Obesity

Metabolic surgery and lower BMI – does it make the cut?

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Excess adiposity (obesity) and type 2 diabetes are closely linked. Increasing weight is associated with increased diabetes risk, while weight loss reduces diabetes risk. Bariatric surgery has the most durable effect on weight loss and has a significant effect on glycaemic control (Leong and Taheri, 2012). Early guidelines advocated bariatric surgery for those with BMI of ≥35 kg/m^2 and associated comorbidities, such as type 2 diabetes. This recommendation, in combination with limitations in the availability of bariatric surgery, resulted in the most complex patients receiving bariatric surgery procedures.

Evidence has emerged that older age, longer diabetes duration, poor diabetes control and insulin treatment reduce the potential of diabetes remission post-bariatric surgery. Simultaneously, Purnell and colleagues (summarised on following page) have provided a greater appreciation of the metabolic effects of bariatric surgery that are independent of weight loss. The above observations have resulted in the renaming of bariatric surgery as "metabolic" surgery and, increasingly, there are recommendations to provide this surgery to those with BMIs less than 35 kg/m^2 (Rubino et al, 2016).

Cummings and Cohen (summarised on following page) write in support of metabolic surgery for those with diabetes and lower BMI than the traditional recommendations. While they make a compelling case for this indication for bariatric surgery, most of the studies they refer to have included a small number of patients, and there are no long-term data regarding sustained improvements in diabetes, quality of life and mortality. Also, generally, the medical interventions employed in surgical trials have not used the full range of medical treatment options available for treatment of obesity and diabetes.

Ikramuddin and colleagues (summarised alongside) examined the impact of bariatric surgery on diabetes in those with BMI range of 30–39.9 kg/m^2, by enrolling 120 patients and randomising them in a multicentre clinical trial to lifestyle intervention alone or lifestyle intervention plus laparoscopic gastric bypass operation. They examined target improvements in HbA_{1c} (<53 mmol/mol [7%]), dyslipidaemia (LDL-cholesterol <2.59 mmol/L [100 mg/dL]) and blood pressure (systolic blood pressure <130 mmHg).

At 12 months, 19% of the lifestyle group achieved the targets set for the three parameters compared to 47% of those who received gastric bypass. At 36 months, these percentages had diminished to 9% and 28% for lifestyle intervention and gastric bypass, respectively. In the lifestyle intervention, 22% achieved an HbA_{1c} <53 mmol/mol (7.0%) at 36 months compared to 58% in the gastric bypass group. At 36 months, 14% of the gastric bypass group achieved the triple end-point without medication compared to 2% in the lifestyle intervention alone group. The gastric bypass group experienced double the number of serious or clinically significant adverse events (51 events) compared to the lifestyle group (24 events).

It should also be noted that while, as expected, the lifestyle group achieved outcomes with more medications compared to the gastric bypass group, the gastric bypass group needed to take additional vitamin replacements.

The findings from this study point out some of the unanswered questions regarding metabolic surgery for those with diabetes and lower BMI: the available studies include few participants, there are few long-term studies, surgery may not be as effective as suggested, the side effects and complications of surgery appear to be under-estimated, and cost-effectiveness remains to be established. ■

Leong WB, Taheri S (2012) The role of bariatric surgery in the treatment of type 2 diabetes mellitus. *J R Coll Physicians Edinb* **42**: 194–8

Rubino F, Nathan DM, Eckel RH et al; Delegates of the 2nd Diabetes Surgery Summit (2016) Metabolic surgery in the treatment algorithm for type 2 diabetes: A joint statement by international diabetes organizations. *Surg Obes Relat Dis* **12**: 1144–62

Diabetes Care

Diabetes Surgery Study: 3-year outcomes

Readability	✓✓✓
Applicability to practice	✓✓✓
WOW! Factor	✓✓

1 In the Diabetes Surgery Study, 120 adult participants with uncontrolled T2D and obesity were randomised into two arms. All received intense lifestyle–medical management for 24 months, while half also received a Roux-en-Y gastric bypass. This article compares the two groups after an additional year of usual care.

2 The endpoint was a composite of HbA_{1c} <53 mmol/mol (7.0%), LDL-cholesterol <2.59 mmol/L (100 mg/dL) and systolic blood pressure <130 mmHg.

3 At 36 months, this goal was met in 9% of the lifestyle–medical management group and 28% of the gastric bypass group (P=0.01), compared to 19% and 49% in the respective groups at 12 months. Mean HbA_{1c} values at 36 months were 70 mmol/mol (8.6%) and 50 mmol/mol (6.7%; P<0.001), respectively.

4 No-one in the lifestyle–medical management group had remission of T2D at 36 months, compared to 17% of the gastric bypass group.

5 When the lifestyle–medical management group was compared with the gastric bypass group, 0% vs 17% had remission of T2D at 36 months and weight loss was 6.3% vs 21.0%. While the former used more medications (3.8 vs 1.8), they reported fewer serious adverse events (24 vs 51).

6 While gastric bypass substantially improved the likelihood of meeting the composite endpoint at 12 months and 24 months, the durability of this effect remains in question.

Ikramuddin S, Korner J, Lee WJ et al (2016) Durability of addition of Roux-en-Y gastric bypass to lifestyle intervention and medical management in achieving primary treatment goals for uncontrolled type 2 diabetes in mild to moderate obesity: A randomized control trial. *Diabetes Care* **39**: 1510–18

Diabetes Care

T2D remission after bariatric surgery

Readability	✓✓
Applicability to practice	✓✓
WOW! Factor	✓✓

1 The investigators examined the effects of Roux-en-Y gastric bypass (RYGBP) and laparoscopic gastric banding (LAGB) surgeries on T2D incidence and remission rates for up to 3 years.

2 In an observational study at ten centres in the US, 1868 obese participants had both baseline and follow-up data. Of these, 627 (34%) had T2D: 466 underwent RYGBP, 140 underwent LAGB and 21 underwent other surgical procedures.

3 Remission of T2D after RYGBP was 71.0% after 1 year and 68.7% after 3 years, while after LAGB it was 29.9% and 30.2%, respectively.

4 Baseline factors that were associated with diabetes remission included a lower weight for LAGB, greater fasting C-peptide value, lower leptin-to-fat mass ratio for RYGBP and, for both procedures, lower HbA_{1c} value without a need for insulin.

5 Greater post-surgical weight loss was associated with T2D remission with both procedures. Diabetes remission rates after RYGBP, however, were higher than predicted by weight loss alone and nearly twofold greater than for LAGB. These rates were not related to weight-associated metabolic factors.

6 The findings suggest that factors unique to RYGBP may have added benefits beyond weight loss on glucose control.

7 To confirm the relationships of these metabolic factors with durability of diabetes remission after bariatric surgery, longer-term studies need to be conducted.

Purnell JQ, Selzer F, Wahed AS et al (2016) Type 2 diabetes remission rates after laparoscopic gastric bypass and gastric banding: Results of the longitudinal assessment of bariatric surgery study. *Diabetes Care* **39**: 1101–7

Diabetes Care

Barriers to use of bariatric surgery

Readability	✓✓
Applicability to practice	✓✓
WOW! Factor	✓✓

1 In cases of T2D where lifestyle and medical interventions have been ineffective, bariatric/metabolic surgery may be considered. There are, however, many barriers to patient uptake.

2 Clinicians, academics, policy makers and patient representatives at the 3rd World Congress on Interventional Therapies for Type 2 Diabetes undertook a "policy Lab" exercise. Its aims were: to provide the latest evidence on the cost-effectiveness of bariatric/metabolic surgery; to identify barriers to its appropriate use; and to develop health policy initiatives that may improve surgical treatment.

3 Before the meeting, the organisers researched the available evidence and provided a summary. There was widespread agreement among the participating stakeholders that surgery is a legitimate and cost-effective approach to the treatment of T2D in obese patients.

4 Four "building blocks" to facilitate policy change regarding bariatric surgery were identified: 1) communicating the scale of the costs and harms associated with rising rates of T2D; 2) articulating the role of metabolic/bariatric surgery for certain populations; 3) identifying the cost-effectiveness arguments that may support expanding the use of surgery; and 4) changing the available resources and processes for incorporating surgery into clinical pathways.

5 Structural and political barriers to change were identified as being related to resources, understanding and processes. However, the group felt that the evidence was strong enough to engage policy-makers and practitioners.

Rubin KR, Hinrichs-Krapels S, Hesketh R et al (2016) Identifying barriers to appropriate use of metabolic/bariatric surgery type 2 diabetes treatment: Policy Lab results. *Diabetes Care* **39**: 954–63

Diabetes Care

Surgery in those with lower BMI

Readability	✓✓✓
Applicability to practice	✓✓✓
WOW! Factor	✓✓

1 Until recently, bariatric surgery has been restricted to those individuals with a BMI ≥35 kg/m^2. However, strong evidence has emerged that such procedures can improve T2D, in part through weight-independent mechanisms, and that baseline BMI does not predict benefits to glycaemic or cardiovascular outcomes.

2 This article discusses the logic and evidence for contemplating the use of bariatric/metabolic surgery to treat T2D in people with a BMI <35 kg/m^2.

3 A meta-analysis of level 1 evidence from 11 published randomised clinical trials (RCTs) was performed for the *2nd Diabetes Surgery Summit* (DSS-II) in 2015. These RCTs directly compared surgical interventions with medical and lifestyle interventions for T2D.

4 The analysis suggested that surgery is superior for T2D remission, glycaemic control and HbA_{1c} lowering. Furthermore, this is the case for those with a baseline BMI above or below 35 kg/m^2. Similar conclusions are drawn from meta-analysis of high-quality non-randomised prospective studies.

5 Also roughly comparable among individuals with a BMI above or below 35 kg/m^2 are the safety, antidiabetes durability and benefits on other cardiovascular risk factors of surgery. Further studies are needed to extend long-term findings.

6 The authors conclude that existing evidence supports the guidelines from DSS-II that advocate surgery for appropriate individuals with BMI <35 kg/m^2.

Cummings DE, Cohen RV (2016) Bariatric/metabolic surgery to treat type 2 diabetes in patients with a BMI <35 kg/m^2. *Diabetes Care* **39**: 924–33

"While the lifestyle group achieved outcomes with more medications compared to the gastric bypass group, the gastric bypass group needed to take additional vitamin replacements."