Can Abdominal Wall Reconstruction Be Safely Performed Without Drains?

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The use of closed suction drains in the abdominal wall is a common practice in abdominal wall reconstruction (AWR) operations. Drains can be a conduit for bacteria and can cause pain and discomfort for patients after surgery. A single hernia program has implemented the principles of clinical quality improvement in an attempt to improve outcomes for hernia patients. An attempt at a process improvement was implemented to eliminate the use of drains in AWR by adapting the technique. A total of 102 patients undergoing AWR were included between 8/11 and 9/15 (49 months). Compared with the group before the attempt at eliminating the use of abdominal wall drains (8/11–9/13), the group of patients after the implementation of the attempted process improvement (9/13–9/15) had less wound and pulmonary complications, a shorter hospital stay, less time in the postanesthesia care unit, and less opioid use in the postanesthesia care unit as well as for the entire hospital stay. In this group of AWR patients, an attempt at process improvement that eliminated the use of drains led to improved outcomes. Abdominal wall drains may be able to be safely eliminated with appropriate technique adaptation for AWR.

CLINICAL QUALITY IMPROVEMENT (CQI) initiatives are focused on improving the value of patient care in the actual clinical environment. Using the principles of CQI is often more appropriate for developing an understanding of the factors that drive improvements in patient care than are randomized controlled trials that aim to prove or disprove a hypothesis.[1] Specifically, traditional randomized controlled trials may not be appropriate for studying complex dynamic processes, such as patients with ventral/incisional hernias undergoing open abdominal wall reconstruction (AWR), because there are many inherently uncontrollable variables that can influence interpretation of trial results. Rather, complex systems science tools, such as CQI and nonlinear statistical analyses, are increasingly recognized as more appropriate for measuring and improving patient outcomes.[1]

Patient care models that attempt to measure and improve patient value have been proposed by the United States business community.[2, 3] By taking a complex systems science view of health care, patient care can be simplified by designing care around definable patient groups, diseases, and/or problems (patient care processes).[4] The information generated by these care processes can then be used to continually improve outcomes over time, resulting in improved overall quality, safety, and patient satisfaction, along with decreased costs, resulting in improved value.[2, 3] Rather than trying to prove or disprove a scientific hypothesis, value-based CQI is implemented with the goal of improving the value of patient care for each process in which these principles are applied. Unlike traditional clinical research, CQI is not restricted only to patients who have specific clinical characteristics defined by study inclusion and exclusion criteria. Instead, CQI allows for more flexible decisions to be made based on situations that health-care providers face in their everyday practice, and CQI can track many outcome measures over the entire cycle of patient care, not just during a predefined study period.

Lawmakers recognize the value of CQI initiatives for improving patient care, and the use of CQI use has been supported since the Health Insurance Portability and Accountability Act was implemented in 1996. The principles of CQI were again supported in the Patient

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Safety and Quality Improvement Act of 2005. In addition, the United States Department of Health and Human Services recognizes that there is a distinction between most quality improvement efforts and research involving human subjects that requires Institutional Review Board (IRB) approval.[5] CQI focuses on local process improvement and real-world, clinical data and analytics that are interpreted by the care team. In addition, whenever possible, patients and their families are included in the CQI and shared decision-making processes.

Open ventral hernia repair using various techniques is one of the most common general surgery procedures performed. A postoperative wound complication, including seroma formation, is one of the most common complications related to this procedure. For large, complex open ventral hernia repairs, placement of closed suction abdominal wall drains is a common method to attempt seroma prevention. However, there is a lack of high quality evidence regarding the use of drains in open ventral hernia repair.[6] Here, we describe a CQI effort to eliminate the use of abdominal wall drains in an attempt to improve outcomes for patients who underwent AWR in a single hernia program.

Methods

Because CQI was implemented as part of the actual patient care process, this initiative was exempt from Health Insurance Portability and Accountability Act rules, and the project was not required to go through an IRB approval process. A meeting with an IRB service was held and it was confirmed that our interpretation of the law as it relates to CQI initiatives was consistent with the interpretation of the IRB service. In addition, this model for patient safety and quality improvement was vetted with the United States government through the Agency for Healthcare Research and Quality. As part of this process, Agency for Healthcare Research and Quality designated our partner clinical research organization (Surgical Momentum, LLC, Daytona Beach, FL) as a Patient Safety Organization. Our hernia team executed a data-sharing agreement with Surgical Momentum to allow for additional data analyses and to obtain access to additional resources that contributed to this CQI initiative. Deidentified patient information could also be shared with others who could add value to the process of data interpretation and contribute process improvement ideas.

Patients

Patients who presented to our center with an abdominal wall hernia between August 2011 and September 2015 were offered a range of surgical treatment and nonsurgical management choices. The surgical options included an open approach (including AWR) and a laparoscopic approach (with a variety of mesh choices) for ventral hernia repair. Patients were provided with a review of current evidence as part of the dynamic care process, and treatment decisions were made as a shared process between patients, their families, and the clinical hernia team, which included the director of patient care management, other patient care specialists, and the surgeon. Patients were encouraged to do their own research, talk with other patients who had undergone similar procedures, and consider alternate options, if desired. Consecutive patients who chose to undergo open AWR (including three patients converted from a laparoscopic to open operation) were included in this analysis. As a part of our CQI process, we periodically include a meeting with patient and family representatives, as well as asking each patient in follow-up communications what we can do to make their experience better.

An Attempt at Process Improvement

At a hernia team CQI meeting in September 2013, we discussed a frequent complaint that patients expressed about their experience with abdominal wall drains. Descriptions of complaints included pain, discomfort, pulling and dislodgement, and the potential for drain related infection. With this feedback, a literature search describing plastic surgery techniques that had eliminated the use of abdominal wall drains for abdominoplasty and through collaborations with several plastic surgeons who do AWR, our hernia team decided to introduce a potential process improvement in the surgical technique that would potentially eliminate the need for abdominal wall drains. Since that time, abdominal wall drains were not used as a part of an AWR procedure.

Procedures

All patients received care from the diverse group of health professionals on the hernia team. This team has regular CQI meetings, during which the members discuss and document ideas to improve the patient care process, and outcomes that measure value are presented and discussed. Patient and family member volunteers, surgical residents, medical students, and other general surgeons were invited to participate in some of these CQI meetings to share their perspectives on how the process could be improved. In addition, feedback from former patients and review of the current literature helped the hernia team continue to refine the patient care process and attempt to improve outcomes that result in improved value for the patient.

The major changes implemented after September 2013 included wide resection of the skin, scar, and soft tissue of the superficial anterior abdominal wall, including resection of the umbilicus. For a subset of patients, this included a low horizontal incision or an inverse "T" incision, however the majority of patients received a wide vertical elliptical excision of tissue that resulted in a vertical midline closure.

After a wide resection of the superficial anterior abdominal wall, typically a transversus abdominus release (TAR) procedure was performed using a long-term resorbable macroporous mesh placed in the retrorectus position in most cases. If intra-abdominal contents could not be covered with peritoneum, a long-term resorbable microporous synthetic mesh was used. If the patient had a prior AWR and/or was a high-risk for recurrence, a permanent nonwoven polypropylene synthetic mesh was used. A more complete description of the surgical technique has been published previously.[7]

Throughout this effort, there were other attempts at process improvement involving the AWR technique. Early in the project, open AWR (external oblique transection with separation from the internal oblique) was the most common technique. For several cases, an endoscopic component separation technique was used in an attempt to decrease wound complications. For the majority of patients who underwent surgery during the most recent two to three years, a TAR approach had been adopted.

A single surgeon (BR) performed all surgical procedures, sometimes with a resident or other attending surgeons assisting. General anesthesia techniques varied based on the preferred techniques of the anesthesiologist who assisted with each procedure. Another attempt at a process improvement was the implementation of a multimodel perioperative pain management and enhanced recovery program. After this was implemented, anesthesiologists performed bilateral transversus abdominus plane blocks in the preoperative holding area using ultrasound guidance for administration of liposomal bupivacaine (266 mg). More recently, an additional intraoperative block was added in an attempt to improve the effectiveness of the anesthetic blocks, especially because of the increased surgical resection of the abdominal wall and increased operative time associated with the addition of layered, quilting sutures. Opioid analgesics were available to all patients to achieve adequate pain control. The nurse and patient determined the need for opioid use during the length of the hospital stay.

Assessments

Outcome measures included duration of stay and opioid use in the postanesthesia care unit (PACU), postsurgical opioid use during the hospital stay, hospital length of stay, wound complication rate, hernia recurrence rate, and 30-day rehospitalization and death rates. Patients were followed from the moment of first symptom or contact until full return to their best possible quality of life. Ongoing contact was maintained with patients for long-term follow-up by the director of patient care management and patient specialists.

Statistical Analysis

Observed data were summarized using descriptive statistics. To allow for standardized comparisons of opioid use, all opioid consumption amounts were converted to intravenous (IV) morphine equivalents using the GlobalRPh Inc. opioid analgesic converter (available at: www.globalrph.com/narcoticonv.htm).

The assumption of normality was assessed using skewness and kurtosis statistics. Any skewness or kurtosis statistic above an absolute value of 2.0 was considered nonnormal. Levene's test for equality of variances was used to test for meeting the assumption of homogeneity of variance. Between-subjects comparisons were conducted using independent samples *t* tests and one-way analysis of variance. Means and standard deviations were reported for continuous variables. To adjust for increased experiment wise error rates when testing multiple comparisons, a Bonferroni corrected alpha value of 0.008 was used to assume statistical significance. In the event of a violation of a statistical assumption, nonparametric Mann-Whitney *U* and Kruskal-Wallis tests were employed. Mann-Whitney *U* tests were further used in a post hoc fashion when significant main effects were found for Kruskal-Wallis tests. Frequency statistics were used to describe categorical variables. Unadjusted odds ratios (OR) with 95 per cent confidence intervals [95% confidence interval (CI)] were used to measure for associations with categorical outcomes. All analyses were conducted using SPSS Version 21 (IBM Corp, Armonk, NY).

Results

The analysis population included 102 consecutive patients who underwent open AWR; 33 patients who underwent AWR before the attempted process improvement to eliminate abdominal wall drains (drain group) and 69 patients who underwent AWR after the attempt at process improvement (no drain group).

Baseline demographic characteristics are summarized in Table 1. There were no significant differences between groups for age, gender, BMI, number of prior abdominal operations, recurrent hernias, smoking history, presence of active wound infection, presence of active mesh infection, or history of mesh infection. Patients in the no drain group were more likely to have

preoperative chronic pain (OR = 2.27, 1.45–6.42) and were less likely to have a history of wound infection (OR = 0.26, 0.11–0.65) compared with the drain group.

Hernia and procedure characteristics are summarized in Table 2. There were no differences between groups for presence of loss of domain, resection of small bowel or resection of colon. Patients in the after-group were more likely to undergo a resection of omentum when compared with the before group (OR = 8.15, 1.02–64.88). There was a significantly increased hernia size in the no drain group compared with the drain group ($P = 0.02$). Mesh size was significantly larger in the no drain group compared with the drain group ($P < 0.001$). There was a significant increase in operative time for the no drain group compared with the drain group ($P = 0.008$).

A summary of outcomes that occurred during the hospitalization and after hospital discharge is presented in Table 3. Significantly less opioids were used during the hospital stay in the after group compared with the before group ($P = 0.002$). There was also a significant decrease in PACU opioid use in the after group compared with the before group ($P = 0.001$). There was a significant decrease in PACU time ($P < 0.001$) and length of hospital stay ($P = 0.009$) in the after group compared with the before group. The after group had a significantly decreased rate of total wound complications compared with the before group ($P = 0.002$), with the after group being 0.21 times less likely to have a major wound complication (95% CI = 0.05–0.88) and 0.24 times less likely to have a minor wound complication (95% CI = 0.07–0.82) compared with the before group. The after group was also 0.23 times less likely to have a pulmonary complication (95% CI = 0.06–0.85) and 0.05 times less likely to have a recurrence (95% CI = 0.01–0.39) when compared with the before group. There were no other statistically significant differences in outcomes between the groups.

TABLE 1. *Patient Demographics and Baseline Characteristics*

Variable	August 2011 to September 2013 (n = 33)	September 2013 to October 2015 (n = 69)
Age, mean (SD), years	59.26 (10.45)	56.26 (12.15)
Range	31–80	28–80
Gender, number (%)		
Male	15 (45)	23 (33)
Female	18 (55)	46 (67)
Body mass index, mean (SD), kg/m^2	36.61 (7.77)	33.30 (8.55)
Range	20.3–52.7	17.6–53.4
Number of prior abdominal operations, mean (SD)	5.79 (5.36)	4.13 (2.40)
Range	1–26	0–11
Comorbidity, number (%)		
Smoker	5 (15)	8 (12)
Prior hernia repair with recurrence	22 (67)	40 (58)
Wound infection, past	24 (73)	28 (41)
Active	8 (24)	17 (25)
Mesh infection, past	13 (39)	15 (22)
Active	5 (15)	9 (13)
Stoma present	3 (9)	5 (7)

SD, standard deviation.

TABLE 2. *Hernia and Surgical Procedure Characteristics*

Characteristic	August 2011 to September 2013 (n = 33)	September 2013 to September 2015 (n = 69)
Loss of domain, number (%)	13 (39)	25 (36)
Resection of omentum, number (%)	1 (3)	14 (20)
Resection of small bowel, number (%)	4 (12)	7 (10)
Patients receiving abdominal wall drain, number (%)	14 (42)	0 (0)
Resection of colon/colostomy reversal, number (%)	2 (6)	5 (7)
Hernia size, mean (SD), cm^2	218.86, 121.48	331.79, 165.27
Range	24–500	33–840
Mesh size, mean (SD), cm^2	404.0, 132.03	535.25, 138.42
Range	150–600	112–962
Duration of surgery, mean (SD), minutes	186.55, 61.03	191.0, 95.3
Range	74–357	100–607

SD, standard deviation.

TABLE 3. *Postoperative Outcomes*

Variable	August 2011 to September 2013 (n = 33)	September 2013 to September 2015 (n = 69)
Inhospital outcomes		
Total amount of postoperative opioids used, median (IQR), mg IV morphine equivalents	373.48, 381.4, 30–1714.1	187.66, 191.42†, 0–1035.7
Total amount of postoperative opioids used in PACU, median (IQR), mg IV morphine equivalents	15.4, 11.05, 0–45	8.85, 8.02†, 0–30
Length of PACU stay, median (IQR), minutes	221.55, 124.52, 60–585	122.88, 65.11†, 0–331
Length of hospital stay, median (IQR), days	10.33, 11.23, 1–49	6.09, 5.41†, 0–32
Post-discharge outcomes		
Wound complications, number (%)*	16 (48)	13 (19)†
Minor	6 (18)	3 (4)†
Moderate	2 (6)	5 (7)
Major	8 (24)	5 (7)†
Hernia recurrence, number (%)	8 (24)	1 (1)*
Hospital readmission within 30 days, number (%)	5 (15)	5 (7)
Death within 30 days, number (%)	2 (6)	1 (1)

IQR, interquartile range.

* Wound complication definitions: Minor, minor procedure performed for wound care in clinic (typically a Q-tip exploration and minor dressing placed); Moderate, referral to a wound clinic and/or outpatient procedure required; and Major, Rehospitalization or prolonged hospitalization with reoperation required to manage wound complication.

† Statistically significant improvement for the after group compared with the before group.

Discussion

This CQI study suggests that abdominal wall drains were safely eliminated from the technique for AWR in a single hernia program. To achieve this successful process improvement, many technical adaptations were implemented by the clinical team. These included the use of techniques that were described in other fields of surgery, particularly plastic surgery.

Similar to open ventral hernia repair, seroma formation is a common occurrence in plastic surgery procedures for the abdominal wall. One technique that has been evaluated to decrease the incidence of this complication, particularly in abdominoplasty, is the use of "quilting sutures" (also called "progressive tension sutures"). Various similar techniques have been used, but the main principle is suture fixation of underlying deep fascia to the superficial (Scarpa's) fascia at multiple points to minimize dead space, shearing forces, and tension in an attempt to avoid seroma formation and other wound complications[8] Multiple studies evaluating both drain use and use of quilting sutures in abdominoplasty have been reported. Two large retrospective series demonstrated low complication rates, specifically low seroma rates, in abdominoplasty with use of progressive tension sutures and no drains.[9, 10] Multiple further studies have compared drains and quilting sutures in abdominoplasty, and one in transverse rectus abdominus myocutaneous flap donor sites,[11] with quilting sutures often recommended[8–14] and many concluding or hypothesizing that drains are not necessary.[8, 12, 14] Other attempts to eliminate the use of drains in abdominoplasty have been studied, such as the use of urethane adhesive glue or fibrin sealant, with less clear benefits.[13, 15] One study raises the concern that infection may be associated with drain placement in a variety of operations, especially when placed near prosthetics such as mesh or orthopedic hardware. In this study, 60 per cent of drains were colonized with bacteria; however, the author's overall conclusion was that drains do not pose a significant infection risk.[16]

In addition to the use of quilting sutures, other techniques for AWR evolved over the duration of the project. Initially, mesh was placed in a retrorectus space limited by the lateral border of the rectus fascia or as an onlay. The initial component separation technique used was an anterior open approach with either vertical unilateral or bilateral transection of the external oblique musculofascia, which was separated from the internal oblique musculofascia. For some patients, endoscopic transection of the external oblique muscles was undertaken in an attempt at process improvement. This avoided the subcutaneous skin flaps created in the open approach but also produced less medialization of the rectus muscle and fascia, and did not address the limitation of mesh coverage confined by the lateral border of the rectus fascia. The most recent technique improvement attempt was the transition to the TAR approach. In this technique, the transversus abdominis muscle is transected at the lateral border of the posterior rectus fascia, just medial to the neurovascular bundles, which allows for much wider mesh coverage and achieves the medialization gains from an open anterior (external oblique) release.

Despite using no abdominal wall drains, the major, minor, and total wound complication rate was lower in the after group compared with the before group. This is most likely due to the many technique adaptations that

were implemented as a part of the attempted process improvement to eliminate the use of abdominal wall drains. In addition to the TAR technique, which eliminates the skin flaps created in the open external oblique component separation technique, other technique improvements were also implemented. Wide resection of skin, scar, umbilicus, and soft tissue, use of layered quilting sutures and avoidance of drains all possibly contributed to the decrease in wound complications. Although these technique adaptations likely contributed to the decrease in the incidence and severity of wound complications, they have also likely contributed to an increase in operative time.

A limitation of this analysis, and of CQI in general, is that results of a project in one local environment may not be reproducible in other local environments. Variations between local environments can result in different patient outcomes from the same process improvement intervention. Another limitation is that the observed improvements in outcomes could be related to other factors unrelated to the implemented attempts at process improvement such as operative technique adaptations implemented during the course of this CQI project. However, CQI as a complex systems science tool is a dynamic method that should result in improvement of value over time for any complex patient care process when implemented according to the principles described in this manuscript.

Conclusion

Abdominal wall drains were safely eliminated for patients who underwent AWR in a single hernia program using the principles of CQI. The implementation of several technique adaptations led to improved outcomes without the use of drains. Although the same technique adaptations applied in a different hernia program may not lead to the same outcomes due to different local variables, the application of the principles of CQI should lead to improved outcomes when applied to any complex patient care process.

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