimick, 2015). These authors found that hospitals that improved quality of care (evidenced by a significant decrease in complication rates between the two time periods) also significantly reduced their Medicare payments. Quality care is disincentivized in the current model in which care is paid based upon volume rather than outcomes. These findings demonstrate the potential financial benefits for patients and payers of quality improvement efforts. Hospitals and providers must balance the cost of quality improvement initiatives with cost reductions associated with improved outcomes. Because of the benefit to patients and payers, payer incentives to hospitals and providers for quality improvement measures would be a plausible solution for covering costs associated with quality improvement. While some quality improvement measures can be expensive to implement and maintain (Hammermeister, 2009), other measures may be less costly.

Closer surveillance with standardized post discharge care especially for high risk patients is one method of potential cost reduction that should be considered for VHR. A recent review of a large cohort of Medicare patients found that follow up with the primary care provider (PCP)

after open VHR did not benefit the patient in terms of decreased risk of hospital readmission as did follow up with PCP following thoracic aortic aneurysm repair (Brooke, Stone, Cronenwett, & et al., 2014). While it has been shown that postoperative complications drive readmissions after VIHR, early and standardized surveillance by the surgical team for complications for high risk patients likely would be beneficial in decreasing readmission rates, which in turn would drive cost reduction. Further study is recommended to understand if there would be a benefit of early follow up with PCP after complex hernia repair in multiply comorbid patients.

This study showed that any complication postoperatively was associated with dramatically increased hospital encounter costs. Wound complications affected the postoperative recovery of 8.3% of our patient cohort. Any wound occurrence was associated with a median of $35,900 ($25, 500, $68, 200) in total admission costs compared to all VHR patient median (IQR) costs of $10,700 ($7,500, $18,600) ($p < .001$) and a median $6,700 ($3,000, $21,800) in 90-day post discharge hospital costs compared to all VHR patients ($0 ($0, $800) ($p< .001$). Wound dehiscence was associated with median (IQR) hospital costs of $12,300 ($3, 400, $42,100) compared to all VHR patients ($0 ($0, $800) ($p < .001$). SSI and wound dehiscence are not only associated with increased hospital costs but also increased financial implications for patients in terms of potential lost wages and transportation costs associated with increased number of office visits and/or emergency room visit or hospital readmission and the additional health care costs associated with home health care. While the full extent of the financial burden of wound complications following VHR is not in the scope of this study, quantifying the complete costs of wound complications is needed to define the comprehensive financial impact of VHR to patients, hospitals and society.

Because of the high incidence, morbidity, and excess utilization of resources associated with central line-associated bloodstream infections (CLABSI), care bundles aimed at reducing the infection rate to near-zero have been introduced in health care systems (Hakko, et al., 2015; Pavia & Mazza, 2016). CLABSI rate prior to introduction of care bundle at one hospital was reported to be 12.8/ 1,000 catheter days. Over time following implementation of the intervention and with judicious process evaluation and monitoring, the infection rate was reported as 0 for a three-year time period (Hakko, et al., 2015). The authors of the study mentioned that a "culture of safety" was related to their success with this program. With implementation and judicious evaluation and monitoring of enhanced recovery protocols, it is within reason that that incidence of complications, including SSI, after VHR can be reduced, but due to the many confounding factors, it is not clear if SSI or other complications after VHR can be reduced to near-zero. Further study would be necessary to answer that question; however, earlier recognition of postoperative complications is an attainable goal, which would likely lead to decreased morbidity and decreased cost.

While risk optimization and quality improvement efforts are critical to cost reduction and enhanced outcomes, and despite significant efforts aimed at prevention, surgical complications continue to occur, likely are not entirely preventable, and are associated with striking cost increases. An investigation of hospital costs, revenues, and contribution margins associated with surgical complications from 2013 reported that 5.3% of the 34,256 surgical patients included in the analysis experienced at least one postoperative complication, finding that the per-patient variable hospital costs, total costs, and contribution margin were significantly higher and per-patient total margin was significantly lower for the patients that experienced a complication compared to those that did not have a postoperative complication (Eappen, Lane, Rosenberg, &

et al., 2013). Also, postoperative complications following hepato-pancreatico-biliary surgery have been shown to be associated with higher hospital costs, higher payments, higher contribution margins and net profits (Gani, et al., 2015). Revised payment strategies will eliminate increased net profits associated with surgical complications. Payment models that consider both the costs associated with preoperative risk and postoperative complications would be helpful in the shift away from fee-for-service payment strategies. Bundled care models for reimbursement would need to adequately risk stratify patients to account for increased costs associated with non-modifiable risk factors.

The current study included open and laparoscopic VHR, and the cost data clearly highlights the variation in costs associated with type repair. In 2013, Colavita et al. utilized the Nationwide Inpatient Sample to compare outcomes and costs between open and laparoscopic VHR. The findings of their review included that short-term outcomes of laparoscopic VHR were more favorable than open repair in terms of length of stay, costs, complication rates and mortality (Colavita et al., 2013). An earlier study by the same authors demonstrated similar recurrence rates between laparoscopic and open repairs (Colavita et al., 2012). While many factors must be considered in determining the ideal approach to hernia repair, from a value perspective, it is plausible to postulate that laparoscopic ventral hernia repair when feasible should result in reduced costs and similar outcomes.

Hernia recurrence is an additional driver of cost and cannot be underestimated. However, in our study, the cost of wound complications far exceeded the cost associated with the repair of recurrent hernias. While it is often said that the most expensive hernia is the one that recurs, the current study demonstrates the significant cost of postoperative complications. Undoubtedly,

those patients developing postoperative infections are even further likely to develop subsequent hernia recurrences.

Our data did not support smoking as a predictor of increased costs for VHR patients; however, it did identify increased hospital costs associated with COPD. Findings of a recent study that assessed the relationship of smoking duration with respiratory symptoms and COPD, concluded that while prevalence of COPD was decreased for smokers who quit ≥10 years previously, smoking duration had a linear relationship with COPD (Liu et al., 2015). The NSQIP data bases smoking status on one item: "current smoker within one year: yes/no." Therefore, it is not known with certainty if our patients were smoking at the time of VIHR, which may be reflected in the lack of association between smoking and costs. This limitation of the NSQIP dataset makes it difficult to make assumptions regarding the impact of smoking upon hernia outcomes. It is the practice of the authors to avoid hernia repair in patients who have not abstained from smoking for at least 4 weeks preoperatively based upon studies demonstrating a reduction in perioperative complications with abstinence for this short duration (Sørensen, 2012).

A further limitation of this study is that post discharge costs that were incurred at a facility other than our two hospitals were not known and therefore not included in our analyses. For example, if a patient reported to an emergency room other than at our facility, the costs associated with that care were not retrievable. Additionally, any costs associated with home health care or repeated office visits, both of which were likely to have occurred for some of the patients that incurred complications were not part of our cost data, which leads to the assumption that the 90PDC in reality, are even greater than our cost data reflect. We are currently conducting a VHR cost analysis that will incorporate all estimated post discharge costs involved for a large cohort patients having undergone open VHR.

The reality of the financial impact of hernia repair surgery is that patients with multiple comorbidities and large hernias command more expensive care. As payment strategies evolve into a value over volume foundation for all surgical care, and with increasing shift of risk to providers, such as penalties for readmission, surgeons must learn to provide high quality care at a reduced cost. This study provides a unique insight into the clinically relevant drivers of cost of VHR allowing an opportunity for pinpointing areas in need of attention. Development of a hernia care bundle payment model that incorporates risk adjustment, complexity of repair, and postoperative outcomes is needed to allow hospitals to care for these patients without incurring a financial loss.

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Table 1: Median hospital costs (interquartile range) for ventral hernia repair by preoperative risk factor. Costs are in thousands of U.S. Dollars. N=385. NS=No significant difference.

Characteristic	Incidence, n (%) of Patients	Operating Room Service and Supply Costs	Total Encounter Costs	90-days Post-VHR discharge Costs
All VHR Patients	385 (100%)	6.9 (5.6-10.0)	10.7 (7.5-18.6)	0 (0-0.8)
Gender		**	***	NS
Female	228 (59.2%)	7.2 (5.8-12.4)	11.5 (8.3-20.5)	
Male	157 (40.8%)	6.6 (5.4-8.8)	9.5 (6.8-14.6)	
Age, years		**[1]	***[1]	NS
<=40	86 (22.3%)	6.6 (5.5-8.8)	9.5 (7.1-14.0)	
41-48	76 (19.7%)	6.6 (5.5-9.0)	9.4 (6.8-15.4)	
49-56	88 (22.9%)	7.0 (5.4-10.3)	10.9 (7.8-18.0)	
57-64	65 (16.9%)	7.6 (5.7-14.3)	13.8 (9.8-21.7)	
65+	70 (18.2%)	7.5 (6.3-14.5)	13.2 (8.2-27.6)	
ASA Class†		***[1]	***[1]	**[1]
I-II	153 (39.7%)	6.3 (5.3-8.5)	8.8 (6.8-12.2)	0 (0-0.2)
III	219 (56.9%)	7.5 (6.0-15.1)	12.6 (8.9-24.4)	0.1 (0-2.1)
IV-V	7 (1.8%)	6.5 (5.8-8.7)	8.1 (6.2-29.7)	0.1 (0-2.3)
Treated Hypertension	217(56.4%)	7.2** (5.8-14.0)	11.7*** (8.0-22.5)	NS
Preoperative Open Wound	15 (3.9%)	20.1*** (10.4-30.0)	29.1*** (23.4-83.0)	NS
BMI > 40 kg/m^2	69 (17.9%)	NS	NS	NS
Smoker	126 (32.7%)	NS	NS	NS
Diabetes	87 (22.6%)	NS	13.4** (8.3-21.9)	NS
COPD	26 (6.8%)	NS	17.6** (10.1-30.0)	NS
Steroid Treatment for Chronic Condition	12 (3.1%)	NS	NS	2.7** (0.5-6.7)

* P < .05; ** P < .01; *** P < .001 from Mann-Whitney U or Kruskal-Wallis tests of group differences in costs. [1] Jonckheere-Terpstra test for ordered alternatives which detects increasing or decreasing differences in medians. †Patients without ASA classification were excluded from the table, they comprised 1.6% of the total.

IQR: interquartile range; VHR: ventral hernia repair; BMI: body mass index; COPD: chronic obstructive pulmonary disease;

Table 2: Median hospital costs (interquartile range) for ventral hernia repair by perioperative factors. Costs are in thousands of U.S. Dollars. N=385.

Characteristic	Incidence, n (%) of Patients	Operating Room Service and Supply Costs	Total Encounter Costs	90-days Post-VHR discharge Costs
All VHR Patients	385 (100%)	6.9 (5.6-10.0)	10.7 (7.5-18.6)	0 (0-0.8)
Wound Class		***[1]	***[1]	**[1]
1 Clean	335 (87.0%)	6.6 (5.5-8.5)	10.1 (7.2-14.4)	0 (0-0.5)
2 Clean/Contaminated	22 (5.7%)	20.3 (8.8-22.9)	29.8 (17.8-35.8)	0 (0-3.6)
3 Contaminated	19 (4.9%)	20.9 (14.3-31.6)	28.6 (21.9-58.2)	1.0 (0-6.0)
4 Dirty/Infected	9 (2.3%)	20.1 (15.0-26.6)	30.6 (24.2-34.9)	0 (0-8.4)
Mesh size, cm^2 tercile		***[1]	***[1]	NS
<=310	143 (37.1%)	5.7 (4.8-6.8)	7.4 (5.9-10.7)	
311-619	133 (34.5%)	7.0 (6.0-17.3)	11.1 (8.2-22.1)	
620+	109 (28.3%)	8.5 (7.2-14.0)	14.8 (11.1-25.2)	
Approach		***	***	NS
Laparoscopic	184 (47.8%)	6.4 (5.5-7.5)	8.2 (6.7-10.7)	
Open	201 (52.2%)	8.4 (5.9-18.1)	15.8 (10.5-27.0)	
Recurrent Hernia vs. Initial	133 (34.5%)	8.5*** (6.4-17.4)	15.3*** (10.8-25.2)	NS
Patient Type		***	***	NS
Inpatient	264 (68.6%)	7.9 (5.9-15.7)	13.7 (10.1-24.2)	
Outpatient	121 (31.4%)	6.1 (5.2-7.0)	6.9 (5.6-8.2)	
Operation Duration, minutes		***[1]	***[1]	NS
<=90	96 (24.9%)	5.5 (4.5, 6.5)	6.8 (5.4, 9.1)	
91 - 150	141 (36.6%)	6.6 (5.5, 7.9)	9.9 (7.7, 12.9)	
151 - 210	77 (20.0%)	8.4 (6.7, 17.1)	15.1 (11.0, 22.2)	
211 - 270	41 (10.6%)	10.7 (8.0, 20.6)	19.6 (13.4, 28.0)	
271+	30 (7.8%)	17.7 (12.6, 21.2)	28.5 (19.1, 32.0)	
Mesh Type		***	***	NS
Synthetic Only	303 (78.7%)	6.3 (5.4-7.6)	9.4 (7.0-12.2)	
Biologic Only	72 (18.7%)	19.3 (16.4-25.6)	27.3 (21.1-35.2)	
Both	10 (2.6%)	21.1 (15.5-26.2)	31.1 (23.7-34.3)	
No. of Mesh Pieces		***[1]	***[1]	NS
1	312 (81.0%)	6.5 (5.4-8.5)	10.1 (7.1-15.4)	
2+	73 (19.0%)	11.3 (8.0-19.9)	17.8 (10.8-29.7)	
Transfusion of PRBCs during or w/in 72hr of operation	6 (1.6%)	21.9** (14.1-32.5)	40.7*** (25.2-93.4)	NS

* P < .05; ** P < .01; *** P < .001 from Mann-Whitney U or Kruskal-Wallis tests of group differences in costs. [1] Jonckheere-Terpstra test for ordered alternatives which detects increasing/decreasing differences in medians.
IQR: interquartile range; VHR: ventral hernia repair

Table 3. Costs Associated with the Diagnostic Related Grouping (DRG) of the Ventral Hernia Repair Admission. The DRG Reflects More Complex Secondary Or Other Operations During The Admission. Median Hospital Costs In Thousands Of U.S. Dollars (Interquartile Range), N=385.

Characteristic	**Incidence, n (%) of Patients**	**Operating Room Service and Supply Costs**	**Total Encounter Costs**	**90-days Post-VHR discharge Costs**
All VHR Patients	100%	6.9 (5.6-10.0)	10.7 (7.5-18.6)	0 (0-0.8)
DRG Group		***	***	NS
Ventral Hernia Repair	205 (53.2%)	7.1 (5.7-9.4)	11.6 (9.7-18.6)	
Outpatient VHR (no DRG assigned)	121 (31.4%)	6.1 (5.2-7.0)	6.9 (5.6-8.2)	
Peritoneal adhesiolysis	24 (6.2%)	12.8 (7.7-17.8)	19.7 (16.1-27.7)	
Major gastrointestinal resection	21 (5.5%)	19.9 (11.1-22.1)	28.5 (20.9-36.0)	
Major Soft tissue procedure	9 (2.3%)	17.3 (9.2-23.3)	24.9 (21.5-36.0)	
Gynecologic procedure	2 (0.5%)	17.9	22.6	
Tracheotomy w/ Mech. Vent. 96+ Hrs.	3 (0.8%)	36.6	101.3	

* p < .05; ** P < .01; *** P < .001 from Kruskal-Wallis tests of group differences in costs.

Table 4: Hospital costs associated with inpatient and post-discharge occurrence of ACS NSQIP morbidities. Median Hospital Costs (interquartile range) in Thousands of U.S. Dollars, N=385.

Characteristic	Inpatient Incidence, n (%) of Patients	Total Encounter Costs	Post-Discharge Incidence, n (%) of Patients	90-days Post-VHR discharge Costs
All VHR Patients	385 (100%)	10.7 (7.5-18.6)	385 (100%)	0 (0-0.8)
Any of the following wound occurrences	8 (2.1%)	35.9*** (25.5-68.2)	24 (6.2%)	6.7*** (3.0-21.8)
Superficial SSI	4 (1.0%)	30.9** (25.5-36.1)	14 (3.6%)	5.6*** (0.1-9.7)
Deep SSI	1 (0.3%)	58.2* No IQR	5 (1.3%)	24.8*** (3.4-78.0)
Organ/Space SSI	1 (0.3%)	159.3* No IQR	4 (1.0%)	20.7** (9.2-27.8)
Dehiscence	3 (0.8%)	71.6* No IQR	7 (1.8%)	12.3*** (3.4-42.1)
Sepsis	6 (1.6%)	36.0** (23.1-61.5)	4 (1.0%)	23.8*** (22.0-28.3)
Septic Shock	4 (1.0%)	124.8** (84.7-165.0)	0 (0%)	NC
UTI	7 (1.8%)	36.5** (11.5-90.2)	2 (0.5%)	13.3* No IQR
Mechanical Ventilation > 48 hrs or Unplanned Intubation	7 (1.8%)	82.9*** (50.0-159.3)	0 (0%)	NC
VTE (DVT or Pulmonary Embolism)	5 (1.3%)	30.9** (20.0-108.4)	1 (0.3%)	NS
Cardiac Arrest/ Acute Myocardial Infarction/ Stroke/ Coma	5 (1.3%)	50.0*** (32.3-119.2)	1 (0.3%)	NS
Transfusion < 72hr Postoperatively	6 (1.6%)	40.7*** (25.5-93.4)	0 (0%)	NC
Pneumonia	3 (0.8%)	47.0** No IQR	0 (0%)	NC

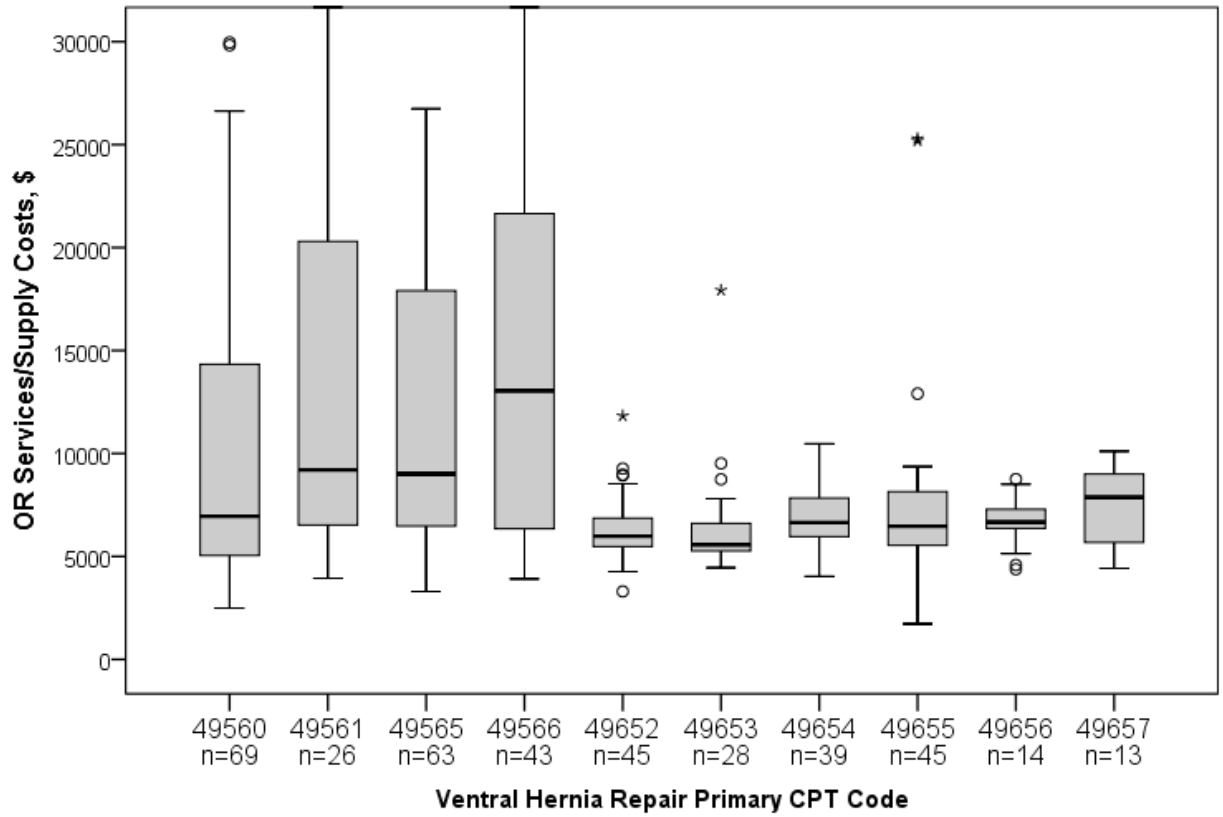
* p < .05; ** p < .01; *** p < .001 from Mann-Whitney U or Kruskal-Wallis tests of group differences in costs. [1] from Jonckheere-Terpstra test for ordered alternatives which detects increasing/decreasing differences in medians.
VHR: ventral hernia repair; SSI: surgical site infection; UTI: urinary tract infection: VTE: venous thromboembolism; DVT: deep vein thrombosis;

Table 5: 90 Day Post-Discharge Encounter Costs for Patients Post Ventral Hernia Repair Discharge, Median (IQR) Hospital Costs, Reported in Thousands of U.S. Dollars, N=385.

90-day Postoperative Encounters		
Characteristic	**Incidence, n (%) of Patients**	**Total Hospital Costs 90-days Post-VHR discharge**
All Patients	385 (100%)	0 (0-0.8)
Emergency Department Visits without Readmission	46 (11.9%)	2.6*** (0.6-9.6)
Readmission	62 (16.1%)	7.7*** (4.7-19.2)
Outpatient Surgery	7 (1.8%)	4.2*** (2.4-6.1)
Outpatient Encounter	120 (31.2%)	0.6*** (0.2, 3.4)

* P < .05; ** P < .01; *** P < .001 from Mann-Whitney U or Kruskal-Wallis tests of group differences in costs.

Figure 1. Operating Room Service and Supply Costs by Type of Ventral Hernia Repair Based on the Primary Current Procedural Terminology (CPT) Code*, Reported in U.S. Dollars, N=385.



* CPT Code Descriptions

49560: Repair initial incisional or ventral hernia; reducible

49561: Repair initial incisional or ventral hernia, incarcerated or strangulated

49565: Repair recurrent incisional or ventral hernia, reducible

49566: Repair recurrent incisional or ventral hernia, incarcerated or strangulated

49652: Laparoscopy, surgical, repair, ventral umbilical Spigelian or epigastric hernia (includes mesh insertion, when performed); reducible

49653: Laparoscopy, surgical, repair, ventral umbilical Spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated

49654: Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible

49655: Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated

49656: Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible

49657: Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated

2016 Professional Edition Current Procedural Terminology. American Medical Association,

2015, Chicago, Il.

Manuscript 3

Outcomes Experienced by Patients Presenting with Ventral Hernias and Morbid Obesity in a Surgical Clinic

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Abstract

Surgeons generally agree that morbid obesity is a contraindication to ventral hernia repair surgery due to risk of adverse outcomes. The purpose of this study was to describe the experience of patients with ventral hernia complicated by morbid obesity by reviewing a population of patients that were seen by a surgical service to determine the characteristics of those patients that had favorable and unfavorable outcomes. A retrospective medical record review was conducted of new patients with ventral hernias and morbid obesity (BMI $\geq$ 40 kg/m^2) seen by one surgical service over a two and a half-year time period. Clinical characteristics were noted, and surgical approach and clinical outcomes were noted for patients that had hernia repair. Patients that did not return were attempted to be contacted for a survey.

A total of 79 new patients with ventral hernias and morbid obesity were seen during the time period described. Eighteen patients did not follow up after initial visit; telephone surveys were conducted with six subjects. Morbidly obese patients with ventral hernias that were amenable to laparoscopic repair had favorable outcomes. Patients that had hernia repair that had met goal weight were few in numbers. Patients that had open hernia repair had increased rate of surgical site issues compared to patients that had laparoscopic repairs. Follow up surveys, because few in number, provided anecdotal information. Further research is needed to understand best practices for patients with ventral hernias complicated by morbid obesity.

Keywords: ventral hernia, morbid obesity, bariatric surgery, weight loss, postoperative complications, hernia recurrence

Introduction

Ventral hernia repair surgery is one of the most commonly-performed surgical procedures in the United States today, as incisional hernias are estimated to occur in as many as 20 percent of patients that have had a previous abdominal operation (Cengiz & Israelsson, 1998). Some but not all patients' hernias are amenable to laparoscopic repair with intraperitoneal mesh implantation (Tobler & Itani, 2016); however, many patients' hernias are much larger measuring as wide as 10-20 centimeters precluding that operative approach (Petro et al., 2015). These larger hernias are more likely to require an open technique of hernia repair which often involves a four to seven-day hospitalization and is known to carry a much greater risk of postoperative complications. Surgical site infection (SSI) is believed to be the most common postoperative complication following ventral hernia repair and frequently leads to hospital readmission (Merkow, Ju, Chung, & et al., 2015). The incidence of SSI following ventral hernia repair is reported to be as high as 19 to 25% for open repairs (Holihan et al., 2015; Liang, Goodenough, Martindale, Roth, & Kao, 2015).

The patients that arrive to a surgical practice that is devoted to care of patients with complex hernias generally are referred by other surgeons who have decided that the patient or the patient's hernia is at a degree of complexity that requires a higher level of expertise. Another important factor is that many, if not most, ventral hernia patients present with multiple comorbidities which also can complicate the postoperative recovery. A recent National Surgical Quality Improvement Program (NSQIP) review of 106,968 patients with ventral hernias identified a 60% incidence of obesity, defined as body mass index (BMI) greater than or equal to 30 kg/m^2, in this ventral hernia population. This rate of obesity is nearly twice that of the estimated 34.9% of the United States adult population (Ogden, Carroll, Kit, & Flegal, 2014).

Evidence of the impact of patient preoperative clinical characteristics, including obesity, on hernia repair outcomes has increased over the last decade. The externally-validated Ventral Hernia Risk Score (VHRS), which allows a prediction of risk for surgical site infection (SSI) after ventral hernia repair utilizes wound class, body mass index (BMI), raising of skins flaps, American Society of Anesthesiologists (ASA) Class, and performance of a concomitant procedure with VHR to calculate the degree of risk (Liang, Goodenough, Martindale, Roth, & Kao, 2015) Also, a recent review of a large cohort of patients with ventral hernias from a national database showed a relationship between obesity and delayed wound healing and wound disruption, cardiac and pulmonary complications and prolonged hospitalization following hernia repair (Novitsky & Orenstein, 2013). And to provide further evidence of the impact of obesity on unfavorable surgical outcomes, according to an expert consensus panel review of ventral hernia management which was guided by a systematic review, the incidence of ventral hernia repair postoperative complications are increased in patients with BMI greater than or equal to 30 kg/m^2 (Liang et al., 2016).

While obesity has been linked to prediction of increased risk of surgical site infection after open repair of ventral hernias, and weight reduction to a BMI no greater than 40 kg/m^2 is recommended (Berger et al., 2013), little information is available concerning recommendations to achieve weight loss prior to hernia repair surgery. The general policy of the Minimally Invasive Surgery (MIS) Service at the University of Kentucky (UK) is that patients desiring ventral hernia repair surgery in the absence of exacerbating symptomatology, urgency or emergency must reach a goal BMI of no greater than 40 kg/m^2 in order to decrease operative risk, to decrease risk of post-operative complications, and to decrease risk of hernia recurrence. Based on individual patient and hernia characteristics, some patients are advised to lose weight

prior to consideration of hernia repair surgery. The surgical providers make recommendations to assist patients with reaching goal weight. Over the past several years, several methods have been recommended by the service to patients, such as:

1) Diabetic obese patients with ventral hernias are referred to the University of Kentucky Barnstable Brown Diabetes and Obesity Center for diabetes management and medical management of weight.
2) Non-diabetic patients are recommended to receive one-on-one counseling by the surgeons at three-month intervals as assistance to reach goal BMI.
3) Referral to a Bariatric Center of Excellence for those patients who after discussion express interest. (UK currently is not a designated Bariatric Center of Excellence making the combination of procedures or staging of procedures at this facility unattainable.)
4) Information is provided to patients with interest in self-referral to the Health Management Resources (HMR) weight loss program.
5) Referral to an outpatient dietician as available in patients' local area.

Although some patients have succeeded in meeting weight loss goals; the reality of the outcomes in terms of weight loss and subsequent suitability for hernia repair for these patients is not known. No calculations have been made concerning the proportion of patients that lose to goal weight and have hernia repair. It has not been systematically determined if the referral appointments to medical or surgical programs are kept, if follow through occurs, other methods patients employ for weight loss, and whether or not the methods prove successful. The proportion of patients that return to the office having achieved weight loss goal and have hernia repair surgery is not known. The percentage of patients who are offered hernia repair surgery without meeting weight loss goals also is not known. It is believed that many patients do not

return for any follow up appointment after the initial visit in which they were recommended weight reduction prior to consideration of hernia repair.

The purpose of this project is to describe the experience of patients with ventral hernias that are complicated by morbid obesity (to be defined as BMI greater than or equal to 40 kg/m^2) by looking back at the population of patients that have been seen by the surgical service. The specific aims of the study were:

1) To describe and quantify the target population (patients seen by the MIS service at UK HealthCare during a two and a half year period that were seen for initial evaluation of ventral hernia and had BMI $\geq$ 40 kg/m^2),
2) To determine the outcomes of patients in the entire cohort that had hernia repair surgery,
3) To determine the surgical outcomes in terms of surgical site occurrence, 30-day hospital readmission rate and hernia recurrence rate for the patients that did or did not meet goal and had hernia repair surgery,
4) To describe the methods recommended to the target population of patients to reach goal BMI and examine the relationships between baseline BMI, weight loss method employed, and outcomes, and
5) To describe the outcomes of patients that failed to return to the MIS Clinic after the initial visit.

Methods

The University of Kentucky Institutional Review Board approved both the retrospective and prospective components of this study. Outpatient clinic schedules from the time period of July 1, 2012, through January 31, 2015, for the surgical service described were obtained by querying the appointment scheduling system. The schedules were reviewed in order to identify the targeted patient population as the schedules list the type of appointment (for example, new patient appointment versus postoperative appointment) and the reason for referral. Only new patient visits were used to identify the potential target population. Inclusion criteria were ages 18-85, new patient status, diagnosis of ventral, incisional, flank, recurrent ventral, complex ventral, and/or parastomal hernia, and body mass index greater than or equal to 40 kg/m^2. Patients were excluded from the study if on evaluation it was noted that surgery would be contraindicated due to functional dependency or severe medical comorbidities. Counts of overall numbers of appointments and of numbers of patients seen for initial consultation for ventral hernia were recorded. Body mass index (BMI) was recorded for all new patients seen for ventral hernia in order to identify the targeted population; however, identifying information was noted only for the targeted population.

Once the study population was identified, a retrospective review of existing medical records of patients with ventral hernias and morbid obesity (BMI $\geq$ 40 kg/m^2) was conducted. Information gathered included patient age, gender, height, weight, body mass index, presence or absence of common comorbidities, smoking status, marital status, employment status, previous abdominal surgery, previous ventral hernia repair, previous weight-loss surgery, previous abdominal wall infection, and previous or current mesh infection.

From the review of the clinic notes, the recommendation for weight loss, amount of weight to lose (pounds), and goal BMI was recorded. For the subset of patients that had hernia

repair surgery (before or after weight loss efforts ensued), the weight and BMI at time of surgery scheduling, whether or not goal weight was achieved, whether or not weight loss was requested, type of approach of hernia repair, type of mesh, and date of procedure was recorded. For follow up purposes, the date of most recent visit was recorded for all patients, and any documentation of postoperative incidence of surgical site event, type of surgical site event, and/or hernia recurrence was recorded for patients that had hernia repair. For patients that were recommended weight loss, date of any further visits along with subsequent visit weight (pounds), body mass index, and methods used were recorded.

As part of the review of existing medical records of the target population, a subset of patients were identified that did not return to the facility for any follow up after the initial surgical consultation. Attempts were made to contact his group of patients by telephone. For any patient that was reached, by utilizing the telephone script, the patient provided or did not provide consent to proceed. For patients that were in agreement with the consent portion of the telephone script, the survey/interview was conducted. For patients that did not agree to participate in the study, no further attempts at contact were made, and the data that was obtained during medical record review was removed from the study file. The purpose of the telephone survey was to determine the outcomes of this subset of patients, e.g. surgery at another facility, emergency surgery, other, and how the individuals that reached goal BMI accomplished their goals.

Descriptive statistics were calculated for continuous variables using means, standard deviations, minimum and maximum. Frequencies and percentages were calculated for categorical variables. Groups were compared using Chi-square, Fisher's Exact tests, paired t-tests, or independent samples t-test as appropriate. Significance was set at $p < .05$.

Results

Description and Quantification of the Target Patient Population

A total of 3,265 patient encounters occurred with the MIS service in the outpatient office during the time period July 1, 2012, through January 31, 2015. Of these visits, a total of 381 patients were seen for initial consultation for diagnosis of ventral hernia. The body mass index (BMI) for each patient was recorded in order to identify the subject population. BMI was not part of the existing medical record for 14 patients; the mean BMI of the remaining 367 patients was 34.4 kg/m^2 (SD = 7.7) with 252 patients (68.7%) noted to have BMI greater than or equal to 30 kg/m^2. The study population, those patients with BMI $\geq$ 40 kg/m^2, was identified from the 367 patients to be 78 patients. (The original study population was 79 patients; however, one subject's data was removed from the study file as when this person was reached for the telephone survey politely asked to not take part.) The mean BMI of the study population (n = 78) was 45.3 kg/m^2 (SD = 4.5). The demographic and clinical characteristics of the full study population are presented in Table 1 (continuous variables reported with mean, standard deviation, minimum and maximum) and Table 2 (categorical variables presented with number of percent). More than three-fourths of the study population were female (79%), and more than half of the patients were seen for recurrent ventral hernia (59%). Nearly two-thirds of the patients (64%) had two or more of the comorbid conditions that were documented for study purposes, highlighting the complexity of the population of patients.

Based on information gathered in the medical record review, the 78 subjects were divided into five major categories (Figure 1).

Group 1: those who were offered hernia surgery after meeting weight loss goals (n = 7)

Group 2: those who were offered hernia repair surgery without weight loss (n=32),

Group 3: those who were recommended weight loss, have returned to the clinic for follow up visit(s), but have not been offered hernia repair (n=15),

Group 4: those who failed to return to the clinic at any time since initial surgical consultation (n=18), and

Group 5: those who are under the care of another provider due to other health problems (n = 6).

Further data analyses were conducted based on this division of subjects. The mean BMI was higher for Groups 3 and 4 compared to Groups 1, 2, and 5 (Table 3). The mean number of pounds recommended to lose for groups 1, 3, and 4 are shown in Table 4, showing that patients in Groups 3 and 4, as would be expected based on increased BMI, were recommended to lose greater number of pounds than patients in Group 1.

Clinical Outcomes of Patients that Underwent Hernia Repair Surgery

Across the review period, 39 patients were offered to be scheduled for hernia repair surgery, and a total of 32 patients underwent a surgical hernia repair procedure. Of these patients, 26 individuals had surgery without weight loss being required (Group 2) and 6 patients met weight reduction goals and underwent hernia repair surgery (Group 1). (Six patients in Group 2 declined surgery, and one patient in Group 1 declined surgery.) Across all patients that had hernia repair, the mean (SD) preoperative age, height, weight and BMI are presented in Table 5. Based on an independent samples t-test, the mean BMI of patients that had hernia repair was significantly lower than mean BMI of patients that did not have hernia repair (43.1 kg/m^2 [SD = 2.6] versus 46.9 kg/m^2 [SD = 4.8], $p < .001$). Of the patients that had hernia repair, 22 had open ventral hernia repair and 10 had laparoscopic repair. Synthetic mesh was implanted for all laparoscopic repairs and for nine open repairs. Biologic mesh was utilized in four open repairs,

and bioresorbable mesh was used in the remaining nine open repairs. Across all repairs, 13 patients (40.6%) experienced a surgical site occurrence, and three patients (9.4%) had hospital readmission within the 30-day postoperative time period. The median number of days of follow up with patients that underwent hernia repair was 122 days (interquartile range: 30, 380). Across the follow up, 2 hernia recurrences (6.3%) were documented.

Clinical Outcomes of Patients that Met Weight Loss Goal and Underwent Hernia Repair Surgery Compared to Patients that Did Not Meet Weight Loss Goals and Underwent Hernia Repair Surgery

Of the 32 patients that underwent hernia repair, 6 patients had achieved weight loss goals and 26 patients had surgery without weight loss requirement. Each of the patients that met weight loss goal (Group 1) required open repair with abdominal wall reconstruction. Ten of the patients in Group 2 (weight loss not required) underwent laparoscopic repair, and the remaining patients had open repair with abdominal wall reconstruction (n = 16). The baseline characteristics of the surgical patients are presented in Table 6, based on weight loss requirement or no weight loss requirement. Chi-square tests of association did not reveal statistically significant differences between the two groups in terms of gender, preoperative comorbidities, or surgical history. The two groups did not different significantly in terms of preoperative BMI based on independent samples t-test. Group 1 mean BMI was 41.8 kg/m^2 (SD = 1.3) and Group 2 mean BMI was 43.4 $kg.m^2$ (SD = 2.8) (p = .059). Patient age was also similar across the two groups.

Many patients experienced postoperative surgical site events, either infection or seroma. In the group that met weight loss goals, 4 of 6 patients (67%) had surgical site issues, and in the group that did not require weight loss, 9 of 26 patients (35%) had wound problems. The

measures required to treat the wound problems included antibiotics, dressing changes, negative pressure wound therapy, and percutaneous drain placement. Details across the two groups of the wound events are shown in Table 7.

Incidence of surgical site problems for patients that underwent hernia repair (Groups 1 and 2 combined) was compared based on surgical approach (laparoscopic versus open ventral hernia repair) using Fisher's exact tests (Table 8). One-half of the 22 patients that had open repair experienced surgical site infection; whereas, none of the 10 patients (0%) that had laparoscopic repair experienced surgical site infection ($p = .006$). No other differences in patient outcomes were revealed based on surgical approach.

Description of Weight Loss Methods Utilized and Patient Weight Loss Outcomes

Based on the medical record review, the median number of pounds that patients were advised to lose prior to consideration of hernia repair was 34 pounds (minimum = 8, maximum = 100). The value that was recommended most often (mode) was 20 pounds. The medical record review provided some information about specific measures recommended to patients to help them reach weight loss goals. Most frequently, note was made by the provider that the patient was recommended to diet and/or see a dietician about weight loss measures ($n = 22$). Six patients were referred to the Barnstable Brown Diabetes and Obesity Center (BBDOC) in order to seek assistance with diabetes management and weight reduction. Five patients expressed interest in weight loss surgery options and were provided referral information to a Bariatric Center of Excellence. Frequently, as part of the recommendations, patients also were recommended to quit smoking, with some referrals noted to smoking cessation providers in conjunction with weight loss recommendations. Three patients were noted to have expressed interest in liquid nutritional weight loss measures, with information provided to those patients.

From the follow up visits, there was minimal information found in the medical records about weight loss measures that patients employed. However, based on the recommendations that were noted in the initial visit documentation, the patients that were recommended to diet and/or see dieticians and had further visits lost an average of 13.4 pounds (minimum: + 10, maximum: - 30) (n = 12 patients). Patients that were seen by the BBDOC lost an average of 7.2 pounds (minimum = 0, maximum = 19) (n = 4). Based on the medical record review no patient had had weight-loss surgery and had followed up with surgical provider regarding weight loss.

For patients that achieved goal weight/BMI (n = 7), the amount of weight lost and time frame required is presented in Figure 2. Paired t-tests were used to compare matched weight data for all subjects that followed up at least once after initial consultation with weight loss recommended (Table 9), showing significant mean difference in weights for Group 1 and for Groups 1 and 3 combined, but not for Group 3 alone.

Anecdotal Outcomes of Patients that Failed to Return to Clinic for Follow-Up that Responded to Telephone Survey

A total of 6 of possible 18 (33%) patients completed the telephone survey. None of these patients had met weight loss goals to this point in time; however, one patient had undergone weight-loss surgery during 2015 and had lost a total of 130 pounds, with a stated 60 additional pounds needed to meet goal weight and pursue hernia repair surgery. This patient stated that the recovery from weight loss surgery was not without complications, but was pleased with the progress to date.

Another patient expressed considerable hope in her ability to lose weight and eventually undergo hernia repair surgery. She stated that she had not met her goal of weight loss, but fully intended to lose weight and wanted to “come back to see that surgeon” as she appreciated the

straightforward approach to educating the patient to understand the potential complications in undertaking a complex repair in the presence of morbid obesity. No patients expressed refusal to lose weight or dissatisfaction with care received at the surgical consultation; however, other than the patient that had weight-loss surgery, no patient reported any progress with meeting their weight loss goal.

Discussion

This study aimed to describe the experience of a cohort of consecutive patients that presented to a specialty hernia clinic for consultation for ventral hernia based primarily on a retrospective chart review. The surgical providers saw over 350 patients with ventral hernias during the study period, and nearly 70% of those patients had body mass index (BMI) greater than or equal to 30 kg/m^2, which falls into the range of obesity. Our data confirms previous evidence that obesity is overrepresented in the population of patients with ventral hernias (Regner, Mrdutt, & Munoz-Maldonado, 2015). Our study population, which consisted of patients with BMI greater than or equal to 40 kg/m^2, comprised 21.5% of the service's hernia population.

Very few patients that were recommended to lose weight prior to consideration of hernia repair surgery were able to meet their goal and undergo hernia repair. Although the numbers are small, more than half of the patients that achieved weight loss to goal and had hernia repair experienced some degree of a surgical site issue, and many of the patients that were not required to lose weight prior to hernia repair also experienced a burden of wound problems (Table 7). It is well-documented that open repair of ventral hernias in the face of obesity are associated with a high percentage of postoperative complications (Berger et al., 2013; Liang, et al., 2016) and our

data was supportive. Fortunately, there were few hospitals readmissions noted in our cohort of patients and none for pulmonary or cardiac complications postoperatively.

For the patients that were offered surgery without meeting weight loss goals, the outcomes were highly favorable for those that were able to undergo a laparoscopic ventral hernia repair (Table 8). Laparoscopic surgery is not feasible for all patients; however, when an obese patient's hernia is of the size and location that laparoscopic repair is possible and not otherwise contraindicated, the benefits in terms of decreased postoperative complications were highlighted by our data. Long-term follow up was not available for most patients; therefore, it is not known if any have had recurrence of hernia, but to the point to which they were last seen, no hernia recurrences were found in the laparoscopic repair cohort. Based on interviews with hernia surgeons, the authors of a recent report noted that these surgeons generally considered that technical factors, infection and other complications are the most likely factors involved in hernia recurrence (Park, Zahiri, Pugh, Vassiliou, & Voeller, 2015). Long-term data on the incidence of recurrence following laparoscopic repair is lacking, and it is imperative that research be conducted to fully understand the implications of the different factors, such as obesity and technical failures, on durability of laparoscopic repair.

Nearly one-fourth of the study population has not returned at any time to the clinic or other departments at the University for health care since the initial consultation with the surgical provider. Based on the few patients in this category that were able to be reached for the telephone survey, little progress was made except for the individual who chose the route of weight-loss surgery. The concern is that the patients were not offered a practical solution to assist them to weight loss goals or that the patient simply did not want to employ the methods that were recommended. Due to the retrospective nature of the study, it is not certain how the

patients perceived the recommendations they were given, but nearly half of the patients (45%) that had not been offered hernia repair scheduling as noted in this review, continued to be seen with hopes of reaching goals in the future. Additionally, of the patients that were reached by phone, none stated they were not interested in losing weight.

A health care system that maintains a large surgical practice devoted to care of complex patients with complex ventral hernias, as described in this study, has an opportunity to facilitate and support a system that could assist the surgical providers to care for this unique patient population. That system would likely involve a multidisciplinary team including administrative assistance to foresee patients that would require weight loss prior to surgical consideration, a mid-level provider to conduct history and physical examinations and counsel patients, an endocrine practice to assist in diabetes management, a smoking cessation educator, and a dietician to provide nutrition and weight loss services. Also, important to keep in mind is the travel barriers of the patient population, because care for this population of patients has become centralized as community surgeons generally are not equipped to provide the care, so that after initial consultation many educational and follow up services could likely be conducted via websites/ online video education/ tele-health services as opposed to in a busy surgical office

Presence of multiple comorbidities likely were part of the clinical decision-making for many of the patients in this study. Diabetes that is not well-managed is associated with unfavorable outcomes for patients undergoing ventral hernia repair, and current recommendations are that hemoglobin A1c level should be less than 8.0% prior to surgical planning (Goodenough et al.). While this study did not document A1c levels, recently it has become of greater priority to be aware of obese patients' A1c levels, whether or not the patient is a known diabetic.

Although the differences did not reach statistical significance, the mean BMI and the mean number of pounds to lose among the groups as categorized in this study were greater for the patients that failed to return to the office and for those that have followed up at least once, leading to the conclusion that weight loss upwards of 40 pounds is an insurmountable task without devoted assistance. Our patient population for the most part likely do not have the means to participate in expensive weight loss programs. However, two recent publications described weight loss measures that do not appear to involve great cost to the individual patient that may be advisable to recommend to patients such as our target population. One study described a multidisciplinary program for patients with complex ventral hernias being seen at a comprehensive hernia center (Rosen et al., 2015). The patients were instructed to use a preoperative modified protein-sparing fast with mean preoperative weight loss of 24kg. Other than bariatric surgery recommendations, this study stood alone as weight loss advice specifically from a hernia standpoint. (Rosen et al., 2015). Another weight loss strategy, referred to as the TOPS program plan, is considered low cost and provides members with information about healthy eating, exercise and behavior modification. The members also receive a six-week lesson plan booklet, a one-year subscription to a newsletter and membership in a local chapter through which weekly meetings are held (Mitchell, Dickinson, Kempe, & Tsai, 2011).

The primary limitation of this study is that data was reviewed in a retrospective manner, which does not allow thorough understanding of the current health of the subject population, only the care that has occurred in the past at our facility. It is not known if any of the subjects have required additional care related to their hernia since they were last seen at our facility. Also, due to the retrospective nature of the study, missing data points, while relatively few in number, lead to uncertainty of results for some variables. An additional limitation is the small

numbers, particularly in the subset of patients who met goal and had hernia repair. As frequently mentioned in hernia research, there is a need for rigorous randomized-controlled trials to help answer many of the questions that remain concerning best practices for hernia management.

Conclusions

For morbidly obese patients with ventral hernias that are amenable to laparoscopic repair, this method should be considered unless other health concerns outweigh potential benefit. For patients that require an open approach to ventral hernia repair, if at all possible, repair should be delayed until patient's BMI likely is less than 35 kg/m^2, as postoperative complications are frequently observed in patients that have repair with BMI of 40 kg/m^2. It is essential that all health care providers address the risk associated with morbid obesity with their patients and that pertinent research be conducted in order to understand most appropriate and effective methods of weight loss for individual patients. It is most likely that different patients require different methods based on degree of obesity, economic factors, and/or other health problems. A surgical practice devoted to the care of patients with complex ventral hernias must develop a program of care that would incorporate individual patient characteristics with a variety of weight-loss strategies in order to provide information to patients at the time of care. Although surgeons are well able to convey the concerns of potential risks, the surgeon is likely not the most appropriate health care provider to provide this consultation. With further research and diligence, care of these patients can be improved with improved assistance to weight loss goals conferring decreased risk of surgical site infection and decreased risk of hernia recurrence.

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Table 1. Means, standard deviations, minimums and maximums for selected continuous variables: all study subjects (N = 78).

Variable	Mean	Standard Deviation	Minimum	Maximum
Age (years)	51.7	11.6	23	76
Height (inches)	65	4.5	56	76
Weight (pounds)	276	45	210	397
Body Mass Index (kg/m^2)	45.3	4.5	40	59.9

Table 2. Frequency distributions for selected categorical variables: All study subjects (N = 78).

Variable	All Subjects N = 78	
	Frequency	**Percent**
Gender		
Male	16	20.5
Female	62	79.5
Employment status		
Employed	18	23.1
Not Employed	49	62.8
Retired	6	7.7
Unknown	5	6.4
Marital Status		
Married	41	52.6
Divorced	12	15.4
Separated	1	1.3
Single	15	19.2
Widow	6	7.7
Unknown	3	3.8
History of Diabetes		
No	39	50.0
Yes	39	50.0
History of Hypertension		
No	25	32.1
Yes	53	67.9
History of Asthma		
No	66	84.6
Yes	12	15.4
History of Anxiety and/or Depression		
No	57	73.1
Yes	21	26.9
Current Smoker		
No	59	75.6
Yes	19	24.4
History Ventral Hernia Repair		
No	31	39.7
Yes	46	59.0
Unknown	1	1.3
History Weight-Loss Surgery		
No	70	89.7
Yes	8	10.3
History Previous/Current Mesh Infection		
No	66	84.6
Yes	10	12.8
Unknown	2	2.6

Table 3. Mean body mass index (kg/m^2), standard deviations, minimums and maximums by group: all study subjects by group category. (N = 78).

Group	n	Mean BMI (kg/m^2)	Standard Deviation	Minimum	Maximum
Group 1: Hernia Repair Offered Having Met Goal Weight	7	43.2	4.0	40.30	51.80
Group 2: Hernia Repair Offered Without Weight Loss	32	43.3	2.7	40.10	49.20
Group 3: Subsequent Visits, No Hernia Repair Offered	15	48.7	4.1	42.40	59.87
Group 4: No Subsequent Visits	18	47.6	5.5	40.10	58.6
Group 5: Under Care of Another Provider/ Other Health Issues	6	43.0	2.4	40.60	59.87

Table 4. Mean amount of weight loss (pounds) recommended, standard deviations, minimums and maximums by group: study subjects in groups 1, 3 and 4. (N = 40).

Group	n	Mean Amount of Weight Loss Recommended (pounds)	Standard Deviation	Minimum	Maximum
Group 1: Hernia Repair With Goal Weight	7	15.2	3.5	10.0	20.0
Group 3: Subsequent Visits, No Hernia Repair	15	42.9	15.5	20.0	66.0
Group 4: No Subsequent Visits	18	45.9	28.6	17.0	100.0

Table 5. Means, standard deviations, minimums and maximums for selected continuous variables: study subjects that underwent hernia repair surgery (N = 32).

Variable	Mean	Standard Deviation	Minimum	Maximum
Age (years)	51.7	10.9	34	76
Height (inches)	64.8	4.6	56	75
Weight (pounds)	262	39.4	212	366
Body Mass Index (kg/m^2)	43.1	2.6	40	49.2

Table 6. Frequency distributions for selected categorical variables: All study subjects that had hernia repair surgery, by preoperative weight loss status (N = 32).

Patient Characteristic	Subjects that Had Hernia Repair Without Weight Loss n = 26		Subjects that Had Hernia Repair Having Met Weight Loss Goal n = 6		Comparison of groups
	Frequency	Percent	Frequency	Percent	p value*
Gender					
Male	3	11.5	1	16.7	1.0
Female	23	88.5	5	83.3	
Employment status					
Employed	10	38.5	3	50	.46
Not Employed	12	46.2	1	16.7	
Retired	3	11.5	1	16.7	
Unknown	1	3.8	1	16.7	
Marital Status					
Married	14	53.8	5	83.3	.49
Divorced	6	23.1	0	0	
Separated	1	3.8	0	0	
Single	3	11.5	0	0	
Widow	2	7.7	1	16.7	
Unknown	0	-	0	0	
History of Diabetes					
No	18	69.2	5	83.3	.65
Yes	8	30.8	1	16.7	
History of Hypertension					
No	9	34.6	1	16.7	.64
Yes	17	65.4	5	83.3	
History of Asthma					
No	22	84.6	0	0	.57
Yes	4	15.4	0	0	
History of Anxiety and/or Depression					
No	19	73.1	5	83.3	1.0
Yes	7	26.9	1	16.7	
Current Smoker					
No	21	80.8	5	83.3	1.0
Yes	5	19.2	1	16.7	
History Ventral Hernia Repair	12	46.2	3	50	
No	14	53.8	3	50	1.0
Yes	0	0	0	0	
Unknown					
History Weight-Loss Surgery					
No	23	88.5	5	83.3	1.0
Yes	3	11.5	1	16.7	
History Previous/Current Mesh Infection					
No	23	88.5	0	0	1.0
Yes	3	11.5	0	0	
Unknown	0	-	0	0	

*Based on Fisher's Exact tests

Table 7. Frequency distributions of categorical surgical outcomes. All study subjects that had hernia repair surgery, by preoperative weight loss status (N = 32).

Outcome Variable	Subjects that Had Hernia Repair, Without Weight Loss Required (n = 26)		Subjects that Had Hernia Repair, Having Met Weight Loss Goal (n = 6)		Comparison of Groups
	Frequency	Percent	Frequency	Percent	p value*
Any Surgical Site Problem	9	34.6%	4	66.7%	.19
Cellulitis	3	11.5%	0	0%	1.0
Superficial	6	23.0%	2	33.3%	.625
Seroma	2	7.7%	2	33.3%	.15
Required VAC care	4	15.4%	0	0%	.57
Required IR procedure	3	11.5%	2	33.3%	.23
30 Day Hospital Readmission	2	7.7%	1	16.7%	.47
Hernia Recurrence	2	7.7%	0	0%	.65

*Based on Fisher's Exact Tests

Table 8. Frequency distributions of categorical surgical outcome variables, by operative approach (open vs. laparoscopic) (N = 32).

Outcome Variable	Laparoscopic Hernia Repair (n = 10)		Open Hernia Repair (n = 22)		Comparison of Groups
	Frequency	Percent	Frequency	Percent	p value*
Surgical Site Infection	0	0%	11	50%	.006
Hernia Recurrence	1	10%	1	4.5%	.53
30 Day Hospital Readmission	0	0%	3	13.6%	.53

*Based on Fisher's Exact Tests

Table 9. Comparison of mean weights (pounds) from initial visit with subsequent (and most recent or preoperative) mean weights (pounds) for patients that were recommended to lose weight and returned to the clinic for follow up visit(s). N = 19.

Group	n	Initial Weight (pounds) (SD)	Subsequent Visit or Preoperative Weight (pounds) (SD)	p value*
Groups 1 and 3 combined	22	282.9 (43.3)	272.9 (49.7)	.008
Group 1	7	250.0 (36.2)	229.9 (39.4)	.002
Group 3	15	298.2 (38.3)	292.7 (41.4)	.214

*Based on paired t-tests

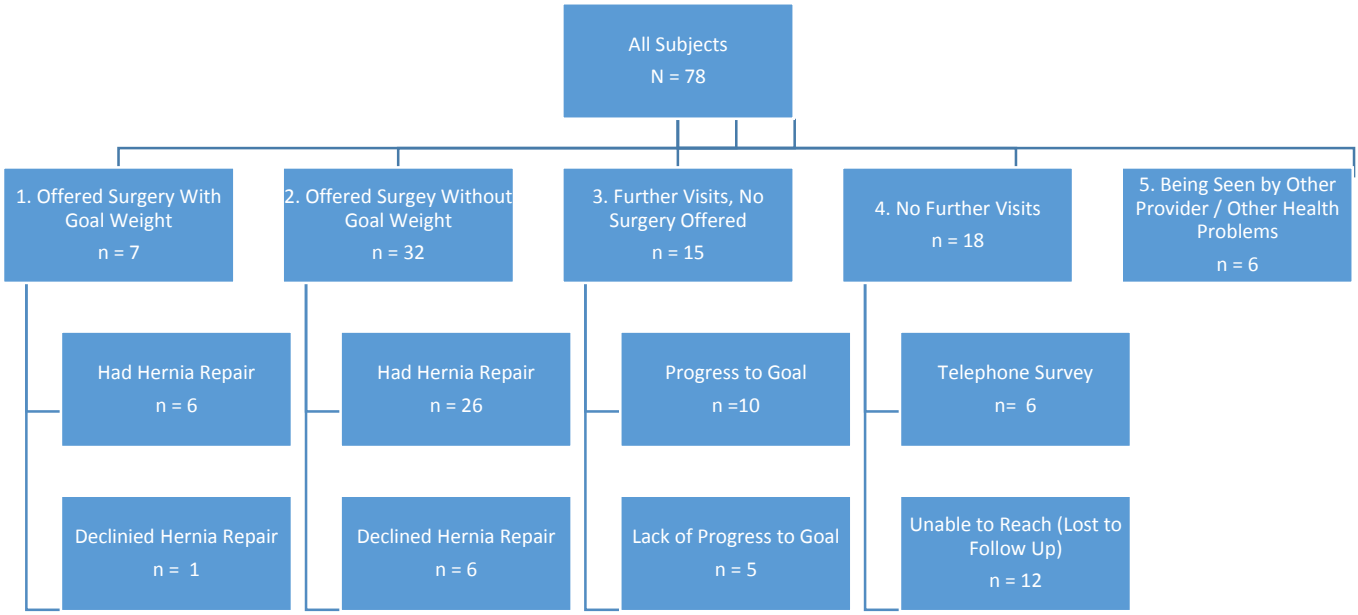
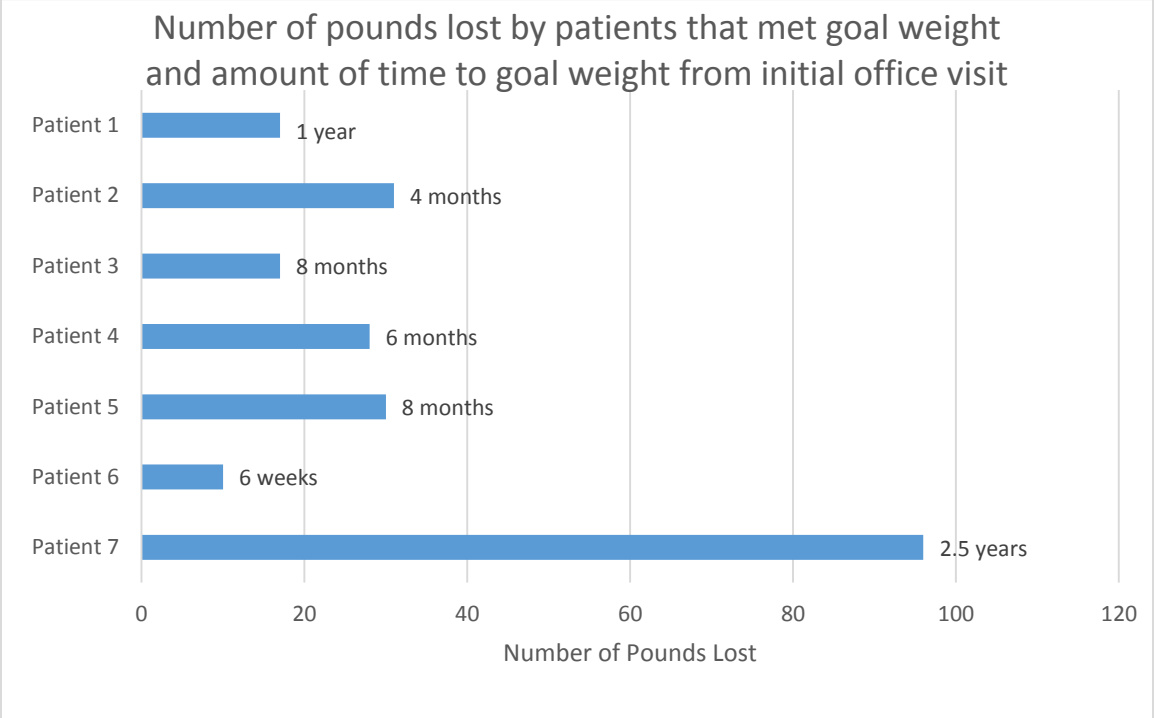


Figure 1. Algorithm of Events for All Study Subjects (N = 78)

Figure 2. Amount of weight lost (pounds) and the amount of time from initial consultation to weight loss goal for all patients in Group 1 (met weight loss goals).



Final Practice Inquiry Project Conclusion

While ventral hernias are a significant and costly problem in health care in the United States today, when coupled with morbid obesity, ventral hernias present a much greater challenge. The population of patients with ventral hernias is more likely to suffer with morbid obesity than the U.S. population as a whole. While, in general, morbid obesity is a contraindication to hernia repair surgery, some evidence exists of favorable surgical outcomes in the short term for a subset of morbidly obese patients that undergo minimally invasive hernia repair. Bariatric surgery as an effective means of weight loss is well-established, and combined weight-loss surgery and ventral hernia repair appears to be an acceptable solution for another subset of this patient population. Effectiveness of weight loss methods other than bariatric surgery are not as well documented. Further research is needed in order to determine the best practices on each of these fronts to care for this patient population.

Based on the cumulative evidence across the three manuscripts presented in this Final Practice Inquiry Project, there is a desperate need for health care systems in the United States to accept responsibility in assisting this patient population to a resolution of these challenging health problems. Effective methods of weight loss and weight maintenance must be identified and utilized in order to allow patients to achieve healthier weight, and this will require the efforts of multidisciplinary health care teams in order to achieve the desired outcome.

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