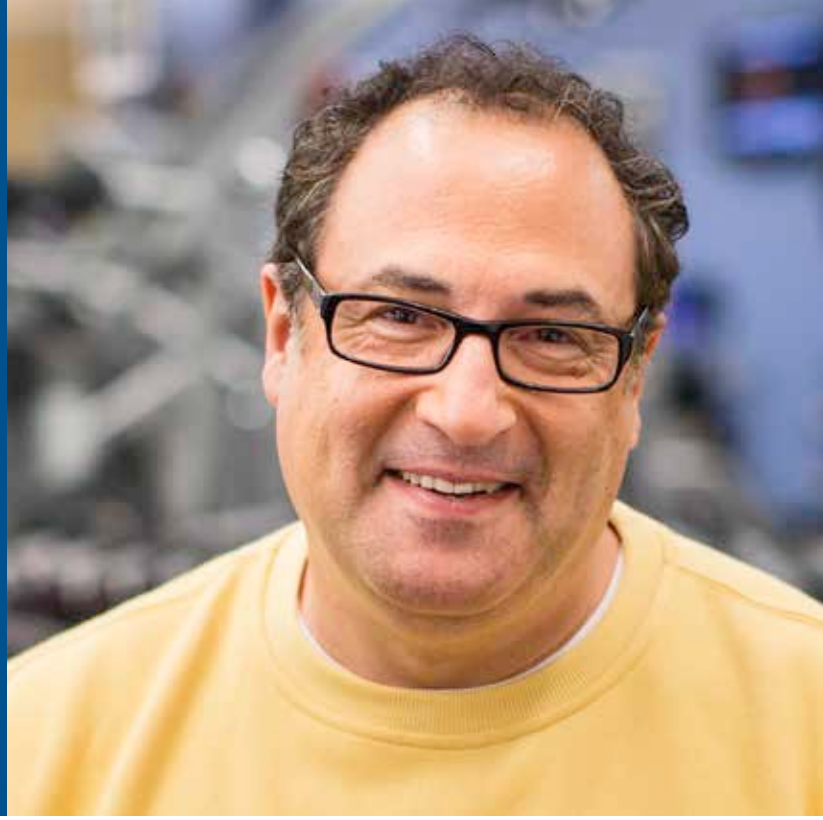
AMERICAN
DIABETES
ASSOCIATION

STANDARDS OF MEDICAL CARE IN DIABETES 2017 METABOLIC SURGERY

ADVANCED
LAPAROSCOPIC SURGEONS

Surgery recommendations based on BMI and glycemic control

BMI (kg/m2) in type 2 diabetes patients	Glycemic control	Surgery guidelines
40+ (37.5+ in Asian Americans)	Controlled or uncontrolled	Recommended
35-39.9 (32.5-37.4 in Asian Americans)	Inadequately controlled	Recommended
30-34.9 (27.5-32.4 in Asian Americans)	Inadequately controlled	Considered



Treatment for overweight and obesity in type 2 diabetes

Treatment	BMI category (kg/m2)				
	23.0* or 25.0 - 26.9	27.0 - 29.9	27.5* or 30.0 - 34.9	35.0 - 39.9	≥ 40
Diet, physical activity, and behavioral therapy					
Pharmacotherapy					
Metabolic surgery					

Treatment may be indicated for selected motivated patients based on BMI range

*Cutoff points for Asian American individuals

Several gastrointestinal (GI) operations promote dramatic and durable improvement of type 2 diabetes. Given the magnitude and rapidity of the effect of GI surgery on hyperglycemia, and experimental evidence that rearrangements of GI anatomy similar to those in some metabolic procedures directly affect glucose homeostasis,[1] GI interventions have been suggested as treatments for type 2 diabetes, and in that context are termed "metabolic surgery."

Recommendations[2]

- Metabolic surgery should be recommended to treat type 2 diabetes in appropriate surgical candidates with BMI ≥ 40 kg/m^2 (BMI ≥ 37.5 kg/m^2 in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with BMI 35.0–39.9 kg/m^2 (32.5–37.4 kg/m^2 in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy.
  Evidence Grading: A (See Appendix for definitions)

- Metabolic surgery should be considered for adults with type 2 diabetes and BMI 30.0–34.9 kg/m^2 (27.5–32.4 kg/m^2 in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin).
  Evidence Grading: B

- Metabolic surgery should be performed in high-volume centers with multidisciplinary teams that understand and are experienced in the management of diabetes and gastrointestinal surgery.
  Evidence Grading: C

- Long-term lifestyle support and routine monitoring of micronutrient and nutritional status must be provided to patients after surgery, according to guidelines for postoperative management of metabolic surgery by national and international professional societies.
  Evidence Grading: C

- People presenting for metabolic surgery should receive a comprehensive mental health assessment.
  Evidence Grading: B

- Surgery should be postponed in patients with histories of alcohol or substance abuse, significant depression, suicidal ideation, or other mental health conditions until these conditions have been fully addressed.
  Evidence Grading: E

- People who undergo metabolic surgery should be evaluated to assess the need for ongoing mental health services to help them adjust to medical and psychosocial changes after surgery.
  Evidence Grading: C

Clinical Evidence

A substantial body of evidence has now accumulated, including data from numerous randomized controlled clinical trials, demonstrating that metabolic surgery achieves superior glycemic control and reduction of cardiovascular risk factors in obese patients with type 2 diabetes compared with various lifestyle/medical interventions.[4]

- Improvements in micro- and macro-vascular complications of diabetes, cardiovascular disease, and cancer have been observed only in nonrandomized observational studies.[5-12] Cohort studies attempting to match surgical and nonsurgical subjects suggest that the procedure may reduce longer-term mortality.[6]
- On the basis of this mounting evidence, several organizations and government agencies have recommended expanding the indications for metabolic surgery to include patients with inadequately controlled type 2 diabetes and BMI as low as 30 kg/m^2 (27.5 kg/m^2 for Asian Americans).[13-16] Please refer to the American Diabetes Association consensus report "Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations" for a thorough review.[4]
- Randomized controlled trials with postoperative follow-up ranging from one to five years have documented sustained diabetes remission in 30–63% of patients.[29]
- Available data suggest an erosion of diabetes remission over time: 35–50% or more of patients who initially achieve remission of diabetes eventually experience recurrence. However, the median disease-free period among such individuals following Roux-en-Y gastric bypass (RYGB) is 8.3 years.[17,18]
- With or without diabetes relapse, the majority of patients who undergo surgery maintain substantial improvement of glycemic control from baseline for at least 5 to 15 years.[6, 7, 9, 18, 20-22]
- Younger age, shorter duration of diabetes (e.g., <8 years)[23], non-use of insulin, and better glycemic control are consistently associated with higher rates of diabetes remission and/or lower risk of recidivism.[6,21,23]
- Greater baseline visceral fat area may also help to predict better postoperative outcomes, especially among Asian American patients with type 2 diabetes, who typically have more visceral fat compared with caucasians with diabetes of the same BMI.[24]
- Beyond improving glycemia, metabolic surgery has been shown to confer additional health benefits in randomized controlled trials, including greater reductions in cardiovascular disease risk factors and enhancements in quality of life.[19,23,25]
- The safety of metabolic surgery has improved significantly over the past two decades, with continued refinement of minimally invasive approaches (laparoscopic surgery), enhanced training and credentialing, and involvement of multidisciplinary teams.
- Mortality rates with metabolic operations are typically 0.1–0.5%, similar to cholecystectomy or hysterectomy.[26-30]
- Morbidity has also dramatically declined with laparoscopic approaches. Major complications rates are 2–6%, with minor complications in up to 15%,[26-34] comparing favorably with other commonly performed elective operations.[30]
- Empirical data suggest that proficiency of the operating surgeon is an important factor for determining mortality, complications, reoperations, and readmissions.[35]
- Although metabolic surgery has been shown to improve the metabolic profiles of morbidly obese patients with type 1 diabetes, establishing the role of metabolic surgery in such patients will require larger and longer studies.[36]
- Retrospective analyses and modeling studies suggest that metabolic surgery may be cost-effective or even cost-saving for patients with type 2 diabetes, but the results are largely dependent on assumptions about the long-term effectiveness and safety of the procedures.[37,38]

Adverse Effects

- Metabolic surgery is costly and has associated risks. Longer-term concerns include dumping syndrome (nausea, colic, diarrhea), vitamin and mineral deficiencies anemia, osteoporosis, and, rarely, severe hypoglycemia from insulin hypersecretion. [39]
- Long-term nutritional and micronutrient deficiencies and related complications occur with variable frequency depending on the type of procedure and require lifelong vitamin/ nutritional supplementation.[40,41]
- Postprandial hypoglycemia is most likely to occur with RYGB.[40,41] The exact prevalence of symptomatic hypoglycemia is unknown. In one study, it affected 11% of 450 patients who had undergone RYGB or vertical sleeve gastrectomy.[42]
- Patients who undergo metabolic surgery may be at increased risk for substance use, including drug and alcohol use and cigarette smoking.[43]
- People with diabetes presenting for metabolic surgery also have increased rates of depression and other major psychiatric disorders.[44]
- Candidates for metabolic surgery with histories of alcohol or substance abuse, significant depression, suicidal ideation, or other mental health conditions should therefore first be assessed by a mental health professional with expertise in obesity management prior to consideration for surgery.[45]
- Individuals with preoperative psychopathology should be assessed regularly following metabolic surgery to optimize mental health management and to ensure psychiatric symptoms do not interfere with weight loss and lifestyle changes.

References

1. Diabetes Care. 2017;40(Suppl. 1):S1–S2. doi: 10.2337/dc17-S001.
2. Rubino F, Marescaux J. Effect of duodenaljejunal exclusion in a non-obese animal model of type 2 diabetes: a new perspective for an old disease. *Ann Surg* 2004. 239:1–11.
3. American Diabetes Association. Obesity management for the treatment of type 2 diabetes. Sec. 7. In Standards of Medical Care in Diabetes 2017. *Diabetes Care*. 2017; 40(Suppl. 1):S57–S63.
4. Rubino F, Nathan DM, Eckel RH, et al.; Delegates of the 2nd Diabetes Surgery Summit. Metabolic surgery in the treatment algorithm for type 2 diabetes: a joint statement by international diabetes organizations. *Diabetes Care*. 2016; 39:861–877.
5. Sjöström L, Lindroos A-K, Peltonen M, et al.; Swedish Obese Subjects Study Scientific Group. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med*. 2004;351:2683–2693.
6. Sjöström L, Peltonen M, Jacobson P, et al. Association of bariatric surgery with long-term remission of type 2 diabetes and with microvascular and macrovascular complications. *JAMA*. 2014;311: 2297–2304.
7. Adams TD, Davidson LE, Litwin SE, et al., Health benefits of gastric bypass surgery after 6 years. *JAMA*. 2012;308:1122–1131.
8. Sjöström L, Narbro K, Sjöström CD, et al.; Swedish Obese Subjects Study. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med*. 2007;357:741–752.
9. Sjöström L, Gummesson A, Sjöström CD, et al.; Swedish Obese Subjects Study. Effects of bariatric surgery on cancer incidence in obese patients in Sweden (Swedish Obese Subjects Study): a prospective, controlled intervention trial. *Lancet Oncol*. 2009;10:653–662.
10. Sjöström L, Peltonen M, Jacobson P, et al. Bariatric surgery and long-term cardiovascular events. *JAMA*. 2012;307:56–65.
11. Adams TD, Gress RE, Smith SC, et al. Long term mortality after gastric bypass surgery. *N Engl J Med*. 2007;357:753–761.
12. Arterburn DE, Olsen MK, Smith VA, et al. Association between bariatric surgery and long-term survival. *JAMA*. 2015;313:62–70.
13. Rubino F, Kaplan LM, Schauer PR, Cummings DE; Diabetes Surgery Summit Delegates. The Diabetes Surgery Summit consensus conference: recommendations for the evaluation and use of gastrointestinal surgery to treat type 2 diabetes mellitus. *Ann Surg*. 2010;251:399–405.
14. Cummings DE, Cohen RV. Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery. *Lancet Diabetes Endocrinol*. 2014;2:175–181.
15. Zimmet P, Alberti KGMM, Rubino F, Dixon JB. IDF's view of bariatric surgery in type 2 diabetes. *Lancet*. 2011;378:108–110.
16. Kasama K, Mui W, Lee WJ, et al. IFSO-APC consensus statements 2011. *Obes Surg*. 2012; 22:677–684.
17. Sjöholm K, Pajunen P, Jacobson P, et al. Incidence and remission of type 2 diabetes in relation to degree of obesity at baseline and 2 year weight change: the Swedish Obese Subjects (SOS) study. *Diabetologia*. 2015;58:1448–1453.
18. Arterburn DE, Bogart A, Sherwood NE, et al. A multisite study of long-term remission and relapse of type 2 diabetes mellitus following gastric bypass. *Obes Surg*. 2013;23:93–102.
19. Mingrone G, Panunzi S, De Gaetano A, et al. Bariatric-metabolic surgery versus conventional medical treatment in obese patients with type 2 diabetes: 5 year follow-up of an open-label, single-centre, randomised controlled trial. *Lancet*. 2015;386:964–973.
20. Cohen RV, Pinheiro JC, Schiavon CA, Salles JE, Wajchenberg BL, Cummings DE. Effects of gastric bypass surgery in patients with type 2 diabetes and only mild obesity. *Diabetes Care*. 2012;35:1420–1428.
21. Brethauer SA, Aminian A, Romero-Talam´as H, et al. Can diabetes be surgically cured? Long-term metabolic effects of bariatric surgery in obese patients with type 2 diabetes mellitus. *Ann Surg*. 2013;258:628–636; discussion 636–637.
22. Hsu C-C, Almulaifi A, Chen J-C, et al. Effect of bariatric surgery vs medical treatment on type 2 diabetes in patients with body mass index lower than 35: five-year outcomes. *JAMA Surg*. 2015; 150:1117–1124.
23. Schauer PR, Bhatt DL, Kirwan JP, et al.; STAMPEDE Investigators. Bariatric surgery versus intensive medical therapy for diabetes–3-year outcomes. *N Engl J Med*. 2014;370:2002–2013.
24. Yu H, Di J, Bao Y, et al. Visceral fat area as a new predictor of short-term diabetes remission after Roux-en-Y gastric bypass surgery in Chinese patients with a body mass index less than 35 kg/m2. *Surg Obes Relat Dis*. 2015;11:6–11.
25. Halperin F, Ding S-A, Simonson DC, et al. Roux-en-Y gastric bypass surgery or lifestyle with intensive medical management in patients with type 2 diabetes: feasibility and 1-year results of a randomized clinical trial. *JAMA Surg*. 2014;149:716–726.
26. Flum DR, Belle SH, King WC, et al.; Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. Perioperative safety in the Longitudinal Assessment of Bariatric Surgery. *N Engl J Med*. 2009;361:445–454.
27. Courcoulas AP, Christian NJ, Belle SH, et al.; Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. Weight change and health outcomes at 3 years after bariatric surgery among individuals with severe obesity. *JAMA*. 2013;310:2416–2425.

References cont.

28. Arterburn DE, Courcoulas AP. Bariatric surgery for obesity and metabolic conditions in adults. *BMJ*. 2014;349:g3961.
29. Young MT, Gebhart A, Phelan MJ, Nguyen NT. Use and outcomes of laparoscopic sleeve gastrectomy vs laparoscopic gastric bypass: analysis of the American College of Surgeons NSQIP. *J Am Coll Surg*. 2015;220:880–885.
30. Aminian A, Brethauer SA, Kirwan JP, Kashyap SR, Burguera B, Schauer PR. How safe is metabolic/diabetes surgery? *Diabetes Obes Metab*. 2015;17:198–201.
31. Birkmeyer NJO, Dimick JB, Share D, et al. Michigan Bariatric Surgery Collaborative. Hospital complication rates with bariatric surgery in Michigan. *JAMA*. 2010;304:435–442.
32. Altieri MS, Yang J, TelemDA, et al. Lap band outcomes from 19,221 patients across centers and over a decade within the state of New York. *Surg Endosc* 2016;30:1725–1732.
33. Hutter MM, Schirmer BD, Jones DB, et al. First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleeve gastrectomy has morbidity and effectiveness positioned between the band and the bypass. *Ann Surg*. 2011;254:410–420; discussion 420–422.
34. Nguyen NT, Slone JA, Nguyen X-MT, Hartman JS, Hoyt DB. A prospective randomized trial of laparoscopic gastric bypass versus laparoscopic adjustable gastric banding for the treatment of morbid obesity: outcomes, quality of life, and costs. *Ann Surg*. 2009;250: 631–641.
35. Birkmeyer JD, Finks JF, O'Reilly A, et al.; Michigan Bariatric Surgery Collaborative. Surgical skill and complication rates after bariatric surgery. *N Engl J Med*. 2013;369:1434–1442.
36. Kirwan JP, Aminian A, Kashyap SR, Burguera B, Brethauer SA, Schauer PR. Bariatric surgery in obese patients with type 1 diabetes. *Diabetes Care*. 2016;39:941–948.
37. Rubin JK, Hinrichs-Krapels S, Hesketh R, Martin A, Herman WH, Rubino F. Identifying barriers to appropriate use of metabolic/ bariatric surgery for type 2 diabetes treatment: Policy Lab results. *Diabetes Care*. 2016; 39:954–963.
38. Fouse T, Schauer P. The socioeconomic impact of morbid obesity and factors affecting access to obesity surgery. *Surg Clin North Am*. 2016;96:669–679.
39. Service GJ, Thompson GB, Service FJ, Andrews JC, Collazo-Clavell ML, Lloyd RV. Hyperinsulinemic hypoglycemia with nesidioblastosis after gastric-bypass surgery. *N Engl J Med*. 2005;353:249–254.
40. Mechanick JI, Kushner RF, Sugerman HJ, et al.; American Association of Clinical Endocrinologists; Obesity Society; American Society for Metabolic & Bariatric Surgery. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient. *Obesity (Silver Spring)*. 2009;17 (Suppl. 1):S1–S70.
41. Mechanick JI, Youdim A, Jones DB, et al.; American Association of Clinical Endocrinologists; Obesity Society; American Society for Metabolic & Bariatric Surgery. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient–2013 update: cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery. *Obesity (Silver Spring)*. 2013;21(Suppl. 1): S1–S27.
42. Lee CJ, Clark JM, Schweitzer M, et al. Prevalence of and risk factors for hypoglycemic symptoms after gastric bypass and sleeve gastrectomy. *Obesity (Silver Spring)*. 2015;23:1079– 1084.
43. Conason A, Teixeira J, Hsu C-H, Puma L, Knafo D, Geliebter A. Substance use following bariatric weight loss surgery. *JAMA Surg*. 2013; 148:145–150.
44. Young-Hyman D, Peyrot M. Psychosocial Care for People with Diabetes. 1st ed. Alexandria, VA, *American Diabetes Association*. 2012; 70.
45. Greenberg I, Sogg S, M Perna F. Behavioral and psychological care in weight loss surgery: best practice update. *Obesity (Silver Spring)*. 2009;17:880–88463.

Appendix: Evidence grading system

The following grading system was developed by the ADA to clarify and codify evidence that forms the basis of recommendations.

A. Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered.
B. Supportive evidence from well-conducted cohort or case control studies.
C. Supportive evidence from poorly controlled or uncontrolled studies.
D. Expert consensus or clinical experience.

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