

# Benefits and Risks of Bariatric Surgery in Adults

## A Review

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**IMPORTANCE** Severe obesity and its related diseases, such as type 2 diabetes, hypertension, dyslipidemia, and sleep apnea, are very common in the United States, but currently very few patients with these conditions choose to undergo bariatric surgery. Summaries of the expanding evidence for both the benefits and risks of bariatric surgery are needed to better guide shared decision-making conversations.

**OBSERVATIONS** There are approximately 252 000 bariatric procedures (per 2018 numbers) performed each year in the US, of which an estimated 15% are revisions. The 1991 National Institutes of Health guidelines recommended consideration of bariatric surgery in patients with a body mass index (calculated as weight in kilograms divided by height in meters squared) of 40 or higher or 35 or higher with serious obesity-related comorbidities. These guidelines are still widely used; however, there is increasing evidence that bariatric procedures should also be considered for patients with type 2 diabetes and a body mass index of 30 to 35 if hyperglycemia is inadequately controlled despite optimal medical treatment for type 2 diabetes. Substantial evidence indicates that surgery results in greater improvements in weight loss and type 2 diabetes outcomes, compared with nonsurgical interventions, regardless of the type of procedures used. The 2 most common procedures used currently, the sleeve gastrectomy and gastric bypass, have similar effects on weight loss and diabetes outcomes and similar safety through at least 5-year follow-up. However, emerging evidence suggests that the sleeve procedure is associated with fewer reoperations, and the bypass procedure may lead to more durable weight loss and glycemic control. Although safety is a concern, current data indicate that the perioperative mortality rates range from 0.03% to 0.2%, which has substantially improved since early 2000s. More long-term randomized studies are needed to assess the effect of bariatric procedures on cardiovascular disease, cancer, and other health outcomes and to evaluate emerging newer procedures.

**CONCLUSIONS AND RELEVANCE** Modern bariatric procedures have strong evidence of efficacy and safety. All patients with severe obesity—and especially those with type 2 diabetes—should be engaged in a shared decision-making conversation about the risks and benefits of surgery compared with continuing usual medical and lifestyle treatment, and the decision about surgery should be driven primarily by informed patient preferences.

JAMA. 2020;324(9):879-887. doi:10.1001/jama.2020.12567

The most effective long-term treatments for severe obesity complicated by type 2 diabetes are bariatric procedures. Few clinicians and patients have conversations about these procedures, mainly because of persistent concerns that the short- and long-term risks of surgery outweigh the benefits.<sup>1</sup> Indeed, bariatric procedures have a checkered history. The jejunoileal bypass, vertical banded gastroplasty, and laparoscopic adjustable gastric banding (AGB) procedures have been largely abandoned due to intolerable adverse effects, high rates of reoperation, or poor long-term efficacy. In contrast, the long-term evidence base for the Roux-en-Y gastric bypass (RYGB) procedure has substantially improved. A relatively new procedure, the sleeve gastrectomy, is now the most commonly performed bariatric procedure worldwide (Box 1). The goal of this review is to update clinicians on the latest evidence for the most common bariatric procedures, with a focus on the long-term outcomes for major obesity-related comorbidities, weight loss, and safety outcomes to guide shared decision-making conversations.

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### Methods

This narrative review was based on articles found by searching PubMed from its inception until January 2020 for the terms *bariatric surgery*, *gastric bypass*, and *sleeve gastrectomy*. Our search was limited to English-language articles. Priority was given to evidence

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**Box 1. Commonly Asked Questions About Bariatric Surgery****What Are the Most Commonly Performed Bariatric Procedures?**

In the United States, procedures have shifted in the last several years such that 61% of the estimated 252 000 primary bariatric procedures performed are sleeve gastrectomy followed by Roux-en-Y gastric bypass (RYGB), which accounts for 17%. The adjustable gastric band (AGB) and biliopancreatic diversion procedures each account for less than 2%.<sup>3</sup> This review focuses primarily on sleeve gastrectomy and RYGB.

**Which Bariatric Procedure Is More Effective for Weight Loss?**

Weight loss with bariatric surgery varies by procedure, and the best procedure for weight loss remains uncertain. Randomized trials comparing procedures have shown that patients undergoing RYGB and sleeve gastrectomy have similar weight loss, while observational studies show that RYGB patients achieve greater weight loss than sleeve gastrectomy patients.

**Do Some Patients Regain All Their Weight After Bariatric Surgery?**

The typical patient can expect to regain some weight over time, usually beginning in the second postoperative year, but weight regain to the point that they are within 5% or less of their preoperative weight is relatively rare (occurring in 3.3% of RYGB patients and 12.5% of those who have undergone sleeve gastrectomy at 5-year follow-up).

**Is Bariatric Surgery More Effective Than Standard Medical Diabetes Treatment?**

Twelve randomized trials have been published including 874 patients in total, with 11 trials showing that bariatric surgery was better than medical therapy in promoting glycemic control and remission of type 2 diabetes through at least 5 years of follow-up. These data are supported by longer-term observational studies suggesting that bariatric surgery is associated with lower rates of micro- and macrovascular complications and mortality than usual medical care for diabetes.

**Which Bariatric Procedure Is More Effective for Diabetes Treatment?**

Randomized trials comparing procedures have shown that patients undergoing RYGB and sleeve gastrectomy have similar improvements in glycemic control, while observational studies generally suggest that RYGB patients achieve greater improvements in glycemic control and more durable diabetes remission than sleeve gastrectomy patients.

**What Is the Effect of Bariatric Surgery on Other Obesity-Related Comorbid Conditions?**

Randomized trials and observational studies have generally shown that bariatric surgery results in greater improvements in hypertension and dyslipidemia and less medication use than nonsurgical treatments. Observational studies suggest that bariatric surgery is associated with a lower risk of cancer and better sleep apnea, osteoarthritis, and incontinence outcomes than nonsurgical treatment, but randomized trials are needed to confirm these findings.

**Which Bariatric Procedure Is the Safest?**

Currently the risk of both short- and long-term major adverse events, including additional operations, interventions, and hospitalizations, appears to be greater after RYGB than sleeve gastrectomy; however, more long-term randomized and observational studies are needed to confirm these findings beyond 5-year follow-up.

**Which Bariatric Procedure Is “the Best” for Me?**

Given the considerable trade-offs between the risks, benefits, and uncertainties of the long-term effects of bariatric procedures, there is currently no best treatment for all patients. Therefore, the choice of procedure should be based on a shared decision-making process that prioritizes the patient's own values and preferences.

<sup>3</sup> The remaining percentage of bariatric procedures are revisions or other rarely performed bariatric procedures.

obtained from systematic literature reviews, meta-analyses, and randomized clinical (RCT) trials when possible.

**Epidemiology of Bariatric Surgery**

As of 2018, there were approximately 252 000 bariatric procedures performed per year in the United States.<sup>2</sup> Currently, approximately 61% of primary bariatric procedures are sleeve gastrectomies, and 17% are RYGB procedures. The AGB and biliopancreatic diversion procedures each account for less than 2%. In the last 3 years, 14% to 15% of all bariatric procedures were revisions. Because RYGB and sleeve gastrectomy now predominate, our review focuses primarily on these procedures.

The characteristics of the patient population undergoing bariatric surgery has changed over the past 2 decades. Nationally representative data show that the mean age increased from 38.9 years in 1993 to 44.4 years in 2016 ( $P < .001$ ).<sup>3</sup> Additionally, the proportions of bariatric surgery patients in the following subgroups increased significantly between 1993 and 2016: men (15.3% to 20.4%), patients who self-identified as Black (11.6% to 17.7%) or Hispanic (1.4% to 13.7%), and patients with Medicaid (8.1% to 17.2%) or Medicare insurance (5% to 14.2%). Rates of bariatric procedures are also increasing in adolescents, although the total number remains small, so this review focuses on adults.

**Eligibility for Bariatric Surgery**

The 1991 National Institutes of Health guidelines recommended consideration of bariatric surgery in patients with a body mass index (BMI [calculated as weight in kilograms divided by height in meters squared]) of at least 40 kg or of at least 35 kg in patients with serious obesity-related comorbidities.<sup>4</sup> These guidelines are still widely used; however, there is increasing evidence that bariatric procedures should also be considered for patients with type 2 diabetes and a BMI of 30.0 to 35.0 kg if hyperglycemia is inadequately controlled, despite optimal medical treatment of type 2 diabetes.<sup>5</sup> Contraindications for bariatric surgery include severe heart failure, unstable coronary artery disease, end-stage lung disease, active cancer, cirrhosis with portal hypertension, uncontrolled drug or alcohol dependency, Crohn disease, severely impaired intellectual capacity, or current or planned pregnancy within the next 1 to 2 years.<sup>6</sup>

**Effects on Obesity-Related Comorbidities****Type 2 Diabetes**

One of the most important advances in the field of bariatric surgery has been the publication of high-quality evidence about its effect on type 2 diabetes outcomes. Currently, 12 RCTs have been

**Table. Twelve Randomized Clinical Trials of Bariatric Surgery vs Medical/Lifestyle Treatment of Type 2 Diabetes (n = 874)**

Source	No. of patients randomized	Patients with body mass index <35, % <sup>a</sup>	Follow-up, y	Remission criteria <sup>b</sup>	Intervention and control group rates of remission, % <sup>c</sup>	P value
<b>AGB vs control</b>						
Dixon et al, <sup>7</sup> 2008	60	22	2	HbA <sub>1c</sub> <6.2%	73 vs 13	<.001
Wentworth et al, <sup>8</sup> 2014	51	100	2	Fasting glucose <7.0 mmol/L	52 vs 8	.001
Ding et al, <sup>9</sup> 2015	45	34	1	HbA <sub>1c</sub> <6.5% <sup>d</sup>	33 vs 23	.46
<b>RYGB vs control</b>						
Ikramuddin et al, <sup>10</sup> 2018	120	59	5	HbA <sub>1c</sub> <7%	55 vs 14	<.001
Liang et al, <sup>11</sup> 2013	101	100	1	HbA <sub>1c</sub> <6.5% <sup>e</sup>	90 vs 0 vs 0	<.001
Simonson et al, <sup>12</sup> 2018	38	34	3	HbA <sub>1c</sub> <6.5%; FPG <126 mg/dL	42 vs 0	.005
Cummings et al, <sup>13</sup> 2016	43	25	1	HbA <sub>1c</sub> <6.0%	60 vs 5.9	.002
Shah et al, <sup>14</sup> 2016	80	85	2	HbA <sub>1c</sub> ≤6.5%	60 vs 2.5	.001
<b>RYGB vs sleeve gastrectomy vs control</b>						
Schauer et al, <sup>15</sup> 2017	150	36	5	HbA <sub>1c</sub> ≤6.0%	22 vs 15 vs 0	<.05
<b>RYGB vs biliopancreatic diversion vs control</b>						
Mingrone et al, <sup>16</sup> 2015	60	0	5	HbA <sub>1c</sub> ≤6.5%	37 vs 63 vs 0	.003
<b>RYGB vs AGB vs control</b>						
Courcoulas et al, <sup>17,18</sup> 2020	69	43	5	HbA <sub>1c</sub> <6.5%	30 vs 19 vs 0	.004
<b>RYGB, AGB, and sleeve gastrectomy vs control</b>						
Parikh et al, <sup>19</sup> 2014	57	100	3	HbA <sub>1c</sub> <6.5%	65 vs 0	<.001

Abbreviations: AGB, adjustable gastric banding; HbA<sub>1c</sub>, glycated hemoglobin A<sub>1c</sub>; RYGB, Roux-en-y gastric bypass.

Conventional conversion factor: To convert glucose to mg/dL, divide the value by 0.0555.

<sup>a</sup> Calculated as weight in kilograms divided by height in meters squared.

<sup>b</sup> Remission defined as reaching HbA<sub>1c</sub> value without medication, unless otherwise specified.

<sup>c</sup> Intervention and control groups are shown in column 1.

<sup>d</sup> With or without medications.

<sup>e</sup> Remission not precisely defined or extrapolated.

published that include a total of 874 patients and compare surgical to medical therapy for treatment of type 2 diabetes (Table).<sup>7-19</sup> These trials included patients with a BMI 25 to 53 and type 2 diabetes ranging from mild to severe, and the RCTs varied in size from 38 to 150 patients per study with follow-up from 1 to 5 years. Eleven of 12 studies included patients with BMI less than 35. Surgical procedures used in these studies included RYGB (9 studies), AGB (5 studies), sleeve gastrectomy (2 studies) and biliopancreatic diversion (1 study). For most of the trials, the primary end point was type 2 diabetes remission, usually defined as a glycated hemoglobin level A<sub>1c</sub> (HbA<sub>1c</sub>) at or below 6.0% to 6.5% without the use of diabetes medications, but definitions and end points varied across studies (Table).

All of these trials, except one (Ding,<sup>9</sup> AGB vs medical therapy), showed that outcomes for surgery were better than for medical therapy for glycemic control and remission of type 2 diabetes, with variable rates of remission at various time points from 1 to 5 years following treatment (Table). Overall, for glycemic control, surgery decreased HbA<sub>1c</sub> by 1.8% to 3.5%, and medical treatments effected smaller decreases of 0.4% to 1.5%. In the 4 studies with 5-year follow up, within each study, there is an annual decline in the prevalence of type 2 diabetes remission (Table).<sup>10,15-18</sup> Most of these studies also showed better performance of surgery relative to medical treatment in achieving secondary end points, including weight loss, reduction in medications, and improvements in lipids at 1 to 5 years. There are limitations to these RCTs: all are relatively small and limited to large medical centers; variable definitions were used for out-

comes; and macrovascular events were too rare to be examined as outcomes in individual RCTs.

There were variable numbers of patients with BMI less than 35 in 11 of the 12 RCTs. Several of these RCTs stratified some outcomes by BMI above and below the 35 threshold. In the STAMPEDE trial, reductions in BMI and in HbA<sub>1c</sub> levels in the surgical groups (RYGB vs glycated hemoglobin) were similar among patients with a BMI of less than 35 (n = 49) and those with a BMI of 35 or more (n = 85).<sup>15</sup> A systematic review and meta-analysis of observational and randomized trials compared surgical vs medical treatment of type 2 diabetes remission in people with a BMI of less than 35. There were 706 total patients with type 2 diabetes included, and follow-up ranged from 12 to 36 months. Bariatric surgery was associated with a higher remission rate of type 2 diabetes (odds ratio [OR], 14.1 [95% CI, 6.7-29.9]; P < .001), higher rate of glycemic control (OR, 8.0 [95% CI, 4.2-15.2]; P < .001), and lower HbA<sub>1c</sub> level (mean difference, -1.4% [95% CI, -1.9% to -0.9%]; P < .001) than medical treatment.<sup>20</sup> It appears that bariatric surgery has better outcomes when compared with medical treatment for short-term remission of type 2 diabetes and glycemic control for patients with BMI less than 35.

There is increasing evidence that bariatric surgery reduces the risk of microvascular and macrovascular complications of type 2 diabetes. One meta-analysis reviewed microvascular outcomes from 3 RCTs<sup>15,16,21</sup> together with data from observational studies in a total of 17 532 people with at least 1-year follow-up.<sup>22</sup> It found a lower incidence of microvascular complications (OR, 0.26 [95% CI,

0.16-0.42]) with surgical compared with medical therapy. Another systematic review identified 7 observational studies including 29 026 patients with at least 5 years of follow-up.<sup>23</sup> Analyses here demonstrated a lower incidence of macrovascular complications (relative risk [RR], 0.52 [95% CI, 0.44-0.61]) and lower mortality (RR, 0.21 [95% CI, 0.20-0.22]) for surgical vs medically treated patients with type 2 diabetes. These findings are supported by 2 recent retrospective observational studies examining microvascular, macrovascular, and mortality outcomes among bariatric surgery patients compared with nonsurgical patients with severe obesity and type 2 diabetes.<sup>24-26</sup> In these studies, surgery was associated with a lower risk for incident microvascular disease (including neuropathy, nephropathy, and retinopathy at 5 years follow-up) compared with usual medical care, and surgery was associated with a significantly lower incidence of macrovascular disease events and all-cause mortality at 5 and at 8 years.<sup>25,26</sup> These findings support a beneficial association between bariatric surgery and long-term type 2 diabetes outcomes, but these are primarily observational studies, which risk unobserved confounding. Long-term RCTs assessing microvascular and macrovascular outcomes are needed, particularly those comparing bariatric surgery outcomes vs outcomes in patients treated with sodium-glucose cotransporter-2 inhibitors and glucagon-like peptide 1 receptor agonists, which appear to have a greater cardiovascular and mortality benefit.<sup>27</sup>

Many recent studies have compared sleeve gastrectomy to RYGB for type 2 diabetes outcomes. Two RCTs found no significant difference in weight loss or diabetes remission between procedures at 5 years.<sup>28,29</sup> Meta-analyses of observational studies have found that most but not all studies observe higher rates of type 2 diabetes remission with RYGB than sleeve gastrectomy.<sup>30</sup> In addition, in long-term observational studies, there is a relapse of type 2 diabetes in as many as one-third of RYGB patients and 42% of sleeve gastrectomy patients who initially experienced remission.<sup>31,32</sup> At present, since neither sleeve gastrectomy nor RYGB is clearly better for type 2 diabetes outcomes, the decision between RYGB and sleeve gastrectomy for patients with type 2 diabetes should be driven primarily by informed patient preferences related to the relative risks of these procedures.

People with earlier-stage type 2 diabetes (ie, those who do not need insulin, with shorter-duration type 2 diabetes, and lower HbA<sub>1c</sub>) appear to have better improvement after bariatric surgery, in terms of remission and relapse rates. Several prediction models have been published and independently validated to identify individuals with a better chance of short- and longer-term type 2 diabetes remission using common clinical characteristics: age, BMI, HbA<sub>1c</sub>, insulin and other medication use for treating type 2 diabetes, C-peptide level, and duration of type 2 diabetes.<sup>33-35</sup> These studies suggest that bariatric surgery should not be delayed until type 2 diabetes is poorly controlled on multiple medications, but more RCTs are needed to establish the long-term benefits and safety of early intervention.

### Dyslipidemia

Sixty-four percent of adults with severe obesity seeking bariatric surgery have dyslipidemia, which includes any or all of the following: a high level of low-density lipoprotein, high triglycerides, and a low level of high-density lipoprotein.<sup>36</sup> In observational studies, bariatric surgery is associated with short-term (1-2-year) improvements

in dyslipidemia.<sup>37</sup> In a long-term cohort study of 1738 RYGB and 610 AGB patients, dyslipidemia prevalence was still reduced at 7 years post-RYGB vs baseline (for high low-density lipoprotein cholesterol, 14.3% vs 33.3%; for high triglycerides, 4.9% vs 23.7%; for low high-density lipoprotein cholesterol, 5.8% vs 34.9%;  $P < .001$  for all) and at 7 years post-AGB vs baseline (for low high-density lipoprotein cholesterol, 16.3% vs 33.0%; high triglycerides, 9.7% vs 21.3%;  $P < .001$  for both).<sup>36</sup> In the largest single RCT comparing surgical to intensive medical management, triglyceride levels decreased from baseline to 5 years by 40% in the RYGB group and by 29% in the sleeve gastrectomy group, but levels were only decreased by 8% in the medical therapy group; comparisons for high-density lipoprotein cholesterol levels from baseline to 5 years were decreased by 32% in the RYGB group and 30% in the sleeve gastrectomy group, but levels were only decreased by 7% in the medical therapy group.<sup>15</sup> A recent meta-analysis of outcomes from RCTs comparing RYGB and sleeve gastrectomy found that the resolution of dyslipidemia was higher for RYGB than sleeve gastrectomy at 1 year (risk ratio, 0.58 [95% CI, 0.46-0.73];  $P < .001$ ; moderate certainty of evidence) and 5 years (risk ratio, 0.68 [95% CI, 0.46-0.99];  $P = .04$ ; low certainty of evidence).<sup>38</sup> In another meta-analysis including more than 7000 people from observational studies and RCTs before 3-year follow-up, improvement or resolution of dyslipidemia was higher with RYGB than sleeve gastrectomy (OR, 1.61 [95% CI, 1.05-2.46];  $P < .05$ ), but there were no significant differences after 3-year follow-up.<sup>39</sup> Longer follow-up is needed to evaluate procedure-specific differences in dyslipidemia outcomes.

### Hypertension

Sixty-eight percent of adults with severe obesity seeking bariatric surgery have hypertension.<sup>36</sup> Systematic reviews indicate that bariatric surgery is associated with a 1-year hypertension remission rate ranging from 43% to 83%.<sup>40</sup> Rates of hypertension remission appear to be higher for patients undergoing RYGB compared with sleeve gastrectomy (5-year RR, 1.26 [95% CI, 1.07-1.48]), but 5-year changes in systolic and diastolic blood pressure may be similar across procedures.<sup>40</sup> Similar findings have been seen for studies comparing bariatric surgery against intensive medical/lifestyle intervention—ie, rates of hypertension remission are higher and antihypertensive medication use is lower among surgical patients compared with nonsurgical ones, but rates of blood pressure control are similar across groups (owing to greater medication use in nonsurgical patients).<sup>15,16,41</sup> The long-term effect of bariatric surgery on hypertension is less well-characterized, but one observational study ( $n = 2010$ ) suggests that as many as 44% of patients who experience initial remission will have a recurrence and need to restart antihypertensive medications within 10 years,<sup>42</sup> which is likely driven by aging as well as weight regain.

### Sleep Apnea

Weight loss improves obstructive sleep apnea and should be recommended in all patients with overweight or obesity.<sup>43</sup> Severity of obstructive sleep apnea is quantified using the apnea-hypopnea index (score range: <5 events/hour, normal; 5-14.9 events/hour, mild; 15-29.9 events/hour, moderate;  $\geq 30$  events/hour, severe).<sup>43</sup> Meta-analyses report significant reductions in BMI and apnea-hypopnea index scores with bariatric surgery, yet many patients remain obese with mildly to moderately increased

scores following surgery.<sup>43-45</sup> One of these meta-analyses found that bariatric surgery significantly improves both daytime sleepiness and the severity of obstructive sleep apnea as measured by the Apnea-Hypopnea Index; however, obstructive sleep apnea persisted based on the index criteria at follow-up in the majority of patients.<sup>44</sup> Of the 27 studies (comprising 1169 patients) included, 15 studies involved either the RYGB or sleeve gastrectomy procedure. The pooled mean presurgery score for the Apnea-Hypopnea Index was 39.3 events per hour, and the mean postsurgery score was 12.5 events per hour, with studies demonstrating greater score reductions among patients with more severe obstructive sleep apnea. Presurgery and postsurgery Epworth Sleepiness Scale scores were available in 10 studies, which demonstrated a significant reduction (mean [SD]) from 11.1 (3.9) to 5.6 (2.8), where a score of greater than 10 indicates excessive sleepiness (score range, 0-24).<sup>44</sup> These data and others suggest that patients undergoing bariatric surgery should be monitored long term for possible residual, clinically significant obstructive sleep apnea and treated accordingly, while taking into account symptoms and comorbid illnesses.<sup>43,45</sup>

### Osteoarthritis

Observational studies suggest that many patients with severe obesity will experience an improvement in knee pain and functional status in the first 6 to 12 months after bariatric surgery, but more rigorous, long-term studies are needed to confirm these findings.<sup>46</sup> A recent systematic review examined 9 observational studies of short- or long-term total joint arthroplasty outcomes among 5743 postbariatric patients and 32 985 patients without a history of bariatric surgery.<sup>47</sup> Bariatric surgery was associated with reduced short-term medical complications, length of stay, and operative time. However, bariatric surgery was not associated with better short-term risks for arthroplasty-related wound infection or venous thromboembolism, or long-term risks for dislocation, periprosthetic infection, periprosthetic fracture, and revision.<sup>47</sup>

### Urinary Incontinence

Obesity is an established risk factor for urinary incontinence, and both mechanical and metabolic factors likely play a role in the pathogenesis. In the Longitudinal Assessment of Bariatric Surgery study, 49% of women and 22% of men had urinary incontinence at baseline. After 1 year, the prevalence of urinary incontinence was significantly lower among both sexes (1-year prevalence among women, 18.3% [95% CI, 16.4%-20.4%] and 1-year prevalence among men, 9.8% [95% CI, 7.2%-13.4%];  $P < .001$ ). The 3-year prevalence was higher than the 1-year prevalence for both sexes (24.8% [95% CI, 21.8%-26.5%] among women and 12.2% [95% CI, 9.0%-16.4%] among men) but was still lower than baseline ( $P < .001$  for all). Weight loss, younger age, and the ability to walk without limitations were each independently related to urinary incontinence remission.<sup>48</sup>

### Cancer

Obesity is associated with an increased risk of several types of cancer including postmenopausal breast, endometrial, colon, liver, pancreatic, and ovarian cancers.<sup>49-51</sup> Data from 8 observational studies involving 635 642 patients suggest that bariatric surgery is associated with a reduced risk of all types of cancer (pooled OR, 0.72 [95% CI, 0.59-0.87]) and a reduced risk of obesity-associated can-

cer (pooled OR, 0.55 [95% CI, 0.31-0.96]), including breast cancer (pooled OR, 0.50 [95% CI, 0.25-0.99]).<sup>49-51</sup>

## Long-term Weight Loss

There is now strong evidence from RCTs and observational studies that bariatric surgery results in greater long-term weight loss than the best available nonsurgical interventions for obesity, regardless of the bariatric procedure used (eTable in the Supplement).<sup>10,12,15,16,52-55</sup> Of the randomized trials that included a nonsurgical medical/lifestyle group, at least 4 of these studies were modeled on the Diabetes Prevention Program and Look AHEAD studies, so were of equal or greater intensity.<sup>10,12,17,52,53</sup>

One challenge of summarizing the literature for weight loss is the lack of standardized reporting. Most experts now agree that weight loss and weight regain should be expressed as a percentage of preoperative weight, which has the added advantage of being easily estimated in clinical practice.<sup>56</sup> However, major studies have reported weight loss in other various ways including mean change in BMI from baseline and percent excess weight loss, which is defined as  $([\text{initial weight}] - [\text{postop weight}]) / ([\text{initial weight}] - [\text{ideal weight}])$ , where ideal weight is defined by the weight corresponding to a BMI of 25.

Weight loss with bariatric surgery varies by procedure, and the best procedure for weight loss remains an area of debate (eTable in the Supplement). RCTs comparing procedures have generally shown that patients undergoing RYGB and sleeve gastrectomy have similar weight loss, while both of those procedures resulted in greater weight loss than AGB.<sup>28,29,53,57</sup> A 2017 systematic review by Kang and colleagues<sup>57</sup> included 6 RCTs and found no significant difference in BMI reduction comparing RYGB vs sleeve gastrectomy ( $-0.76$  [95% CI, 1.6 to  $-3.1$ ]). This finding is backed by 2 subsequent 5-year randomized trials with patient follow-up above 80%.<sup>28,29</sup>

In contrast, observational studies generally show that RYGB patients achieve greater weight loss than sleeve gastrectomy patients.<sup>55,58-60</sup> For example, the PCORnet Bariatric Study compared weight loss outcomes of 32 208 RYGB patients, 29 693 sleeve gastrectomy patients, and 3192 AGB patients from 41 health systems in the United States and reported a 5-year mean percent total weight loss of 25.5% (95% CI, 25.1%-25.9%) for RYGB, 18.8% (95% CI, 18.0%-19.6%) for sleeve gastrectomy, and 11.7% (CI, 10.2% to 13.1%) for AGB. Comparing RYGB vs sleeve gastrectomy directly, the 5-year difference in percent total weight loss was 6.7% (CI, 5.8%-7.7%).<sup>58</sup> Taken together, the findings from observational studies suggest that the differences in weight loss outcomes between RYGB and sleeve gastrectomy are slightly larger in nonrandomized settings and may be due to unmeasured differences in patient and surgeon preferences; patients' attitudes, motivations, and behaviors; as well as surgical technique.

Long-term durability of weight loss is seen as a key requirement for the broad acceptance of bariatric surgery.<sup>61</sup> O'Brien and colleagues conducted a systematic review of studies with 10-year follow-up to assess long-term weight loss.<sup>61</sup> They found 14 studies of RYGB including 9386 patients (2512 patients with follow-up beyond 10 years; 69% average follow-up rate across studies). The mean percent excess weight loss beyond 10 years was 60% for RYGB. For

**Box 2. Early and Late Complications of Gastric Bypass and Sleeve Gastrectomy Procedures****Gastric bypass**

Complications &lt;30 days postprocedure (early)

- Bowel obstruction
- Venous thromboembolism
- Gastrointestinal or intra-abdominal bleeding
- Anastomotic leak
- Wound infection
- Internal hernia

Complications ≥30 days postprocedure (late)

- Anastomotic stricture
- Bowel obstruction
- Marginal ulceration
- Cholelithiasis
- Incisional hernia
- Nutritional and vitamin deficiencies
- Dumping syndrome
- Malabsorption
- Gastrogastric fistula
- Internal hernia

**Sleeve gastrectomy**

Complications &lt;30 days postprocedure (early)

- Venous thromboembolism
- Gastrointestinal or intra-abdominal bleeding
- Staple line leak
- Wound infection

Complications ≥30 days postprocedure

- Sleeve stricture
- Gastroesophageal reflux disease
- Cholelithiasis
- Incisional hernia
- Nutritional and vitamin deficiencies

AGB, they found 17 studies including 8485 patients (1002 patients with follow-up beyond 10 years; 80% average follow-up rate). The mean percent excess weight loss for AGB was 49%. Finally, they found only two 10-year studies of sleeve gastrectomy that included 163 patients (79 with 10-year follow-up) who had an average percent excess weight loss of 57%.

Regardless of the procedure chosen, the typical patient can expect to regain some weight over time, usually beginning in the second postoperative year. Weight regain estimates in the literature vary widely, owing largely to differences in calculations. One way to illustrate differences in weight regain across procedures is to consider the proportion of patients who regain weight to the point that they are within 5% or less of their preoperative weight. The PCORnet Bariatric Study found that this occurred in 3.3% of RYGB patients, 12.5% of those with sleeve gastrectomy, and 36.0% of AGB patients at 5-year follow-up.<sup>58</sup> A separate study of veterans found that this outcome occurred in 2.5% of RYGB patients, 14.6% of those with sleeve gastrectomy, and 30.5% of AGB patients at

4-year follow-up; the same study reported that this event occurred in only 4.4% of RYGB patients at 10-year follow-up.<sup>55</sup>

**Update on Safety and Long-term Survival**

Modern bariatric procedures, such as the RYGB and sleeve gastrectomy, have numerous studies demonstrating their short-term safety. Fewer studies address outcomes beyond 5-year follow-up, and there is an ongoing problem regarding lack of standardized reporting of complications after bariatric procedures, which makes it difficult to firmly establish the rates of major adverse events. Overall, the literature seems to support that the short- and long-term risk of major adverse events, including operations, interventions, and hospitalizations, is greater after RYGB than sleeve gastrectomy, and **Box 2** compares the most common complications.

Short-term assessments of the safety of bariatric surgery generally focus on perioperative mortality and serious adverse events within the first 30 to 90 days, including venous thromboembolism, hemorrhage, staple line or anastomotic leak, reoperation, and readmission. Data currently demonstrate perioperative mortality rates ranging from 0.03% to 0.2%, which has improved dramatically since early 2000s.<sup>60,62-65</sup> Similarly, the 30-day risk of serious adverse events (such as reoperation, prolonged hospitalization, and venous thromboembolism) across studies is generally less than 6%, ranging from 0.8% to 5.6% for patients undergoing sleeve gastrectomy and 1.4% to 9.4% for those undergoing RYGB. Rates of short-term reoperation and readmission also vary by procedure, with reoperation rates ranging from 0.5% to 3.0% for sleeve gastrectomy and 0.7% to 5.0% for RYGB, and readmission rates ranging from 2.8% to 4.8% for sleeve gastrectomy and 4.7% to 6.5% for RYGB.<sup>60,63-67</sup>

Evaluations of longer-term safety most often center on rates of reoperation and reinterventions. Cohort studies demonstrate rates of reoperation following bariatric surgery ranging from 5% to 22.1%, with higher rates of reoperation for RYGB as compared with sleeve gastrectomy.<sup>68-72</sup> These findings are supported by recent observational studies involving 35 273 patients from Kaiser Permanente (hazard ratio [HR] comparing reoperation for sleeve gastrectomy vs RYGB, 0.78 [95% CI, 0.74-0.84]), 13 027 patients from Optum (HR, 0.80 [95% CI, 0.72-0.89]), and 33 560 patients from the National Patient-Centered Clinical Research Network (HR, 0.72 [95% CI, 0.65-0.79]).<sup>68,71,72</sup> Two small RCTs reported no significant difference in 5-year rates of reoperations for RYGB vs sleeve gastrectomy, although the point estimates suggested higher rates for RYGB. Specifically, the SLEEVEPASS trial reported a 8.3% reoperation rate following sleeve gastrectomy and a 15.1% rate of reoperation for RYGB ( $P = .10$ ).<sup>28</sup> Data from the SM-BOSS trial mirrored these finding with rates of reoperation at 15.8% for sleeve gastrectomy vs 22.1% for RYGB ( $P = .33$ ).<sup>29</sup> There are few studies with follow-up at 10 years. Among 7 studies of RYGB with at least 10-year follow-up, rates of reoperation ranged from 8% to 64% (median 29%). Among the only 2 studies of sleeve gastrectomy with at least 10-year follow-up, rates of reoperation were 32% and 36%,<sup>61</sup> but more long-term multicenter studies of sleeve gastrectomy are needed.

Long-term follow up for bariatric and other obesity treatments are characterized by low rates of completeness that may lead to the overestimation of effectiveness and underestimation of

complications.<sup>37</sup> Several additional challenges exist in capturing the short- and long-term adverse outcomes following bariatric surgery, likely contributing to the wide variability in reported rates. Such challenges include incomplete or inaccurate coding of complications following readmissions. Revisional or other emergent operations related to complications may have been performed at centers other than the center the original procedure was performed. Also, determining whether a reoperation was or was not a direct complication of sleeve gastrectomy or RYGB is challenging.

Multiple observational studies have suggested that patients who undergo bariatric surgery are associated with a lower long-term risk of all-cause mortality compared with matched nonsurgical patients.<sup>73-75</sup> For example, Adams et al observed a 7-year all-cause mortality of 2.7% for 2925 RYGB patients and 4.1% for 7925 matched nonsurgical patients in Utah ( $P < .001$ ).<sup>73</sup> Similarly, a study from the Veterans Administration health system found that the 5- and 10-year all-cause mortality was 6.4% and 13.8% in 2500 bariatric patients compared with 10.4% and 23.9% for 7462 matched nonsurgical patients (hazard ratio 0.45 and 0.47).<sup>75</sup> Most patients in these studies underwent RYGB.

The evidence base for bariatric surgery has evolved rapidly over the past few decades. Given the current evidence for the long-term efficacy and safety of bariatric surgery, all patients with severe obesity, and particularly those with type 2 diabetes, should be

engaged by their physicians in a shared decision-making conversation about the role of bariatric surgery in the long-term treatment of these conditions.<sup>76</sup> This conversation should include a balanced discussion of the risks, benefits, and uncertainties related to these procedures, and the final decision should be guided by the informed patient's preferences for treatment. Primary care clinicians have critical roles to play in initiating the conversation about treatment options, ordering specialty referral for interested patients, and supporting patients long term with bariatric-specific follow-up care. It is important that patients are referred to surgeons who are equally comfortable performing RYGB and sleeve gastrectomy procedures so that they have the greatest opportunity to make an informed choice.

## Conclusions

Modern bariatric procedures have strong evidence of efficacy and safety. All patients with severe obesity—and especially those with type 2 diabetes—should be engaged in a shared decision-making conversation about the risks and benefits of surgery compared with continuing usual medical and lifestyle treatment, and the decision about surgery should be driven primarily by informed patient preferences.

### ARTICLE INFORMATION

**Accepted for Publication:** June 26, 2020.

**Author Contributions:** Dr Arterburn had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Concept and design:** Arterburn.

**Acquisition, analysis, or interpretation of data:** Telem, Kushner, Courcoulas.

**Drafting of the manuscript:** Arterburn, Telem, Kushner.

**Critical revision of the manuscript for important intellectual content:** Telem, Courcoulas.

**Administrative, technical, or material support:** Courcoulas.

**Supervision:** Arterburn, Telem.

**Conflict of Interest Disclosures:** Dr Arterburn reported grants from the National Institutes of Health during the conduct of the study; and grants from the Patient-Centered Outcomes Research Institute and nonfinancial support from International Federation for the Surgery of Obesity and Metabolic Disorders Latin American Chapter outside the submitted work. Dr Telem reported grants from the National Institutes of Health during the conduct of the study; and grants from the Agency for Healthcare Research and Quality and from Medtronic outside the submitted work. Dr Courcoulas reported grants from Allurion and Covidien/Ethicon outside the submitted work. No other disclosures were reported.

**Funding/Support:** Drs Arterburn and Courcoulas were funded by a grant from the National Institute for Diabetes and Digestive and Kidney Diseases (R01 DK105960). Drs Telem and Arterburn were funded by a grant from the National Institute for Diabetes and Digestive and Kidney Diseases (R01 DK115408).

**Role of the Funder/Sponsor:** The National Institute for Diabetes and Digestive and Kidney Diseases had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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