A Clinical Quality Improvement (CQI) Project to Improve Pain After Laparoscopic Ventral Hernia Repair

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ABSTRACT

Patients who undergo laparoscopic ventral hernia repair can have significant post-operative pain and discomfort from both somatic pain due to mesh fixation and visceral pain due to CO2 insufflation pressure. In an attempt to improve outcomes, a Clinical Quality Improvement (CQI) project was implemented by a multi-disciplinary hernia team.

CQI tools were applied for consecutive patients who underwent laparoscopic ventral hernia repair from June 2012 through September 2015 (39 months). Initiatives for improved patient outcomes during this period included the administration of a transversus abdominis plane (TAP) block and/or an intra-operative block with long-acting local anesthetic first, and then a low pressure pneumoperitoneum (LPP) system was implemented later in the project.

One-hundred-twenty patients who underwent a laparoscopic ventral/incisional hernia repair were

included in the analysis. Fifty-three patients had no block and had conventional insufflation at 15 mmHg (No Block-No LPP group). Outcomes for this group included a median time in the Post-Anesthesia Care Unit (PACU) of 126 minutes, a median length of stay of 4.0 days, a median use of opioid morphine equivalents (MEQ) in the PACU of 10.0, and a total use of opioid MEQ for the entire hospital stay of 100.0. Thirty-seven patients had blocks with a long-acting local anesthetic and conventional insufflation at 15 mmHg (Block only group). Outcomes for this group showed improvement for all outcomes, but none were statistically significant. Thirty patients had blocks with a long-acting local anesthetic and a low pressure pneumoperitoneum system with a standard pressure of 8 mmHg. Outcomes for this group included a median time in PACU of 83.6 minutes, a median length of stay of 1.5 days, a median amount of opioid use in the PACU of 5.0 MEQ, and a median use of opioid use for the entire hospital stay of 26.0 MEQ. All of these outcomes were statistically significant improvements compared with the No Block-No LPP and Block only groups.

Implementation of a CQI program, including long-acting local anesthetic blocks and a low pressure pneumoperitoneum system as part of a multi-modal pain strategy for patients who underwent laparoscopic ventral hernia repair, was associated with decreased PACU time, decreased length of stay, and less opioid use in the PACU and for the entire hospital stay.

INTRODUCTION

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, 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 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] 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 the use of CQI use has been supported since the Health Insurance Portability and Accountability Act (HIPAA) law was implemented 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 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.

Laparoscopic ventral hernia repair was first reported by LaBlanc in 1993.[6] A laparoscopic approach for ventral hernia repair has been noted to reduce the rate of wound and mesh complications compared with open ventral hernia repair techniques. However, as opposed to other laparoscopic procedures, pain and discomfort can be significant after a laparoscopic ventral hernia repair. It is thought that this is due to the mesh fixation techniques, typically tack and

transfascial sutures, and pain will typically be increased with the increasing size of the mesh. For our hernia program, it was felt that the significant pain and discomfort after laparoscopic ventral hernia repair was an opportunity to try to improve outcomes utilizing the principles of CQI.

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 United States government through the Agency for Healthcare Research and Quality (AHRQ). As part of this process, AHRQ designated our partner clinical research organization (Surgical Momentum, LLC, Daytona Beach, Florida) as a Patient Safety Organization (PSO). 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. 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) 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 and had a successful laparoscopic ventral hernia repair 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.

Attempts at process improvement

At hernia team CQI meetings throughout the time period of the project, we discussed several potential opportunities for process improvement related to the pain and discomfort associated with a laparoscopic ventral hernia repair. Some of the post-operative symptoms discussed included pain, discomfort, pulling, burning and tearing sensations, and the potential for the development of chronic suture site pain. With this feedback, a literature search was done evaluating the use of multi-modal pain management and enhanced recovery programs in other specialties and from centers in Europe. One anesthesiologist, who had a fellowship in pain blocks, suggested using a variety of combinations of medications to attempt pre-operative transversus abdominus plane (TAP) blocks to help with pain management. In addition to decadron and bupivacaine, a newer long-acting local anesthetic-liposomal bupivacaine (EXPAREL®, Pacira Pharmaceuticals, Inc., Parsippany-Troy Hills, New Jersey) was used in the mixture.

After observing some improvement in outcomes, our hernia team learned about a new low pressure pneumoperitoneum system (AirSeal®, Conmed Corporation, Utica, New York) which could potentially address the visceral pain associated with pneumoperitoneum that would not be addressed by the pain blocks primarily used to address somatic pain. The CQI meeting that stimulated the search for a low pressure system occurred after a laparoscopic ventral hernia repair procedure was aborted due to a CO2 embolus shortly after the initiation of standard insufflation at a pressure of 15 mmHg. At about the same time, an additional field block was instituted by injecting the entire periphery of the mesh after completion of all tack and suture fixation in an attempt to maximize the effect of the local anesthetic blocks.

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.

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. Opioid analgesics (intravenous and oral options) were available to all patients to achieve adequate pain control. The nurse and patient determined the need for opioid use during the time in the PACU and for the length of the hospital stay.

Assessments

Outcome measures included duration of stay and opioid use in the PACU, postsurgical opioid use during the hospital stay, hospital length of stay (LOS), wound complication rate, hernia recurrence rate, and 30-day re-hospitalization 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 IV morphine equivalents using the GlobalRPh Inc. opioid analgesic converter (available at:

Table I
Patient demographics and baseline characteristics

Variable	No Block-No LPP (n = 53)	Block Only (n = 37)	Block and LPP (n = 30)
Age, mean (SD), years (range)	61.76 (12.08) (37 – 93)	56.00 (13.66) (21 – 85)	57.00 (10.89) (37 – 75)
Gender, n (%)			
Male	24 (45)	20 (54)	12 (40)
Female	29 (55)	17 (46)	18 (60)
Body mass index, mean (SD), kg/m^2 (range)	35.53 (8.58) (22.93 – 59.54)	35.79 (9.00) (22.92 – 58.74)	33.37 (10.49) (18.03 – 62.44)
Number of prior abdominal operations, median, interquartile range (IQR)	2.00 (4.0)	2.00 (3.0)	2.50 (3.0)
Comorbidity, n (%)			
Current Smoker	7 (13)	6 (16)	8 (27)
Former smoker	17 (32)	12 (32)	9 (30)
Prior hernia repair with recurrence	30 (57)	19 (51)	14 (47)

There are no significant differences between groups for these factors
LPP—Low pressure pneumoperitoneum, SD—Standard deviation

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-subjects, comparisons were conducted using independent samples t-tests and one-way ANOVA. Means and standard deviations were reported for continuous variables. In order to adjust for increased experimentwise 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. Frequency statistics were used to describe categorical variables. Unadjusted odds ratios (OR), with 95% confidence intervals (95% CI), were used to measure for associations with categorical outcomes. All analyses were conducted using SPSS Version 21 (IBM Corporation Armonk, New York).

RESULTS

The analysis population included 120 consecutive patients who underwent laparoscopic ventral hernia repair. This included: 53 patients who underwent

Table II
Hernia and surgical characteristics

Characteristic	No Block-No LPP (n = 53)	Block Only (n = 37)	Block and LPP (n = 30)
Pneumoperitoneum pressure, mmHg, mean (SD)	15 (15)	15 (15)	8.87 (1.43) *
Hernia size, median (IQR), cm2	42.00 (130.0)	80.00 (159.0)	46.50 (68.0)
Mesh size, mean (SD), cm2	432.0 (463.0)	572.0 (644.0)	459.0 (327.0)
Duration of surgery, median (IQR), minutes	135.0 (105.0)	111.0 (76.0)	101.0 (63.0) #

*** There is a significant difference compared with the No Block-No LPP and with the Block only groups**
 # There is a significant difference compared with the No Block-No LPP group
There are no other significant differences for the other factors between groups
LPP—Low pressure pneumoperitoneum, SD—Standard deviation

Table III
Post-operative outcomes

Variable	No Block No LPP (n = 53)	Block Only (n = 37)	Block and LPP (n = 30)
Total amount of post-operative opioids used, median (IQR), mg IV morphine equivalents	100.00 (178.8)	59.00 (74.4)	26.00 (59.0)*
Total amount of post-operative opioids used in PACU, median (IQR), mg IV morphine equivalents	10.00 (15.0)	8.00 (8.3)	5.00 (8.3)*
Length of PACU stay, median (IQR), minutes	126.00 (144.0)	111.50 (81.0)	83.60 (61.0)*
Length of hospital stay, median (IQR), days	4.00 (3.0)	3.00 (3.0)	1.5 (3.0)*

*** There is a significant difference compared with the No Block-No LPP and with the Block only groups**
LPP—Low pressure pneumoperitoneum, IQR—Interquartile range

laparoscopic ventral hernia repair before the attempted process improvement to somatic pain (No block-No LPP group); 37 patients who underwent laparoscopic ventral hernia repair after the attempt at process improvement by implementing a long-acting local anesthetic block by using a transversus abdominus plane (TAP) block pre-operatively, and/or an intra-operative long-acting local anesthetic block using direct laparoscopic visualization with infiltration of local anesthetic around the entire periphery of the mesh after fixation was completed (Block only group); and 30 patients who received both the long-acting local anesthetic block(s) and the low pressure pneumoperitoneum system in an attempt to minimize visceral pain (Block and LPP group).

Baseline demographic characteristics are summarized in Table I. There are no significant differences between groups for age, gender, BMI, number of prior abdominal operations, recurrent hernias, or for being a current or former cigarette smoker.

Hernia and procedure characteristics are summarized in Table II. There are no differences between groups for hernia size or mesh size. The pneumoperitoneum pressure is significantly lower in the Block-LPP group compared with both the No Block-No LPP and the Block only groups ($p < .001$). There is a significantly lower operative time for the Block-LPP group compared with the No Block-No LPP group ($p = .02$).

A summary of outcomes that are related to pain and short-term recovery is presented in Table III. There was significantly less opioid morphine equivalents used in the Block-LPP group compared with the No Block-No LPP group ($p = .002$), and the Block only group, ($p = .004$), while in the PACU. For the entire hospital stay, less opioid morphine equivalents were used in the Block-LPP group compared with the No Block-No LPP group ($p = .001$), and the Block only group ($p = .02$). There was a significantly shorter PACU time for the Block-LPP group compared with the No Block-No LPP group ($p = .001$), and the Block only group ($p = .03$). There was also a significantly shorter length of hospital stay for the Block-LPP group compared with the No Block-No LPP group ($p < .001$), and the Block only group ($p = .02$). There were no other statistically significant differences in outcomes between the groups.

DISCUSSION

This CQI study suggests that a combination of long-acting local abdominal wall blocks to address somatic pain and a low pressure pneumoperitoneum system to address visceral pain led to a decrease in opioid use and length of stay with no apparent unintended consequences related to these improvement attempts. To achieve this successful process improvement, many people contributed to this effort, including a collaboration with anesthesia, and from significant feedback and input from patient, family, and industry collaborations. The primary group that facilitated the CQI process and implemented the ideas for improvement were the various members of the hernia team including the patient care manager, patient specialists, engineers, and the surgeon.

The ideas for potential improvement come from many sources. One source is the published literature. The main attempts at process improvement had published studies that supported the potential for positive impact in our patient group. The use of long-acting local anesthetic had been shown to decrease pain in a variety of surgical procedures, including laparoscopic ventral hernia repair.[7,8] The use of low pressure pneumoperitoneum has been shown to decrease shoulder pain and decrease the inflammatory response in other types of laparoscopic procedures.[9,10] Other sources of ideas for improvement include others involved in the care process mentioned above, including anesthesiologists, nurses, industry representatives, patients, and family members. Additionally, we have received input from perspectives that have not traditionally contributed to attempts at improving patient care. Some individuals who have participated in our CQI meetings include engineers, business persons, hospital administrators, and data scientists. Applying the principles of CQI is optimally done by learning to utilize the collective intelligence of multi-disciplinary teams that are open to collaboration.

The concept of continuous improvement for patient care has been demonstrated in healthcare, primarily for a sub-process of care, not in the context of a definable patient care process for the whole cycle of care. An example of the use of process improvement for a subprocess of care spanning many care processes is the attempt to decrease

central line infection rates.[11] Many different patient care processes require a central line to be placed in the Intensive Care Unit. The attempt to improve a sub-process without measuring the impact on the whole process may lead to suboptimization. This occurs when the improvement in outcomes of the sub-process does not improve the outcomes of the whole patient process and can result in unintended consequences. A recent publication demonstrated a process improvement attempt for laparoscopic ventral hernia repair that resulted in improved outcomes for the cycle of care related to decreasing pain, length of stay, and costs.[12] Our project demonstrated this concept for continuous improvement by demonstrating attempts at improvement over multiple time points for the same definable patient care process. We also demonstrated the potential synergy between multiple process improvement factors (somatic pain blocks and low pressure pneumoperitoneum). The important principles for applying these techniques include that the factors and outcomes are collected in the context of a definable care process for the whole cycle of care.

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. A significant challenge is to include long-term follow-up to make sure the whole cycle of care is addressed. Probably the most challenging factor to measure is the costs for the entire cycle of care. A measurement of costs is required to be able to measure the value of care, which should be our goal—to measure and improve the value of care. 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

A combination of abdominal wall long-acting local anesthetic blocks and a low pressure pneumoperitoneum system was implemented in a single hernia program using the principles of CQI. The implementation of these attempts at improvement led to improved outcomes including less opioid use postoperatively in the PACU and the hospital, and a shorter length of stay in the PACU and the hospital. 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 in any local environment. STI

AUTHORS' DISCLOSURES

Dr. Ramshaw is a speaker and consultant for and is receiving fees from: Medtronic, Ethicon Inc., W. L. Gore and Associates, Pacira Pharmaceuticals, Inc., ConMed Corporation, BG Medical, Inc., B Braun Medical Inc., and Atrium Medical.

All other authors have no conflicts of interest to disclose.

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