




Patient Selection and 30-Day Outcomes of SADI-S Compared to RYGB: a Retrospective Cohort Study of 47,375 Patients

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Abstract

Purpose Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) offers a novel bariatric procedure with few comparative studies evaluating patient selection or perioperative outcomes. We aim to compare SADI-S to Roux-en-Y gastric bypass (RYGB).

Materials and Methods The 2020 Metabolic and Bariatric Accreditation and Quality Improvement Program (MBSAQIP) registry was analyzed, comparing SADI-S to RYGB. Bivariate analysis was performed to determine intergroup differences. Multivariable logistic regression determined factors associated with serious complications and mortality.

Results We evaluated 47,375 patients, with 501 (1.1%) receiving SADI-S. Patients undergoing SADI-S had higher body mass index (51.4 ± 9.7 kg/m² SADI-S vs. 44.6 ± 7.9 kg/m² RYGB; $p < 0.001$), and more metabolic comorbidities including non-insulin dependent diabetes (21.7% SADI-S vs 19.0% RYGB; $p = 0.011$), insulin dependent diabetes (12.0% SADI-S vs. 8.6% RYGB; $p = 0.011$), and hypertension (54.9% SADI-S vs 47.6% RYGB; $p < 0.001$). Patients undergoing SADI-S experienced more anastomotic leaks (2.2% vs. 0.5%; $p < 0.001$), reoperations (5.0% vs 2.6%; $p < 0.001$), pneumonias (1.6% vs 0.5%; $p < 0.001$), had sepsis more frequently (1.4% vs 0.3%; $p < 0.001$), and required more unplanned reintubations (1.2% vs 0.3%; $p = 0.004$). SADI-S was independently associated with serious complications (OR 1.45, CI 1.09–1.95, $p < 0.001$) but was not a predictor of mortality (OR 3.29, $p = 0.060$).

Conclusions In comparison to RYGB, patients undergoing SADI-S were found to have more metabolic comorbidities. Compared to RYGB, SADI-S has worse perioperative outcomes and is independently associated with serious complications. It remains unclear whether this represents a learning curve or true findings and prospective studies analyzing the risk–benefit ratio following SADI-S are needed.

Key Points SADI-S is offered to younger patients with more metabolic comorbidities.

SADI-S may have increased perioperative risks compared to RYGB.

SADI-S may be independently associated with serious complications.

Future studies remain needed to completely characterize SADI-S outcomes.

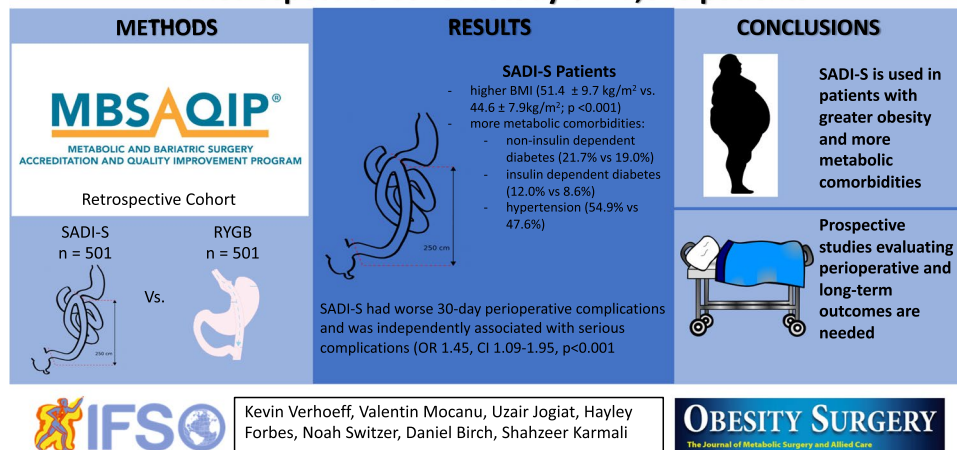
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Graphical abstract

Patient Selection and 30-Day Outcomes of SADI-S Compared to RYGB: A Retrospective Cohort Study of 47,375 patients



Keywords SADI-S · Bariatric surgery · Single anastomosis duodeno-ileal bypass with sleeve gastrectomy · Duodenal switch · RYGB

Introduction

Studies evaluating single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) have increased dramatically in the last decade. Initially described by Sanchez-Pernaute in 2007, SADI-S combines sleeve gastrectomy (SG) with a modified duodenal switch (DS) procedure using only one anastomosis [1]. Its description originated primarily due to concerns regarding substantial perioperative risk with the classic DS, despite recognized metabolic benefits. By completing only one anastomosis but achieving similar anatomy to a DS and adding a restrictive component, proponents suggest that SADI-S could achieve improved long-term metabolic outcomes to Roux-en-Y gastric bypass (RYGB) with similar or better perioperative outcomes [2]. Despite many studies reporting improved perioperative outcomes with SADI-S compared to DS [3–9], only one single-center retrospective cohort study has compared SADI-S to RYGB, the gold-standard metabolic procedure. To best evaluate the risk–benefit profile of SADI-S, studies investigating patient selection and perioperative outcomes compared to RYGB are needed.

The original statement on SADI-S from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) in 2018 considered potential benefits from SADI-S, but suggested ongoing evaluation due to limited studies [10]. Since then, several studies and two systematic reviews have evaluated SADI-S suggesting that perioperative risks for SADI-S are reduced compared to DS and

demonstrating promising short and medium term outcomes [3–8]. In response, an updated statement from IFSO stated that SADI-S has substantial weight loss and comorbidity improvements, but suggested additional evidence evaluating perioperative outcomes, and long-term results [11].

We aimed to provide the largest study to date evaluating patient selection and perioperative outcomes for patients undergoing SADI-S compared to RYGB. Understanding which patients are being selected for SADI-S and comparing outcomes to RYGB, the current gold standard bariatric procedure, will enable better assessment of the utility of SADI-S for bariatric surgeons and will help guide future studies evaluating this relatively new technique.

Materials and Methods

Data Source

Data from the 2020 MBSAQIP database was evaluated for this study. This data is prospectively collected for patients undergoing bariatric surgery from 885 centers in North America and characterized key pre-operative, operative, and post-operative outcomes for nearly 1 million patients. Only MBSAQIP accredited centers contribute data and all participating centers are subject to frequent review of data collection practices to ensure accuracy and reliability. Data is collected based on well-defined, uniform variables and collected anonymously [12]. Due to data anonymity and the

source of data, this study was exempt from research ethics board review.

Study Design, Patient Population, and Variable Definitions

This is a retrospective cohort study of prospectively collected data. The primary outcomes of this study were to comparatively assess patient selection and 30-day perioperative outcomes for patients undergoing SADI-S compared to RYGB. Secondary outcomes evaluated the influence of SADI-S on serious postoperative complications and 30-day mortality among bariatric surgery patients.

Patients included in this study were categorized into two distinct cohorts, those undergoing SADI-S and those undergoing RYGB as categorized by the MBSAQIP. Patients receiving other procedures including sleeve gastrectomy, intragastric balloon, standard DS, and gastric band were excluded; this was done in order to directly compare SADI-S to the gold-standard bariatric surgery procedure. Only patients undergoing first-time elective bariatric surgery were included.

To assess patient selection, demographics were obtained and compared between both cohorts. Comparisons were made evaluating gender, race, and pre-operative body mass index (BMI). Cardiac comorbidities evaluated were hyperlipidemia, hypertension, previous myocardial infarction (MI), previous percutaneous coronary intervention (PCI), and previous cardiac surgery. Pulmonary comorbidities evaluated were presence of active smoking, sleep apnea, and chronic obstructive pulmonary disease (COPD). Other comorbidities evaluated to characterize patient selection were history of venous thromboembolism (VTE), gastroesophageal reflux disease (GERD), diabetes mellitus (DM), venous stasis, renal insufficiency, dialysis dependency, therapeutic anticoagulation, and chronic steroid use. Operative time was also assessed to comparatively assess procedure time of both techniques.

Perioperative outcomes evaluated 30-day readmission to hospital, reoperation, and reintervention based on MBSAQIP definitions [12]. Additionally, infectious complications such as the rate of anastomotic leak, deep surgical site infection (SSI), wound disruption, urinary tract infection (UTI), pneumonia, and sepsis are reported. Other post-operative complications evaluated include unplanned intubation, acute renal failure (described as any renal failure requiring dialysis), myocardial infarction (MI), and cerebral vascular accidents (CVA). We also evaluated emergency department re-presentation and the need for outpatient dehydration treatment. Furthermore, we evaluated mortality, and serious complications, post-operative bleeding, and anastomotic leak as defined in the appendix.

Statistical Analysis

In all cases, categorical data was expressed as absolute values with percentages, while continuous data were expressed as a weighted mean \pm standard deviation. Cohort differences were evaluated using chi-squared for categorical data and ANOVA for continuous data. All statistical analysis was completed using the STATA 17 statistical software (Stata-Corp, College Station, TX, USA).

To adjust for comorbidities and determine independent predictors of 30-day post-operative serious complications and mortality, a non-parsimonious multivariable logistic regression model was developed using a hypothesis-driven purposeful selection methodology. Bivariate analysis of variables with a p -value < 0.1 or from variables previously deemed clinically relevant to our primary outcome were used to generate a main effects model. The Brier Score (BS) and the receiver operating characteristic (ROC) curve were used to assess goodness of fit.

Results

Patient Demographics

A total 47,375 were included in this study, with 501 (1.1%) undergoing SADI-S. Patients selected for SADI-S were younger (43.2 ± 11.6 SADI-S vs. 45.4 ± 11.5 RYGB; $p < 0.001$) and were more likely to be female (76.3% SADI-S vs 74.8% RYGB; $p < 0.001$). Patients undergoing SADI-S also had a significantly higher BMI (51.4 ± 9.7 kg/m² SADI-S vs. 44.6 ± 7.9 kg/m² RYGB; $p < 0.001$) and a higher ASA classification, with over twice as many being ASA class 4–5 (9.8% SADI-S vs 4.1% RYGB; $p < 0.001$; Table 1). Additionally, patients receiving SADI-S had more metabolic comorbidities including non-insulin dependent diabetes (21.7% SADI-S vs 19.0% RYGB; $p = 0.011$), insulin dependent diabetes (12.0% SADI-S vs 8.6% RYGB; $p = 0.011$), hypertension (54.9% SADI-S vs 47.6% RYGB; $p < 0.001$), and had more hyperlipidemia, although this difference was not statistically significant (29.5% SADI-S vs 26.1% RYGB; $p = 0.081$). Otherwise, SADI-S and RYGB patients were similar with regards to other comorbidities (Table 1).

Bivariate Analysis of Post-Operative Outcomes

Patients undergoing SADI-S were more likely to experience anastomotic leak (2.2% vs. 0.5%; $p < 0.001$) and required reoperation twice as frequently (5.0% vs 2.6%; $p < 0.001$; Table 2). Other key perioperative differences between groups included that patients undergoing SADI-S experienced sepsis more frequently (1.4% vs 0.3%; $p < 0.001$),

Table 1 Patient characteristics comparing patients undergoing single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) to those undergoing Roux-en-Y gastric bypass (RYGB)

	SADI-S <i>n</i> = 501 <i>n</i> (%)	RYGB <i>n</i> = 46,874 <i>n</i> (%)	<i>p</i> -value*
Age, years			
Mean ± SD	43.2 ± 11.6	45.4 ± 11.5	<0.001
Gender			<0.001
Female	382 (76.3)	129,429 (74.8)	
Male	119 (23.8)	7593 (16.2)	
Non-binary	0 (0)	15 (0.03)	
BMI, kg/m ²			
Mean ± SD	51.4 ± 9.7	44.6 ± 7.9	<0.001
ASA class			
1–2	46 (9.2)	7841 (16.7)	<0.001
3	405 (80.8)	37,060 (79.1)	
4–5	49 (9.8)	1922 (4.1)	
Smoker	44 (8.8)	2285 (6.0)	0.010
Diabetes			
No or diet controlled	332 (66.3)	125,419 (72.5)	0.011
Non-insulin dependent	109 (21.7)	32,864 (19.0)	
Insulin dependent	60 (12.0)	14,827 (8.6)	
Hypertension	275 (54.9)	22,293 (47.6)	0.001
GERD	123 (24.6)	21,461 (45.8)	<0.001
COPD	10 (2.0)	690 (1.5)	0.334
Hyperlipidemia	148 (29.5)	12,231 (26.1)	0.081
Chronic steroid use	15 (3.0)	1018 (2.2)	0.210
Renal insufficiency	2 (0.4)	264 (0.6)	0.625
Dialysis dependent	1 (0.2)	96 (0.2)	0.980
History of DVT	12 (2.4)	1033 (2.2)	0.772
Venous stasis	4 (0.8)	368 (0.8)	0.973
Preoperative therapeutic anticoagulation	18 (3.6)	1467 (3.1)	0.554
Sleep apnea	222 (44.3)	19,274 (41.1)	0.149
History of MI	5 (1.0)	553 (1.2)	0.708
Previous major cardiac surgery	5 (1.0)	429 (0.9)	0.847
Previous PCI	2 (0.4)	784 (1.7)	0.066
Conversion to Open	0 (0)	10 (0.2)	0.923
Operative time, minutes			
Mean ± SD	142.1 ± 60.3	131.2 ± 63.2	<0.001

SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; SD, standard deviation; BMI, body mass index; ASA, American Society of Anesthesiologists; GERD, gastroesophageal reflux disease; COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis; MI, myocardial infarction; PCI, percutaneous coronary intervention

**p*-values were determined using chi-squared analysis for categorical data and ANOVA for continuous data

required unplanned reintubation (1.2% vs 0.3%; *p* = 0.004), and had more acute renal failure (1.0% vs 0.2%; *p* < 0.001), and pneumonia (1.6% vs 0.5%; *p* < 0.001). Patients undergoing RYGB required more outpatient dehydration treatment (4.1% vs 3.8%; *p* = 0.034); however, emergency department re-representation was similar between groups (9.5% vs 13.2%; *p* = 0.987). Most notably, patients undergoing SADI-S had significantly increased mortality (0.6% vs 0.1%; *p* = 0.004). Serious complications were higher after SADI-S but

differences were not statistically significant (10.6% vs 8.3%; *p* = 0.070), and other complications were similar between groups (Table 2).

Multivariable Logistic Regression Evaluating Predictors of Serious Complications and Mortality

On multivariable analysis, renal insufficiency and prior MI were the most substantial contributors to serious

Table 2 Thirty-day post-operative outcomes for patients undergoing single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) to those undergoing Roux-en-Y gastric bypass (RYGB)

	SADI-S n=501 n (%)	RYGB n=46,874 n (%)	p-value
Anastomotic leak	11 (2.2)	215 (0.5)	<0.001
Gastrointestinal bleed	7 (1.4)	352 (0.8)	0.407
Readmission	38 (7.6)	2703 (5.8)	0.083
Reintervention	14 (2.8)	901 (1.9)	0.158
Reoperation	25 (5.0)	1221 (2.6)	<0.001
Urinary tract infection	1 (0.2)	223 (0.5)	0.669
Deep SSI	2 (0.4)	79 (0.2)	0.448
Sepsis	7 (1.4)	121 (0.3)	<0.001
Wound disruption	0 (0)	46 (0.1)	0.774
Unplanned intubation	6 (1.2)	146 (0.3)	0.004
Acute renal failure	5 (1.0)	82 (0.2)	<0.001
Pneumonia	8 (1.6)	214 (0.5)	<0.001
Myocardial infarction	1 (0.2)	14 (0.03)	0.034
Outpatient dehydration treatment	19 (3.8)	1925 (4.1)	0.031
Emergency re-presentation	4 (9.5)	641 (13.2)	0.987
Cerebral vascular accidents	0 (0)	16 (0.03)	0.679
Serious complications	53 (10.6)	3905 (8.3)	0.070
Mortality	3 (0.6)	60 (0.1)	0.004

SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; SSI, surgical site infection

complications followed closely by SADI-S procedure (*OR* 1.45, *CI* 1.09–1.95, $p < 0.001$ Table 3). Other factors independently associated with serious complications included GERD, COPD, prior DVT, and smoking history. On the other hand, increased age and BMI, and male gender, appeared to be protective (Table 3). The multivariable model predicted serious complications accurately with an area under the curve of 0.8847 and Brier score of 0.0012.

The most substantial factors associated with mortality were complications including anastomotic leak (*OR* 20.65, $p < 0.001$) and postoperative bleed (*OR* 9.90, $p < 0.001$), followed by renal insufficiency (*OR* 7.21, $p < 0.001$). Other independent factors statistically associated with mortality were previous MI, increased age, and BMI (Table 4). SADI-S had higher odds of mortality, although the effect was not statistically significant (*OR* 3.29, $p = 0.060$). This multivariable model for mortality had an area under the curve of 0.6029 and Brier score of 0.0755.

Discussion

This is the largest study to date comparatively evaluating patient selection and perioperative outcomes following SADI-S. Although patients undergoing SADI-S were

Table 3 Multivariable logistic regression for serious complications

Risk factor	Odds ratio	95% confidence interval	p-value
SADI-S (as compared to RYGB)	1.45	1.09–1.95	0.012
Age (compared by decade)	0.96	0.93–0.99	0.019
Male gender	0.78	0.71–0.86	<0.001
BMI	0.94	0.92–0.96	<0.001
Renal insufficiency	1.84	1.32–2.57	<0.001
Dialysis dependence	1.55	0.89–2.69	0.121
Previous MI	1.62	1.27–2.06	<0.001
GERD	1.25	1.16–1.33	<0.001
Hypertension	1.10	1.02–1.18	0.018
Hyperlipidemia	1.07	0.98–1.17	0.133
Diabetes	0.85	0.77–0.93	0.001
Non-insulin dependent	1.15	1.03–1.29	0.015
Insulin dependent			
COPD	1.42	1.13–1.78	0.002
Smoker	1.16	1.02–1.32	0.025
Prior DVT	1.39	1.14–1.70	0.001
Sleep apnea	1.04	0.97–1.12	1.04

SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; BMI, body mass index; MI, myocardial infarction; GERD, gastroesophageal reflux disease; COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis

younger, they had increased BMI and greater metabolic comorbidities than patients receiving RYGB. SADI-S resulted in worse perioperative outcomes, including a significant increase in anastomotic leak, reoperation, sepsis, unplanned reintubation, acute renal failure, pneumonia, and mortality. After adjusting for comorbidities, SADI-S remained a substantial independent contributor to 30-day serious complications. Overall, patients selected for SADI-S appears to be more comorbid, while perioperative outcomes should be evaluated with caution and require further investigation to determine the effect of SADI-S learning curves and center experience.

Previous studies evaluating SADI-S have shown similar findings for patient selection. Both current systematic reviews evaluating SADI-S, one evaluating observational studies and the other comparative studies, both found that patients undergoing SADI-S had increased rates of DM and higher BMI compared to other procedures including RYGB [9, 13, 14]. Studies comparing demographics specifically between patients receiving SADI-S and RYGB have had similar findings [15, 16]. Because DS procedures were previously reported to be highly effective in terms of metabolic comorbidity reversal, and that SADI-S has been purported as a safer surgical option with similar benefits, these patient selection findings make sense [9, 17]. Early and medium term outcomes following SADI-S have also

Table 4 Multivariable logistic regression for 30-day mortality

Risk factor	Odds ratio	95% confidence interval	<i>p</i> -value
SADI-S (as compared to RYGB)	3.29	0.95–11.34	0.060
Age (compared by decade)	2.37	1.77–3.18	<0.001
Male gender	1.78	0.97–3.27	0.061
BMI	1.46	1.26–1.69	<0.001
Renal insufficiency	7.21	2.91–17.87	<0.001
Dialysis dependence			
Previous MI	2.74	1.05–7.17	0.040
GERD	1.73	0.98–3.05	0.057
Hypertension	1.49	0.73–3.03	0.278
Hyperlipidemia	1.08	0.58–2.00	0.802
Diabetes (as compared to no diabetes)	0.75	0.36–1.58	0.456
Non-insulin dependent	0.97	0.45–2.08	0.941
Insulin dependent			
COPD	0.19	0.02–1.49	0.113
Smoker	1.24	0.46–3.35	0.670
Anticoagulation	1.34	0.56–3.20	0.512
Operative duration	1.00	1.00–1.00	0.027
Anastomotic leak	20.65	9.44–45.19	<0.001
Postoperative bleed	9.90	4.69–20.90	<0.001
Prior DVT	2.50	0.91–6.90	0.077

SADI-S, single anastomosis duodeno-ileal bypass with sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; BMI, body mass index; MI, myocardial infarction; GERD, gastroesophageal reflux disease; COPD, chronic obstructive pulmonary disease; DVT, Deep Vein Thrombosis

shown substantial benefits in terms of comorbidity resolution, potentially matching those for RYGB, and DS [2, 9, 18, 19].

In spite of the potential benefits for patients with increased BMI and metabolic comorbidities, the risks associated with SADI-S must be considered to evaluate the overall benefit for future patients. While previous reports, including a recent systematic review by Verhoeff et al. (2022) have suggested that SADI-S offers a safe alternative to metabolic procedures including DS [3–9], comparing outcomes to RYGB, the gold standard metabolic procedure provides surgeons with a better perspective on perioperative complications. This comparison has only been completed by Surve et al. (2021), who evaluated a matched cohort of 61 patients undergoing SADI-S and RYGB from a single site and found similar perioperative outcomes between groups [2]. The results from our study contradict previous studies and introduces potential concerns regarding the perioperative risk associated with SADI-S, especially considering its independent association with serious complications. Notably, however, it should be highlighted that MBSAQIP outcomes represent procedures completed at 885 centers,

including those who are adept at SADI-S and those who are just beginning its use. Our data suggest a nearly double rate of mortality, reoperation, and complication compared to the recent systematic review by Verhoeff et al. (2022) and therefore, results should be interpreted cautiously [9]. SADI-S represents a relatively new technique and complications found in this study may represent a learning curve as it is introduced more broadly. Furthermore, the definition of serious complications represents a composite variable including several outcomes and may explain some of the differences in outcomes found in this study. Comparative evaluation of outcomes over time may be beneficial. Furthermore, the metabolic benefits for high risk patients that appear to be selected for SADI-S may also outweigh these risks in certain circumstances.

To summarize, it appears that patients selected for SADI-S appear to have more comorbidities, which most studies have found. On the other hand, while experienced centers have found promising outcomes following SADI-S, this study suggests higher complications. While results from this study may represent findings due to a learning curve and should be considered, they do not necessarily preclude use of SADI-S. They do however highlight that a patient-by-patient risk–benefit assessment is required. For example, SADI-S may offer a potential treatment option for patients suffering from super-obesity, which represent a growing population that are often difficult to treat, especially with regards to long-term metabolic outcomes [20–25]. In these patients, the benefits of rapid metabolic improvements potentially achieved with SADI-S may prove to be life-saving. Additionally, offering SADI-S as a revisional procedure following SG, or as a two stage procedure, may reduce perioperative complications and maintain metabolic benefits [26–36]. Ongoing studies evaluating implementation of SADI-S, long term outcomes, and data evaluating the learning curve of this procedure would greatly benefit surgeons as they attempt to best serve a variety of patients.

This study has a number of limitations, most substantial of which is that this study is retrospective in nature and limited by data collected by the MBSAQIP. Applying a retrospective analysis may introduce important selection or bias that should be recognized. Data collected during this study was collected during the COVID-19 pandemic, which may also affect patient selection or outcomes. Unfortunately, the MBSAQIP did not definitively characterize outcomes for patients undergoing SADI-S previously, preventing us from presenting a longitudinal analysis. However, the COVID-19 pandemic is likely to affect both groups equally and has recently been shown to not affect perioperative outcomes substantially in bariatric surgery patients [37]. Furthermore, this study only evaluates primary, single stage SADI-S procedures, and the outcomes, risks, and potential benefits may differ in scenarios where SADI-S is applied as a revisional

procedure or two stage procedure, both of which have been described [26–36, 38]. The MBSAQIP also collects data from 885 centers, which although offers the strength of large sample sizes, fails to characterize outcomes from specific centers. As discussed, outcomes presented here represent those from North American centers as a whole, including those who are just beginning SADI-S, and those who are proficient; this may account for higher complication rates found in this study compared to those reported by single centers with large SADI-S volumes. Similarly, this data represents only an average of patient selection and outcomes for those 885 centers, and outcomes or patient selection may vary among those centers. Finally, the MBSAQIP does not capture long-term outcomes, limiting our evaluation of the potential metabolic benefits offered by SADI-S.

Despite limitations, this is the largest study comparatively evaluating patient selection and perioperative outcomes for patients undergoing SADI-S compared to RYGB. While patients selected for SADI-S appear to be more comorbid, this study should help inform surgeons with regard to perioperative outcomes following SADI-S. Prospective studies evaluating long-term outcomes, novel approaches to SADI-S such as the two-stage procedure, and the potential for a learning curve with improved outcomes in the future are needed.

Conclusion

Current evidence, including findings from this study, suggest that SADI-S is being utilized in patients with greater BMI and metabolic comorbidities. While previous studies have suggested relative perioperative safety with SADI-S, findings here suggest significantly worse perioperative outcomes including a significant increase in anastomotic leak, reoperation, sepsis, unplanned reintubation, acute renal failure, pneumonia, and mortality. Additionally, after adjusting for comorbidities, SADI-S was independently associated with serious complications at 30-days. These findings need to be considered during the surgical risk assessment for potential patients. High quality prospective studies evaluating the balance of risks and benefits are needed prior to widespread uptake of this initially promising technique.

Appendix

Data Collection Definitions

Anastomotic leak — Defined by any of the following: reoperation for anastomotic/staple line leak, readmission for anastomotic/staple line leak, reintervention for anastomotic/

staple line leak, drain present 30 days postoperatively, or death caused by anastomotic/staple line leak.

Postoperative bleed — Defined by any of the following: reoperation for bleed, readmission for bleed, reintervention for bleed, transfusion required in first 72 h of surgery start time, and death caused by bleeding.

Serious complication — Defined by any of the following: cardiac complications, pneumonia, acute renal failure, reoperation, reintervention, venous thromboembolism, deep surgical site infection, wound disruption, sepsis, unplanned intubation, leak, bleed, coma > 24 h, and cerebral vascular accident.

Declarations

Ethics Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent to Participate Informed consent does not apply for this study.

Conflict of Interest The authors declare no competing interests.

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