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Laparoscopic approach for the treatment of chronic groin pain after inguinal hernia repair

Laparoscopic approach for inguinodynia

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Abstract

Background Traditional methods of clinical research may not be adequate to improve the value of care for patients with complex medical problems such as chronic pain after inguinal hernia repair. This problem is very complex with many potential factors contributing to the development of this complication.

Methods We have implemented a clinical quality improvement (CQI) effort in an attempt to better measure and improve outcomes for patients suffering with chronic groin pain (inguinodynia) after inguinal hernia repair. Between April 2011 and June 2016, there were 93 patients who underwent 94 operations in an attempt to relieve pain (1 patient had two separate unilateral procedures). Patients who had prior laparoscopic inguinal hernia repair (26) had their procedure completed laparoscopically. Patients who had open inguinal hernia repair (68) had a combination of a laparoscopic and open procedure in an attempt to relieve pain. Initiatives to attempt to improve measurement and outcomes during this period included the administration of pre-operative bilateral transversus abdominis plane and intra-operative inguinal nerve blocks using long-acting local anesthetic as a part of a multimodal regimen, the introduction of a low pressure pneumoperitoneum system, and the expansion of a pre-operative questionnaire to assess emotional health pre-operatively.

Results The results included the assessment of how much improvement was achieved after recovery from the operation. Forty-five patients (48%) reported significant improvement, 39 patients (41%) reported moderate improvement, and 10 patients (11%) reported little or no improvement. There were 3 (3%) complications, 13 (11%) hernia recurrences, and 15 patients (13%) developed a new pain in the inguinal region after the initial pain had resolved.

Conclusions The principles of CQI can be applied to a group of patients suffering from chronic pain after inguinal hernia repair. Based on these results additional process improvement ideas will be implemented in an attempt to improve outcomes.

Keywords Clinical quality improvement (CQI) · Inguinodynia · Chronic pain · Data science · Laparoscopy · Inguinal hernia

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Chronic pain is a well-recognized complication after open and laparoscopic inguinal hernia repair [1-6]. Due to the significant negative impact on a patient's quality of life and the incidence of chronic pain after inguinal hernia repair, it is considered a more significant complication than a hernia recurrence. Although the incidence of severe chronic pain that leads to disability and alters a person's ability to do work or enjoy leisure activities is probably less than 10%, this is still a major issue due to the large number of inguinal hernia repairs performed. In the US alone, the incidence of this complication predicts that tens of thousands of people suffer from this complication each year. Although hernia mesh has been identified as one contributing factor to the development of chronic pain after inguinal hernia repair, this is a very complex issue and it is clear that mesh alone is not the only factor involved. Most

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people who have a mesh placed for inguinal hernia repair do not develop severe, life altering chronic pain. Other factors that may contribute to the development of chronic pain include the surgical technique, the type of fixation and there are also patient factors that contribute to the development of chronic pain. One patient factor identified as a risk factor for the development of chronic pain after surgery is the emotional state of the patient pre-operatively [7]. Due to the many factors involved in the development of this complication, traditional methods for clinical research are inadequate to attempt to improve treatment outcomes because they are not designed to address this level of complexity. Other tools from systems and data science are much more appropriate to address complex problems like this.

Clinical quality improvement (CQI) and non-linear analytics are tools from systems and data science. These tools are designed for complex problems in a system that is constantly changing. These tools also accommodate the reality of biologic variability where a single device (i.e., hernia mesh) placed with a specific technique can result in very different outcomes for different patient sub-populations. 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. Specifically, prospective randomized controlled trials may not be appropriate for studying complex dynamic processes, such as patients with chronic pain after inguinal hernia repair, because there are many inherently uncontrollable variables that can influence interpretation of trial results. Rather, systems science tools, such as CQI and non-linear analytics, are increasingly recognized as more appropriate for measuring and improving patient outcomes. There is a peer-reviewed, published international guideline recommending that this is the case for improving outcomes for patients with a ventral/incisional hernia [8]. This should also be the case for patients with other medical conditions including patients with the complication of chronic pain after inguinal hernia repair.

Patient care models that define and measure patient outcomes in terms of value have been proposed by the US business community [9, 10]. By taking a systems science view of healthcare, patient care can be simplified by designing care around definable patient groups, diseases, and/or problems (patient care processes) [11]. 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 [9, 10]. 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 promoted since the Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996. Health care operations, including care coordination and quality improvement activities, are listed as an exemption from the HIPAA regulations as a part of the law. The principles of CQI were again supported in the Patient Safety and Quality Improvement Act of 2005. To help clarify the distinction between CQI and human subjects research, the US Department of Health and Human Services recognized that most quality improvement efforts do not require submission to the Institutional Review Board (IRB) and they have a list of frequently asked questions on their website distinguishing the differences between CQI and human subjects research including the fact that the intent to publish clinical outcomes that are generated from a CQI effort that is not considered human subjects research does not require an IRB submission [12].

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, FL, USA) 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. 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 hernia team with chronic pain after inguinal hernia repair and underwent a surgical procedure between April 2011 and June 2016 were offered a range of surgical and non-surgical management choices. Patients typically traveled from other states to obtain surgical treatment because it is not commonly available in most surgical practices. Patients were guided through a shared decision process with the help of a patient care manager and patient specialists.

Procedures

All patients received care from the diverse group of health professionals on our 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.

A single surgeon (BR) performed all surgical procedures. In some cases, a surgical resident and/or another attending surgeon assisted in the operation. The operations consisted of either a laparoscopic approach only or a combined laparoscopic and open approach. The laparoscopic approach involved a laparoscopic lysis of adhesions if intraabdominal adhesions were present, an exploration of the extraperitoneal space of the groin to remove mesh and any fixation devices, performing a neurolysis (if possible) and/or neurectomy (if nerves could not be separated from the fibrosis/mesh) for all involved nerves, and a suture closure for any remaining defect using absorbable suture. The open portion of the operation included excision of prior scar(s), excision of all mesh and fixation devices (including suture material) with neurolysis and/or neurectomy of any involved nerves, and primary reconstruction of the groin approximating three musculofascial layers using absorbable suture. One of the attempts at process improvement, included adding a long-acting local anesthetic nerve block during the operation. For the laparoscopic portion, a spinal needle is used to block the nerves in the extraperitoneal space (genital branch, femoral branch, and the lateral femoral cutaneous) using direct laparoscopic visualization. In the open approach, the nerve and field blocks include the genital branch, ilioinguinal nerves, and iliohypogastric nerves. A complete description of the surgical technique has been published previously [13].

Assessments

Outcome measures included the degree of pain improvement after recovery from the operation. Patients were asked to determine if they had total or near-total relief of their pain (significant), if there had some relief but still had some pain that required management (moderate), or if they had little or no improvement at all (little or none). Also, complications, inpatient versus outpatient, the development of a recurrent hernia, and the development of a new type of groin pain were recorded.

Statistical analysis

Descriptive statistics were used to describe the sample in regards to categorical and continuous variables. Means and standard deviation were reported for continuous variables. Frequency and percentage statistics were presented for categorical variables. χ^2 tests were used to find associations between categorical variables. Unadjusted odds ratios with 95% confidence intervals (95% CIs) were reported for χ^2 analyses. Skewness and kurtosis statistics were used to test the assumption of normality for continuous outcomes. An absolute value of 2.0 was used to assume normality. Homogeneity of variance was established for between-subjects comparison using Levene's test for equality of variances. Normal outcomes were compared between independent groups using independent samples *t*-*i*ests and one-way ANOVA. Principal component analysis (PCA) was used as a means of data reduction to better understand the underlying relationships between patient factors and treatment factors, and how much variance they accounted for with outcomes such as outpatient versus inpatient, hernia recurrence, complications, new pain development, and the degree of pain improvement. 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 0.5 or higher were interpreted. An oblique rotation was employed to more easily interpret the factors. All analyses were conducted using SPSS version 21 (Armonk, NY: IBM Corp.).

Results

The analysis population included 94 consecutive operations for chronic groin pain after elective inguinal hernia repair in 93 patients.

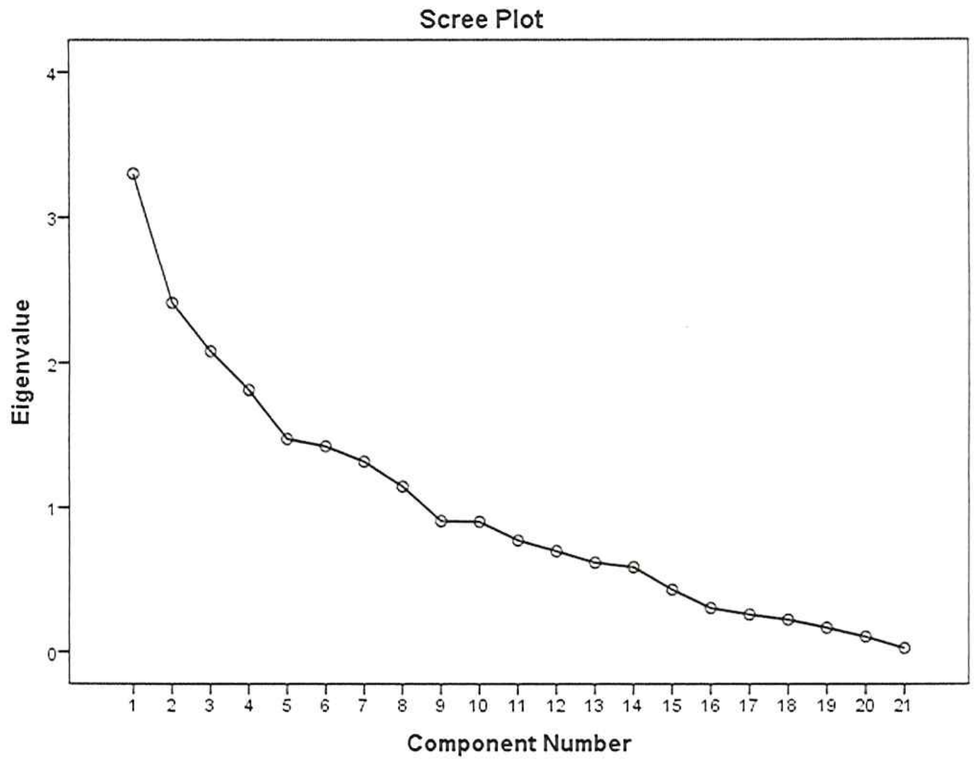


Fig. 1 Scree plot factors are evaluated to the point where the line begins to flatten after five in this case

Patient factors collected are listed in Table 1, treatment/process factors are listed in Table 2, and outcome measures are listed in Table 3. The results included the assessment of how much improvement was achieved after recovery from the operation. Forty-five patients (48%) reported significant improvement, 39 patients (41%) reported moderate improvement, and 10 patients (11%) reported little or no improvement. There were 3 (3%) peri-operative complications, 13 (11%) hernia recurrences, and 15 patients (13%) developed a new pain in the inguinal region after the initial pain had resolved.

Statistical assumptions of the PCA were met as per KMO and Bartlett's statistics. The PCA yielded a total of five factors/factor groups that accounted for 52.81% of the variance in the aforementioned outcomes (Table 4). The first factor group included low pressure pneumoperitoneum, pre-operative transversus abdominis plane (TAP) block by anesthesiologist, and intra-operative block by surgeon (15.72% of the variance). Then, one or more prior operations to relive pain accounted for 11.49% of the variance, followed by continued pain post-operatively and location (9.91%), BMI, smoking, and multiple prior hernia repairs (8.65%), and pre-operative use of one or more opioid medications (7.04%).

Additional bivariate comparisons between patient and treatment/process factors and specific outcomes. The following are the statistically significant findings (95% CI in parentheses): patients taking opioid medication pre-operatively were 70% less likely to be discharged on the day of surgery (23.60–88.21%), patients with at least one previous operation in an attempt to relieve pain were

Table 1 Patient factors

Total procedures (94)	
Gender	
Male, *n* (%)	75 (80)
Female, *n* (%)	19 (20)
Age: mean, years (range)	47.9 (19–81)
BMI: mean (range)	26.19 (16.9–40.4)
Current smoker, *n* (%)	14 (15)
Pre-operative opioid use, *n* (%)	39 (41)
Pre-operative on more than one opioid, *n* (%)	12 (13)
Multiple prior hernia repairs, *n* (%)	22 (23)
At least one prior operation for pain, *n* (%)	36 (38)
Multiple prior operations for pain, *n* (%)	19 (20)
First inguinal hernia repair	
Bilateral, *n* (%)	26 (28)
Left, *n* (%)	29 (31)
Right, *n* (%)	39 (41)
Pain developed	
After first hernia repair, *n* (%)	84 (89)
After second hernia repair, *n* (%)	10 (11)
Presentation of pain after repair	
Immediate, *n* (%)	52 (55)
Delayed, *n* (%)	42 (45)

Table 2 Treatment/process factors

Total procedures (94)	
Operative approach	
Laparoscopic, *n* (%)	26 (28)
Open, *n* (%)	68 (72)
Location of procedure	
Bilateral, *n* (%)	23 (24)
Left, *n* (%)	30 (32)
Right, *n* (%)	41 (44)
Pre-operative TAP block	
Yes, *n* (%)	35 (37)
No, *n* (%)	59 (63)
Intra-operative block	
Yes, *n* (%)	36 (38)
No, *n* (%)	58 (62)
Low pressure pneumoperitoneum	
Yes, *n* (%)	35 (37)
No, *n* (%)	59 (63)

Table 3 Outcome measures

Total procedures (94)	
Complications	
Intra-operative, *n* (%)	2 (2)
Post-operative, *n* (%)	1 (1)
Total, *n* (%)	3 (3)
Pain improvement	
Significant, *n* (%)	45 (48)
Moderate, *n* (%)	39 (41)
Little or none, *n* (%)	10 (11)
Total groins operated on 117	
Recurrent hernia	
Yes, *n* (%)	13 (11)
No, *n* (%)	104 (89)
New pain	
Yes, *n* (%)	15 (13)
No, *n* (%)	102 (87)

63.9% less likely to be discharged on the day of surgery (8.00–85.80%), patients who had low pressure pneumoperitoneum were 7.81 times more likely to be discharged on the day of surgery (2.85–21.43), patients who had low pressure pneumoperitoneum were 80.5% less likely to develop a new type of groin pain post-operatively (8.40–95.90%), patients who had an intra-operative nerve block were 7.81 times more likely to be discharged on the day of surgery (2.85–21.43), and patients who had an intra-operative nerve block were 80.50% less likely to develop a new type of groin pain post-operatively (8.40–95.90%).

Discussion

There have been only a few published reports of laparoscopy being used as a part of the surgical management of chronic pain after inguinal hernia repair [14–16]. There are no publications describing the use of systems science tools such as CQI and non-linear analytics in an attempt to learn how to improve the outcomes for this problem. The main findings of this CQI project suggest that implementing the principles of CQI can allow us to measure the outcomes of patient care for a complex patient care process like chronic pain after inguinal hernia repair. As a part of the CQI process, the impact of any attempt to improve outcomes such as adding new components to the multimodal pain management regimen (e.g., bilateral TAP blocks and intra-operative inguinal blocks with long-acting local anesthetic) can be measured in a variety of ways. Although not yet a part of our outcome measurement, financial data, including total costs of care should be collected and analyzed so we can develop a true measurement of value for the entire care process. Another opportunity for the application of CQI is to develop better measurement tools. In this project, we identified that the emotional state of the patient pre-operatively could be a significant factor that contributes to the outcomes. Figure 2 shows the measurement tool we developed working with social workers and other experts to attempt to better define what cognitive issue each patient is dealing with. We have recently implemented mandatory pre-operative cognitive therapy prior to offering an operation. This is another attempt to improve outcomes based on our own data and evidence from other research looking at factors that influence the intensity of acute pain and the outcomes for the treatment of chronic pain [17, 18].

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. Analytic techniques that attempt to demonstrate the significance of a number of variables include 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 potentially be modified in an attempt to improve outcomes and to assess the impact of the implementation of process improvement ideas. 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 analysis) is best performed by the team of people who contribute to the care of this patient group. The combination of a team of people

Table 4 The factor combinations that accounted for the majority of variance in outcomes measured

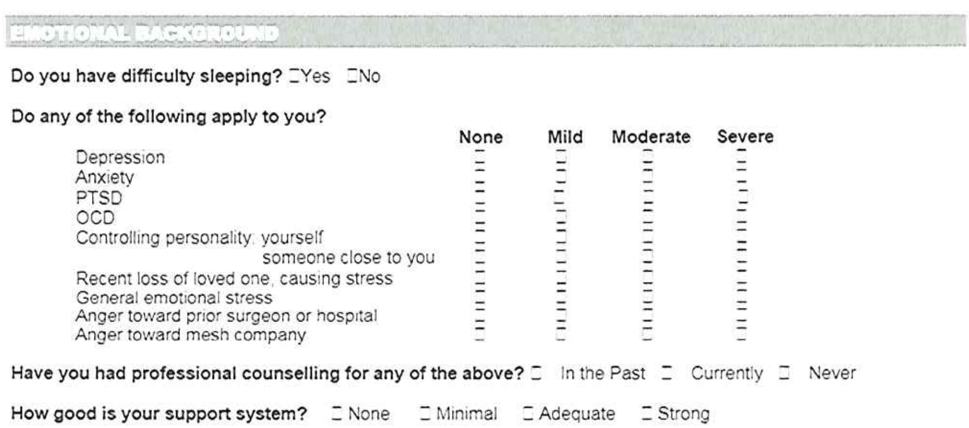
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Airseal	0.876				
TAP block	0.824				
Intra-operative block	0.891				
Operation to relieve pain		−0.870			
Multiple operations to relieve pain		−0.816			
Groin pain after repair			0.925		
Location			0.945		
BMI				0.602	
Smoking status				−0.639	
Multiple hernia repairs				−0.762	
Narcotic medications					−0.778
Multiple narcotic medications					−0.801

who program what goes in and interpret what is generated from this variety of computing capabilities and the computing capability itself is one interpretation, which is what is called machine learning (also known as artificial intelligence).

From this PCA, we can see that there were five groups of factors that were correlated (positively or negatively) with outcomes. The closer a number is to +1, the more positively correlated with the outcomes measured and the closer to −1, the more negatively correlated with the outcomes measured. In the first group of factors, low pressure pneumoperitoneum (0.876), TAP (0.824), and intra-operative (0.891) local anesthetic blocks were positively correlated with good outcomes (day of surgery discharge, relief of pain, lack of complications, etc.). The second group of factors, one prior operation to relieve pain (−0.870) and multiple prior operations to relieve pain (−0.816) were negatively correlated with good outcomes. In the third group of factors, relief of pain post-operatively (0.925) and location, left groin (0.945) had strong positive correlations. However, these two factors may not have as much importance as the others. The fact that relief of pain post-operatively is correlated with other positive outcomes is not surprising and a location (R, L, or bilateral) having a positive correlation may be a spurious correlation. The fourth group of factors have two negative correlations with outcomes, smoking (−0.639) and multiple prior hernia repairs (−0.762) and one positive correlation, BMI (0.602). The fifth set of factors showed a negative correlation when patients are taking one (−0.778) or more (−0.801) opioid medications pre-operatively.

There were three significant peri-operative complications that occurred. Two patients had injuries to the iliac vein during mesh excision, one laparoscopic and one open. One (laparoscopic injury) was repaired laparoscopically with a vascular surgeon available, the other (open injury) was repaired by a vascular surgeon. Both patients were discharged on post-operative day 1 and had no sequelae from their injuries. One patient who had a lap and open procedure developed a wound infection that required operative drainage done by another surgeon closer to his home. The patient healed well and has had no other complication.

Based on this analysis, there are several opportunities to implement improvement ideas. The use of long-acting local anesthetic and low pressure pneumoperitoneum have


EMOTIONAL BACKGROUND

Do you have difficulty sleeping? ☐Yes ☐No

Do any of the following apply to you?

	None	Mild	Moderate	Severe
Depression	☐	☐	☐	☐
Anxiety	☐	☐	☐	☐
PTSD	☐	☐	☐	☐
OCD	☐	☐	☐	☐
Controlling personality: yourself	☐	☐	☐	☐
someone close to you	☐	☐	☐	☐
Recent loss of loved one, causing stress	☐	☐	☐	☐
General emotional stress	☐	☐	☐	☐
Anger toward prior surgeon or hospital	☐	☐	☐	☐
Anger toward mesh company	☐	☐	☐	☐

Have you had professional counselling for any of the above? ☐ In the Past ☐ Currently ☐ Never

How good is your support system? ☐ None ☐ Minimal ☐ Adequate ☐ Strong

Fig. 2 Questions assessing emotional state of the patient pre-operatively appeared to improve outcomes. We now only perform intra-operative blocks because our hernia program moved to another location where anesthesia does not offer a TAP block pre-operatively. It will be interesting to see if this has any impact on our outcomes. We will also be adding the costs of care (including some increased costs of care for the low pressure pneumoperitoneum systems and the long-acting local anesthetic) to see if the additional costs of some process improvement attempts are offset by other outcome improvements in measures such as length of stay and complications. Several of the outcomes suggest that pre-operative cognitive therapy might aid in the improvement of outcomes. For patients who had multiple prior hernia repairs and one or more prior operations to relieve pain, these patients might have some PTSD type of symptoms or other cognitive issues that are negatively impacting outcomes. Smoking cessation and opioid cessation as part of a prehabilitation program prior to surgery might also lead to improved outcomes based on this analysis. We have begun to implement these requirements prior to surgery in addition to pre-operative cognitive therapy. The positive correlation between increased BMI and better outcomes is interesting and is reflected in the mean BMI for this group of patients who presented with chronic pain after hernia repair. It might be appropriate to counsel patients who present with an inguinal hernia who have a low BMI that this factor may contribute to an increased risk of chronic pain. Using the principles of CQI and non-linear analytics over time can lead to ideas for prevention of whatever disease process is being evaluated, in this case chronic pain after inguinal hernia repair.

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 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

The principles of CQI can be applied to a group of patients suffering from chronic pain after inguinal hernia repair. Based on these results and the analysis of these results, additional process improvement ideas will be implemented in an attempt to improve outcomes.

Compliance with ethical standards

Disclosures Bruce Ramshaw has received honoraria and/or consulting fees for providing speaking and/or advisory services for WL Gore, Medtronic, Ethicon, Pacira, Acelity, B Braun, Atrium, BG Medical ConMed, and Ariste Medical. He is also Founder and a Shareholder in CQInsights, a healthcare data analytics company. Brandie Forman is a Founder and Shareholder in CQInsights. Matthew Mancini has received honoraria for providing speaking services from Olympus, Medtronic, WL Gore, Pacira, and Mallinckrodt. Eric Heidel has received consulting fees for consulting services from CQInsights. Vincent Vetrano and Mayuri Jagadish have no conflicts of interest or financial ties to disclose.

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