

## Appendix L. 30-day Postoperative Safety Outcomes

This analysis reports short-term outcomes for metabolic and bariatric surgeries (MBS) in adults and adolescents.

### Background

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) registry<sup>1</sup> is the largest bariatric-specific clinical database in North America. The MBSAQIP registry prospectively collects patient-level perioperative data in a standardized fashion from more than 800 accredited centers in the US and Canada.<sup>2</sup> Each entry in the database reflects a single surgical procedure and up to 30 days follow-up.<sup>2</sup> It is important to note that the MBSAQIP registry collects all-cause adverse events within the 30-day postoperative period, therefore reported adverse events may not necessarily be associated with an MBS procedure.

### Methods

We analyzed HIPAA-compliant patient-level data from the MBSAQIP registry for the years 2016 to 2022. Only data from individuals, undergoing MBS as a primary surgery (i.e., not a revisional procedure) at an MBSAQIP-accredited center and who had a full 30 days of follow up were included in our analysis. Exclusion criteria included a prior MBS, conversion or revision procedures, and emergency surgery. Adult and pediatric patients with missing values for height or weight, for whom body mass index (BMI) could not be calculated, were excluded. We also omitted records for adult patients with biologically implausible values for height (i.e., < 48 inches or > 84 inches) or weight (i.e., < 75 lbs or > 800 lbs), as defined by Noel and colleagues.<sup>3</sup>

For patients 18 years and older, analysis was restricted to individuals with a BMI of at least 30 kg/m<sup>2</sup>. It should be noted that in 2004 the World Health Organization (WHO) consulted with experts from the Asia-Pacific region to define appropriate BMI thresholds in these populations.<sup>4</sup> The Asia-Pacific WHO expert panel defined overweight as a BMI of at least 23 kg/m<sup>2</sup> and less than 25 kg/m<sup>2</sup>, and obesity as a BMI greater than or equal to 25 kg/m<sup>2</sup> based on risk of comorbid conditions (e.g., type 2 diabetes mellitus, hypertension).<sup>4</sup> While these lower thresholds still have not been formally accepted by WHO globally, they are used within the Asia-Pacific region.<sup>5</sup> In keeping with recommendations from the National Institute for Health and Care Excellence (NICE), the BMI threshold for obesity has been reduced to a BMI  $\geq$  27.5 kg/m<sup>2</sup> for individuals of Black and Asian ancestry.<sup>6</sup> Obesity has generally been divided into 3 classes, but some researchers and organizations have expanded the classes and we have used these expanded definitions for our analysis. The obesity classes for this analysis are defined:

- Class 1 obesity (BMI  $\geq$  30 to < 35 kg/m<sup>2</sup>, or  $\geq$  27.5 to < 35 kg/m<sup>2</sup> for Black and Asian individuals)
- Class 2 obesity (BMI  $\geq$  35 to < 40 kg/m<sup>2</sup>)
- Class 3 obesity (BMI  $\geq$  40 to < 50 kg/m<sup>2</sup>)
- Class 4 obesity (BMI  $\geq$  50 to < 60 kg/m<sup>2</sup>)
- Class 5 obesity (BMI  $\geq$  60.0 kg/m<sup>2</sup>)

### Identifying Procedure Type in the MBSAQIP

Currently 8 procedures are endorsed by the American Society for Bariatric and Metabolic Surgery and some require the use of specific devices (e.g., intragastric balloons [IGBs]). When reporting multiple types of MBS through synthesis (e.g., meta-analysis), it is common for MBS to be categorized as combined, malabsorptive, or restrictive, therefore we have used these categories and are classified as:

- Combined: Roux-en-Y (RYGB) and single-anastomosis duodenal ileostomy with sleeve (SADI-S)
- Malabsorptive: biliopancreatic diversion (BPD), with or without, and one-anastomosis gastric bypass (OAGB)
- Restrictive: adjustable gastric banding (AGB), endoscopic sleeve gastroplasty (ESG), IGB, and sleeve gastrectomy (SG)

These categories are related to the primary surgical approach taken, and were used in analysis with the acknowledgement that metabolic changes associated with bariatric surgery are complex and go beyond the specific means of anatomic rearrangement.<sup>7,8</sup> The categories are widely used in analysis of MBSAQIP data.<sup>9-11</sup>

No data was available for SADI-S prior to 2020. Endoscopic sleeve gastroplasty procedures could not be definitively identified prior to 2020, when additional procedure coding variables were added to the registry, therefore we only used data from 2020 through 2022.<sup>12, 2023, Ali</sup> Data on all other procedures were available for the full 7-year period from 2016 to 2022.

Furthermore, while we are only interested in current FDA-approved devices, the MBSAQIP registry does not always include the specific device used, therefore results may include devices no longer available on the market or only available outside the US (e.g., Canada). Our analysis includes descriptive statistics, chi-square testing for relationships between categorical variables, and t-tests and ANOVA (analysis of variance) for comparison of means for continuous variables (e.g., BMI). All analyses were conducted using SAS v.9.4 (SAS Institute, Cary, NC).

### 30-day Safety Outcomes for Adults

#### Patient Characteristics

We identified a total of 1,089,905 patients who met inclusion criteria. Mean age was 44.0 years and mean BMI was 45.2 kg/m<sup>2</sup> (mean range, 37.0 to 51.7 kg/m<sup>2</sup>; Table 1). While we didn't include individuals with a BMI less than 30 kg/m<sup>2</sup> in our analysis, these patients made up 0.06% of reported procedures (BMI range, 15.8 to 29.9 kg/m<sup>2</sup>). Patients were mostly female (80.7%), White (68.9%) or Black (18.9%), and non-Hispanic (83.9%). Most (75%) patients had at least 1 obesity-related comorbidity with the most common being high blood pressure (46.1%), sleep apnea (38.1%), gastroesophageal reflux disease (GERD; 30.4%), and T2DM (24.9%).

Table 1. Mean BMI and Obesity Class by MBS procedure

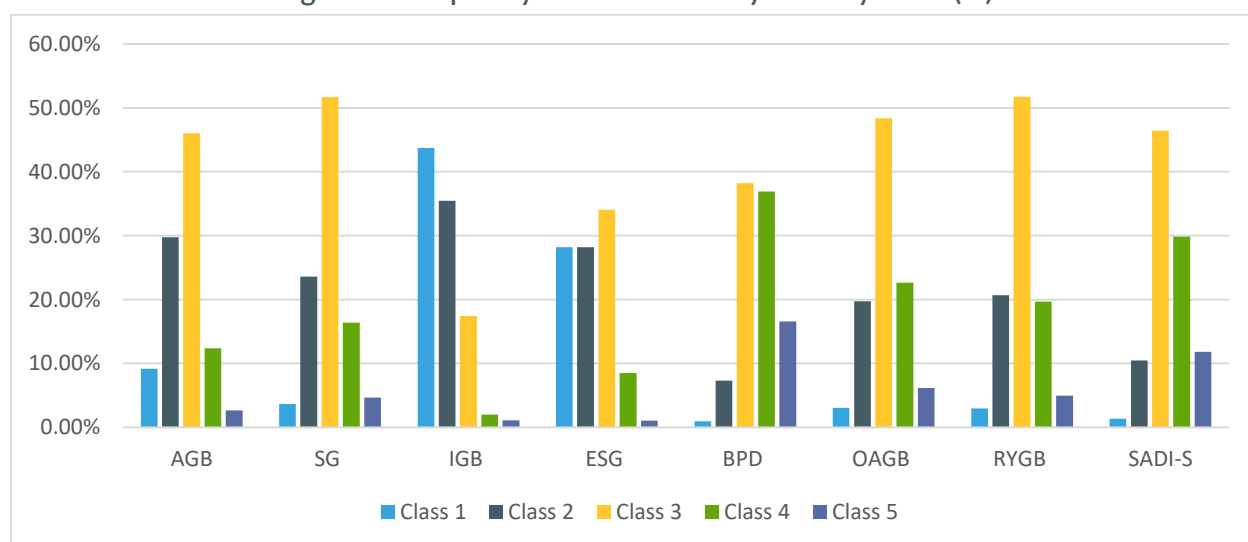
MBS Procedure	Number of Patients	Mean BMI		Obesity Class				
		kg/m <sup>2</sup>	SD	1	2	3	4	5
AGB	8,973	42.98	7.13	9.19	29.74	46.03	12.37	2.66
BPD	11,180	51.67	9.26	0.94	7.31	38.19	36.93	16.6
ESG	1,480	40.12	7.11	28.18	28.18	34.05	8.51	1.08
IGB	3,072	37.02	5.95	43.72	35.48	17.41	1.99	1.11
OAGB	7,630	46.36	7.99	3.04	19.75	48.4	22.66	6.15
RYGB	273,474	45.73	7.63	2.94	20.69	51.71	19.7	4.95
SADI-S	2,394	49.44	8.80	1.38	10.48	46.45	29.87	11.82
SG	765,770	44.97	7.66	3.67	23.6	51.69	16.37	4.67

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; BPD: biliopancreatic duodenal switch; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SD: standard deviation; SG: sleeve gastrectomy.

Most patients underwent SG (71.3%) or RYGB (25.5%); the remaining 6 procedures represented only 3.2% of all procedures included in analysis. The most common MBS procedures among male patients were BPD (27.1%) and SADI-S (21.1%; *P* < .001). Black patients were more likely to undergo AGB (20.3%), SG (20.7%), or ESG (17.8%) and least likely to undergo BPD (11.7%) or IGB (10.9%; *P* < .001).

Figure 1 illustrates the distribution of procedures by obesity class. Most procedures targeted individuals with class 3 obesity. Individuals with class 1 or class 2 obesity were more likely to undergo IGB and ESG. Meanwhile, BPD was performed more often in individuals with class 4 or class 5 obesity (*P* < .001).

Figure 1. Frequency of Procedures by Obesity Class (%)



Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic duodenal switch; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; SG: laparoscopic sleeve gastrectomy; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy.

## Overview

In the 1.1 million MBS procedures reported across 7 years, only 2 adverse events of any type occurred in more than 1% of adult patients: 1 or more emergency department visits (7.5%; n = 81,478) and dehydration-related events requiring outpatient treatment (4.0%; n = 43,502; Table 2). The most common serious adverse events were transfusions required within 72 hours of the start of the procedure and unplanned admissions to intensive care units (ICU), both occurring in less than 1% of all procedures performed (Table 2). Readmissions, reoperations, and postoperative interventions (e.g., therapeutic or diagnostic endoscopy) occurred in less than 5% of patients, and fewer than 1,000 deaths (0.08%) occurred within the first 30 postoperative days. An overview of the adverse events and serious adverse events is available in Table 2. This section will further explore these outcomes by category of MBS procedure (e.g., malabsorptive), MBS procedure type, and adverse events of special interest (e.g., death, reoperation).

Table 2. All Recorded Adverse Events Occurring Within 30-Days in Adults

Type of Event	% of Patients Affected	Number of Patients Affected
<b>Adverse events</b>		
≥ 1 emergency department visit	7.48	81,478
Outpatient treatment for dehydration	3.99	43,502
Postoperative GI tract bleeding <sup>a</sup>	0.40	1,333
Postoperative superficial incisional SSI	0.37	4,041
Postoperative urinary tract infection	0.35	3,803
Postoperative organ or space SSI	0.25	2,672
Postoperative pneumonia	0.18	1,921
Postoperative deep incisional SSI	0.05	533
Postoperative wound disruption	0.05	588
<b>Serious adverse events</b>		
Transfusion within 72 hours of surgery start	0.65	7,073
Unplanned admission to ICU	0.58	6,374
Postoperative bowel obstruction <sup>a</sup>	0.28	937
Postoperative DVT requiring therapy	0.20	2,212
Postoperative anastomotic or staple-line leak <sup>a</sup>	0.17	792
Postoperative pulmonary embolism	0.12	1,264
Postoperative unplanned intubation	0.11	1,187
Postoperative sepsis	0.10	1,127
<i>Clostridium difficile</i> colitis	0.09	1,018
Death within 30 days	0.08	901
Postoperative septic shock	0.06	625
Postoperative ventilator > 48 hours	0.06	676
Postoperative renal failure	0.06	622
Intra-operative or postoperative cardiac arrest requiring CPR	0.04	427
Intraoperative or postoperative myocardial infarction	0.03	294
Postoperative stroke or cerebrovascular accident	0.01	142

Type of Event	% of Patients Affected	Number of Patients Affected
Readmissions, reoperations, and adverse events requiring intervention		
≥ 1 hospital readmission	3.35	35,512
≥ 1 reoperation	1.11	12,098
≥ 1 intervention required	0.97	10,572

Note. The total number of patients was 1,089,950. <sup>a</sup> Variable was not available for all years in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry.

Abbreviations. CPR: cardiopulmonary resuscitation; DVT: deep vein thrombosis; GI: gastrointestinal; ICU: intensive care unit; SSI: surgical site infection.

### Adverse Events by Procedure Category

We conducted chi-square testing to identify within- and between-group differences in the frequency of the most common adverse events among the 3 procedure categories—combined, restrictive, and malabsorptive. Because some adverse events, such as staple-line leak, do not pertain to all procedures, chi-square testing was also conducted for procedure subgroups. Some small differences were observed in the frequency of adverse events and serious adverse events between the 3 categories though these differences were larger for reoperations and readmissions (Table 3). In all instances, patients undergoing restrictive procedures (e.g., IGB, SG) experienced higher rates of adverse events of any type compared with combined procedures (e.g., RYGB; all,  $P < .01$ ). In most cases, more adverse events and serious adverse events occurred in patients who underwent a malabsorptive procedure (e.g., OAGB) versus a combined procedure (Table 3).

Table 3. Differences in 30-Day Adverse Events Between Procedure Categories

Type of Event	<sup>a</sup> Combined, %	<sup>b</sup> Malabsorptive, %	<sup>c</sup> Restrictive, %	Malabsorptive vs. Combined	Restrictive vs. Combined
Total number of patients	275,868	18,810	779,295	N/A	N/A
<b>Any adverse event</b>					
≥ 1 emergency department visits	9.97	9.15	6.55	<i>P</i> < .001	<i>P</i> < .001
Outpatient treatment for dehydration <sup>f</sup>	4.91	4.63	3.65	<i>P</i> = .09	<i>P</i> < .001
Surgical site infection	1.19	1.47	0.43	<i>P</i> < .001	<i>P</i> < .001
Other infection	1.14	1.25	0.55	<i>P</i> = .17	<i>P</i> < .001
Postoperative wound disruption	0.08	0.11	0.04	<i>P</i> = .14	<i>P</i> < .001
Postoperative GI tract bleeding <sup>d</sup>	0.75	0.69	0.25	<i>P</i> = .70	<i>P</i> < .001
<b>Serious adverse events</b>					
Transfusion within 72 hours of surgery start	1.02	0.82	0.51	<i>P</i> = .009	<i>P</i> < .001
Unplanned admission to ICU	0.90	1.41	0.44	<i>P</i> < .001	<i>P</i> < .001
Postoperative bowel obstruction <sup>d</sup>	0.89	0.64	0.04	<i>P</i> = .046	<i>P</i> < .001
Medical emergency <sup>e</sup>	0.41	0.53	0.34	<i>P</i> = .02	<i>P</i> < .001
Postoperative anastomotic or staple-line leak <sup>d</sup>	0.23	0.60	0.13	<i>P</i> < .001	<i>P</i> < .001
Postoperative unplanned intubation	0.18	0.28	0.08	<i>P</i> = .002	<i>P</i> < .001
Postoperative DVT requiring therapy	0.18	0.19	0.21	<i>P</i> = .72	<i>P</i> = .005
Postoperative pulmonary embolism	0.17	0.29	0.09	<i>P</i> < .001	<i>P</i> < .001
<i>Clostridium difficile</i> colitis	0.15	0.14	0.07	<i>P</i> = .92	<i>P</i> < .001
Death	0.13	0.23	0.06	<i>P</i> < .001	<i>P</i> < .001
Postoperative renal failure	0.09	0.13	0.04	<i>P</i> = .08	<i>P</i> < .001
Postoperative ventilator > 48 hours	0.12	0.20	0.04	<i>P</i> = .005	<i>P</i> < .001
<b>Readmissions and reoperations</b>					
≥ 1 readmission	5.29	5.62	2.58	<i>P</i> = .047	<i>P</i> < .001
≥ 1 reoperation	2.01	2.41	0.73	<i>P</i> < .001	<i>P</i> < .001

Notes. The total number of patients analyzed was 1,089,950. <sup>a</sup> Combined procedures are RYGB and SADI-S. <sup>b</sup> Malabsorptive procedures are BPD and OAGB. <sup>c</sup> Restrictive procedures are AGB, ESG, IGB, and SG. <sup>d</sup> Variable was not available for all years in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry. <sup>e</sup> Medical emergencies include cardiac arrest, myocardial infarction, stroke, pulmonary embolism, and deep vein thrombosis. <sup>f</sup> Dehydration included nausea and vomiting or fluid, electrolyte, or nutritional depletion.

Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic diversion; ESG: endoscopic sleeve gastropasty; GI: gastrointestinal; ICU: intensive care unit; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve; SG: sleeve gastrectomy.

### *Adverse Events in Restrictive MBS Procedures in Adults*

Among the restrictive procedures, adverse events were most common in patients undergoing ESG or SG compared with AGB or IGB (Table 4).

Patients who underwent SG or ESG were significantly more likely to experience at least 1 readmission, a medical emergency (e.g., cardiac arrest, pulmonary embolism), or deep vein thrombosis (DVT) requiring therapy compared with other restrictive procedures ( $P < .001$ ; Table 4). The likelihood of an emergency department visit, unplanned admission to an ICU, or a transfusion initiated within 72 hours of the surgery start was significantly more likely among individuals undergoing SG ( $P < .001$ ) compared with other restrictive procedures. Compared with other restrictive procedures, postoperative pulmonary embolism was significantly more common among patients undergoing ESG ( $P \leq .01$ ).

Patients undergoing AGB were less likely to require treatment for dehydration compared with other restrictive procedures (range, 3.68% to 5.63%;  $P < .001$ ). Wound disruption was more commonly associated with AGB than SG ( $P = .004$ ); no wound disruption events were recorded for ESG or IGB. There were no surgical site infections associated with IGB procedures and no significant differences between the remaining restrictive procedures ( $P = .55$ ).

Table 4. 30-Day Adverse Events for Restrictive MBS Procedures

Adverse Event	Overall, %	AGB, %	ESG, %	IGB, %	SG, %	Across MBS type
Total number of patients	779,295	8,973	1,480	3,072	765,770	N/A
<b>Any adverse event</b>						
≥ 1 emergency department visits	6.55	4.01	3.92	4.04	6.59	<i>P</i> < .001
Outpatient treatment for dehydration <sup>a</sup>	3.65	0.90	4.66	5.63	3.68	<i>P</i> < .001
Other infection	0.55	0.29	0.41	0.23	0.55	<i>P</i> < .001
Surgical site infection	0.43	0.40	0.27	0.00	0.44	<i>P</i> = .002
Postoperative GI tract bleeding <sup>b</sup>	0.25	0.13	0.28	0.00	0.26	<i>P</i> = .43
Postoperative wound disruption	0.04	0.11	0.00	0.00	0.04	<i>P</i> = .006
<b>Serious adverse events</b>						
Transfusion within 72 hours of surgery start	0.51	0.08	0.00	0.00	0.51	<i>P</i> < .001
Unplanned admission to ICU	0.44	0.16	0.27	0.13	0.44	<i>P</i> < .001
Medical emergency <sup>c</sup>	0.34	0.14	0.68	0.03	0.34	<i>P</i> < .001
Postoperative DVT requiring therapy	0.21	0.07	0.34	0.00	0.21	<i>P</i> < .001
Postoperative anastomotic or staple-line leak <sup>b</sup>	0.13	0.00	0.00	0.00	0.13	<i>P</i> = .10
Postoperative pulmonary embolism	0.09	0.07	0.34	0.00	0.09	<i>P</i> = .004
Postoperative unplanned intubation	0.08	0.02	0.07	0.07	0.08	<i>P</i> = .29
<i>Clostridium difficile</i> colitis	0.07	0.00	0.07	0.00	0.07	<i>P</i> = .04
Death	0.06	.01	0	.03	.06	<i>P</i> = .18
Postoperative bowel obstruction <sup>b</sup>	0.04	0.00	0.09	0.00	0.04	<i>P</i> = .61
Postoperative renal failure	0.04	0.01	0.00	0.00	0.04	<i>P</i> = .27
Postoperative ventilator > 48 hours	0.04	0.03	0.07	0.00	0.04	<i>P</i> = .67
<b>Readmissions and reoperations</b>						
≥ 1 readmission	2.58	1.64	2.57	1.69	2.59	<i>P</i> < .001
≥ 1 reoperation	0.73	0.79	0.54	1.11	0.73	<i>P</i> = .07

Notes. <sup>a</sup> Dehydration included nausea and vomiting or fluid, electrolyte, or nutritional depletion. <sup>b</sup> Variable was not available for all years in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry. <sup>c</sup> Medical emergencies include cardiac arrest, myocardial infarction, stroke, pulmonary embolism, and deep vein thrombosis. Abbreviations. AGB: adjustable gastric band; ESG: endoscopic sleeve gastropasty; GI: gastrointestinal; ICU: intensive care unit; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; N/A: not applicable; SG: sleeve gastrectomy.

**Adverse Events for Malabsorptive MBS Procedures in Adults**

Patients undergoing BPD were significantly more likely to experience at least 1 hospital readmission or reoperation, unplanned admission to an ICU, or unplanned intubation compared with OAGB (all, *P* ≤ .05; Table 5). Meanwhile, patients undergoing OAGB were more likely to experience at least 1 emergency department visit, treatment for dehydration, or transfusion within 72 hours of surgery start compared with BPD patients (all, *P* ≤ .01; Table 5).



Table 5. 30-Day Adverse Events for Malabsorptive MBS Procedures

Adverse Event	Overall, %	BPD, %	OAGB, %	BPD vs. OAGB
Total number of patients	18,810	11,180	7,630	N/A
<b>Any adverse event</b>				
≥ 1 emergency department visits	9.15	8.06	10.75	$P < .001^c$
Outpatient treatment for dehydration	4.63	3.81	5.83	$P < .001^c$
Surgical site infection	1.47	1.57	1.30	$P = .11$
Other infection	1.25	1.38	1.06	$P = .06$
Postoperative GI tract bleeding <sup>a</sup>	0.69	0.70	0.68	$P = .94$
Postoperative wound disruption	0.11	0.15	0.05	$P = .047$
<b>Serious adverse events</b>				
Unplanned admission to ICU	1.41	1.67	1.04	$P < .001$
Transfusion within 72 hours of surgery start	0.82	0.69	1.02	$P = .01^c$
Postoperative bowel obstruction <sup>a</sup>	0.64	0.52	0.80	$P = .20$
Postoperative anastomotic/staple-line leak <sup>a</sup>	0.60	0.74	0.43	$P = .09$
Medical emergency <sup>b</sup>	0.53	0.57	0.46	$P = .31$
Postoperative pulmonary embolism	0.29	0.32	0.25	$P = .41$
Postoperative unplanned intubation	0.28	0.36	0.17	$P = .02$
Death within 30 days of operation	0.23	0.28	0.17	$P = .17$
Postoperative ventilator > 48 hours	0.20	0.22	0.16	$P = .40$
Postoperative DVT requiring therapy	0.19	0.22	0.14	$P = .24$
<i>Clostridium difficile</i> colitis	0.14	0.13	0.16	$P = .70$
Postoperative renal failure	0.13	0.16	0.09	$P = .23$
<b>Readmissions and reoperations</b>				
≥ 1 readmission within 30 days	5.62	5.86	5.28	$P = .09$
≥ 1 reoperation within 30 days	2.41	2.81	1.83	$P < .001$

Notes. <sup>a</sup> Variable was not available for all years in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry. <sup>b</sup> Medical emergencies include cardiac arrest, myocardial infarction, stroke, pulmonary embolism, and deep vein thrombosis. <sup>c</sup> Favors OAGB.

Abbreviations. BPD: biliopancreatic diversion; DVT: deep vein thrombosis; GI: gastrointestinal; ICU: intensive care unit; MBS: metabolic and bariatric surgery; N/A: not applicable; OAGB: one-anastomosis gastric bypass.

### Adverse Events in Combined MBS Procedures in Adults

We identified few significant differences in the frequency of adverse events between procedures (Table 6). Patients undergoing RYGB were significantly more likely to have at least one hospital readmission, emergency department visit, or postoperative bowel obstruction compared with SADI-S. Meanwhile, patients undergoing SADI-S were significantly more likely than those undergoing RYGB to experience a postoperative anastomotic or staple-line leak or postoperative renal failure.

Table 6. 30-Day Adverse Events for Combined MBS Procedures

Adverse Event	Overall, %	RYGB, %	SADI-S, %	RYGB vs. SADI-S
Total number of patients	275,868	273,474	2,394	N/A
<b>Any adverse event</b>				
≥ 1 emergency department visits	9.97	9.99	8.23	<i>P</i> = .004
Outpatient treatment for dehydration	4.91	4.91	4.68	<i>P</i> = .63
Surgical site infection	1.19	1.19	1.17	<i>P</i> = .93
Other infection	1.14	1.14	1.17	<i>P</i> = .85
Postoperative GI tract bleeding <sup>a</sup>	0.75	0.75	0.52	<i>P</i> = .28
Postoperative wound disruption	0.08	0.08	0.00	<i>P</i> = .27
<b>Serious adverse events</b>				
Transfusion within 72 hours of surgery start	1.02	1.02	1.00	<i>P</i> = .94
Unplanned admission to ICU	0.90	0.90	0.75	<i>P</i> = .51
Postoperative bowel obstruction <sup>a</sup>	0.89	0.90	0.46	<i>P</i> = .048
Medical emergency <sup>b</sup>	0.41	0.41	0.54	<i>P</i> = .33
Postoperative anastomotic/staple-line leak <sup>a</sup>	0.23	0.22	0.54	<i>P</i> = .004 <sup>c</sup>
Postoperative unplanned intubation	0.18	0.18	0.25	<i>P</i> = .32
Postoperative DVT requiring therapy	0.18	0.18	0.17	<i>P</i> = .87
Postoperative pulmonary embolism	0.17	0.17	0.25	<i>P</i> = .31
Clostridium difficile colitis	0.15	0.15	0.04	<i>P</i> = .28
Death within 30 days	0.13	0.13	0.17	<i>P</i> = .55
Postoperative ventilator > 48 hours	0.12	0.12	0.13	<i>P</i> = .76
Postoperative renal failure	0.09	0.09	0.25	<i>P</i> = .02 <sup>c</sup>
<b>Readmissions and reoperations</b>				
≥ 1 readmission within 30 days	5.29	5.30	4.26	<i>P</i> = .02
≥ 1 reoperation within 30 days	2.01	2.01	2.05	<i>P</i> = .88

Notes. <sup>a</sup> Variable was not available for all years in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry. <sup>b</sup> Medical emergencies include cardiac arrest, myocardial infarction, stroke, pulmonary embolism, and deep vein thrombosis. <sup>c</sup> Favors SADI-S

Abbreviations. DVT: deep vein thrombosis; GI: gastrointestinal; ICU: intensive care unit; MBS: metabolic and bariatric surgery; N/A: not applicable; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy.

### Relationship Between Adverse Events and Preoperative Comorbidities

The majority of patients (75%) had at least one chronic comorbid condition (e.g., high blood pressure, T2DM, sleep apnea) at the time of their MBS procedure, and 3% had a history of cardiac-related events (e.g., cardiac surgery, pulmonary embolism). The severity of comorbidities are categorized as mild (1 to 2 comorbidities), moderate (4 to 6 comorbidities), or high (≥ 7 comorbidities). Patients with at least 1 comorbid condition or a prior surgery were significantly more likely to experience any adverse event compared with those with no preoperative comorbidities (*P* < .001; Table 7). Furthermore, individuals with a higher number of comorbidities experience higher a higher frequency of adverse events.

Table 7. Frequency of Select Adverse Events and the Severity of Preoperative Comorbidities

Adverse Event	None, %	Mild, %	Moderate, %	High, %	No Comorbidities vs. $\geq 1$ Comorbidity
Total number of patients	276,336	521,833	288,717	3,019	N/A
<b>Any adverse event</b>					
> 1 emergency department visit	7.29	7.48	7.63	9.94	$P < .001$
Treatment for dehydration	3.90	4.10	3.87	4.64	$P < .001$
<b>Serious adverse events</b>					
Unplanned ICU admission	0.22	0.46	1.13	3.81	$P < .001$
Death	0.03	0.06	0.17	0.70	$P < .001$
Unplanned intubation	0.03	0.08	0.22	0.89	$P < .001$
<b>Readmissions and reoperations</b>					
Reoperation	0.79	1.05	1.50	2.91	$P < .001$
Readmission	2.59	3.16	4.38	8.89	$P < .001$

Note. Levels of comorbidity severity are defined as mild (1 to 2 comorbidities), moderate (3 to 5 comorbidities), and high ( $\geq 7$  comorbidities).

Abbreviation. ICU: intensive care unit; N/A: not applicable.

### All-Cause Death Within 30 Days of MBS Procedure in Adults

Postoperative death within 30 days occurred 901 (0.08%) patients (Table 8). Despite nearly 90% of deaths occurring in individuals who underwent SG or RYGB, individuals who underwent BPD (0.28%), OAGB (0.17%), or SADI-S (0.17%) were significantly more likely to die within 30 days of their MBS procedure ( $P < .001$ ). The primary causes of death were pulmonary embolism, bleeding, abdominal sepsis, respiratory failure, and anastomotic or staple-line leak. For the 5-year period of 2016 through 2020, approximately half of the 576 (315; 54.9%) were likely attributable to an MBS procedure (Table 9).

Table 8. All-Cause Death Within 30 Days of MBS Procedure in Adults

Procedure	Number of procedures	Number of Deaths	Proportion, %
BPD	11,180	31	0.28
OAGB	7,630	13	0.17
SADI-S	2,394	4	0.17
RYGB	273,474	347	0.13
SG	765,770	462	0.06
IGB	3,072	1	0.03
AGB	8,973	1	0.01
ESG	1,480	0	0
Overall	1,089,905	901	0.08

Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic duodenal switch; ESG: endoscopic sleeve gastropasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy

Table 9. Deaths Likely Attributable to an MBS Procedure From 2016 Through 2020

Most Likely Cause of Death	Number of patients	BPD, n	OAGB, n	RYGB, n	SG, n
Overall Number of Deaths	315	19	3	135	158
Pulmonary embolism	60	2	1	24	33
Bleeding	33	1	0	9	23
Other abdominal sepsis	32	3	1	14	14
Other respiratory failure	31	1	0	13	17
Anastomotic or staple-line leak	24	5	1	12	6
GI perforation	14	0	0	6	8
Pneumonia	7	0	0	3	4
Intestinal obstruction	6	0	0	4	2
Deep vein thrombosis requiring therapy	6	0	0	0	6
Dehydration-related	1	0	0	1	0
Infection or fever	1	0	0	0	1
Internal hernia	1	0	0	0	1
Wound infection or evisceration	1	0	0	1	0
Other	98	7	0	48	43

Abbreviations. BPD: biliopancreatic duodenal switch; GI: gastrointestinal MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy

### Emergency Department Visits Within 30 Days of MBS Procedure for Adults

Emergency department visits were the most common adverse event experienced over the 7-year period across all MBS procedure types with approximately 7.5% (81,478 of nearly 1.1 million) of patients attending an emergency department. For the 4-year period of 2016 through 2019, abdominal pain and nausea or vomiting accounted for nearly half of all emergency department visits (25% and 22%, respectively), overall and for each procedure type; they also represented the only 2 complaints reported in at least 1% of all visits regardless of MBS procedure.

### Reoperations Within 30 Days of MBS Procedure for Adults

Only 1.11% (12,084 of nearly 1.1 million) of all reported MBS procedures required a reoperation within 30 days of the primary surgery. Reoperations were significantly less likely for patients who underwent SG (0.73%) or AGB (0.79%), and significantly more likely for BPD (2.81%;  $P < .001$ ). There were no significant differences in rates of reoperation among restrictive procedures ( $P = .07$ ) or combined procedures ( $P = .88$ ). Among malabsorptive procedures, reoperation was significantly more likely for individuals undergoing BPD (2.81%) compared with OAGB (1.83%;  $P < .001$ ).

Table 9 reports the type for reoperation by MBS procedure and Table 11 reports the top 3 reasons for reoperation by MBS category (e.g., restrictive) and individual MBS procedure.

Table 10. Reason for Reoperation by MBS Procedure.

Procedure	Total Number of Patients, n	Repair, n	Revision, n	Feeding tube, n	Gastrectomy, n	Reversal, n	Unspecified, n
RYGB	273,474	384	136	28	6	4	891
SG	765,770	254	15	12	3	1	1,102
BPD	11,180	19	2	0	1	0	44
OAGB	7,630	11	8	0	1	0	28
SADI-S	2,394	7	1	0	0	0	25
AGB	8,973	1	2	0	0	5	8
IGB	3,072	0	0	0	0	2	0
ESG	1,480	1	0	0	0	0	4
Total	1,073,973	677	164	40	11	12	2,102

Note. Unspecified Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic diversion; ESG: endoscopic sleeve gastropasty; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy.

Table 11. Top 3 Reasons for Reoperation by MBS Procedure Category and Individual MBS Type

MBS Procedure	Total Number of Patients	Total Number of Reoperations	Top 3 Reasons for Reoperation, n
<b>Restrictive Procedures</b>			
Overall	679,020	• 3,008	<ul style="list-style-type: none"> <li>• GI tract bleeding, 485</li> <li>• Anastomotic/staple-line leak, 313</li> <li>• Bleeding, 297</li> </ul>
AGB	8,249	• 31	<ul style="list-style-type: none"> <li>• Band slippage/prolapse, 5</li> <li>• Planned surgery, 3</li> <li>• Planned non-MBS surgery, 2</li> </ul>
ESG	1,480	• 8	<ul style="list-style-type: none"> <li>• GI tract perforation, 4</li> </ul>
IGB	3,072	• 4	<ul style="list-style-type: none"> <li>• Planned surgery, 1</li> <li>• Difficulty swallowing, 1</li> <li>• Obstruction, 1</li> </ul>
SG	765,770	• 2,965	<ul style="list-style-type: none"> <li>• GI tract bleeding, 484</li> <li>• Anastomotic or staple-line leak, 313</li> <li>• Bleeding, 296</li> </ul>
<b>Malabsorptive Procedures</b>			
Overall	16,287	• 236	<ul style="list-style-type: none"> <li>• Anastomotic or staple-line leak, 40</li> <li>• GI tract stricture or obstruction, 32</li> <li>• GI tract bleeding, 18</li> </ul>
BPD	9,761	• 151	<ul style="list-style-type: none"> <li>• Anastomotic/staple-line leak, 31</li> <li>• GI tract stricture or obstruction, 17</li> <li>• GI tract bleeding, 11</li> </ul>
OAGB	6,526	• 85	<ul style="list-style-type: none"> <li>• GI tract stricture or obstruction, 15</li> <li>• Anastomotic or staple-line leak, 9</li> <li>• GI tract bleeding, 7</li> </ul>

MBS Procedure	Total Number of Patients	Total Number of Reoperations	Top 3 Reasons for Reoperation, n
<b>Combined Procedures</b>			
Overall	239,590	• 3,117	<ul style="list-style-type: none"> <li>• GI tract stricture or obstruction, 660</li> <li>• Anastomotic/staple-line leak, 308</li> <li>• GI tract bleeding, 227</li> </ul>
RYGB	237,836	• 3,068	<ul style="list-style-type: none"> <li>• GI tract stricture or obstruction, 655</li> <li>• Anastomotic/staple-line leak, 296</li> <li>• GI tract bleeding, 221</li> </ul>
SADI-S	1,754	• 49	<ul style="list-style-type: none"> <li>• Anastomotic/staple-line leak, 12</li> <li>• GI tract bleeding, 6</li> <li>• GI tract stricture or obstruction, 5</li> </ul>

*Abbreviations.* AGB: adjustable gastric band; BPD: biliopancreatic diversion; ESG: endoscopic sleeve gastroplasty; GI: gastrointestinal; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy.

### Readmissions Within 30 Days of MBS Procedure in Adults

Among restrictive procedures, readmission within 30 days was significantly more likely for ESG and SG than either AGB or IGB ( $P < .001$ ; Table 4). Among combined procedures, patients undergoing RYGB were significantly more likely to be readmitted compared with patients who underwent SADI-S ( $P = .02$ ; Table 6). There was no significant differences between malabsorptive procedures ( $P = .09$ ; Table 5). The most common reasons for readmission, occurring in at least 5% of patients, were nausea or vomiting (22.68%), abdominal pain (9.97%), and GI tract stricture or obstruction (5.15%; Table 11). Note that there is significant overlap in diagnoses between readmissions and reoperations.

Readmission was unplanned in 95% of cases. Proportion of readmissions that were unplanned differed significantly across procedure types ( $P < .001$ ), ranging from 92.6% for OAGB to 100% for IGB procedures. For the 4-year period of 2016 through 2019, nearly 80% (17,676 of 22,465) of readmissions were suspected to be procedure-related. Significant differences in procedure-related readmissions were seen across MBS procedures ranging from 75.2% for SG to 85.0% for IGBs ( $P < .001$ ). Readmissions were less likely to be related to the MBS procedure for restrictive procedures (75.3%) compared with malabsorptive (80.7%) or combined (83.4%) procedures ( $P < .001$ ). In ANOVA testing, higher mean BMI was significantly associated with readmission ( $P < .001$ ), but not unplanned readmission ( $P = .67$ ).

Table 12. Reasons for Readmission Occurring in  $\geq 5\%$  of Patients

Reason for Readmission	Number of Patients Affected	%
Dehydration-related	4,475	22.68
Abdominal pain	1,967	9.97
Gastrointestinal tract stricture or obstruction	1,016	5.15

### 30-day Safety Outcomes for Children and Adolescents

The MBSAQIP included records on 2,181 eligible pediatric patients ages 10 to 17 years who underwent an MBS procedure during the 7-year period of 2016 through 2022. We excluded 17 patients under the age of 13 years due to the small number in this group. Among adolescents who underwent an MBS procedure, boys had a significantly higher mean BMI (49.4 kg/m<sup>2</sup>) compared with girls (46.6 kg/m<sup>2</sup>;  $P < .001$ ). Patients were primarily female (64.7%) and White (41.2%) or Black (29.4%). No Asian or Native American pediatric patients were reported.

Nearly 90% of pediatric patients underwent SG followed by RYGB (8%). Due to small numbers, only SG and RYGB were analyzed for the frequency of adverse events. Frequency of RYGB procedures decreased slightly over the 7-year period, while SG procedures increased over time.

### Adverse Events in Adolescents

Among 2,127 adolescents who underwent RYGB (184) or SG (1,943), the most common adverse events were emergency department visits (5.2%), hospital readmissions (2.6%), and outpatient treatment for dehydration (2.36%; Table 12). Only DVT requiring therapy ( $P = .007$ ) and the related category of medical emergencies, defined as experiencing cardiac arrest, myocardial infarction, stroke, pulmonary embolism, or DVT ( $P = .02$ ) were significantly more likely in adolescents who underwent SG.

Table 13. Adverse Events Related to RYGB and SG in Adolescents Aged  $\geq 13$  years.

Adverse event	RYGB, n (%)	SG, n (%)	Between-group Difference
Total number of patients	184	1,943	N/A
<b>Any adverse event</b>			
Emergency department visit not resulting in inpatient admission	14 (7.61)	98 (5.04)	$P = .16$
Outpatient treatment for dehydration	7 (3.80)	44 (2.26)	$P = .20$
Other infection type	0	8 (0.41)	$P = .38$
Surgical site infection	0	7 (0.36)	$P = .41$
Postoperative GI tract bleed <sup>a</sup>	0	2 (0.30)	$P = .74$
Wound disruption	0	1 (0.05)	$P = .76$
<b>Serious adverse events</b>			
Unplanned ICU admission	0	8 (0.41)	$P = .38$
Medical emergency <sup>b</sup>	2 (1.09)	1 (0.05)	$P = .02$
Death within 30 days	0	2 (0.10)	$P = .66$
Unplanned intubation	0	2 (0.10)	$P = .66$
Staple-line leak <sup>a</sup>	0	2 (0.22)	$P = .73$
DVT requiring therapy	2 (1.09)	0	$P = .007$
Postoperative <i>Clostridium difficile</i> colitis	0	1 (0.05)	$P = .76$
Transfusion within 72 hours of surgery start	0	1 (0.05)	$P = .76$
Postoperative ventilator > 48 hours	0	1 (0.05)	$P = .76$
Pulmonary embolism	0	1 (0.05)	$P = .76$
Bowel obstruction <sup>a</sup>	0	0	N/A
Renal failure	0	0	N/A

Adverse event	RYGB, n (%)	SG, n (%)	Between-group Difference
<b>Readmissions and reoperations</b>			
≥ 1 readmission within 30 days	7 (3.80)	49 (2.52)	P = .33
≥ 1 reoperation within 30 days	2 (1.09)	8 (0.41)	P = .21

Notes. <sup>a</sup> Variable was not available in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program registry from 2016 through 2019 therefore only cases from 2020 through 2022 are reflected for this outcome. <sup>b</sup> Medical emergencies include cardiac arrest, myocardial infarction, stroke, pulmonary embolism, and deep vein thrombosis.

Abbreviations. DVT: deep vein thrombosis; GI: gastrointestinal; ICU: intensive care unit; MI: myocardial infarction; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy.

### **All-Cause Death Within 30 Days of MBS Procedure in Adolescents**

Only 2 deaths occurred within the 30 day postoperative period, both in the SG group. Frequency of death overall for SG in adolescents was 0.10%.

### **Reoperations Within 30 Days of MBS Procedure in Adolescents**

Less than 1% (10 of 2,181) of patients required reoperation within 30 days. The largest number of reoperations (8) were associated with SG, although proportionally more reoperations were associated with RYGB (2 of 184; 1.09%) those these differences were not significant.

### **Readmission Within 30 Days of MBS Procedure in Adolescents**

Approximately 3% (56 of 2,181) of patients required readmission within 30 days. Readmissions were more likely, proportionally, for RYGB compared with SG, but these differences were not found to be significant.



## Appendix L References

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