

# Bariatric Surgery: Surgical Options and Outcomes

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## KEY MESSAGES FOR HEALTHCARE PROFESSIONALS



- Bariatric surgery should be considered for patients with body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup> and patients with a BMI  $\geq 35$  kg/m<sup>2</sup> and at least one adiposity-related disease.
- Bariatric surgery could be considered for patients with BMI  $\geq 30$  kg/m<sup>2</sup> with an uncontrolled obesity-related disease refractory to medical management.
- The choice of bariatric procedure should be tailored to patients' needs and based on a collaborative, multi-disciplinary discussion of risk, benefit and side effects.
- Several procedures are currently performed in Ireland (sleeve gastrectomy, gastric bypass, adjustable gastric banding, intra-gastric balloon and others), but variations exist. Laparoscopic gastric banding is no longer routinely performed.
- For patients with complicated obesity, surgery offers superior outcomes compared to best medical management in terms of quality of life, long-term weight loss and resolution or improvement of obesity-related complications, primarily type 2 diabetes mellitus, obstructive sleep apnoea, non-alcoholic fatty liver disease and hypertension.
- A laparoscopic surgical approach should be standard and is associated, for most patients, with a low mortality rate (< 0.1%) and a low rate of serious complications (< 5%).
- Bariatric surgery improves life expectancy.
- Novel surgical and endoscopic approaches are being used and developed and can represent an option for selected patients.

## RECOMMENDATIONS



1. Bariatric surgery can be considered for people with body mass index (BMI)  $\geq 40 \text{ kg/m}^2$  or BMI  $\geq 35 \text{ kg/m}^2$  with at least one adiposity-related disease (Level 4, Grade D, Consensus) to:

- Reduce long-term overall mortality (Level 2b, Grade B)<sup>1,2</sup>;
- Induce significantly better long-term weight loss compared to medical management alone (Level 1a, Grade A)<sup>3</sup>;
- Induce control and remission of type 2 diabetes mellitus (T2DM), in combination with best medical management, over best medical management alone (Level 2a, Grade B)<sup>4,5</sup>;
- Significantly improve quality of life (Level 3, Grade C)<sup>6</sup>; and
- Induce long-term improvement or remission of most obesity-related diseases, including dyslipidaemia (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 BMI between  $30 \text{ kg/m}^2$  -  $35 \text{ kg/m}^2$  with inadequately controlled T2DM despite optimal medical management (Level 1a; Grade A)<sup>10</sup>.

3. Bariatric surgery may be considered to facilitate weight loss and management of obesity-related disease in persons with BMI between  $30 \text{ kg/m}^2$  -  $35 \text{ kg/m}^2$ , in whom optimal medical and behavioural management has been insufficient to produce significant or sufficient weight loss (Level 2a, Grade B)<sup>11</sup>.

4. We suggest the choice of bariatric procedure be decided according to the patient's need, in collaboration with an experienced inter-professional 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>.

## KEY MESSAGES FOR PEOPLE LIVING WITH OBESITY



- If you live with obesity (when the amount or location of adipose or fat tissue in your body causes health problems), bariatric surgery may be an appropriate treatment option for you.** Behavioural interventions and obesity medications are often not effective enough to obtain significant long-term weight loss and remission of obesity-related diseases.
- Bariatric surgery combined with healthy behaviours can result in significant long-term weight loss (20% – 40% of your body weight) and improvement**

**of obesity-related disease, including type 2 diabetes, sleep apnoea, fatty liver disease and hypertension.**

- Different surgical options exist with varying levels of effectiveness. You should have an extensive discussion with your multi-disciplinary healthcare team before deciding which option may provide the greatest benefit.**
- All bariatric surgeries have adverse effects and potential risks and require lifelong follow-up to monitor mineral and vitamin supplementation and support for healthy behaviours.**

## Introduction

Bariatric surgery is the most clinical and cost-effective treatment for complex obesity. Compared to best medical management, it consistently provides better weight loss and long-term improvement in medical complications, such as type 2 diabetes mellitus (T2DM). It is also associated with a reduction in cardiovascular disease and complicated liver disease related to non-alcoholic fatty liver disease (NAFLD)<sup>5,13-15</sup>.

## Which patients should be offered bariatric surgery?

The first-line management of obesity is a multi-disciplinary team (MDT) evaluation, with nutritional and medical optimisation,

psychological support, behavioural support where needed and increased physical activity. Non-surgical interventions are less likely to sustain durable weight loss and remission of T2DM<sup>16</sup>. Bariatric surgical procedures have evolved over the last 40 years, with many procedures becoming redundant along the way<sup>17</sup>.

The National Institute for Health and Care Excellence guidelines for bariatric surgery are generally followed in Ireland. These guidelines restate the basic principles outlined in the original National Institutes of Health consensus statement on the role of surgery for treatment of obesity from 1991<sup>18</sup>. Updated guidelines from 2014<sup>19</sup> are summarised here:

Bariatric surgery is a treatment option for people with obesity if all

of the following criteria are fulfilled:

- They have a body mass index (BMI) of 40 kg/m<sup>2</sup> or more, or between 35 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup> and other significant diseases (for example, T2DM or high blood pressure) that could be improved with weight loss.
- All appropriate non-surgical measures have been tried, but adequate, clinically beneficial weight loss has not been achieved or maintained.
- The person has been receiving or will receive intensive management in a weight management service.
- The person is generally fit for anaesthesia and surgery.
- The person agrees to the need for long-term follow-up.

Updated guidelines with regards to T2DM<sup>19</sup>:

- Offer an expedited assessment for bariatric surgery for people with a BMI of 35 kg/m<sup>2</sup> or over who have recent-onset T2DM as long as they are also receiving or will receive assessment in a weight-management service.
- Consider an expedited assessment for bariatric surgery for people with a BMI of 30 kg/m<sup>2</sup> – 34.9 kg/m<sup>2</sup> who have recent-onset T2DM if they are also receiving or will receive assessment in a weight-management service.
- Consider an assessment for bariatric surgery for people of Asian family origin who have recent-onset T2DM at a lower BMI than other populations as long as they are also receiving or will receive assessment in a weight-management service.

These important changes reflect the growing evidence that bariatric surgery can effectively treat T2DM.

Individual patient selection for bariatric surgery should be discussed in a multi-disciplinary meeting to consider the potential health benefits and peri-operative risks associated with surgery. If surgery is offered, the patient should be supported to understand the risks, benefits, and alternatives, including obesity medications. The need for lifelong medical surveillance to prevent and correct potential long-term nutritional deficiencies after surgery should be emphasised.

Relative contraindications to bariatric surgery include active or recent substance abuse (alcohol, drugs), non-stable or untreated psychiatric conditions (i.e., changes in psychiatric medications in the last six months), a limited life expectancy and any contraindication to general anaesthesia<sup>20</sup>.

Patients should not be denied bariatric surgery because of their age. 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. A systematic review including 26 articles and 8149 patients reported

a pooled 30-day mortality of 0.01% and an overall complication rate of 14.7%. At one-year follow-up, mean excess weight loss (EWL) was 53.8%, diabetes resolution was 54.5%, hypertension resolution was 42.5% and lipid disorder resolution was 41.2%<sup>21</sup>.

The role of metabolic surgery in adolescents has been summarised in the recent American Society for Metabolic and Bariatric Surgery paediatric metabolic and bariatric surgery guidelines<sup>22</sup> (note this reference is given for information only and exploration of this topic is outside the scope of these guidelines).

## Which bariatric surgery should be offered?

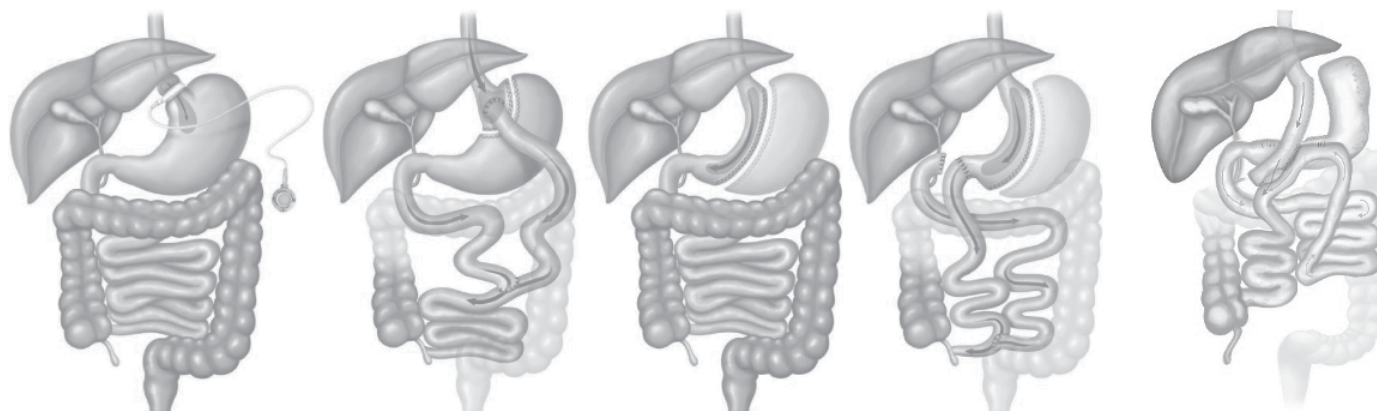
Bariatric surgical procedures have evolved over the last 40 years, with many techniques becoming redundant<sup>17</sup>. Laparoscopic sleeve gastrectomy and laparoscopic gastric bypass are the most common bariatric operations performed worldwide. The Fourth IFSO (International Federation for the Surgery of Obesity and Metabolic Disorders) Global Registry Report 2018 showed that they make up 92% of all bariatric procedures (46% each)<sup>23</sup>. The decision for the type of surgery is made in collaboration with a MDT, 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 and resolution of complications and side effects. The goal is to balance the complications and risk of mortality associated with obesity, 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 of the surgery.

**Adjustable gastric banding (AGB)** has evolved over the last 20 years from an open technique with a non-adjustable gastric band to laparoscopic adjustable gastric banding. An adjustable silicone band is placed 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 access port. By injection into the access port, the band can be inflated or deflated to control the amount of restriction.

**Sleeve gastrectomy (SG)** was traditionally the first step in a staged approach to reducing peri-operative complications in high-risk patients<sup>24</sup>. Its relative technical simplicity and outcomes comparable to gastric bypass led to a worldwide surge in popularity as a stand-alone procedure. It involves dividing the omentum and short gastric vessels along the greater curve of the stomach and excision of approximately 70% of the patient's stomach, leaving a narrow gastric tube that remains in continuity with the gastrointestinal tract and without disruption of the pylorus.

**Roux-en-Y gastric bypass (RYGB)** involves the creation of a small lesser curve-based gastric pouch. The first 75 cm – 150 cm of small bowel from the duodenojejunal flexure is measured and then transected (the biliopancreatic limb). The distal small bowel is brought up to the pouch and anastomosed, then approximately 100 cm of the alimentary limb is measured, and the biliopancreatic limb is anastomosed.

**Figure 1:** From left to right: Adjustable gastric banding, Roux-en-Y gastric bypass, sleeve gastrectomy and biliopancreatic diversion with duodenal switch (copyright: Graphics department, Quebec Heart and Lung Institute, Laval University. Reprinted with permission), one-anastomosis gastric bypass image (reproduced from<sup>25</sup>).



**One-anastomosis gastric bypass (OAGB)** involves the creation of a longer lesser curve-based gastric pouch and bypassing approximately 150 cm – 200 cm of small bowel from the duodenojejunal flexure, then creating an anastomosis between the gastric pouch and the jejunum. IFSO endorses the procedure, and metabolic outcomes are similar to RYGB<sup>26</sup>. It is a relatively new procedure, and therefore there are some non-consensus aspects associated with it, such as the ideal length of the gastric pouch, the ideal length of the biliopancreatic limb and the use of OAGB in the setting of reflux, all of which are still under investigation<sup>27</sup>.

**Duodenal switch (DS)** combines moderate restrictive and hypoabsorptive mechanisms by creating a wider sleeve gastrectomy. 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 is technically complex, and patients are at high risk for long-term nutritional deficiencies. It is rarely performed in Ireland.

## Risks

A systematic review and meta-analysis published in 2014 reported a mortality rate within 30 days of 0.08% (95% CI, 0.01% – 0.24%); the mortality rate after 30 days was 0.31% (95% CI, 0.01% – 0.75%). The overall complication rate ranged from 10-17%, and the re-operation rate was 7%. The peri-operative mortality and complication rates were highest for RYGB, lowest for AGB and SG was in between<sup>28</sup>.

A network meta-analysis reported that RYGB had the highest post-operative complication rate, with lower similar rates described for SG and OAGB<sup>29</sup>. The most common complications after bariatric surgery are bleeding, venous thromboembolism, and wound infection; each is associated with a < 1% risk. Bleeding and leakage are associated with the greatest impact on re-operation rates and length of stay, and venous thromboembolism (VTE) can be targeted for prevention using extended thromboprophylaxis<sup>30</sup>.

In a large analysis of bariatric registries in the United States (n = 134,142), SG was associated with half the risk-adjusted odds of death (0.1% vs. 0.2%), serious morbidity (5.8% vs. 11.7%) and leak (0.8% vs. 1.6%) in the first 30 days compared to RYGB<sup>31</sup>.

Each procedure has specific risks. RYGB is associated with internal herniation, kinking or obstruction of the jejunal-jejunal anastomosis, marginal ulceration and nutritional deficiencies. SG is associated with worsening or de novo reflux. OAGB is associated with bile reflux, marginal ulceration and nutritional deficiencies. The risk of internal herniation is much less than reported with RYGB. The risk of nutritional deficiencies increases as the length of the bypassed jejunal limb increases. The concern with bile reflux is the potential carcinogenic risk which has been evaluated in several studies without a definite conclusion. The risk of conversion to RYGB for marginal ulceration or symptomatic bile reflux is reported at 1% – 4%<sup>32,33</sup>. AGB is associated with slippage, erosion, and intolerance, necessitating removal in up to 40% of patients<sup>34-36</sup>.

**Table 1** summarises the risks and benefits of four different surgeries.

## Metabolic effects of bariatric surgery

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

Patients living with complicated obesity have lower perceived health across all dimensions of QoL<sup>37</sup>. For most patients, bariatric surgery has a positive influence on QoL. The impact varies considerably across studies, with bariatric surgery showing a significantly better effect on physical QoL compared to mental QoL. Improvement in health-related quality of life (HRQOL) is typically correlated with weight loss. Meta-analyses of short-term (1 year) and long-term (≥ 5 years) HRQOL following bariatric surgery versus non-surgical management in patients with a BMI of ≥ 35 kg/m<sup>2</sup> show evidence for a substantial improvement in physical and mental health favouring the surgical group compared with controls, spanning five to 25 years after surgery<sup>38,39</sup>.

In a systematic review comparing bariatric surgery to medical treatment in adults with obesity (BMI > 30 kg/m<sup>2</sup>), bariatric surgery resulted in greater improvements in QoL than other treatments. Significant differences in QoL improvements were found between different types of bariatric surgery, and greater improvements in physical QoL versus mental QoL were found<sup>40</sup>. Similarly, a meta-analysis reported a positive effect on QoL, particularly physical wellbeing after bariatric surgery<sup>6</sup>.

Patients with complicated obesity randomised to RYGB reported a significant improvement in HRQOL compared to a non-surgical group. Weight loss correlated with improvement in HRQOL<sup>41</sup>.

### What is the impact on weight?

One of the largest prospective trials in bariatric surgery, the Swedish Obese Subjects (SOS) Study<sup>1,42</sup>, involved 4,047 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 follow-up period of 15 years. After 10 years, the total weight loss was 25% after RYGB, 16% after vertical banded gastroplasty (VBG) and 14% after AGB. A meta-analysis of 22 randomised controlled trials (RCTs), representing 1496 patients allocated to surgery and 302 to non-surgical interventions, demonstrated similar outcomes between RYGB and SG. Both procedures had better outcomes than AGB. For people with very high BMI, DS resulted in greater weight loss than RYGB<sup>3</sup>.

A series of 250 patients with an initial BMI of 45 kg/m<sup>2</sup> to 60 kg/m<sup>2</sup> were randomised to RYGB or AGB. At 10-year follow-up, the mean total body weight (TBW) loss was -42 ± 20 kg for RYGB vs. -27 ± 15 kg for AGB (p < 0.05). Late re-operation was significantly higher after AGB than RYGB (31% vs. 8%, respectively, p < 0.01). At 10 years, RYGB was associated with better long-term weight loss, lower late re-operation rate and improved remission of obesity-related complications compared to AGB<sup>12</sup>.

Five-year outcomes of RYGB and DS were also compared in an RCT involving 60 patients with an initial BMI of 50 kg/m<sup>2</sup> to 60 kg/m<sup>2</sup><sup>43</sup>. At five years, DS resulted in greater weight loss and improvements in low-density lipoprotein (LDL) cholesterol, triglyceride and glucose levels compared with RYGB, while improvements in QoL were similar. However, DS was associated with more surgical, nutritional, and gastrointestinal adverse effects<sup>43</sup>.

SG was compared to RYGB in two RCTs with five-year outcomes. Both resulted in equivalent, long-standing QoL improvement. RYGB resulted in more stable weight loss (75% vs. 65% EWL at five years, p = 0.017) but was associated with higher re-admission rates. Similar improvements in QoL were found in the second RCT; EWL was 49% after SG vs. 57% after RYGB, but the difference did not reach significance. Overall morbidity was 19% for SG and 26% for RYGB (p = 0.19)<sup>44,45</sup>.

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

The incidence of T2DM continues to increase and now affects 10% of adults aged 50 years and over in Ireland<sup>46</sup>. T2DM most

often arises (80%) due to excess or dysfunctional adiposity and has become the leading cause of macro- and micro-vascular disease, including diabetic nephropathy, retinopathy, and limb ischaemia. Bariatric surgery has proven consistently more effective than best medical treatment and psychological/behavioural interventions to induce durable control and remission of T2DM<sup>47</sup>.

The SOS study reported remission rates for T2DM of 72% and 36% at two and 10 years, respectively, in the 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<sup>47</sup>.

Several RCTs have specifically studied T2DM response to different surgical procedures versus medical treatment. Mingrone *et al.* reported 75% and 95% remission of T2DM at three years after RYGB and DS, respectively, compared to no response with medical intervention alone. At five years, remission was maintained in 37% of the RYGB patients and 63% of the DS patients<sup>4</sup>. Schauer *et al.* reported remission of T2DM in 42% and 37% after RYGB and SG, respectively, compared to 12% achieved with medical therapy (n = 50). At five years, the criterion for the primary endpoint was met by 5% of patients who received medical treatment alone, compared to 29% who underwent RYGB and 23% who underwent SG. The mean reduction in glycated haemoglobin was 2.1% vs. 0.3% (p = 0.003) in the surgery versus medical group. Change in TBW was -23%, -19% and -5% in the RYGB, SG and medical therapy groups, respectively; the triglyceride levels were -40%, -29% and -8%; high-density lipoprotein (HDL) 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<sup>5</sup>. Five- to 20-year remission rates after DS are even higher, with observational studies showing complete remission in the range of 93% and discontinuation of insulin therapy in 97%<sup>48</sup>.

All studies comparing bariatric surgery to a non-surgical group consistently show superior control and remission of T2DM in the surgical arms<sup>49-51</sup>, including superior weight loss and lower hemoglobin A1c (HbA1c)<sup>52</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 may confer a higher likelihood of remission)<sup>53</sup>. Continued post-operative monitoring of glycaemia is warranted, as the effect of surgery may diminish over time with relapse of hyperglycaemia<sup>50</sup>.

## What is the impact on other complications?

### Hypertension

A meta-analysis of the effect of bariatric surgery on hypertension included 57 studies. Some 32 studies reported significant improvement in hypertension in 64% patients (OR = 13.24; 95% CI 7.7, 22.7; p < 0.00001) and 46 studies reported resolution of hypertension in 50% patients (OR = 1.7; 95% CI 1.1, 2.6; p = 0.01)<sup>8</sup>. A systematic review and meta-analysis on the early impact of bariatric surgery on T2DM, hypertension and dyslipidaemia

reported a reduction in cardiovascular risk, with a BMI reduction of 5 kg/m<sup>2</sup> after surgery corresponding to reduced T2DM in 33%, reduced hypertension in 27% and reduced dyslipidaemia in 20%<sup>54</sup>. The impact of SG on hypertension was assessed in a systematic review, including 33 studies and 3997 patients. There was a resolution of hypertension in 58% of patients and improvement or resolution in 75% of patients<sup>55</sup>.

### Sleep apnoea

There is limited high-level evidence regarding the impact of bariatric surgery on sleep apnoea. A meta-analysis including 15 studies (11 RCTs) and 636 patients showed a significant improvement in nocturnal hypoxaemia, although significant inter-study heterogeneity was noted<sup>56</sup>. A large cohort study from the National Bariatric Surgery Register of UK and Ireland patients demonstrated nearly 60% remission after bariatric surgery, with greatest chance of remission after RYGB (64.5%), followed by SG (56.1%) and AGB (31.2%)<sup>57</sup>.

The American Thoracic Society recommends that patients with sleep apnoea and a BMI of 35 kg/m<sup>2</sup>, whose weight has not improved despite participating in a comprehensive behavioural intervention programme and who have no contraindications, be referred for bariatric surgery evaluation<sup>58</sup>.

### Dyslipidaemia

Bariatric surgery significantly improves serum lipids, but changes vary widely, likely due to anatomic alterations unique to each procedure. A literature review including 178 studies with 25189 subjects identified significant reductions in total cholesterol (TC, -0.7 mmol/L), LDL cholesterol (LDL-C, -0.6 mmol/L) and triglycerides (-0.7 mmol/L), and a significant increase in HDL cholesterol (HDL-C, 0.2 mmol/L) at one year post-operatively ( $p < 0.00001$  for all). The magnitude of this change was significantly greater than that seen in non-surgical control patients (e.g., LDL-C; -0.6 mmol/L vs. -0.1 mmol/L). When assessed separately, the magnitude of changes varied greatly by procedure ( $p$  interaction  $< 0.00001$ ; e.g., LDL-C: DS -1.1 mmol/L, RYGB -0.6 mmol/L, AGB -0.2 mmol/L, SG -0.2 mmol/L). In the cases of AGB (TC and LDL-C) and SG (LDL-C), the response one year following surgery was not significantly different from non-surgical control patients<sup>7</sup>.

### Urinary incontinence

In a series of 470 patients undergoing bariatric surgery, the prevalence of urinary incontinence was 66%<sup>59</sup>. Other pelvic floor disorders are also frequent. A meta-analysis of the effects of bariatric surgery on pelvic floor disorders included 11 cohort studies in which a total of 784 participants were assessed for pelvic floor disorders with a variety of questionnaires before and after bariatric surgery. Bariatric surgery was associated with a significant improvement in pelvic floor disorders, specifically with regard to urinary incontinence and pelvic organ prolapse. There was no significant improvement in faecal incontinence and sexual function<sup>59</sup>. In a prospective analysis of 140 patients undergoing bariatric surgery, bariatric surgery 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  $p < 0.0001$ )<sup>60</sup>. In addition, a

reduction in the prevalence of urinary incontinence correlated significantly with weight loss ( $p = 0.01$ )<sup>61</sup>.

### Non-alcoholic fatty liver disease

The NAFLD spectrum ranges from hepatic steatosis to more severe non-alcoholic steatohepatitis and fibrosis that can progress to cirrhosis, end-stage liver disease and hepatocellular carcinoma (HCC). NAFLD is strongly associated with components of the metabolic syndrome, including obesity, T2DM, and hypertension<sup>62</sup>. A recent international consensus has suggested renaming the disease as Metabolic Associated Fatty Liver Disease or MAFLD<sup>63</sup>; however, this has not yet gained universal acceptance<sup>64</sup>. NAFLD prevalence is estimated to be around 25% globally and more than 80% in patients with complicated obesity<sup>65</sup>. Non-alcoholic steatohepatitis develops in about a quarter of patients with NAFLD. It is set to become the leading cause of liver transplantation ahead of hepatitis C and alcohol liver disease<sup>65,66</sup>.

Interventions for NAFLD focus on weight loss and improvement in insulin resistance and associated obesity complications. There are no approved medications for NAFLD at present. There is growing evidence to show improvement of NAFLD after bariatric surgery, and a large meta-analysis showed a 66% and 50% improvement in steatosis and fibrosis, respectively, after bariatric surgery<sup>67</sup>. Both SG and RYGB seem effective without a significant difference between the procedures.

In a systematic review, the pooled proportion of patients with improvement or resolution in steatosis was 91.6%, 81.3% in steatohepatitis, 65.5% in fibrosis and 69.5% for complete resolution of non-alcoholic steatohepatitis<sup>9</sup>.

Lassailly et al. showed that 84% of patients had resolution of non-alcoholic steatohepatitis (NASH) without worsening fibrosis five years after surgery. There was a 70% improvement in fibrosis and 50% resolution. A proportion of patients had persistent NASH, and they demonstrated insufficient weight loss or weight regain<sup>68</sup>. In patients with non-cirrhotic NASH, bariatric surgery reduced the risk of developing a major liver event by 88% compared to a non-surgical group. The risk of a major surgical complication was 9.5%<sup>15</sup>.

### Renal function

Obesity is an independent risk factor for the development and progression of chronic kidney disease (CKD). A systematic review and meta-analysis including 30 observational studies found a significant reduction in hyperfiltration, albuminuria and proteinuria after bariatric surgery<sup>69</sup>. In another systematic review of 29 studies incorporating 18172 patients (and consisting of four randomised controlled trials, five cohort studies and 20 before-and-after studies; all at moderate to high risk of bias), there was 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 a lower risk of new-onset

albuminuria (OR 18, 95% CI 0.03 to 0.99 from RCTs)<sup>70</sup>. Low-quality evidence suggests that bariatric surgery improves albuminuria and uACR in patients with T2DM. However, the effect on other outcomes is uncertain.

### Malignancy

Bariatric surgery is increasingly recognised as a tool for reducing cancer risk<sup>71,72</sup>. This appears to be more profound for women than men. The evidence is particularly strong for ovarian, endometrial and breast cancer, with a recent meta-analysis demonstrating a 49%, 67% and 53% reduction in risk, respectively<sup>73</sup>. There is data to support a reduction in gastrointestinal cancer risk, at least to bring it in line with patients without obesity<sup>74</sup>. In contrast, limited data suggest that changes in bile salt absorption after RYGB may increase the risk of rectal cancer<sup>75</sup>. RYGB can lead to regression of Barrett's oesophagus and can prevent progression to advanced disease. However, there is mixed reporting of oesophageal pathology after other procedures which may alter reflux and lower oesophageal pressure, particularly after SG<sup>76-79</sup>. Data shows a reduction in HCC<sup>75</sup>, and skin cancers, including melanoma, after bariatric surgery<sup>80</sup>.

Furthermore, bariatric surgery may be used to induce weight loss and reduce the amount of oestrogen in the active management of obesity-related endometrial dysplasia or early-stage endometrial carcinoma<sup>81</sup>.

### Does bariatric surgery decrease long-term mortality risk?

A large observational cohort study has shown that bariatric surgery significantly decreases overall mortality and reduces the risk of chronic conditions in people with severe obesity. Patients who underwent bariatric surgery had a significant reduction in risk of developing cardiovascular, cancer and endocrine conditions (including T2DM), as well as infectious, psychiatric and mental disorders compared with the control group. 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%<sup>82</sup>.

In the SOS study, bariatric surgery reduced the incidence of total and fatal cardiovascular events over 20 years compared to matched non-surgical controls. 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. Weight loss did not correlate with cardiovascular events in the surgical cohort, indirectly suggesting weight loss-independent mechanisms<sup>1</sup>.

A meta-analysis from Syn *et al.*, including 16 matched cohort studies and 174772 patients, demonstrated a 49% reduction in hazard rate of death and a median increase of life expectancy by 6.1 years. This effect was particularly profound for patients with pre-existing diabetes, who gained a median of 9.3 years life expectancy after

bariatric surgery compared to the non-surgical cohort<sup>83</sup>.

### Is bariatric surgery indicated in patients with BMI 30 – 35 kg/m<sup>2</sup>?

A meta-analysis from Cohen *et al.* evaluated patients with T2DM and a BMI of 30 kg/m<sup>2</sup> – 40 kg/m<sup>2</sup> undergoing RYGB vs. medical treatment. Five RCTs were identified; 43.3% of the patients had a BMI below 35 kg/m<sup>2</sup>. RYGB 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])<sup>10</sup>.

The International Diabetes Federation 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<sup>84</sup>. In 2016, over 50 international medical societies endorsed new guidelines to include metabolic surgery in the treatment algorithm for patients with uncontrolled T2DM and BMI above 30 kg/m<sup>2</sup><sup>85</sup>.

Other metabolic outcomes are also improved in patients with mild to moderate obesity. Ikramuddin *et al.* randomised 120 patients with BMI 30 kg/m<sup>2</sup> – 40 kg/m<sup>2</sup> to RYGB or medical management and looked at a composite main endpoint of hyperglycaemia, hypertension, and dyslipidaemia resolution. At 12 months, the primary endpoint was reached in 49% of the RYGB group vs. 19% (95% CI 10% – 32%) of the medical group. Participants in the RYGB group required on average three fewer medications and lost 26.1% vs. 7.9% of their TBW compared with the medical management group. Regression analyses indicated that achieving the composite endpoint was primarily attributable to weight loss<sup>11</sup>.

### 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-ileal bypass with sleeve (SADI-S)

Sánchez-Pernaute described this simplified DS technique. It involves the creation of a sleeve gastrectomy, and then transection of the duodenum. The duodenojejunal flexure is identified, and then an omega loop of jejunum is measured and anastomosed to the proximal end of the duodenum. This procedure requires only one intestinal anastomosis instead of two for the traditional DS. The length of the common intestinal channel allowing digestion and absorption (250 cm) is more than doubled compared to the standard duodenal switch (100 cm), which could attenuate side effects related to dietary fat- and fat-soluble vitamin malabsorption<sup>86</sup>.

This procedure is endorsed by IFSO based on satisfactory medium-term outcomes and peri-operative safety data; however, high-level evidence such as RCTs are not available, and surgeons are advised to input their data into national registries<sup>87</sup>.

This procedure is emerging as a potential option for non-responders after sleeve gastrectomy or T2DM recurrence. A systematic review including 14 studies and 1086 patients who had primary or revisional SADI-S demonstrated total weight loss of 21.5% to 41.2% and no weight regain at 24 months. There was resolution of T2DM, dyslipidaemia and hypertension in 72.6%, 77.2% and 59%, respectively<sup>88</sup>.

### Gastric plication

Laparoscopic gastric plication was first described by Talebpour *et al.* This involves imbrication of the greater curvature of the stomach with two layers of non-absorbable sutures. The overall goal is to duplicate the effects of SG while avoiding any gastric stapling or resection<sup>89</sup>. The procedure is associated with significant post-operative nausea and food intolerance and does not reduce the risk of a gastric leak. A systematic review of 14 studies and 1450 patients reported EWL ranging 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 0% to 15.4% (average 3.7%)<sup>90</sup>.

Two-year outcomes were assessed in an RCT comparing SG to gastric plication. At two years, the total weight loss and complication rates were not significantly different between the two groups<sup>89</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.

## Current endoscopic therapies

Several endoscopic approaches have emerged which are typically placed between medical therapy and surgical therapy in terms of effectiveness, risks, and side effects.

### Intra-gastric balloons

Intra-gastric balloons (IGB) were first described in 1982 by Nieben *et al.* and represent the oldest endoscopic procedure for weight loss<sup>91</sup>. Modifications have improved tolerability, reduced the risk of perforation and increased ease of placement and retrieval. Most IGBs still require upper gastrointestinal endoscopy with sedation or general anaesthesia and need to be retrieved endoscopically after six to 12 months. Most patients experience some side effects, such as nausea (24%), vomiting (2.7%), abdominal fullness (6.3%) or pain (14%), deflation (6%) and gastric ulcer (12.5%)<sup>92</sup>. Rare complications can also occur, including gastric or oesophageal perforation, small bowel obstruction and hypoxia at the time of extraction. A contemporary meta-analysis including 13 RCTs and 1523 patients showed a significant difference in weight (4.4%, 6.1 kg) and BMI (2.13 kg/m<sup>2</sup>) between the IGB and control groups<sup>93</sup>. The role of IGB as bridging therapy to a stapled bariatric procedure is emerging.

### Endoscopic bypass

A number of endoscopic procedures have been developed recently to mimic the metabolic effect of RYGB. The most advanced endoscopic bypass (EndoBarrier<sup>®</sup> or duodenojejunal endoscopic bypass) involves the placement of a one-metre plastic sleeve in the duodenum to prevent contact of food with bile acids and to bring undigested food into the proximal jejunum. The sleeve is placed endoscopically under sedation and is retrieved after six months. Small RCTs show an EWL of 32.0% (22.0% – 46.7%) vs. 16.4% (4.1% – 34.6%) in the control group ( $p < 0.05$ ) with improvement in glucose metabolism<sup>94</sup>. Meta-analysis identified 151 patients who underwent an endoscopic bypass, with a total weight loss of -5.1 kg (95% CI -7.3, -3.0) and EWL of 12.6% (95% CI 9.0, 16.2), respectively<sup>95</sup>. It is associated with a risk of serious adverse events, such as acute pancreatitis (3%), device migration, early explant, gastrointestinal bleeding and liver abscess<sup>96-98</sup>. This device is currently licensed for investigational use only.

### Endoscopic sleeve gastroplasty (ESG)

Endoscopic procedures have been developed to reduce gastric volume. The most common (the POSE<sup>®</sup> [Primary Obesity Surgery Endoluminal] procedure) involves endoluminal placement of full-thickness sutures to plicate the fundus and distal body of the stomach. Large RCTs have shown acceptable short-term weight loss with low peri-operative complications. Sullivan *et al.* randomised 332 patients to ESG or behavioural modification. At 12 months, weight loss was  $4.9 \pm 7\%$  in ESG group vs.  $1.4 \pm 5.6\%$  in the control group ( $p < 0.0001$ ). The proportion of patients achieving  $\geq 5\%$  weight loss was 41.5% after ESG and 22.1% in the control group ( $p < 0.0001$ ); mean responder result was 11.5% TBW loss. Procedure-related serious adverse event rates were 5.0% (active) and 0.9% (sham,  $p = 0.068$ )<sup>99</sup>.

### Aspiration therapy

A percutaneous gastrostomy device (AspireAssist<sup>®</sup>) has been described to treat patients with BMI  $> 35$  kg/m<sup>2</sup>. The procedure is performed under sedation and consists of placing 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.* randomised 207 patients in a 2:1 ratio to treatment with AspireAssist<sup>®</sup> plus behavioural counselling. At 52 weeks, participants in the AspireAssist<sup>®</sup> group had lost significantly more weight ( $12.1 \pm 9.6\%$  TBW) than in the counselling group ( $3.5 \pm 6.0\%$  TBW). Adverse events included abdominal pain (38%), nausea/vomiting (17%) and peristomal bacterial infection (13.5%). Serious adverse events were reported in 3.6% of participants, including severe abdominal pain, peritonitis, gastric ulcer, and tube replacement<sup>100</sup>. Medium-term results are starting to appear, with studies confirming the maintenance of weight loss, at  $19 \pm 13\%$  weight loss, up to four years<sup>101</sup>.

## Peri-operative care

### Enhanced recovery after bariatric surgery (ERABS)

Enhanced recovery protocols mitigate surgical stress and are associated with reduced length of stay (typically two days), without



increasing readmission rates<sup>102</sup>. Typical interventions undertaken in the peri-operative care period are outlined in [Table 2](#). Some pre-operative interventions take place weeks or months before surgery. Comprehensive ERABS guidelines have been published by the *World Journal of Surgery*, incorporating the best available evidence for all aspects of peri-operative care<sup>103</sup>.

### **Bariatric anaesthesia**

Patients undergoing bariatric surgery present challenges in each phase of anaesthesia. UK national guidelines recommend that a lead for anaesthesia for the patient with obesity be appointed in each department<sup>104</sup>. Experienced anaesthetic staff should manage patients presenting for bariatric surgery as they represent a higher risk patient population. The Society for Obesity and Bariatric Anaesthesia (SOBAUK) has published comprehensive guidance on all aspects of anaesthetic management for this patient group<sup>104</sup>. The SOBAUK single-sheet guidance on anaesthesia consent for the patient with obesity is a valuable resource when discussing peri-operative risks with patients in an individualised, non-stigmatising manner<sup>103,105-108</sup>. The recent Enhanced Recovery after Surgery (ERAS) society guidance is an additional valuable source of information<sup>103</sup>.

### **General Considerations for Anaesthesia for the patient with obesity**

Specific equipment includes larger size non-invasive blood pressure cuffs, a head-elevating laryngoscopy position pillow or similar, high-flow nasal oxygen (HFNO), equipment for managing a difficult airway and an inflatable mattress to facilitate positioning.

It is advisable to induce anaesthesia in the operating theatre rather than the anaesthesia induction room. Patients should be positioned whilst awake in the ramped position, ideally using a wedged pillow designed for this purpose. Pre-operative sedation poses risks in a patient with obstructive sleep apnoea (OSA) and is not generally required. TBW and lean body weight should be calculated and used to prepare appropriate drug doses. Intravenous access is more difficult in a patient with obesity, and ultrasound should be available. In addition to standard monitoring, invasive arterial blood pressure monitoring is advisable in those patients with significant cardiovascular co-morbidities or when non-invasive cuffs are deemed inaccurate due to body habitus. The use of quantitative neuromuscular monitoring has particular importance in this patient group, both intraoperatively to ensure adequate muscle relaxation to facilitate surgical access and post-operatively to confirm the full reversal of paralysis before tracheal extubation.

### **Airway management**

Patients with obesity have a reduced functional residual capacity (FRC) due to cephalad displacement of the diaphragm. Patients with co-existing OSA have increased fat deposition in the upper airway and reduced pharyngeal cross-sectional area<sup>109</sup>. These factors predispose this patient population to more rapid oxygen desaturation during periods of apnoea. Moreover, reduction in pharyngeal tone on induction of anaesthesia reduces the cross-sectional area of the upper airway, further making mask ventilation more challenging. Careful planning and meticulous attention to detail are vital in approaching airway management of this patient group.

Pre-oxygenation in the ramped or semi-sitting position improves respiratory dynamics by increasing the FRC and is the optimal position for airway management. Wedge pillows ease bag-mask ventilation (BMV) and improve the laryngoscopic view by aligning the pharyngeal, laryngeal and oral airway axis when compared to a neutral position<sup>110</sup>. Predicting the most challenging airways is essential. Obesity alone is not necessarily predictive of difficult tracheal intubation<sup>111</sup>. Neck circumference greater than 50 cm, the ratio of neck circumference to thyromental distance (NC/TMD ratio)<sup>112</sup>, male gender, Cormack - Lehane classification > 2 and American Society of Anesthesiologists physical status classification > 2 are risk factors for difficult tracheal intubation<sup>113</sup>. The prediction of difficult mask ventilation is arguably of greater importance. Factors predictive of difficult BMV are the presence of a beard, Mallampati classification 3 or 4, severely limited mandibular protrusion and a history of snoring<sup>114</sup>. If difficult airway management is predicted, relevant planning must be done, including consideration of awake fibre-optic tracheal intubation.

HFNO for apnoeic oxygenation during laryngoscopy and airway management in the anaesthetised patient has been demonstrated to be an effective method for reducing the time to oxygen desaturation in patients with obesity. An RCT of 40 patients with BMI > 40 kg/m<sup>2</sup> undergoing bariatric surgery compared HFNO at 40 - 60L/min with standard pre-oxygenation and found significantly longer safe apnoea times (average 76 seconds) and higher minimum oxygen saturation during anaesthesia induction in the HFNO group compared to the control group<sup>115</sup>.

People living with obesity are at increased risk of developing VTE<sup>116</sup>. Symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE) are encountered in up to 6.4% of bariatric patients<sup>117</sup>. The incidence of venous thrombotic events in the literature is variable, with DVT accounting for up to 2.2% of complications after bariatric surgery<sup>118</sup>. Formal recommendations for prophylaxis include the use of intermittent compression devices and early mobilisation along with chemoprophylaxis with both low molecular weight heparin (LMWH) and unfractionated heparin (UH). A systematic review of 30 publications, mostly uncontrolled retrospective studies including open and laparoscopic bariatric procedures, reported variable anti-coagulation dosing regimens. In the absence of RCTs and data supporting higher doses, the use of UH 5000 IU subcutaneously eight hourly or LMWH 30 mg – 40 mg 12 hours starting before surgery is encouraged by current literature<sup>119</sup>.

### **Opioid-free anaesthesia (OFA)**

Opioid-free or opioid-sparing anaesthetic techniques are part of ERABS protocols<sup>120</sup>. They reduce the incidence of opioid-induced respiratory depression, post-operative nausea, and vomiting (PONV), constipation and urinary retention. Drugs commonly used include paracetamol, non-steroidal anti-inflammatory drugs, ketamine, magnesium sulphate, intravenous lidocaine infusions and alpha-2 agonists<sup>121</sup>.

A systematic review and meta-analysis of 21 RCTs including 1,039 patients comparing intra-operative administration of remifentanyl and dexmedetomidine demonstrated the superiority

of dexmedetomidine with improved post-operative pain scores for up to 24 hours, and a lower incidence of hypotension, shivering and PONV compared to remifentanyl<sup>122</sup>. In a meta-analysis of trials, a dexmedetomidine infusion group had lower post-operative morphine consumption, lower PONV incidence and lower pain scores post-operatively compared to conventional analgesia<sup>123</sup>.

Lidocaine has been found to reduce opioid consumption and the duration of post-operative ileus following laparoscopic abdominal surgery. Recent studies demonstrate that an initial bolus of 1.5 mg/kg followed by an intra-operative infusion of 2 mg/kg/hr infusion of lidocaine, calculated on adjusted body weight, results in serum lidocaine concentrations in the accepted safe range<sup>124</sup>. Regional anaesthesia is technically challenging in this patient population. There is moderate to low-level evidence that transversus abdominus plane block improves post-operative analgesia after bariatric surgery up to 24 hours post-operatively<sup>125</sup>.

### Drug dosing in bariatric anaesthesia

Blood pressure, cardiac workload and cardiac output are increased

in patients with obesity, with variable impacts on hepatic and renal perfusion. NAFLD, T2DM or CKD make dosing of anaesthetic agents challenging<sup>126</sup>. Current guidance advocates using lean body weight for optimal dosing of hydrophilic drugs, such as neuromuscular blocking agents, opioids, local anaesthetics, and paracetamol. TBW is considered appropriate for suxamethonium given the increased plasma cholinesterase activity<sup>104</sup>. Actual body weight (ABW) is advised when calculating the dose of sugammadex. An RCT of 207 patients with BMI > 40 kg/m<sup>2</sup> revealed a 1.5 min faster recovery time when 2 mg/kg sugammadex was dosed on ABW compared to ideal body weight<sup>127</sup>.

Total intravenous anaesthesia (TIVA) is associated with a reduction in postoperative nausea and vomiting; however, the Marsh and Schnieder pharmacokinetic propofol TIVA models may not be accurate in the patient with obesity. The maximum weight accepted by the Marsh model is 150 kg. Newer algorithms are emerging that address this limitation. The Eleveld propofol model allows for accurate target concentrations for patients with BMIs below 52.9 kg/m<sup>2</sup>. Applicability, broad clinical availability, and incorporation in clinical practise are yet to be established<sup>128</sup>.

Table 1: **Bariatric Procedures**<sup>3</sup>

	Adjustable gastric banding	Sleeve gastrectomy	Roux-en-Y gastric bypass / One-anastomosis gastric bypass	Duodenal switch
<b>Total weight loss (%)</b>	20	25	30	40
<b>Resolution rate of T2DM (%)</b>	20	30	40	80
<b>Resolution rate of hypertension (%)</b>	20	30	40	60
<b>Resolution rate of sleep apnoea / hypopnoea syndrome (%)</b>	30	40	50	70
<b>Mortality rate (%)</b>	0.01	0.01	0.01	0.02
<b>Serious adverse events (%)</b>	2	2	3	5
<b>Common side effects</b>	Dysphagia, vomiting	Vomiting, constipation	Dumping syndrome	Increased bowel movements, bloating
<b>Long-term risks</b>	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

Table 2: Enhanced Recovery After Bariatric Surgery

Pre-operative	Intra-operative	Post-operative
Extensive education by multi-disciplinary team	Avoidance of fluid overload	Post-operative analgesia, anti-emetics & laxatives
Encouraged to increase activity	Bariatric anaesthetic protocol	Early mobilisation
Pre-operative weight loss	Laparoscopic approach	Thromboprophylaxis (extended to three weeks)
Pre-operative anaesthetic assessment	Intermittent pneumatic compression devices	Early post-operative feeding
Shortened (two-hour) fluid fasts	Omission of urinary catheterisation	Incentive spirometry
Day of surgery admission	Avoidance of surgical drains and nasogastric tubes	

Reproduced from Kearns, E. C. *et al.* (2021) Enhanced Recovery After Bariatric Surgery: Feasibility and Outcomes in a National Bariatric Centre<sup>129</sup>.

The Bariatric Surgery: Surgical Options and Outcomes chapter is adapted from the Canadian Adult Obesity Clinical Practice Guidelines (the "Guidelines"), which Obesity Canada owns and from whom we have a license. ASOI adapted the Guidelines having regard for any relevant context affecting the Island of Ireland using the [ADAPTE Tool](#).

ASOI acknowledges that Obesity Canada and the authors of the Guidelines have not reviewed the Bariatric Surgery: Surgical Options and Outcomes chapter and bear no responsibility for changes made to such chapter, or how the adapted Guidelines are presented or disseminated. As Obesity Canada and the authors of the original Guidelines have not reviewed the Bariatric Surgery: Surgical Options and Outcomes chapter, such parties, according to their policy, disclaim any association with such adapted Materials. The original Guidelines may be viewed in English at: [www.obesitycanada.ca/guidelines](http://www.obesitycanada.ca/guidelines).

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