Real-World Clinical Quality Improvement for Complex Abdominal Wall Reconstruction

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ABSTRACT

Introduction: Traditional methods of clinical research may not be adequate to improve the value of care for patients undergoing abdominal wall reconstruction (AWR). These patients are prone to high complication rates and high costs. Here, we describe a clinical quality improvement (CQI) effort to enhance outcomes for patients undergoing AWR.

Materials and Methods: CQI was applied for the entire care cycle for consecutive patients who underwent AWR from August 2011–September 2015. Initiatives for improving value during this period included use of long-term resorbable synthetic mesh as well as administration of preoperative bilateral transversus

abdominus plane (TAP), and intraoperative abdominal wall blocks using long-acting bupivacaine as a part of a multimodal regimen. Outcomes data that measure value in the context of AWR were collected to compare outcomes for the patients who received TAP blocks only, TAP and intraoperative blocks, and those who received no block.

Results: One hundred and two patients who had AWR for abdominal wall pathology were included. Outcomes including total opioid use, duration of stay and opioid use in the postanesthesia care unit (PACU), length of hospital stay (LOS), major wound complications, and costs, all improved over time. Specifically, PACU opioid use, total opioid use, and LOS were decreased in the two groups that received blocks versus a group that did not have any type of block.

Conclusions: CQI program implementation in patients undergoing AWR resulted in measurable improvement of value-based outcomes over time. A CQI effort applied to the entire patient cycle of care should be routinely utilized.

INTRODUCTION

Clinical quality improvement (CQI) initiatives are focused on improving the value of care from the patient's perspective. 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 the 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 define and measure improvement of patient value have been proposed by the US business community.[2,3] By taking a complex systems science view of healthcare, 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] Evidence suggests that CQI initiatives are a better way to evaluate surgical outcomes in real-world patient care than randomized controlled trials. Presumably, this is because there are numerous inherently uncontrollable variables associated with surgical procedures. In addition, traditional prospective, randomized controlled trials are producing diminishing returns in the current environment of rapidly changing technology and healthcare policies and structures. Furthermore, the linear research and statistical methods used in controlled clinical trials are incomplete when applied in real-world patient care. 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 healthcare 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 CQI use has been supported since the Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996. The principles of CQI were again supported in the Patient Safety and Quality Improvement Act of 2005. In addition, the US Department of Health & Human Services recognizes that there is a clear distinction between most quality improvement efforts and research involving human subjects that requires institutional review board (IRB) approval.[5] True CQI focuses on local process improvement and real-world, evidence-based data and analytics that are interpreted by the clinical team. In addition, whenever possible, patients and their families are included in the CQI and shared decision-making processes.

Patients who undergo AWR are prone to high complication rates and high costs. Here, we describe a CQI effort to improve outcomes that measure value for the entire cycle of patient care for patients who underwent an AWR in a single hernia program. Key outcome measures that were collected in an attempt to measure value included the duration of stay in the postanesthesia care unit (PACU), length of hospital stay (LOS), postoperative opioid use, wound complications, hernia recurrence, and hospital costs.

MATERIALS AND METHODS

Because CQI was implemented as part of the actual patient care process, this initiative was exempt from HIPAA 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 US government through the Agency for Healthcare Research and Quality (AHRQ). As part of this process, the AHRQ designated our partner clinical research organization (Surgical Momentum, LLC, Daytona Beach, Florida) as a Patient Safety Organization. The 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. De-identified 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) for hernia repair 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 alternative options, if desired. Consecutive patients who chose to undergo open AWR were included in this analysis.

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 analyzed. Patient and family member volunteers, surgical residents, medical students, and other general surgeons are 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 helps the hernia team continue to refine the patient care process in an attempt to improve outcomes that reflect improved value for the patient.

The major changes (attempts at process improvement) implemented during the project included the use of long-term resorbable synthetic mesh as well as preoperative bilateral transversus abdominus plane (TAP) and intraoperative abdominal wall blocks with liposomal bupivacaine (EXPAREL®, bupivacaine liposome injectable suspension; Pacira Pharmaceuticals, Inc., Parsippany, New Jersey)[6] for postsurgical pain relief. Patients that underwent surgery between August 2011 through December 2012 did not receive the TAP blocks. Patients who underwent surgical procedures from January 2013 to September 2015 received the TAP blocks, except for patients who refused the blocks or for the anesthesiologist's preference. Beginning in September 2014, in addition to the TAP blocks, intraoperative bilateral rectus sheath blocks using liposomal bupivacaine were also administered in an attempt to improve pain relief. The intraoperative rectus sheath blocks were performed by the surgeon along the neurovascular bundles at the lateral border of the rectus muscle in the retrorectus space bilaterally just prior to transection of the transversus abdominus musculofascial tissue.

There were also 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 (CST) was utilized in an attempt to decrease wound complications. For the majority of patients who underwent surgery during the most recent 2 to 3 years, a transversus abdominus release (TAR) approach had been adopted. The AWR techniques and incisions used are presented in Table I. Other technique process improvement attempts included: wide resection of anterior scar, skin, soft tissue, and umbilicus to include more healthy, vascularized tissue in the closure; elimination of the use of drains by using layered quilting sutures to eliminate dead space and distribute tension on the closure of the skin and soft tissue; use of visceral reduction (typically omentum, small bowel, and/or colon) if the midline fascia could not be approximated; and use of subcuticular stitches for skin closure instead of staples, except in patients at high risk for wound infection. All patients had midline fascial closure without the need for mesh bridging a residual defect.

Another attempt at process improvement was implemented at the beginning of the project: due to the high cost associated with biologic mesh, less costly meshes, primarily synthetic resorbable meshes, were used instead. In patients where the mesh was not in contact with bowel, a macroporous long-term resorbable synthetic mesh was used primarily. In patients where bowel was potentially exposed to the mesh, a microporous long-term resorbable synthetic mesh was used primarily. In certain cases, where it was felt that a permanent synthetic was required, either a lightweight polypropylene mesh or a nonwoven polypropylene mesh was used. In a few cases, more than one synthetic mesh was used, and in one case, no mesh was used due to patient preference to avoid the use of even absorbable mesh. The list of meshes used in this project is presented in Table I.

A single surgeon (BR) performed all surgical procedures. In some cases, a surgical resident and/or another attending surgeon assisted in the operation. General anesthesia techniques varied based on the preferred techniques of the anesthesiologist who assisted with each procedure. The anesthesiologists performed the bilateral TAP blocks in the preoperative holding area using ultrasound guidance for administration of liposomal bupivacaine (266 mg). Opioid analgesics were available to all patients (whether they received a TAP block or not) as rescue to achieve adequate pain control. The nurses and patients determined the need for opioid use throughout the duration of the hospital stay.

Table I
Types of AWR procedures, incision types, and mesh types used through the course of the CQI project

Parameter	No Block (8/11 – 12/12) n = 24 n (%)	TAP Block Only (1/13 – 8/14) n = 40 n (%)	TAP and Intraoperative Block (9/14 – 9/15) n = 36[a] n (%)
Type of AWR procedure			
Open CST (external oblique transection)	10 (42)	4 (10)	0
Endoscopic CST	7 (29)	0	0
Transversus abdominus release	2 (8)	36 (90)	35 (97)
Other AWR technique	5 (21)	0	1 (3)
Incision type			
Inverted "T" (fleur-de-lis)	4 (17)	5 (13)	3 (8)
Low horizontal	0	4 (10)	1 (3)
Vertical midline	20 (83)	31 (78)	32 (89)
Mesh type			
Macroporous resorbable synthetic	19 (79)	39 (98)	29 (83)
Nonwoven polypropylene microfiber	0	0	4 (11)
Macroporous resorbable synthetic and microporous resorbable synthetic (2 meshes used)	1 (4)	0	0
Microporous resorbable synthetic and lightweight polypropylene (2 meshes used)	2 (8)	0	0
Macroporous resorbable synthetic and nonwoven polypropylene microfiber (2 meshes used)	0	0	1 (3)
Macroporous resorbable synthetic, microporous resorbable synthetic, and lightweight polypropylene (3 meshes used)	2 (8)	0	0
No mesh	0	0	1 (3)
Microporous resorbable synthetic	0	1 (3)	1 (3)

AWR abdominal wall reconstruction; *CQI* clinical quality improvement; *TAP* transversus abdominus plane; *CST* component separation technique
[a] Two patients are not included in this group because they received only an intraoperative block without a TAP block due to an inability to find the correct plane for TAP infiltration

Assessments

Outcome measures included duration of stay in the PACU, postsurgical opioid use during the hospital stay (systemic and oral administration), hospital LOS, proportion of patients with a hospital stay of 0 to 3 days, postsurgical wound complication rate, hernia recurrence rate (identified during postsurgical physical examination), and related hospital costs (direct plus indirect hospital costs). 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 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 non-normal. Levene's Test for Equality of Variances was used to test for meeting the assumption of homogeneity of variance. Between-subject comparisons were conducted using independent sample *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 .008 was used to assume statistical significance. In the event of a violation of a statistical assumption, non-parametric 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. Medians and interquartile ranges were reported for non-parametric tests. Frequency statistics were used to describe categorical variables. Unadjusted odds ratios (ORs) with 95% confidence intervals (CIs) were used to measure for associations with categorical outcomes. Principal component analysis (PCA) was used as a means of data reduction to better understand which demographic, prognostic, and predictor variables accounted for the most variance in outcomes such as hospital LOS, use of opioids postoperatively, and wound complications.

Kaiser-Meyer-Olkin (KMO) and Bartlett's test were used to meet the statistical assumptions of PCA. A scree plot was used to select the number of factors to be interpreted (Fig. 1). Only variables with an absolute factor loading of .5 were interpreted. An oblique rotation was employed to more easily interpret the factors. All analyses were conducted using SPSS Version 21 (IBM Corp., Armonk, New York).

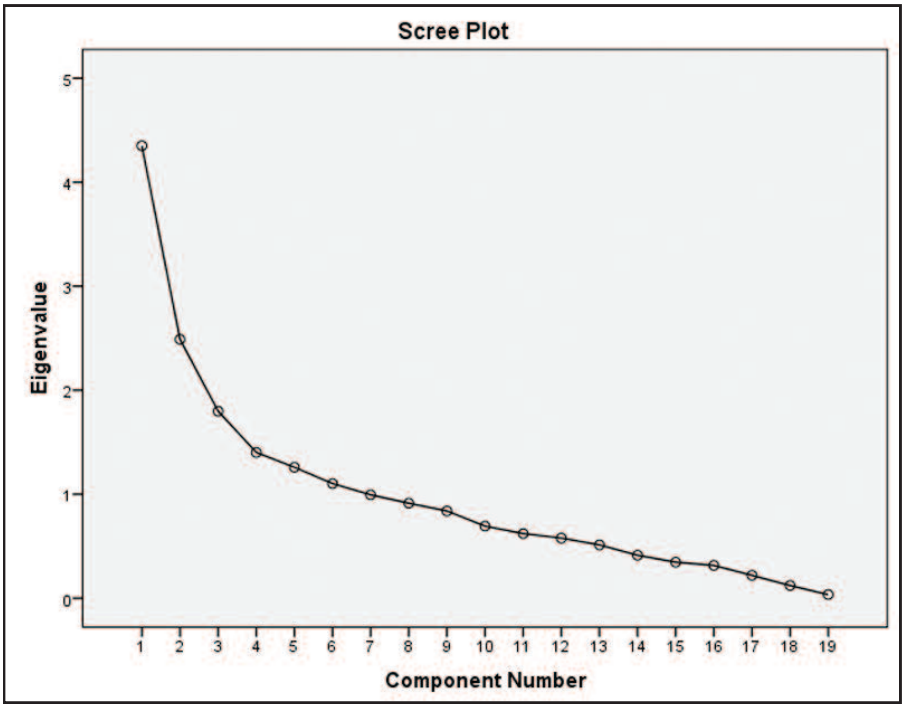

Figure 1. A scree plot of the factor combinations to perform a principal component analysis.

RESULTS

The analysis population included 102 consecutive patients who underwent open AWR; 24 who received no block, 40 who received only the preoperative TAP blocks without the intraoperative blocks, and 36 who received both the TAP blocks as well as the intraoperative blocks (two patients received an intraoperative block only and were not included in the group comparisons).

The type of procedure, incision type, and mesh used are presented in Table I. There were no differences between groups for the type of incision used. There was a significant increase in the use of the TAR approach for both the TAP block only group (OR = 99.0, 95% CI 16.7–586.1) and the TAP and intraoperative block group (OR = 385.0, 95% CI 32.9–4501.7) compared with the no block group.

Baseline demographic characteristics are summarized in Table II. There were no significant differences between groups for age, gender, body mass

Table II
Patient demographics and baseline characteristics

Variable	No Block (8/11 – 12/12) n = 24	TAP Block Only (1/13 – 8/14) n = 40	TAP and Intraoperative Block (9/14 – 9/15) n = 36[a]
Age, mean (SD), years	61.03 (8.10)	58.25 (13.16)	54.03 (11.85)
Gender, n (%)			
Male	11 (46)	14 (35)	13 (36)
Female	13 (54)	26 (65)	23 (64)
Body mass index, mean (SD), kg/m²	35.48 (7.89)	34.85 (8.59)	32.67 (8.66)
Range	(20.3–50.8)	(21.4–52.7)	(17.6–53.4)
Number of prior abdominal operations, median, (IQR)	3.5 (5.8)	4.0 (5.5)	3.0 (3.0)
Comorbidity, n (%)			
Smoker	5 (21)	4 (10)	4 (11)
Prior hernia repair with recurrence	17 (71)	24 (60)	20 (56)
Preoperative chronic pain	9 (38)	19 (48)	24 (67)
Preoperative opioid use, n (%)			
Overall	9 (38)	19 (48)	19 (53)
Scheduled opioid-use regimen	6 (25)	9 (23)	10 (28)
"As-needed" opioid-use regimen	3 (13)	10 (25)	9 (25)

TAP transversus abdominus plane; *SD* standard deviation; IQR interquartile range
[a] Two patients are not included in this group because they received only an intraoperative block without a TAP block due to an inability to find the correct plane for TAP infiltration

Table III
Hernia and surgical characteristics

Characteristic	No Block (8/11 – 12/12) n = 24	TAP Block Only (1/13 – 8/14) n = 40	TAP and Intraoperative Block (9/14 – 9/15) n = 36[a]
Loss of domain, n (%)	9 (38)	16 (40)	12 (33)
Resection of omentum, n (%)	0	7 (18)	7 (19)
Resection of small bowel, n (%)	3 (12)	3 (8)	3 (8)
Resection of colon/colostomy reversal, n (%)	1 (4)	2 (5)	3 (8)
Hernia size, median (IQR), cm^2	224.0 (162.0)	285.0 (186.0)	304.0 (280.0)[b]
Mesh size, mean (SD), cm^2	384.71 (121.49)	484.13 (114.08)[c]	570.6 (157.57)[b]
Duration of surgery, median (IQR), minutes	170.0 (65.3)	191.0 (95.3)	231.5 (133.5)[d]

TAP transversus abdominus plane; IQR interquartile range; SD standard deviation
[a] Two patients are not included in this group because they received only an intraoperative block without a TAP block due to an inability to find the correct plane for TAP infiltration. [b]p < .001 vs. the no block group. [c]p = .007. [d]p < .001 vs. the no block group, p = .004 vs. the TAP block only group

index, number of prior abdominal operations, recurrent hernias, smoking history, or preoperative opioid use (regular or as needed). Patients in the TAP and intraoperative block group were more likely to have preoperative chronic pain in comparison to the no block group (OR = 3.3, 1.1–9.8).

Hernia characteristics and proportions of patients requiring visceral reduction are summarized in Table III. There was a significant increased hernia size in the TAP and intraoperative block group when compared with the no block group ($p < .001$). Mesh size was significantly higher in the TAP and intraoperative block group in comparison to the no block group ($p < .001$) and the TAP block only group ($p = .007$). There was a significant increase in operative time for the TAP and intraoperative block group compared with the no block group ($p < .001$) and TAP block only group ($p = .004$).

A summary of outcomes that occurred during the hospitalization and those that occurred after hospital discharge in the three treatment groups is presented in Table IV. Significantly less opioids (measured by total morphine equivalents) were used in the TAP block only group ($p = .006$) and in the TAP and intraoperative block ($p = .007$) groups in comparison to the no block group. There was a significant decrease in PACU opioid use ($p < .001$) and hospital LOS ($p = .002$) in the TAP block only group compared with the group with no block. There was a significant decrease in PACU opioid use ($p < .001$) and hospital LOS ($p = .007$) in the TAP and intraoperative block group when compared with the group with no block. The TAP and intraoperative block group was much more likely to require no opioids in the PACU (OR = 10.5, 95% CI 1.6–87.7) in comparison to the no block group. TAP block only patients (OR = 17.0, 95% CI 2.1–138.5) and TAP and intraoperative block patients (OR = 10.1, 95% CI 1.2–84.7) were much more likely to be discharged within three or less days in comparison to the no block patients. The TAP and intraoperative block group was 86% less likely to have major wound complications (95% CI 0.2%–99%) when compared with the no block group. There were no other statistically significant differences in post-discharge outcomes between the groups.

Figure 2 shows the cumulative percentage of patients discharged by each postoperative day for the groups who received a TAP block only and the

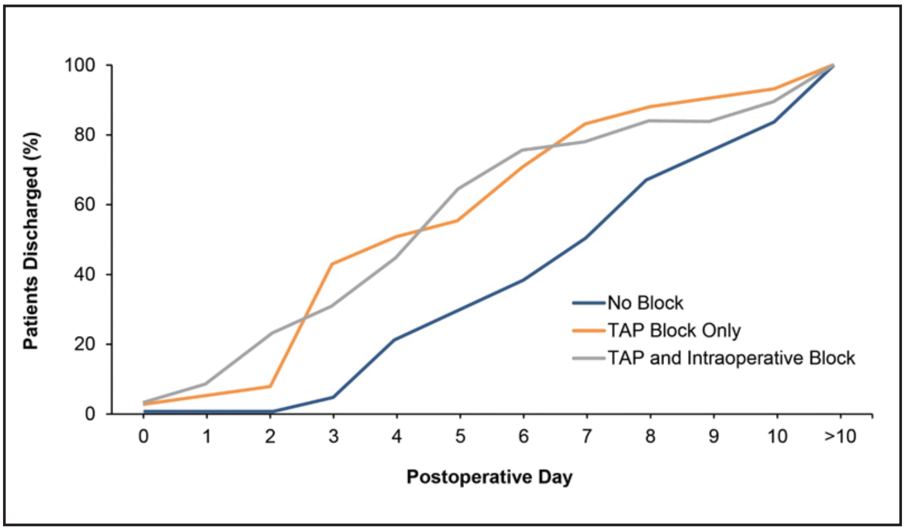

Figure 2. Cumulative percent of patients discharged on each postoperative day.

Table IV
Postoperative outcomes

Variable	No Block (8/11 – 12/12) n = 24	TAP Block Only (1/13 – 8/14) n = 40	TAP and Intraoperative Block (9/14 – 9/15) n = 36[a]
In-hospital outcomes			
Total amount of postoperative opioids used, median (IQR), mg IV morphine equivalents	212.4 (298.4)	134.3 (173.2)[b]	105.8 (252.6)[b]
Total amount of postoperative opioids used in PACU, median (IQR), mg IV morphine equivalents	172.5 (171.8)	10.0 (8.4)[b]	5.6 (11.3)[b]
Proportion using no opioids in PACU, n (%)	1 (4)	6 (15)	12 (33)[b]
Length of PACU stay, median (IQR), minutes	172.5 (171.8)[c]	134.0 (97.0)	98.0 (77.8)
Length of hospital stay, median (IQR), days n (%)	7.5 (4.8)	4.5 (4.0)[b]	5.0 (3.8)[b]
Proportion with hospital stay of ≤3 days, n (%)	1 (4)	17 (43)[b]	11 (31)[b]
Post-discharge outcomes			
Wound complications, n (%)d	7 (29)	12 (30)	4 (11)
Minor	1 (4)	5 (13)	3 (8)
Moderate	1 (4)	5 (13)	0
Major	5 (21)	2 (5)	1 (3)b
Hernia recurrence, n (%)	6 (25)	3 (8)	0
Hospital readmission within 30 days, n (%)	3 (13)	5 (13)	2 (6)
Death within 30 days, n (%)	2 (8)	1 (3)	0

TAP transversus abdominus plane; *IQR* interquartile range; *IV* intravenous; *PACU* post anesthesia care unit
[a] Two patients received only an intraoperative block without a TAP block and are not included in this group
[b] Statistically significant improvement compared with the group with no block
[c] PACU time and opioid usage data were not collected in two patients
[d] Wound complication definitions: minor—minor procedure performed for wound care in clinic (typically a cotton swab exploration and minor dressing placed); moderate—referral to a wound clinic and/or outpatient procedure required; major—re-hospitalization and/or re-operation required to manage wound complication

group who had a TAP and intraoperative block versus the patients who had no blocks. Almost half of the patients in the groups that received regional anesthetic techniques were discharged within three days or less compared with only one patient discharged within this time period in the group without blocks.

An attempt was made to obtain real hospital cost and reimbursement data for all patients. At the time of this submission, total cost (direct plus indirect costs) and net margin (total reimbursement minus total cost) data were available for 30 consecutive patients, all of whom were in the TAP block only group. Figure 3 presents a scatterplot of total costs for these 30 patients plotted against the hospital LOS. A scatterplot of hospital margin data plotted against hospital LOS is presented in Figure 4. The trend lines show costs increased (Fig. 3) and net profit margins decreased (Fig. 4) as LOS increased.

Statistical assumptions of the PCA were met as per KMO and Bartlett's statistics. The PCA yielded a total of four factors that accounted for 52.8% of the variance in the aforementioned outcomes (Table V). The first factor comprised open CST, TAR, intraoperative drain, preoperative TAP block by anesthesiologist, intraoperative block by surgeon, and postoperative major wound (22.9% of the variance). Then, preoperative active wound infection and intraoperative SB resection accounted for 13.1% of the variance, followed by preoperative emotional complexity (9.5%) and prior hernia repairs (7.4%).

DISCUSSION

The main findings of this study suggest that measuring the impact of process improvements, such as evolving the surgical technique, adding new components to the multimodal pain management regimen (e.g., bilateral TAP blocks and intraoperative abdominal wall blocks with liposomal bupivacaine), and commitment to an enhanced recovery program were correlated with several improvements in quality measures, such as less use of opioids in the PACU, less total opioid use, and a reduction in LOS, which would presumably decrease costs and increase hospital profit margin based on the sample of 30 patients for which financial

Table V
Factor loadings from the PCA

	Factor 1	Factor 2	Factor 2	Factor 3
Prior hernia repairs				.796
Preoperative active wound infection		.710		
Preoperative emotional complexity			.861	
Open CST	.902			
TAR	-.787			
Intraoperative SB resection		.761		
Intraoperative drain	.875			
Preoperative TAP block by anesthesiologist	-.563			
Intraoperative block by surgeon	-.507			
Postoperative major wound	.506			

Positive numbers represent positive correlation; higher positive numbers signify that a given factor strongly contributed to negative outcomes (e.g., longer LOS, more opioid use, more complications). Negative numbers represent negative correlation; lower negative numbers signify that a given factor strongly contributed to positive outcomes (e.g., shorter LOS, less opioid use, fewer complications).

PCA principal component analysis; *LOS* length of stay; *CST* component separation technique; *TAR* transversus abdominus release; *SB* small bowel; *TAP* transversus abdominus plane

data were available.

One area of growing interest to support CQI is the variety of data analytics and visualization techniques available to assist with generating ideas for process improvement. Examples of visualization techniques include the line graph in Figure 2 and the scatterplots with trend lines in Figures 3 and 4. In addition to analytic techniques that attempt to demonstrate the significance of a number of variables, there are also a variety of linear and non-linear methods that generate weighted correlations for a number of factors (patient and process/treatment) to demonstrate their impact on identified outcome measures. In this CQI project, PCA was used to identify factors that could be potentially modified in an attempt to improve outcomes and to assess the impact of the implementation of process improvement ideas, such as the use of long-acting local anesthetic blocks and the change from anterior external oblique CSTs (open and endoscopic) to a posterior component separation (TAR) technique. Table V shows the correlation of various factors to poor outcomes—longer hospital LOS, more total opioid use, and complications. The weights and combinations of factors can be used to predict outcomes in predictive algorithms in the future. The decision about what factors and outcome measures are collected and analyzed (programming the computing) and what to do about the results of the analysis and visualization of the data (interpretation of the computation) is best performed by the team of people who contribute to the care of this patient group. The combination of a team of people who program what goes in the computer programs and interpret what is generated from this variety of computing capabilities, and the computing capability itself, is the appropriate application of human-computing symbiosis as a foundation for healthcare learning organizations and networks.

From this PCA, we can see that many of the attempts at process improvement contributed to the improved outcomes (Table V). The transition from the open external oblique CST had a strong positive correlation (+.902) with poor outcomes, while the TAR approach had a strong negative correlation (-.787) with poor outcomes. Both the addition of the preoperative TAP block (-.563) and intraoperative block (-.507) with long-acting local anesthetic included as a part of a multimodal pain management and enhanced recovery effort had strong negative correlations with poor outcomes. Although some of the factors that had positive correlations with poor outcomes, such as prior hernia repair (+.796), were not modifiable, there were also factors, such as the patient with high emotional complexity (post-traumatic stress disorder, depression, anxiety, etc.) preoperatively (+.861) and active wound infection preoperatively (+.710), which could potentially be modified through counseling and other psycho-social-emotional therapies and aggressive wound care to potentially heal wounds prior to elective surgery.

The techniques for AWR evolved over the duration of the project. Initially, mesh was placed in a limited space (retrorectus) or as an onlay. The initial CST was an anterior open approach with either vertical unilateral or bilateral transection of the external 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 posterior rectus fascia. The most recent technique improvement attempt was the transition to the TAR approach. In this technique, the transversus abdominus 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.

The major wound complication rate was lower in the TAP and intraoperative block group compared with the no block group. This is most likely due to process improvement attempts related to the technique. In addition to the TAR technique, which eliminates the skin flaps created in the open external oblique CST, 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 improvements likely contributed to the decrease in the incidence and severity of wound complications, there has been an increase in operative time after implementing these changes in technique.

Another major area of focus for process improvement was in the area of postoperative pain management. As we included the patient and family in our CQI effort, we were impressed by the fear and apprehension felt by patients in anticipation of the potential for significant postoperative pain. Therefore, we instituted multimodal perioperative pain management in collaboration with our anesthesia colleagues. Regional analgesia techniques are critical components of an optimal multimodal analgesia technique, as they improve pain relief and reduce opioid requirements.[7,8] This should reduce the opioid-related adverse events (ORAEs) including nausea, constipation, and postoperative ileus[9,10] that can be particularly burdensome following abdominal surgeries such as AWR. Because ORAEs have been shown to increase hospital costs and LOS and decrease patient satisfaction,[11] reduced opioid use should influence these outcomes. In the TAP block and TAP block plus intraoperative block groups (i.e., regional anesthesia groups), 43% and 31% of the patients, respectively, had a total LOS that was ≤ 3 days compared with only one of 24 patients (4%) in the group that did not receive blocks.

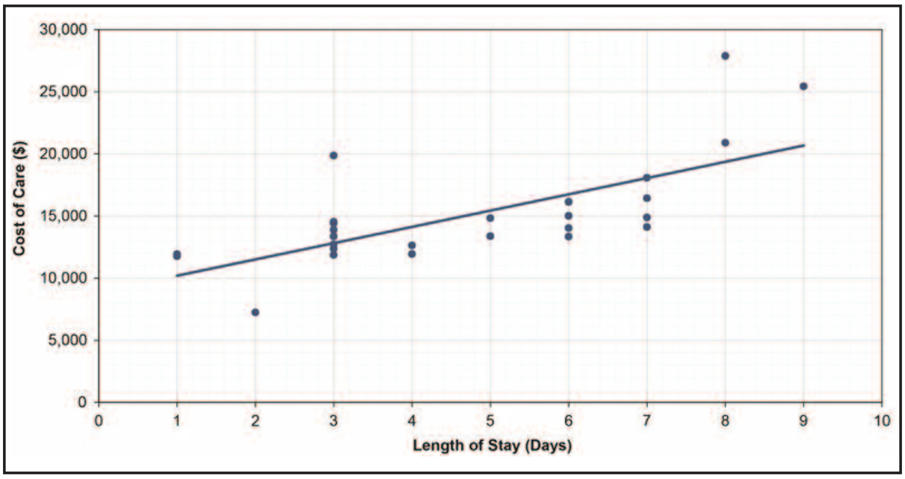

Figure 3. Costs of care correlated with hospital length of stay for 30 patients in the TAP block group who underwent AWR TAP transversus abdominus plane; AWR abdominal wall reconstruction.

Several studies have reported analgesic efficacy of TAP block in patients undergoing abdominal surgical procedures.[12,13] Therefore, TAP block is increasingly being used as an integral part of multimodal analgesic strategies that reduce postoperative opioid requirements. However, one of the major limitations of local/regional analgesia is the relatively short duration of action of bupivacaine and ropivacaine, which is typically 12 hours or less.[14] Liposomal bupivacaine is a prolonged-release formulation of bupivacaine indicated for administration into the surgical site to produce postsurgical analgesia.[6] Several studies have reported clinical efficacy of liposomal bupivacaine after different types of surgical procedures.[15] We found that the introduction of TAP blocks with or without intraoperative blocks with liposomal bupivacaine, along with changes in surgical techniques, reduced the hospital LOS. In fact, a higher percentage of patients receiving regional anesthesia were able to leave the hospital in ≤ 3 days. Nevertheless, it is important to realize that regional anesthesia techniques are just one component of an optimal multimodal analgesic technique. In addition to regional anesthesia, use of other nonopioid analgesics such as acetaminophen, nonsteroidal anti-inflammatory drugs, and cyclooxygenase-2 specific inhibitors, as well as analgesic adjuncts such as gabapentinoids (e.g., gabapentin, pregabalin), can further improve pain management and reduce opioid requirements. The addition of an

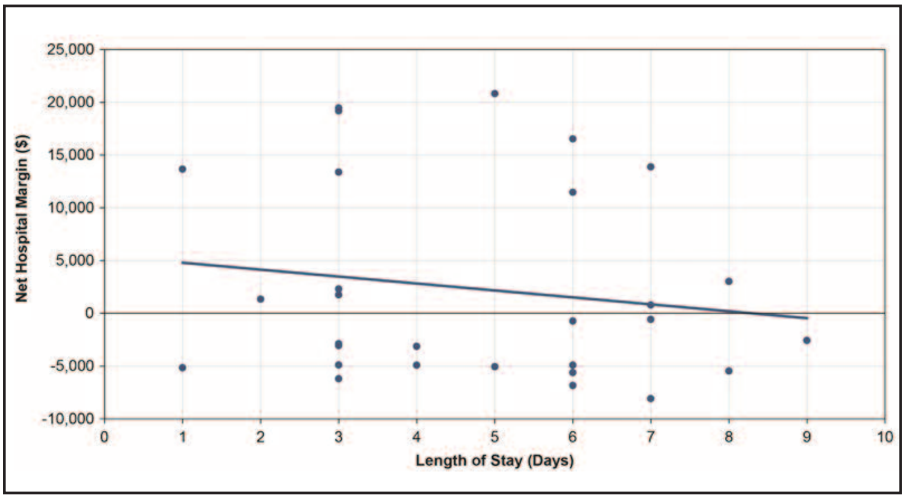

Figure 4. Hospital margin correlated with hospital length of stay for 30 patients in the TAP block group who underwent AWR TAP transversus abdominus plane; AWR abdominal wall reconstruction.

intraoperative block was introduced in an attempt to improve the impact of the anesthetic block. It is difficult to determine the impact of this attempt at improvement because, although the outcomes were similar between the TAP only and TAP and intraoperative block groups, there were more patients with chronic pain, larger hernias, and longer operative times in the TAP and intraoperative block group.

Even though the primary goal of CQI is to improve value for the patient, it is also appropriate to measure and improve financial sustainability for the hospital and physician. In this study, the implementation of a CQI process resulted in a savings of several thousands of dollars per patient with improvement in the hospital margin from near breakeven to a net positive, primarily due to a decrease in hospital LOS and by using less-expensive hernia meshes. One key component of a value measurement is to determine the actual cost of care. Making that determination is difficult, and may be the greatest challenge faced when attempting to define measurements of value in our current healthcare system. In most industries, not knowing the cost to manufacture a product or provide a service would be unheard of. A business that is ignorant of production or service costs would not remain viable for long. However, the healthcare system has been immune to this basic business tenet due to the archaic healthcare payment model and perception of value associated with doing tests and procedures and prescribing drugs; clearly, this healthcare model is not sustainable. Recognizing that the true costs of care are difficult to generate, we were able to obtain data on direct costs (materials, equipment, etc.) and combine them with indirect costs (electricity, space, administrative overhead, etc.) in an attempt to generate a relatively accurate estimation of cost for the hospital stay. Ideally, true costs for the entire cycle of care would include pre-hospital and post-hospital costs, but the great majority of costs for this patient group are typically generated during the hospital stay.

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 improvements and multimodal pain management strategies implemented during the course of this CQI project. However, CQI as a complex systems science tool is a dynamic process that should result in continuous improvements of value over time when implemented according to the principles described in this manuscript.

CONCLUSION

In patients who underwent open AWR in a hernia program as part of a CQI project, surgical technique modifications, the use of less-expensive mesh, and the use of a multimodal pain management strategy—including the use of TAP blocks and intraoperative abdominal wall blocks with liposomal bupivacaine—led to shorter hospital stays, less opioid use in the PACU, and less total opioid use for the hospital stay. By measuring real costs for the entire hospital stay, it was demonstrated that these improvements could lead to decreased costs and improved hospital margins. These findings suggest that through CQI initiatives, it is possible to improve outcomes that measure value (improved quality measures and decreased costs) in a local, real-world clinical environment.

Continued efforts are needed to refine processes, define value-based outcomes, and apply non-linear data analytics to improve the value of care delivered in each local environment. As more facilities begin to apply CQI for the entire patient cycle of care, opportunities for collaboration between centers will arise, which could produce sustainable, valuable improvements for patients with abdominal wall hernia disease as well as for other complex medical problems. STI

AUTHORS' DISCLOSURES

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