Concomitant Hiatal Hernia Repair with Sleeve Gastrectomy: A 5-Year Analysis

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ABSTRACT

Background: The sleeve gastrectomy (SG) can be associated with postoperative gastroesophageal reflux and when a hiatal hernia (HH) is present, it should be fixed. Earlier studies have shown that 20% of SG have a concomitant hiatal hernia repair (SG+HHR). The aim of this project is to determine the rate of SG+HHR in a large state administrative database.

Methods: The Texas Inpatient Public Use Data File (IPUDF) and Outpatient Public Use Data File (OPUDF) for the years 2013-2017 were examined for patients that underwent SG+HHR at the same time. Patient demographics, diagnosis, and charge data were also examined. A t-test was performed between groups and P was considered significant at < 0.05.

Results: In the OPUDF, there were 6,193 (33.7%) patients who underwent SG+HHR out of 18,403 patients who underwent SG. Mean charges were $94,741 [standard deviation (SD) = $87,284]. Length of stay (LOS) was 2.1 (SD = 3.5) vs 2.3 days (SD = 3.3) with a shorter stay for SG+HHR vs SG alone (P < 0.001). In the IPUDF, there were 11,536 (21.1%) patients who underwent SG+HHR out of 54,545 patients who underwent SG. Mean charges were $69,006 (SD = $46,365). LOS was 1.59 days (SD = 3.7) for SG+HHR vs 1.63 days (SD = 1.6) for SG (P = .043). The rate of SG+HHR increased over the study period.

Conclusions: SG+HHR is common in both the outpatient and inpatient setting. There is a yearly trend of increasing rates of SG+HHR.

Key Words: Sleeve Gastrectomy, Hiatal Hernia Repair, Administrative Database.

INTRODUCTION

Bariatric surgery is the most effective treatment of morbid obesity, diabetes mellitus, and many other diseases. The most common bariatric operation in the US is the sleeve gastrectomy (SG). Texas performs 10% of bariatric surgery in the United States. Currently over 65% of the bariatric cases performed are sleeve gastrectomy. SG is known to be associated with de novo occurrence of gastroesophageal reflux disease (GERD), but the exact role and mechanisms the SG plays in the genesis of GERD is unknown. It has been observed that up to 10-30% of patients will develop new onset GERD. This clinical picture remains unclear, as some patients with GERD will actually improve their symptoms after an SG.

There is an emerging consensus to look for a hiatal hernia (HH) at the time of SG and repair it if present. Results from the last International Consensus Conference on Sleeve Gastrectomy indicated that 84% of bariatric surgeons look for HH and think it should be repaired if found. There have been many case series published that address concurrent hiatal hernia repair during SG (SG+HHR). This can be done with or without mesh. Post-operative GERD symptoms can be severe enough to warrant conversion to another procedure, such as a laparoscopic Roux-en-Y gastric bypass (LRYGB), or even a biliopancreatic diversion or duodenal switch. The largest study to date regarding concomitant SG+HHR was recently published. The authors used the Metabolic and Bariatric Surgery Quality Improvement Program (MBSAQIP) database and showed that SG is combined with HHR in up to 21% of patients. They found that only 10% of patients undergoing LRYGB underwent concurrent HHR. This was in spite of the fact that patients undergoing SG had less preoperative GERD.
These papers indicate that bariatric surgeons are interested in GERD after SG, and that HHR is not uncommon at the time of SG.

Administrative databases are one way to evaluate the current state of surgical practice. However, the data must be interpreted with caution as clinical data is not the focus of these databases. Instead, charge data and diagnosis and procedure codes are collected, and these can be used to describe current practice but not show causality. The Texas Department of State Health Services tracks outcomes using the Texas Public Use Data File (PUDF). There are both inpatient (IPUDF) and outpatient databases (OPUDF), each with admission and discharge diagnoses, procedures, length of stay, etc. They are de-identified and HIPPA compliant. We proposed using the IPUDF and OPUDF to determine the percentage of SG+HHR in a large state administrative database. We wanted to determine the percentage of SG+HHR in a large state, as clinical data is not readily available from this administrative database.

METHODS

Databases

The Texas OPUDF contains data on outpatient surgical and radiological procedures from Texas hospitals and ambulatory surgery centers. The Texas Department of State Health Services is responsible under Sections 108.011 through 108.0135 in the Texas Health and Safety Code for collecting data on outpatient surgical and radiological services from hospitals and ambulatory surgery centers except those that are statutorily exempt from the reporting requirement. The data reported are revenue codes and services, Current Procedural Terminology (CPT) codes, and related Healthcare Common Procedure Coding System codes covering hospital outpatient or ambulatory surgical center visits. This includes patients who have had invasive surgical or radiological procedures that are required to be reported. Exempt facilities include those located in a county with a population of less than 35,000. Also exempt are those facilities located in a county with a population of more than 35,000 and fewer than 100 licensed hospital beds, and is not located in an area that is delineated as an urbanized area by the United States Bureau of the Census. Exempt hospitals also include hospitals that do not seek insurance payment or government reimbursement and also federal hospitals. Despite that, the database captures over 12 million pieces of charge data per quarter and covers most of the population in Texas.

The State of Texas also maintains the Texas Hospital Inpatient Discharge Public Use Data File (IPUDF) which collects hospital discharge data from all state licensed hospitals except those that are statutorily exempt from the reporting requirement. The Texas IPUDF also contains information such as ICD-10 procedure and diagnosis codes. The collection of admission, discharge, demographics, and cost data are similar to the OPUDF. A Data Use Agreement was obtained from the Texas Department of State Health Services.

Data collection

The Texas IPUDF and OPUDF for the years 2013-2017 were queried to examine the number of SG performed in Texas with and without HHR. For the IPUDF, we used the International Classification of Diseases version 9 Clinical Modification (ICD-9-CM) procedure and diagnoses codes for the years 2013 to the third quarter 2015; for the fourth quarter of 2015 on we used ICD-10 procedure codes for SG, HHR and for morbid obesity. For the OPUDF, we used CPT codes and the ICD diagnoses codes as this is how the data is reported for the outpatient database. The diagnosis and procedure codes are listed in Table 1.

Statistical Methods

Statistical analyses included independent sample between group t-tests conducted to find significant differences in length of stay and total operation cost. A $P$ was considered significant at 0.05. These t-tests were performed by separating the variables of interest in the IPUDF and the OPUDF. They were further separated into groups based on whether patients underwent solely a sleeve gastrectomy or sleeve gastrectomy and hiatal hernia repair.

Outcomes

The primary outcome of interest was the number of SG+HHR. Secondary outcomes of interest included length of stay, inpatient vs outpatient status, and cost. We also looked at HHR with mesh. This study was exempt from institutional review board approval, as the data were publicly available in a de-identified manner.
RESULTS
From the years 2013-2017, there were 72,948 SG performed in Texas. Overall, 24.3% of these patients underwent SG + HHR. In the OPUDF, there were 6,193 (33.7%) patients who underwent SG + HHR out of 18,403 patients who underwent SG. Over 52% of patients were white, 9.5% Hispanic, and 81.2% female. SG alone had an average of $31,000 less billed charges than SG + HHR. The length of stay (LOS) was 2.1 [standard deviation (SD) = 3.5] vs 2.3 (SD = 3.3) days with a shorter stay for SG + HHR vs SG alone (P < 0.001). In the IPUDF, there were 11,536 (21.1%) patients who underwent SG + HHR out of 54,545 patients who underwent SG. Of these, 61% were white patients, 21.2% Hispanic, and 81.4% female. SG alone had $5,392 billed less charges than for SG + HHR. LOS was 1.59 for SG + HHR vs 1.63 days for SG (P = 0.04). Figure 1 shows the volume of SG vs SG + HHR over the study period.

The number of SG increased continuously throughout the 5-year period. In 2013, 12,271 SG were performed, by 2017, 15,752 SG were performed. The rate of SG + HHR also increased for the first 3 years, dropped in 2016 by 63% from 2015, and then started to rebound in 2017.

There were 800 cases that used mesh in the SG + HHR. This is 4.5% of all patients that underwent SG + HHR. There were significant differences in LOS and cost with SG + HHR with mesh having a LOS of 1.41 days vs 1.77 days (P < 0.006) and an increase in charges of $34,000 (P < 0.001).

DISCUSSION
Our finding of 24.3% of patients undergoing SG + HHR is somewhat higher than has been previously found in other similar large studies. There was a higher rate in patients in the outpatient database (33.7%). We also saw a decrease in HHR in the third quarter of 2015. This was during the transition to ICD-10 and we feel this is probably a coding issue. Mesh placement was also rare at 4%. The Texas PUDF uses billed charges and not actual payments from

| Operation                                      | Diagnosis Code                        | Procedural Code | ICD-10 | CPT |
|------------------------------------------------|---------------------------------------|-----------------|--------|-----|
| Sleeve gastrectomy                             | Morbid obesity (278.01)               | 43.82           | 0DB64Z3| 43775|
|                                                | Morbid (severe) obesity due to excess calories (E66.01) |                 |        |     |
|                                                | Morbid (severe) obesity with alveolar hypoventilation (E66.2) BMI codes for 35.0 and greater for both ICD-9-CM and ICD-10 |                 |        |     |
| Laparoscopic repair of paraesophageal hernia    | Diaphragmatic hernia with gangrene (551.3) | 53.71           | 0BQT4ZZ| 43281|
| Laparoscopic repair of paraesophageal hernia with placement of mesh | Diaphragmatic hernia with obstruction (552.3) | 53.75           | 0BUT4JZ| 43282|

ICD-9-CM, International Classification of Diseases version 9; Clinical Modification; ICD-10, International Classification of Diseases version 10; BMI, body mass index.
the second party payors so the numbers seem inflated. Also, hospitals have a different fee structure for inpatient procedures and that is also different for ambulatory surgery centers. Therefore, the difference in billed charges between SG and SG+HHR is very different in the IPUDF vs the OPUDF.

Docimo et al. found a 21% rate of SG+HHR using the MBSAQIP 2015 data. They did not evaluate if the HHR was with mesh. The other large study that looked at this used the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database. The study spanned the years 2010-2014 and found SG+HHR was performed in 14% of patients. The sample size was somewhat smaller than the MBSAQIP, with only 32,000 patients undergoing SG. Our study, using an administrative database, falls between these two, with 54,545 patients undergoing SG and 17,729 having SG+HHR. The MBSAQIP and NSQIP are both clinical databases, designed to capture clinically relevant data but administrative databases are usually created around charge data. The NSQIP data from 2010-2014 showed a rate of 14%, this increased to 21% in the 2015 MBSAQIP data and in our data spanning 2013-17, it increased further to 24%. Future analysis of the MBSAQIP is needed to see if this rate climbs or stabilizes.

The rate of SG+HHR that we found using this administrative database is a reflection of codes used by facilities to bill third party payors. A major limitation of administrative databases is the lack of detail provided. For example, the rate of HHR may not correlate with the rate of HH in the obese population. Although administrative databases are valuable tools and can be used to independently validate clinical databases, our group has previously published on the substantial differences in the capture rate and reporting between the two types of databases.

The Texas PUDF captures statewide data, so this reflects the broad practice of surgery in the state. We were not able to evaluate by healthcare system or practice, and there may be wide variability in individual surgeon practices. We used the ICD procedure codes and CPT codes for HHR, but that presupposes that the correct codes were reported and that the surgeons doing the operation actually did a formal dissection and cruroplasty. A formal HHR should include a complete mobilization of the gastroesophageal junction, mediastinal mobilization of the esophagus, resection of the hernia sac, and a posterior cruroplasty. Simple anterior repairs may be coded as an HHR, but do not really meet the formal criteria. This may reflect “upcoding,” but there is no way to tell this from the codes used. One would hope this is a rare event, but there is no way to evaluate the operative reports to determine this. This database (or any other large database such as the ACS-NSQIP or MBSAQIP) does not allow for this kind of granular detail. The only formal posterior repairs we can be sure about are the 800 patients who had mesh placed on the diaphragm. To place this mesh, a formal posterior cruroplasty has to be performed, although there are surgeons who perform HHR with an anterior placement of mesh, and the same CPT code is used as for the posterior placement. In this case, we would not be able to differentiate the type of HHR. We also saw an increase in cost with mesh, but a decrease in LOS. This database does not have the detail to determine exactly why that is. The increase in cost is self-explanatory but we are unclear as to why that would lead to earlier discharge.
Hiatal hernia repair at the time of SG

A review of the literature would indicate that repairing the hiatus at time of SG is important. Soricelli et al. reported on a series of SG with and without HHR. There was a total of 97 patients who received SG+HHR and 281 patients who received SG alone. Fifty-five of the 97 patients receiving a SG+HHR were diagnosed with HH intraoperatively, despite a full work up pre-operatively. This indicates the need for adequate inspection of the hiatus during surgery. Their results showed that at 18 months of follow-up, 44 of the 60 patients (73.3%) who had GERD symptoms pre-operatively showed remission of symptoms; the remaining 16 patients showed diminished anti-reflux medication usage. “De novo” GERD symptoms developed in 22.9% of the patients undergoing SG alone compared with 0% of the patients undergoing SG+HHR. A similar study by Samakar et al. demonstrated conflicting data. They reported that 34.6% of symptomatic patients had resolution of their symptoms from medical therapy following SG+HHR, while the rest remained symptomatic and required anti-secretory therapy. A limitation of that study was the subjective nature of the symptoms of reflux as they did not use standardized GERD questionnaires. They also noted “de novo” GERD symptoms in 15.6% of patients following SG+HHR.

The question of post-operative GERD matters because of the sequelae of this disease. Many surgeons see de novo GERD after sleeve to be the Achilles heel of the sleeve gastrectomy. The end stage treatment is usually a conversion to another bariatric procedure, typically a LRYGB. Studies involving single institutions have documented de novo GERD as a significant percentage of indications for conversion from sleeve gastrectomy to LRYGB. Quezada et al. reported GERD as an indication for 32% of their revisions from SG to LRYGB over a 10-year period. Over 90% of their patients with GERD had their symptoms resolve after revision. Landreneau et al. reported similar outcomes over a 9-year period at their institution. Refractory GERD was a complication that resulted in 40.5% of their revisions. Maybe more alarming is a study by Felsenreich et al. that showed a high incidence of Barrett’s esophagus after SG. They showed that at 10 years of follow-up, of the patients that were not converted to RYGB due to intractable reflux, 45% showed de novo hiatal hernias and 15% showed metaplasia on esophagogastro-duodenoscopy. If these numbers bear out, then the SG will see a dramatic decrease in volume.

Our findings are similar to previous reports from large databases. Bariatric surgeons repair HH in about one quarter of patients undergoing SG. There seems to be a general consensus in the literature and the bariatric community that an HH, if present, should undergo repair at the time of the SG. There seems to be high recurrence rates after both SG and SG+HHR. GERD does seem to be reduced with SG+HHR, but with the recent publication by Felsenreich et al. raising the specter of Barrett’s, this issue of GERD and HH becomes even more important.

This study raises many issues that cannot be addressed by administrative databases, and clinical studies will be needed. First and foremost, bariatric surgeons will need to follow their patients and report on rates of recurrence of HH as well as de novo occurrence of HH after SG. Will placement of mesh in a SG+HHR decrease recurrence rates? If mesh does decrease recurrence rates, which mesh is better? And what role does the technique of HHR play in recurrence? These questions will only be answered by clinical studies and close follow-up by surgeons.

Strengths and Limitations

The main limitation of the Texas Inpatient and Outpatient PUDFs is the lack of a unique identifier to follow individual patients over time. A strength is that the databases are mutually exclusive, that is, a patient cannot be entered in both databases for the same visit. The PUDF cannot tell us data that is important to clinicians, such as operative length, 30-day complication rates, or readmissions. We also did not look at mortality as an endpoint. The main focus of this study, given the limitations of this database, was the trend of SG+HHR. There are some demographic limitations which are based on county population of less than 35,000 or more than 35,000 with 100 hospital beds or less and not designated as an urban area. Also exempt are facilities that do not seek reimbursement from governmental sources and federal facilities. Since many ASCs are partly owned by surgeons and can offer a lower price for SG, they may have a higher rate of cash pay patients. Administrative databases are inherently subject to bias if there are errors in the diagnosis or procedure codes that are reported. The state mandates the specific data to be collected, but each hospital is responsible for turning in the data. As a result, there are probably wide variations in data collection, with no standardized training of the data entry personnel. This could also lead to wide variation in reported discharge diagnosis.

CONCLUSIONS

SG+HHR is common in both the outpatient and inpatient setting. SG+HHR costs more in the outpatient setting and
had a shorter LOS than SG. This data agrees with the previously reported studies. Further studies are needed to determine if SG+HHR actually does decrease or prevent GERD long term. There is a yearly trend of increasing rates of SG+HHR and future studies are needed to determine if that rate will continue to climb or stabilize.

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