Patient Safety and Quality Improvement Initiatives in Contemporary Metabolic and Bariatric Surgical Practice

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KEYWORDS

• Bariatric surgery • Patient safety • Quality improvement • Outcomes

KEY POINTS

- Patient safety and quality improvement have been part of bariatric surgery since its inception.
- A strong accreditation program exists in bariatric surgery (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program [MBSAQIP]), as a result of the merger of the American Society for Metabolic and Bariatric Surgery (ASMBS) and American College of Surgeons (ACS)-led programs.
- Accreditation has been shown to have a favorable impact on outcomes of bariatric surgery, including, morbidity, mortality, length of stay, failure to rescue, and costs.
- Bariatric surgery lends itself well to improvements in processes and use of perioperative protocols, such as ulcer and thromboembolic prophylaxis prevention or gallstone prevention and management.
- With a comprehensive data reporting requirement, MBSAQIP provides a strong platform for quality improvement initiatives, such as the decrease in readmissions project from ASMBS.

INTRODUCTION

Quality improvement has been a core aspect of surgery for more than a century. In 1910, Ernest A. Codman, envisioned that poor outcomes could be linked to the absence of adequate patient records and resultant lack of feedback on patient's ultimate outcomes. When the ACS was founded 3 years later, Dr Codman was appointed to chair a committee on hospital standardization. This led to the 1919 minimum standard document.[1] This short document already describes the necessity for

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"accurate and complete records be written for all patients and filled in in an accessible manner in the hospital." This document ultimately led to the creation of the Joint Commission on Accreditation of Hospitals in 1951 and the Joint Commission on Accreditation of Healthcare Organizations in 1987. But beyond this, the idea he developed of adequately documenting outcomes to learn from them is the cornerstone concept behind the ACS National Surgery Quality Improvement Program. This program takes the concept one step further, however, allowing obtaining standardized data on a larger scale to better analyze outcomes and benchmark current results to population means. As surgical outcomes have improved, the amount and detail of data necessary to detect improvements and outcomes are constantly increasing. In 1999, the Institute of Medicine published a report, "To Err is Human."[2] This research on medical errors in the United States highlighted the fact that preventable medical errors in hospitals exceeded the number of deaths from motor vehicle accidents or breast cancer. This report served as a wakeup call, leading to multiple initiatives ranging from government to nonprofit organizations and to health care providers.

PATIENT SAFETY AND QUALITY IMPROVEMENT IN BARIATRIC SURGERY

As discussed previously, the first and necessary step to improving quality is to have a means of accurately measuring outcomes. As a young specialty, bariatric surgery was born in the era of quality improvement and patient safety and rapidly adopted its own programs: the ACS and the ASMBS created 2 parallel accreditation programs for bariatric surgery in 2004 and 2005. These programs have now merged their accreditation systems to create the MBSAQIP in 2013.[3] More than 800 centers currently participate in MBSAQIP and more than 650 bariatric surgery centers are accredited throughout the United States. This program, however, is not limited to a database. If the reporting of outcomes is a cornerstone of this program, it also focuses on quality improvement: it emphasizes surgeon leadership and multidisciplinary teams and defines and monitors the current bariatric center accreditation process. These features relate back to the principles defined by Avedis Donabedian, whereby quality of health care can be assessed by measuring aspects of structure, processes, and outcomes.

Bariatric surgery outcomes have followed a significant improvement in mortality and morbidity over the past 15 years. Between 1998 and 2004, the number of cases performed increase practically 10-fold whereas inpatient mortality decreased by nearly the same amount (0.2% to 0.03%).[4] Since then, the implementation of center accreditation as led to further improvements. The different aspects of quality improvement in bariatric surgery are described.

ACCREDITATION

Accreditation is a core feature of quality in surgery. It addresses all 3 aspects: structure, processes, and outcomes. Accreditation has also been topical in bariatric surgery for more than a decade. The Centers for Medicare and Medicaid Services (CMS) had initially made accreditation a prerequisite for reimbursement of bariatric surgery procedures. This policy has recently been reverted by CMS; however, all major insurers require bariatric surgery center accreditation and the preponderance of evidence clearly supports accreditation. Furthermore, without a requirement for accreditation, hospitals would be reluctant to provide resources to maintain data collection.

To be an accredited MBSAQIP center, all programs must report their outcomes to a centralized database. These should include all bariatric surgeries performed and require a minimum 90-day follow-up. All potential adverse events are clearly

predefined, such as superficial versus deep surgical site infections, blood transfusions, and reoperations. In addition, data are collected by members independent of the care team.

The centers also need to meet core standard requirements. These requirements are different depending on the level of the center, defined as low-acuity centers versus comprehensive centers. Low-acuity centers are accredited to perform bariatric surgery, but the revisional procedures or high-risk patients are reserved for comprehensive centers. The fundamental difference between the 2 types of centers is focused on minimal annual volumes of procedures performed as well as resources available. If low-acuity centers must perform a minimum of 25 bariatric procedures every year procedures every year, comprehensive centers must perform a minimum of 50 cases annually to be accredited as such. High-risk patients are defined for this purpose as adults over the age of 65, men with a body mass index greater than 55 kg/m^2, women with body mass index greater than 60 kg/m^2, transplant patients, or patients with organ failure. Case volume constitutes the first of 7 core standards defined for accreditation. The other standards are commitment to quality of care, appropriate equipment and instruments, 24/7 critical care support, continuum of care, data collection, and continuous quality improvement process (**Table 1**). The rationale for case volume has also been settled law but has long been a debated topic in the surgical literature. A recent systematic review did show a positive association between high-volume centers and high-volume surgeons and patient outcomes.[5] Some modest discrepancy existed, however, among the studies cited, with 5 of the 24 studies failing to show association.[6–10] Prior minimum annual case requirements for bariatric surgery centers of excellence were higher (100 cases per 24 month/surgeon and more than 125 cases per institution/year). These cases did not differentiate, however, between a Roux-en-Y gastric bypass and a gastric band placement, for example. A more recent study, using the most recent MBSAQIP volume cutoff numbers, supports these new requirements by demonstrating a 2.5-times decrease in mortality in higher-volume centers.[11] Furthermore, the increased mortality appears to be more significant in higher-risk patients, supporting the requirement for these patients to undergo surgery at comprehensive centers. In a historical study by Flum and colleagues[12] the mortality rates for patients greater than 65 years old was 9% at 30 days and 21% at 1 year if volume was less than 15 cases/y, compared with 2.2% and 5.0% in patients younger than 65 years. This is compared with higher procedures performed in higher-volume centers with mortality rates of 1.1% and 3.6% in patients over 65% and 1.2% and 3.1% in the younger patients.

Impact of Accreditation

Multiple studies have established the impact of accreditation on bariatric surgery outcomes. Five of them have shown a reduction in mortality compared with nonaccredited centers, reductions ranging between 2.26-fold and 3.5-fold.[11,13–16] Regarding complications, only 1 study showed an increase in serious morbidity (odds ratio 0.84) in accredited centers.[11] However, 6 other recent studies have demonstrated a reduction in morbidities when bariatric surgery is performed in an accredited center. These studies encompass data for more than 430,000 patients with odds ratios ranging from 1.09 to 1.39.[14,15,17–20] Studies comparing accredited and nonaccredited centers also demonstrated an improvement in other outcomes: reduction in reoperation from 3.2% to 2.1%[21]; reduced readmission rates: 19.9% to 15.4%[21]; payments ($24,363 to $19,746)[21]; and length of stay: 3.5 versus 3.1 days.[19]

Another concept increasingly taken into consideration is “failure to rescue.” This metric is tracked and defined by the Agency for Healthcare Research and Quality

Table 1
Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program core standard requirements

Standards	Requirements				
Case Volume	Depends on center designation (see text)				
Commitment to quality care	Bariatric committee, including a director/ surgeon, a coordinator, a clinical reviewer	Facility accreditation (Joint Commission)	Surgeons • Credentialed in bariatric surgery • Undergo annual verification • Cover a bariatric call schedule	Clinic and inpatient • Designated area available • Trained nursing staff	Multidisciplinary specialized team, including • Nursing staff • Registered dieticians • Psychologists/psychiatrists • Physical therapists
Appropriate equipment and instruments	Extremely detailed and includes every aspect of care: operating room tables, imaging equipment, blood pressure cuffs, adequate bedding, showers, toilets, etc.				
Critical care support	Presence of Advanced Cardiovascular Life Support qualified provider	Stabilization and transfer capabilities	Established protocols and availability for bariatric patient management • Anesthesia • 24/7 Critical/intensive care unit • Endoscopy • Diagnostic and interventional radiology		Written transfer agreement to transfer patients to a facility providing services, such as interventional radiology if not available on site
Continuum of care	Use of clinical education and perioperative protocols			Long-term follow-up and available support groups	
Data collection	See text.				
Continuous quality improvement process	Maintain a collaborative between all bariatric surgeons in the institution		Minimum of 1 quality improvement initiative per year		Continuous monitoring of safety and outcomes

and takes into account the mortality rate in patients having experienced a serious complication, such as pulmonary embolism, sepsis, or acute bleeding.[22] This metric has a potential for increased sensitivity to detect adverse events compared with complications alone for example. The authors' group has previously demonstrated a reduction of approximately 50% of failure to rescue bariatric surgery patients in accredited versus nonaccredited centers.[15]

PROCESSES AND QUALITY IMPROVEMENT

Many of the processes commonly used in bariatric surgery are part of the accreditation requirements, notably the need for multidisciplinary teams and patient assessment. Also, the preoperative patient evaluation and patient selection are discussed in another article in this issue (See Guerron Cruz AD, Portenier DD: Patient Selection and Surgical Management of High Risk Patients with Morbid Obesity, in this issue). It is, however, important that the difference between the 2 tiers of accreditation (ie, comprehensive and low-acuity centers) revolves around the ability to manage high-risk patients. It is, therefore, important to carefully evaluate patients preoperatively to determine the risk status and ensure they are treated in the facility most adequate to their risk profile.

As discussed later in the paragraph about decreasing remissions, the nature of bariatric surgery lends itself well to standardization of perioperative management. Some aspects of these processes are highlighted.

Deep Venous Thromboembolism Prevention

Pulmonary embolism (PE) remains one of the leading causes of postbariatric surgery mortality.[23] According to the Rogers score,[24] all laparoscopic sleeve gastrectomy or Roux-en-Y gastric bypass patients are considered medium risk for venous thromboembolism (VTE). This score uses preoperative factors to determine VTE/PE risk, with 7 points medium risk and 10 representing a high risk for deep venous thrombosis/PE. A procedure with a relative value unit greater than 17, gastrointestinal surgery, and a clean/contaminated wound is sufficient to add up to a score of 8, which constitutes an intermediate risk. This risk is often higher in the authors' patient population because an American Society of Anesthesiologists (ASA) score of 2 is an extra point, an ASA score of 3 or more is 2 points, and female gender adds 1 point. These risk factors common occurrences and these patients are considered high risk based on this score. Based on this evaluation and others,[25] VTE prophylaxis is, therefore, warranted for all patients undergoing a Roux-en-Y gastric bypass or a sleeve gastrectomy. The type of prophylaxis however is still somewhat debated. The most recent guidelines[26,27] recommend that all bariatric patients receive at least mechanical prophylaxis (intermittent pneumatic compression) and early ambulation. All high-risk patients (defined by 1 of the previous scores) should, in addition, receive chemoprophylaxis in the form of low-molecular-weight or unfractioned heparin. This includes, for example, an ASA 2 female patient.

Ulcer Prophylaxis

In patients undergoing Roux-en-Y gastric bypass, an additional risk exists regarding the development of marginal ulcers at the gastrojejunostomy site. The reported incidence of this pathology ranges from 0.6% to 25%.[28] The pathogenesis is still unclear, but acid exposure as well as mucosal ischemia in the pouch are likely causes of marginal ulcer development. Multiple recent studies have tried to identify risk factors for the development of these ulcers: diabetes and smoking or nonsteroidal anti-inflammatory drugs seem the most commonly reported risk factors, but other

risk factors include history of peptic ulcers, use of nonabsorbable sutures, corticosteroids, *Helicobacter pylori*, and hypertension.[28–35] Even if the pathophysiology and risk factors are debated, the literature regarding the use of postoperative prophylactic proton pump inhibitors is rather unanimous.[36–40] This has also resulted in a wide adoption of proton pump inhibitor prophylaxis after Roux-en-Y gastric bypass: a recent international survey showed that approximately 90% of bariatric surgeons prescribe prophylaxis for 30 to 90 days postoperatively.[41] The authors currently systematically prescribe 6 months of proton pump inhibitors to all bariatric surgery patients.

Gallstone Prophylaxis

Contrary to ulcer prophylaxis, the management of gallstone prophylaxis is significantly debated and varies significantly. The increased risk of gallstone formation with rapid weight loss after bariatric surgery is not disputed. Prevention strategies vary, however, and can be summarized as follows: chemoprophylaxis alone, selective cholecystectomy at the time of bariatric surgery (based on the presence of gallstones on systematic preoperative ultrasound), or systematic cholecystectomy in all bariatric surgery patients. The discussion regarding prophylactic cholecystectomy is outside of the realm of this article. A large retrospective study, however, of more than 20,000 cholecystectomies in bariatric surgery patients, recently advocated for systematic cholecystectomy[42] whereas a recent meta-analysis on more than 6000 patients showed a cholecystectomy rate of 6.8% after gastric bypass, with 0% mortality and 1.8% morbidity.[43] Common bile duct pathologies occurred in 0.2% of cases for common bile duct stones and 0.2% for biliary pancreatitis. The impetus for some form of gallstone prophylaxis is, therefore, not contested. From quality and process perspectives, it is important to have a systematic protocol in place for the management of this issue: if cholecystectomy is not performed at time of gastric bypass surgery, chemoprophylaxis in the form of ursodiol should be systematically used. Ursodiol has been demonstrated to significantly reduce the incidence of symptomatic/gallstone formation, from 32% to 2%, and a recent meta-analysis also showed a significant reduction, with 8.8% of patients on prophylaxis developing gallstones compared with 27.7% for placebo.[44–46]

PROCESS IMPROVEMENT: DECREASING READMISSIONS THROUGH OPPORTUNITIES PROVIDED

In the past decade, the field of bariatric surgery has made significant gains in improving quality. Since the advent of hospital and center-based accreditation in 2007, both mortality and serious complications have decreased substantially. Currently, individual serious complications, such as anastomotic leak, small bowel obstruction, venous-thrombotic events, and myocardial infarction, all are less than 1%, according to the 2014 MBSAQIP data registry.

An area for potential quality improvement for metabolic and bariatric surgery is 30-day readmissions after principal operative surgical procedures. This particular outcome has become an outcome of interest for payers, including the CMS and others.

Additionally, all-cause 30-day readmissions are a metaoutcome, incorporating multiple elements of care, including complications, cost, and physician and patient satisfaction. At this time, the MBSAQIP data registry reports that all-cause 30-day readmissions are at approximately 5%, indicating an opportunity for improvement. Furthermore, the new MBSAQIP standards call for each center to actively participate in a quality improvement project, and the Decreasing Readmissions through

Opportunities Provided (DROP) project is in alignment with this (see "Standard 7: Continuous Quality Improvement Process" from *Resources for the Optimal Care of the Metabolic and Bariatric Surgery Patient 2014*).[47]

Several metabolic and bariatric surgery programs have demonstrated improvement in 30-day readmissions through better coordination of care, as indicated in the 2013 Obesity Week readmissions symposium. For example, the Stanford Bariatric Surgery Program reported a 69% decline in 30-day readmissions after implementing a readmission bundle. In the 2013 Obesity Week forum, current best practices were identified. The coordination of care incorporates the 3 phases of operative care: preoperative, inpatient, and postoperative. The DROP program provides a specific toolkit and standardization, which address 30-day readmissions in all phases of operative care, which include

DROP readmission bundle for metabolic and bariatric surgery patients

- Preoperative
  - Education video modules (surgeon, nurse, nutrition, psychologist, pharmacy)
  - Postoperative prescription given
  - Postoperative visit scheduled
  - On-call and clinic phone numbers given
- Inpatient
  - Clinical roadmap implementation
  - Discharge checklist completed
  - Nutritional consult
- Postoperative
  - Follow-up phone call completed
  - Postoperative visit with surgeon and nutritionist completed
  - Primary care provider letter sent
  - Monthly readmissions review

The goal of the project is to decrease 30-day all-cause readmissions for primary bariatric procedures by 20% nationally.

Program inclusion criteria:

- Participation in a comprehensive accredited MBSAQIP program
- Agreement to participate in complete hospital survey and monthly webinars and provide hospital specific and collaborative data to complete the project
- Complete custom fields in the MBSAQIP Data Registry for the readmission bundle

The completion of DROP is anticipated in March 2016, with full analysis completed in September 2016. In addition to demonstrating reduction of readmissions, it is anticipated that patient satisfaction may increase based on the higher level of coordination of care provided by DROP centers.

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