





# Bariatric Surgery: Surgical Options and Outcomes

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# KEY MESSAGES FOR HEALTHCARE PROVIDERS

- Bariatric surgery should be considered for patients with severe obesity (body mass index (BMI) ≥ 35 kg/m²) and obesity-related diseases, or BMI ≥ 40 kg/m² without obesity-related diseases.
- Bariatric surgery could be considered for patients with obesity (BMI ≥ 30 kg/m²) with severe obesity-related diseases not responding to medical management.
- The choice of bariatric procedure should be tailored to patients' needs, in collaboration with a multi-disciplinary team and based on the discussion of risks, benefits and side effects.
- Several procedures are currently performed in Canada (adjustable gastric banding, sleeve gastrectomy, gastric bypass, duodenal switch and others) but variations exist.

- For patients with severe obesity, surgery offers superior outcomes compared to best medical management, in terms of quality of life, long-term weight loss and resolution of obesity-related diseases, especially type 2 diabetes, sleep apnea, fatty liver disease and hypertension.
- Laparoscopic approach should be standard and is associated, for most patients, with a low mortality rate (< 0.1%) and low serious complication rate (< 5%).
- Bariatric surgery improves life expectancy.
- Novel surgical and endoscopic approaches are being used and developed and can represent an option for specific patients.

#### **RECOMMENDATIONS**

- 1. Bariatric surgery can be considered for people with BMI  $\geq$  40 kg/m<sup>2</sup> or BMI  $\geq$  35 kg/m<sup>2</sup> with at least one adiposity-related disease (Level 4, Grade D, Consensus) to:
  - a. Reduce long-term overall mortality (Level 2b, Grade B);1,2
  - b. Induce significantly better long-term weight loss compared to medical management alone (Level 1a, Grade A);<sup>3</sup>
- c. Induce control and remission of type 2 diabetes, in combination with best medical management, over best medical management alone (Level 2a, Grade B);<sup>4,5</sup>
- d. Significantly improve quality of life (Level 3, Grade C);6
- e. Induce long-term remission of most obesity-related diseases, including dyslipidemia (Level 3, Grade C),<sup>7</sup> hypertension (Level 3, Grade C),<sup>8</sup> liver steatosis and non-alcoholic steatohepatitis (Level 3, Grade C).<sup>9</sup>

- 2. Bariatric surgery should be considered in patients with poorly controlled type 2 diabetes and Class I obesity (BMI between 30 and 35 kg/m²) (Level 1a; Grade A)¹0 despite optimal medical management.
- 3. Bariatric surgery may be considered for weight loss and/ or to control adiposity-related diseases in persons with Class 1 obesity, in whom optimal medical and behavioural management have been insufficient to produce significant weight loss (Level 2a, Grade B).<sup>11</sup>
- 4. We suggest the choice of bariatric procedure (sleeve gastrectomy, gastric bypass or duodenal switch) be decided

- according to the patient's need, in collaboration with an experienced interprofessional team (Level 4, Grade D, Consensus).
- 5. We suggest that adjustable gastric banding not be offered due to unacceptable complications and long-term failure (Level 4, Grade D).<sup>12</sup>
- 6. We suggest that single-anastomosis gastric bypass not be routinely offered, due to long-term complications in comparison with standard Roux-en-Y gastric bypass (Level 4, Grade D). 13

# KEY MESSAGES FOR PEOPLE LIVING WITH SEVERE OBESITY

- If you are suffering from severe obesity, you should enquire about bariatric surgery. In your situation, behavioural interventions and medical therapies are important but usually not effective enough to obtain significant long-term weight loss and remission of obesity-related diseases.
- Bariatric surgery in combination with modifications to health behaviours can result in significant long-term weight loss (20% to 40% of your body weight) and control, or, in some cases, complete remission, of obesity-related diseases, including type 2 diabetes, sleep apnea, fatty liver disease and hypertension.
- Different surgical options exist (e.g., sleeve gastrectomy, gastric bypass and duodenal switch), with different levels of effectiveness. You should have an extensive discussion with the surgical team before deciding which surgical option seems to be the best for you.
- All surgeries have some adverse effects and potential risks, and require lifelong management to follow-up, mineral and vitamin supplementations and behavioural changes.

### Introduction

For most individuals with severe obesity, health behaviour interventions, perhaps effective in inducing short-lived weight loss, are frequently ineffective for long-term weight loss maintenance and durable metabolic recovery. For example, the vast majority (74%) of individuals living with severe obesity undergoing intensive behavioural intervention in the Look AHEAD (Action for Health in Diabetes) trial did not maintain a weight loss greater or equal to 10% of initial body weight after four years. <sup>14</sup> Accordingly, few benefits were observed in this study subgroup from the cardiovascular risk standpoint. <sup>14</sup> Bariatric surgeries, also called metabolic surgeries, now clearly represent a reasonable option for these individuals, especially since the seminal demonstrations that bariatric surgery is more effective than standard medical approaches, including use of medication and dietary counselling, to improve glycemic control in severe obesity and uncontrolled type 2 diabetes mellitus (T2DM). <sup>4,5</sup>

# Which patients should be offered bariatric surgery?

The first-line management of obesity should include a multi-disciplinary evaluation with nutritional and medical counselling, as

well as behavioural modifications and increased physical activity. Unfortunately, the medium-term weight loss associated with the best medical treatments is modest, and the chances of remission of T2DM, once established, are anecdotal.<sup>15</sup> Weight loss (bariatric) surgery has thus become an integral part for the management of patients with severe obesity.

A number of surgical procedures have emerged over the last 40 years, including Roux-en-Y gastric bypass in 1971, adjustable gastric banding in 1980, duodenal switch in 1989 and sleeve gastrectomy in 2000. 16 Indications for the surgical management of severe obesity were outlined by the National Institute of Health (NIH) consensus development panel in 1991 and continue to represent generally accepted guidelines. 17 Interestingly, even though these guidelines were developed almost 30 years ago, and were based on expert opinions, they have not yet been revised. Potential candidates should be aged between 18 and 60 years and willing to participate in their treatment and long-term follow-up.

Patients with a BMI between 35 and 40 kg/m² with at least one major obesity-related disease (e.g., T2DM, obesity-related cardiac disease, sleep apnea), or patients with a BMI  $\geq$  40 kg/m² with or without associated diseases, are potential surgical candidates. In addition, bariatric surgery may be offered to patients with obesity

(BMI ≥ 30 kg/m²) and significant obesity-associated disease(s), when psychological and behavioural interventions and medical management are insufficient to achieve optimal weight loss and control of comorbidities.¹¹ These patients should be evaluated and carefully selected by a multi-disciplinary team experienced in the field of obesity surgery. Team members should educate patients regarding the risks, benefits and alternatives to bariatric surgery, including use of anti-obesity medications. Patients should also understand the need for lifelong medical surveillance to prevent and correct potential long-term nutritional deficiencies after surgery. Contraindications for bariatric surgery include recent substance abuse (alcohol, drugs), non-stable psychiatric conditions (i.e., changes in psychiatric medications in the last six months), a diagnosis of cancer or an expected life expectancy less than five years.

Even though an age limit of 60 years is considered in the NIH recommendations, multiple studies have assessed the risks and benefits of bariatric surgery in the elderly. These are summarized in a systematic review that identified 26 articles encompassing 8149 patients. Pooled 30-day mortality was 0.01% and overall complication rate was 14.7%. At one-year follow-up, mean excess weight loss was 53.8%, diabetes resolution was 54.5%, hypertension resolution was 42.5% and lipid disorder resolution was 41.2%. The authors conclude that outcomes and complication rates of bariatric surgery in patients older than 60 years are comparable to those in a younger population, independent of the type of procedure performed. Patients should not be denied bariatric surgery because of their age alone.

On the same topic, the literature supporting metabolic surgery in adolescents has been summarized in the recent American Society for Metabolic and Bariatric Surgery pediatric metabolic and bariatric surgery guidelines.<sup>19</sup> (NB: This reference is given for information only and is outside the purpose of these guidelines.)

## Which bariatric surgery should be offered?

Surgical procedures are described in Figure 1. Historically, weight loss surgeries were classified based on their supposed mechanisms of action. Adjustable gastric banding was considered as a purely restrictive surgery, but a high long-term complication rate associated with weight regain, slippage and erosions has led to a loss of interest with this procedure in favour of surgeries with a metabolic impact. Hypoabsorptive surgeries were thought to decrease the absorption of nutrients by bypassing portions of the small intestine (i.e., gastric bypass or duodenal switch). However, mechanistic studies have described many metabolic modifications, including changes in incretins, gut hormones, bile acids levels and microbiota, which has led to referring to these surgeries as "metabolic operations."

The decision for the type of surgery is made in collaboration with a multi-disciplinary team, based on the patient's medical condition, including weight, obesity-related diseases, expected adherence with supplementation and follow-up, patients' personal goals and preferences in terms of expected weight loss, resolution of comorbidities and side effects. This team typically may include

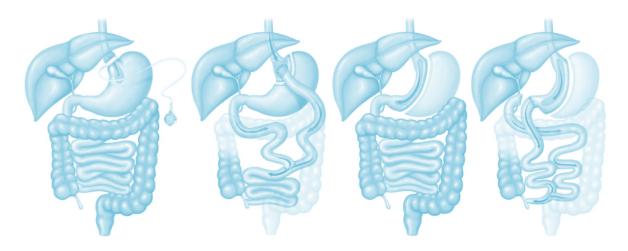
a bariatric nurse, dietitian, mental health specialist, social worker and an internist/bariatric physician, in addition to the bariatric surgeon. The goal is to find a balance between the complications and risk of mortality associated with the obesity itself, and to improve the patient's quality of life (QOL) and reduce obesity-related diseases while aiming for acceptable short- and long-term complications and side effects related to the surgery itself. As a rule of thumb, early and long-term risks and side effects, but also maintenance of weight loss and remission of comorbidities, are proportional to the intestinal bypass. Other bariatric procedures such as single-anastomosis duodeno-ileostomy and single-anastomosis gastric bypass are becoming more popular, but are still lacking substantial scientific rationale. They are discussed in the "New surgical and endoscopic approaches" section of this chapter.

Adjustable gastric banding is one of the procedures that has evolved the most over the last 20 years, from a non-adjustable gastric band performed by laparotomy to laparoscopically performed adjustable gastric banding. Iterations of the technique have always aimed to reduce the complications that appeared over time. The procedure consists in placing an adjustable silicone band at the level of the cardia, creating a small stomach pouch above the band, with the rest of the stomach below the band. The gastric band is connected by a silicone tube to a subcutaneous reservoir. The reservoir can be inflated or deflated to control the opening between the pouch and the remainder of the stomach. Even though this procedure is associated with the lowest short-term complication rate, it is associated with a high long-term complication rate and weight regain, which has led to its progressive replacement by sleeve gastrectomy.

Sleeve gastrectomy was first used by laparoscopy as a staged approach in order to reduce peri-operative complications in highrisk patients.<sup>20</sup> Interestingly, some patients experienced appreciable weight loss with sleeve gastrectomy alone and did not require second-stage surgery, thus avoiding the side-effects of malabsorption. Its relative technical simplicity and good outcomes led to a worldwide surge in popularity as a stand-alone procedure, starting around 2008. This procedure involves resection of the lateral part of the stomach to create a narrow gastric tube along the lesser curvature. It promotes weight loss through reduced meal volume and reduced appetite. It has become the most frequently performed surgical approach, representing 45.9% and 58.3% of all surgeries in the world and in North America, respectively.<sup>21</sup> These numbers are likely to be maintained given the recent confirmation of the five-year efficacy of sleeve gastrectomy in two randomized controlled trials.<sup>22,23</sup> In addition, sleeve gastrectomy is typically easier to revise in case of weight regain compared with Roux-en-Y gastric bypass.

**Roux-en-Y gastric bypass** involves the creation of a small gastric pouch at the level of the cardia. This pouch is connected to the proximal small bowel by bypassing the first 75–150 cm and bringing a 100–150 cm alimentary limb onto the gastric pouch. Short-term metabolic and hormonal effects have been studied extensively in numerous studies.<sup>24</sup> It has been considered as the gold standard in bariatric surgery until recently, when it was supplanted

Figure 1



From left to right: Adjustable gastric banding, Roux-en-Y gastric bypass, sleeve gastrectomy and biliopancreatic diversion with duodenal switch. Copyright: Graphic department, Quebec Heart and Lung Institute, Laval University. Reprinted with permission.

by sleeve gastrectomy. Long-term data have been reported in numerous studies, <sup>12</sup> and are summarized below.

**Duodenal switch** combines moderate restrictive and hypoabsorptive mechanisms by creating a wider sleeve gastrectomy, while the duodenum is transected distal to the pylorus and anastomosed to a 250 cm alimentary limb, leaving a 100-cm common channel for nutrient absorption. Duodenal switch reduces morbidity and mortality, improves T2DM and corrects many features of the metabolic syndrome in long-term studies.<sup>25</sup> This operation compares very advantageously with the other surgical options available, offering the most pronounced and durable weight loss and 80–90% remission rates for T2DM.<sup>26</sup> Yet, the technical complexity and the risk for long-term nutritional deficiencies has hindered its widespread use. According to the most recent data, duodenal switch represented 1.1% of the total number of surgeries worldwide and 5–6% of all bariatric operations in Canada.<sup>21</sup>

#### Risks

Even though bariatric surgery provides substantial and sustained effects on weight loss and ameliorates obesity-attributable comorbidities in the majority of bariatric patients, risks of complication, reoperation and death exist. In a systematic review and meta-analysis published in 2014, a total of 164 studies, randomized control trials and 127 observational studies were identified.<sup>27</sup> Analyses included 161756 patients, with a mean age of 44.6 years and BMI of 45.6. In randomized control trials, the mortality rate within 30 days was 0.08% (95% CI, 0.01–0.24%); the mortality rate after 30 days was 0.31% (95% CI, 0.01–0.75%). BMI loss at five years post-surgery was 12 to 17. The complication rate was 17% (95% CI, 11–23%), and the reoperation rate was 7% (95% CI, 3–12%). Gastric bypass was more effective in weight loss but associated with more complications. Adjustable gastric banding had lower mortality and complication rates; yet, the reoperation rate was

higher and weight loss was less substantial than gastric bypass. In a large analysis of United States bariatric registries (n = 134142), sleeve gastrectomy was associated with half the risk-adjusted odds of death (0.1% versus 0.2%), serious morbidity (5.8% versus 11.7%) and leak (0.8% versus 1.6%) in the first 30 days compared to Roux-en-Y gastric bypass. Sleeve gastrectomy appeared to be more effective in weight loss than adjustable gastric banding and comparable with gastric bypass. Table 1 summarizes the risks and benefits of the four different surgeries.

## Metabolic effects of bariatric surgery

### What is the quality of life after bariatric surgery?

Patients living with severe obesity have lower perceived health across all dimensions of QOL.<sup>28</sup> Moreover, the impact on functioning is so important that severe obesity can be described as a cause of disability. For most patients, bariatric surgery has a significant positive influence on QOL. The impact varies considerably across studies, with bariatric surgery showing a significantly greater positive influence on physical QOL compared with mental QOL. Also, improvement in health-related quality of life (HRQOL) is typically associated with the amount of weight loss. Meta-analyses of short-term (one year) and long-term (≥ 5 years) HRQOL following bariatric surgery versus non-surgical management in patients with Class II or III obesity, showed evidence for a substantial and significant improvement in physical and mental health favouring the surgical group compared with controls, spanning five to 25 years after surgery. <sup>29,30</sup> In a systematic review comparing bariatric surgery to medical treatment in adults with obesity (BMI > 30kg/m<sup>2</sup>),<sup>31</sup> bariatric surgery resulted in greater improvements in QOL than other obesity treatments. However, significant differences in QOL improvements were found between different types of bariatric surgery, and greater improvements in physical QOL than mental QOL were found. Similarly, Lindekilke

et al.,<sup>6</sup> in a meta-analysis of the impact of bariatric surgery on QOL in adults receiving surgery for obesity, reported a positive effect on QOL, especially when looking at physical wellbeing. In another series of 139 patients with severe obesity randomized to Roux-en-Y gastric bypass (n = 76) versus intensive behavioural intervention (n = 63), Karlsen et al.<sup>32</sup> reported a significant improvement in HRQOL after one year, with a weaker response in the behavioural group. Significant association between weight reduction in percent of baseline weight and HRQOL was found, explaining the weaker response of intensive behavioural changes compared to Roux-en-Y gastric bypass.

#### What is the impact on weight?

Many studies have confirmed the long-term superior weight loss following surgery, compared to non-surgical interventions. As a rule of thumb, weight loss and remission of comorbidities is proportional to intestinal bypass, which is a surrogate of the metabolic effect of the surgery (e.g., adjustable gastric banding < sleeve gastrectomy < Roux-en-Y gastric bypass < duodenal switch). There is, however, no direct comparison of these four surgeries in a single prospective trial. Table 1 summarizes the average weight loss following surgery.

One of the largest prospective trials in bariatric surgery, called the Swedish Obese Subjects (SOS) Study, 1,33 involved 4047 subjects living with obesity who underwent bariatric surgery (n = 2010) or conventional treatment (n = 2037) in a matched control group. The average weight change in control subjects was less than 2% during the period of follow-up to 15 years. After 10 years, the total weight loss was 25% after gastric bypass, 16% after vertical banded gastroplasty and 14% after banding. Colquitt et al.3 did a meta-analysis of studies comparing surgery with non-surgical interventions. A total of 22 randomized controlled trials were identified, representing altogether 1496 patients allocated to surgery and 302 to non-surgical interventions. Outcomes were similar between Roux-en-Y gastric bypass and sleeve gastrectomy, and both of these procedures had better outcomes than adjustable gastric banding. For people with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than Rouxen-Y gastric bypass.

A series of 250 patients with an initial BMI of 45 to 60 kg/m² were randomized to Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding. At 10-year follow-up, the mean total body weight loss was -42  $\pm$  20 kg for gastric bypass versus -27  $\pm$  15 kg for gastric banding (p < 0.05). Late reoperation was significantly higher after gastric banding compared with the gastric bypass group (31% vs. 8%, respectively, p < 0.01). At 10 years and compared with gastric banding, gastric bypass was associated with better long-term weight loss, lower rate of late reoperation and improved remission of comorbidities.

Five-year outcomes of laparoscopic Roux-en-Y gastric bypass and laparoscopic biliopancreatic diversion with duodenal switch were also compared in a randomized control trial involving 60 patients with an initial BMI of 50 to 60 kg/m².²6 At five years, duodenal switch surgery resulted in greater weight loss and greater

improvements in LDL cholesterol, triglyceride and glucose levels compared with gastric bypass, while improvements in QOL were similar. However, duodenal switch was associated with more surgical, nutritional and gastrointestinal adverse effects. Excess weight loss was assessed after sleeve gastrectomy in a systematic review.<sup>34</sup>

Sleeve gastrectomy was also compared to Roux-en-Y gastric bypass in two randomized control trials with five-year outcomes. <sup>22,23</sup> Roux-en-Y gastric bypass and sleeve gastrectomy resulted in equivalent, long-standing QOL improvement. Roux-en-Y gastric bypass resulted in more stable weight loss (75% versus 65% excess weight loss at five years, p = 0.017) but was associated with higher re-admission rates. Similar improvements in QOL were found in the second randomized control trial; excess weight loss was 49% in the sleeve gastrectomy group versus 57% in the Roux-en-Y gastric bypass group, but the difference did not reach significance. Overall morbidity was 19% for sleeve gastrectomy and 26% for Roux-en-Y gastric bypass (p = 0.19).

#### What are the effects on type 2 diabetes?

Over the last two decades we have witnessed a dramatic increase in the incidence of T2DM, now affecting 10% of the adult population. Most (80%) is due to excess weight or obesity and T2DM has become the leading cause of chronic kidney disease, blindness and non-traumatic amputation. Overall, bariatric surgery procedures have been consistently more effective than standard medical approaches, including intensive medical treatment and psychological/behavioural interventions to induce durable control and remission of T2DM.<sup>35</sup>

The SOS study is a prospective controlled trial with one of the longest periods of follow-up in the bariatric literature. This study has shown impressive results with respect to sustained remission of T2DM.<sup>35</sup> At two (n = 1762) and 10 years (n = 1216), remission rates were 72% and 36%, respectively, in the pooled surgical group. Reductions in glucose, insulin and homeostatic model assessment for insulin resistance increased with increasing weight loss, and changes were typically related to weight change within each surgery group. Several randomized control trials have specifically studied T2DM response to different surgical procedures versus medical treatment. Mingrone et al.4 reported rates of remission of diabetes at three years to be 75% and 95% in Roux-en-Y gastric bypass and duodenal switch groups, compared to no response with medical intervention alone. At five years, remission was maintained in 37% of the Roux-en-Y gastric bypass patients and 63% of the biliopancreatic diversion patients.4 Further, Schauer et al.5 studied the impact of Roux-en-Y gastric bypass, sleeve gastrectomy and best medical management for patients with poorly controlled T2DM and severe obesity (BMI 27 to 43 kg/m²). At three years, Roux-en-Y gastric bypass (n = 50) and sleeve gastrectomy (n = 50) resulted in improved diabetes outcomes and remission in 42% and 37% of patients, respectively, compared to 12% achieved with medical therapy (n = 50). At five years,<sup>5</sup> the criterion for the primary end point was met by 5% of patients who received medical therapy alone, compared to 29% who underwent Roux-en-Y gastric bypass and 23% who underwent sleeve gastrectomy. Mean reduction in glycated hemoglobin was 2.1% vs. 0.3% (p = 0.003) in the surgery versus medical croup. Changes from baseline observed in the Roux-en-Y gastric bypass and sleeve gastrectomy groups were also superior to the changes seen in the medical therapy group with respect to body weight. These changes were -23%, -19% and -5% in the Roux-en-Y gastric bypass, sleeve gastrectomy and medical therapy groups, respectively; the triglyceride levels were -40%, -29% and -8%; high density lipoprotein cholesterol levels were 32%, 30% and 7%; use of insulin was -35%, -34% and -13%; and QOL measures were p < 0.05 for all comparisons. Five- to 20-year remission rates after duodenal switch are even higher, with observational studies showing complete remission in the range of 93% and discontinuation of insulin therapy in 97%.<sup>25</sup>

In general, metabolic outcomes of adjustable gastric banding are less impressive compared with bypass procedures. In a randomized control trial comparing adjustable gastric banding to intensive medical diabetes and obesity management in patients with T2DM and BMI of 30–45 kg/m², $^{36}$  laparoscopic adjustable gastric banding and medical programs had similar one-year benefits on diabetes control, cardiometabolic risk and patient satisfaction. The proportion meeting the primary glycemic endpoint was achieved in 33% of the laparoscopic adjustable gastric banding patients and 23% of the intensive medical diabetes and weight management patients (p = .457). Glycated hemoglobin (HbA1c) reduction was similar between groups at both three and 12 months (-1.2 +/- 0.3 vs. -1.0 +/- 0.3%; p = .496). Weight loss was similar at three months but greater at 12 months after laparoscopic adjustable gastric banding. These outcomes and others favour metabolic surgeries in cases of T2DM.

An abundance of literature, including prospective and randomized trials comparing different metabolic procedures to medical treatment, have been identified by our literature search. All studies consistently showed superior control and remission of T2DM in the surgical arms<sup>37–39</sup>, including superior weight loss and lower HbA1c three years after duodenal switch compared with Roux-en-Y gastric bypass.<sup>40</sup> Variations in reported outcomes are multi-factorial and include differences in study design, surgical technique, duration of follow-up and patient characteristics, such as higher pre-surgical BMI and shorter duration of T2DM (both of which confer higher likelihood of remission).<sup>41</sup>

Also, continued monitoring of glycemic control is warranted because the effect of surgery tends to diminish over time with potential relapse of hyperglycemia.<sup>38</sup> The place of metabolic surgery in the management of T2DM was ultimately recognized by the International Federation on Diabetes in 2011<sup>42</sup> and the Canadian Diabetes Association in 2013.<sup>43</sup> Both stated that surgery represents a valid option for T2DM management in patients with severe obesity who have failed initial medical and nutritional management.

## What is the impact on other comorbidities?

#### Hypertension

A meta-analysis of the effect of bariatric surgery on hypertension was performed by Wilhelm et al.<sup>8</sup> Of the 57 studies, 32 report-

ed improvement of hypertension in 32628 of 51241 patients (OR = 13.24; 95% CI 7.7, 22.7; p < 0.00001); 46 studies reported the resolution of hypertension in 24902 of 49844 patients (OR = 1.7; 95% CI 1.1, 2.6; p = 0.01). Another systematic review and meta-analysis on the early impact of bariatric surgery on T2DM, hypertension and hyperlipidemia was performed by Ricci et al.44 There was an overall reduction of cardiovascular risk after bariatric surgery. According to their analysis, a BMI reduction of five after surgery corresponds to a T2DM reduction of 33%, a hypertension reduction of 27% and a hyperlipidemia reduction of 20%. The impact of sleeve gastrectomy on hypertension was assessed in a systematic review.<sup>45</sup> A total of 33 studies were identified, involving a total of 3997 patients. Laparoscopic sleeve gastrectomy resulted in resolution of hypertension in 58% of patients and improvement or resolution in 75%. Based on these reviews, bariatric surgery has a significant effect on hypertension, inducing resolution or improvement in the majority of cases.

#### Sleep apnea

There is limited high-level evidence regarding the impact of bariatric surgery on sleep apnea. We identified three randomized clinical trials assessing the impact of adjustable gastric banding versus clinical management on sleep apnea. For Aguiar et al. To bariatric surgery was effective in reducing neck and waist circumference, in increasing maximum ventilatory pressures, enhancing sleep architecture and reducing respiratory sleep disorders, specifically obstructive sleep apnea. On the other hand, Feigel-Guiller et al. did not find significant difference in the rate of weaning from non-invasive ventilation between laparoscopic adjustable gastric banding and medical treatment at one year (35% vs. 13%) or three years (14% versus 21%). Decreases in the Apnea-Hypopnea Index were observed in the laparoscopic adjustable gastric banding group from baseline to year one (44%, p = 0.001) and from baseline to year three (-26%, p = 0.04).

The American Thoracic Society recently released a clinical practice guideline on the management of sleep apnea.<sup>49</sup> Their conditional recommendation for patients with sleep apnea and a BMI of 35 kg/m², whose weight has not improved despite participating in a comprehensive behavioural intervention program and who have no contraindications, is to refer patients for bariatric surgery evaluation. They, however, assessed certainty in the estimated effect as very low. More randomized control trials, particularly including other types of surgeries than adjustable gastric banding, are thus needed to confirm these findings given the high degree of heterogeneity using respiratory events scoring.

### Lipid metabolism

Improvements in lipid metabolism have been reported consistently in various prospective and retrospective studies. Contemporary bariatric surgical techniques produce significant improvements in serum lipids, but changes vary widely, likely due to anatomic alterations unique to each procedure. A literature review by Heffron et al.<sup>7</sup> identified 178 studies, with 25189 subjects, reporting changes in lipids from baseline to one year after surgery. In patients

undergoing any bariatric surgery compared to baseline, there were significant reductions in total cholesterol (TC, -28.5 mg/dL), low density lipoprotein cholesterol (LDL-C, -22.0 mg/dL) and triglycerides (-61.6 mg/dL), and a significant increase in high density lipoprotein cholesterol (6.9 mg/dL) at one year (p < 0.00001 for all). The magnitude of this change was significantly greater than that seen in non-surgical control patients (e.g., LDL-C; -22.0 mg/ dL vs. -4.3 mg/dL). When assessed separately, the magnitude of changes varied greatly by surgical type (p interaction < 0.00001; e.g., LDL-C: DS -42.5 mg/dL, Roux-en-Y gastric bypass -24.7 mg/ dL, adjustable gastric banding -8.8 mg/dL, sleeve gastrectomy -7.9 mg/dL). In the cases of adjustable gastric banding (TC and LDL-C) and sleeve gastrectomy (LDL-C), the response at one year following surgery was not significantly different from non-surgical control patients. These differences may be relevant in deciding the most appropriate technique for a given patient.

#### **Urinary incontinence**

Urinary incontinence is extremely frequent in patients seeking bariatric surgery. In a series of 470 patients undergoing bariatric surgery, the prevalence of urinary incontinence was 66%.50 Other pelvic floor disorders are also frequent and, in general, surgically induced weight loss is very efficient in improving these conditions. Lian et al.<sup>51</sup> performed a meta-analysis of the effects of bariatric surgery on pelvic floor disorders. Eleven cohort studies were identified, involving 784 participants assessed for pelvic floor disorders with a variety of guestionnaires, before and after bariatric surgery. Bariatric surgery was associated with a significant improvement in pelvic floor disorders on the whole, and with significant improvements in urinary incontinence and pelvic organ prolapse. There was no significant improvement in fecal incontinence and sexual function. In a prospective analysis of 140 patients undergoing bariatric surgery, Said and colleagues<sup>52</sup> reported that surgery-induced weight loss was associated with an improvement in stress urinary incontinence (40% at baseline vs. 15.5% at one year), urge incontinence (37% at baseline vs. 8%), dysuria (20% at baseline vs. 3.4%) and QOL related to urinary symptoms (all P < .0001). In addition, reduction in prevalence of urinary incontinence was significantly associated with decreases in BMI (p = .01).<sup>53</sup>

#### Steatosis and steato-hepatitis

The non-alcoholic fatty liver disease (NAFLD) spectrum ranges from hepatic steatosis to more severe non-alcoholic steato-hepatitis and fibrosis that can progress to cirrhosis, end-stage liver disease and hepatocellular carcinoma. The prevalence of NAFLD is estimated to be around 70% in people living with obesity and 85% to 95% in patients with severe obesity. The prevalence of non-alcoholic steatohepatitis is as high as 18.5% in people living with obesity and 33% in those living with severe obesity. At present, interventions for NAFLD focus on weight loss and improvement in insulin resistance and associated comorbidities. Medical treatment for weight loss with drugs, nutrition, exercise and other psychological/behavioural interventions has limited efficacy, especially in those living with severe obesity. On the other hand, liver steatosis, steatohepatitis and even liver fibrosis appear to improve

or completely resolve in the majority of patients after bariatric surgery-induced weight loss.<sup>54</sup> In a systematic review of the literature (15 studies with 766 paired liver biopsies),<sup>9</sup> the pooled proportion of patients with improvement or resolution in steatosis was 91.6% (95% CI, 82.4–97.6%), 81.3% in steatohepatitis (95% CI, 61.9–94.9%), 65.5% in fibrosis (95% CI, 38.2–88.1%) and 69.5% for complete resolution of non-alcoholic steatohepatitis (95% CI, 42.4–90.8%). Lassailly et al.<sup>55</sup> prospectively followed 109 patients with biopsy-proven non-alcoholic steatohepatitis who underwent bariatric surgery. One year after surgery, non-alcoholic steatohepatitis had disappeared from 85% of the patients (95% CI, 75.8–92.2%). Non-alcoholic steatohepatitis disappeared from a higher proportion of patients with mild non-alcoholic steatohepatitis before surgery (94%) than severe non-alcoholic steatohepatitis (70%) (p < .05), according to Brunt score.

#### **Renal function**

Obesity is an independent risk factor for the development and progression of chronic kidney disease. However, data on the benefits of bariatric surgery in patients living with obesity who have impaired kidney function are limited. A recent systematic review and meta-analysis<sup>56</sup> assessed the impact of bariatric surgery on glomerular filtration rate, proteinuria or albuminuria. The authors included 30 observational studies and found a significant reduction in hyperfiltration, albuminuria and proteinuria after bariatric surgery. Main limitations were the lack of randomized control trials and long-term follow-up. In another systematic review of the impact of bariatric surgery on renal function in patients with T2DM, Zhou et al<sup>57</sup> identified 29 studies (four randomized controlled trials, five cohort studies, 20 before-and-after studies; all at moderate to high risk of bias) involving 18172 patients. Analyses of changes before and after surgeries suggested a significantly lower proportion of albuminuria (difference -21.2%, 95% CI -28.8% to -13.5%), 24-hour urine albumin excretion rate (weighted mean difference -48.78 mg/24 heart rate, 95% CI -75.32 to -22.24) and urine albumin-to-creatinine ratio (uACR) (weighted mean difference -16.10 mg/g, 95% CI -22.26 to -9.94) after surgery. Compared with non-surgical treatment, bariatric surgery was associated with a statistically lower level of uACR and lower risk of new onset albuminuria (OR.18, 95% CI.03-.99 from randomized controlled trials). Even though low-quality evidence suggests that bariatric surgery possibly improves albuminuria and uACR in patients with T2DM, its effects on other outcomes are uncertain. Large, randomized prospective studies with a longer follow-up are needed.

# Does bariatric surgery decrease long-term mortality risk?

An observational two-cohort study comparing the morbidity and mortality of 1035 patients with severe obesity treated with bariatric surgery to 5746 control subjects with severe obesity has shown that bariatric surgery significantly decreases overall mortality as well as reduces risk of chronic conditions in subjects with severe obesity. The bariatric surgery subjects had significant risk reductions for developing cardiovascular, cancer, endocrine conditions

(including T2DM), as well as infectious, psychiatric and mental disorders compared with the control group.<sup>58</sup> The mortality rate in the bariatric surgery cohort was 0.68% compared with 6.17% in controls, translating to a reduction in the relative risk of death by 89%.

In the SOS study,<sup>1</sup> surgical treatments were shown to decrease the incidence of total and fatal cardiovascular events over 20 years compared to contemporaneously matched controls of those living with obesity receiving usual care. There were 129 deaths in the control group and 101 deaths in the surgery group. The hazard ratio adjusted for age, sex and risk factors was 0.71 in the surgery group (p = 0.01) as compared with the control group. The most common causes of death were myocardial infarction and cancer. Analyses of the SOS data failed to demonstrate an association between initial BMI and post-operative health benefits. Even the magnitude of surgery-induced weight loss did not predict cardiovascular events in that cohort, indirectly pointing toward weight loss-independent beneficial mechanisms.

In a meta-analysis of the published literature on long-term (> 2 years) mortality after bariatric surgery, Cardoso et al. identified 12 observational studies involving 27258 operated patients and 97154 non-operated controls of those living with obesity. Eight studies were eligible for the meta-analysis, which showed a reduction of 41% in all-cause mortality (hazard ratio, 0.59; 95% CI 0.52–0.67; p < .001).

Indeed, surgical weight loss seems to reduce the incidence of some cancer forms and cancer-related mortality. In the SOS trial,  $^{59}$  the number of first time cancers after inclusion was lower in the surgery group (n = 117) than in the control group (n = 169; heart rate 0.67, 95% CI 0.53–0.85, p = 0.0009). Bariatric surgery was associated with reduced cancer incidence in women with obesity but not in men living with obesity.

# Is bariatric surgery indicated in patients with Class I obesity (BMI 30–35)?

With the improved understanding of hormonal and metabolic changes related to the intestinal bypass, bariatric surgery has evolved conceptually from bariatric surgery to metabolic surgery, particularly for patients with a metabolic complication (especially T2DM) that is more of a problem than weight itself. A number of randomized trials have looked at the impact of such surgeries on T2DM, compared to the best medical management.<sup>5,60–62</sup> These studies were summarized in a meta-analysis by Cohen et al.<sup>10</sup> looking at patients with BMI of 30-40 kg/m<sup>2</sup> undergoing Rouxen-Y gastric bypass vs. medical treatment.<sup>10</sup> A total of five randomized control trials were identified, with 43.3% of the patients with a BMI below 35 kg/m<sup>2</sup>. Roux-en-Y gastric bypass significantly improved total and partial remission of T2DM (OR 17.48 [95% CI 4.28-71.35] and OR 20.71 [95% CI 5.16-83.12], respectively). HbA1c was also reduced at longest follow-up in the surgery group (-1.83 [95% CI 2.14;-1.51]). This meta-analysis reinforced the view that adding metabolic surgery, particularly Roux-en-Y gastric bypass, to the best medical treatment is a good option for the management of uncontrolled T2DM in patients with a BMI 30 kg/m<sup>2</sup>.

The place of metabolic surgery in the management of T2DM was recognized by the International Federation on Diabetes in 2011.<sup>42</sup> This position statement called for bariatric surgery to be considered earlier in eligible patients, to help stem the serious complications that can result from diabetes. In addition to considering surgery in people with T2DM and a BMI  $\geq$  35 kg/m<sup>2</sup>, the International Federation on Diabetes task force stated that surgery should be considered as an alternative treatment option in patients with a BMI between 30 and 35 kg/m<sup>2</sup> when diabetes cannot be adequately controlled by optimal medical regimens, especially in the presence of other major cardiovascular disease risk factors. In 2016, over 50 international medical societies endorsed new guidelines where metabolic surgery was included in the treatment algorithm for patients with uncontrolled T2DM and BMI above 30 kg/ m<sup>2</sup>.63 Other metabolic outcomes were also improved in patients with mild to moderate obesity. Ikramuddin et al. randomized 120 patients with BMI between 30 and 40 kg/m<sup>2</sup> to Roux-en-Y gastric bypass versus intensive management and looked at a composite main endpoint of hyperglycemia, hypertension and dyslipidemia resolution. 11 At 12 months, the primary endpoint was reached in 49% (95% CI, 36-63%) versus 19% (95% CI 10-32%) of the surgical versus medical patients, respectively (OR 4.8; 95% CI, 1.9-11.7). Participants in the gastric bypass group required 3.0 fewer medications (mean, 1.7 vs. 4.8; 95% CI for the difference, 2.3-3.6) and lost 26.1% vs. 7.9% of their initial body weight compared with the behavioural-medical management group (difference, 17.5%; 95% CI 14.2–20.7%). Regression analyses indicated that achieving the composite end point was primarily attributable to weight loss.

# New surgical and endoscopic approaches

Bariatric surgery is one of the fastest evolving fields of general surgery. Surgical procedures are being modified and new concepts emerge over time; only some withstand the test of time and scientific evaluation. The most common surgical modifications performed around the world are described below.

#### Single-anastomosis duodenal switch

This simplified duodenal switch technique has been put forward by Sánchez-Pernaute.<sup>64</sup> Much like the duodenal switch developed by Marceau<sup>65,66</sup> and first performed laparoscopically by Gagner,<sup>65</sup> it involves the creation of a sleeve gastrectomy, but the duodenum is transected and connected to an omega-shaped loop of small bowel (Figure 1) This new procedure has the advantage of being simpler than the duodenal switch because only one intestinal anastomosis is needed instead of two. The other potential benefits are to decrease the rate of peri-operative complications and increase access to this type of surgery. In addition, the length of the common intestinal channel allowing digestion and absorption (250 cm) is more than doubled compared to standard duodenal switch (100 cm), which could attenuate side effects related to dietary fat- and fat-soluble vitamin malabsorption. This procedure was recently endorsed by the International Federation for the Surgery of Obesity and American Society for Metabolic and Bariatric Surgery,<sup>67</sup> based on its similarities and commonly accepted decreased risk compared to standard duodenal switch. Single-anastomosis duodeno-ileostomy is emerging

as a potential option for sleeve gastrectomy weight regain or T2DM recurrences. A single small series of 16 patients who had two-stage single-anastomosis duodeno-ileostomy experienced an increase in excess weight loss from 39.5% to 72% two years after the second stage (n = 5). Remission rate for T2DM was 88%, 60% for hypertension and 40% for dyslipidemia.

### **Gastric plication**

Laparoscopic gastric plication was first described by Talebpour et al.68 This procedure consists in imbricating the greater curvature of the stomach with two layers of non-absorbable sutures. The overall goal is to duplicate the effects of a sleeve gastrectomy, while avoiding any gastric stapling or resection. The procedure is, however, associated with significant post-operative nausea and food intolerance and does not seem to reduce the risk of gastric leak. A systematic review identified 14 studies involving 1450 patients who underwent gastric plication.<sup>69</sup> Excess weight loss ranged from 32% to 74% with follow-up from six to 24 months. No mortality was reported in these studies and the rate of major complications requiring re-operation ranged from nil to 15.4% (average 3.7%). However, it remains unclear if weight loss following laparoscopic gastric plication is durable in the long term. Two-year outcomes were assessed in a randomized control trial comparing sleeve gastrectomy to gastric plication. At two years, the total weight loss and complication rates were not significantly different between the two groups.<sup>68</sup> Additional comparative trials and long-term follow-up are needed to further define the role of laparoscopic gastric plication in the surgical management of obesity.

#### Single-anastomosis gastric bypass

Roux-en-Y gastric bypass has long been considered as the gold standard in bariatric surgery, offering a good compromise between benefits (weight loss, QOL, remission of comorbidities) and surgical risks and side effects. It was recently replaced by sleeve gastrectomy as the most common bariatric procedure. However, some technical limitations (difficulty in creating a gastrojejunostomy) and the risk of weight and comorbidities recidivism have led to the development of single-anastomosis gastric bypass (SAGB). This procedure was initially described in 2001 by Rutledge, and consists of creating a long and narrow gastric reservoir (+/-10 cm, vs. 5 cm long for standard Roux-en-Y gastric bypass) associated with a typically longer single loop (biliopancreatic limb of 200 cm). This technique is increasingly popular in Europe and Asia and has been endorsed by the International Federation for the Surgery of Obesity.<sup>70</sup> It is, however, not currently approved outside of Institutional Review Board protocols in the U.S. Long-term benefits of SAGB compared to standard Roux-en-Y gastric bypass are still questioned regarding the risk of bile reflux and long-term risk of esophageal and gastric cancer associated with chronic exposure to bile acids. A recent randomized control trial compared single-anastomosis gastric bypass to Roux-en-Y gastric bypass and sleeve gastrectomy (200 patients in each groups). The authors reported superior weight loss (98% vs. 76% vs. 77% in the single-anastomosis gastric bypass, sleeve gastrectomy and Roux-en-Y gastric bypass groups, respectively) and similar remission rate of metabolic syndrome, including remission of T2DM, in 94% versus

87% versus 90% after SAGB, sleeve gastrectomy and Roux-en-Y gastric bypass.<sup>71</sup> However, the long-term risk associated with bile acid exposure has not yet been clearly addressed.

### **Current endoscopic therapies**

It is conservatively estimated that approximately 600000 to 1200000 Canadians might be eligible for bariatric surgery assuming that 2% to 4% of the Canadian adult population is living with severe obesity. Only a fraction of Canadians seek surgical intervention for obesity. Approximately 10000 bariatric surgeries were performed in 2017. Many patients are interested in less invasive procedures in order to decrease post-operative complication rates, hospitalization and risks of micronutrient deficiencies typically associated with standard surgical therapies. A number of endoscopic approaches have emerged over time and are typically placed between medical therapy and surgical therapy, in terms of effectiveness, risks and side effects.

### Intra-gastric balloons

Intra-gastric balloons were first described in 1982 by Nieben et al.73 and represent the oldest endoscopic procedure for weight loss. Multiple modifications have been realized to improve the tolerability, risk of perforation and ease of placement and retrieval. Most balloons still require upper gastrointestinal endoscopy with sedation or general anesthesia, and need to be retrieved after three to six months using the same technique. Most patients experience some side effects, like nausea (24%), vomiting (2.7%), abdominal fullness (6.3%) or pain (14%), deflation (6%) and gastric ulcer (12.5%).74 Rare complications can also occur, including gastric or esophageal perforation, small bowel obstruction and hypoxia at the time of extraction. In a meta-analysis of 20 randomized control trials involving 1195 patients, Saber et al. calculated the following significant effect sizes: 1.6 and 1.3 kg/m<sup>2</sup> for overall and threemonths BMI loss, respectively, and 4.6 and 4.8 kg for overall and three-month weight loss, respectively.74 In another meta-analysis by Zheng et al.75 effect size was 8.9 kg for weight loss, 3.1 kg/ m² for BMI reduction and 21% for excess weight loss after six months. However, most patients will regain weight after balloon extraction, and there is insufficient evidence supporting its longterm effectiveness.74 The last modifications of this technique allow the balloon to be swallowed<sup>76</sup> and even self-excreted.<sup>77</sup> Initial studies have demonstrated its safety and short-term efficacy.

#### **Endoscopic bypass**

A number of endoscopic procedures have been developed recently that attempt to mimic the metabolic effect of Roux-en-Y gastric bypass. The most advanced endoscopic bypass (EndoBarrier,® or duodeno-jejunal endoscopic bypass) consists in placing a 1 mm plastic sleeve in the first duodenum to prevent contact of food with bile acids and to bring undigested food into the proximal jejunum. The sleeve is placed, under sedation, with a gastroscope. It needs to be retrieved after six months. Small randomized control trials showed an excess weight loss of 32.0% (22.0–46.7%) versus 16.4% (4.1–34.6%) in the control group (p < 0.05) with improvement in glucose metabolism.<sup>78</sup> Meta-analysis identified 151 patients who underwent

an endoscopic bypass, with a weight loss of -5.1 kg (95% CI -7.3, -3.0) and excess weight loss of 12.6% (95% CI 9.0, 16.2), respectively. However, it is associated with a risk of serious adverse events, like acute pancreatitis in 3% of patients, device migration, early explant, gastrointestinal bleeding and liver abscess. 80-82

#### **Endoscopic sleeve gastroplasty**

Different endoscopic procedures have been developed to endoscopically reduce gastric volume. The most common (the Pose procedure) involves endoluminal placement of full-thickness suture to plicate the fundus and distal body of the stomach. Large randomized control trials have assessed the technique and shown acceptable short-term weight loss with low peri-operative complications. Sullivan et al. <sup>83</sup> performed a randomized control trial of the procedure versus behavioural modifications (332 patients). At 12 months, weight loss was  $4.9 \pm 7\%$  in active versus  $1.4 \pm 5.6\%$  in the sham group (p < 0.0001). The proportion of patients achieving  $\geq 5\%$  weight loss was 41.5% in active and 22.1% in sham groups, respectively (p < 0.0001); mean responder result was 11.5% total body weight loss. Procedure-related serious adverse event rates were 5.0% (active) and 0.9% (sham, p = 0.068).

## **Aspiration therapy**

Percutaneous gastrostomy device (AspireAssist®) has been recently described for the treatment of patients suffering from Class II and

III obesity. The procedure is performed under sedation and consists of placement of a gastrostomy tube and an external device to facilitate drainage of about 30% of the calories consumed in a meal, in conjunction with behavioural modifications. Thompson et al.84 randomized 207 patients in a 2:1 ratio to treatment with AspireAssist® plus behavioural counselling (n = 137; mean BMI was  $42.2 + 1/-5.1 \text{ kg/m}^2$ ) or behavioural counselling alone (n = 70; mean BMI was 40.9 +/- 3.9 kg/m²). At 52 weeks, participants in the AspireAssist® group had lost a mean (+/-s.d.) of 12.1 +/- 9.6% total body weight, whereas those in the behavioural counselling group had lost a mean of 3.5 +/- 6.0% total body weight, (p < 0.001). Most adverse events were those known to be associated with percutaneous endoscopic gastrostomy tubes (abdominal pain in 38%, nausea/vomiting in 17%, peristomal bacterial infection in 13.5%). Serious adverse events were reported in 3.6% of participants, including severe abdominal pain, peritonitis, gastric ulcer and tube replacement. Medium-term results are starting to appear, with studies confirming maintenance of weight loss, at 19 +/- 13% weight loss, up to four years.85 Even though these results seem to be promising, patients and physicians' acceptability of the procedure, the need for long-term nutritional surveillance and lack of long-term data and cost itself are among factors limiting the adoption of this procedure.

Table 1: Weight Loss Surgeries<sup>3</sup>

	Adjustable gastric banding	Sleeve gastrectomy	Roux-en-Y gastric bypass	Duodenal switch
Total weight loss (%)	20	25	30	40
Resolution rate of T2DM (%)	20	30	40	80
Resolution rate of hypertension (%)	20	30	40	60
Resolution rate of sleep apnoea/ hypopnoea syndrome (%)	30	40	50	70
Mortality rate (%)	0.01	0.01	0.01	0.02
Serious adverse events (%)	2	3	3	5
Common side effects	Dysphagia, vomiting	Vomiting, constipation	Dumping syndrome	Increased bowel movements, bloating
Long-term risks	Band erosion, band intolerance, weight regain	Gastro-esophageal reflux, Barrett's esophagus, weight regain	Anastomotic ulcer, internal hernia, small bowel obstruction, nesidioblastosis (uncommon)	Protein malnutrition, vitamin deficiency, small bowel obstruction, internal hernia

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The summary of the Canadian Adult Obesity Clinical Practice Guideline is published in the Canadian Medical Association Journal, and contains information on the full methodology, management of authors' competing interests, a brief overview of all recommendations and other details. More detailed guideline chapters are published on the Obesity Canada website at www.obesitycanada.ca/guidelines.

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