ASMBS American Society for Metabolic and Bariatric Surgery

TYPE 2 DIABETES and METABOLIC SURGERY

Fact Sheet

Overview

- Diabetes affects 9.4% of the total U.S. population (30.3 million people)[1]
  - 23.1 million people have been diagnosed
  - 7.2 million people are unaware they suffer from the disease
- Once exclusively regarded as a weight-loss procedure for patients with severe obesity, mounting evidence over more than 20 years supports metabolic surgery as an effective treatment for type 2 diabetes resulting in improvement or remission in most cases
- Obesity – medically defined as a body mass index (BMI) of 30 kg/m^2 or more – is a major independent risk factor for developing the disease -- about 90% of people with type 2 diabetes have obesity or are overweight (BMI of at least 25)[2]
- Randomized clinical trials show metabolic surgery, particularly gastric bypass, results in complete remission or improvement of diabetes within two years for more than 90% of patients,[3] in some cases at the time of hospital discharge and even before significant weight loss occurs[4]
- Head-to-head studies show metabolic surgery is superior to nonsurgical treatment including drug therapy and intensive lifestyle intervention in producing long-term diabetes remission with 25-50% more surgery patients maintaining glycemic control without medication for up to five years[5,6]
- Global clinical guidelines endorsed by 45 medical professional societies include metabolic surgery as a treatment option for type 2 diabetes in patients with BMI of 30 or more[7]

MAJOR GUIDELINES and RECOMMENDATIONS

- **2018:** The American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on the role of bariatric surgery in class I obesity (BMI 30.0–34.9 kg/m2) states "Particularly given the presence of high-quality data in patients with type 2 diabetes, bariatric and metabolic surgery should be strongly considered for patients with BMI 30 to 35 kg/m2 and type 2 diabetes." The statement is supported by the American Diabetes Association (ADA) and has been endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).[8]
- **2018:** ADA's annually updated guidelines "Standards of Medical Care in Diabetes – 2018" maintain an emphasis on metabolic surgery for the treatment of type 2 diabetes, which includes the 2017-expanded indication for metabolic surgery in patients with inadequately controlled diabetes who have mild obesity with a BMI as low as 30. The ADA's recommends surgery should be recommended as an option to treat type 2 diabetes in patients with:

- BMI ≥40 kg/m2 (BMI ≥37.5 kg/m2 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/m2 (32.5–37.4 kg/m2 in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy – and BMI 30.0–34.9 (27.5–32.4 in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications

- **2016:** Delegates from the 2nd Diabetes Surgery Summit (DSS-I) developed global guidelines about metabolic surgery stating there is "sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among antidiabetes interventions for people with [type 2 diabetes] and obesity." The guidelines are endorsed in a joint statement from 45 international professional organizations including the ASMBS, ADA and International Diabetes Federation.[9]

- **2015:** Joint statement by the American Heart Association and the ADA recommends bariatric surgery be considered for adults who have a BMI greater than 35 and an obesity-related co-morbidity, in particular if a patient's diabetes is difficult to control with lifestyle and pharmacologic therapy[10]

SURGICAL TREATMENT of TYPE 2 DIABETES

Impact of Metabolic Surgery on Diabetes

- Meta-analysis of more than 135,000 metabolic surgery patients (mean BMI 47.9) in 621 studies (1990-2006) found 86.6% of those with type 2 diabetes experienced improvement or remission, and overall average excess weight loss (EWL) was 59.9% (American Journal of Medicine, 2009)[11]

- JAMA Surgery meta-analysis of nearly 162,000 patients with obesity (mean BMI 45.6) in 164 studies (2003-2012) shows of those with type 2 diabetes (26.2%) who had metabolic surgery, improvement or remission was achieved by:[12]

    - 92% of patients in randomized controlled trials (mean EWL 57%)
        - 95.1% gastric bypass; 73.8% gastric banding; N/A sleeve gastrectomy; 17.6% nonsurgical
    - 86% of patients in observational studies (mean EWL 46%)
        - 92.8% gastric bypass; 67.5% gastric banding; 85.5% sleeve gastrectomy; N/A nonsurgical

Metabolic Surgery vs. Medical Therapy

- Randomized clinical trials have demonstrated that metabolic surgery is more effective than medical and/or lifestyle interventions including pharmacological therapy in producing diabetes remission, glycemic control, and weight loss

    - Final five-year results of the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiency (STAMPEDE) Study show in patients with uncontrolled type 2 diabetes (mean BMI 37), metabolic surgery plus intensive medical therapy was more effective than intensive medical therapy alone for achieving and maintaining glycemic control, weight reduction, medication reduction, and improvements in lipid levels (NEJM, 2017)[13,14,15]

        - Diabetes remission rates at years one, three and five with metabolic surgery were about 40% (42% gastric bypass; 37% sleeve gastrectomy), 31% (38% gastric bypass; 24% sleeve gastrectomy), and 26% (29% gastric bypass; 23% sleeve gastrectomy), respectively; compared to 12%, 5% and 5% for medical therapy

    - Diabetes remained in remission for up to two years in 85% of patients with a BMI of 35 or greater randomized to metabolic surgery compared to no medical therapy patients (NEJM, 2012)[16] – 50% remission rates for metabolic surgery at 5 years and zero for medical therapy[17]

Long-Term Results with Metabolic Surgery

- Among patients with type 2 diabetes who had metabolic surgery, 24% experienced complete, long-term remission – five years or more – of their diabetes; 26% experienced partial remission and 34% improved from baseline; mean excess weight loss was 55% (Annals of Surgery, 2013)[18]
- Six years after metabolic surgery, 62% of gastric bypass patients with severe obesity (mean BMI 45.9) experienced diabetes remission compared to only 6-8% in control groups (JAMA, 2012)[19]
  - Surgery patients lost an average of 27.7% of their initial body weight compared with 0.2% in controls
- Fifteen years after metabolic surgery, 30.4% of patients maintained remission of their diabetes, compared to 6.5% of control patients (JAMA, 2014)[20]

Reducing Diabetes-Related Mortality and Health Complications

- Metabolic surgery significantly decreases the likelihood of death, leads to durable improvements in important cardiovascular risk factors, and reduces the risk of developing microvascular complications
  - Patients with severe obesity who had gastric bypass reduced the risk of mortality from type 2 diabetes by 92% for up to seven years (NEJM, 2007)[21]
  - Gastric bypass in patients with type 2 diabetes was associated with a 58% reduction in relative risk of death from any cause five years after surgery (The Lancet, 2015)[22]
    - Risk of death from myocardial infarction (heart attack) dropped nearly 60%
    - Risk of suffering non-fatal or fatal heart attack reduced 49%
  - At 12 years, patients with type 2 diabetes who had gastric bypass saw lower rates of hypertension (16% vs. 47%) and dyslipidemia compared with those who did not have surgery (NEJM, 2017)[23]
  - Meta-analysis of 17,532 patients in 1,559 studies shows metabolic surgery was superior to medical treatment alone in patients with obesity for preventing microvascular complications of diabetes (OR: 0.16 vs. 0.42) including nephropathy, neuropathy, and retinopathy (British Journal of Surgery, 2018)[24]
  - For patients with diabetes and severe obesity who had metabolic surgery, risk of microvascular complications at five years was less than half that of patients receiving medical management – 16.9% vs. 34.7%, respectively (Annals of Internal Medicine, 2018)[25]

Metabolic Surgery in Patients with Lower BMIs

- Systematic review of more than 50 studies shows metabolic surgery in patients with mild-to-moderate obesity (BMI 30 to 35) produced greater glycemic control (range, 0.9-1.43-point improvements in blood sugar levels) and weight loss (range, 14.4-24 kg) after 12 months to two years compared to nonsurgical treatments (JAMA, 2013)[26]
- Remission of diabetes was achieved by 93% of gastric bypass and 47% of sleeve gastrectomy patients with BMIs 24 to 30 one year after surgery (Archives of Surgery, 2011)[27]
- Five-year data in patients with BMIs lower than 35 shows after metabolic surgery, 36% maintained complete diabetes remission and 28% maintained partial remission compared to 1.2% and 1.6% of patient treated with medical therapy alone (JAMA Surgery, 2015)[28]

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[1] National Diabetes Statistic Report, 2017. Centers for Disease Control and Prevention. http://www.diabetes.org/assets/pdfs/basics/cdc-statistics-report-2017.pdf
[2] World Health Organization. Obesity and Overweight Fact Sheet. How Does Excess Body Fat Impact Health.http://www.who.int/dietphysicalactivity/media/en/gsfs_obesity.pdf
[3] Chang S., JAMA Surgery. (2014). The Effectiveness and Risks of Bariatric Surgery. 2003-2012. JAMA Surg. 149(3):275–287. doi:10.1001/jamasurg.2013.3654
[4] Schauer, P.R., et al. (2003). Effect of Laparoscopic Roux-En Y Gastric Bypass on T2DM Section: Discussion. Annals of Surgery. doi: 10.1097/01.sla.0000089851.41115.1b
[5] Schauer, P. R., et al. (2017). Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes. NEJM DOI: 10.1056/NEJMoa1600869
[6] Mingrone, G., et al. (2015). Bariatric–metabolic surgery versus conventional medical treatment in obese patients with T2D: 5 year follow-up of an open-label, single-centre, randomised controlled trial. The Lancet. 386;999, P964-973. DOI: https://doi.org/10.1016/S0140-6736(15)00075-6
[7] ADA (2016). Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: Diabetes Care. 39(6): 861-877.https://doi.org/10.2337/dc16-0236
[8] American Society for Metabolic and Bariatric Surgery (ASMBS). (2018). ASMBS updated position statement on bariatric surgery in class I obesity (BMI 30–35 kg/m2). Article in Press: June 9, 2018. DOI: https://doi.org/10.1016/j.soard.2018.05.025
[9] ADA (2016). Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: Diabetes Care. 39(6): 861-877.https://doi.org/10.2337/dc16-0236
[10] ADA. (2013). Update on Prevention of Cardiovascular Disease in Adults With Type 2 Diabetes Mellitus in Light of Recent Evidence: A Scientific Statement From the American Heart Association and the American Diabetes Association. Diabetes Care. dci150012. https://doi.org/10.2337/dci15-0012
[11] Buchwald, H., et al. (2009). Weight and Type 2 Diabetes after Bariatric Surgery: Systematic Review and Meta-analysis. Am J Med. https://doi.org/10.1016/j.amjmed.2008.09.041
[12] Chang S., JAMA Surgery. (2014). The Effectiveness and Risks of Bariatric Surgery. 2003-2012. JAMA Surg. doi:10.1001/jamasurg.2013.3654
[13] Schauer, P. R., et al. (2017). Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 5-Year Outcomes. NEJM DOI: 10.1056/NEJMoa1600869
[14] Schauer, P. R., et al. (2012). Bariatric Surgery vs. Intensive Medical Therapy in Obese Patients with Diabetes. NEJM; 366:1567–1576 DOI: 10.1056/NEJMoa1200225
[15] Schauer, P.R., et al. (2014). Bariatric Surgery versus Intensive Medical Therapy for Diabetes — 3-Year Outcomes. NEJM 370:2002-2013. DOI: 10.1056/NEJMoa1401329
[16] Mingrone, G., et al. (2012). Bariatric surgery vs. conventional medical therapy for type 2 diabetes. New Engl J Med. 366:1577-1585. DOI: 10.1056/NEJMoa1200111
[17] Mingrone, G., et al. (2015). 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. The Lancet. 386;999, P964-973. DOI: https://doi.org/10.1016/S0140-6736(15)00075-6
[18] Brethauer, S. A., et. al. (2013). Can Diabetes Be Surgically Cured? Annals of Surgery. doi: 10.1097/SLA.0b013e3182a5034b
[19] Adams T. D., et. al. (2012). Health Benefits of Gastric Bypass Surgery After 6 Years. JAMA. 308(11):1122-1131. doi:10.1001/2012.jama.11164
[20] Sjostrom L., et al. (2014). Association of bariatric surgery with long-term remission of T2D and with microvascular and macrovascular complications. JAMA. doi:10.1001/jama.2014.5988
[21] Adams, T. D., et al. (2007). Long-term mortality after gastric bypass surgery. New Engl J Med. 357:753-761 DOI: 10.1056/NEJMoa066603
[22] Eliasson, B., et al. (2015). Cardiovascular disease and mortality in patients with type 2 diabetes after bariatric surgery in Sweden: a nationwide, matched, observational cohort study. The Lancet Diabetes & Endocrinology. 3:11, P847-854. DOI:https://doi.org/10.1016/S2213-8587(15)00334-4
[23] Adams T. D., et al. (2017). Weight and metabolic outcomes 12 years after gastric bypass. N Engl J Med. 377:1143-1155. doi: 10.1056/NEJMoa1700459
[24] Billeter et al.. (2018). Meta-analysis of metabolic surgery versus medical treatment for microvascular complications in patients with T2DM. BrJSurg, doi:10.1002/bjs.10724.
[25] O'Brien P. E., et. al. (2018). Microvascular Outcomes in Patients With Diabetes After Bariatric Surgery Versus Usual Care: Annals of Internal Medicine. DOI: 10.7326/M17-2383
[26] Maggard-Gibbons M., et. al. (2013). Bariatric Surgery for Weight Loss and Glycemic Control in Non Obese Adults With Diabetes. JAMA. doi:10.1001/jama.2013.4851
[27] Lee, W. J., et al. (2011). Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: a randomized controlled trial. Arch Surg. 146(2):143-8. doi: 10.1001/archsurg.2010.326.
[28] Chih-Cheng H., et al. (2015). Effect of Bariatric Surgery vs Medical Treatment on T2D in Patients With BMI Lower Than 35. JAMA Surg. doi:10.1001/jamasurg.2015.2602