Decreasing Surgical Site Infections after Ventral Hernia Repair: A Quality-Improvement Initiative

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Abstract

Background: Surgical site infections (SSIs) remain prevalent after ventral hernia repair (VHR). In 2013–2014, a safety-net academic hospital initiated a two-pronged quality-improvement (QI) project: (1) Development and implementation of evidence-based guidelines; and (2) creation of a specialized hernia clinic to manage challenging patients and complex ventral hernias. Our objective was to decrease SSI rates after elective VHR.

Methods: The primary outcome was SSI 30 days post-operatively, which was assessed in aggregate and with a stratified analysis based on case complexity using the χ^2 test.

Results: A total of 399 patients in the pre-QI period and 390 patients in post-QI period (178 patients in general surgery clinics; 212 patients in the specialty hernia clinic) underwent VHR. Patients treated in the post-QI period were less likely to experience an SSI (13.5% vs. 1.5%; $p < 0.001$). On subgroup analysis of the post-QI clinics, specialty hernia clinic patients had an even lower risk of SSI than those in general surgery clinics (1.4% versus 1.7%).

Conclusions: The QI initiatives of evidence-based guidelines and the specialty hernia clinic were associated with lower SSI rates. Differences in peri-operative management included differences in patient selection and pre-operative preparation and increased use of synthetic mesh and laparoscopy. Future studies must investigate the long-term outcomes of these initiatives.

Keywords: surgical site infection; ventral hernia

SURGICAL SITE INFECTION (SSI) is a potentially preventable complication that has a substantial impact on the patient and on the cost to the healthcare system. Many quality-improvement (QI) projects have focused on decreasing SSI rates. Common approaches have included standardizing care through evidence-based guidelines and centralizing care among specialists and high-volume surgeons.

Although many specialties have described reductions in SSI rates among ventral hernia repair (VHR) cases [1–3], SSI remains prevalent. This may be attributable to multiple barriers specific to VHR. Evidence-based interventions that improve long-term outcomes may worsen short-term results. For example, although mesh reinforcement decreases hernia recurrence, it also increases the risk of SSI [4]. In addition, until recently, there have been no widely endorsed guidelines for standardizing care of ventral hernias. Furthermore, because of

the prevalence of the disease, limiting care to specialty centers can be challenging, with the limited capacity of specialists and the reluctance of general surgeons to lose case volume and hernia-related operative skills. Finally, specialists in VHR may not easily demonstrate better outcomes because of patient and disease heterogeneity. By tackling more challenging patients and cases, specialists may paradoxically experience higher rates of complications.

In 2013–2014, a safety-net academic hospital initiated a two-pronged QI project. First, evidence-based guidelines were developed and instituted hospital-wide. These guidelines have been updated and published as a consensus statement [4,5]. The guidelines include recommendations on patient selection for elective surgery, pre-operative risk modification, and operative technique (see Supplemental Table 1 [4,5]). Second, a specialized hernia clinic was established to manage challenging

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patients and complex ventral hernias. The purpose of the clinic was to improve outcomes and control costs by involving high-volume surgeons in more complex VHR operations. The specialty clinic has three high-volume hernia surgeons and a dedicated clinic day each week to administer care to its patients. It also partners with other surgical clinics, physical therapy personnel, dietitians/nutritionists, and other hospital groups to provide comprehensive treatment. We considered a clinician to be a high-volume hernia specialist if he/she had performed more than 50 VHRs in the previous year and had presented or published ventral hernia-related research in an international or national forum [4].

The purposes of this QI initiative were to decrease SSI rates by: (1) Developing and implementing evidence-based guidelines; and (2) creating a specialized hernia clinic to manage challenging patients and complex ventral hernias.

Patients and Methods

The described study was a pre-post intervention QI project. This manuscript was written using the guidelines provided by the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) Framework [6].

Study setting

The setting of the QI project was a single-center safety-net academic institution in Houston, Texas. From 2010 to 2011, prior to the establishment of the operative guidelines, patients underwent VHR in general surgery clinics. Data for this period were collected retrospectively as the “pre-QI” stage. The method has been reported [7, 8].

The QI intervention

In 2013 to 2014, consensus guidelines were developed, disseminated, and implemented among the general surgery division. These guidelines were subsequently updated and published. Buy-in was obtained among general surgeons by review of hospital-wide outcomes, review of the literature, and consensus on patient selection criteria, pre-operative optimization, and operative technique. For operative technique, utilization of mesh and laparoscopy were emphasized. In addition, a specialty hernia clinic was established to care for complex patients or ventral hernias >3 cm wide. A patient qualified as complicated if there were multiple co-morbidities, one or more poorly controlled co-morbidities, multiple prior abdominal operations, or complications after prior abdominal surgery or failed hernia repair. However, general surgeons had the option to repair larger hernias in uncomplicated cases. Data for this post-period were collected prospectively [8–11].

Measures and analysis

All patients who underwent VHR were included in this study if they presented for a followup clinic visit one mo after the operation. Acute VHR and those in which the primary procedure was not a VHR were excluded (e.g., laparoscopic cholecystectomy and umbilical hernia repair). During patients' post-operative visits, surgeons blinded to this study's hypotheses assessed them. Trained research assistants and coordinators, also blinded to this study's hypotheses, entered the data. Surgical Care Improvement Project guidelines [12] were followed in both time periods. Pre-operative antibiotic

protocols and operating room protocols (including hair clipping, skin preparation, and hypothermia) did not change between the time periods examined.

Baseline characteristics and operative variables. Pre-operative/demographic variables collected were age, gender, race, American Society of Anesthesiologists (ASA) score, body mass index (BMI), chronic obstructive pulmonary disease, diabetes mellitus, hemoglobin A_{1c}, tobacco use, immunosuppression, prostatitis/benign prostate hyperplasia, alcohol use disorder, prior SSI, prior VHR, and prior abdominal surgery. Abdominal wall defects were characterized as to whether they were primary or incisional as well as by their size (small, medium, or large) per the European Hernia Society (EHS) classifications [13]. Additional operative variables collected were surgical approach (open, laparoscopic, converted, hybrid), use of mesh, specific mesh type utilized (synthetic vs. biologic), operative duration, mesh size, and wound class.

Primary outcome. The primary outcome was SSI within 30 d post-operatively. An SSI was defined in accordance with the U.S. Centers for Disease Control and Prevention guidelines with the exception of up to 30 d rather than 90 d of followup [14]. Secondary outcomes were the proportion of cases that adhered to the following evidence-based guidelines: (1) Elective VHR is not recommended for patients with BMI ≥ 35 kg/m²; (2) elective VHR is not recommended for current smokers; (3) elective VHR is not recommended for patients with a hemoglobin A_{1c} concentration $\geq 8.0\%$; (4) patients with BMI 30–50 kg/m² or serum hemoglobin A_{1c} 6.5%–8.0% require individualized interventions to reduce surgical risk; (5) mesh reinforcement is recommended for elective VHR with no contamination; and (6) laparoscopy is recommended for clean elective VHR [4].

Statistical analyses

To determine a 10% difference in SSI rate between patients in the pre-QI and post-QI project periods with an alpha of 0.05 and a beta of 0.20, we estimated that we would need at least 129 patients per group.

Demographic variables and outcomes were compared using the χ^2 test for categorical variables and the Kruskal-Wallis rank test or unpaired *t*-test for continuous variables. To adjust for case complexity, the primary outcome also was assessed with a stratified analysis based on the EHS Ventral Hernia Classification system [13] using χ^2 with Bonferroni correction to account for multiple comparisons ($p < 0.01$ was considered significant). Logistic regression was also performed to assess an association between SSI rates, pre-post period, and specialty hernia clinic after controlling for ASA score, BMI, tobacco use, age, and case complexity with the EHS system.

Ethical considerations

No patient was considered to be at higher than usual risk of SSI or any other adverse event within the pre- or post-QI project periods. This study was approved by the Lyndon Baines Johnson Hospital Institutional Review Board and met the guidelines of the responsible governmental agency.

Results

A total of 789 cases were examined; 399 patients in the pre-QI project period and 390 patients in the post-QI project period underwent VHR and had at least one mo of followup. In the post-period, 212 patients were treated in the specialty hernia clinic and 178 patients in the general surgery clinic. The flowsheet of patients included in the study is provided in Supplemental Fig. 1). The pre-operative demographic variables of pre-QI period, post-QI general surgery clinic, and post-QI specialty hernia clinic patients are shown in Tables 1 and 2.

Pre-QI vs. Post-QI periods

Compared with the pre-period, patients treated in the post-period were significantly more likely to be female and of non-white race. Although they were more likely to have a higher ASA score, they also were more likely to have a lower BMI and hemoglobin A_{1c} and were less likely to use tobacco or have an alcohol use disorder. Patients in the post-period also were significantly more likely to present with prior abdominal surgery and more complex ventral hernias. Considering operative details, patients undergoing care in the post-period were more likely to undergo laparoscopic VHR and to have synthetic and larger pieces of mesh placed intra-operatively.

Compared with patients in the general surgery clinics, patients in the specialty hernia clinic were significantly more likely to present with higher ASA scores, higher BMIs, more

complex ventral hernias, and previous SSIs, VHRs, and abdominal surgery. Compared with patients in the general surgery clinics, patients undergoing care in the specialty hernia clinic also were significantly more likely to undergo laparoscopic VHR and have larger pieces of mesh placed intra-operatively.

Outcomes

The outcomes were better after the QI intervention (SSI rate pre-QI 13.5% vs. general surgery clinics 1.7% and specialty hernia clinic 1.4%; $p < 0.001$; Table 3). Logistic regression modeling showed treatment in the specialty hernia clinic to be associated with the lowest odds of developing an SSI (odds ratio [OR] 0.07, 95% confidence interval [CI] 0.02–0.24, with pre-QI clinics as the reference value) after adjusting for case complexity, ASA, BMI, tobacco use, and age (Table 4).

Compliance with existing guidelines

The specialty clinic demonstrated significantly greater compliance with evidence-based guidelines (Table 5). This better adherence was most marked for the following: Elective VHR is not recommended for patients with BMI ≥ 35 kg/m² (pre-QI 69.4% vs. general surgery clinics 94.4% vs. specialty hernia clinics 76.9%; $p < 0.001$); elective VHR is not recommended for current smokers (pre-QI 80.7% vs. general

TABLE 1. PRE-OPERATIVE CHARACTERISTICS

	Pre-QI project (n = 399)	Post-QI project clinic		p
		General surgery (n = 178)	Specialty hernia (n = 212)	
Mean age (y) (SD)	44.7 (10.8)	44.9 (11.4)	49.0 (11.4)	<0.001
Male sex (%)	197 (49.4)	66 (37.1)	83 (39.2)	0.006
White race (%)	66 (16.5)	7 (3.9)	22 (10.4)	<0.001
American Society of Anesthesiologists' class (%)				<0.001
1, 2	331 (83.0)	147 (82.6)	142 (67.0)	
3, 4	68 (17.0)	31 (17.4)	70 (33.0)	
Mean BMI (SD)	32.6 (6.6)	29.9 (3.3)	31.9 (4.3)	<0.001
Chronic obstructive pulmonary disease (%)	11 (2.8)	2 (1.1)	2 (0.9)	0.203
Diabetes mellitus (%)	59 (14.8)	27 (15.2)	38 (17.9)	0.582
Median hemoglobin A _{1c} (IQR) ^a	6.6 (5.8–7.8)	5.8 (5.5–6.3)	5.8 (5.5–6.1)	<0.001
Tobacco use (%)	77 (19.3)	15 (8.4)	20 (9.4)	<0.001
Immunosuppressed	8 (2.0)	8 (4.5)	7 (3.3)	0.241
Prostatitis/benign prostate hyperplasia (%)	6 (1.5)	2 (1.1)	5 (2.4)	0.602
Alcohol use disorder (%)	17 (4.3%)	2 (1.1%)	0	0.002
Prior SSI (%)	9 (2.3)	1 (0.6)	13 (6.1)	0.003
Prior ventral hernia repair (%)	50 (12.5)	10 (10.7)	49 (23.1)	<0.001
Prior abdominal surgery (%)	232 (58.1)	100 (56.2)	158 (74.5)	<0.001
Primary ventral hernia (%)				
Small	109 (27.3)	77 (43.3)	12 (5.7)	<0.001
Medium	52 (13.0)	1 (0.6)	17 (8.0)	<0.001
Large	6 (1.5)	0	24 (11.3)	<0.001
Incisional ventral hernia (%)				
Small	147 (36.8)	87 (48.9)	47 (22.2)	<0.001
Medium	64 (16.0)	11 (6.2)	100 (47.2)	<0.001
Large	21 (5.3)	2 (1.1)	12 (5.7)	0.050

^aHemoglobin A_{1c} determinations were made in all patients pre-operatively.

BMI = body mass index; IQR = interquartile range; QI = quality improvement; SD = standard deviation; SSI = surgical site infection.

TABLE 2. INTRA-OPERATIVE VARIABLES

	<i>Pre-QI project</i> (<i>n</i> = 399)	<i>Post-QI project clinic</i>		<i>p</i>
		<i>General surgery</i> (<i>n</i> = 178)	<i>Specialty hernia</i> (<i>n</i> = 212)	
Type of surgery (%)				<0.001
Laparoscopic	94 (23.6)	115 (64.6)	192 (90.6)	
Open	292 (73.2)	60 (33.7)	17 (8.0)	
Converted	13 (3.3)	1 (0.6)	1 (0.5)	
Hybrid	0	2 (1.1)	2 (0.9)	
Use of mesh (%)	314 (78.7)	141 (79.2)	204 (96.2)	<0.001
Mesh type (%)				<0.001
Synthetic	280 (70.2)	140 (78.7)	199 (93.9)	
Biologic	27 (6.8)	1 (0.6)	4 (1.9)	
Missing data	7 (1.8)	0	1 (0.5)	
Median operating room time (min) (IQR)	74.0 (49.0–116.0)	41.0 (32.5–56.5)	80.0 (55.0–117.0)	<0.001
Median mesh width (IQR)	8.0 (6.0– 15.0)	12.0 (9.0–12.0)	15.0 (15.0– 15.0)	<0.001
Median mesh length (IQR)	8.0 (6.0– 15.0)	12.0 (9.0–15.0)	15.0 (15.0– 20.0)	<0.001
Incision class (%)				0.380
Clean, clean-contaminated	393 (98.5)	177 (99.4)	211 (99.5)	
Contaminated, dirty	6 (1.5)	1 (0.6)	1 (0.5)	

IQR = interquartile range; QI = quality improvement.

surgery clinics 91.6% vs. specialty hernia clinics 90.6%; $p < 0.001$); patients with BMI 30–50 kg/m² or serum hemoglobin A_{1c} 6.5%–8.0% require individualized interventions to reduce surgical risk (relevant programs available only in the specialty hernia clinic); mesh reinforcement is recommended for elective VHR (pre-QI 78.7% vs. general surgery clinics 79.2% vs. specialty hernia clinics 96.2%; $p < 0.001$); and laparoscopy is recommended for elective VHR (pre-QI 23.6% vs. general surgery clinics 64.6% vs. specialty hernia clinics 90.6%; $p < 0.001$).

Discussion

The QI interventions, implementation of consensus guidelines, and establishment of the specialty hernia clinic significantly decreased rates of SSI one mo post-operatively compared with patients seen in the pre-QI period. The general surgery clinic achieved better outcomes through greater adherence to recommendations concerning patient selection, pre-operative preparation, and intra-operative guidelines. The specialty hernia clinic achieved better outcomes in more complicated patients who presented with larger abdominal-wall defects. Differences in peri-operative management included patient selection and pre-operative preparation (fewer

alcohol abusers and better glucose control among persons with diabetes mellitus overall and fewer tobacco users than in pre-specialty hernia clinics), increased use of synthetic mesh, application of laparoscopy in more complex cases, and greater adherence to developed guidelines regarding VHR. We included within the logistic multivariable model variables that reflected both expertise (EHS classification and type of clinic) as well as compliance with guidelines (BMI, recent tobacco use) to emphasize that better outcomes were attributable to more than just technical ability.

Our data add to the existing literature supporting the role of specialization in improving outcomes in hernia repair [15–17]. Public and private healthcare stakeholders are increasingly emphasizing regionalization [17,18] as multiple publications have shown that specialization improves outcomes in both complex and routinely performed surgical procedures [17–19]. Specialization may improve outcomes through pre-operative, intra-operative, and post-operative factors such as patient selection criteria [20], management of patient co-morbidities [19], increased volume and technical expertise [17,18,20], reproducibility of technique and procedure [17,20], and modified peri-operative regimens [19,20]. Focused centers may also utilize the most recent evidence-based findings, employ their surgical work in translational research efforts [17], and enjoy

TABLE 3. THIRTY-D OUTCOMES (No. [%])

	<i>Pre-QI project</i> (<i>n</i> = 399)	<i>Post-QI project clinic</i>		<i>p</i>
		<i>General surgery</i> (<i>n</i> = 178)	<i>Specialty hernia</i> (<i>n</i> = 212)	
Surgical site infection	15/167 (9.0)	2/ 78 (2.6)	1/ 53 (1.9)	0.055
Primary incision small	16/147 (10.9)	1/ 87 (1.1)	1/ 47 (2.1)	0.006
Incision medium	12/ 64 (18.8)	0/ 11	0/100	<0.001
Incision large	11/ 21 (52.4)	0/ 2	1/ 12 (8.3)	0.021
Overall	54/399 (13.5)	3/178 (1.7)	3/212 (1.4)	<0.001

QI = quality improvement.

TABLE 4. LOGISTIC MULTIVARIABLE REGRESSION MODEL OF 30-D SURGICAL SITE INFECTION RATES

	<i>Odds ratio</i>	<i>p</i>	<i>95% Confidence interval</i>
European Hernias Society Classification	Reference		
Primary incision small	1.12	0.746	0.56– 2.24
Incision medium	1.74	0.175	0.78– 3.89
Incision large	9.82	<0.001	3.79–25.42
American Society of Anesthesiologists' Score			
1, 2	Reference		
3, 4	1.64	0.334	0.60– 4.51
Clinic			
Pre-QI	Reference		
Post-QI (general surgery clinics)	0.14	0.001	0.04– 0.46
Post-QI Project (specialty hernia clinic)	0.07	<0.001	0.02– 0.24
BMI	1.02	0.408	0.98– 1.06
Recent tobacco use	1.05	0.896	0.49– 2.25
Age	1.01	0.532	0.98– 1.04

BMI=body mass index; QI=quality improvement.

the benefits of greater technological resources, better facilities [17,18], and multi-specialty, coordinated care [17,18]. The handful of studies that have discussed the challenges and limitations of specialization in hernia surgery typically assessed inguinal and not ventral hernias [15,21], depended entirely on surgeon recall of outcomes [22], and had highly relevant financial conflicts that could have influenced the use of certain products [22].

Laparoscopy and judicious patient selection concerning tobacco and alcohol use have each been associated with reduced SSI rates [4, 23–27]. In the multi-variable analysis, we did not adjust for laparoscopy because this variable was surgeon dependent and would not account for hernia specialists' ability to complete complex cases with a laparoscopic approach. Laparoscopy would therefore be collinear with the type of clinic. The logistic regression model shows that multiple factors, including closer compliance with evidence-based practices such as mesh reinforcement and decreased use of biologic mesh in elective cases [28], were

associated with a lower SSI rate. Mesh reinforcement has been recommended for clean cases based on multiple randomized controlled trials for almost two decades. Despite this, in the pre-QI period, almost one-fourth of patients did not receive mesh repair. These findings are in line with previous publications of other hospital systems [29–31]. The QI intervention was able to improve the proportion of patients repaired with mesh and laparoscopic technique. The better outcomes may also be related to increased technical expertise. Surgeons not skilled in minimally invasive techniques in complex VHR may experience more conversions to open surgery, enterotomies, or missed enterotomies. In this study, general surgeons were six times as likely to convert to open operations compared with hernia surgeons.

Our results also suggest a symbiotic relation between the specialty hernia and the general surgery clinics. Following an emphasis on existing guidelines, general surgeons achieved superior outcomes with straightforward VHRs. Cases with greater complexity were simultaneously referred to the specialty hernia

TABLE 5. CONSENSUS GUIDELINES AND PROPORTIONS OF ADHERENT CASES

	<i>Pre-QI project (n=399)</i>	<i>Post-QI project</i>		<i>p</i>
		<i>General surgery clinic (n=178)</i>	<i>Specialty hernia clinic (n=212)</i>	
Elective VHR is not recommended for patients with BMI ≥ 35 kg/m ² .	277 (69.4%)	168 (94.4%)	163 (76.9%)	<0.001
Elective VHR is not recommended for current smokers.	322 (80.7%)	163 (91.6%)	192 (90.6%)	<0.001
Elective VHR is not recommended for patients with Hemoglobin A1c greater than or equal to 8.0%.	372 (93.2%)	173 (97.2%)	204 (96.3%)	0.081
Patients with BMI 30–50 kg/m ² or Hemoglobin A1c 6.5–8.0% require individualized interventions to reduce surgical risk.	None	None	Prehabilitation program available to optimize BMI (61 patients enrolled)	n/a
Mesh reinforcement is recommended for elective VHR.	314 (78.7%)	141 (79.2%)	204 (96.2%)	<0.001
Laparoscopy is recommended for elective VHR.	94 (23.6%)	115 (64.6%)	192 (90.6%)	<0.001

N refers to numbers of patients; QI=quality improvement; BMI=body mass index; VHR=ventral hernia repair.

clinic and also had better outcomes. The QI interventions were associated with better adherence to evidence-based recommendations, such as mesh use, and improved outcomes among both general and hernia surgeons. The greater compliance may also have resulted from more dialogue between the general and hernia surgeons, as well as an institution-wide emphasis on such practices encouraged by the specialty hernia clinic.

Although other studies have suggested that a specialty hernia clinic may be associated with financial loss [29], our results suggest otherwise. By reducing SSI rates through the standardization of practices based on the best available evidence, such a center could have financial benefits [33]. General surgeons were more likely to utilize expensive resources, such as biologic meshes, than were specialists. The specialty hernia clinic therefore may produce cost savings with better outcomes. One of the goals of this hernia clinic was to improve cost-consciousness choices. Future studies should examine the financial implications of specialty hernia clinics more extensively.

The limitations of our study include the pre- and post-intervention design and unclear study reproducibility. Although a randomized, controlled trial could establish a causal relation between a QI intervention and better outcomes, such a study design would be unlikely to be feasible. The multifaceted interventions and changes in infrastructure needed to implement such a project would preclude running a parallel-arm randomized trial in a single institution. Evaluation of large databases (e.g., quality improvement databases) or pre-post study designs may represent the highest-quality, realistically obtainable data to provide insight to answer these questions. Hernia specialty centers also are difficult to establish and maintain because they must have the specialists and resources to manage various comorbidities and complex operations. For these reasons, the generalizability of our findings to other settings, institutions, and surgeons may be limited. Not all “hernia centers” may achieve similar results. However, we were able to achieve better outcomes despite the limitations at a safety-net hospital such as limited resources and high-risk patients who were largely uninsured or underinsured, minority, and unemployed, disabled, or both [34].

Conclusions

The QI interventions of the specialty hernia clinic and implementation of evidence-based guidelines were associated with significantly lower rates of SSI one mo post-operatively. General surgeons and hernia specialists can co-exist symbiotically to improve outcomes and care for large volumes of patients with complex medical conditions. Optimizing peri-operative management through evidence-based guidelines including patient selection (fewer tobacco and alcohol users) and greater use of synthetic mesh and laparoscopy can improve short-term outcomes. Future studies must investigate the long-term clinical outcomes of the QI interventions.

Author Disclosure Statement

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