

# Safety of Revision Sleeve Gastrectomy Compared to Roux-Y Gastric Bypass After Failed Gastric Banding

## Analysis of the MBSAQIP

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**Objective:** The aim of this study was to assess the safety of revisional surgery to laparoscopic sleeve gastrectomy (LSG) compared to laparoscopic Roux-Y gastric bypass (LRYGB) after failed laparoscopic adjustable gastric banding (LAGB).

**Background:** The number of reoperations after failed gastric banding rapidly increased in the United States during the last several years. A common approach is band removal with conversion to another weight loss procedure such as gastric bypass or sleeve gastrectomy in a single procedure. The safety profile of those procedures remains controversial.

**Methods:** Preoperative characteristics and 30-day outcomes from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Participant Use Files 2015 were selected for all patients who underwent a 1-stage conversion of LAGB to LSG (conv-LSG) or LRYGB (conv-LRYGB). Conv-LSG cases were matched (1:1) with conv-LRYGB patients by age ( $\pm 1$  year), body mass index ( $\pm 1$  kg/m<sup>2</sup>), sex, and comorbidities including diabetes, hypertension, hyperlipidemia, venous stasis, and sleep apnea.

**Results:** A total of 2708 patients (1354 matched pairs) were included in the study. The groups were closely matched as intended. The mean operative time in conv-LRYGB was significantly longer in comparison to conv-LSG patients (151  $\pm$  58 vs 113  $\pm$  45 minutes,  $P < 0.001$ ). No mortality was observed in either group. Patients after conv-LRYGB had a clinically increased anastomotic leakage rate (2.07% vs 1.18%,  $P = 0.070$ ) and significantly increased bleed rate (2.66% vs 0.44%,  $P < 0.001$ ). Thirty-day readmission rate was significantly higher in conv-LRYGB patients (7.46% vs 3.69%,  $P < 0.001$ ), as was 30-day reoperation rate (3.25% vs 1.26%,  $P < 0.001$ ). The length of hospital stay was longer in conv-LRYGB.

**Conclusions:** A single-stage conversion of failed LAGB leads to greater morbidity and higher complication rates when converted to LRYGB versus LSG in the first 30 days postoperatively. These differences are particularly notable with regards to bleed events, 30-day reoperation, 30-day readmission, operative time, and hospital stay.

**Keywords:** bariatric surgery, gastric banding, laparoscopic roux-y gastric bypass, laparoscopic sleeve gastrectomy, Metabolic and Bariatric Surgery

Accreditation and Quality Improvement Program (MBSAQIP), revisional surgery

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The introduction of adjustable gastric banding (AGB) was an important step in the evolution of bariatric surgery. The development of the laparoscopic approach to AGB (LAGB) led to an increase in the popularity of this type of surgery. LAGB was very popular technique in the late 1990s and early 2000s as a restrictive alternative to open, and later laparoscopic Roux-Y Gastric Bypass (LRYGB).<sup>1</sup> LAGB quickly became the most popular bariatric operation performed in the United States and Canada because of its relatively low complexity, good short-term results, low perioperative morbidity, and reversibility.<sup>2,3</sup> However, long-term studies revealed that the procedure often leads to serious late complications including band erosion, slippage, and gastric pouch enlargement.<sup>4</sup> Studies with long-term follow-up showed that as many as 61% of patients after LAGB required band removal or conversion to another bariatric procedure because of weight regain and complications.<sup>5–9</sup> As a result, the number of reoperations after LAGB rapidly increased in the United States.<sup>10,11</sup> Many surgeons prefer to convert the gastric banding to another bariatric procedure, usually a gastric bypass (conv-RYGB) or sleeve gastrectomy (conv-SG) at the time of band removal.<sup>12–14</sup> Both techniques are feasible and effective options after LAGB. Satisfactory weight loss has been described after both procedures.<sup>15</sup> An increase in surgery-related complications with these revisions compared with primary procedures has been previously described.<sup>10,16</sup> The safety profile of conv-RYGB versus conv-SG procedures has not been compared in large populations before. The aim of our study was to assess the safety of revision laparoscopic sleeve gastrectomy (LSG) compared to LRYGB after failed LAGB in a large population.

## METHODS

The study is based on analysis of data from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database. The MBSAQIP prospectively collects detailed data on more than hundreds of variables, including standardized and audited demographic variables, preoperative comorbidities, laboratory values, and 30-day postoperative mortality and morbidity outcomes for patients undergoing bariatric procedures in academic and community hospitals in United States. The program has used several mechanisms to ensure that the data collected are of the highest consistency and reliability.<sup>17</sup> We identified all patients who underwent AGB removal with 1-stage conversion to LSG (conv-LSG) or LRYGB (conv-LRYGB) using their respective Current Procedural Terminology codes (AGB removal: 43774, 43772; LSG:43775; LRYGB:43644). A total of 4855 patients from 2015 were included. Conv-LSG cases were matched (1:1) with conv-LRYGB patients by age ( $\pm 1$  year), body mass index (BMI)

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The authors report no conflicts of interest.

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( $\pm 1$  kg/m<sup>2</sup>), sex, and comorbidities including diabetes, hypertension, hyperlipidemia, venous stasis, and sleep apnea to control the confounding factors using the algorithm described by Kawabat (1:1 matching procedure).<sup>18</sup> Cases for whom we could not identify suitable matching control subjects were excluded from the study. The primary outcomes of interest were mortality, leak rate (defined as leak-related 30-day readmission, drain present >30 days, organ space surgical site infection, or leak-related 30-day reoperation or intervention), bleeding event (defined as bleed-related 30-day readmission, bleed-related 30-day reoperation, or requiring a transfusion within 72 hours postoperatively), 30-day readmission, and 30-day reoperation. The secondary outcomes included length of hospital stay (LOS), operative time, and 30-day morbidity [unplanned admission rate to intensive care unit (ICU) within 30 days, pulmonary embolism, space surgical site infections, progressive renal insufficiency, postoperative sepsis, unplanned intubation, postoperative urinary tract infections, vein thrombosis requiring therapy, acute renal failure, postoperative cardiac arrest requiring cardiopulmonary resuscitation (CPR), coma >24 hours, stroke or cerebrovascular accident, postoperative deep incisional surgical site infections, and postoperative myocardial infarction].<sup>19</sup> Analysis was performed using SAS software, University Edition (SAS Institute Inc, Cary, NC). The analysis of matched (dependent) data is different from unmatched (independent) data and is described in detail by Breslow and Day.<sup>20</sup> Continuous outcomes were analyzed using the paired *t* test or Wilcoxon signed ranks test. Dichotomous outcomes were analyzed using McNemar test. Post-hoc analysis was done to explore the observational power for leak rate comparison.

## RESULTS

A total of 2708 patients (1354 matched pairs) were included in the study. The baseline characteristics are presented in Table 1. The

groups were closely matched as intended. We did not observe any significant difference in preoperative steroid or immunosuppressant use for chronic conditions. The numbers of current smokers were comparable between groups. However, a greater percentage of conv-LRYGB-reported gastroesophageal reflux disease (35.97% vs 31.76%, *P* = 0.017), chronic obstructive pulmonary disease was more frequent in patients who underwent conversion to LSG (0.15% vs 0.66%, *P* = 0.035).

No death was observed in analyzed groups. In the conv-LRYGB group, a total of 28 (2.07%) patients experienced a leak and 36 (2.66%) patients experienced a bleed. Patients who underwent conversion to LRYGB had a clinically increased leak rate (2.07% vs 1.18%, *P* = 0.070). Statistical significance was not achieved. However, the post-hoc analysis for leak rate comparison revealed low observational power (0.398). Based on this finding, we may recognize this result as clinically significant. In conv-LRYGB, there was a significantly increased bleed rate (2.66% vs 0.44%, *P* < 0.001) when compared to those who underwent conversion to LSG. Thirty-day readmission rate was significantly higher in conv-LRYGB patients (7.46% vs 3.69%, *P* < 0.001), as was 30-day reoperation rate (3.25% vs 1.26%, *P* < 0.001) (Table 2). Operative time and LOS are reported in Table 3. The mean operative time in conv-LRYGB was significantly longer in comparison to conv-LSG patients (151 ± 58 vs 113 ± 45 minutes, *P* < 0.001). There was no significant difference in conversions rate of laparoscopic approach to open between conv-LRYGB and conv-LSG patients (0.15% vs 0.44%, *P* = 0.157). Patients after conv-LRYGB had a longer hospital stay in comparison to conv-LSG (2.3 ± 2.8 vs 1.8 ± 2.1 days, *P* < 0.001). Unplanned admission rate to intensive care unit within 30 days was significantly higher in conv-LRYGB (1.48% vs 0.37%, *P* = 0.003). Pulmonary embolism was more frequent in conv-LRYGB patients (1.33% vs 0.15%, *P* < 0.001). Superficial incisional surgical site infection rate

**TABLE 1.** Descriptive Characteristics of Patients

Variable	Conv-LSG	Conv-LRYGB	<i>P</i>	Definition
	N = 1354	N = 1354		
	Mean (SD) or N (%)			
Basic characteristic				
Age, y	44.6 (9.4)	44.5 (9.3)	0.490	—
Sex, female	96.16%	96.16%	—	—
Preoperative BMI (kg/m <sup>2</sup> )	40.6 (5.2)	40.6 (5.2)	0.864	Calculated based on the preoperative weight and height.
Hypertension	71.42%	71.42%	—	Hypertension requiring medication for >2 weeks.
Diabetes type 2	3.33%	3.33%	—	Treatment regimen of the patient's chronic, long-term management (treated >2 weeks) within the 30 days before the principal operative procedure or at the time the patient is being considered a candidate for surgery.
OSA	13.15%	13.15%	—	Obstructive sleep apnea requiring CPAP or BiPAP (or similar technology) as prescribed by a physician.
Dyslipidemia	7.24%	7.24%	—	Current treatment owing to hyperlipidemia or history of treatment with medications before weight loss or dietary modification
GERD	31.76%	35.97%	0.017	A patient with the diagnosis of GERD in which they regularly take prescribed or over-the-counter medication within 30 days of the principal operative procedure
Chronic steroid use	1.77%	1.48%	0.546	Regular administration of oral or parenteral corticosteroid or immunosuppressant medications, within the 30 days before the surgery for a chronic medical condition fulfills this definition
COPD	0.66%	0.15%	0.035	COPD resulting in any ≥1 of the following: functional disability, previous hospitalization, on chronic medications, and abnormal pulmonary function test.
Smoking status	6.57%	6.43%	0.876	Current smoker within 1 year.

BiPAP indicates bilevel positive airway pressure; COPD, chronic obstructive pulmonary disease; CPAP, continuous positive airway pressure; GERD, gastroesophageal reflux disease.

**TABLE 2.** Comparison of Primary Outcomes

Outcome	Conv-LSG	Conv-LRYGB	P	Definition
	N = 1345	N = 1354		
	%			
Mortality	0%	0%	—	Death
Leak/anastomotic leakage rate	1.18%	2.07%	0.070	One of following: drain present >30 days, organ space surgical site infection, leak-related 30-day readmission, or leak-related 30-day reoperation or intervention.
Bleeding event	0.44%	2.66%	<0.001	One of following: bleed-related 30-day readmission, bleed-related 30-day reoperation, or requiring a transfusion within 72 hours postoperatively.
30-day readmission	3.69%	7.46%	<0.001	Any readmission to an acute care bed (eg, OBS, in-patient) or 23-hour observation within 30 days following the bariatric or metabolic surgery procedure.
30-day reoperation	1.26%	3.25%	<0.001	Return to the operating room within 30 days following the bariatric or metabolic surgery procedure.

OBS indicates observation.

was higher in patients who underwent conversion to LRYGB (2.95% vs 0.37%,  $P < 0.001$ ).

We did not observe any significant difference regarding following secondary outcomes: space surgical site infections, progressive renal insufficiency, postoperative sepsis, unplanned intubation, postoperative urinary tract infections, and vein thrombosis requiring therapy.

We did not observe any episodes of coma during 24 hours, acute renal failure, postoperative cardiac arrest requiring CPR, stroke or cerebrovascular accident, or postoperative myocardial infarction.

## DISCUSSION

To our knowledge, this is the first MBSAQIP database analysis of perioperative outcomes comparing 1-stage conversion of LAGB to either gastric bypass or sleeve gastrectomy. We found that 1-stage

revision sleeve gastrectomy compared to 1-stage Roux-Y gastric bypass after failed gastric banding had better safety profile in the short term. There were no fatal cases. Our analysis revealed that patients converted to LRYGB had higher 30-day reoperation and 30-day readmission rates. Conversion to LRYGB was associated with a significantly increased bleed rate. We also found that in conv-LRYGB, there were more cases of anastomotic leakage in comparison to leak rate after conv-LSG. Owing to a clear trend toward significance and low observational power for this comparison, this result is clinically significant. The longer operative time and increased LOS in the RYGB group reflect the more complex nature of this procedure as compared to sleeve gastrectomy. The present study shows that laparoscopic revisions to either LSG or LRYGB can be performed safely in approximately 99% of patients. The need for conversion to open in our study was low.

**TABLE 3.** Comparison of Secondary Outcomes

Outcome	Conv-LSG	Conv-LRYGB	P	Definition
	N = 1354	N = 1354		
	Mean (SD) or N (%)			
Hospital stay, days	1.8 (2.1)	2.3 (2.8)	<0.001	Time from procedure to discharge.
Operative time, min	113 (45)	151 (58)	<0.001	—
30-day morbidity				
Space surgical site infections	0.44%	0.66%	0.439	Infection involving any anatomic structure rather than the surgical incision which appears to be related to the operation.
Superficial incisional surgical site infections	0.37%	2.95%	<0.001	Infection that occurs within 30 days after the principal operative procedure and involves only skin or subcutaneous tissue of the incision.
30 days unplanned admission to ICU	0.37%	1.48%	0.003	An unplanned admission to the ICU at any time within the 30 day postoperative period.
Unplanned intubation	0%	0.07%	NA	The placement of an endotracheal tube or other similar breathing tube (laryngeal mask airway, nasotracheal tube, among others) and ventilator support, which was not intended or planned.
Pulmonary embolism	0.15%	1.33%	<0.001	Based on positive V-Q scan, CT scan, pulmonary arteriogram, or any other definitive modality.
Vein thrombosis requiring therapy	0.15%	0.15%	1.000	Documented with imaging studies and requiring therapy.
Progressive renal insufficiency	0.15%	0.22%	0.655	Worsening of renal function postoperatively requiring dialysis, in a patient who did not require dialysis preoperatively.
Postoperative urinary tract infections	0.15%	0.37%	0.257	Infection in the urinary tract (kidneys, ureters, bladder, and urethra) within 30 days following bariatric procedure.

Insufficient effectiveness in terms of weight loss and the risk of serious complications are the primary indications for revision or reversal of LAGB. Authors have reported that 8% to 61% of patients after LAGB required band removal or conversion to another bariatric procedure.<sup>5–9</sup> According to the literature, the most common indication for conversion is insufficient weight loss. The second most common indication is a problem related to band (ie, slippage or erosion). Other indications included dysphagia, gastric pouch dilatation, and intractable gastroesophageal reflux.<sup>21</sup>

There is a lot of controversy about which type of surgery is the best revisional procedure after a failed gastric banding. LRYGB and LSG are the most common operations for revision after failed LAGB. Conversion of LAGB to LSG is controversial because LSG is considered another restrictive procedure. Many note that if a patient failed 1 restrictive operation, then another restrictive procedure will have equally poor outcomes in terms of weight loss. Therefore, some surgeons have preferred LRYGB after a failed LAGB.<sup>13</sup> However, studies have reported comparable effectiveness of converting LAGB to LRYGB or LSG in terms of weight loss.<sup>1,22,23</sup> Based on these studies, conversions from band to LSG or LRYGB are feasible. The purpose of this article is to analyze short-term outcomes and safety. Perhaps these findings should be taken in context with the long-term outcomes in terms of weight loss and efficacy.

Safety in revisional bariatric surgery is a major concern. Risk of anastomotic leakage or staple line leakage following revision of a previous LAGB conceptually increases because of the thick tissue of the band capsule and the altered anatomy.<sup>24</sup> Higher leakage rate after revisional LSG may indicate that the tissue of the stomach after banding needs time to recover.<sup>25</sup> Interestingly, the findings of that study are contradicted by our findings in a large population.

This analysis of the American College of Surgeons (ACS) NSQIP PUF for 2010 to 2014 demonstrates that converting LAGB to LSG is associated with a modest increase in risk-adjusted adverse 30-day outcomes in comparison to the index surgery, but less than conversion to RYGBP. Most notable were the deep surgical site infections, which may reflect the presence of leakage (LSG: 0.05 vs LSG-Conv: 0.40%).<sup>16</sup> In an analysis published by Aurora et al,<sup>26</sup> the overall risk of leak after primary LSG was at 2.4%. In our analysis, LSG after gastric banding showed a leakage rate of 1.18%, which is lower than that study, but higher than that reported from primary sleeve gastrectomy in the MBASQIP database (0.9%).<sup>27</sup>

According to the first report from ACS-Bariatric Surgery Center Network (ACS-BSCN), the overall risk of anastomotic leak after primary LRYGB was 0.78%.<sup>28</sup> Analysis of ACS-NSQIP Database done by Ramly et al has shown that the rate of sepsis—used as a surrogate marker for leakage—following LRYGB with concomitant gastric band removal is similar to that following primary LRYGB (0.78% vs 0.74%). These authors concluded that revisional RYGB is not associated with higher morbidity and mortality compared to primary LRYGB.<sup>29</sup> In our study, an anastomotic leakage percentage of 2.07% was found in conv-LRYGB group. After primary LRYGB, this number is reported between 1.1% and 5.0%.<sup>30,31</sup> The rate of reoperations after revisional LRYGB was 3.25%. This is comparable to reoperation rates reported in the literature after primary LRYGB (3.2%).<sup>32</sup>

There is a debate whether revisional procedures should be concomitant (1-stage) or delayed (2-stage). Theunissen et al, in an analysis of 107 patients converted to LRYGB after gastric banding, stated that the overall complication rate in 1-step and 2-step groups was similar (16.9% vs 16.7%). Interestingly, they found more major complications in the 2-step group, which was previously believed to be the safer option (1.4% vs 5.6%).<sup>33</sup> Similar results were reported by Emous et al (4.6% vs. 4.5%).<sup>34</sup> The analysis of the German Bariatric Surgery Registry showed that LRYGB as 1-stage approach had

comparable leakage rate to the 2-stage approach (1.9% vs 2.6%). Yet, the authors stated in conclusion that the multivariable analysis for overall intraoperative complications revealed a significant difference between the 2-step and the 1-step procedure, favoring the 1-step approach.<sup>35</sup>

However, a separate analysis of the same database revealed that conversion of LAGB to LSG is more safe with the 2-stage approach. Authors reported that the incidence of leakage following a 1-step conv-LSG after LAGB was significantly higher (4.4%) than for a 2-step approach (0%). The bleeding rate required transfusions was higher in 2-step approach (0.8% vs 5.4%).<sup>36</sup> It needs to be emphasized that in that analysis, the sample size was low and those differences were not significant. In our study, we focused on the 1-stage approach because proper identification of patients who underwent 2-step procedure was not possible utilizing this database.

Studies comparing LSG and LRYGB after failed gastric band did not report significant differences in short-term complications. Authors stated that both techniques are safe.<sup>1,15,22</sup> A meta-analysis published by Magouliotis et al<sup>36</sup> showed no significant difference between LRYGB and LSG groups in terms of leaks, postoperative bleeding, and abscess. A systematic review published by Coblijn et al revealed that long-term complications were seen in 8.9% of patients after LRYGB and stenosis at the gastrojejunostomy was the most common complication at 6.5%. In this analysis, only 3 studies reported long-term complications after LSG.<sup>25</sup> Of those, only 1 case of an internal herniation was reported.<sup>37</sup> Angrisani et al noticed 3 cases of dumping syndrome and 1 case of internal hernia during first year after LRYGB. In contrast, there was no complication in patients after revision to LSG.<sup>15</sup>

Our study shows that the main advantage of conv-LSG carries a significantly lower risk of short term complications in comparison to conv-LRYGB. It is difficult to determine whether both procedures are comparable in terms of long-term complications because there are not enough data. Based on the aforementioned studies, long-term complications were reported mainly in patients after LRYGB. Despite these complications, Magouliotis et al noted an important benefit of LRYGB after failed gastric banding. They found percentage of excess weight loss and BMI reduction were significantly greater after 24 months in conv-LRYGB group in comparison to LSG. The authors recommended caution with those results because of the lack of randomized control trials.<sup>21</sup> The dataset used for this study cannot assess efficacy of the procedures, but the large population allows for robust data on short-term safety.

Our study has several important limitations. First, despite all the advantages of MBSAQIP, database-collected data are observational. The association between adverse events should be tested in a controlled environment and in a prospective manner to evaluate a potential causal relationship. Considering the low rate of adverse events, it would be very difficult to conduct a randomized control study with enough power to show a difference. Even in our study, we failed to reach sufficient power for a true leak rate comparison. Based on the leak rates from the analysis, the estimated number of pairs should be 4225 to rule out the possibility of II type error. Second, there is important intraoperative variation in technique and experience of the surgeons that is not captured and could contribute to the outcomes of these patients. Numerous technical aspects of the procedure were not assessed. Third, the variables available in PUF 2015 does not allow for efficacy assessment. Likewise, some important factors that could affect risk profile such as operative findings and indications are not included. For example, conversion for band erosion may be associated with higher risk profile than conversion for weight regain. Finally, MBSAQIP is a large, clinical database that may contain errors or omissions that could distort or alter our findings.

Available studies assessing LRYGB and LSG after gastric banding are limited by small sample size and the presence of confounders.<sup>16,21,29</sup> Age, BMI, diabetes, and hypertension are identified factors associated with higher odds of serious complication in bariatric surgery.<sup>16</sup> Our analysis of prospectively collected data from MBASQIP allowed for us to overcome the sample size limitation and control the influence of important cofounders by using a strict matching process. These advantages of our study make the results unique and reliable.

## CONCLUSIONS

This study demonstrates that single-stage laparoscopic Roux-Y gastric bypass and laparoscopic gastric sleeve as revisional procedures after gastric banding are relatively safe in the short term with an acceptable complication rate and no mortality. However, LRYGB is more challenging as a conversion procedure and is associated with significantly increased rates of bleed events, 30-day reoperation, 30-day readmission, longer operative time, and longer hospital stay. It is also notable that LRYGB is associated with a clinically significant increase in leak rate. In the short term, conversion of failed gastric banding to sleeve gastrectomy is associated with significantly fewer 30-day complications than conversion to gastric bypass. The decision to perform such a conversion should be based on individual surgeon's preference, while taking these risks into account. These risks reflect only the safety of the procedures; however, the efficacy still requires further evaluation in large populations.

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