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Hospital Variation in Rates of Acid-Reducing Medication Use after Laparoscopic Sleeve Gastrectomy

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Abstract

Background—Postoperative gastroesophageal reflux is one of the most important long-term complications of sleeve gastrectomy, the most common bariatric procedure.

Objective—To assess variation in hospital performance with laparoscopic sleeve gastrectomy using rates of acid-reducing medication use at postoperative 1 year.

Setting—Clinical registry of bariatric surgical patients at academic and community hospitals in Michigan.

Methods—We studied 2,923 patients who underwent laparoscopic sleeve gastrectomy across 39 hospitals in the Michigan Bariatric Surgery Collaborative, 2007–2014. We compared risk- and reliability-adjusted rates of new-onset reflux—defined by new use of acid-reducing medication—across hospitals and in relation to surgical quality indicators (hospital procedure volume and 30-day complications).

Results—Overall, 20% of patients were newly taking acid-reducing medication at postoperative 1 year. Hospital rates of new medication use varied three-fold, ranging from 10% (95% CI, 7–15%) to 31% (95% CI, 23–40%) of patients. Of the 2 hospitals with significantly lower rates of new medication use, 1 was high-volume and 1 was medium-volume. The 1 hospital with significantly higher rates was medium-volume. Rates of acid-reducing medication use did not correlate with hospital volume or perioperative complications.

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Conclusions—Across Michigan hospitals, rates of new acid-reducing medication use at 1 year after laparoscopic sleeve gastrectomy varied widely and did not correlate with traditional quality indicators. Future research could explore differences in surgical technique to better understand the factors underlying variation in long-term outcomes after sleeve gastrectomy.

Keywords

hospital variation; sleeve gastrectomy; acid-reducing medication; postoperative reflux

Introduction

Laparoscopic sleeve gastrectomy is now the most commonly performed operation to treat obesity and its related comorbidities.[1] This operation has demonstrated near-comparable effectiveness for weight loss and improved safety when compared to laparoscopic Roux-en-Y gastric bypass.[2–4] However, postoperative gastroesophageal reflux has emerged as one of the most important long-term complications of sleeve gastrectomy.[5–7] It is thought that the risk of postoperative reflux may be mitigated by technical factors associated with the operation itself, such as concurrent repair of a hiatal hernia and avoidance of narrowing the incisura.[8] Therefore, rates of reflux represent a reasonable indicator for surgical quality for this emerging procedure.

The extent to which rates of reflux vary across hospitals following laparoscopic sleeve gastrectomy is unclear. Hospital variations could reflect suboptimal diffusion of appropriate surgical techniques. Thus, studying this variation could potentially identify high-performing hospitals that may serve as a target for surgical quality improvement initiatives. Alternatively, hospital variation in outcome rates could reflect differences in overall surgical quality, which can be gauged using well-established quality indicators for surgery such as procedure volume and short-term postoperative complication rates.[9–11] Whether these quality measures are predictive of long-term outcomes, such as gastroesophageal reflux, for sleeve gastrectomy is not yet understood. A better understanding of the underlying sources of variation in long-term complications may identify tangible targets for improving patients' health and quality of life after bariatric surgery.

In this study, we used data from the Michigan Bariatric Surgery Collaborative to assess hospital-level differences in new-onset reflux, defined as treatment with acid-reducing medication, at 1 year after patients underwent laparoscopic sleeve gastrectomy. Additionally, we sought to explain hospital variation by examining the relationships between rates of acid-reducing medication use, procedure volume, and short-term complication rates.

Methods

Data Sources and Study Population

This study analyzed data from the Michigan Bariatric Surgery Collaborative (MBSC), a statewide payer-funded consortium of hospitals and surgeons providing bariatric surgical care.[12, 13] The MBSC consists of all Michigan hospitals that perform a minimum of 25 bariatric surgery cases per year (38 hospitals and 68 surgeons in 2014). Described in greater

detail elsewhere, participating hospitals submit data to a clinical registry for all patients who undergo a bariatric procedure, including sleeve gastrectomy, Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and biliopancreatic diversion with or without duodenal switch.[9] Data collected includes patient demographic and preoperative clinical information, perioperative and intraoperative outcomes for inpatient and outpatient procedures, and in-hospital records for up to 30 days after surgery.

Patients who consent to long-term follow-up with the MBSC complete a baseline preoperative survey and annual postoperative surveys (written or electronic). The baseline surveys request demographic information about race, education, employment, and income; annual surveys include questions about current weight, additional hospitalizations and/or procedures, and satisfaction with their primary operation. Furthermore, the annual surveys request information regarding medication usage (including acid-reducing medications) in a yes/no format, general health status, and overall quality of life.[5]

In this study, we identified all adult patients who underwent laparoscopic sleeve gastrectomy between June 2006 and December 2014 (n=16,413). We limited analysis to patients who completed both baseline and 1-year follow-up survey questions regarding medication use (n=4,703; 29% of all patients who underwent laparoscopic sleeve gastrectomy). To evaluate new-onset postoperative reflux, only patients who reported not taking any acid-reducing medication at baseline were included in the final analysis (n=2,923 patients; 18% of all patients who underwent laparoscopic sleeve gastrectomy).

Outcome and Study Variables

The primary outcome of interest was the risk- and reliability-adjusted rates of new-onset reflux 1 year after laparoscopic sleeve gastrectomy, assessed at the hospital level. For this study, new-onset reflux was defined by treatment with acid-reducing medication among patients who did not take that medication at baseline.[5, 6] Use of acid-reducing medication indicated a patient's use of a proton-pump inhibitor, H2-blocker, or antacid. As done previously, postoperative reflux was identified for each patient from 1-year follow-up survey questions regarding the patient's use of these medications.[5]

The primary exposure variable was the individual hospital where a patient received an operation, identified through the MBSC registry. Patient characteristics, including demographics and comorbidities, were used as covariates in the logistic regression model that determined rates of acid-reducing medication use at 1 year after surgery for individual hospitals. Patient demographic data included age, gender, race, insurance type, body mass index, smoking history, and mobility limitations. Comorbid conditions included history of gastroesophageal reflux, peptic ulcer disease, diabetes, liver disease, musculoskeletal disease, and psychiatric disease. Comorbidity status was obtained from the MBSC registry and was defined by documentation of that condition or its treatment in the medical record.

To explore the degree to which hospital variation in rates of reflux correlated with traditional surgical quality indicators, we compared rates of acid-reducing medication use with hospital procedure volume and with overall 30-day postoperative complication rates.

Statistical Analysis

For each hospital, we generated risk- and reliability-adjusted rates of acid-reducing medication use 1 year after the index operation, calculated mean annual procedure volumes for laparoscopic sleeve gastrectomy, and determined risk- and reliability-adjusted rates of overall complications. We first calculated risk-adjusted rates of acid-reducing medication use. Backward stepwise methods were used to create a multivariate logistic regression model, with log-odds of medication use at 1 year modeled as a linear function of baseline covariates. This model was tested using various potential predictors of reflux, including patient demographics and comorbidities as listed above, and procedure year. The final mixed-effects logistic regression model included the following significant ($P<0.05$) predictors of acid-reducing medication use as fixed effects: gender, race, history of mobility limitations, total number of comorbidities, and procedure year. The identifier for individual hospitals was incorporated as a random effect to account for clustering of patients within hospitals.

We used the random effects of individual hospitals to determine reliability-adjusted estimates of these calculated rates of medication use. Reliability adjustment employs empirical Bayes methods to account for random variation of surgeons' outcomes within hospitals.[9, 14] This is particularly important for hospitals with small numbers of cases, whose crude outcome measures may be skewed due to statistical "noise" (i.e. with small sample sizes, it is difficult to tell whether extremely high or low rates of new-onset reflux are due to chance or due to true differences in surgical quality).[15] The effect of the reliability adjustment is that it shrinks the point estimate of new medication use for a given hospital back toward the average rate of new medication use for the entire population, with the degree of shrinkage proportional to the reliability at each hospital.[14, 15] This method, in effect, produces a truer measure of acid-reducing medication use that allows for more accurate comparisons of quality in laparoscopic sleeve gastrectomy among hospitals in the MBSC.

Based on these risk- and reliability-adjusted estimates, hospitals were grouped into quartiles of new acid-reducing medication use at 1 year after laparoscopic sleeve gastrectomy. The middle 2 quartiles were combined for purposes of presenting the findings. Characteristics of patients who underwent laparoscopic sleeve gastrectomy were compared using Pearson chi-squared test for categorical variables and one-way analysis of variance for continuous variables.

Hospitals were then re-grouped into equal quartiles of mean annual procedure volume for laparoscopic sleeve gastrectomy, and the middle quartiles were combined to present 3 categories of hospital volume (<35 , $35-82$, and >82 procedures per year). Adjusted rates of acid-reducing medication use were compared according to hospital volume. Finally, risk- and reliability-adjusted rates of overall 30-day complications (including non-life-threatening, potentially life-threatening, and life-threatening complications associated with residual disability[9]) were determined for each hospital, in the manner described above. Adjusted rates of acid-reducing medication use were compared with hospitals' overall 30-day complication rates.

Statistical analyses were performed using STATA version 11.2 (Stata Corp, College Station, Texas). All hypotheses were tested using a two-sided approach with a significance level of 0.05.

Results

Patient Characteristics

Across hospital quartiles of new use of acid-reducing medication, several patient characteristics differed significantly (Table 1). Compared to patients who underwent laparoscopic sleeve gastrectomy at hospitals with low rates of new medication use, patients at hospitals with high rates were more likely to be white and male but less likely to have had gastroesophageal reflux documented in their past medical history. Patients at hospitals with low and high rates of new medication use had a similar probability of receiving concurrent hiatal hernia repair; however, patients at hospitals with medium rates of medication use were slightly more likely to receive this procedure concurrently (20% vs. 27% vs. 22% at hospitals with low, medium, and high rates of new medication use, respectively; $P=0.002$). Other differences between patient groups were statistically significant but not clinically meaningful.

Hospital Variation in Rates of New Acid-Reducing Medication Use

The overall proportion of patients newly taking acid-reducing medication at 1 year after undergoing laparoscopic sleeve gastrectomy was 19.7% (95% confidence interval [CI], 18.3–21.1%). Risk- and reliability-adjusted rates of new medication use varied three-fold across Michigan hospitals, ranging from 10.3% (95% CI, 6.8–15.2%) to 30.7% (95% CI, 22.5–40.3%) of patients (Figure 1).

Three hospitals had rates of new medication use that were significantly different from the cohort mean (2 had lower rates, and 1 had a higher rate). The remaining hospitals did not significantly differ from the cohort mean.

Relationship between New Acid-Reducing Medication Use and Hospital Volume

No systematic relationship was detected between hospital volume and rates of new use of acid-reducing medication at 1 year. Of the 2 hospitals with significantly lower rates of new medication use, 1 was a high-volume hospital for laparoscopic sleeve gastrectomy (>82 procedures per year), and 1 was a medium-volume hospital (35–82 procedures per year). The 1 hospital with significantly higher rates of acid-reducing medication use was a medium-volume hospital. Low-volume hospitals (<35 procedures per year) were interspersed with medium- and high-volume hospitals regarding their rates of acid-reducing medication use (Figure 1).

When hospitals were re-grouped into quartiles of annual procedure volume for laparoscopic sleeve gastrectomy, adjusted rates of new acid-reducing medication use at 1 year did not differ significantly across annual volume quartiles (19.0% vs. 21.3% vs. 19.5% for low-, medium-, and high-volume hospitals, respectively; $P=0.36$) (Figure 2). The odds of newly taking acid-reducing medication at 1 year when operated on at a high-volume hospital were

not significantly different than when operated on at a low-volume hospital (odds ratio, 1.36; 95% CI, 0.83–2.22).

Relationship between New Acid-Reducing Medication Use and Hospital Complication Rates

When hospitals were re-grouped into quartiles of risk- and reliability-adjusted rates of overall 30-day complications, adjusted rates of acid-reducing medication use again did not differ significantly across quartiles of overall complication rates (21.3% vs. 19.0% vs. 21.7% for hospitals with low, medium, and high overall complication rates, respectively; $P=0.24$) (Figure 3). Similarly, the odds of newly taking acid-reducing medication at 1 year when operated on at hospitals with high overall complication rates were not significantly different than when operated on at hospitals with low overall complication rates (odds ratio, 1.10; 95% CI, 0.87–1.39).

Discussion

This study reports wide variation in the occurrence of new-onset gastroesophageal reflux, defined as the new use of acid-reducing medication, at 1 year among patients who underwent laparoscopic sleeve gastrectomy at hospitals in the Michigan Bariatric Surgery Collaborative. Overall, about 1 in 5 patients reported newly taking acid-reducing medication at 1 year after their operation. Adjusted rates of new acid-reducing medication use varied three-fold across individual hospitals, from 10% to 31% of patients. However, rates of new medication use did not correlate with traditional surgical quality indicators such as procedure volume or short-term complications.

Despite similar weight-loss outcomes and improved short-term safety compared to gastric bypass,[2–4, 9] a major long-term consequence of sleeve gastrectomy has been the development of new-onset or worsening of preexisting gastroesophageal reflux.[5–7] Among Michigan hospitals in this study, nearly 20% of patients reported developing new-onset reflux requiring treatment with acid-reducing medication. This estimate is consistent with that reported by Varban et al., who in a cross-sectional study of all bariatric procedure types found that 21.6% of patients who underwent sleeve gastrectomy were newly taking acid-reducing medication at 1 year.[5] Although several studies have documented worsening of reflux symptoms after patients undergo laparoscopic sleeve gastrectomy,[5–7, 16] this study goes above and beyond prior work by systematically studying hospital-level variation in this long-term complication. Detecting this variation is important for identifying high-performing hospitals as quality improvement targets; understanding the reasons behind this variation is key for determining how to design surgical quality improvement initiatives.

Traditionally, high-volume hospitals have been associated with better outcomes across most surgical specialties and procedure types.[11, 17–19] Existing literature that supports the high-volume argument in bariatric surgery primarily describes the field when the technically complex gastric bypass was the predominant procedure.[20–22] However, the relative importance of volume for predicting outcomes in bariatric surgery has been questioned.[23, 24] In this analysis of laparoscopic sleeve gastrectomy, a long-term indicator of surgical quality (postoperative reflux requiring treatment with acid-reducing medication) was not

correlated with hospital procedure volume. This suggests that increasing operative experience may not necessarily produce better long-term results for laparoscopic sleeve gastrectomy.

Similarly, short-term postoperative complication rates are commonly used to gauge surgical quality at hospitals.[9, 23, 25] Whether short-term outcomes can predict results 1 year after surgery is less clear for sleeve gastrectomy. This study revealed that new use of acid-reducing medication was not associated with hospitals' short-term complication rates. The null relationship between rates of acid-reducing medication use, procedure volume, and short-term complication rates suggests that experience and traditional surgical quality metrics do not predict postoperative reflux, a major long-term complication of sleeve gastrectomy. Thus, other factors, such as details of the surgical technique, may play a larger role in the occurrence of new-onset reflux following laparoscopic sleeve gastrectomy.

This study has several limitations. First, the size of the study cohort was reduced to only those patients who voluntarily returned surveys 1 year after their operation and who also indicated that they did not take acid-reducing medication at baseline (18% of patients who underwent laparoscopic sleeve gastrectomy during the study period). Patients who completed 1-year surveys were more likely to be white (81% vs. 56%) and more likely to be taking an acid-reducing medication at baseline (38% vs. 28%) than those who did not complete surveys. This may limit generalizability of these observational findings due to selection bias. However, in comparing patients who completed 1-year surveys with those who did not, no clinically meaningful differences in comorbidities existed between these patient groups (data not shown).

Some may further question the generalizability of these results because they reflect outcomes of bariatric surgery centers that participate in a statewide quality collaborative. While perioperative complication rates have been shown to be remarkably low among hospitals in the MBSC,[9] this analysis demonstrated that rates of a longer-term complication were relatively high and varied three-fold across hospitals that are actively engaged in quality improvement initiatives for bariatric surgery. Therefore, it is reasonable to believe that these findings may be generalizable to hospitals nationwide, as rates of reflux might vary even more widely across different types of academic, community, and private practice institutions.

It is important to acknowledge that gastroesophageal reflux was not directly measured in this study; therefore, we cannot conclusively attribute the self-reported use of acid-reducing medication as a surrogate for postoperative reflux. However, acid-reducing medication use has served as a proxy for reflux in previous studies.[5, 6, 26] While proton pump inhibitors and H2-blockers may be used to treat conditions other than reflux (as in the management of postoperative complications such as leaks, strictures, and ulcers), these events occurred infrequently (<1% combined) among all patients who underwent sleeve gastrectomy during the study period. Despite being a well-known complication of gastric bypass,[27] ulcers are not a common complication for sleeve gastrectomy.[5] Therefore, acid-reducing medication use is a reasonable proxy for reflux disease and can better reflect its presence for laparoscopic sleeve gastrectomy patients compared to gastric bypass patients.

Finally, the cross-sectional design of this study limited our ability to analyze precisely when and for what indication a patient begins to take acid-reducing medication. Recognizing that prescribing accuracy with acid-reducing medication varies across primary care providers and specialists,[28] we could not identify whether the bariatric surgeon or other physicians on a patient's care team initiated pharmaceutical therapy. Still, besides reflux symptoms, there are few other reasons that would justify prescribing acid-reducing medication in this postoperative period. Although prescribing patterns by individual physicians could not be assessed in this study, use of these medications can reasonably suggest reflux symptoms, an important long-term problem from both the patient and provider perspectives.

In recent years, laparoscopic sleeve gastrectomy has quickly grown in popularity, surpassing laparoscopic Roux-en-Y gastric bypass and laparoscopic adjustable gastric banding as the most commonly performed bariatric procedure.[1, 29] Its rapid adoption has been facilitated by patients' perception of a less complex procedure and by its comparable outcomes to gastric bypass. Despite its perceived simplicity, several technical aspects are still widely debated by bariatric surgeons, including the width of the gastric sleeve, the shape of the distal section, and the inclusion of any concurrent anti-reflux operations.[8, 30] Although many mechanisms have been proposed to explain the relationship between sleeve gastrectomy and postoperative reflux,[31] the literature has not yet revealed substantial evidence of a true cause. Technical factors are thought to be likely influences on the risk of developing gastroesophageal reflux as a long-term complication of this procedure,[8] in addition to proper patient selection and thorough preoperative evaluation.[32] As a result of its rapid uptake, surgical techniques have not yet been standardized for laparoscopic sleeve gastrectomy, presenting a prime opportunity for improvement. While it could be argued that variation in hospital rates of new-onset postoperative reflux might reflect differences in surgical quality across hospitals, traditional markers of surgical quality (procedure volume and short-term complication rates) were not associated with hospital rates of acid-reducing medication use in this study. Furthermore, rates of hiatal hernia repair (which intentionally addresses a risk factor for developing reflux) did not differ between hospitals with high and low rates of new acid-reducing medication use. These findings suggest that differences in surgical technique may account for the observed variation with this significant long-term complication of laparoscopic sleeve gastrectomy. This variation could be addressed by systematically evaluating differences in technique and correlating them with outcomes to establish and disseminate best practices. Objective measures for reflux, such as endoscopy or pH monitoring, could provide more conclusive evidence for variation in this long-term quality indicator for sleeve gastrectomy. Given the high prevalence and variability of this important long-term complication, systematic evaluation will be crucial for understanding the factors driving this variation and for identifying appropriate measures to prevent reflux following the most common bariatric procedure.

Conclusion

In conclusion, rates of new acid-reducing medication use at 1 year after laparoscopic sleeve gastrectomy were relatively high and varied widely across bariatric surgery centers in Michigan. These rates did not correlate with traditional surgical quality indicators such as procedure volume or short-term complications. Therefore, as laparoscopic sleeve

gastrectomy continues to grow in popularity, a better understanding of the factors underlying this variation in long-term outcomes may be found in studying optimal surgical technique.

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Figure 1. Hospital variation in adjusted rates of new-onset reflux at 1 year after laparoscopic sleeve gastrectomy

Rates of new-onset reflux—defined by new use of acid-reducing medication—were risk- and reliability-adjusted. Volume designation refers to a hospital's mean annual volume for laparoscopic sleeve gastrectomy. Horizontal line indicates overall proportion of patients that experienced new-onset reflux at 1 year.

Figure 2. Adjusted rates of new-onset reflux after laparoscopic sleeve gastrectomy, according to hospital volume

Rates of new-onset reflux—defined by new use of acid-reducing medication—were risk- and reliability-adjusted. Volume refers to a hospital's mean annual procedure volume for laparoscopic sleeve gastrectomy: low-volume (<35 procedures/year), medium-volume (35–82 procedures/year), and high-volume (>82 procedures/year).

Figure 3. Adjusted rates of new-onset reflux after laparoscopic sleeve gastrectomy, according to adjusted overall complication rates

Rates of new-onset reflux—defined by new use of acid-reducing medication—were risk- and reliability-adjusted, as were rates of overall 30-day complications. Hospitals were grouped into quartiles based on adjusted overall complication rates.

Hospital and patient characteristics, according to hospital quartile of new-onset reflux—defined by new use of acid-reducing medication—at 1 year after laparoscopic sleeve gastrectomy.

Table 1

Hospital Characteristic	Hospital Quartile of New-Onset Reflux at 1 Year**			P-value
	Low	Medium	High	
No. hospitals	10	20	9	
No. patients	732	1,619	572	
Annual procedure volume, median (IQR) *	73 (30–83)	57 (18–87)	49 (36–74)	
Adjusted rate of new-onset reflux at 1-year postop (%) †	14.6	20.3	26.4	
Patient Characteristic	% of patients, unless otherwise specified			
Demographics				
Age, mean years (SD)	45 (11)	46 (12)	47 (12)	0.002
Gender, % female	80	75	75	0.011
Race, % white	68	82	87	<0.001
Private insurance, %	84	85	86	0.625
Preoperative body mass index (kg/m ²), mean (SD)	49.4 (8.6)	48.1 (8.6)	48.0 (8.9)	0.001
Comorbidities				
Lung disease	21	19	16	0.064
Cardiovascular disease	51	51	51	0.987
Hypertension	49	49	51	0.803
Hyperlipidemia	44	46	44	0.331
Diabetes	29	29	29	0.947
Gastroesophageal reflux	29	28	15	<0.001
Peptic ulcer disease	1	4	1	<0.001
Cholelithiasis	24	26	24	0.462
Liver disease	6	6	3	0.019
Kidney failure	0.1	0.2	0	0.588
Urinary incontinence	30	23	14	<0.001

Hospital Characteristic	Hospital Quartile of New-Onset Reflux at 1 Year**			P-value
	Low	Medium	High	
Prior venous thromboembolism	4	3	2	0.079
Obstructive sleep apnea	39	42	39	0.264
Musculoskeletal disorder	72	75	55	<0.001
Psychiatric disorder	48	47	41	0.012
History of abdominal hernia repair	3	2	2	0.146
Total comorbidities, mean (SD)	4.0 (2.0)	4.0 (1.9)	3.4 (1.9)	<0.001
Patient Characteristic	% of patients, unless otherwise specified			P-value
Mobility limitations	4	5	3	0.198
Concurrent hiatal hernia repair	20	27	22	0.002
<i>Postoperative Results</i>				
Adjusted rate of overall 30-day complications, % ‡	6.3	5.9	6.7	0.546
Percent excess weight loss at 1 year, %	54.9	60.3	58.1	<0.001
<i>Healthcare Utilization</i>				
Length of hospital stay, mean no. days (SD)	1.8 (0.8)	1.9 (0.8)	2.1 (1.0)	<0.001
Emergency department visits	6.6	6.8	7.2	0.910
Readmissions	3.6	4.4	2.6	0.152
Reoperations	0.6	1.2	0.5	0.190
Transfers	0	0.1	0.4	0.232

* Annual procedure volume: Mean number of laparoscopic sleeve gastrectomy procedures performed per year at a given hospital.

‡ Risk- and reliability-adjusted rates of new-onset reflux, defined by the new use of acid-reducing medication, at 1 year after laparoscopic sleeve gastrectomy were adjusted for patient risk factors that were statistically significant in multivariate analysis (gender, race, mobility limitations, and total number of comorbidities) and procedure year. Rates were significantly different across the hospital quartiles of new-onset reflux ($P<0.001$).

‡ Risk- and reliability-adjusted hospital rates of overall 30-day complications after laparoscopic sleeve gastrectomy were adjusted for patient risk factors that were statistically significant in multivariate analysis (history of mobility limitations, hyperlipidemia, and total number of comorbidities) and procedure year.