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Effects of a comprehensive bariatric program implementation on 30-day readmission and 30-day ER/infusion clinic visit rates due to dehydration

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Abstract

Background: Program accreditation requires adherence to MBSAQIP standards to assist patient in making needed changes to his/her diet and lifestyle. However, literature provides conflicting information regarding the value of a comprehensive bariatric program accreditation and its effects on 30-day readmission and 30-day ER/infusion clinic visit due to dehydration development.

Objectives: To examine the effects of implementing a comprehensive bariatric surgical program on 30-day readmission rates, and 30-day emergency room (ER) and infusion clinic visit rates due to dehydration for bariatric surgical patients.

Methods: Our study was a retrospective separate sample pre-post intervention chart review. The data were collected before and after implementing a comprehensive bariatric program using a convenience sample of 180 adult patients (age ≥18) that had bariatric surgery at an acute care hospital. We conducted Chi-square analyses with significance levels set at 0.05.

Results: Among the 180 patients, majority had laparoscopic gastric bypass (n=112, 62.2%). Among the 180 patients, 55 (31%) were in the pre-intervention and 125 (69%) were in the post-intervention group. A total of 7 (3.9%) had 30-day readmission. Significantly more patients (n=5, 9.1%) in the pre-intervention group had 30-day readmission compared to those in the post-intervention group (n=2, 1.6%; X^2=5.73, p=0.03). Among the 180 patients, 8 (4.4%) had 30-day ER/infusion clinic visit due to dehydration. No difference was found in 30-day ER/infusion clinic visit between the pre-intervention (n=5, 9.1%) and the post-intervention groups (n=3, 2.4%; X^2=4.03, p=0.06).

Conclusion: Implementation of comprehensive bariatric program was effective in lowering 30-day readmission rates.

Background

As the volume of patient undergoing bariatric surgery increases, it becomes increasingly important to measure and monitor surgery outcomes and readmissions rates. The American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS) developed the Metabolic and Bariatric Surgery Accreditation Quality Initiative Program (MBSAQIP, 2014) that provides standards and guidelines for the care of bariatric patients and bariatric program accreditation. Given the complex causes of obesity, associated comorbidities and the interplay of physical, psychological, social, and emotional issues involved in the development and treatment of obesity, it is important that hospitals providing bariatric surgery follow the MBSAQIP guidelines, collect, analyze, and learn from the data on 30-day readmissions, 30-day ER/clinic visits, and complications.

As a measurable indicator of quality, 30-day readmission is a meta-outcome that touches on patient/physician satisfaction, cost, coordination of care, and complications (Morton, 2014). The hospital 30-day readmission rate prior to the development of a comprehensive bariatric program in our study was 4.96% for the year 2014. Literature review on 30-day readmission rates provides rates ranging from 2.9% to 15.7%. However, there are no data on the rate of 30-day dehydration development with subsequent visits to ER or infusion clinic. Our hypothesis was that 30-day ER and infusion clinic visit rates due to dehydration are closely linked to the same factors as 30-day readmission and we will see positive effects of comprehensive program implementation.

Problem Statement

Bariatric patients need to make life long changes to diet and life style to be successful in weight loss, and are most vulnerable to the development of postoperative complications such as

nausea, vomiting and dehydration within the first 30 days following surgery due to postoperative changes in their stomach and the rest of the gastrointestinal system (Gallagher Camden, 2009). Interestingly, there is ongoing research aimed at understanding the causes of obesity and the ways that obesity affects an individual's health (CDC, 2015, Morton, 2014). However, little is known about how a comprehensive bariatric program affects 30-day readmission rates and dehydration. Most readmissions and ER visits occur within a few days or weeks following the operation (Brethauer et al., 2015; Garg et al. 2016). Our hospital has been offering bariatric surgeries for several years, but only developed and implemented the elements of a comprehensive bariatric program in June of 2015 that lead to MBSAQIP accreditation in December of 2015.

Purpose

The purpose of this study was to examine the effects of the development and implementation of a comprehensive bariatric surgical program as per MBSAQIP guidelines on the 30-day readmission rates and 30-day ER and infusion clinic visit rates due to dehydration for bariatric surgical patients in an acute care hospital.

Specific Aims

The specific aims of the study were to:

1. Measure the 30-day readmission rate in bariatric surgical patients before and after the development and implementation of a comprehensive bariatric program.

2. Measure the 30-day ER and infusion clinic visits rates in bariatric surgical patients before and after the development and implementation of comprehensive bariatric program.

Hypotheses

1. There is a difference in the 30-day readmission rate in bariatric surgical patients that receive surgery before versus after the development and implementation of a comprehensive bariatric surgical program.
2. There is a difference in the 30-day ER and infusion clinic visit rates due to dehydration in bariatric surgical patients that received surgery before versus after the development and implementation of a comprehensive bariatric surgical program.

Significance

Reducing 30-day readmissions and 30-day ER visits due to dehydration after bariatric surgery is important for patients, physicians and organizations because they lead to additional time spent in ER and/or hospital, additional treatments and interventions, and increase financial costs for both the patient and the organization. The usefulness of the data analysis on 30-day readmissions and 30-day ER/clinic visits as a measure of quality of care is founded in the belief that readmissions and ER/clinic visits might have been prevented by implementing standardized care and improving preoperative and postoperative patient education. (El Chaar, 2014; Wilson, Gomberawalla, Mahoney, & Lutfi, 2014). In addition to expanding the current knowledge base regarding 30-day readmission rates, this study fills the gap about the influence of developing and implementing a comprehensive bariatric program on 30-day all-cause readmission rates and 30-day ER/infusion clinic visits due to dehydration. The data analysis allowed for 30-day readmission and 30-day ER/infusion clinic rates comparison before and after the implementation of a comprehensive bariatric program within the same hospital.

Literature Review

Literature Review on Accredited Comprehensive Bariatric Program

Current literature provides conflicting information regarding the value of the development and implementation of a comprehensive bariatric program and accreditation and overall impact on surgery outcomes (Blackstone, Dimick & Nguyen, 2014). Before MBSAQIP accreditation, the ASMBS accredited programs as centers of excellence (COE). Livingston (2009) compared the outcomes of patients undergoing bariatric procedures in hospitals designated as COE compared with non-designated hospitals using the 2005 National Inpatient Survey (NIS) from the Agency for Healthcare Research and Quality (AHRQ). In this study, the author reports the same complication rate of 6.3% for both groups. However, Blackstone et al. (2014) studied post-surgery outcomes for 47,030 Medicare insured bariatric patients in non-accredited and accredited bariatric surgery centers and examined the value and impact of accreditation on surgical outcomes such as 90-day readmission rate and 90-day mortality and found that accreditation leads to better outcomes. Blackstone et al. (2014) refuted the findings from the Livingston (2009) study emphasizing that the development and implementation of a comprehensive bariatric program and accreditation by ASMBS and ACS maximized safe care and resulted in better outcomes. Similar findings were reported by Nguyen et al. (2012) who analyzed the perioperative outcomes of 35,284 bariatric surgery patients, such as in-hospital mortality, length of stay, 30-day readmission, overall complications and cost, performed at accredited versus non-accredited academic centers, and found that the rate of in-hospital mortality was significantly lower in accredited centers. Not surprisingly, Dumon, Edelson, Raper, Foster-Kilgarriff and Williams (2011) reported a significant reduction in 30-day readmission rates from 15.7% to 8.1%, and a reduction in overall complication rates from 18.6%

to 4.8% after the implementation of a comprehensive bariatric program. Similarly, Gebhart, Young, Phelan, and Nguyen (2013) compared rates of in-hospital mortality after the bariatric surgery outcomes in accredited and non-accredited centers for 277, 068 patients and found that patients who had surgery in non-accredited centers had higher rates of serious complications and there was threefold increase of in-hospital mortality at non-accredited centers. Furthermore, a study by Talem et al. (2014) showed that accreditation is associated with fewer major complications when compared to unaccredited hospitals and within the same hospital compared to pre-accreditation. In the systematic review done by Azagury and Morton (2016) authors evaluated the impact of bariatric accreditation on surgical outcomes for 1.5 million bariatric patients included in thirteen studies. Ten out of the 13 studies identified substantial benefit of accreditation on reducing mortality and morbidity. Also, Kwon et al. (2012) reviewed the overall impact of accreditation on safety and outcomes after bariatric surgery and reported that there were reductions in inpatient mortality and readmission rates in the accredited bariatric centers.

Literature Review on 30-Day Readmission Rates

Han et al. (2007) conducted the retrospective review on 835 bariatric patients and reported a 3.2% 30-day readmission rate. Similar 30-day readmission rate of 2.9% was reported by Li et al. (2015) who conducted a retrospective review of 2,399 bariatric patients' charts at a single, high volume, multicenter regional integrated healthcare delivery system. Additional studies, such as El Chaar, Claros, Ezeji, Miletic, and Stoltzfus (2014) examined the feasibility and safety of clinical pathways in managing patients undergoing bariatric surgery at MBSAQIP accredited center and reported a 3.0% 30-day readmissions rate for all readmissions, including patients who were admitted for observation and stayed less than 24 hours. Meanwhile, Wilson, Gomberawalla, Mahoney, and Lutfi (2014) conducted a retrospective study to determine what, if

any, demographic or technical factors influence 30-day readmission rates for patients that had sleeve gastrectomy surgery. The authors reported that 21 patients had an ER visit (10.5%) and 12 patients were readmitted (6%) within 30 days following surgery. However, this study had limited representativeness because the patient population consisted of sleeve gastrectomy patients only. Similarly, Garg et al. (2016) reported a 5.2 % 30-day readmission rate, for 18,296 patients in their study that included patients who underwent either LGB, LSG or laparoscopic band placement. In prospective study done in non-accredited bariatric center by Barecca, Renzi, Tankel, Shalhoob, and Sangupta (2015) authors found overall 30-day readmission rate of 4.9% for 288 patients that had either LGB or LSG surgery. Interestingly, in a comprehensive review by Patterson, Peoples, Foster and Gesten (2014) on the 30-day readmission for 10,448 bariatric surgery patients the authors reported an overall rate of 5.3%, with open gastric bypass patients having the highest readmission rate (8.8%). They reported that the laparoscopic gastric bypass readmission rate was 6.1% and the sleeve gastrectomy rate was 4.3%. But, the limited applicability of this study to our research hypotheses lies in the fact that they included laparoscopic band surgery in overall 30-day readmission rate while our study excluded patients that has laparoscopic band surgery due to low number of surgeries.

In summary, the literature review of 30-day readmission rates provides a wide range of rates on 30-day readmission for open gastric bypass, laparoscopic gastric bypass surgery and laparoscopic sleeve gastrectomy patients that ranges between 6.3% and 15.7% in non MBSAQIP accredited centers (Dumon, Edelson, Raper, Foster-Kilgarriff &Williamd, 2011; Han et al. 2007; Li et al. 2015; Barreca et al. 2015) and between 2.9% and 6.1% at MBSAQIP accredited centers (El Chaar et al. 2014; Wilson et al. 2014, Doumouras, Saleh & Hong, 2015).

Theoretical Foundation

Self-Determination Theory (SDT)

The Self-Determination Theory (SDT) explains the relationship between psychological variables and the patient's perception of self-control over health practices and his/her ability to control socioenvironmental factors that influence the bariatric patient's ability to adopt to the changes. Rutten, Meis, Hendriks, Hamers, Veenhof and Kremens (2014) studied the role of SDT in lifestyle coaching of overweight patients and reported that SDT can be used successfully to explain and affect a patient's three basic needs (i.e. autonomy, competence and relatedness), and if a patient experiences an insufficient level in one of these needs, it can jeopardize both the patient's and the healthcare provider's efforts toward weight loss.

Theory of Planned Behavior (TPB)

Another theory that guided our study was the Theory of Planned Behavior (TPB) which states that "attitude toward the behavior, subjective norm, and perception of behavioral control lead to the formation of a behavioral intention" (Smith, Larkey, Celaya &Blackstone et al., 2014). TPB provides empirical evidence to understand the relationship between attitudes, intention and subsequent behavior that leads to a patient's success or failure with weight loss depending on his/her ability to implement behavioral changes that affect treatment adherence, efficacy and outcome following weight loss surgery.

Schema Theory (ST)

Aramburu, Alegria and Larsen (2013) used the Schema theory to study self-views (often identified as one's most salient characteristics, values, and traits) of weight loss surgery patients and their influence on the patient's success with weight loss surgery. The authors write that self-

views remain stable through routine day-to-day activities and interactions, and can be difficult to modify, but that anticipated and unanticipated events or conditions-desired or not-can destabilize these self-views, requiring efforts to reintegrate them. The most valuable finding from this study offers a new knowledge that perceived body changes are of greater significance than actual changes in body image. This theoretical framework provided guidelines towards understanding the effects of preoperative and postoperative patients' education.

Methods

Our study was a retrospective, separate sample, pre-post intervention electronic chart review to assess 30-day readmission rates and 30-day dehydration development that resulted in ER or infusion clinic visits before and after the implementation of a comprehensive bariatric program. The pre-intervention sample included patients who underwent bariatric procedures from June 15, 2014 to May 15, 2015 and the post-intervention sample included patients who underwent bariatric procedures from July 10, 2015 to May 10, 2016.

Study Population:

The target population was adult (age 18 and older), male and female bariatric patients of all ethnic and racial background that had open gastric bypass (OGB) or laparoscopic gastric bypass (LGB) or gastric sleeve (LGS) weight loss surgery in our hospital.

The **Roux-en-Y gastric bypass** is the most commonly performed operation for morbid obesity (Madura &DiBaise, 2012). It can be done by open approach or laparoscopic approach, and it is both a restrictive and mal-absorptive procedure. It reduces the amount of food that can be ingested at one meal and bypasses a segment of the small bowel, leading to incomplete digestion. In this procedure, a small proximal gastric pouch is created that can hold only 15 to 30 mL of ingested food and liquid. This pouch is connected to the small intestine, and a variable

amount of proximal small bowel is bypassed. The Roux-en-Y gastric bypass can be performed both open and laparoscopically. Early complications include stricture/stenosis development and the inability to tolerate oral intake, dysphagia, anastomotic leak, intra-abdominal bleeding, as well as deep venous thrombosis or pulmonary embolism. The reported anastomotic leak rates are as high as 5.9% (ASMBS, 2014), and the incidence of stenosis at the gastrojejunostomy has been reported to be as low as 2% and as high as 11.4% (ASMBS, 2014). These patients often present with a progressive inability to tolerate solid and then liquid intake.

The **sleeve gastrectomy** (Madura &DiBaise, 2012) is most often done via laparoscopic or robotic approach and it involves the removal of 80% to 90% of the stomach, leaving only a gastric "sleeve." The sleeve shaped stomach that remains has a capacity ranging from about 60 to 150 mL, depending on the surgeon performing the procedure. In contrast to gastric bypass surgery, the outlet valve and the nerves to the stomach remain intact and, although the stomach is drastically reduced in size, its function is preserved. Gastric leak is one of the most serious and dreaded complications of sleeve gastrectomy. It occurs in up to 5% of patients following sleeve gastrectomy (Sarkhosh, Birch, Sharma and Karmali, 2013).

In our study sample, there was no difference in the length of hospital stay between the pre-intervention and post-intervention groups. All patients in this study stayed in the hospital an average of two to three nights. However, there are different complication risks associated with each specific bariatric procedure. One complication that develops more often in gastric bypass patients is the development of "dumping syndrome" that develops less often in sleeve gastrectomy patients. Dumping syndrome is often associated with feelings of fullness, abdominal pain, nausea, vomiting, diarrhea, sweating, flushing, light-headedness and rapid heartbeat. This syndrome only occurs after the ingestion of food that contains a lot of sugar and fat and can be

prevented by making appropriate food choices. Not all gastric bypass patients report experiencing dumping syndrome, which could be attributed to adequate preoperative education and the ability to follow postoperative diet instructions. However, both gastric bypass and sleeve gastrectomy patients can develop postoperative nausea and vomiting (PONV) requiring intravenous fluids. Preoperative and postoperative education regarding the need for adequate fluid intake and the need to follow dietary instructions are shown to positively affect the postoperative recovery and minimize the development of PONV (Morton, 2014). Fluids should be sugar-free, caffeine-free, and noncarbonated. Extensive teaching regarding diet, physical activity, and lifestyle is vital in helping patients make these necessary changes, achieve and maintain weight loss, and adjust to life after surgery.

Our study had two groups of patients: the first group of patients consisted of adult patients that had qualified bariatric surgery in our hospital from June 15, 2014 to May 15, 2015, and the second group included adult patients that had qualified bariatric surgery in our hospital from July 10, 2015 until May 10, 2016.

These were the **inclusion criteria:**

Pre-Intervention inclusion criteria: Laparoscopic or open gastric bypass or laparoscopic sleeve gastrectomy bariatric surgery done in our hospital between June 15, 2014 and May 15, 2015, before the development and implementation of comprehensive bariatric program.

Post-Intervention inclusion criteria: Laparoscopic or open gastric bypass or laparoscopic sleeve gastrectomy bariatric surgery done in our hospital between July 10, 2015 and May 10, 2016 after the development and implementation of comprehensive bariatric program.

Exclusion Criteria included:

- Bariatric surgeries that are aborted in the operating room due to various reasons
- Laparoscopic band surgery due to a low number of this type of surgery being performed at our hospital.
- Patient undergoing bariatric surgical revisions
- Patient expired during or after the bariatric procedure
- Any patient that stayed in the hospital greater than 96 hours after the bariatric surgery

Sample Size: A convenience sample was used to capture all patients that met inclusion criteria during the study timeline. The data were collected on 180 patients that met study inclusion criteria for pre-and post- intervention group during the study period.

Setting: Data collection took place in a 190-bed community hospital located in Northern Virginia. For the past few years three practicing surgeons performed between 50-80 bariatric surgeries each year, but the number of bariatric surgeries doubled in the last year after the accreditation. There are 10 operating rooms (OR) in the hospital. Patients are transferred from OR to post anesthesia recovery room (PACU) that has 30 beds, and from there patients are transferred to 58-bed surgical unit when allowed by anesthesia services.

Intervention

The intervention in this study was the development and implementation of a comprehensive bariatric program as per MBSAQIP guidelines.

Before the development and implementation of the comprehensive bariatric program preoperative education was provided by either a surgeon or physician assistant. There were three different surgeons with three independent surgery practices and this education was different for each practice with no standardized approach. Preoperative screening and tests were also not

standardized. Because there was no bariatric program, there was no one serving in the role of bariatric coordinator. This role is usually served by a registered nurse with training and certification in bariatric nursing.

The following five elements are described in more detail because they are found to have the most influence on the patient's post-operative recovery. These elements were measured in this study to ensure that patients in the post-intervention group received all five elements:

Preoperative Education

Preoperative education was provided by the bariatric coordinator and registered dietitians who have specific training in bariatric nutrition to provide information on the steps that a patient needs to take to prepare for surgery. If a patient could not attend the preoperative education class, he/she was offered an individual meeting with bariatric coordinator and dietitian or a standard Power Point presentation was sent to the patient via e-mail, followed by a phone call from the bariatric coordinator and dietitian, during which time all concepts of the preoperative education were reviewed and the patient's questions were answered.

Standardized Order Sets

Standardized inpatient clinical pathways included orders on preoperative, intraoperative and postoperative medications and intervention. An essential part of the standardized postoperative orders was patient education on oral intake and diet progression after the surgery. Patients start oral intake by sipping about one ounce (oz.) of bariatric clear liquid every 10-15 minutes using a small one oz. medication cup. The oral intake gradually progresses to a minimum of 48 oz. per day to maintain hydration.

Bariatric Coordinator Rounding

The role of the bariatric coordinator included rounding on each bariatric patient daily and serving as a resource to both the patient and his/her primary nurse in solving problems and answering any questions. The bariatric coordinator reviewed pain management, nausea management, ambulation, the use of Sequential Compression Devices (SCDs), the use of Incentive Spirometry (IS) and Continuous Positive Airway Pressure (CPAP) if indicated, diet progression and the tolerance of oral intake with the patient. In addition, the coordinator provided detailed discharge teachings regarding signs and symptoms of dehydration as well as steps to take to prevent dehydration.

Dietitian Consults in the Hospital

On postoperative day one, all patients were seen by the hospital dietitian to review dietary changes and post discharge nutritional needs specific to each bariatric surgery with the patient.

Post Discharge Phone Call Within 24-48 Hours of Discharge

The bariatric coordinator conducted follow-up post discharge phone calls within 24-72 hours following patient discharge during which time the discharge instructions specific to each patient's bariatric surgery were reviewed and reinforced, and the patient was assisted in solving any problems.

Procedural Considerations

To assure treatment fidelity, the principal investigator (PI) collected the data to ensure that the patients included in the study's post-intervention group all received these five elements of the program and the data were collected on each of these elements. To address threats to internal validity in this retrospective chart review study, we included the following elements in

the study design: selection bias was eliminated due to the study's convenience sample and because the intervention already occurred in the past, there was no threat to history and maturation. To minimize the threat to internal validity by having missing and inaccurate data, two data entry audits were conducted using a random number generator (http://www.randomnumbergenerator.com/) and included a total of 100 data points. The first data entry audit was a self-audit of data entry conducted by the PI, who entered the data in an Excel datasheet and the second data entry audit was conducted by the Reston Hospital Center research coordinator. Both data entry audits revealed no errors with the observed rate being the same as expected at 100% accuracy. To minimize external validity threats, we conducted a literature review of studies done on bariatric surgery outcomes for similar patient population done in non-accredited and accredited bariatric centers. The convenience sample design allowed for reasonable belief that the patient sample in this study represented the larger sample of bariatric surgery patients.

Instrument and Data Collection

Our hospital uses Meditech which provides electronic health record (EHR) software solutions and the Horizon Patient Folder (HPF), a document management and imaging solution that electronically captures, indexes, completes and stores a legal electronic medical record. **Meditech and HPF**: To obtain information on patients that had surgery at our hospital, we accessed Meditech and utilized "Bariatric cases report". This report provides a list of all patients who had bariatric surgery in our hospital. This report was used to verify in HPF that a patient did have surgery and to collect the following variables: type of bariatric surgery, use of standardized order sets, bariatric coordinator rounding, dietitian consult, 30-day readmission, 30-day ER/clinic visit due to dehydration, age, gender, race, ethnicity, education level, marital status, employment

status, smoking/tobacco chewing use, alcohol use, diagnosis of diabetes, diagnosis of depression, diagnoses of hypertension, and BMI.

Physician's office documents: Using the bariatric cases report, the physician's office charts were reviewed for any documentation of 30-day readmission and/or 30-day ER/infusion clinic visits to other hospitals.

Program administrative data: The bariatric program has administrative data that documents the patient's attendance of preoperative education. The binder with this information is retained in the bariatric coordinator's office in a locked cabinet for MBSAQIP accreditation purposes. The bariatric cases report was used to search preoperative education documentation for evidence of preoperative education.

The data were manually added by PI to the Excel sheet (Appendix B, Table 2) that was stored on a password protected computer with a secure hard drive with access allowed only to the PI and during the data entry audit to Reston Hospital Research Coordinator. Only the PI was abstracting, collecting and entering data utilizing a standardized process and forms after Institutional Review Board (IRB) approval was obtained. All data needed for this study were abstracted at one time when accessing the patient's chart and program administrative data. Each patient was assigned a "Study Patient Number (#)" in the Excel spreadsheet and abstracted data were entered and bariatric case reports were shredded. Patient identifiers were not included and the PI did not retain any list with patient identifiers to eliminate any possibility of linking the data and the subject's identity.

The following demographic and clinical data were gathered and entered on the data collection spreadsheet: demographic (age, gender, race, ethnicity, education level, marital status,

and employment status); and clinical data (weight loss surgery information, smoking status, alcohol use, and data on presence of diagnoses of diabetes, depression, hypertension and BMI). To ensure that all intervention elements of the bariatric program were received by post-intervention patients, data were collected on all five elements including:

1. Preoperative education
2. Standardized order set
3. Bariatric coordinator rounding
4. Dietitian consult post operatively
5. Post discharge phone call within 24-48 hours following the discharge

The variables are presented in Table 1 in Appendix A.

Definition of Terms

The outcomes of the study included 30-day readmissions and 30-day ER and clinic visits for the diagnoses and treatment for dehydration after the bariatric surgery.

Bariatric surgery: Bariatric surgery refers to weight loss surgery (ASMBS, 2014). This study looks at two specific bariatric surgeries: gastric bypass done by an open approach or by laparoscopic approach, and sleeve gastrectomy surgery making it three types of surgery included in the study.

MBSAQIP accreditation: refers to national accreditation standard for bariatric surgery centers. MBSAQIP accreditation was developed by the American College of Surgeons (ACS, 2014) and the American Society for Metabolic and Bariatric Surgery (ASMBS, 2014). A bariatric surgical center achieves accreditation following a rigorous review process during which it proves that it can maintain certain physical resources, human resources, and standards of practice. All accredited centers report their outcomes to the MBSAQIP database.

30-day readmission: In this study, the 30-day readmission refers to all-cause unplanned readmission to the hospital within 30 days of bariatric surgery

30-day dehydration and ER/clinic visit: In this study**,** 30-day dehydration and ER/clinic visit refers to a visit to the ER infusion clinic due to dehydration within 30 days of bariatric surgery.

Data Analyses

There were two types of statistics: both descriptive statistics and Chi-square (for research hypothesis testing) were performed. The significance level was set at 0.05.

Descriptive statistics: Descriptive statistics were performed to calculate and examine the sample characteristics and the study variables. This study collected categorical data and we reported the frequency, percentage, and means for study's variables (Appendix C, Table 3).

Inferential statistics and hypothesis testing: Once the descriptive statistics were completed, we performed data analysis using inferential statistics to answer the research questions and to draw conclusions about the population using the sample data. Our study examined categorical variables and Chi-square tests (X^2) were performed to test the two hypotheses in this study (Appendix D, Table 4).

Ethical Considerations

The research team in this study assured that ethical principles such as principles of beneficence, nonmaleficence, and justice, as well as regulations of biomedical ethics and protection of research subjects were respected. This research study was deemed as exempt by Reston Hospital's IRB and the George Washington University IRB. The treatment fidelity for the post-intervention group was assured including only participants that received all elements of the intervention. The participants' identity was protected by removing all possible links between the data and the individual patient.

Results

Demographic and Clinical Characteristics

There were a total of 180 patients among which 55 (31%) were in the pre-intervention and 125 (69%) were in the post-intervention group. Among the 180 patients, majority had laparoscopic gastric bypass (n=112, 62.2%), followed by laparoscopic sleeve gastrectomy (n=52, 28.9%) and open gastric bypass (n=16, 8.9%). Among the pre-intervention patients, majority had laparoscopic gastric bypass (n=28, 50.9%) closely followed by laparoscopic sleeve gastrectomy (n=25, 45.5%) and very small number of patients had open gastric bypass (n=2, 3.6%). Among the post-intervention patients, higher percentage had laparoscopic gastric bypass (n=84, 67.2%) than laparoscopic sleeve gastrectomy (n=27, 21.6%) and open gastric bypass (n=14, 11.2%).

For the total group, most of the patients were 31-45.9 (n=87, 48.3%) and 46-60.9 (n=52, 28.9%) years of age and most (n=130, 72.2%) were female (Table 3). The majority were white (n=125, 69.4%) and not Hispanic or Latino (n=162, 90%). The majority finished grade 12, GED, or some college (n=100, 55.6%) and 4-year college (n=78, 43.3%); majority were married (n=118, 65.6%), and were employed (n=152, 84.4%). The majority did not smoke (n=177, 98.3%), did not drink alcohol (n=175, 97.2%), majority did not have diabetes (n=135, 75%), did not have depression (n=151, 83.9%), and majority had hypertension (n=91, 50.6%). The majority had BMI >40 (n=120, 66.7%).

30-Day Readmission

Among the 180 patients, 7 (3.9%) had 30-day readmission (Table 4). Significantly more patients (n=5, 9.1%) in the pre-intervention group had 30-day readmission compared to those in post-intervention group (2, 1.6%; X^2=5.73, p=0.03). Of the 55 patients in pre-intervention group, five patients (9.1%) had 30-day readmission, two patients had LGB, two patients had LSG and

one patient had OGB. Among 125 patients in the post-intervention group two patients (1.6%) had 30-day readmission, and both patients had LGB

30-Day ER/Infusion Clinic Visit Due to Dehydration

Among the 180 patients, 8 (4.4%) had 30-day ER/infusion clinic visit due to dehydration (Table 4). No difference was found in 30-day ER/infusion clinic visit between the pre-intervention (n=5, 9.1%) and the post-intervention groups (n=3, 2.4%; X^2=4.026, p=0.06). However, the p value was close to significance. Of the five patients in the pre-intervention group that had 30-day ER/infusion clinic visit three patients had LGB and two patients had LSG. In the post-intervention group three patients had ER/infusion clinic visit, and all three had LGB surgery.

Discussion

As a newly accredited bariatric program we were in a unique position to assess the effects of the development and implementation of a comprehensive bariatric program on 30-day readmission and 30-day ER/infusion clinic visit due to dehydration. No differences were found between the demographic and clinical characteristics of the pre-intervention and the post-intervention groups. Demographic and clinical factors were equally distributed in pre-intervention and post-intervention group, they did not influence study results.
This is significant and implies study's high external validity and representativeness. The study population was representative of adult patients (age ≥18) that had one of bariatric surgeries included in our study (OGB, LGB, and LSG).

We hypothesized that there would be a difference in the 30-day readmission and 30-day ER/infusion clinic visit rates among patients that had bariatric surgery before and after the implementation of comprehensive bariatric program in the same hospital. Our results showed

lower 30-day readmission rates for bariatric surgery patients that had bariatric surgery after the implementation of comprehensive bariatric program for our sample although the numbers were small in both groups. Consistent with previous studies, our study demonstrates positive impact of accreditation on 30-day readmission rates.

Blackstone et al. (2014) found that patients who had surgery at accredited centers (35,284 patients vs 11,746 patients that had surgery in non-accredited centers) had 90-day mortality decreased from 1.5% to 0.7%, and 90-day readmission rate decreased from 3.2% to 2.1%. Also, Telem et al. (2014) conducted retrospective study of 47,342 patients with objective to evaluate impact of accreditation on perioperative and long term outcomes after bariatric surgery. Controlling for patient demographics and clinical variables, data analysis demonstrated accreditation as independently associated with fewer major complications versus unaccredited hospitals and within the same hospital following accreditation. Similarly, Dumon et al. (2011) implemented bariatric clinical program and studied its effect on outcomes and quality indicators of 1886 patients. The authors found that implementation of designated bariatric program resulted in reduction of 30-day readmission rates from 15.7% to 8.1%. In addition, Kwon et al. (2012) found that for total of 30,755 patients 90-day readmission rates went down from 10.8% to 8.8% for 17,896 patients that has surgery in accredited centers. The authors stated that patients who had surgery in accredited centers also had lower rates of reoperations and complications. Lower rate (0.06%) of in-hospital mortality for 35, 284 patients that underwent bariatric surgery at accredited academic bariatric centers were found than in non- accredited academic bariatric centers (0.21%) by Nguyen et al. (2012). In a large study of outcomes of bariatric surgery in accredited versus non-accredited centers for 277,068 bariatric patients, Gebhart et al. (2013) found that accredited programs had three-fold reduction in risk-adjusted in hospital mortality.

Similarly, Morton et al. (2014) studied the impact of hospital bariatric program accreditation on bariatric surgery outcomes on 117, 478 patients and found that accredited hospitals had safer outcomes, shorter length of stay and lower total charges after bariatric surgery.

Further support for bariatric program accreditation was reported by Azagury and Morton (2016) who conducted extensive systematic review of medical literature (studies published from 200-2014) to examine the impact of bariatric accreditation on surgical outcomes. The authors reported that thirteen studies in their review included more than 1.5 million patients and that ten of the 13 studies identified substantial benefit of accreditation on reducing mortality and morbidity.

We expected that 30-day ER/infusion clinic visit rates would be also lower, but the results were not statistically significant (p=0.06). However, reducing the 30-day ER/infusion clinic visit rates from 9% in the pre-intervention group to 2% in the post-intervention group may be considered as clinically significant. The results of 30-day ER/infusion clinic visits were approaching statistical significance (X^2=4.03, p=0.06).

Study Limitations

Main limitations of this study are related to the retrospective chart review design. Our analysis was limited to those variables pre-recorded within the Meditech, the physician office administrative data and the bariatric program administrative data. No data on patient's psychosocial support before and after surgery was available, which may affect patient's ability to adjust to life-style and behavioral changes needed after bariatric surgery and patient's motivation to attend support groups, therefore potentially affecting 30-day readmission and dehydration development (Sarvey, 2009; Robinson et al. 2014). MBSAQIP accreditation standards require programs to provide support groups but this study did not include it as one of the variables. The

data analysis of self-reported presence and quality of psychosocial support and records of support group attendance might have provided additional insight into the value of patient teaching and patient support elements of comprehensive bariatric program.

The study had small sample and study design included convenience sample which did not allow for randomization. The pre-intervention sample (55 patients, 30.6% of total sample) was significantly smaller than post-intervention sample (125 patients, 69.4% of total sample). Our hospital had an increase in bariatric surgery volume after the implementation of bariatric program and it resulted in much larger post-intervention sample. Significant difference might have been found for ER/infusion clinic visit rates if the sample size had been larger.

Implications/Recommendations for Policy, Practice, and Research

The results of this study have implications for healthcare organizations offering bariatric surgery, demonstrating lower 30-day readmission rates for patients that had surgery after the development and implementation of a comprehensive bariatric program than before the program was implemented. 30-day readmissions after bariatric surgery can be viewed as a single, measurable quality parameter (Morton, 2014) and bariatric programs need to use all available initiatives such as accreditation standards to minimize 30-day readmission and ER/infusion clinic visit rates. The Centers for Medicare and Medicaid Services (CMS) describes readmissions as "costly, adverse events" (Chen et al. 2015) and some studies describing it as a single measure of the quality of health care (Morton, 2014) and as potentially preventable (Doumouras et al. 2014; Patterson et al. 2014). During the 30-day readmission and/or ER/infusion clinic visit patient and healthcare organization must endure the increased financial cost of treatments provided during

patient's stay in the hospital or in the ER/infusion clinic. Readmissions can triple the healthcare resources use after gastric bypass (Doumouras, 2014).

There is a scarcity of literature on 30-day ER/infusion clinic visits. A literature review provided data on 30-day ER/infusion clinic visits that were reported together with 30-day readmission rates. One of the objectives of this study was to evaluate effects of implementation of comprehensive bariatric program on 30-day ER/infusion clinic visits due to dehydration and although the results were not significant, they were approaching statistical significance and likely are clinically significant. After implementing a comprehensive bariatric program, the number of bariatric surgeries doubled at our hospital within a year, which resulted in a larger sample of patients in the post-intervention group. A larger pre-and post-intervention study sample may have detected significant differences between the two groups for clinical visits. Although our study did not document the impact of a comprehensive bariatric program on reducing 30-day ER/infusion clinic visits due to dehydration, our findings offer valuable information for bariatric programs given the scarcity of literature on 30-day ER/infusion clinic visits.

In addition to improving surgery outcomes, as measured by indicators such as 30-day readmission rates and 30-day ER/infusion clinic visit rates due to dehydration, implementing comprehensive bariatric program brings resources and experience that can bring potential benefit for all obese patients undergoing surgery at the same hospital (Dumon et al., 2011; Morton et al., 2014). Two most essential components of bariatric program implementation are structural (i.e. designated bariatric team, investment in bariatric appropriate equipment, providing training and education to required personnel) and process elements (i.e. bariatric pathways, data collection, required quality improvement initiatives, support group, etc). Achieving MBSAQIP accreditation and better surgical outcomes help bariatric programs become recognized by patients and health

insurance payers and assist them in making the decision on where to receive the care. MBSAQIP accreditation represents a commitment by the institution, surgeons, and staff to provide the care as per agreed national standards.

Further research is needed with a larger study sample to analyze how the development and implementation of a comprehensive bariatric program affects 30-day readmission and 30-day ER/infusion clinic visits due to dehydration. Among all 180 patients in this study, laparoscopic gastric bypass was most often performed surgery (67.2% of total sample). Further research with larger sample is needed to analyze how each different bariatric surgical procedure affects patient's risk for 30-day readmission and 30-day ER/infusion clinic visit.

Conclusion

As the number of bariatric surgeries and cost of healthcare services continuously increase, healthcare organizations are using 30-day readmissions as a quality measure. It is becoming increasingly important to implement measures to minimize readmissions. MBSAQIP accreditation offers clear guidelines and standards for bariatric programs together with access to national benchmarks and evidence based practices aimed to improve the quality of patient care. Our study demonstrated that patients who had bariatric surgery after the development and implementation of bariatric program had significantly lower rates of 30-day readmission than those who had surgery before the implementation of comprehensive bariatric program.

Appendix A

Variables Table

Table 1: Variables table

Variable	Type of variable	Theoretical Definition	Operational Definition
Bariatric surgery	Clinical	Weight loss surgery such as gastric bypass or sleeve gastrectomy	1=Open approach Gastric Bypass surgery 2=Laparoscopic approach Gastric Bypass surgery 3=Laparoscopic Sleeve Gastrectomy surgery
Preoperative education	Independent	Preoperative education regarding preparation for surgery and changes after surgery	0= No 1=Yes
Standardized order set	Independent	Standardized orders for pre-op testing, pain and nausea management post operatively, diet progression, activity level, thromboprophylaxis	0= No 1=Yes
Bariatric coordinator rounding	Independent	Daily rounding by bariatric coordinator	0= No 1=Yes
Dietitian consult	Independent	Dietitian consult post-operatively	0= No 1=Yes
Phone call post-discharge	Independent	Phone call by bariatric coordinator within 24-72 hours of discharge	0= No 1=Yes
30-day readmission rate	Dependent	Admission to the hospital within 30 days following bariatric surgery	0=No 1=Yes
30-day ER or infusion clinic visits due to dehydration	Dependent	ER or infusion clinic visit due to dehydration within 30 days following bariatric surgery	0=No 1=Yes

Age	Demographic	Chronologic age in years	1=18-30.9 2=31-45.9 3=46-60.9 4=61 and more
Gender	Demographic	Patient's biological sex	0=Male 1=Female
Race	Demographic	Reported self-identification with the person or population group having shared genetic or biological traits	1=White 2=African American 3=Asian 4= Other
Ethnicity	Demographic	Reported self-identification with the person or population group having shared genetic or biological traits	1=Hispanic 2=Not Hispanic or Latino 3=Prefer not to disclose
Education level	Demographic	Level of education completed	1= Less than high school 2 = Grades 12 or GED (High School graduate); some college 3 = 4 years College and graduate school 4 = Refused
Marital status	Demographic	Current relationship status	1=Married 2=Not married
Employment status	Demographic	Status of current employment	1=Employed 2=Not employed 3=Disabled 4=Retired
Smoking/tobacco chewing	Clinical	Daily use of cigarettes or chewing tobacco	0=No 1=Yes
Alcohol	Clinical	Daily alcohol drinking	0=No alcohol 1=One drink a day 2=More than one drink a day
Diabetes	Clinical	Individual has been diagnosed with diabetes and has been taking medications	0=No 1=Yes
Depression	Clinical	Individual has been told of having a depressive	0=No 1=Yes

		disorder, including depression, major depression, dysthymia, or minor depression at any time during lifetime	
Hypertension	Clinical	Individual has been diagnosed with hypertension and has been taking medications	0=No 1=Yes
Body Mass Index (BMI)	Clinical	BMI is defined as the body weight (in kilograms), divided by the square of the height (in meters). The result is expressed as a number - usually between 15 and 70- in units of kilograms per square meter.	1=BMI 35-40 2=BMI > 40

Appendix B

Sample Data Collection Worksheet Instrument (Excel)

Table 2: Sample Data Collection Worksheet Instrument (Excel)

Study Patient #	Date of surgery	Pre=1 post intervention=2	Weight loss surgery 1=Open gastric bypass 2=Lap gastric bypass3=Lap sleeve	Preoperative education No=0 Yes=1	Standardized order set No=0 Yes=1	Bariatric coordinator rounding No=0 Yes=1	Dietitian consult	Phone call post discharge No=0 Yes=1	30-day readmission No=0 Yes=1	30-day dehydration/ER /clinic visit	Age 1=18-30 2=31- 45 3=46-60 4=>60	Gender M=0 F=1	Race *	Ethnicity **	Education level ***	Marital status ****	Employment status *****	Smoking/tobacco chewing +	Alcohol use+++++	Diabetes++++	Depression+++	Hypertension++	BMI ++++++

Race * 1=White 2=African American 3=Asian 4= Other

Ethnicity ** 1=Hispanic 2=Not Hispanic or Latino 3=Prefer not to disclose

Education level *** 1= Less than high school 2 = Grades 12 or GED (High School graduate), some college; 3 = 4 year College 4 = Refused

Marital status **** 1=Married 2=Not married

Employment status ***** 1=Employed 2=Not employed 3=Disabled 4=Retired

Smoking/tobacco chewing + No=0 Yes=1

Alcohol use+++++ No=0, One drink a day=1, More than one drink a day=2

Diabetes++++ No=0 Yes=1

Depression +++No=0 Yes=1

Hypertension ++ No=0 Yes=1

BMI ++++++ 1=BMI 35-40 2=BMI> 40

Appendix C

Demographic and clinical characteristics of sample

Table 3: Demographic and clinical characteristics of sample

Variable	**Total Sample** 180 (100%) n (%)	**Pre-Intervention** 55 (31%) n (%)	**Post-Intervention** 125 (69%)n (%)	**Statistics** X^2	**p Value**
Weight loss surgery				**X2=11.6**	**.003**
Open gastric bypass	16 (8.9%)	2 (3.6%)	14 (11.2%)		
Laparoscopic gastric bypass	112 (62.2%)	28 (50.9%)	84 (67.2%)		
Laparoscopic sleeve gastrectomy	52 (28.9%)	25(45.5%)	27 (21.6%)		
Age (years)				**X2=2.02**	**0.57**
18-30.9	22 (12.2%)	7 (12.7%)	15 (12.0%)		
31—45.9	87 (48.3%)	23 (41.8%)	64(51.2%)		
46-60.9	52 (28.9%)	17(30.9%)	35 (28.0%)		
>60	19 (10.6%)	8 (14.5%)	11 (8.8%)		
Gender				**X^2=0.07**	**0.79**
Male	50 (27.8%)	16 (29.1%)	34(27.2%)		
Female	130(72.2%)	39 (70.9%)	91(72.8%)		
Race				**X^2=5.951**	**0.11**
White	125 (69.4%)	43 (78.2%)	82 (65.6%)		
African American	31 (17.2%)	7 (12.7%)	24 (19.2%)		
Asian	1 (0.6%)	1 (1.8%)	0 (0%)		
Other	23 (12.8%)	4 (7.3%)	19 (15.2%)		
Ethnicity				**X2=0.07**	**0.79**
Hispanic	18 (10%)	6 (10.9%)	12 (9.6%)		
Not Hispanic or Latino	162 (90%)	49 (89.1%)	113 (90.4%)		
Prefer not to disclose	0 (0%)	0 (0%)	0 (0%)		
Education level				**X^2=1.79**	**0.41**
Less than high school	2 (1.1%)	0 (0%)	2 (1.6%)		

Grades 12 or GED, some college	100 (55.6%)	28(50.9%)	72(57.6%)		
4 year college and graduate school	78 (43.3%)	27 (49.1%)	51 (40.8%)		
Refused	0 (0%)	0 (0%)	0 (0%)		
Marital status				**X^2=0.13**	**0.72**
Married	118 (65.6%)	35 (63.6%)	83 (66.4%)		
Not married	62 (34.4%)	20 (36.4%)	42 (33.6%)		
Employment status				**X^2=1.51**	**0.68**
Employed	152 (84.4%)	48 (87.3%)	104 (83.2%)		
Not employed	19 (10.6%)	4 (7.3%)	15 (12.0%)		
Disabled	1 (0.6%)	0 (0.0%)	1 (0.8%)		
Retired	8 (4.4%)	3 (5.5%)	5 (4.0%)		
Smoking/tobacco chewing current use				**X^2=0.01**	**0.92**
No	177 (98.3%)	54 (98.2%)	123 (98.4%)		
Yes	3 (1.7%)	1 (1.8%)	2 (1.6%)		
Alcohol use (current)				**X^2=0.30**	**0.60**
No	175 (97.2%)	54 (98.2%)	121 (96.8%)		
One drink a day	5 (2.8%)	1 (1.8%)	4 (3.2%)		
More than one drink a day	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Diabetes				**X^2=0.22**	**0.64**
No	135 (75.0%)	40 (72.7%)	95 (76.0%)		
Yes	45 (25.0%)	15 (27.3%)	30 (24.0%)		
Depression				**X^2=1.91**	**0.17**
No	151 (83.9%)	43 (78.2%)	108 (86.4%)		
Yes	29 (16.1%)	12 (21.8%)	17 (13.6%)		
Hypertension				**X^2=0.00**	**0.95**
No	89 (49.4%)	27 (49.1%)	62 (49.6%)		
Yes	91 (50.6%)	28 (50.9%)	63 (50.4%)		
BMI				**X^2=3.78**	**0.05**
BMI 35-40	60 (33.3%)	24 (43.6%)	36 (28.8%)		
BMI >40	120 (66.7%)	31 (56.4%)	89 (71.2%)		

Appendix D

Outcomes table

Hypotheses

Hypothesis 1: There is a difference in the 30-day readmission rate in bariatric surgical patients that receive surgery before versus after the development and implementation of a comprehensive bariatric surgical program.

Hypothesis 2: There is a difference in the 30-day ER and infusion clinic visit rates due to dehydration in bariatric surgical patients that received surgery before versus after the development and implementation of a comprehensive bariatric surgical program.

Table 4: Outcomes table

Variables	**Total Group** 180 (100%) n (%)	**Pre-intervention group** 55 (31%) n (%)	**Post-intervention group** 125 (69%) n (%)	**Statistics**	**p Value**
30-day readmission				**X^2=5.73**	**0.03**
• Yes	7 (3.9%)	5 (9.1%)	2 **(1.6%)**		
• No	173 (96.1%)	50 (90.9%)	123 (98.4%)		
30-day ER and infusion clinic visit				**X^2=4.03**	**0.06**
• Yes	8 (4.4%)	5 (9.1%)	3 (2.4%)		
• No	172 (95.6%)	50 (90.1%)	122 (97.6%)		

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