



Effective Health Care Program

Comparative Effectiveness Review
Number 82

Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m²



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Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m²

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Prepared by:

Southern California Evidence-based Practice Center
Santa Monica, CA

Investigators:

Margaret A. Maglione, M.P.P.
Melinda Maggard Gibbons, M.D.
Masha Livhits, M.D.
Brett Ewing, M.S.
Jianhui Hu, M.P.P.
Alicia Ruelaz Maher, M.D.
Zhaoping Li, M.D. Ph.D.
Tanja Perry, B.H.M.
Paul G. Shekelle, M.D., Ph.D.

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Addendum - Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m²

As part of the preparation of a paper to appear in the Journal of the American Medical Association (JAMA), we added to our analysis two additional elements:

1. We updated our literature search through September 2012. This resulted in including eight additional surgical observational studies (1-8 below).
2. We attempted to compare the weight loss and glucose control outcomes of bariatric surgery with nonsurgical therapy in the two RCTs that directly compared these in patients with diabetes for only those patients with a body mass index (BMI) of 30.0 to 34.9 kg/m². The mean baseline BMI was 37.0 kg/m² in both RCTs. For the trial reported by Schauer and colleagues, we used the results of an analysis presented as supplemental material with their original publication. This analysis found no statistically significant evidence that the study outcomes differed in patients above and below the mean BMI of 37 kg/m². For the trial reported by Dixon and colleagues, we obtained patient-level data from the authors, and compared weight loss and glucose outcomes in the 13 patients included in that trial that had a BMI of less than 35 kg/m². There were statistically significantly better weight loss and glucose control outcomes in the patients treated with bariatric surgery compared to those treated nonsurgically.

These additions did not change our conclusions regarding the effectiveness and safety bariatric surgery in this population.

For further information, see:

Maggard-Gibbons M, Maglione M, Livhits M, et al. Bariatric surgery for weight loss and glycemic control in nonmorbidly obese adults with diabetes: a systematic review. JAMA. 2013 June 5;309(21):2250-2261. DOI 10.1001/jama.2013.4851.

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang M.D., M.P.H.
Director, EPC Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Mary Nix M.S., M.T.(A.S.C.P.), S.B.B., P.M.P.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Key Informants

Caroline M. Apovian, M.D., FACP, FACN
Boston University School of Medicine
Boston, MA

Pam Davis, R.N., CBN, CCM
Centennial Center for the Treatment of
Obesity
Nashville, TN

Jim Fivecoat, M.B.A.
Member, Obesity Action Coalition
Taylors, SC

Jeff Haaga
Member, Obesity Action Coalition
West Jordan, UT

Monali Misra, M.D., FRCSC, FACS
Dr. Feiz and Associates
Beverly Hills, CA

John Morton, M.D., M.P.H., FACS
Stanford School of Medicine
Stanford, CA

Joe Nadglowski
President and CEO
Obesity Action Coalition
Tampa, FL

Jamshid Nazarian, M.D., FACS
Beverly Hills, CA

Chuck Stemple, M.D.
Humana
Cincinnati, OH

Technical Expert Panel

Caroline M. Apovian, M.D., FACP, FACN
Boston University School of Medicine
Boston, MA

George Bray, M.D.
Pennington Biomedical Research
Foundation
Baton Rouge, LA

John B Dixon, M.B.B.S., Ph.D., FRACGP
Monash University, Baker IDI Heart and
Diabetes Institute
Melbourne, Australia

David Heber, M.D.
Ronald Reagan UCLA Medical Center
Los Angeles, CA

Edward Harry Livingston, M.D., FACS, UT
Southwestern Medical Center
Dallas, TX

John Morton, M.D., M.P.H., FACS
Stanford School of Medicine
Stanford, CA

Christine J. Ren-Fielding, M.D.
NYU Langone Medical Center
New York, NY

Bruce Wolfe, M.D.
Oregon Health & Science University
Portland, OR

Peer Reviewers

David Arterburn, M.D., M.P.H.
University of Washington
Seattle, WA

Alison Avenell, Ph.D.
University of Aberdeen
Aberdeen, Scotland, U.K.

Scott A. Cunneen, M.D.
Cedars-Sinai Medical Center
Los Angeles, CA

Ken Fujioka, M.D.
Scripps Clinic Del Mar
San Diego, CA

James Hill, Ph.D.
University of Colorado
Denver, CO

Joe Nadglowski
President and CEO
Obesity Action Coalition
Tampa, FL

Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m²

Structured Abstract

Objectives. To systematically review the scientific evidence on efficacy, safety, and comparative effectiveness of various types of bariatric surgery for treating adult patients with a body mass index (BMI) of 30.0 to 34.9 kg/m² and diabetes or impaired glucose tolerance (IGT) and to compare effectiveness of surgery versus nonsurgical interventions in this population.

Data sources. Systematic reviews, case series, cohort, case control studies and controlled trials, found through searching PubMed®, Embase, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Abstracts of Reviews of Effects (DARE), and Clinicaltrials.gov through March, 2012.

Review methods. To be included, studies had to report on laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD), sleeve gastrectomy (SG), or nonsurgical treatment, and had to include patients with a BMI of at least 30 kg/m² but less than 35 kg/m² with diabetes or IGT. The following studies were excluded: (1) those with no outcomes of efficacy, effectiveness, or safety/adverse events; (2) nonsurgical studies with less than one year followup; (3) nonsurgical studies already included in previous systematic reviews; and (4) studies with a sample size of less than three. Two reviewers, each trained in the critical analysis of scientific literature, independently reviewed and abstracted each study.

Results. We found only 24 studies reporting bariatric surgery results in this specific target population. Two were trials comparing different procedures, three were trials of surgical versus nonsurgical interventions, and the rest were observational studies. Both weight and blood glucose improved significantly for surgery patients in the trials. In the observational studies, surgery patients showed much greater weight loss at 1 year than reported in systematic reviews and randomized controlled trials (RCTs) on diet, exercise, medication, and other behavioral interventions. While both behavioral interventions and medications lowered HbA1c (glycosylated hemoglobin) levels significantly, the decreases reported in surgery patients were much greater. Improvements in blood glucose measures were reported as early as one month postsurgery. Improvements in hypertension, low-density lipoprotein (LDL) cholesterol, and triglycerides were also reported in some studies. Short-term rates of adverse events associated with bariatric surgery were relatively low. One death, a case of sepsis at 20 months in an LAGB patient, was reported. Short-term complications were minor and tended not to require major intervention. Due to the dearth of long-term studies of bariatric surgery in this particular target population, few data exist about long-term adverse effects, and we found no evidence regarding major clinical endpoints such as all-cause mortality, cardiovascular mortality and morbidity, and peripheral arterial disease.

Conclusions. According to blood glucose outcomes, there is moderate strength evidence of efficacy for RYGB, LAGB, and SG as treatment for diabetes and IGT in patients with a BMI

between 30 kg/m² and 35 kg/m² in the short term (up to 2 years). The strength of evidence for BPD is rated low because there are fewer studies, and these have smaller sample sizes. Evidence on comparative effectiveness of surgical procedures is insufficient. Short-term adverse events are relatively minor; strength of evidence is low due to small sample size with low power to detect rare events. Strength of evidence is insufficient regarding adverse events in the long-term (2 years or more postsurgery). Longitudinal studies of bariatric surgery patients are needed to assess overall safety and comparative effectiveness regarding diabetes-related morbidity such as kidney failure and blindness.

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Executive Summary

Background

Bariatric surgery, also known as weight-loss surgery, refers to surgical procedures usually performed on people who are morbidly obese for the purpose of losing weight and to treat, as well as prevent, obesity-related comorbidities. Bariatric surgery has evolved since its introduction in the 1950s, with some procedures that were popular initially (like jejunoileal bypass) having been abandoned because of unacceptable complication rates. The types of bariatric surgery that are most commonly performed now include laparoscopic adjustable gastric banding (LAGB); Roux-en-Y gastric bypass (RYGB); biliopancreatic diversion with duodenal switch (BPD); and sleeve gastrectomy (SG), also referred to as gastric sleeve. Newer procedures—gastric sleeve with ileal interposition, duodenal-jejunal bypass, and duodenal-jejunal exclusion—are being studied outside of the United States (one study in the United States was conducted in 2008, but the results were not published). The mechanism of weight loss and metabolic impact are under investigation, but they are not regularly performed in the United States currently. Thus, they are beyond the scope of this report.

Studies show that these procedures cause significant weight loss in morbidly obese patients. In addition, bariatric surgeries such as LAGB and RYGB in morbidly obese patients have been found to be far more effective than conventional nonsurgical therapy at lowering blood sugar to improve diabetes in the short term. Improvement in diabetes has been demonstrated to start rapidly after bariatric surgery, especially for patients undergoing RYGB, before significant weight loss has occurred. The mechanism of postoperative metabolic improvements has not been fully elucidated and may in part be independent from weight loss, suggesting that bariatric surgery may improve metabolic comorbidities, even for patients who are not morbidly obese.

Bariatric surgery is an accepted practice for patients with a body mass index (BMI) of 40 kg/m² or greater, and for patients with a BMI of between 35 and 40 kg/m², who have significant obesity-related comorbidities such as diabetes, hypertension, cardiovascular disease, dyslipidemia, obstructive sleep apnea, and degenerative arthritis. The National Institutes of Health (NIH) criteria state that patients should undergo medically supervised weight loss attempts before bariatric surgery.

In the past few years, bariatric surgery has been suggested as an option for patients with a lower BMI (at least 30 kg/m², but less than 35 kg/m²) as a way to treat diabetes and other metabolic conditions. Given a lack of consensus regarding the minimum BMI requirement and uncertainties regarding the comparative effectiveness of different bariatric procedures, especially in the long term, a review of the relative risks and benefits of the various surgical and more conservative approaches to treatment of diabetes or impaired glucose tolerance (IGT) in patients whose BMI is between 30 and 35 kg/m² was suggested by a constituent group. The topic was refined by the Southern California Evidence-based Practice Center (EPC) in conjunction with Key Informants, including bariatric surgeons, researchers, consumers, and payers.

Objectives

This systematic review aims to address the following Key Questions (KQs).

KQ1. What does the evidence show regarding the comparative effectiveness of bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions, including diabetes? Are certain surgical procedures more effective than others (LAGB, RYGB, or SG)?

KQ2. What does the evidence show regarding the comparative effectiveness of bariatric surgery versus conventional nonsurgical therapies for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions?

KQ3. What are the potential short-term adverse effects and/or complications associated with bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² who have metabolic conditions?

KQ4. Does the evidence show racial and demographic disparities with regard to potential benefits and harms associated with bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions? What other patient factors (social support, counseling, preoperative weight loss, compliance with recommended treatment) are related to successful outcomes?

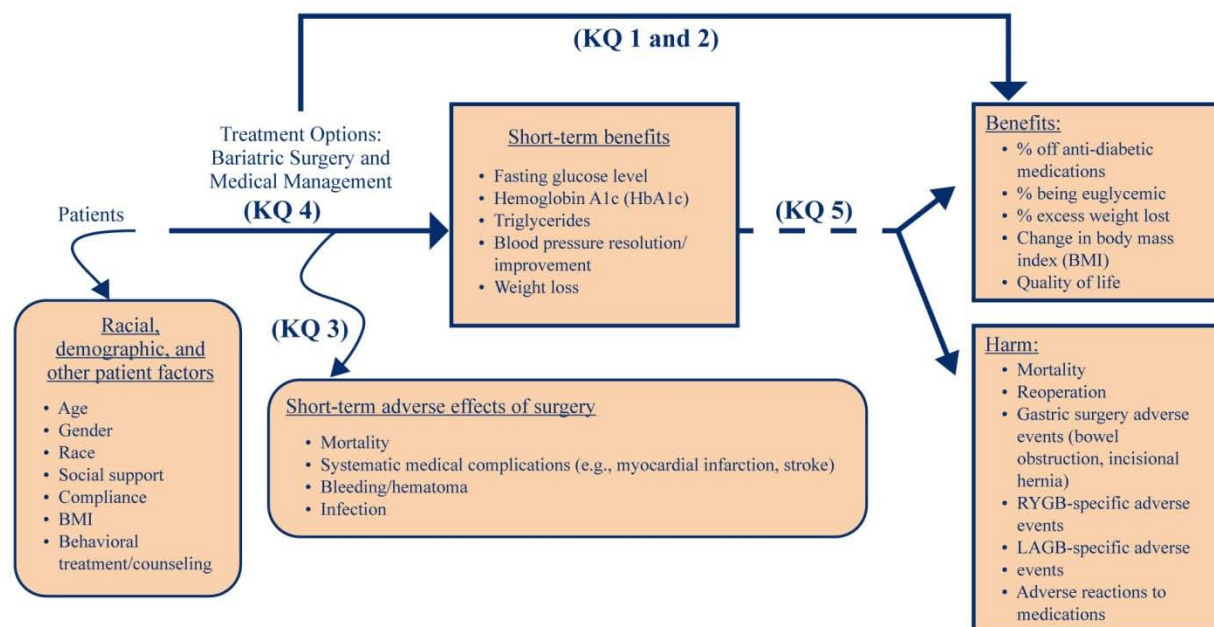
KQ5. What does the evidence show regarding long-term benefits and harms of bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and who have metabolic conditions? How do the long-term benefits and harms of bariatric surgery compare to short-term outcomes (within 1 year after surgery)?

Analytic Framework

Figure A presents the analytic framework for this comparative effectiveness review (CER). Using data from controlled trials, cohort studies, and case series, we sought evidence of the benefits and harms of different types of bariatric surgeries and in treating targeted patients (those with diabetes or IGT and a BMI of ≥ 30 kg/m² and < 35 kg/m²). The evidence for both short- and long-term outcomes was assessed. Planned comparisons included (1) among different surgical procedures such as RYGB, LAGB, SG, and BPD to answer KQ1; and (2) surgical procedures to conventional nonsurgical therapies (e.g., diet, exercise, and pharmaceuticals) to answer KQ2. Documented short- and long-term benefits and harms of surgical procedures were compared to answer KQ3 and KQ5.

Benefits and harms for specific subpopulations (by gender, age, and race/ethnicity) and other patient factors (social support, counseling, preoperative weight loss, and compliance with recommended treatment) were examined and summarized to answer KQ4.

Figure A. Analytic framework for evaluating the effectiveness and safety of alternative approaches to treatment of metabolic conditions in the patient population with BMI $\geq 30 < 35$



KQ = Key Question; LAGB = laparoscopic adjustable gastric banding LAGB; RYGB = Roux-en-Y gastric bypass

Methods

We searched the electronic databases PubMed[®], Embase[®], CINAHL (Cumulative Index to Nursing and Allied Health Literature), the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials (CENTRAL), and the Cochrane Database of Abstracts of Reviews of Effects (DARE) for studies addressing our KQs. Other sources included Clinicaltrials.gov, references of included studies and relevant reviews, and personal files from projects with related topics. The original search was conducted in March 2010; electronic search updates were conducted monthly through March 2012. We used various search terms for each type of procedure and for nonsurgical interventions. Further details and surgery strategies are included in the full report. There were no limits on publication date or language.

We searched the literature for systematic reviews, case series, cohort, case control studies and controlled trials. To be included, studies had to report on one of the surgical procedures listed above or nonsurgical treatment, and had to include patients with a BMI of at least 30 kg/m² but less than 35 kg/m² with diabetes or IGT. The following studies were excluded: (1) studies that did not report any outcomes of efficacy, effectiveness, or safety/adverse events; (2) nonsurgical studies with less than 1 year followup; (3) nonsurgical studies already included in previous systematic reviews; and (4) studies with fewer than three subjects.

We note here that we are dealing with two concepts—weight and disorders of glucose metabolism—that are a continuum physiology, but in the KQs, are treated as dichotomous. In other words, we expect the risk of excess weight to be similar for a person with a BMI of 29.5 kg/m² and a person with a BMI of 31.5 kg/m², yet our KQs deal with the latter and not the former. Indeed, the published literature does not always conform to the same threshold specified in the KQs. We judged that studies that included substantial numbers of patients within the threshold of our KQs, but also some outside the range, were still informative and were included. Thus, if a study included patients with a BMI of 29 kg/m²–37 kg/m², we judged that it would be

more relevant to the KQs to include rather than exclude, it. Similar decisions were made about the presence of IGT and the clinical diagnosis of diabetes.

We reviewed the studies retrieved from the various sources against our exclusion criteria. Items included specific surgical procedures or nonsurgical treatments, study design, sample size, and types of outcomes reported (i.e. metabolic, mortality, adverse events). Two reviewers, each trained in the critical analysis of scientific literature, independently reviewed each study and resolved disagreements by consensus. The lead investigator resolved any disagreements that remained after discussions between the reviewers. Results from controlled trials, case-control studies, cohort studies, and case series of surgical procedures were abstracted by researchers using Distiller[®] software (Evidence Partners, Ottawa, Canada). Because of study heterogeneity, meta-analysis was not possible; thus, we summarized the data by procedure and intervention. Data abstracted included metabolic outcomes (glucose, blood pressure, lipids) and weight loss, mortality, and adverse events. Other details included setting; population characteristics (including sex, age, ethnicity, and comorbidities); eligibility and exclusion criteria; any cointerventions, including allowed medication; comparisons; and results for each outcome. Intent-to-treat results were recorded if available. For each study that provided sufficient information, we calculated the mean change from baseline to followup. A negative mean change indicated a decrease in outcome measure (e.g. BMI). We used these estimates to calculate a weighted mean change within surgery type and outcome.

The overall strength of evidence for intervention efficacy was assessed by using guidance suggested by the Agency for Healthcare Research and Quality (AHRQ) for its Effective Health Care Program. This method is based loosely on one developed by the GRADE working group, and classifies the grade of evidence according to the following criteria:

High = High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence on the estimate of effect.

Moderate = Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

Low = Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

Insufficient = Evidence is either unavailable or does not permit a conclusion.

The evidence grade is based on four primary (required) domains and four optional domains. The required domains are risk of bias, consistency, directness, and precision; the additional domains are dose-response, plausible confounders that would decrease the observed effect, strength of association, and publication bias. For this review, global implicit judgment about “confidence” was used in the result.

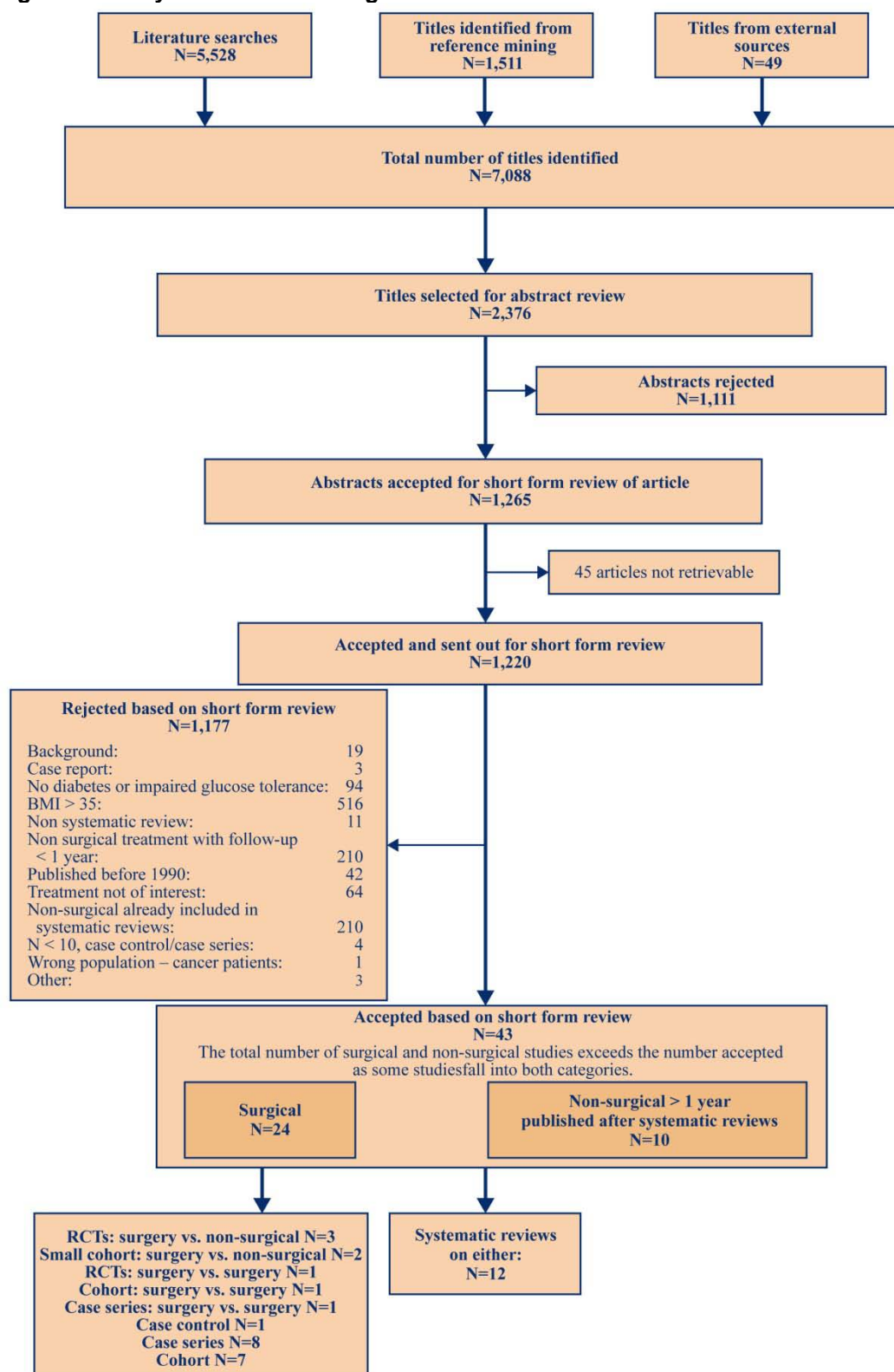
Results

Figure B displays the results of our literature search. We identified 7,088 titles through our electronic database searches, by reference mining, and by locating those suggested by our Technical Expert Panel. We also reviewed scientific information packets received from device manufacturers. Our researchers selected 2,376 for further review; almost half were rejected upon

abstract review. Of the 1,220 studies that underwent full-text review, we retained 24 surgical studies, 12 systematic reviews, and 10 nonsurgical studies. The most common reasons for exclusion of surgical studies were focus on patients outside the BMI range (516 studies) or that the study did not include patients with diabetes or IGT (94 studies). The most common reasons for excluding nonsurgical studies were followup of less than 1 year or inclusion in previous systematic reviews.

Of the 24 studies reporting bariatric surgery results in patients with diabetes or IGT and a BMI of at least 30 but less than 35 kg/m², we found two head-to-head trials, one cohort study, and one case series comparing surgical procedures. We identified three controlled trials and two small cohort studies comparing surgery with nonsurgical intervention. (One of the trials contained two different surgical arms.) The remaining included studies were observational, with no comparison group. Six of the studies included only a portion of patients with diabetes or IGT; in the rest, all patients had one of these disorders.

Figure B. Study/literature flow diagram



BMI = body mass index; RCT = randomized controlled trial

Of the 24 surgery studies, there were 13 RYGB arms, 7 LAGB arms, 5 BPD arms, and 3 gastric sleeve arms. We also included 20 systematic reviews on diet, exercise, medication, or bariatric surgery in our target population. Table A presents a summary of our findings.

Short-Term Outcomes

Based primarily on glucose control outcomes, there is moderate strength evidence of efficacy of bariatric surgery in treating diabetes in patients with a BMI of at least 30 but less than 35 kg/m² in the short term. At 1 year, surgery patients show much greater weight loss than usually seen in studies of diet, exercise, or other behavioral interventions. With the exception of GLP-1T agonists, diabetes medications do not cause significant weight loss. While both behavioral interventions and various medications lower HbA1c (glycosylated hemoglobin) levels significantly, the decreases reported in bariatric surgery patients at one year are greater. Improvements in glucose control outcomes have been reported as early as 1 month post-surgery. Several studies report improvement in hypertension and cholesterol at 1 year. We rated the overall evidence as moderate due to sparseness of data—three randomized controlled trials (RCTs) directly compared surgical with nonsurgical interventions, and two came from the same group of researchers. Observational data, which start as low strength evidence, were upgraded due to consistency of results regarding BMI and blood sugar. Thus, the total body of evidence is considered moderate strength, based on moderate strength of evidence for BMI and glucose outcomes. Strength of evidence for cholesterol and blood pressure outcomes is low.

Long-Term Outcomes

There are few long-term data on patients with diabetes or IGT in this weight class who have undergone bariatric surgery. We identified only two studies with followup of more than 2 years. One, a case series of LAGB patients in Italy, reported followup at 5 years for 29 of the 210 initial patients, for a followup rate of only 13.8 percent. Another very small Italian study followed seven BPD patients for at least 5 years. Thus, despite promising short-term outcomes reported, the evidence that bariatric surgery is an effective way to treat diabetes in patients with a BMI of at least 30 kg/m² but less than 35 kg/m² in the long term is insufficient. Strength of evidence is insufficient for all outcomes, including BMI, blood glucose, cholesterol, and hypertension. In contrast, behavior and medication interventions have been studied extensively for decades; several large, long-term RCTs have found improved HbA1c continues for 10 years. Several long-term trials and meta-analyses have reported clinically significant improvements in microvascular and macrovascular outcomes as a result of behavioral or medication interventions.

Specific Bariatric Procedures

We found two head-to-head trials comparing bariatric procedures (one also had a medication-only group). An average-size trial (N=60) conducted in Taiwan compared RYGB with SG; the RYGB group had better weight and diabetes outcomes at 1 year postsurgery. A recent U.S. trial comparing these same procedures found similar results.

We also found two observational studies that compared procedures. One conducted in the United States compared RYGB with LAGB. This study was fairly large (N=235), and had an adequate followup rate (61.9% for RYGB, 69.2% for LAGB) at 6 to 12 months. Some patients were followed for 2 years. Weight loss was similar among groups; diabetes outcomes were generally better for RYGB patients. The other study, conducted in Germany, compared results

for 12 BPD patients with 4 RYGB patients. Both groups lost a significant amount of weight. At 1 year, decrease in HbA1c was significantly greater in the BPD group.

Observational studies of surgical procedures without a comparison arm reported clinically meaningful decreases in BMI with all types of bariatric surgery at less than 1 year. Clinically meaningful diabetes outcomes were also reported at less than 1 year for all surgery types. At a year or more, weight loss was maintained or improved in all groups; RYGB patients had the greatest decrease in BMI.

Taking into consideration the entire body of evidence, we rate the strength of evidence of efficacy as moderate for RYGB, LAGB, and SG in treating diabetes and IGT in patients with a BMI of between 30 kg/m² and 35 kg/m² in the short term (up to 2 years), based primarily on glucose control outcomes. For BPD, both the number of studies and their sample sizes are much lower; thus the strength of evidence of efficacy is rated low. Evidence on comparative effectiveness of surgical procedures is insufficient.

Table A. Summary of data on interventions and outcomes in patients with diabetes or impaired glucose tolerance

Outcome	Behavioral Changes (Data Almost Entirely From Systematic Reviews, RCTs)	Intervention Medications (Data Almost Entirely From Systematic Reviews, RCTs)	Bariatric Surgery (Data Primarily From Observational Studies)
Weight loss at 1 year	2.8 kg for diet, exercise, behavioral vs. usual care	Weight gain from 1 to 5 kg with some drugs. 2.8 kg weight loss with GLP-1R agonists; no weight change with metformin	BMI loss of 5 to 7 kg/m ² (about 15 to 20 kg for someone 5 feet 6 inches tall)
Weight loss at 2 years	2.7 kg for diet, exercise, behavioral vs. usual care	Data unavailable	BMI loss of 4 to 8 kg/m ² (about 11 to 23 kg for someone 5 feet 6 inches tall)
Long-term weight loss (5 years and more)	1.7 kg for diet, exercise, behavioral vs. usual care at 5 years	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found no significant change with metformin at 10 years	BMI loss of 5.7 kg/m ² at 5 years, in one study of 29 LAGB patients
HbA1C, percentage of total hemoglobin, at 1 year	Decrease of 0.3 to 2.2 percentage points	Decrease of 0.5 to 1.0 percentage points	Decrease of 2.6 to 3.7 percentage points
HbA1C at 2 years	No significant change	Data unavailable	Decrease of 1.8 to 3.1 percentage points
HbA1C at 5 years and more	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found HbA1C concentrations lower in behavioral group at 10 years (vs. placebo)	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found HbA1C concentrations lower in metformin group at 10 years (vs. placebo)	Data unavailable

Table A. Summary of data on interventions and outcomes in patients with diabetes or impaired glucose tolerance (continued)

Outcome	Behavioral Changes (Data Almost Entirely From Systematic Reviews, RCTs)	Intervention Medications (Data Almost Entirely From Systematic Reviews, RCTs)	Bariatric Surgery (Data Primarily From Observational Studies)
Other metabolic outcomes at 1 year	Diet improved fasting glucose (1.3%-36.6% reduction) and triglycerides (11.3%-58.9% reduction); the Spain PREDIMED study found Mediterranean diet reduced metabolic syndrome prevalence by 13.7% at 1 year; the Finnish Diabetes Prevention Study (DPS) found behavioral change reduced metabolic syndrome prevalence at 3.9 years (odds ratio: 0.62)	Most medications had minimal effects on systolic & diastolic blood pressure (< 5 mmHg change); metformin and second-generation sulfonylureas generally decreased LDL cholesterol levels	Mixed results, one RYGB and one BPD study reported slight increase in triglycerides at 1 year
Other metabolic outcomes at 5 years and more	Data unavailable	Data unavailable	Of 7 BPD patients followed, all had normal serum cholesterol and triglycerides
Microvascular outcomes (renal disease, neuropathy, retinopathy, etc.)	Data unavailable	U.K. Prospective Diabetes Study (UKPDS) found patients taking sulfonylurea, insulin, or metformin had 24% risk reduction for microvascular disease at 10 years	Data unavailable
Macrovascular outcomes (cardiovascular disease, stroke, heart attack)	Few data; the China Da Qing Diabetes Prevention Study (CDQDPS) found no significant difference in first CVD event, CVD mortality and all-cause mortality between intervention and control group	Meta-analysis of 5 trials with 33,040 participants found that on an average A1C reduction of 0.9% there was a 19% reduction in non-fatal myocardial infarction and a 15% reduction on coronary heart disease, and no statistically significant effect on stroke or all-cause mortality	Data unavailable
Prevention of diabetes	Hazard ratio 0.51 for behavioral interventions vs. standard advice at 1 to 5 years; the U.S. Diabetes Prevention Program (DPP) found diabetes incidence in 10 years reduced by 34% by behavioral change vs. placebo, and the China Da Qing Diabetes Prevention Study (CDQDPS) found it was 43% lower in behavioral group over 20 years	Hazard ratio 0.70 for oral medications vs. control at 1 to 5 years; the U.S. Diabetes Prevention Program (DPP) found diabetes incidence in 10 years reduced by 18% in the metformin group vs. placebo	Data unavailable

BMI = body mass index; BPD = biliopancreatic diversion with duodenal switch; CVD = cardiovascular disease; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoproteins; RCT = randomized controlled trial; RYGB = Roux-en-Y gastric bypass

Adverse Events

The strength of evidence for short-term harms is low for all four surgical procedures. In the two RCTs comparing SG with RYGB, complications were minor, and rates were similar between groups. The surgical complications reported for RYGB and LAGB in observational studies were fairly consistent; they differ due to the nature of the procedures. Complications related to LAGB include band slippage, tube problems, and band erosion, while those related to RYGB include stricture, ulcer, and on rare occasions, hemorrhage.

Studies were included in our mortality analyses only if they reported or mentioned either the number of deaths or lack of any deaths. Thus, 14 studies were included, which accounted for five LAGB arms, one gastric sleeve arm, nine RYGB arms, and one BPD arm. Only one death was reported—an LAGB patient with complications of a gastric perforation. Thus, the reported rate of mortality was 0.48 percent for LAGB and 0.0 percent for gastric sleeve, RYGB, and BPD.

The low strength of evidence reflects several limitations in the data. The majority of the adverse events data were submitted by surgeons, and thus subject to possible publication bias. Few studies were clear exactly when adverse events took place, and patients who were lost to followup had no adverse events data. In addition, definitions of complications varied from study to study.

We found no data on long-term adverse events of bariatric surgery in diabetes or IGT patients in our specific BMI range. Thus, strength of evidence for long-term adverse events is rated insufficient.

Discussion

The literature on bariatric surgery for diabetes or IGT patients with BMI of at least 30 kg/m² and less than 35 kg/m² has many limitations. Most important, very few studies of this target population have long-term followup. Only two studies followed patients for more than 2 years; one has a followup rate of only 13.8 percent and the other includes only seven patients. Thus, we have almost no data on long-term efficacy and safety. No evidence was found on major clinical endpoints such as all-cause mortality, cardiovascular mortality or morbidity, or peripheral arterial disease. The studies of bariatric surgery in this population have measured only intermediate or surrogate endpoints regarding glucose control. While control of glucose is certainly important, the available evidence from the diabetes literature indicates it may be premature to assume that controlling glucose to normal or near normal levels completely mitigates the risk of microvascular and macrovascular events. Thus, claims of a “cure” for diabetes based on glucose control within 1 or 2 years require longer term data before they can be substantiated.

Randomized controlled trials are considered the highest level of medical evidence. We found three RCTs of surgery versus nonsurgical treatment (one of these also compared two procedures) and another RCT comparing surgical procedures. This was expected given the difficulty in conducting RCTs of surgery. Still, we identified only two observational studies comparing surgical procedures and two small cohort studies comparing surgery with nonsurgical approaches. The rest of our data came from studies with no comparison group and with data submitted primarily by the practicing surgeons. The sample sizes, regardless of methodological design, are far smaller than those of most trials of diet, exercise, and medications.

Applicability of this research to the larger treatment population of diabetes and IGT patients with BMI between 30.0 kg/m² and 34.9 kg/m² is important in interpreting the results. The participation rate, population characteristics, representativeness of the setting, and representativeness of the individuals are used to assess applicability. One RCT comparing surgery with nonsurgery was performed in the United States and included two of the more commonly performed procedures—RYGB and SG. However, it was of modest size and was conducted in an academic setting in a select group of patients with uncontrolled type II diabetes at baseline. Two RCTs of LAGB versus nonsurgical interventions conducted in Australia comprised primarily Caucasian patients. However, the RCT comparing LAGB with SG was conducted in Taiwan, where diets and lifestyle may differ considerably from those of the West. One of the cohort studies comparing procedures was conducted in the United States, but only three of the remaining observational studies were conducted here. The others were conducted in Western Europe, South America, India, Asia, and Australia. Diet, behavior, and culture in many of these locations may differ dramatically from that in the United States. In addition, there may be biological or genetic differences. Thus, the results seen in studies in other countries may not be directly applicable to patients in the United States.

Data reported on adverse events also have several limitations. Most studies were not primarily designed to assess these outcomes and reflect surgeon or surgery team-reported events. There were only 20 instances in which 100 or more patients contributed data to a particular adverse event category; thus, the rate estimate for most adverse events is imprecise. Additionally, in 76 percent of instances, only a single study contributed data to a particular adverse event rate calculation, meaning the generalizability of the estimate is questionable. Followup times and rates were variable, and many studies did not state exactly when adverse events occurred, other than “within a year postsurgery.” As such, the rates of adverse events may be biased and lower than actual. Comparisons between procedure types are limited for the same reasons. Again, we found almost no long-term adverse events data for our target population.

Finally, although our literature-search procedures were extensive and included canvassing experts for studies we may have missed, the possibility of publication bias still exists. For all surgical procedures, there is the concern that published studies usually come from academic medical centers with high-performing surgical teams and careful patient selection. Outcomes for such patients may not reflect the outcomes achieved in the wider community. (The difference between complication rates seen in the major clinical trials of carotid endarterectomy and those observed in the general Medicare population is one well-known example of this phenomenon.) For bariatric surgery, there are media reports (Los Angeles Times) on several deaths following LAGB surgery. Whether there is any causal relationship between the surgery and the deaths has not yet been assessed in a peer-reviewed publication, so no conclusions can be drawn. Still, it illustrates the potential for there to exist adverse events and/or beneficial outcomes in as-yet-undescribed populations.

Future Research

Future research should focus on long-term outcomes of bariatric surgery in U.S. patients with diabetes or IGT and a BMI of 30 kg/m² to 34.9 kg/m². In this population, there is no evidence that bariatric surgery is effective in preventing the clinical consequences of diabetes—microvascular and macrovascular endpoints such as diabetic retinopathy, kidney failure, and myocardial infarction. Studies with followup of 5 to 10 years are needed.

We found one trial and one cohort study comparing procedures performed in the United States. The cohort study used the BOLD (Bariatric Outcomes Longitudinal Database), a resource created by the Surgical Review Corporation to monitor outcomes from the Bariatric Surgery Center of Excellence (BSCOE) program. As of June 2009, 235 patients with diabetes within our BMI range were in the BOLD database. The study we identified reported outcomes at 6 to 12 months. Outcomes at 12 to 24 months were reported for only a small number of patients (6.8 percent) presumably because that followup time had not expired for most of the patients. Continued followup of these patients and publication of findings will shed light on which, if any, bariatric procedures mitigate long-term sequelae of diabetes.

In addition, according to the U.S. clinical trials database (Clinicaltrials.gov), several bariatric surgery trials are being conducted in the target population. In addition to monitoring weight loss, these studies will frequently collect important metabolic data, including measures of blood sugar, cholesterol, triglycerides, and blood pressure. Long-term followup of the research subjects, if funded, could add to our knowledge base on the effects of bariatric surgery and cardiovascular morbidity and mortality. Collection and reporting of psychological and quality of life outcomes will also help inform prospective patients and providers.

Glossary

Bariatric surgery: Surgery on the stomach and/or intestines to help a person lose weight.
Biliopancreatic diversion with duodenal switch (BPD): Surgery that involves removing 70 percent of the stomach, along with bypassing a significant proportion of small intestine.

Body mass index (BMI): An individual's weight, in kilograms, divided by his or her height, in meters squared. It is used to define normal weight, overweight, obesity, and morbid obesity.

GLP-1 agonists: Glucagon-like peptide-1 agonists, a class of diabetes drugs targeting the incretin system.

HbA1c: Glycosylated hemoglobin.

Impaired glucose tolerance (IGT): Prediabetic state of high blood sugar associated with insulin resistance.

Laparoscopic adjustable gastric banding (LAGB): A surgical weight-loss procedure that involves the placement of an adjustable belt around the upper portion of the stomach, restricting the size of the stomach and the amount of food it can hold.

LDL (low-density lipoprotein) cholesterol: Cholesterol that may collect in the walls of blood vessels, causing blockage.

Metabolic condition: A constellation of syndromes including impaired fasting glucose (prediabetes) and diabetes mellitus that increase the risk of cardiovascular disease.

Roux-en-Y gastric bypass (RYGB): A surgical weight-loss procedure that involves the creation of a small stomach pouch to restrict food intake and construction of bypasses of the duodenum

and other segments of the small intestine to cause malabsorption (decreased ability to absorb nutrients from food). Often referred to as gastric bypass.

Sleeve gastrectomy (SG): A surgical weight-loss procedure in which the stomach is reduced to about 15 percent of its original size by surgical removal of a large portion of the stomach. There are variations on the sleeve gastrectomy that involve the addition of intestinal bypasses.

References

Please refer to the reference list in the full report for documentation of statements contained in the Executive Summary.

Introduction

In 2010, diabetes affected 25.8 million people in the United States, or 8.3 percent of the population. About 1.9 million people aged 20 years or older were newly diagnosed with diabetes in 2010. In 2005-2008, based on fasting glucose or hemoglobin A1c levels, 35 percent of U.S. adults (79 million people) aged 20 years or older had prediabetes (50 percent of adults aged 65 years or older).¹ Among adults with diabetes, the prevalence of individuals considered as overweight or higher (body mass index [BMI] ≥ 25 kg/m²) was 80.3 percent; and the prevalence of obesity or higher (BMI ≥ 30 kg/m²) was 49.1 percent.¹

Diabetes is considered a chronic, progressive disease. Traditional medical therapy focuses on glycemic control and control of long-term complications such as retinopathy, renal failure, and cardiovascular disease. Management may involve injecting insulin daily or using oral medications for a life time.

Studies show that bariatric surgeries such as laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion with duodenal switch (BPD) in morbidly obese patients have been found to be far more effective than conventional nonsurgical therapy at improving diabetes in the short term.² A recent randomized controlled study (RCT) studying a population with BMI >35 kg/m² found that no patients in the medical treatment alone group had resolution of diabetes (defined as HgA1c <6.5 percent and fasting blood glucose <100 mg/dL) compared with 75 percent resolution in RYGB and 95 percent in BPD.³

Improvement in diabetes has been demonstrated to start rapidly after bariatric surgery, especially for patients undergoing RYGB, before significant weight loss has occurred. Additionally, the degree of weight loss achieved may not predict the improvement in hyperglycemia.³ The mechanism of postoperative metabolic improvements has not been fully elucidated and may in part be independent from weight loss, suggesting that bariatric surgery may improve metabolic comorbidities even for patients who are not morbidly obese.

Bariatric surgery is an accepted practice for patients with a BMI of 40 kg/m² or greater, and for patients with a BMI of between 35-40 kg/m² who have significant obesity-related comorbidities such as diabetes, hypertension, cardiovascular diseases, dyslipidemia, obstructive sleep apnea, and degenerative arthritis.

In the past few years bariatric surgery has been suggested as an option for lower BMI (at least 30 kg/m² but less than 35 kg/m²) patients as a way to treat diabetes and other metabolic conditions. Given a lack of consensus regarding the minimum BMI requirement and uncertainties regarding the comparative effectiveness of different bariatric procedures, especially in the long term, a review of the relative risks and benefits of the various surgical and conservative approaches to treatment of diabetes or impaired glucose tolerance (IGT) in patients whose BMI is at least 30 kg/m² and less than 35 kg/m² was suggested by a constituent group; the topic was refined by the Southern California Evidence-based Practice Center in conjunction with Key Informants, including bariatric surgeons, researchers, consumers, and payers.

Conventional Therapy for Obesity and Diabetes

Conventional nonsurgical therapy for overweight patients with diabetes or IGT includes diet, exercise, and medications (summarized below). Most interventions combine multiple modalities such as diet and exercise and must be sustained long-term to prevent weight regain.

Diet

A variety of diets have been proposed to assist obese patients in losing weight. Low calorie diets are typically high in carbohydrates (55 percent – 60 percent of total daily energy intake), low in fat (< 30 percent of energy intake), and produce a negative energy balance. Other strategies focus on decreasing the proportion of carbohydrates or fats. Low carbohydrate, high fat/protein diets (e.g. Atkins) induce weight loss primarily through decreased calorie intake but can have mixed effects on lipid profiles. Very-low-calorie diets (VLCDs) – typically 800 kcal per day – can be effective to induce rapid weight loss, especially when used as a short-term adjunct prior to bariatric surgery. More recently, the Mediterranean diet, which emphasizes eating fruit, vegetables, and whole grains has become popular. Finally, the low glycemic index diet, originally designed for diabetes patients, ranks carbohydrate foods from 1 to 100 according to glucose level, with 100 as the reference for pure glucose.

Exercise

Aerobic exercise can induce weight loss as well as decrease blood sugar levels for those with impaired glucose tolerance, though it is often difficult for morbidly obese patients due to comorbidities such as osteoarthritis. There is some debate regarding the optimal level of physical activity necessary to induce weight loss. The National Heart, Lung and Blood Institute (NHLBI) Obesity Education Initiative Expert and the United States (U.S.) Preventive Services Task Force guidelines suggest that at least 30 minutes of aerobic activity daily (amounting to an energy expenditure of 2,500 to 3,500 kcal per week) is necessary to promote weight loss and reduce comorbidities.⁴

Behavior Modification

These interventions include individual counseling and community-based programs to provide detailed strategies to assist with weight loss. Recommendations may include those regarding diet and exercise, as well as counseling regarding the deleterious effects of obesity and associated comorbidities. Cognitive behavioral therapy, targets specific psychological processes that may interfere with weight loss or maintenance, can be included in a behavior modification program.

Medications

Anti-obesity medications rely on increasing metabolism, decreasing appetite or altering food absorption. Commonly used drugs have included orlistat, which inhibits pancreatic lipases and prevents fat absorption, and sibutramine, a serotonin-norepinephrine reuptake inhibitor that decreases appetite. The latter was recently withdrawn from the United States and other markets due to increased risks of myocardial infarction and stroke.⁵ Phentermine, approved for short-term weight loss, is another popular appetite suppressant. Conventional pharmaceutical therapy for weight loss has not been very effective at producing significant and sustained weight loss in

obese patients.^{6,7} The combination of diet and weight loss medications like orlistat results in a mean weight loss of only 3-4 kg at one year.⁶ Such medications can improve glycemic control and dyslipidemia in obese patients with type 2 diabetes, but this improvement is modest.⁸

Conventional therapy for diabetes also includes specific medications meant to lower plasma glucose levels. Pharmacotherapy for obese patients with diabetes includes insulin or oral hypoglycemic agents, which work through a variety of mechanisms (e.g. sulfonylureas, which increase insulin secretion; biguanides, which reduce hepatic glucose production; and thiazolidinediones or glitazones, which reduce insulin resistance mainly in the periphery). Medications used for obese patients with diabetes, such as insulin or sulfonylureas (e.g. glyburide), do not produce significant weight loss and can even cause weight gain, exacerbating insulin resistance and glucose intolerance.⁹ Recently developed GLP-1 receptor agonists such as liraglutide and exenatide treat diabetes by reducing meal-related hyperglycemia by increasing insulin secretion and delaying gastric emptying. These drugs have been shown to cause weight loss in clinical trials.^{10,11} Cardiovascular risk reduction medications (statins, aspirin, angiotensin converting enzyme inhibitors, etc.) are also mainstays of diabetes management.

Bariatric Surgery

Bariatric surgery was first introduced in the 1950s and has evolved significantly since that time, leading to some procedures that were initially performed being abandoned due to unacceptably complication rates secondary to malabsorption that led to reduced nutrient intake (e.g. jejunoileal bypass) or poor long-term benefit (i.e., vertical banded gastroplasty). The most common procedures currently performed are RYGB, laparoscopic adjustable gastric banding, and gastric sleeve. These procedures result in weight loss via different mechanisms and most likely involve a combination. Pre-surgery assessments of weight history, food preferences, psychological issues and medical history impact decisions regarding which surgery is most appropriate.

Researchers are still learning about all the specifics of how weight loss is achieved. Two general components employed, alone or in combination, include (1) restricting the size of the stomach to limits the quantity of food a patient can consume at a single meal, and (2) inducing malabsorption which decreases the proportion of nutrients that are absorbed from a meal. These procedures can also produce behavior changes, such as aversions to high carbohydrate foods. As the gastrointestinal tract communicates with the central nervous system, these procedures also appear to lead to hunger control and satiety, the details of which are still being studied. Descriptions of selected bariatric procedures (those performed currently) are provided below.

Gastric Bypass (RYGB)

The most common bariatric procedure, Roux-en-Y gastric bypass, often referred to as “gastric bypass,” achieves weight loss through complex mechanisms. The surgery involves creating a small gastric pouch (and outlet) along with a proximal intestinal bypass. This small pouch (30 cc) is connected to a segment of the jejunum (which is downstream), thus bypassing the duodenum and very proximal small intestine. Although the procedure generates minimal malabsorption, significant changes in hormones and neural signals to the gastrointestinal tract lead to hunger control and satiety. In addition, following ingestion of high-density carbohydrates, some patients may experience the resultant “dumping” syndrome, whose unpleasant symptoms include flushing, palpitations, abdominal pain, cramping, and diarrhea. As a result, these patients develop an aversion to high-carbohydrate foods that leads to behavior changes in diet and eating

habits. RYGB for weight loss has been performed regularly since the early 1980s. It was first performed laparoscopically in the early 1990s and is now one of the most common types of weight loss procedures.

Laparoscopic Adjustable Gastric Band (LAGB)

Gastric banding achieves weight loss predominately by gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch with a capacity of approximately 15 to 30 cubic centimeters (cc). The band consists of an inflatable doughnut-shaped balloon whose diameter can be adjusted in the clinic by adding or removing saline via a reservoir port positioned beneath the skin. The bands are adjustable to allow the size of the gastric outlet to be modified as needed, depending on clinical symptoms and eating behaviors. A full understanding of how weight loss is achieved is still being investigated, but likely includes components of behavioral diet and eating changes as well as inducing satiety through neuropeptide changes. Currently, banding procedures are performed laparoscopically (laparoscopic adjustable gastric banding). While this procedure is technically reversible (e.g., removal of the band for failed weight loss), doing so exposes the patient to potential risks associated with a second operation and, of course, will necessitate identifying an alternative method for weight loss.

Sleeve Gastrectomy

Also known as gastric sleeve, vertical sleeve gastrectomy, is a relatively new restrictive type of procedure. Approximately 60 to 80 percent of the stomach is removed laparoscopically, leaving a small tube (or “sleeve”) which remains connected to the original stomach outlet. The cutaway part of the stomach is removed, making this procedure irreversible, and no foreign objects are implanted in the body.

The mechanism by which gastric sleeve induces weight loss is not clear. At least one study has demonstrated increased or rapid gastric emptying following gastric sleeve resection, leading to a possible mechanism of neural-hormonal phenomena similar to RYGB. This procedure may also lower plasma ghrelin, a natural hormone, which produces hunger. Originally gastric sleeve surgery was the first stage of two-stage procedure, biliopancreatic diversion with duodenal switch in high risk patients. (discussed below). However, many patients lost sufficient weight after the gastric sleeve such that the second stage surgery was not needed, and it has been gaining popularity as a stand-alone procedure since the early 2000s. In South America, the procedure has been paired with ileal interposition, with very good results reported. However, as that process is considered experimental and rarely performed in the United States, it is beyond the scope of this report.

Biliopancreatic Diversion/Duodenal Switch (BPD)

BPD involves removing 70 percent of the stomach along with bypassing a significant proportion of small intestine. By reducing the size of the stomach, less acid is produced, but the remaining capacity is generous compared with that achieved with RYGB. As such, patients eat relatively normal-sized meals and do not need to restrict intake severely. Malabsorption is a component of how weight loss is generated, but it has not been clearly established as the main cause. Malabsorption is generated by (1) the diversion of food downstream, decreasing the opportunity for nutrient absorption and (2) reduction in the quantities of enzymes and bile in the

bypassed segment, which decreases absorption. Patients develop steatorrhea from the decrease in fat absorption.

Although this procedure is not as commonly performed as either banding procedures or RYGB, the approach is favored by some bariatric surgery specialists. The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure that, until recently, was performed mostly in Italy and only rarely performed in the United States. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis.

Newer procedures, gastric sleeve with ileal interposition, duodenal-jejunal bypass, and duodenal-jejunal exclusion, are being studied outside in the United States (one study in the United States in 2008 was conducted but the results were not published). The mechanism of weight loss and metabolic impact are under investigation and they are not standardly performed in the United States currently. Thus, they are beyond the scope of this report.

Bariatric Surgery in Lower Weight Patients

Currently the standard criteria for bariatric surgery candidates include having a BMI ≥ 40 kg/m² or ≥ 35 kg/m² with significant obesity-related comorbidities. This is based on National Institutes of Health (NIH) guidelines¹² and has been endorsed by the Center for Medicare & Medicaid Services (CMS), which covers a variety of bariatric procedures for patients with BMI ≥ 35 kg/m² and comorbidities.¹³ Bariatric surgery has been shown to improve or resolve metabolic conditions such as diabetes in the short term, at least in part due to the associated weight loss.¹⁴ However, there may be other mechanisms involved (particularly for RYGB) as metabolic improvements are often seen rapidly after surgery, before significant weight loss has occurred. Bariatric surgery has therefore been advocated as a treatment for metabolic conditions even for the non-morbidly obese patients. Though experts have suggested that the minimum BMI requirement for bariatric candidates with type 2 diabetes be lowered below 35 kg/m², CMS in 2006 denied coverage for lower BMI patients with diabetes, specifically for open and laparoscopic RYGB, LAGB, and open and laparoscopic BPD/DS.¹⁵ In 2011, the International Diabetes Federation recommended that diabetic patients with BMI of at least 30 kg/m² to 35 kg/m² be eligible for bariatric surgery if they have a HbA1c level of $> 7.5\%$.¹⁶ More recently, the Food and Drug Administration (FDA) expanded the indications for a specific brand of laparoscopic adjustable gastric banding to include patients with a BMI between 30 kg/m² and 34.9 kg/m² and at least one obesity-related comorbidity.¹⁷

Methods

Original Proposed Key Questions (KQs)

KQ1. What does the evidence show regarding the comparative effectiveness of bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions, including diabetes? Are certain surgical procedures more effective than others (LAGB, RYGB, or SG)?

KQ2. What does the evidence show regarding the comparative effectiveness of bariatric surgery versus conventional nonsurgical therapies for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions?

KQ3. What are the potential short-term adverse effects and/or complications associated with bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² who have metabolic conditions?

KQ4. Does the evidence show racial and demographic disparities with regard to potential benefits and harms associated with bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and metabolic conditions? What other patient factors (social support, counseling, preoperative weight loss, compliance with recommended treatment) are related to successful outcomes?

KQ5. What does the evidence show regarding long-term benefits and harms of bariatric surgery for treating adult patients with a BMI of 30.0 to 34.9 kg/m² and who have metabolic conditions? How do the long-term benefits and harms of bariatric surgery compare to short-term outcomes (within 1 year after surgery)?

Technical Expert Panel

For each Agency for Healthcare Research and Quality (AHRQ) evidence report, a Technical Expert Panel (TEP) is assembled to provide clinical expertise and context. We invited a distinguished group of scientists and clinicians, including individuals with expertise in obesity, surgery, and metabolic conditions such as diabetes, to participate in the TEP for this report. A list of members is included in the front matter of this report. A TEP conference call was held on October 4, 2010. On the call, staff presented the KQs as well as the preliminary literature search results and asked experts to help define the scope of the review (e.g. types of metabolic conditions and bariatric procedures to include). Panel members reviewed a draft version of this report and provided feedback.

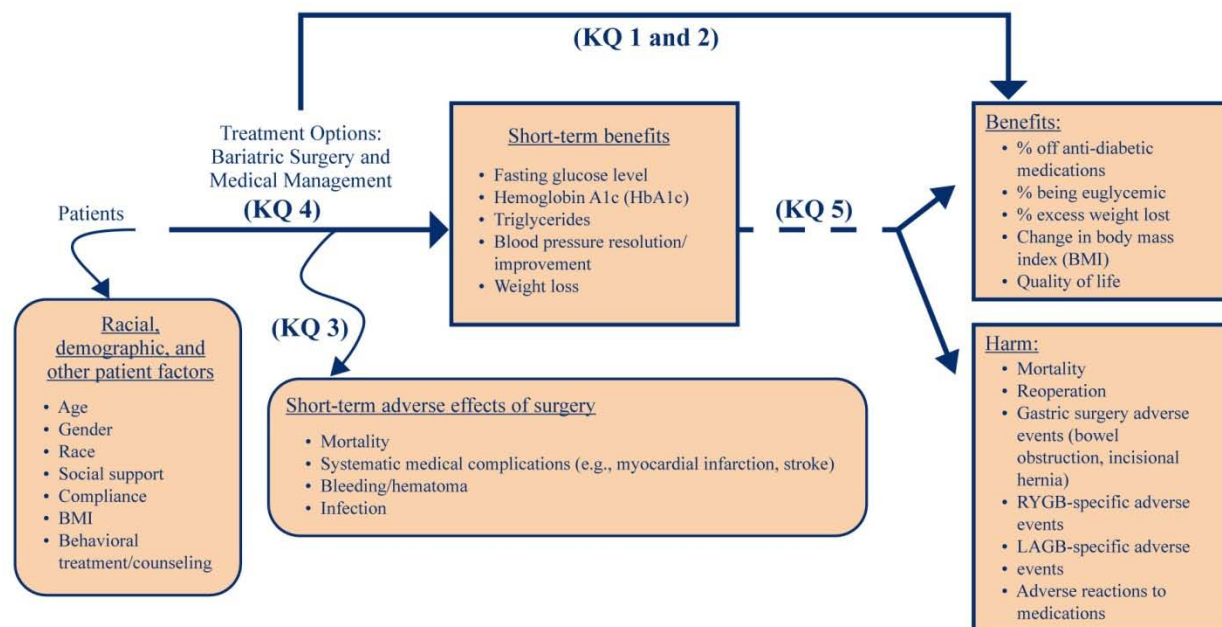
Analytic Framework

Figure 1 presents the analytic framework for this comparative effectiveness review (CER). Using data from controlled trials, cohort studies, and case series, we documented evidence of the benefits and harms of different types of bariatric surgeries and conventional nonsurgical therapies in treating targeted patients (those with diabetes or impaired glucose tolerance [IGT] and a body mass index [BMI] of 30 to 34.9 kg/m²). The evidence for both short- and long-term outcomes was assessed. Comparisons included: (1) among different surgical procedures such as Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), sleeve gastrectomy (SG), and biliopancreatic diversion with duodenal switch (BPD) to answer KQ1, and (2) of surgical procedures to conventional nonsurgical therapies (e.g., diet, exercise, and

pharmaceuticals) to answer KQ2. Documented short- and long-term benefits and harms of surgical procedures were compared to answer KQ3 and KQ5.

Benefits and harms for specific subpopulations (by gender, age, and race/ethnicity) and other patient factors (social support, counseling, preoperative weight loss, compliance with recommended treatment) were examined, where available, to answer KQ4.

Figure 1. Analytic framework for evaluating the effectiveness and safety of alternative approaches to treatment of metabolic conditions in the patient population with BMI $\geq 30 < 35$



KQ = Key Question; LAGB = laparoscopic adjustable gastric banding LAGB; RYGB = Roux-en-Y gastric bypass

A protocol for this review was available for public comment on the AHRQ Effective Healthcare Web site <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=595&pageaction=displayproduct>.

Literature Search

Our search for studies began in April 2009, with an electronic search of PubMed[®] and Embase[®] for reports on bariatric surgery and patients with diabetes or IGT. We also searched the CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane library of systematic reviews, Cochrane Central Register of Controlled Trials (CENTRAL) and the Cochrane Database of Abstracts of Reviews of Effects (DARE). (The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of health care interventions.) Other sources included Clinicaltrials.gov, references of included studies, and relevant reviews, and personal files from projects with related topics. Reviewers performed additional reference mining by scanning titles listed in the reference section of each selected study to identify additional potential articles. The literature search was updated in March 2010, and October 2010 after the TEP call, and search updates were conducted monthly through March 2012. Appendix A shows our specific search terms. We also searched for studies of nonsurgical treatments (diet, exercise, education, medications, and other interventions). The

following bariatric procedures: laparoscopic adjustable gastric banding (LAGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion (BPD) were included in our searches. Jejunioileal bypass, one of the earliest procedures performed for weight loss, was not included, as this procedure was abandoned about 25 years ago due to a high rate of complications. We used various search terms for each type of procedure. For example, for Roux-en-Y gastric bypass, we also used gastric bypass, RYGB, laparoscopic gastric bypass, and open gastric bypass. We ordered all articles on metabolic conditions and weight loss interventions, regardless of language or publication date.

The strongest evidence to assess the relative benefits and harms of bariatric surgery with nonsurgical therapy would come from randomized controlled trials comparing the treatment options, including only patients in the BMI range of our KQs ($30 \text{ kg/m}^2 - 34.9 \text{ kg/m}^2$) and measuring relevant outcomes such as glucose control and use of diabetic medications, but also the outcomes that treating diabetes is meant to prevent: microvascular and macrovascular complications. Because a priori we expected there to be very few RCTs comparing surgical with nonsurgical therapy, we expected – as in our prior Evidence Report on surgical and nonsurgical weight loss therapies in more obese patients¹⁸ – that we would need to make indirect comparisons between the best available data on the effects of surgery and the best available data on the effects of nonsurgical therapy. For the former, we expected to use case series data. For the latter, there is a voluminous literature on the management of diabetes, and we expected to use existing systematic reviews supplemented with any recent trials published after the search dates of these reviews.

Article Review

Study Inclusion

We searched the literature for systematic reviews, case series, cohort, case control and controlled trials. Editorials, historical pieces, and descriptive articles without data were excluded. The studies included in this report are of one of the following types.

Review articles identified by the search were classified as either systematic (including meta-analyses) or nonsystematic. *Systematic reviews* were identified by reading the methods section of the article to determine whether an acceptable method was employed to identify evidence (such as a description of the name of the computerized database searched and the full set of search terms used, as well as details about the method for accepting and rejecting identified articles).

Randomized controlled trials (RCTs) are studies where the participants are definitely assigned prospectively to one of two (or more) alternative forms of intervention, using a process of random allocation (e.g., random number generation, coin flips).

Controlled clinical trials (CCTs) are studies where participants (or other units) are either

- (a) definitely assigned prospectively to one of two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier)
OR
- (b) possibly assigned prospectively to one of two (or more) alternative forms of health care using a process of random or quasi-random allocation.

Observational studies (such as cohort and cases series) are those where the investigators do not control who gets the interventions.

To be included, studies had to report on one of the surgical procedures or conservative nonsurgical treatments described in the introduction, and had to include patients with BMI 30.0

to 34.9 kg/m² with diabetes or IGT. Systematic reviews of interventions both surgical and nonsurgical were the exception to this rule, since they often synthesized data over a number of studies with varying BMI patient population. The following studies were excluded: (1) studies that did not report any outcomes of efficacy, effectiveness, or safety/adverse events; (2) nonsurgical studies with less than one year followup; (3) nonsurgical studies already included in previous systematic reviews; (4) background articles; and (5) studies with less than three subjects. We note here that we are dealing with two concepts, weight and disorders of glucose metabolism, that are a continuum physiology, but in the KQs are treated as dichotomous. In other words, we expect the risk of weight to be similar for a person with a BMI of 29.5 kg/m² and a person with a BMI of 31.5 kg/m², yet our key questions deal with the latter and not the former. Indeed, the published literature does not always conform to the same threshold specified in the KQs. We judged that studies that included substantial number of patients within the threshold of our KQs, but perhaps also some outside the range, were still informative, and were included. Thus, if a study included patients with a BMI of 29 kg/m²–37 kg/m² we judged that it would be more informative to the KQs to include rather than exclude it. Similar decisions were made about the presence of impaired glucose tolerance and the clinical diagnosis of diabetes.

Screening

Using a single-page “screening form” (included in Appendix B), we reviewed the studies retrieved from the various sources against our exclusion criteria. Items included specific surgical procedure or nonsurgical treatment, study design, sample size, and type of outcomes reported (i.e. metabolic conditions, mortality, adverse events). Two reviewers, each trained in the critical analysis of scientific literature, independently reviewed each study and resolved disagreements by consensus. The lead investigator resolved any disagreements that remained after discussions between the reviewers.

Data Abstraction and Synthesis of Results

Results from controlled trials, case-control studies, cohort studies, and cases series were abstracted by researchers using Distiller[®] software. Because of study heterogeneity, meta-analysis was not possible; thus, we summarize the data both quantitatively and qualitatively. Data abstracted included metabolic outcomes (glucose, blood pressure, lipids) and weight loss, mortality, and other adverse events. Other details included trial name (if applicable), setting, population characteristics (including sex, age, ethnicity, and diagnosis), eligibility and exclusion criteria, any co-interventions, other allowed medication, comparisons, and results for each outcome. Intent-to-treat results were recorded if available. For each study that provided sufficient information, we calculated the mean change from baseline to followup, where a negative mean change indicates decrease in outcome measure (e.g. BMI). We used the estimates to calculate a weighted mean change within surgery type and outcome.

Assessment of Methodological Quality

To arrive at a quantitative measure for controlled trials, the Jadad scale was used, which was originally developed for drug trials.¹⁹ This method measures quality on a scale that ranges from 0–5, assigning points for randomization and blinding and accounting for withdrawals and dropouts. (Across a broad array of meta-analyses, an evaluation of the scale found that trials scoring from 0–2 report exaggerated results when compared with trials scoring from 3–5.²⁰ The

latter scores indicate studies of “good” quality and the former indicate those of “poor” quality.) For any disagreement that arose during the quality assessment, issues were discussed in the project meeting, and group decisions were made by the research team.

To assess the quality of included systematic reviews and meta-analyses, we used AMSTAR—a measurement tool for the assessment of multiple systematic reviews.²¹ This tool contains eleven yes/ no items, such as whether the literature search was comprehensive, if dual abstraction was used, and if individual study characteristics are displayed. The tool has strong face and content validity, inter-rater reliability, and construct validity.²² A copy is included in Appendix B.

Grading the Evidence for Each KQ

The overall strength of evidence for intervention effectiveness was assessed by using guidance suggested by AHRQ for its Effective Health Care Program.^{23,24} This method is based loosely on one developed by the GRADE working group,²⁵ and classifies the grade of evidence according to the following criteria:

High = High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence on the estimate of effect.

Moderate = Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

Low = Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

Insufficient = Evidence either is unavailable or does not permit a conclusion.

The evidence grade is based on four primary (required) domains and four optional domains. The required domains are risk of bias, consistency, directness, and precision; the additional domains are dose-response, plausible confounders that would decrease the observed effect, strength of association, and publication bias. Information on the required domains is presented in Table 1 below.

Table 1. Grading the strength of a body of evidence: required domains and their definitions

Domain	Definition and Elements	Score and Application
Risk of Bias	<p>Risk of bias is the degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through two main elements:</p> <ul style="list-style-type: none"> • Study design (e.g., RCTs or observational studies) • Aggregate quality of the studies under consideration. <p>Information for this determination comes from the rating of quality (good/fair/poor) done for individual studies.</p>	<p>Use one of three levels of aggregate risk of bias:</p> <ul style="list-style-type: none"> • Low risk of bias • Medium risk of bias • High risk of bias
Consistency	<p>The principal definition of consistency is the degree to which reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements:</p> <ul style="list-style-type: none"> • Effect sizes have the same sign (that is, are on the same side of “no effect”) • The range of effect sizes is narrow. 	<p>Use one of three levels of consistency:</p> <ul style="list-style-type: none"> • Consistent (i.e., no inconsistency) • Inconsistent • Unknown or not applicable (e.g., single study) <p>As noted in the text, single-study evidence bases (even megatrials) cannot be judged with respect to consistency. In that instance, use “Consistency unknown (single study).”</p>
Directness	<p>The rating of directness relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Two types of directness, which can coexist, may be of concern: Evidence is indirect if:</p> <ul style="list-style-type: none"> • It uses intermediate or surrogate outcomes instead of health outcomes. In this case, one body of evidence links the intervention to intermediate outcomes and another body of evidence links the intermediate to most important (health or ultimate) outcomes. • It uses two or more bodies of evidence to compare interventions A and B – that is, studies of A versus placebo and B versus placebo, or studies of A versus C and B versus C but not A versus B. <p>Indirectness always implies that more than one body of evidence is required to link interventions to the most important health outcomes.</p> <p>Directness may be contingent on the outcomes of interest. EPC authors are expected to make clear the outcomes involved when assessing this domain.</p>	<p>Score dichotomously as one of two levels directness</p> <ul style="list-style-type: none"> • Direct • Indirect <p>If indirect, specify which of the two types of indirectness account for the rating (or both, if that is the case)—namely, use of intermediate/surrogate outcomes rather than health outcomes, and use of indirect comparisons. Comment on the potential weaknesses caused by, or inherent in, the indirect analysis. The EPC should note if both direct and indirect evidence was available, particularly when indirect evidence supports a small body of direct evidence.</p>
Precision	<p>Precision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately).</p> <p>If a meta-analysis was performed, this will be the confidence interval around the summary effect size.</p>	<p>Score dichotomously as one of two levels of precision:</p> <ul style="list-style-type: none"> • Precise • Imprecise <p>A precise estimate is an estimate that would allow a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions. For example, results may be statistically compatible with both clinically important superiority and inferiority (i.e., the direction of effect is unknown), a circumstance that will preclude a valid conclusion.</p>

EPC = Evidence-based Practice Center; RCT = randomized controlled trial

For this systematic review, we focused on the inherent risk of bias in study design (e.g., in general, randomized controlled trials have less bias than observational studies) and within study design, certain aspects of execution and reporting (e.g. proportion lost to followup, baseline differences between the comparison groups). Regarding consistency, we judged the evidence as consistent if, *all other factors being equal*, a super majority of the studies reported results in the same direction. For directness, we judged the evidence to be direct if, *all other factors being equal*, studies reported relevant health outcomes such as weight loss, micro or macrovascular complications of diabetes, stroke myocardial infarction, etc. rather than indirect outcomes such as fasting blood sugar or HbA1c. We consider weight loss per se to be a health outcome since it is something patients can feel, although it is also an intermediate towards improvement in comorbid conditions. For precision, we defined the evidence as precise if, all other factors being equal, the data were sufficiently within its 95% confidence interval to support a decision, i.e. if the evidence is on one side of a decision threshold. The most important additional domain was publication bias, because surgeons submitting case series for publication may be unrepresentative of the community as a whole.

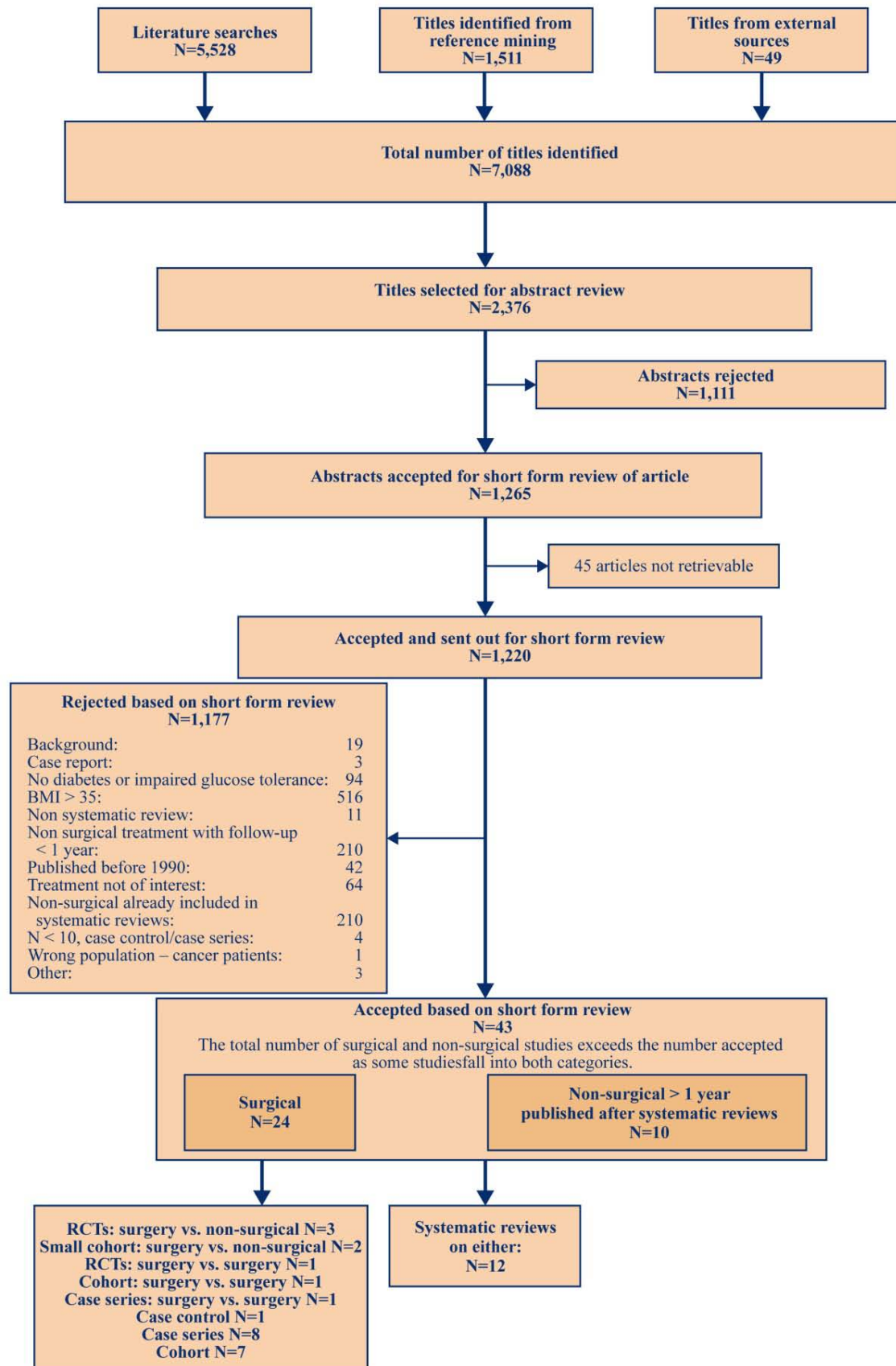
Peer Review and Public Commentary

A draft of this report was prepared in September 2011. The AHRQ Effective Healthcare Program Scientific Resource Center located at Oregon Health Sciences University coordinated peer review by experts and stakeholders. The report was also posted on AHRQ's Web site for a month for public comment. Resulting comments were considered by the EPC in preparation of the final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers, and service as a peer reviewer or member of the TEP cannot be construed as endorsement of the report's findings.

Results

Figure 2 displays the results of our literature search. We identified 7,088 titles through our electronic database searches, reference mining, scientific information packets received from manufacturers, and expert panel suggestions. Our researchers selected 2,376 for further review; almost half were rejected upon abstract review. Of the 1,220 studies that underwent full-text review, we included 24 studies that included a surgical arm, 12 systematic reviews, and ten large studies of nonsurgical interventions published after those reviews. The most common reasons for exclusion of surgical studies were wrong body mass index (BMI) range (516 studies) or the study did not include patients with diabetes or impaired glucose tolerance (IGT) (94 studies). The most common reasons for excluding nonsurgical studies were followup of less than one year or inclusion in previous systematic reviews.

Figure 2. Study/Literature flow diagram



BMI = body mass index; RCT = randomized controlled trial

Key Question (KQ)1: What does the evidence show regarding the comparative effectiveness of bariatric surgery for treating adult patients with BMI of 30 to 34.9 and metabolic conditions, including diabetes? Are certain surgical procedures more effective than others (laparoscopic adjustable gastric banding, gastric bypass, or sleeve gastrectomy)?

KQ2: What does the evidence show regarding the comparative effectiveness of bariatric surgery versus conventional nonsurgical therapies for treating adult patients with BMI of 30 to 34.9 and metabolic conditions?

Of the 24 studies reporting bariatric surgery results in patients with diabetes or IGT and a BMI of $\geq 30 < 35 \text{ kg/m}^2$, we found two head to head, one cohort study, and one case series comparing surgical procedures. We also identified three controlled trials with a nonsurgical comparison arm (one of which also compared two surgical procedures) and two small cohorts with a nonsurgical arm. The rest of the studies were observational with no comparison group. Six studies included only a portion of patients with diabetes or IGT; in the rest, all patients had these disorders. The majority of the surgical studies came represented single institutions. Of these, three studies reported that only one surgeon performed the cases, three others reported that two surgeons performed the cases, and one study reported procedures were performed by three surgeons. It is unknown how many surgeons performed the cases in the remaining studies.

There were thirteen Roux-en-Y gastric bypass (RYBG) arms, seven laparoscopic adjustable gastric banding (LAGB) arms, five biliopancreatic diversion with duodenal switch (BPD) arms, and three sleeve gastrectomy (SG) arms. Table 2 displays the followup times for each study, along with whether BMI, HbA1c, and/or fasting glucose were measured at each point. Many studies measured additional metabolic outcomes; however, no studies reported on diabetes sequelae such as nephropathy or retinopathy. The vast majority of the studies included followup between 10 and 12 months postsurgery. Unfortunately, few studies followed patients more than two years. It is important to note that when assessing outcomes across time points (for example, 4–6 month data and 10–12 month data) the patients contributing data at 4–6 months may not be the same patients contributing data at 10–12 months, either within study across studies.

Table 2. Bariatric outcomes by followup time

Study	Surgery	0-3 mths	4-6 mths	7-9 mths	10-12 mths	13-24 mths	>24 mths
Cohen, 2006 ²⁶	RYGB					§	
Lee, 2008 ²⁷	RYGB				† § #		
DeMaria, 2010 ²⁸	RYGB	†	†		†	†	
Shah, 2010 ²⁹	RYGB	§ #	§ #	† § #			
Boza, 2011 ³⁰	RYGB				#		
de Sa, 2011 ³¹	RYGB					† § #	
Frenken, 2011 ³²	RYGB				† #		
Huang, 2011 ³³	RYGB		† § #		† § #		
Lee, 2011 ³⁴	RYGB	† #	† #		† #		
Lee, 2011 ³⁵	RYGB	† § #	† § #		† § #	† § #	
Ramos, 2011 ³⁶	RYGB					#	
Schauer, 2012 ³⁷	RYGB	† § #	† § #	† § #	† § #		
Serrot, 2011 ^{a38}	RYGB				† #		
Angrisani, 2004 ³⁹	LABG		†		†	†	†
O'Brien, 2006 ⁴⁰	LABG		†		†	† §	
Parikh, 2006 ⁴¹	LABG				†	†	†
Dixon, 2008 ⁴²	LABG					† # §	
Sultan, 2009 ⁴³	LABG		†		†	†	
Choi, 2010 ^{b44}	LABG						
DeMaria, 2010 ²⁸	LABG	†	†		†	†	
Lee, 2011 ³⁴	Sleeve	† #	† #		† #		
Lembach, 2011, T2DM ⁴⁵	Sleeve				† § #		
Lembach, 2011, IR ^{c45}	Sleeve				† §		
Schauer, 2012 ³⁷	Sleeve	† § #	† § #	† § #	† § #		
Noya, 1998 ⁴⁶	BPD			†			
Scopinaro, 2007 ⁴⁷	BPD				† §	† §	
Chiellini, 2009 ⁴⁸	BPD				† #	† #	
Frenken, 2011 ^{d32}	BPD				† #		
Scopinaro, 2011, OB ^{e49}	BPD	† § #	† § #	† § #	† § #	† § #	
Scopinaro, 2011, OW ^{f49}	BPD	† § #	† § #	† § #	† § #	† § #	

BMI = body mass index; BPD= biliopancreatic diversion; BPD/DS = biliopancreatic diversion with duodenal switch; IR = insulin resistant patients; LABG = laparoscopic adjustable gastric banding; mths = months; OB = obese; OW = overweight;

RYGB = Roux-en-Y gastric bypass; Sleeve = sleeve gastrectomy; T2DM = type 2 diabetes mellitus

† BMI.

HbA1c.

§ Glucose.

^a Only reported Median, used in outcome table.

^b Only usable outcome is % diabetes remission: defined as "% improved/resolved" not otherwise specified.

^c IR=insulin resistant patients.

^d BPD-DS & BPD treated as 1 group.

^e Obese (BMI 30-35).

^f Overweight (BMI 25-30).

Head-to-Head Trials of Bariatric Surgery Versus Nonsurgical Interventions

We identified three randomized controlled trials (RCTs) comparing bariatric surgery with a nonsurgical intervention. One study by Schauer³⁷ compared medical treatment alone with medical treatment following laparoscopic RYGB or gastric sleeve in diabetic patients. Approximately one third of subjects had a baseline BMI in the target range (38%, 28%, and 36% respectively). Outcomes were assessed at 12 months. Two RCTs from an Australian research group assessed weight loss and diabetes outcomes for LAGB compared with nonsurgical interventions in our target population. O'Brien⁴⁰ focused on patients with BMI 30 kg/m²–35 kg/m² and Dixon⁴² included patients with somewhat higher BMI (range 30 kg/m²–40 kg/m²). The comparison arms included medical care and usual diabetes care. Patients were followed up to 24 months. Information on these studies is displayed in Table 3.

Schauer³⁷ conducted a recent RCT in 150 patients with uncontrolled type 2 diabetes (HbA1c >7.0%) and BMI of 27–43 kg/m² comparing intensive medical treatment alone with medical treatment following either RYGB or gastric sleeve. Study inclusion/exclusion criteria and randomization protocol were described in detail. Ninety-three percent of patients completed the 12 month follow-up. Eight patients withdrew from the study (seven in the medical therapy only group did not attend follow-up appointment and one subject in the SG group decided against surgery). Two additional patients in the medical therapy only group did not complete their nine month or 12 month follow-up—leaving 41 patients in the medical therapy alone group, 50 patients in the RYGB group and 49 in the SG group at 12 month followup.

The medical therapy alone group lost less weight at 12 months (–5.4 kg+/-8 kg) than medical therapy with RYGB (–29.4+/-9 kg,) or SG (–25.2+/-8.5 kg, p<.0001 for both comparisons). More patients in the surgical arms achieved glycemic control of HbA1c <6.0 percent: 12 percent in medical group, 42 percent in RYGB (p=0.002), and 37 percent in SG (p=0.008). Mean HbA1c at one year was lower following surgery: 7.5+/-1.8 percent for medical group, 6.4+/-0.9 percent for RYGB (p<0.001), and 6.6+/-1.0 percent for SG (p=0.003). The surgical groups reduced the mean number of both cholesterol medication and hypertension medications significantly compared with the surgical group. (p<.0001).

O'Brien⁴⁰ performed an RCT comparing LAGB (n=40) and medical management (n=40) which included low calorie diet, pharmacotherapy, and behavioral change. Patients had a mean baseline BMI of 33 kg/m² and were well-matched for baseline characteristics; the randomization process was well-described, as were dropouts. No patients were excluded from the analysis. One patient randomized to the surgical arm dropped out preoperatively; seven patients in the medical management did not attend followup at 24 months.

Both groups lost a similar amount of weight at six months (13.8 percent of initial weight in both arms). The surgical arm continued to lose weight out to 24 months (21.6 percent of initial weight), but the medical arm regained much of the weight they initially lost. At that followup, the surgical arm (n=39) had a mean BMI of 26.4 kg/m² and the medical arm (n=33) mean BMI was 31.5 kg/m². The surgical group experienced significantly greater weight loss (p<0.001). The majority of other outcomes were improved to a statistically significant degree in the surgical arm as compared with the medical arm, including diastolic blood pressure and lipid levels. Fasting blood glucose was lower in the surgical patients at 24 months as compared with the medical group (which did not experience a decrease). Metabolic syndrome was present in 37.5 percent of patients in both groups at baseline and decreased to 2.7 percent in the surgical patients (p<0.001) and 24 percent in the medical patients (p=0.22) at followup. A greater proportion of patients in

the surgical group improved metabolic syndrome than in the medical group ($p=.0006$). Other laboratory values, such as HbA1c or use of diabetes medications, were not reported. Of note, quality of life (by short form 36) scores improved to a statistically significant degree in 5 of the 8 domains in the surgical group (8 of 8 subscores) as compared with the medical group (3 of 8).

Dixon et al⁴² performed a similar study but included patients of somewhat higher BMI (mean baseline 37 kg/m^2). Sixty patients were randomized to LAGB or diabetes care as usual. Usual care focused on weight loss via conventional methods including counseling on diet and exercise. Authors described the randomization process and dropouts; patient baseline characteristics were similar following randomization.

At two years, 55 of 60 patients completed the followup. Surgical patients lost a mean of 21.1 kg initial weight compared with 1.5 kg in the conventional treatment arm ($p<0.001$ between groups). BMI decreased to 29.6 kg/m^2 in the surgery patients and 36.7 kg/m^2 in the conventional therapy group ($p<0.001$ between groups). Fasting blood glucose (105.2 versus 139.6) was significantly lower in the surgery patients at two years as compared with the medical group (mean difference -32.8 [95% confidence interval (CI) $-53.1, -12.3$]). HbA1c was also improved to a greater degree in the surgical patients at two years as compared with the convention therapy group (6.00 versus 7.21 ; mean difference -1.43 [95% CI $-2.1, -0.80$]). Remission of type 2 diabetes was seen in 73 percent of the surgical group and 13 percent of the usual care group; relative risk of remission was 5.5 (95% CI $2.2, 14.0$). Remission of diabetes was defined as fasting plasma glucose levels less than 126 mg/dL and HbA1c less than 6.2 percent without the use of oral hypoglycemic or insulin. Eighty percent of surgery patients had HbA1c <6.2 percent at 24 months compared with 20 percent of conventional therapy group ($p<0.001$). Resolution of type 2 diabetes was related to weight loss and lower baseline HbA1c levels.

Table 3. RCTs with comparison nonsurgical arms

Author/ Study Type	Procedure/ # Patients	Weight Outcomes at 12 Months		Diabetes and Metabolic Syndrome Outcomes at 12 Months				
		Weight Change, kg (SD)	BMI at 12 mo	Fasting Blood Glucose Change, mg/dL (SD)	HbA1c, % (SD)	HbA1c <6.0% at 12 mo	Average # Diabetes Meds, at 12 mo,	Diabetes Remission*, % at 12 mo [Change]
Schauer ³⁷ RCT	Medical therapy +RYGB (n=50) Medical therapy + GS (n =50) Medical therapy alone (n=50)	-29.4 (9.0) -25. (8.5) -5.4 (8.0) p<0.0001 [†]	26.5 27.2 34.4 p<0.001 [†]	99 97 120 p<=0.002 [†]	6.4 (0.9) 6.6 (1.0) 7.5 (1.8) p<=0.003 [†]	42% 37% 12% p<=0.002 [†]	0.3 0.9 3.0 p<0.001 [†]	
Author/ Study Type	Procedure/ # Patients	Weight Outcomes at 24 mo		Diabetes and Metabolic Syndrome Outcomes at 24 mo				
		Weight Change, kg (SD)	BMI at 24 mo [95% CI]	Fasting Blood Glucose change, mg/dL (SD)				Metabolic Syndrome, % at 24 mo, [change]
O'Brien ⁴⁰ RCT	LAGB (n=40) Medical Care (n=40) Betw grp comparison Baseline BMI = 33.5 (SD =1.4)	-20.5, (6.4) -6.1, (8.5) 95% CI [-18.9, -11.6]	26.4 [25.6, 27.2] 31.5, [30.6, 32.4] p<0.001	-7.3 (15.2) 0.35 (8.3) 95% CI [-13, -0.7]	---	---	---	2.7, [-35] 24, [-12] p=.0006
		Weight Change, kg (SD)	BMI at 24 mo [Change]	Fasting Blood Glucose Change, mg/dL (SD)	HbA1c, % Change, (SD)	HbA1c <6.2% at 24 mo	Taking DM Meds, % at 24 mo, [Change]	Diabetes Remission, % at 24 mo* [Change]
Dixon ⁴² RCT	LAGB (n=30) Conventional (n=30) Betw grp comparison Baseline BMI = 37.0 (SD = 2.7)	-21.1 (10.5) -1.5 (5.4) -19.6 [23.8,15.2] p<0.001	29.6, [-7.4] 36.7, [-0.5] p<0.001	-51.2, (37.2) -18.4, (41.2) -32.8 [-53.1, -12.3] p=0.002	-1.81, (1.24) -0.38, (1.26) -1.43 [-2.1, - 0.80] p<0.001	80% 20% p<0.001	13.3, [-79.7] 73.3, [-13.4] p<0.001	73 [-73] 13 [-13] p<0.001

betw = between; BMI = body mass index; CI = confidence interval; DM = diabetes mellitus; grp = group; LAGB = laparoscopic adjustable gastric banding; meds = medications; mo = months; RCT = randomized controlled trial; RYGB = Roux-en-Y gastric bypass; SD = standard deviation

*Diabetes remission defined as fasting blood glucose <126mg/dL, HbA1c <6.2% without the use of insulin or oral hypoglycemics.

[†]Medical treatment compared with each surgical group.

Note: n=33 in the Medical Care Group.

Head-to-Head Trials of Surgical Procedures

We identified two RCTs comparing surgical procedures in our target population (Table 4). Lee³⁴ randomized 60 diabetic patients in Taiwan to RYGB or SG. Baseline demographics and clinical characteristics (mean BMI=30.3 kg/m²) were similar between the groups. At 12 months followup the RYGB group had lost more weight: BMI was 22.8 kg/m² for RYGB, compared with 24.4 kg/m² for SG (p=0.009). Diabetes outcomes were also better in the RYGB group with 93 percent remission compared with 47 percent in SG group (p=0.02). Diabetes type 2 remission was defined as fasting plasma glucose levels less than 126 mg/dL and HbA1c values less than 6.5 percent without the use of oral hypoglycemics or insulin. HbA1c decreased by 4.2 percentage points in the RYGB versus 3.0 percentage points in the SG patients (p<0.05). Fasting glucose was lower in the RYGB patients compared with SG (99.3 versus 140.1; p<0.001). Total cholesterol level, triglycerides, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol improved in both groups but to a greater degree in the RYGB patients. A composite measure of diabetes improvement (HbA1c<7 percent, LDL<100 mg/dL, and triglycerides<150 mg/dL) revealed greater improvement in the RYGB group (57 percent versus 0 percent; p<0.001). Complication rates were similar between groups and were minor. Operative time and hospital stay were no different.

Schauer randomized 150 U.S. patients to either RYGB, SG, or intensive medical therapy alone (discussed earlier). The surgical groups also received the same intensive medical therapy. Patients' baseline characteristics were similar. Mean BMI was 37.0 ± 3.3 for the RYGB group, compared with 36.2 ± 3.9 for the gastric sleeve group. At 12 month followup, the bypass group had lost significantly more weight (p=.02) and had a slightly lower mean BMI (26.8 vs. 27.2). Changes in blood glucose were similar; however, all patients in the bypass group who achieved a pre-determined target glycated hemoglobin level (6 percent) did so without medications, while 28 percent in the sleeve group required medications to reach this level.

Changes in blood pressure and cholesterol did not differ significantly by surgical group.

Table 4. RCT with comparison surgical arms – Outcomes at one year

Author/ Study Type	Procedure/ # Patients	Weight Change (%)	BMI, kg/m ² (SD)	Fasting Blood Glucose Mean, mg/dL (SD)	HbA1c %, Mean (SD)	Metabolic Syndrome No (%)	Successful Treatment Diabetes, [†] No (%)	Diabetes Remission, [‡] No (%)
Lee ³⁴ RCT	Roux-en-Y gastric bypass (n=30)	-23.3	22.8 (2.2)	99.3 (19.4)	5.7 (0.5)	2 (6.6)	17 (57)	28 (93)
	Sleeve gastrectomy (n=30)	-19.9	24.4 (2.4)	140.1 (53.0)	7.2 (1.5)	18 (60.0)	0 (0)	14 (47)
	Betw grp comparison*	p=0.02	p=0.009	p<0.001	p<0.001	p<0.001	p<0.001	p=0.02
Schauer ³⁷ RCT	Roux-en-Y gastric bypass (n=50)	-27.6	26.8	99.0	6.4 (0.9)	N/A	21 (42)	21 (42)
	Sleeve gastrectomy (n=49)	-25.0	27.2	97.0	6.6 (1.0)	N/A	18 (37)	13 (27)
	Betw grp comparison*	p=.02 [§]	p=.03 [§]	p=.86	p=.23	N/A	p=.59	p=.10

BMI = body mass index; btw = between; grp = group; LDL-C = low-density lipoprotein cholesterol; N/A = not applicable; No = number; RCT = randomized clinical trial; SD = standard deviation

*Between group comparisons are mean difference and 95% CI.

[†]Successful treatment of diabetes mellitus (HbA1c <7%, LDL-C <100 mg/dL, and triglycerides <150 mg/dL in Lee; HbA1c ≤ 6 percent in Schauer).

[‡]Remission defined as fasting plasma glucose levels less than 126 mg/dL and HbA1c values less than 6.5% without the use of oral hypoglycemics or insulin in Lee; HbA1c values ≤ 6 percent without use of oral hypoglycemic or insulin in Schauer.

[§] p for mean change from baseline.

Observational Studies With Surgical Procedure Comparisons

One cohort study compared RYGB with LAGB. Demaria²⁸ accessed a large retrospective database of patients operated on in the United States from 2005 to 2007 (n=66,264) and identified 235 who met the lower weight criteria (BMI ≥30 and <35 kg/m²). 109 patients underwent RYGB, the same number had had laparoscopic adjustable gastric band. (The remaining 17 underwent other procedures.) The study methods did not comment on the rationale of procedure choice for patients, but groups did not differ by baseline weight (33.7 kg/m² versus 33.9 kg/m²), gender, race, or age. Followup was 61.9 percent and 69.2 percent at 6-12 months for RYGB and laparoscopic adjustable gastric band patients, respectively. At 6-12 months, RYGB patients lost more weight than those undergoing laparoscopic adjustable gastric band (6-12 months: BMI 27.1 kg/m² and 30.9 kg/m²; p=0.0002). RYGB achieved better diabetes control for all time intervals as the number of patients off diabetes medications (at 6-12 months: 55.2 percent versus 27.2 percent; p=.0199), with the exception of the latest followup at 12-24 months (but only 4 RYGB and 11 LAGB patients were followed up at that time interval). For patients with diabetes controlled with oral medications, 60.9 percent and 38.5 percent, for RYGB and laparoscopic adjustable gastric band, respectively, were able to stop their diabetes medications within 3-6 months. For patients on insulin and oral medications, 50 percent and 11.1 percent,

respectively, were able to stop their medications. Complications, while minor, occurred more commonly in the RYGB group (18 percent versus three percent, $p < 0.05$).

One small study conducted in Germany compared results for twelve BPD patients with the results for four RYGB patients.³² Both groups lost a significant amount of weight. At one year, decrease in HbA1c in the RYGB group was significantly greater than in the BPD group.

Small Cohorts: Surgery Versus Nonsurgical Interventions

We found two small cohort studies matching data from surgical patients with data from similar patients who did not have bariatric surgery. One small study by Chiellini⁴⁸ compared patients undergoing BPD ($n=5$) with those managed by diet ($n=7$). The study did not specify what variables the patients were matched on and only one month followup was reported. In this very short-term followup, HbA1c and weight were significantly lower in both groups. The BPD group did see a significant decrease in the blood glucose (at 2 hr) during an oral glucose tolerance test, whereas the diet arm did not.

Serrot³⁸ retrospectively compared data for 17 diabetic patients who underwent RYGB with 17 matched patients on routine medical management for diabetes / weight control. The nonsurgical group received counseling regarding diet, physical activity, and weight management. At one year, BMI did not change significantly in the routine management group, but decreased significantly from 34.6 kg/m^2 to 25.8 kg/m^2 in the RYGB group. HbA1c decreased significantly from a mean 8.2 percent at baseline to 6.1 percent at one year in the RYGB group, but did not change significantly in the comparison group. Systolic blood pressure and LDL cholesterol did not change significantly in either group; however, 41% of the RYGB group ceased use of antihypertension medications and 35% ceased use of antihyperlipidemia medications despite lack of clinically meaningful improvement on these outcomes.

Observational Studies—Diabetes Outcomes

Tables 5 and 6 display data from the observational studies. Table 5 presents data for the studies where all patients entering had type 2 diabetes or IGT; Table 6 displays the remaining handful of studies where only a portion of patients had these metabolic conditions. The tables are organized by outcome, surgery type, and followup time. Each table displays BMI, HbA1c, fasting glucose, percentage of patients off diabetes medication, and percentage of diabetes patients in remission, at three post-surgery intervals: 0 to 3 months, 6 to 11 months, and 12 months or more. Unlike RCTs, which try to measure outcomes at exact followup times, in these observational studies patient outcomes are measured at a wide range of times, depending on availability / convenience. Thus, we also include a column displaying the exact range of followup points included.

BMI

At up to three months followup, mean decrease in BMI ranged from 2.3 kg/m^2 in one study of LABG to 4.4 kg/m^2 in three studies of RYGB. Between six and 11 months followup, BMI decrease continued. Decreases were similar for BPD (5.2 kg/m^2), sleeve (5.3 kg/m^2) and RYGB (5.4 kg/m^2). The one LABG study that reported BMI during this time showed a decrease of 6.8 kg/m^2 (in contrast, this study reported a mean decrease of 4.0 kg/m^2 from baseline to 12 months.) At 12 to 24 months, mean BMI decrease was 5.6 kg/m^2 for BPD, 6.4 kg/m^2 for SG, and 7.9 kg/m^2 for RYGB.

Blood Glucose

Metabolic improvements after surgery were reported various ways including changes in HbA1c and plasma glucose, percentage of patients who no longer required diabetes medication, and remission or resolution of diabetes. There were six surgery arms reporting change in HbA1c at six to 11 months. Baseline HbA1c values were quite high ranging from 9.3 percent for BPD to 10.0 percent for SG. Considerable decreases were reported after surgery, with a mean drop of 2.9 percentage points for BPD, 2.6 percentage points for sleeve and 3.7 percentage points for RYGB. Unfortunately, none of the observational studies of LAGB reported HbA1c outcomes. Studies that reported HbA1c at one year or more also reported clinically significant improvement. RYGB patients had a mean decrease of 2.4 percentage points, compared with 3.1 percentage points for SG and 3.1 percent points for BPD patients.

Studies also reported clinically significant improvements in plasma glucose levels. Many patients were hyperglycemic preoperatively. In studies reporting results at six to 11 months, baseline levels ranged from 203.3 mg/dL for RYGB patients to 220.0 mg/dL for sleeve. These studies reported decreases in plasma glucose of 68.0 mg/dL for BPD to 102.0 mg/dL in the one sleeve study. Studies with followup of at least one year reported decreases in plasma glucose ranging from 62.6 mg/dL in one sleeve study to 92.4 mg/dL for BPD. At this time point, most surgical patients were euglycemic.

Medication Needs

A few studies reported the percentage of patients who no longer required diabetes medication after surgery. The majority of these studies regularly measured and reported corresponding data on HbA1c, fasting glucose, C-Peptide, etc. One LAGB study (Parikh, 2006⁴¹) reported only the data regarding medication use, making it impossible to confirm whether discontinuation was appropriate; all eight diabetic patients discontinued medication.⁴¹ At three months or less, two RYGB studies reported that 46.6 percent of their patients no longer needed diabetes medication, compared with 21.1 percent of patients in one LABG study. Two RYGB studies reported that 70.5 percent of patients no longer required medication at six to 11 months after surgery compared with 27.5 percent in an LABG study and 30.0 percent in a BPD study. At 12 months, the LABG study reported 36.4 percent of patients discontinued medications. At 24 months, a BPD study of seven patients reported that all had discontinued medications. Three RYBG studies reported a mean 87.2 percent of patients had discontinued diabetes medications between 12 to 20 months. At 12 to 24 months followup, discontinuation rate was 87.2 percent in three RYGB studies.

Remission/Resolution

Eight studies reported at 12 months or more. Definitions of remission and resolution varied; however, all these studies monitored metabolic data regularly. 87.2 percent of RYGB patients in six studies had resolved their diabetes, along with half of SG patients in one study and 83.5 percent of BPD patients in one study.

Table 5. Bariatric surgery results—by surgery type, studies of only diabetes or IGT patients

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
BMI	0-3m	0-3m*	3	RYGB	201	32.1	1.2	163	27.7	2.3	-4.4
BMI	0-3m	0-3m*	1	LABG	109	33.9		90	31.6		-2.3
BMI	0-3m	3m	1	Sleeve	30	30.3		30	26.0		-4.3
BMI	0-3m	1m	1 [‡]	BPD	30	30.6	2.5	30	26.7	2.4	-3.9
HbA1c	0-3m	3m	3	RYGB	107	9.8	0.1	90	6.3	0.4	-3.5
HbA1c	0-3m			LABG							
HbA1c	0-3m	3m	1	Sleeve	30	10.0		30	7.8		-2.2
HbA1c	0-3m	1m	1 [‡]	BPD	30	9.3	0.2	30	7.3	0.0	-2.0
Glucose	0-3m	3m	2	RYGB	77	203.0	14.7	60	115.5	1.9	-89.6
Glucose	0-3m			LABG							
Glucose	0-3m			Sleeve							
Glucose	0-3m	1m	1 [‡]	BPD	30	220.0	14.0	30	165.0	11.0	-55.0
% on Diabetes Meds	0-3m	0-3m*	2	RYGB	124	100.0	0.0	103	53.4	22.0	-46.6
% on Diabetes Meds	0-3m	0-3m*	1	LABG	109	100.0		90	78.9		-21.1
% on Diabetes Meds	0-3m			Sleeve							
% on Diabetes Meds	0-3m										
Diabetes Remission/Resolution	0-3m			RYGB							
Diabetes Remission/Resolution	0-3m			LABG							
Diabetes Remission/Resolution	0-3m			Sleeve							
Diabetes Remission/Resolution	0-3m			BPD							
BMI	6-11m	6-<12m*	5	RYGB	124	31.8	0.9	44	25.5	1.4	-5.4
BMI	6-11m	6-<12m*	1	LABG	109	33.9		40	27.1		-6.8
BMI	6-11m	6	1	Sleeve	30	30.3		30	25.0		-5.3
BMI	6-11m	8m	2 [‡]	BPD	40	31.3	1.7	40	26.1	1.0	-5.2
HbA1c	6-11m	6-9m	4	RYGB	129	9.7	0.1	107	5.9	0.1	-3.7

Table 5. Bariatric surgery results—by surgery type, studies of only diabetes or IGT patients (continued)

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
HbA1c	6-11m		0	LABG							
HbA1c	6-11m	6m	1	Sleeve	30	10.0		30	7.4		-2.6
HbA1c	6-11m	6m	1 [‡]	BPD	30	9.3	0.2	30	6.4	0.5	-2.9
Glucose	6-11m	6-9m	3	RYGB	99	203.3	9.2	77	103.4	5.9	-102.0
Glucose	6-11m		0	LABG							
Glucose	6-11m			Sleeve							
Glucose	6-11m	8m	1 [‡]	BPD	30	220.0	14.0	30	152.0	19.0	-68.0
% on Diabetes Meds	6-11m	6-<12m*	2	RYGB	124	100.0	0.0	44	29.5	21.2	-70.5
% on Diabetes Meds	6-11m	6-<12m*	1	LABG	109	100.0		40	72.5		-27.5
% on Diabetes Meds	6-11m			Sleeve							
% on Diabetes Meds	6-11m	8m	1	BPD	10	40.0		10	10.0		-30.0
Diabetes Remission/Resolution	6-11m	6m	1	RYGB				37	97.3		
Diabetes Remission/Resolution	6-11m		0	LABG							
Diabetes Remission/Resolution	6-11m		1	Sleeve							
Diabetes Remission/Resolution	6-11m		0	BPD							
BMI [†]	12-24m	12-24m	8	RYGB	315	32.2	0.6	168	23.9	0.5	-7.9
BMI	12-24m	>12m*	1	LABG	109	33.9		11	29.9		-4.0
BMI	12-24m	12-13m	2	Sleeve	42	31.9	2.5	42	25.5	1.7	-6.4
BMI	12-24m	12-24m	4 [‡]	BPD	54	31.3	1.1	54	25.7	0.6	-5.6
HbA1c [†]	12-24m	12-24m	9	RYGB	433	8.6	0.3	275	5.9	0.1	-2.4
HbA1c	12-24m		0	LABG							
HbA1c	12-24m	12-13m	2	Sleeve	42	9.2	1.3	42	6.3	1.4	-2.9
HbA1c	12-24m	12-24m	3 [‡]	BPD	47	9.1	0.2	47	6.0	0.4	-3.1
Glucose	12-24m	12-24m	5	RYGB	192	178.2	10.0	150	94.0	3.6	-79.3
Glucose	12-24m		0	LABG							
Glucose	12-24m	12-13m	1	Sleeve	12	150.6		12	88.0		-62.6
Glucose	12-24m	24m	2 [‡]	BPD	37	226.2	12.8	37	133.9	16.1	-92.4

Table 5. Bariatric surgery results—by surgery type, studies of only diabetes or IGT patients (continued)

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
% on Diabetes Meds	12-24m	12-20m	3	RYGB	293	100.0	0.0	188	12.8	4.6	-87.2
% on Diabetes Meds	12-24m	12m*	1	LAGB	109	100.0		11	63.6		-36.4
% on Diabetes Meds	12-24m		0	Sleeve							
% on Diabetes Meds	12-24m	24m	1	BPD	7	71.4		7	0.0		-71.4
Diabetes Remission/Resolution	12-24m	12-20m	6	RYGB				323	77.7	5.3	
Diabetes Remission/Resolution	12-24m		0	LAGB							
Diabetes Remission/Resolution	12-24m	12m	1	Sleeve				30	46.7		
Diabetes Remission/Resolution	12-24m	12m	1 [‡]	BPD				30	83.5	16.5	

BL= baseline; BMI = body mass index; BPD = biliopancreatic diversion; chg = change; F-up = followup; IGT = impaired glucose tolerance; IQR = inter-quartile range; LAGB = laparoscopic adjustable gastric banding; m = month; meds = medications; N = sample size; RYGB = Roux-en-Y gastric bypass; SE = standard error ; Sleeve = sleeve gastrectomy

*DeMaria et al. 2010²⁸ reported results as 0-3m, 3-6m, 6-12m,12-24m. The range 6-12m was reported in the 6-11m category, 12-24m was reported in the >=12mth category.

†Serrot, 2011 (6027) only reported median and IQR. Median value used instead of mean for summary calculations.

‡Scopinaro et al. 2001⁴⁹ reports data for obese and overweight patients separately, both subgroups contribute to this analysis but it is only counted as 1 study/article.

Table 6. Bariatric surgery results—by surgery type, studies with less than 100% diabetes or IGT patients

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
BMI	6-11m		0	RYGB							
BMI	6-11m	6m	2	LABG	263	33.74	0.32	244	30.68	1.04	-3.11
BMI	6-11m		0	Sleeve							
BMI	6-11m		0	BPD							
HbA1c	6-11m		0	RYGB							
HbA1c	6-11m		0	LABG							
HbA1c	6-11m		0	Sleeve							
HbA1c	6-11m		0	BPD							
Glucose	6-11m		0	RYGB							
Glucose	6-11m		0	LABG							
Glucose	6-11m		0	Sleeve							
Glucose	6-11m		0	BPD							
% on Diabetes Meds	6-11m		0	RYGB							
% on Diabetes Meds	6-11m		0	LABG							
% on Diabetes Meds	6-11m		0	Sleeve							
% on Diabetes Meds	6-11m		0	BPD							
Diabetes Remission/Resolution	6-11m		0	RYGB							
Diabetes Remission/Resolution	6-11m	6m	1	LABG				210	100.00		
Diabetes Remission/Resolution	6-11m		0	Sleeve							
Diabetes Remission/Resolution	6-11m		0	BPD							

Table 6. Bariatric surgery results—by surgery type, studies with less than 100% diabetes or IGT patients (continued)

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
BMI	12-24m		0	RYGB							
BMI	12-24m	24m	3	LABG	356	33.47	0.38	302	28.09	0.68	-5.47
BMI	12-24m	12m	1	Sleeve	9	33.60		9	23.40		-10.20
BMI	12-24m		0	BPD							
HbA1c	12-24m		0	RYGB							
HbA1c	12-24m		0	LABG							
HbA1c	12-24m		0	Sleeve							
HbA1c	12-24m		0	BPD							
Glucose	12-24m		0	RYGB							
Glucose	12-24m		0	LABG							
Glucose	12-24m	12m	1	Sleeve	9	99.20		9	76.00		-23.20
Glucose	12-24m		0	BPD							
% on Diabetes Meds	12-24m		0	RYGB							
% on Diabetes Meds	12-24m		0	LABG							
% on Diabetes Meds	12-24m		0	Sleeve							
% on Diabetes Meds	12-24m		0	BPD							
Diabetes Remission/Resolution	12-24m		0	RYGB							
Diabetes Remission/Resolution	12-24m	12m	1	LABG				66	33.33		
Diabetes Remission/Resolution	12-24m		0	Sleeve							
Diabetes Remission/Resolution	12-24m		0	BPD							

Table 6. Bariatric surgery results—by surgery type, studies with less than 100% diabetes or IGT patients (continued)

Outcome	F-Up	F-Up Range	# Studies	Surg Type	BL (N)	BL Mean (%)	BL (SE)	F-Up (N)	F-Up Mean (%)	F-Up (SE)	Mean Chg
BMI*	36m		2	LAGB	303	33.53	0.55	277	26.85	0.26	-6.76
BMI*	48m		1	LAGB	210	33.90		210	27.90		-6.00
BMI*	60m		1	LAGB	210	33.90		210	28.20		-5.70
% on Diabetes Meds*	36m		1	LAGB	93	8.60		67	0		-8.60

BL= baseline; BMI = body mass index; BPD = biliopancreatic diversion with duodenal switch; chg = change; F-up = followup; IGT = impaired glucose tolerance; LAGB = laparoscopic adjustable gastric banding; m = month; meds = medications;

N = sample size; RYGB = Roux-en-Y gastric bypass; SE = standard error ; Sleeve = sleeve gastrectomy

*Angrisani et al. 2004³⁹ has BMI data for 36m-60m, Parikh et al. 2006⁴¹ has BMI data at 36m and % off diabetes meds at 36m.

Observational Studies – Other Health Outcomes

Blood Pressure

Eight surgery studies reported blood pressure outcomes; measures reported included percent of patients with hypertension, percent able to discontinue blood pressure medication, and mean systolic and diastolic blood pressure. One study (primarily of non-diabetics) followed patients for 12 months after undergoing LAGB and found that the percentage of patients with hypertension decreased from 4.3 percent to 0.5 percent.³⁹ Another reported that hypertension improved or resolved in 28.6 percent of patients, 18 months after receiving LAGB.⁴⁴ Two LAGB studies reported the number who no longer required antihypertensive medications; one found that 75 percent were able to discontinue 24 months after surgery, while another found that 46 percent were able to 36 months post-op.^{41,43} Unfortunately, these two studies did not report corresponding systolic or diastolic blood pressure data. Four RYGB studies reported blood pressure outcomes. One reported that 41 percent of patients were off hypertension medications at one year; however, they did not report baseline percentage taking the medications. Mean systolic blood pressure in this RYGB group actually increased from 126.0 at baseline to 132.0 at one year.³⁸ Another RYGB study³⁰ reported hypertension resolved in 46.7 percent of patients at one year; however diastolic and systolic blood pressure data were not reported. Another RYGB study²⁹ reported a mean 11 point drop in systolic blood pressure at six months. One study⁵⁰ reported a mean decrease of 9 mmHg in diastolic and 11 mmHg in systolic blood pressure at six months.

Cholesterol and Triglycerides

Cholesterol and triglyceride outcomes were reported inconsistently. One small BPD study followed seven patients at one, two, three, and five years⁴⁷ and reported that none had hypercholesterolemia or high triglycerides at any followup. Baseline mean triglycerides were 311.6 mg/dL in this study. Another study of 10 BPD patients reported a mean decrease of 106.3 mg/dL in total cholesterol at followup of two to 18 months. One LAGB study⁴³ reported that 33.3% of patients no longer needed cholesterol medications at two years but gave no other details on this outcome. Lembach⁴⁵ reported SG results separately for patients with diabetes versus impaired glucose tolerance (IGT) at one year post-surgery. Triglycerides decreased 69 mg/dL and 76 mg/dL respectively.

Five RYGB studies^{26,27,29,37,38} reported on cholesterol. Decreases in LDL ranged from only 3 mg/dL to 53.8 mg/dL at one year. Two studies reported change in total cholesterol. Shah²⁹ reported a decrease of 40 mg/dL at nine months, while Cohen²⁶ reported a decrease of 80 mg/dL at 20 months.

GERD and Sleep Apnea

A few studies reported on gastroesophageal reflux disease (GERD) and obstructive sleep apnea (OSA); these studies included a small subset of patients who had preoperative GERD or OSA who underwent LAGB. In one study that included five patients with preoperative GERD, all had complete resolution at one year after surgery.³⁹ In a slightly larger study that included 22 patients with preoperative GERD, only 31.3 percent experienced improvement or resolution at one year after LAGB.⁴⁴ Neither study detailed the exact methods of diagnosing resolution of GERD. Of the three studies that reported on OSA, one study found that half of the 19 patients had complete resolution (defined as discontinuation of continuous positive airway pressure

[CPAP] mask use) at two years after LAGB and an additional 30 percent had improvement (decreased CPAP use).⁴³ In another study that included seven patients with preoperative OSA, six had OSA resolution (did not require CPAP use) by three years after LAGB.⁴¹ In a third study, only three of nine patients with OSA had improvement or resolution at one year (definition of improvement or resolution not specified).⁴⁴

Systematic Reviews on Behavioral Interventions

The effects of interventions such as exercise, diet, and health education on weight loss and diabetes outcomes have been studied for decades. Thus, the primary literature on these topics is extensive. In such cases we attempt to find existing reviews.⁵¹ We identified six fair to excellent quality systematic reviews; four focused on adults with pre-existing diabetes while the other two focused on diabetes prevention in adults with impaired glucose tolerance. Details on the reviews are displayed in Table 7.

Pooling 22 RCTs with a total of 4,659 participants and a followup interval of 1 to 5 years, Norris and colleagues⁵² assessed the effectiveness of lifestyle and behavioral interventions on weight loss or weight control among adults with type 2 diabetes (mean BMI = 33.2kg/m², mean duration of diabetes = 6.5 years). Interventions examined included physical activity, low calorie diet, and behavioral interventions such as self-monitoring blood glucose and spousal involvement in education. Comparisons of three groups of studies were conducted: any intervention versus usual care, very low-calorie diet versus low-calorie diet, and physical activity versus no or less intensive physical activity. The pooled weight loss for intervention group (any intervention) in comparison with usual care was 1.7 kg at 1 and 2 years of followup, and the pooled weight loss for very low-calorie diets in comparison with low-calorie diets was 3.0 kg at 72 and 104 weeks of followup. Among those who received identical dietary and behavioral interventions, the pooled weight loss for intensive physical activity in comparison with no or less physical activity was 3.9 kg. Of the six intervention types (including usual care and different combinations of interventions), all interventions were associated with significant weight loss, but a very low-calorie diet combined with physical activity and behavioral therapy produced the largest weight loss effect. However, changes in glycated hemoglobin level were not significant.

Kirk and colleagues (2008) evaluated 13 studies (including nine RCTs) that examined effects of carbohydrate-restricted diets in type 2 diabetes patients (mean weight = 77 to 132 kg, mean HbA1c = 6.9 – 9.8) in North America.⁵³ Seven outcomes were reported: weight, fasting glucose, HbA1c, total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides. At 3 to 26 weeks followup, weight loss after carbohydrate-restricted diets ranged from 0.5 to 8.7 kg, representing 0.5 percent to 7.5 percent changes from baseline; decrease in HbA1c ranged from 0.2 to 2.2, representing 2.9 percent to 22.4 percent changes from baseline; and reduction in fasting glucose ranged from 1.8 to 83.0, representing 1.3 percent to 36.6 percent changes from baseline. They also found a greater mean reduction in fasting glucose and HbA1c in the lower-carbohydrate diet phase compared with the higher-carbohydrate diet phase. While triglyceride reductions were observed in both lower- and higher-carbohydrate phases, an especially strong relationship was found in the lower-carbohydrate phase. No significant relationships were found for the three cholesterol outcomes.

Dyson, 2008⁵⁴ reviewed 6 studies (including one RCT) that examined short-term effect and associated risks of low and reduced carbohydrate diets in type 2 diabetes patients (mean BMI = 28.5 to 42.2kg/m², mean HbA1c = 7.3 to 9.7). Meta-analysis was not conducted due to heterogeneity of the studies. Sample size ranged from 10 to 206; only two studies had sample size over 100). Short-term effects (followup duration n= 14 days – 22 months but only two

studies with data beyond six months) were reported and carbohydrate levels ranged from <20g/day to 95g/day. All studies reported reductions in body weight and glycated hemoglobin: reductions in body weight ranged from 1.2 to 11.4 kg, reductions in BMI ranged from 0.4 to 4.1 kg/m², and reductions in HbA1c ranged from 0.5 to 1.7 points. A few studies also recorded either reduction or discontinuation of glucose-lowering medications such as metformin and thiazolidinediones.

Kodama and colleagues⁵⁵ conducted a meta-analysis to assess the influence of fat and carbohydrate proportions on glucose and lipid parameters in type 2 diabetes patients. Pooling 22 trials with a total of 306 participants (mean BMI = 22.7 to 33.1 kg/m², diabetes duration = 5 to 8 years) and an intervention period of 1.4 to 12 weeks, the study compared the effects of a low-fat high-carbohydrate (LFHC) diet with a high-fat low-carbohydrate (HFLC) diet. While no significant differences in the reduction in HbA1c, total cholesterol, and LDL cholesterol were found between the LFHC and HFLC diets, LFHC diet led to significant increases in fasting insulin (8.4 percent, with marked elevations observed when the carbohydrate/fat ratio ≥ 3) and triglycerides levels (13.4 percent), and a significant reduction in HDL cholesterol (6 percent). They also found significant positive relationships among the change in fasting plasma glucose, fasting insulin, and triglycerides. They concluded that replacing fat with carbohydrate have negative implications for diabetes patients.

Norris and colleagues⁵⁶ examined the effects of weight-loss interventions in 9 RCTs consisting a total of 5,168 overweight or obese participants (mean BMI = 25.8 to 34.0 kg/m², mean glycated hemoglobin (GHb) = 5.7 to 5.9) with pre-diabetes (impaired fasting glucose or impaired glucose tolerance). Most of the studies reported long-term data, with followup durations ranging from 1 to 10 years. Weight-loss strategies included diet, physical activity, and behavioral interventions, while comparison group interventions consisted of usual care or general information and counseling. Compared with usual care, these weight-loss interventions led to 2.8 kg weight loss at one year (representing 3.3 percent of baseline body weight) and 2.7 kg at two years; reduction in BMI was 1.4 kg/m² at 1 year. The most notable mean weight change was observed in the lifestyle intervention of the DPP (Diabetes Prevention Program) study, which had the largest study population. It reported a mean weight loss of 5.5 kg at an average followup of 2.8 years. A few studies reported small decreases in systolic and diastolic blood pressure, minor improvements in lipids, and 0.0 to 0.2 decreases in GHb. Three large trials also demonstrated a significant lower cumulative incidence of diabetes in the intervention versus control groups, at three to six years followup.

Gillies and colleagues⁵⁷ also reviewed studies that evaluated interventions to delay or prevent type 2 diabetes among patients with impaired glucose tolerance. Behavioral interventions included diet and exercise; pharmacological/herbal interventions included acarbose, flumamine, glipizide, metformin, phenformin, orlistat, and herbal jiangtang busheng. They identified 21 RCTs and conducted a meta-analysis using 17 RCTs with a total of 8,084 participants (mean BMI = 23.8 to 37.3 kg/m², baseline risk of type 2 diabetes = 2.6 to 30.0 cases per 100 person years). They found high strength of evidence in favor of interventions compared with controls, the pooled effects (in terms of hazard ratios) were 0.51 for overall behavioral interventions (corresponding to a relative 49 percent reduction in risk of developing diabetes), 0.67 for diet, 0.49 for exercise, 0.49 for diet and exercise combined, 0.70 for oral diabetes drugs, 0.44 for orlistat, and 0.32 for the herbal Jiangtang busheng recipe. All except for the herbal Jiangtang busheng recipe were statistically significant. The authors concluded that behavioral interventions were at least as effective as pharmacological interventions.

In sum, compared with surgical options, the effects of nonsurgical weight loss or weight control strategies among type 2 diabetes patients have been widely investigated. Evidence has shown that exercise, diet, lifestyle, and behavioral interventions are associated with significant weight loss and improved blood sugar outcomes (e.g., decreasing HbA1c or fasting glucose) among adult patients with pre-existing type 2 diabetes. Evidence is stronger for the weight loss effect, compared with the diabetes improvement effect, and more intensive and sustained interventions seem more effective. These findings were consistent with those found in non-diabetic but high-risk population with impaired glucose tolerance or impaired fasting glucose. Among those patients, nonsurgical interventions were associated with reduced risk of developing diabetes in the long run. However, studies also pointed out that the magnitude of effects of nonsurgical interventions in reducing weight and improving blood sugar outcomes are often small, although statistically significant. Most of these systematic reviews reported that studies were very heterogeneous with respect to the interventions; thus the effects should be interpreted cautiously.

Table 7. Systematic reviews on nonsurgical interventions

Author / Year	Intervention	Patients	Search Through	# of Included Studies	AMSTAR	Findings
Norris, 2004 ⁵²	Exercise, diet, behavioral	Type 2 DM mean BMI = 33 range 23-38 mean HbA1C* = 10 range 7-13 Mean age = 55	August 2003	22 RCTs duration 1 year-5 years (16/22 ≤ 1.5 yr)	10	1.7 kg weight loss for all interventions pooled, vs. usual care, at 1-5 years. Physical activity + very low cal diet lost 3.0 kg more than physical activity + low cal diet (N = 126). Identical diets + more intense physical activity lost 3.9 kg more. Differences in glycated hemoglobin and fasting glucose not significant.
Kirk, 2008 ⁵³	Low carbohydrate diets	Type 2 DM Mean weight = 77 – 132 kg Mean HbA1c* = 6.9 – 9.8 North America only	April 2006	13 studies (9 RCTs) duration 3 weeks-26 weeks	6	No pooling conducted. Weight loss ranged from 0.5 to 8.7 kg from baseline at 3 to 26 weeks Decrease in HbA1c ranged from 0.3 to 2.2 points.
Dyson, 2008 ⁵⁴	Low carbohydrate diets	Type 2 DM Mean weight = 76 – 131 kg Mean BMI = 28 – 42 Mean age = 51 – 66	March 2007	6 trials (1 RCT) duration 14 days – 22 months	6	No pooling conducted. Weight loss ranged from 1.2 to 11.4 kg from baseline . Decrease in HbA1c* ranged from 0.5 to 1.4. Decrease in BMI ranged from 0.4 to 4.1 points.
Kodama, 2009 ⁵⁵	Low carbohydrate diets vs. low fat diets	Type 2 DM Mean BMI = 23 – 33 Mean age = 48 – 66 Mean % on diabetes meds = 52	2007	19 RCTs duration < 1 year	9	Low carb high cholesterol diet led to significant increases in fasting insulin and triglycerides from base, and decreases in HDL. Changes in HbA1c* were not significant.

Table 7. Systematic reviews on nonsurgical interventions (continued)

Author / Year	Intervention	Patients	Search Through	# of Included Studies	AMSTAR	Findings
Norris, 2005 ⁵⁶	Weight loss Interventions (diet, physical activity, behavioral)	Adults with IGT, BMI range 26-34 Mean BMI 28.7 Mean age 51.2 Mean GHb 5.8	August 2003	9 RCTs f/u 1 to 10 years 7 of the RCTs were diet vs. usual care/ counseling	10	Pooled results 2.8 kg weight loss at 1 year compared with usual care & decrease in BMI of 1.4; at 2 years, 2.7 kg weight loss. No pooling for GHb. Decrease in GHb ranged from 0.0 to 0.2 percentage points. 3 studies reported diabetes incidence; one reported decrease of 31% at 2.8 years.
Gillies, 2007 ⁵⁷	Treatment to delay or prevent DM (pharma, diet, exercise)	Adults with IGT Mean age ranged 38.7 to 56.7 Mean BMI ranged 23.8 to 37.3	July 2006	12 RCTs of behavioral interventions 12 RCTs of herbal/ pharmacological 4 other studies	9	Hazard ratios for progression to diabetes: 0.51 for lifestyle vs. standard advice 0.70 for oral diabetes meds vs. control 0.44 for orlistat vs. control 0.32 for herbal jiang tang bushen vs. advice

AMSTAR = measurement tool to assess the methodological quality of systematic reviews; BMI = body mass index;

DM = diabetes mellitus; GHb = glycated hemoglobin IGT = impaired glucose tolerance; RCTs = randomized controlled trials

*HbA1c measured as a percentage of total hemoglobin.

Systematic Reviews of Diabetes Medications

Four high quality systematic reviews focused on the efficacy and safety of diabetes medications in patients with type 2 diabetes. Two of the reviews^{11,58} examined incretin-based agents (exenatide, liraglutide, vildagliptin, and sitagliptin), another⁵⁹ examined oral agents (second-generation sulfonylureas, biguanides, thiazolidinediones, meglitinides, and α -glucosidase inhibitors), and one⁶⁰ examined newer agents available for blood glucose control (exenatide, sitagliptin and vildagliptin, glargine and detemir, and thiazolidinediones). These reviews provide evidence that most blood glucose control medications are effective in glycemic control; some of them also lead to weight loss. However, clinical data such as effects on all-cause and cardiovascular mortality are limited. Results are summarized in Table 8.

Fakhoury and colleagues⁵⁸ conducted a systematic review and a meta-analysis to compare incretin-based agents with placebo. They identified 38 RCTs directly comparing either exenatide and liraglutide, which are GLP-1R agonists, or the dipeptidyl / peptidase-4 (DPP-4) inhibitors, vildagliptin and sitagliptin with placebo. Mean baseline HbA1c of participants included in the study ranged from 6.7 to 9.4 percent, mean duration of diabetes from 1.7 to 9.0 years, and mean baseline weight from 61.5 to 104.0 kg. Duration of trials ranged from 4 to 52 weeks. While all incretin-based agents significantly reduced HbA1c level in comparison with placebo (weighted mean difference [WMD]= -0.79 percentage points, -0.75, and -0.67 percentage points for sitagliptin, exenatide, and vildagliptin, respectively), liraglutide was found to produce the greatest reduction (WMD= - 1.03 percentage points) although this value was not statistically different from the other incretin-based drugs. A statistically significant weight gain was found in vildagliptin and sitagliptin groups, while a statistically significant weight reduction was found in the exenatide and liraglutide groups, especially in the exenatide group. Participants in sitagliptin and exenatide groups were more likely to experience some hypoglycemia compared with participants in the placebo group. The authors concluded that incretin-based agents produced beneficial effect on glycemic control, and that exenatide and liraglutide also led to weight loss. A

new meta-analysis on these two GLP-1R agonists was published recently.¹¹ RCTs comparing exenatide or liraglutide with placebo, oral antidiabetic medication, or insulin were included. The authors found that patients taking these GLP-1R agonists lost a mean 2.90 kg (95% CI 2.22 kg to 3.59kg) more than patients in the control groups. Decrease in systolic blood pressure averaged 3.57 mmHg (95% CI 5.49 to 7.66) more than in the control groups, while decrease in diastolic blood pressure was also significantly greater (1.38 mmHg, 95% CI 0.73 to 2.22). Reduction in HbA1c (0.63 percentage points, 95% CI 0.80 to 0.46) was also superior in the GLP-1R agonistic groups. Gastro-intestinal adverse events including nausea, vomiting, and diarrhea were more common in the groups taking these medications.

Bolen and colleagues⁵⁹ reviewed the benefits and harms of oral agents in treating type 2 diabetes patients in the United States. Two hundred and sixteen controlled trials and cohort studies were included. No evidence was found to support the effectiveness of oral agents on major clinical end points such as all-cause mortality, cardiovascular mortality or morbidity, peripheral arterial disease, neuropathy, retinopathy, or nephropathy. However, most oral agents showed a beneficial effect on intermediate outcomes such as glycemic control: thiazolidinediones, metformin, and repaglinide decreased HbA1c level by about one percentage point; nateglinide and α -glucosidase inhibitors produced weaker reductions in HbA1c by about 0.5 percentage point. Most oral agents other than metformin were associated with one to five kg of weight gain. Different agents were associated with different adverse events: sulfonylureas and repaglinide were associated with greater risk for hypoglycemia, thiazolidinediones with greater risk for heart failure, and metformin with greater risk for gastrointestinal problems. The authors concluded that older agents such as second-generation sulfonylurea and metformin were at least as effective as other oral agents on intermediate outcomes such as glycemic control.

A group of UK researchers reviewed newer pharmacological agents⁶⁰ for blood glucose control in type 2 diabetes patients from four classes: the glucagon-like peptide-1 (GLP-1) analogue exenatide; dipeptidyl peptidase-4 (DPP-4) inhibitors sitagliptin and vildagliptin; the long-acting insulin analogues, glargine and detemir; and thiazolidinediones. While focused on cost-effectiveness and comparing newer agents with neutral protamine Hagedorn (NPH), the study found that exenatide and DPP-4 inhibitors were all clinically effective in glycemic control: in patients with inadequate control on dual oral combination therapy, adding exenatide produced a one percentage point reduction in HbA1c level; when combined with metformin, the DPP-4 inhibitors reduced HbA1c level by about 0.8 percentage point. Exenatide was found to be associated with an added benefit of weight loss. Hypoglycemia, weight gain, heart failures, fractures, and cardiovascular events were among the side effects associated with the agents.

Table 8. Systematic reviews of medications

Author / Year	Intervention	Patients	Search Through	# of Included Studies	AMSTAR	Findings
Fakhoury, 2010 ⁵⁸	Incretin-based medications: exenatide, liraglutide, vildagliptin, and sitagliptin	Type 2 DM mean weight = 61.5 - 104.0 kg mean HbA1C* = 6.7 - 9.4 Mean age = 50.9 - 62.9	July 2009	38 RCTs Duration 4 - 52 weeks	7	All agents significantly reduced HbA1c* level in comparison with placebo (pooled results of weighted mean differences: -1.03, -0.79, -0.75, -0.67 percentage points for liraglutide, sitagliptin, exenatide, and vildagliptin, respectively); weight loss associated with exenatide (WMD= -1.10).
Waugh, 2010 ⁶⁰	Exenatide, sitagliptin and vildagliptin, glargine and detemir, and thiazolidinediones	Type 2 DM mean weight/BMI/HbA1c* separately reported for each arm	April 2008	Hard to count # of included studies since reported separately for individual arms; but > 24 RCTs and 10 Systematic reviews Duration >=12 weeks	9	Exenatide and DPP-4 inhibitors were effective in glycemic control: adding exenatide produced a 1 percentage point point reduction in HbA1c* in patients with inadequate control on dual oral combination therapy; DPP-4 inhibitors + metformin reduced HbA1c by 0.8 percentage points; pioglitazone + insulin reduced HbA1c by 0.54 percentage points.
Bolen, 2007 ⁵⁹	Oral medications: second-generation sulfonylureas, biguanides, thiazolidinediones, meglitinides, and α -glucosidase inhibitors	Type 2 DM	January 2006	216 Controlled trials and cohort studies 2 Systematic reviews Duration >= 3 mo	10	Pooled result: thiazolidinediones, metformin, and repaglinide decreased HbA1c* by one percentage point; No pooling for nateglinide and α -glucosidase inhibitors: reduced HbA1c by 0.5 percentage point; No effectiveness evidence on all-cause mortality, cardiovascular mortality or morbidity, peripheral arterial disease, neuropathy, retinopathy, or nephropathy.
Visboll, 2012 ¹¹	GLP-1R agents: Exenatide, Liraglutide	Overweight or obese patients with or without Type 2 DM	May 2011	25 RCTs Duration \geq 20 weeks	9	Patients with diabetes lost a mean 2.8kg on the drugs; weight loss was greater with higher doses. Control groups included placebo, insulin, and oral diabetic medication groups. GLP-1R agonist groups had significantly greater decreases in blood pressure, cholesterol, and HbA1c than control groups. Gastro-intestinal adverse events including nausea, vomiting, and diarrhea were common in the GLP-1R agonist groups.

AMSTAR = measurement tool to assess the methodological quality of systematic reviews; BMI = body mass index;

DM = diabetes mellitus; DPP-4 = dipeptidyl peptidase-4; GLP-1R = GLP-1 Agonists; Glucagon-like peptide-1 agonists, a class of diabetes drugs targeting the incretin system; RCTs = randomized controlled trials, WMD = weighted mean difference

*HbA1C measured as percentage of total hemoglobin.

Major Trials Published After the Systematic Reviews

Since the systematic reviews discussed above were published, several long-term followups of included studies have been published. These studies assessed the long-term effects of nonsurgical interventions in China⁶¹ (behavioral intervention), Finland⁶² (behavioral), United States⁶³ (behavioral and medications), and the United Kingdom⁶⁴ (medications). Weight loss

effects that were observed during active intervention period did not always persist in the long run, while the reductions in diabetes incidence and diabetes-related end points persisted. This effect was consistent across locations. However, behavioral interventions did not lead to any significant reduction in some major clinical end points such as mortality. Pharmacological interventions reduced mortality in the long run only in the U.K. study⁶⁴. More long-term data are needed to investigate morbidity reduction effects of nonsurgical interventions.

In China, Li and colleagues⁶¹ conducted a 20-year followup study of the China Da Qing Diabetes Prevention Study (CDQDPS), which compared behavioral interventions (diet, exercise, and diet plus exercise) with a control group among adults with impaired glucose tolerance. Long-term effect on the risk of diabetes, diabetes-related macrovascular and microvascular complications, and mortality were reported. Although changes in body weight during the entire 20-year followup period did not differ significantly by intervention and control groups, participants in the intervention group had a 43 percent lower incidence of diabetes over the 20-year period, compared with those in control group. The average annual incidence of diabetes and 20-year cumulative incidence of diabetes were lower in the intervention group (7 percent annual incidence and 80 percent cumulative incidence) than those in the control group (11 percent annual incidence and 93 percent cumulative incidence). Diabetes onset was delayed an average of 3.6 years in the intervention group. However, no significant difference was observed in the rate of first cardiovascular disease (CVD) event, CVD mortality, and all-cause mortality between intervention group and control group. The authors concluded that behavioral interventions produced a long-lasting reduction in the incidence of type 2 diabetes.

Ilanne-Parikka and colleagues⁶² reported on the Finnish Diabetes Prevention Study and assessed effects of behavioral intervention on metabolic syndrome and its components. Mean BMI at baseline was 31.2, with a standard deviation of 4.6 kg/m². At mean followup of 3.9 years, they found that intensive behavioral intervention produced a significant reduction in the prevalence of metabolic syndrome (from 74.0 percent to 58.0 percent), compared with the standard care provided to the control group (from 74.0 percent to 67.7 percent). A reduction in the prevalence of abdominal obesity in the long term was also observed in intervention group (odds ratio = 0.48).

In the United States, Knowler and colleagues⁶³ conducted a 10-year followup study of the DPP and investigated the persistence of the diabetes incidence and weight loss effects of behavioral and medication interventions that were observed during the intervention period. The effect of an intensive behavioral intervention and metformin on diabetes incidence, weight loss, and cardiovascular disease risk were compared with that of placebo. During the 10-year followup period, the behavioral group lost the most weight initially, and then gradually regained weight (but still weighed less than they did at baseline), while the metformin group maintained a modest weight loss. Cumulative incidence of diabetes in the 10 years was reduced by 34 percent in the behavioral group and 18 percent in the metformin group. It remained lower in the behavioral and metformin groups than in the placebo group, although diabetes incidence during the 10-year followup did not differ significantly between groups. Diabetes onset was delayed in behavioral group and metformin group by four years and two years, respectively, compared with placebo group. The authors concluded that both behavioral and metformin interventions reduced cumulative incidence of diabetes; this effect persisted for at least 10 years.

Holman and colleagues⁶⁴ performed a 10-year followup study of the United Kingdom Prospective Diabetes Study (UKPDS), which compared effects of an intensive glucose therapy (sulfonylurea or insulin or, in overweight patients, metformin) with conventional dietary therapy. No significant difference in mean body weight had been found between groups. After one year,

between-group differences in mean glycated hemoglobin levels were lost: participants in both groups had similar improvements. However, the sulfonylurea/insulin group maintained significant reductions in relative risk for any diabetes-related end point (risk reduction 9 percent) and microvascular disease (risk reduction 24 percent) observed during the active intervention period. Overtime, the sulfonylurea/insulin intervention reduced risks for diabetes-related mortality, myocardial infarction, and all-cause mortality by 17 percent, 15 percent, and 13 percent, respectively, compared with the conventional dietary therapy. Among overweight patients, over 10 years, metformin reduced risks for any diabetes-related end point, diabetes-related mortality, myocardial infarction, and all-cause mortality by 21 percent, 30 percent, 33 percent, and 27 percent, respectively.

Three large RCTs recently published initial findings that were not included in the systematic reviews. The studies assessed nonsurgical interventions in India,⁶⁵ Spain,⁶⁶ and the U.K. Findings suggest that interventions can be effective across different ethnic populations, despite different BMI and other clinical and diabetes related characteristics.

In India, Ramachandran and colleagues⁶⁵ conducted a RCT in urban Asian Indians (mean BMI 25.8, SD 3.5 kg/m²) with persistent IGT that evaluated the effects of behavioral modifications and metformin on the development of type 2 diabetes. With a median followup duration of 30 months, they found that compared with the control group, both behavioral modification and metformin significantly reduced the cumulative incidence of diabetes at year 3 (39.3 percent, 40.5 percent, and 55.0 percent in behavioral modification, metformin, and control group, respectively), while no added benefit was observed to combine lifestyle modification and metformin (39.5 percent). This represented a relative risk reduction of 28.5 percent, 26.4 percent, and 28.2 percent with behavioral modification, metformin, and the combination, in comparison with control, respectively.

In Spain, Salas-Salvado and colleagues⁶⁶ reported one year data from the PREDIMED trial, which evaluated the effect of two diet interventions (Mediterranean diet plus virgin olive oil and Mediterranean diet plus nuts) on metabolic syndrome status compared with a control (low-fat diet advice) among older participants at high risk for CVD. Mean BMI at baseline was 29.3 kg/m². They found a significant reduction of overall prevalence of metabolic syndrome in the Mediterranean diet plus nuts group (prevalence reduced by 13.7 percent), compared with that in control group (prevalence reduced by 2.0 percent). Although no significant difference in the incidence rates of metabolic syndrome was observed among groups, the effect of Mediterranean diet plus nuts seemed more a consequence of higher rates of reversion among those who had the metabolic syndrome at the baseline. Mediterranean diet plus virgin olive oil showed a nonsignificant reduction in metabolic syndrome prevalence. The authors concluded that a beneficial effect on metabolic syndrome could be achieved by diet alone.

Finally, a 12-month RCT⁶⁷ was carried out in 13 sites in primary care in the UK to evaluate the effectiveness of a structured group education program focused on behavior change among newly diagnosed type 2 diabetes patients (mean BMI= 32.3 kg/m²; mean HbA1c=8.1). In addition to weight loss and blood glucose outcomes, this study also reported behavioral outcomes (smoking status and physical activity), psychosocial outcomes (illness belief and depression), and quality of life at 4, 8, and 12 months. Compared with usual care, the education intervention was found to be associated with significant weight loss (2.98 kg in education intervention group vs. 1.86 kg in usual care group), a significant reduction in triglyceride levels at eight months, a significant reduction in smoking status at all time points, and a significantly greater increase in physical activity at 4 months. The education intervention group also showed significantly greater understanding of their illness and its seriousness, and had a lower depression

score. However, changes in HbA1c level and quality of life scores were not significantly different between groups at any time point.

Summary

Table 9 displays a summary of data on interventions and outcomes in patients with diabetes or IGT. While direct comparisons of these interventions in many cases have not been assessed in randomized trials, it is nonetheless useful to present the data in a side-by-side format. We discuss the limitations of such comparisons in detail in the discussion section; readers should keep in mind that patients enrolled in the nonsurgical trials of medication and behavioral interventions differ in important ways from those participating in the surgical studies.

Short-Term Outcomes

Based on glucose outcomes, there is moderate strength evidence of efficacy of bariatric surgery in treating diabetes in patients with BMI of at least 30 but less than 35 kg/m² in the short term. At one year, surgery patients show much greater weight loss than usually seen in studies of diet, exercise, or other behavioral interventions. With the exception of GLP-1T agonists, diabetes medications do not cause significant weight loss. While both behavioral interventions and various medications have been shown to lower HbA1c levels significantly, the decreases reported in bariatric surgery patients at one year are greater. Improvements in glucose control outcomes have been reported as early as one month post-surgery.⁶⁸ Improvements in hypertension, and cholesterol have been reported at one year in some studies. We judged this evidence as moderate due to sparseness of data - only three RCTs directly compared surgery with nonsurgical interventions; two came from the same group of researchers. Observational data, which start as “low” strength evidence, were upgraded due to consistency of results regarding BMI and blood sugar. Thus, the total body of evidence is considered moderate strength.

Long-Term Outcomes

There are few long-term data on patients in this weight class with diabetes or IGT who have undergone bariatric surgery. We identified only two studies, both observational, with followup of three or more years. One, a case series of LAGB patients in Italy, reported followup at five years for 29 of the 210 initial patients, for a followup rate of only 13.8 percent. Another small Italian study followed BPD patients for over 10 years; there were only seven patients total. Thus, the evidence that bariatric surgery is an effective way to treat diabetes or IGT in patients with BMI of at least 30 kg/m² but less than 35 kg/m² in the long term is insufficient, due to the small number of patients followed. In contrast, behavior and medication interventions have been studied extensively for decades; several large long-term RCTs have found improved HbA1c levels continue for ten years. Some long-term trials and meta-analyses have reported clinically significant improvements in microvascular and macrovascular outcomes as a result of behavioral or medication interventions.

Specific Bariatric Procedures

Taking into consideration the entire body of evidence, we rate the strength of evidence as moderate for RYGB, LAGB and gastric sleeve for treating diabetes and IGT in patients with a BMI of between 30 kg/m² and 35 kg/m², in the short term (up to two years). Each of these procedures have shown efficacy in two randomized trials, in addition to numerous observational

studies. In contrast, BPD has not been studied in randomized trials in this particular population, although five observational studies have been published. Thus, the strength of evidence for BPD is rated low.

In two RCTs, RYGB patients lost significantly more weight than gastric sleeve patients. Both RCTs reported better blood glucose outcomes for RYGB; the difference was statistically significant in one. Observational data echo these findings, and also support that RYGB patients have greater changes in weight and blood glucose in the short term than those undergoing LABG. These results must be balanced with the different adverse event profiles of the procedures, discussed in the results for KQ 3.

Table 9. Summary of data on interventions and outcomes in patients with diabetes or impaired glucose tolerance

Outcome	Behavioral Changes (Data Almost Entirely From Systematic Reviews, RCTs)	Intervention Medications (Data Almost Entirely From Systematic Reviews, RCTs)	Bariatric Surgery (Data Primarily From Observational Studies)
Weight loss at one year:	2.8 kg for diet, exercise, behavioral vs. usual care.	Weight gain from 1 to 5 kg with some drugs. 2.8 kg weight loss with GLP-1R agonists. No weight change with metformin.	BMI loss of 5 to 7 kg/m ² (about 15 to 20 kg for someone 5 foot 6 inches tall)
Weight loss at two years:	2.7 kg for diet, exercise, behavioral vs. usual care.	Data unavailable.	BMI loss of 4 to 8 kg/m ² (about 11 to 23 kg for someone 5 foot 6 inches tall)
Long term weight loss (five years and more):	1.7 kg for diet, exercise, behavioral vs. usual care at 5 years.	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found no significant change with metformin at 10 years.	BMI loss of 5.7 kg/m ² at 5 years, in one study of 29 LABG patients
HbA1C, percentage of total hemoglobin, at one year:	Decrease of 0.3 to 2.2 percentage points.	Decrease of 0.5 to 1.0 percentage points.	Decrease of 2.6 to 3.7 percentage points.
HbA1C at two years:	No significant change.	Few data; the UKPDS study found no significant difference in HbA1c for sulfonylurea-insulin or metformin at 2 year time-point.	Decrease of 1.8 to 3.1 percentage points.
HbA1C at five years and more:	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found HbA1C concentrations lower in behavioral group at 10 years (vs. placebo).	Few data; the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) found HbA1C concentrations lower in metformin group at 10 years (vs. placebo).	Data unavailable.
Other metabolic outcomes at one year:	Diet improved fasting glucose (1.3%-36.6% reduction) and triglycerides (11.3% - 58.9% reduction); the Spain PREDIMED study found Mediterranean diet reduced metabolic syndrome prevalence by 13.7% at 1 year; the Finnish Diabetes Prevention Study (DPS) found behavioral change reduced metabolic syndrome prevalence at 3.9 years (odds ratio: 0.62).	Most medications had minimal effects on systolic & diastolic blood pressure (< 5 mmHg change). Metformin and second generation sulfonylureas generally decreased LDL cholesterol levels.	Mixed results, one RYGB and one BPD study reported slight increase in triglycerides at one year.

Table 9. Summary of data on interventions and outcomes in patients with diabetes or impaired glucose tolerance (continued)

Outcome	Behavioral Changes (Data Almost Entirely From Systematic Reviews, RCTs)	Intervention Medications (Data Almost Entirely From Systematic Reviews, RCTs)	Bariatric Surgery (Data Primarily From Observational Studies)
Other metabolic outcomes at five years and more:	Data unavailable.	Data unavailable.	Of 7 BPD patients followed, all had normal serum cholesterol and triglycerides.
Microvascular outcomes: (Renal disease, neuropathy, retinopathy, etc)	Data unavailable.	UK Prospective Diabetes Study (UKPDS) found patients taking sulfonylurea, insulin, or metformin had 24% risk reduction for microvascular disease at 10 years.	Data unavailable.
Macrovascular outcomes: (Cardiovascular disease, stroke, heart attack)	Few data; the China Da Qing Diabetes Prevention Study (CDQDPS) found no significant difference in first CVD event, CVD mortality and all-cause mortality between intervention and control group.	Meta-analysis of 5 trials with 33,040 participants found that on an average A1C reduction of 0.9% there was a 19% reduction in non-fatal myocardial infarction and a 15% reduction on coronary heart disease, and no statistically significant effect on stroke or all cause mortality.	Data unavailable.
Prevention of diabetes:	Hazard ratio 0.51 for behavioral interventions vs. standard advice at 1 to 5 years; the U.S. Diabetes Prevention Program (DPP) found diabetes incidence in 10 years reduced by 34% by behavioral change vs. placebo, and the China Da Qing Diabetes Prevention Study (CDQDPS) found it was 43% lower in behavioral group over 20 years.	Hazard ratio 0.70 for oral medications vs. control at 1 to 5 years; the U.S. Diabetes Prevention Program (DPP) found diabetes incidence in 10 years reduced by 18% in the metformin group vs. placebo.	Data unavailable.

HbA1C = Glycosylated hemoglobin; BPD = biliopancreatic diversion; BMI = body mass index; CVD = cardiovascular disease; GLP-1R = GLP-1 Agonists: Glucagon-like peptide-1 agonists, a class of diabetes drugs targeting the incretin system; LAGB = laparoscopic adjustable gastric banding; LDL = low-density lipoprotein cholesterol; RCT = randomized controlled trial; RYGB = Roux-en-Y gastric bypass

KQ3: What are the potential short-term adverse effects (AEs) and/or complications involved with bariatric surgery for treating adult patients with BMI of 30 to 34.9 who have metabolic conditions?

The incidence of adverse events following bariatric surgery is displayed in Table 10 for all studies, including case series, cohorts and controlled trials. Adverse events for the few nonsurgical arms of these studies are also displayed. Followup times varied widely from the day of surgery to 2 years; the exception are two studies that reported events up to 3 and 5 years post-surgery. Few studies were clear exactly when the adverse events took place, and patients who were lost to followup had missing adverse events data. Adverse events were often identified and self-reported by the surgical team, with definitions of some complications varying from study to study. Little administrative data were available to diminish these biases. In addition, there were

few studies that compared adverse events between different surgical procedures, making direct comparisons difficult.

Studies were included in our mortality analyses only if they reported/mentioned either the number of deaths or lack of any deaths. Thus, 14 studies were included, which accounted for five LAGB arms, one gastric sleeve arm, nine RYGB arms, and one BPD arm. Only one death was reported—an LAGB patient with complications of a gastric perforation. Thus, the reported rate of mortality was 0.48 percent for LAGB and 0.0 percent for gastric sleeve, RYGB and BPD.

Medical complications (cardiovascular, respiratory, gastrointestinal) were reported in several studies. Four studies reported cardiovascular or respiratory complications. A BPD study reported that one of ten patients had a pulmonary embolism, while an RYGB study reported one case of arrhythmia and three cases of pneumonia. (It is not clear whether these cases were mutually exclusive or in separate patients.) Another study reported two cases of pneumonia in RYGB patients, one case in a gastric sleeve patient and none in the nonsurgical arm. This same study noted two patients with arrhythmias in the nonsurgical arm, one case in a gastric sleeve patient, and none in the RYGB arm. One study of LAGB versus nonsurgical treatment reported one transient ischemia attack (TIA) among 30 patients in the nonsurgical arm.

Metabolic issues were also reported. Self-reported hypoglycemia was common in one RCT of diabetes patients who were receiving aggressive medical treatment in both surgical and nonsurgical: 28 of 50 (56.0 percent) RYGB patients, 39 of 49 (79.6 percent) SG patients, and 35 of 43 (81.4 percent) nonsurgical patients. The same study reported ketoacidosis in one of the RYGB patients and none of the SG or nonsurgical patients. In another study, hypoglycemia was reported by one of 30 LAGB patients and did not occur in the non-surgery arm. Vitamin deficiency was reported in one of 109 patients in an RYGB study, and one study each of RYGB and LAGB mentioned that no patients suffered from malnutrition. Anemia was reported in an RCT by 12.0 percent of RYBG, 12.2 percent of SG, and almost 7 percent of nonsurgical patients.

Gastrointestinal (GI) complications were reported at a relatively low rate. Feeding difficulties were reported by 3.6 percent of LAGB patients, 0.9 percent of RYGB patients, and 4.3 percent of nonsurgical patients. There were no reports of feeding difficulties among BPD or gastric sleeve patients. Similarly, hiatal hernia or reflux was reported in four of 146 LAGB patients (2.7 percent), but in no studies of the other procedures. In one RCT, dehydration was reported in 22.0 percent of RYGB patients, 9.3 percent of SG patients, and 8.16 percent of nonsurgical patients. Gastroplegia was reported in one study of 30 BPD patients; the rate was 13.33 percent.

Wound infections were reported in three RYGB studies; the rate was 4.3 percent. A study of 30 LAGB patients also reported one wound infection. Incisional hernias were reported in two RYGB studies; rate was 4.5 percent.

Anastomotic and pouch complications were reported in gastric sleeve and RYGB patients. Five percent of RYGB patients experienced stricture. One RYGB patient and one sleeve patient experienced an anastomotic leak. Ulcer was reported in nine percent of RYGB patients. One RYBG study reported an anastomotic hemorrhage in one of 22 patients. Likewise, one RYGB study reported an intra-abdominal hemorrhage in one of 109 patients.

Several complications specific to LAGB were reported. Band slippage was reported in 2.3 percent of patients, port or tube problems in about two percent, and 3.3 percent of LAGB patients had the band removed. Five of 40 patients in one study had unspecified surgical complications. 5.42 percent of LAGB patients had pouch dilation post-surgery.

Two gastric sleeve patients, six RYGB patients, and another BPD patient required re-operation for unspecified reasons. In addition, one BPD patient required a revision due to chronic diarrhea.

Summary

In the two RCTs comparing SG with RYGB complications were minor and rates were similar between groups. The surgical complications reported for RYGB and LAGB in observational studies were fairly consistent; they differ due to the nature of the procedures. Complications related to LABG include band slippage, tube problems, and band erosion, while those related to RYGB include stricture, ulcer, and on rare occasions, hemorrhage. We rate the strength of evidence for overall short term harms as low for all four procedure types.

The low strength of evidence reflects several limitations in the data. The majority of the adverse events data were submitted by surgeons, and thus subject to possible publication bias. There were only 20 instances where 100 or more patients contributed data to a particular adverse event category; thus, the rate estimate for most adverse events is imprecise. Additionally, in 76 percent of instances, only a single study contributed data to a particular adverse event rate calculation, meaning the generalizability of the estimate is questionable. Few studies were clear exactly when adverse events took place, and patients who were lost followup had no adverse events data. In addition, definitions of complications varied from study to study.

Table 10. Incidence of adverse events - surgical weight loss treatments

Adverse Event*	Subcategory	Nonsurgical Arms				LAGB				Gastric Sleeve				RYGB				BPD			
		# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**
Cardiovascular/ Respiratory	Pulmonary embolism																	1	1	10	10.00
	TIA	1	1	30	3.33																
	Arrhythmia	1	2	43	4.65					1	1	49	2.04	2	1	159	0.63				
	Pneumonia	1	0	43	0.00					1	1	49	2.04	3	5	268	1.87				
Constitutional	Cellulitis (nonwound related)	1	1	43	2.33	1	1	30	3.33	1	0	49	0.00	1	0	50	0.00				
	Not specified	1	1	30	3.33																
Gastro-intestinal	Anorexia or excessive weight loss	1	0	43	0.00					1	0	49	0.00	3	0	69	0.00				
	Cholecystitis/Other biliary	2	4	83	4.82	1	1	40	2.50	1	0	49	0.00	2	2	159	1.26				
	Dehydration	1	4	43	9.30					1	4	49	8.16	1	11	50	22.00				
	Excessive weight gain	1	3	43	6.98					1	0	49	0.00	1	0	50	0.00				
	Feeding difficulties	2	3	70	4.29	2	3	83	3.61					1	1	109	0.92				
	Reflux/Hiatal hernia					2	4	146	2.74					1	0	37	0.00				
	Diarrhea	1	1	30	3.33									1	1	22	4.55				
	Gastroplegia																	1	4	30	13.33
	Ileus					1	1	109	0.92												
	Vomiting and/or nausea					1	1	109	0.92					1	4	109	3.67				
	Not specified	2	10	70	14.29	1	1	30	3.33												
Metabolic	Ketoacidosis	1	0	43	0.00					1	0	49	0.00	1	1	50	2.00				
	Anemia	1	3	43	6.98					1	6	49	12.24	1	6	50	12.00				
	Hypoglycemia [†]	2	36	73	49.32	1	1	30	3.33	1	39	49	79.59	2	28	67	41.79				
	Hypokalemia	1	1	43	2.33					1	2	49	4.08	1	2	50	4.00				
	Vitamin deficiency													1	1	109	0.92				
Renal	Kidney stone	1	1	43	2.33					1	0	49	0.00	1	0	50	0.00				
	Renal insufficiency	1	0	43	0.00					1	0	49	0.00	1	1	50	2.00				

Table 10. Incidence of adverse events - surgical weight loss treatments (continued)

Adverse Event*	Subcategory	Nonsurgical Arms				LAGB				Gastric Sleeve				RYGB				BPD			
		# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**	# Arms	# With Event	N	%**
SURGICAL																					
Band Related	Band erosion					1	1	66	1.52												
	Band removal					1	7	210	3.33												
	Port or tubing complication					5	9	462	1.95												
	Band slippage					6	13	571	2.28												
	Pouch dilation					2	13	240	5.42												
Bleeding/Hematoma	Anastomotic hemorrhage													1	1	22	4.55				
	Intraabdominal hemorrhage													1	1	109	0.92	1	1	30	3.33
	Transfusion NOS									1	1	49	2.04	1	1	50	2.00				
Minor Surgical	Incisional hernia									1	0	49	0.00	2	3	67	4.48				
	Wound infection/seroma	1	0	43	0.00	1	1	30	3.33	1	0	49	0.00	3	8	186	4.30				
	Not specified									1	3	30	10.00	1	3	30	10.00				
Pouch/Anastomosis	Leak									1	1	49	2.04	3	1	239	0.42				
	Fistula													1	1	147	0.68				
	Stricture													4	18	363	4.96				
	Ulcer									1	0	49	0.00	2	6	67	8.96				
Reoperation	Not specified									2	2	98	2.04	3	6	180	3.33	1	1	10	10.00
Revision	Revision secondary to diarrhea																	1	1	30	3.33
Other	Morbidity major - unspecified													1	2	44	4.55				
	Other adverse event - unspecified													1	1	109	0.92				
	Readmission									1	1	30	3.33	1	1	30	3.33				
	Internal hernia													1	1	109	0.92				
	Surgical NOS					1	5	40	12.50	1	0	30	0.00	3	0	72	0.00	1	0	30	0.00

BPD = biliopancreatic diversion with duodenal switch; gastric sleeve = sleeve gastrectomy; LAGB = laparoscopic adjustable gastric banding; N = number; NOS = not otherwise specified;

RYGB = Roux-en-Y gastric bypass; TIA = transient ischemia attack

*Studies may have reported on >1 adverse event category and the majority reported on >1 surgical weight loss treatment. Some patients had >1 adverse event. The total number of adverse events was counted for each category.

**% = number of patients with adverse event/total number of patients.

†Schauer et al. 2012³⁷ hypoglycemia was self-reported.

KQ4: Does the evidence show racial and demographic disparities with regard to potential benefits and harms associated with bariatric surgery for treating adult patients with BMI of 30 to 34.9 and metabolic conditions? What other patient factors (social support, counseling, pre-operative weight loss, compliance) are related to successful outcomes?

There were insufficient data in the included surgery studies to assess whether racial and demographic disparities exist in terms of weight loss and metabolic outcomes. However, previous research shows that some patient-level factors are associated with successful weight loss after bariatric surgery. Regardless of procedure type, patients who lose more weight tend to be younger, have a lower preoperative BMI, and be non-diabetic.⁶⁹⁻⁷¹

One recent systematic literature review identified a number of psychosocial patient factors that may be associated with weight loss after bariatric surgery.^{72,73} This review was based on observational studies that included all bariatric patients, including those with baseline BMI > 35 kg/m² and those without diabetes. Data specific to patients with a BMI less than 35 kg/m² and diabetes are not available. Preoperative factors include baseline BMI, with heavier patients losing less weight than their lighter counterparts in 37 out of 62 studies. Meta-analysis revealed a decrease of 10.1 percent more EWL (excess weight loss) for super obese versus non-super obese patients (95% CI 3.7 percent – 16.5 percent). Some programs request that bariatric candidates lose a modest degree of weight (generally 10-20 pounds) in the weeks immediately prior to surgery. This mandatory preoperative weight loss was associated with successful outcomes after bariatric surgery in many studies. In a meta-analysis on the association between preoperative weight loss versus no weight loss and postoperative weight loss, the preoperative weight loss group lost a mean of 5.0 percent greater EWL (95% CI 2.7 to 7.3 percent).⁷⁴

Social support is believed to be an important component of successful weight loss, and support group attendance in particular is associated with improved weight loss outcomes after surgery. For example, one study of RYGB patients found that when controlling for time elapsed since surgery, the number of support group meetings attended explained some variance in weight loss ($R^2 = .09$, $P < 0.05$).⁷⁵ Another study of patients who underwent LAGB reported that patients who attended support groups had greater weight loss starting at 6 months after surgery, and continuing at 12 months (9.7 vs. 8.1 BMI points decrease at 12 months, $P < 0.05$).^{76,77}

Support groups can help to provide continuing postoperative education regarding behavior modification, as well as identify any problems early on. Increased postoperative physical activity was also associated with greater postoperative weight loss in the majority of studies (11 out of 13 studies). A meta-analysis assessing the association of exercise versus no exercise and postoperative weight loss at 12 months showed that the exercise group lost a mean of 4.2 percent greater total BMI (95% CI 0.3 to 8.1 percent).⁷² Other factors that may be predictive of postoperative weight loss include specific eating habits or disorders, such as hunger and emotional eating. The emotional and physical stresses of such dramatic weight loss can trigger maladaptive responses in patients with preexisting eating disorders. The impact of other eating disorders and psychiatric disorders such as depression is not clear. This is in part due to variability in how eating and psychiatric disorders are defined from study to study, which survey instruments are used, and the followup time.

Summary

There was insufficient evidence in the studies of patients with diabetes or IGT and BMI 30 to 34.9 kg/m² on demographic disparities regarding benefits and harms of bariatric surgery. The same is true for patient factors related to successful outcomes. A recent systematic review on patients with higher BMI found that mandatory pre-operative weight loss, social support, and increased physical activity were associated with better outcomes.

KQ5: What does the evidence show regarding long-term benefits and harms of bariatric surgery for treating adult patients with BMI of 30 to 34.9 and who have metabolic conditions? How do they compare to short-term outcomes (within 1 year from surgery)?

Few long-term data exist on patients with diabetes or IGT in this weight class who have undergone bariatric surgery. Fifteen surgical studies reported outcomes at 13 to 24 months; however, only a handful included followup of more than two years. This section focuses on those studies.

A case series of 210 LAGB patients in Italy with baseline BMI of 30 to 34.9 kg/m² included only four patients with diabetes. The authors reported that diabetes had resolved in all four at one year, but resolution was not defined and metabolic evidence was not presented. Authors attempted to followup on the entire group at two, three, four, and five years. Five-year data were reported for only 29 of the 210 initial patients, for a followup rate of only 13.8 percent.³⁹ No other diabetes related outcomes were reported. Another study of 93 LAGB patients of one surgeon in Australia⁴¹ reported on followup at one, two, and three years. Response rate was good, ranging from 79 to 89 percent per year. Only eight patients had diabetes at baseline; none needed diabetes medications at three years. Again, no other metabolic evidence was presented. For the entire group, mean BMI decreased from 32.7 kg/m² at baseline to 27.0 kg/m² at one year, and this BMI was maintained at two and three years. Finally, one author followed seven BPD patients with diabetes and BMI < 35 kg/m² for over five years in Italy.⁴⁷ Serum glucose was normalized at one, two, and three years in all patients. At five years, serum glucose had increased to above 125 mg/dL in five patients. Diabetes had “resolved” in the other two patients. At each follow-up, all patients had normal cholesterol and triglyceride levels. None of these studies reported long-term (over two years) adverse events, although the Italian LAGB study reported a death at 20 months post-surgery from sepsis due to perforation of a dilated gastric pouch.

For comparison, one RCT of surgery versus nonsurgical treatment in our target population⁴⁰ reported BMI at six, 12, 18 and 24 months. Both LAGB and medical management groups lost 13.8 percent of excess weight at six months. However, the medical management group gained weight at each subsequent followup while the LAGB group continued to lose weight. Mean BMI decreased from 33.7 kg/m² at baseline to 28.9 kg/m² at six months, 27.0 kg/m² at 12 months, 26.7 kg/m² at 18 months, and 26.4 kg/m² at two years. (Detailed results for LAGB versus usual care in this study are discussed in the section on KQs 1 and 2.) Metabolic outcomes were not reported at these intervals.

Though not within the parameters of this systematic review, we note the results of a recent European study on long-term outcomes of laparoscopic adjustable gastric band⁷⁸ because it reports the longest followup we identified in the bariatric literature published to date. Of 151 consecutive patients from a single institution operated on from 1994-1997, the mean

preoperative BMI was 41.57 kg/m² (range, 35-57). Of these patients, 82 (54.3 percent) were available for long-term followup at 13 years. The number of patients varied somewhat for each outcome depending on preoperative data availability. For example, complete weight loss data were available for 70 of 151 patients. Overall, 43 percent maintained a loss of excess weight, nearly 60 percent required reoperation, and obesity-related comorbidities such as diabetes, hypertension, and sleep apnea persisted. Of 78 patients, 20 (25.6 percent) were treated for hypertension before band insertion and 23 (29.5 percent) were treated for hypertension 12 years after their laparoscopic adjustable gastric band ($p=.72$). Of 78 patients, 5 (6.4 percent) had type 2 diabetes before band insertion and 11 had diabetes 12 years after surgery. Of the 78 patients, two (2.6 percent) needed continuous positive pressure for sleep apnea before surgery and 6 (7.7 percent) after surgery. Nearly one-third of patients experienced band erosion, while 17 percent were converted to a RYGB. Intent to treat excess weight loss was 33.92 percent (range 24 percent – 143 percent). 36 patients (51.4 percent) still had the band in place and their mean excess weight loss was 48 percent (range 38 percent – 58 percent).

This study on long-term outcomes included patients with preoperative weight higher than that of our target population. It is not clear how these results translate to a lower weight group. Additionally, the study was limited in its ability to draw conclusions as almost 50 percent of patients were not available for followup, which may contribute to significant bias. Still, the study described above draws attention to the importance of having long-term outcomes following bariatric surgery as some obesity-related comorbidities were not resolved at 12 years and there was a high rate of significant band-related complications.

Summary

Due to the dearth of data available, the strength of evidence that bariatric surgery is an effective way to treat diabetes or IGT in patients with BMI of at least 30 kg/m² but less than 35 kg/m² in the long term is insufficient. There are very few long-term (over two years) studies, each includes only a handful of patients in our target population, and none includes a comparison group. We identified no long-term reports of surgery-related adverse events in our target population; thus strength of evidence for harms is also insufficient.

Summary and Discussion

We conducted an extensive literature search, data abstraction, and quantitative analysis where possible, to assess the comparative effectiveness of bariatric surgery in patients with diabetes or impaired glucose tolerance (IGT) and a body mass index (BMI) of at least 30 but less than 35. Here we describe the limitations of our systematic review then present our conclusions. We also discuss the implications of our findings for future research.

Limitations

The research on bariatric surgery in patients with BMI of at least 30 kg/m² and less than 35 kg/m² and diabetes or IGT has many limitations. Most importantly, very few studies have long term followup (more than two years). Two report data at five years or more; one has a followup rate of only 13.8 percent, while the other includes only seven patients. Thus, we have almost no data on long-term efficacy and safety. No evidence was found on major clinical end points such as all-cause mortality, cardiovascular mortality or morbidity, or peripheral arterial disease. Some evidence from the diabetes literature indicates it may be premature to assume that controlling glucose to normal or near normal levels completely mitigates the risk of microvascular and macrovascular events. While it is more likely than not that this is true, conclusive proof is lacking, and the point is still debated in the diabetes literature.

Another limitation is the dearth of high quality studies. Randomized controlled trials (RCTs) are considered the highest level of medical evidence. We found three RCTs of surgery versus nonsurgical treatment (one of these also compared two procedures) and another RCT comparing surgical procedures. This was expected given the difficulty in conducting randomized trials of surgery. Still, we identified only two observational studies comparing surgical procedures and two small cohort studies comparing surgery with nonsurgical approaches. The rest of our data come from studies with no comparison group, with data submitted primarily by the practicing surgeons. The sample sizes, regardless of methodological design, are far smaller than those of most trials of diet, exercise, and medications.

Applicability of this research to the larger treatment population of diabetes and IGT patients with BMI between 30.0 kg/m² and 34.9 kg/m² is important in interpreting the results. The participation rate, population characteristics, representativeness of the setting, and representativeness of the individuals are used to assess applicability. One RCT comparing surgery with non-surgery was performed in the United States and included two of the more commonly performed procedures – Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG). However, it was of modest size and was conducted in an academic setting in a select group of patients with uncontrolled type II diabetes at baseline. Two RCTs of LAGB versus nonsurgical interventions conducted in Australia were comprised primarily of Caucasian patients. However, the RCT comparing laparoscopic adjustable gastric banding (LAGB) with SG was conducted in Taiwan, where diets and lifestyle may differ considerably from the West. One of the cohort studies comparing procedures was conducted in the U.S, but only three of the remaining observational studies were conducted here. The others were conducted in Western Europe, South America, India, Asia, and Australia. Diet, behavior, and culture in many of these locations may differ dramatically from that in the United States. In addition, there may be biological or genetic differences. Thus, the results seen in non-U.S. studies may not be directly applicable to American patients.

Data reported on adverse events have several limitations. Most studies were not designed to assess these outcomes and reflect surgeon or surgery-team reported events. Additionally, followup times and rates were variable, and many studies did not state exactly when adverse events occurred, other than “within a year post surgery.” As such, the rates of adverse events may be biased and lower than actual. Comparisons between procedure types are limited for the same reasons. We found almost no long-term adverse events data for our target population.

Key stakeholders, especially consumers, expressed interest in quality of life (QOL) and psychological outcomes post-surgery. These were rarely reported in the studies we identified.

Finally, although our literature search procedures were extensive and included canvassing experts for studies we may have missed, the possibility of publication bias still exists. For all surgical procedures there is the concern that published studies usually come from academic medical centers with high performing surgical teams and careful patients selection. Outcomes reported for such patients may not be representative of the outcomes achieved in the wider community. The difference between complication rates seen in the major clinical trials of carotid endarterectomy and those observed in the general Medicare population is one well-known example of this phenomenon. In addition, there are media reports (Los Angeles Times) on a number of deaths following LAGB surgery. Whether there is any causal relationship between the surgery and the deaths has not yet been assessed in a peer-reviewed publication, so no conclusions can be drawn. Still, it illustrates the potential for there to exist adverse events and/or beneficial outcomes in as-yet-undescribed populations.

Conclusions

Short-Term Outcomes

Based on glucose control outcomes, there is moderate strength evidence of efficacy of bariatric surgery in treating diabetes in patients with BMI of at least 30 but less than 35 kg/m² in the short term. At one year, surgery patients show much greater weight loss than usually seen in studies of diet, exercise, or other behavioral interventions. With the exception of GLP-1T agonists, diabetes medications do not cause significant weight loss. While both behavioral interventions and various medications lower HbA1c levels significantly, the decreases reported in bariatric surgery patients at one year are greater. Improvements in glucose control outcomes have been reported as early as one month post-surgery. Several studies report improvement in hypertension and cholesterol at one year. We rated the overall evidence as moderate due to sparseness of data - three RCTs directly compared surgery with nonsurgical interventions, and two came from the same group of researchers. Observational data, which start as “low” strength evidence, were upgraded due to consistency of results regarding BMI and blood sugar. Thus, the total body of evidence is considered moderate strength, based on moderate strength of evidence for BMI and glucose outcomes. Strength of evidence for cholesterol and blood pressure outcomes is low.

Long-Term Outcomes

There are few long-term data on patients with diabetes or IGT in this weight class who have undergone bariatric surgery. We identified only two studies with followup of more than two years. One, a case series of LAGB patients in Italy, reported followup at five years for 29 of the 210 initial patients, for a followup rate of only 13.8 percent. Another very small Italian study

followed seven biliopancreatic diversion with duodenal switch (BPD) patients for at least 5 years. Thus, despite promising short term outcomes reported, the evidence that bariatric surgery is an effective way to treat diabetes in patients with BMI of at least 30 kg/m² but less than 35 kg/m² in the long term is insufficient. Strength of evidence is insufficient for all outcomes, including BMI, blood glucose, cholesterol, and hypertension. In contrast, behavior and medication interventions have been studied extensively for decades; several large long-term RCTs have found improved HbA1c continues for 10 years. Several long-term trials and meta-analyses have reported clinically significant improvements in microvascular and macrovascular outcomes as a result of behavioral or medication interventions.

Specific Bariatric Procedures

We found two head to head trials comparing bariatric procedures (one also had a medication only group). An average size trial (N=60) conducted in Taiwan compared RYGB with SG; the RYGB group had better weight and diabetes outcomes at one year post surgery. A recent United States trial comparing these same procedures found similar results.

We also found two observational studies that compared procedures. One conducted in the United States compared RYGB with LAGB. This study was fairly large (N = 235), and had an adequate followup rate (61.9 percent for RYGB, 69.2 percent for LAGB) at 6 to 12 months. Some patients were followed for two years. Weight loss was similar among groups; diabetes outcomes were generally better for RYGB patients. The other study, conducted in Germany, compared results for twelve BPD patients with four RYGB patients. Both groups lost a significant amount of weight. At one year, decrease in HbA1c was significantly greater in the BPD group.

Observational studies of surgical procedures without a comparison arm reported clinically meaningful decreases in BMI with all types of bariatric surgery at less than one year. Clinically meaningful diabetes outcomes were also reported at less than a year for all surgery types. At a year or more, weight loss was maintained or improved in all groups; RYGB patients had the greatest decrease in BMI.

Taking into consideration the entire body of evidence, we rate the strength of evidence of efficacy as moderate for RYGB, LAGB, and SG in treating diabetes and IGT in patients with a BMI of between 30 kg/m² and 35 kg/m², in the short term (up to two years) based primarily on glucose control outcomes. For BPD, both the number of studies and their sample sizes are much lower; thus the strength of evidence of efficacy is rated low. Evidence on comparative effectiveness of surgical procedures is insufficient.

Adverse Events

We rate the strength of evidence for overall short term harms as low for all four procedure types. In the two RCTs comparing SG with RYGB complications were minor and rates were similar between groups. The surgical complications reported for RYGB and LAGB in observational studies were fairly consistent; they differ due to the nature of the procedures. Complications related to LABG include band slippage, tube problems, and band erosion, while those related to RYGB include stricture, ulcer, and on rare occasions, hemorrhage.

The low strength of evidence reflects several limitations in the data. The majority of the adverse events data were submitted by surgeons, and thus subject to possible publication bias. Few studies were clear exactly when adverse events took place, and patients who were lost

followup had no adverse events data. In addition, definitions of complications varied from study to study.

We found no data on long term adverse events of bariatric surgery in diabetes or IGT patients in our specific BMI range. Thus, strength of evidence for long term adverse events is rated insufficient.

Future Research

Future research should focus on long-term outcomes of bariatric surgery in U.S. patients with diabetes or impaired glucose tolerance and a body mass index of 30 kg/m² to 34.9 kg/m². For this population there is no evidence that bariatric surgery is effective in preventing the clinical consequences of diabetes – microvascular and macrovascular endpoints such as diabetic retinopathy, kidney failure, and myocardial infarction. Studies with followup of five to ten years are needed. Studies in other populations have led to concern about potential for long-term nutritional complications in bariatric surgery patients, so nutritional endpoints should also be measured.

We found only one U.S. cohort study comparing procedures; this study used the BOLD (Bariatric Outcomes Longitudinal Database), a resource created by the Surgical Review Corporation to monitor outcomes from the Bariatric Surgery Center of Excellence (BSCOE) program. As of June 2009, there were 235 patients with diabetes within our BMI range in the BOLD database. The study we identified reported outcomes at 6 to 12 months. Outcomes at 12 to 24 months were reported for only a small number of patients (6.8 percent) presumably because that followup time had not expired for most of the patients. Continued followup of these patients and publication of findings is needed to assess the degree to which bariatric surgery mitigates long-term sequelae of diabetes.

In addition, according to the U.S. clinical trials database, there are several bariatric surgery trials currently being conducted in the target population. In addition to monitoring weight loss, these studies will frequently collect important metabolic data including measures of blood sugar, cholesterol, triglycerides, and blood pressure. Long-term followup of the research subjects, if funded, could add to our knowledge base on the effects of bariatric surgery and cardiovascular morbidity and mortality. Collection and reporting of psychological and quality of life outcomes will also help inform prospective patients and providers.

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Abbreviations/Acronyms

AHRQ	Agency for Healthcare Research and Quality
AMSTAR	Measurement tool created to assess the methodological quality of systematic reviews
BL	Baseline
BMI	Body Mass Index
BPD	Biliopancreatic Diversion
cc	Cubic Centimeters
CCTs	Controlled Clinical Trials
CDQDPS	China Da Qing Diabetes Prevention Study
CENTRAL	Cochrane Central Register of Controlled Trials
CER	Comparative Effectiveness Review
CHIP	Children's Health Insurance Program
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMS	Center for Medicare & Medicaid Services
CPAP	Continuous Positive Airway Pressure
CV	Cardiovascular
CVD	Cardiovascular Disease
DARE	Cochrane Database of Abstracts of Reviews of Effects
DM	Diabetes Mellitus
DPP	Diabetes Prevention Program
EPC	Evidence-based Practice Center
EWL	Excess Weight Loss
FDA	Food and Drug Administration
GERD	Gastroesophageal Reflux Disease
GHb	Glycated Hemoglobin
GI	Gastrointestinal
HbA1c	Glycosylated Hemoglobin
HDL	High-Density Lipoprotein
HFLC	High-Fat Low-Carbohydrate Diet
IDPP	Indian Diabetes Prevention Programme
IGT	Impaired Glucose Tolerance
LAGB	Laparoscopic Adjustable Gastric Banding
LDL	Low-Density Lipoprotein
LFHC	Low-Fat High-Carbohydrate Diet
N	Sample Size

OSA	Obstructive Sleep Apnea
QOL	Quality of Life
RCTs	Randomized Controlled Trials
RYGB	Roux-en-Y Gastric Bypass
SE	Standard Error
SG	Sleeve Gastrectomy
TEP	Technical Expert Panel
UKPDS	United Kingdom Prospective Diabetes Study
VBG	Vertical Banded Gastroplasty
VLCDs	Very-Low-Calorie Diets
WMD	Weighted Mean Difference

Appendix A. Search Methodology

BARIATRIC SURGERY & METABOLIC CONDITIONS – SEARCH METHODOLOGIES

Search performed 3/5/2010:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed - All years

SEARCH STRATEGY:

diabetes OR diabetic* OR diabetes mellitus

AND

lifestyle* OR life style* OR life style OR exercis*[tiab] OR exercise therapy OR physical activity OR diet, reducing OR diet OR diets OR dieting OR nutrition

AND

obese OR obesity OR (weight AND reduce) OR (weight AND reducing) OR (weight AND reduction) OR weight-reducing OR (decreas* AND weight) OR "weight loss" OR (weight AND lost) OR overweight

AND

intervention OR patient education as topic OR "look ahead" OR prevent*[tiab] OR prevention[sh] OR psychology[sh]

AND

follow-up studies OR follow-up[tiab] OR followup[tiab] OR longitudinal studies OR longitudinal[tiab] OR outcome assessment (health care) OR treatment outcome OR randomi* OR randomized controlled trial[pt] OR double-blind OR double blind OR prospective studies

NUMBER OF RESULTS: 1413

Search performed 3/10/2010:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed - All years

SEARCH STRATEGY:

[diabetes[tiab] OR diabetic* OR diabetes mellitus

AND

patient utilities OR "quality of life" OR "standard gamble" OR "time tradeoff" OR "time trade-off" OR cost-utilit* OR patient utilit* OR utility OR utilities]

AND

bariatric OR obesity/su OR (obesity AND (surgery OR surgical))

NUMBER OF RESULTS: 161

Search performed 3/11/2010:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed - All years

SEARCH STRATEGY:

diabetes[tiab] OR diabetic* OR diabetes mellitus

AND

cost-utitit* OR patient utilitit* OR "standard gamble" OR "time tradeoff" OR "time trade-off"
OR bariatric OR obesity/su OR (obesity AND (surgery OR surgical))

NUMBER OF RESULTS: 108

Search performed 3/25/2010:

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed - All years

SEARCH STRATEGY:

diabetes[tiab] OR diabetic* OR diabetes mellitus

AND

obese OR obesity OR (weight AND reduce) OR (weight AND reducing) OR (weight AND
reduction) OR weight-reducing OR (decreas* AND weight) OR "weight loss" OR (weight
AND lost) OR overweight

AND

lifestyle* OR life style* OR life style OR exercis*[tiab] OR exercise therapy OR physical
activity OR diet, reducing OR diet OR diets OR dieting OR nutrition

AND

systematic[sb] OR systematic review* OR meta-analy* OR meta analy* OR metaanaly*
OR meta-analysis[pt] OR randomized controlled trial* OR rct* OR randomized controlled
trial[pt] OR controlled clinical trial* OR cct* OR controlled clinical trial[pt]

NUMBER OF RESULTS: 1766

Appendix B. Data Collection Forms

Short Form Screener

EPC PROJECT: **SCREENER FORM BARIATRIC SURGERY/METABOLIC CONDITIONS**

FINAL 05-10-2010

ID: _____

Reviewer: _____

Last name, first author: _____

Year of publication: _____

1. Does article report on cases with BMI between 30 and 35? (Circle one)
- Yes.....1
Other weight determination.....2
No/Unclear.....3 (STOP)

2. Does article include cases with type II diabetes or other metabolic conditions? (Circle one)
- Yes.....1
No.....2 (STOP)

3. Does article report on any of these treatments? (Check all that apply)
- Non-surgical treatments of metabolic conditions ☐
- Surgical treatments:
- Lap adjustable banding (LAGB) ☐
Roux-en-y gastric bypass..... ☐
Sleeve gastrectomy ☐
Other bariatric surgeries ☐
Biliopancreatic diversion (BPD/DS)..... ☐
(if only BPD/DS, then STOP)
- None of the above ☐ (STOP)
(To flag an article for background go to Q4; to flag duplicate data go to Q9; to order a reference go to Q10.)

4. Study design: (Circle one)
- Background (historical, editorial etc.)1 (STOP)
Non-systematic review2 (STOP)
Systematic review / Meta-analysis.....3 (STOP)
Case Report.....4 (STOP)
Case series.....5
Cohort.....6
Case control.....7
Controlled trial.....8
Other.....9

5. Does the study focus on the following outcomes? (Check all that apply)
- Blood glucose/diabetes related ☐
Blood pressure..... ☐
Lipids/cholesterol ☐
Weight loss outcomes..... ☐
Quality of life measures ☐
Removal rates..... ☐
Band-to-RYGB conversion rates..... ☐
Mortality ☐
Healthcare utilization/economics..... ☐
Adverse events/complications..... ☐
Other relevant outcomes..... ☐

6. Total sample size entering study. If entering sample not reported then enter total completing: (Enter # or 999 if no sample reported)

7. Total duration of follow up:

Duration #	Units Code
_____	_____

Unit Codes		
01. Hour	03. Week	05. Year
02. Day	04. Month	99. NR

8. Language of article: (Circle one)
- English.....1
Other.....2

Language (specify): _____

9. Do you think that this article might be a duplicate or include the same data as another study? (Circle one)
- Yes1
No.....2
If YES, which one(s) : _____

(Enter study ID #, author or 9999 if don't know.)

10. Is there a reference that needs to be checked? (Circle one)
- Yes1
No.....2
If YES, which one(s) : _____

(Enter reference # and/or author or 9999 if don't know.)

Notes:

Notes:

Detailed Abstraction Form

and go to ☐ or [Skip to Next](#)

Participants

Country

- | | | | |
|--|---|---|---|
| <input type="checkbox"/> US | <input type="checkbox"/> UK | <input type="checkbox"/> Japan | <input type="checkbox"/> Unclear |
| <input type="checkbox"/> Canada | <input type="checkbox"/> Western Europe | <input type="checkbox"/> Asia (not Japan) | <input type="checkbox"/> Other <input type="text"/> |
| <input type="checkbox"/> South/Central America | <input type="checkbox"/> Eastern Europe | <input type="checkbox"/> India | |
| | <input type="checkbox"/> Australia/NZ | <input type="checkbox"/> Middle East | |

Race

% Caucasian % Black/African Ancestry % Asian % Hispanic % Middle-eastern % American Indian/Alaskan Native % other race

☐ Race not reported

Instructions: If study has only one arm, please put data into the "Arm 1" box, rather than the "Overall" box.

	Arm 1	Arm 2	Overall
Sample Size	<input type="text"/>	<input type="text"/>	<input type="text"/>
Intervention	<input type="text"/>	<input type="text"/>	
Sex - % female	<input type="text"/>	<input type="text"/>	<input type="text"/>
Ages - Min	<input type="text"/>	<input type="text"/>	<input type="text"/>
Max	<input type="text"/>	<input type="text"/>	<input type="text"/>
Mean	<input type="text"/>	<input type="text"/>	<input type="text"/>
Median	<input type="text"/>	<input type="text"/>	<input type="text"/>
Std Dev	<input type="text"/>	<input type="text"/>	<input type="text"/>

Baseline weight

BMI:	Min	Max	Mean	Median	Std Dev
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Weight:	Min	Max	Mean	Median	Std Dev
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Diabetes

Overall

Arm 1

Arm 2

% with Diabetes	<input type="text"/>	<input type="text"/>	<input type="text"/>
Severity	<input type="checkbox"/> Years since dx <input type="text"/> <input type="checkbox"/> Need for Meds (%) <input type="text"/> <input type="checkbox"/> hgbA1c <input type="text"/> <input type="checkbox"/> Pre-diabetes/IGT <input type="text"/>	<input type="checkbox"/> Years since dx <input type="text"/> <input type="checkbox"/> Need for Meds (%) <input type="text"/> <input type="checkbox"/> hgbA1c <input type="text"/> <input type="checkbox"/> Pre-diabetes/IGT <input type="text"/>	<input type="checkbox"/> Years since dx <input type="text"/> <input type="checkbox"/> Need for Meds (%) <input type="text"/> <input type="checkbox"/> hgbA1c <input type="text"/> <input type="checkbox"/> Pre-diabetes/IGT <input type="text"/>
Severity of Diabetes-Other	Label: <input type="text"/>	Data: <input type="text"/>	Label: <input type="text"/>
	<input type="text"/>	<input type="text"/>	<input type="text"/>

Comorbidities	%			Comorbidities	%			Comorbidities	%		
	0	1	2		0	1	2		0	1	2
Asthma	<input type="text"/>	<input type="text"/>	<input type="text"/>	Hypertension	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sleep apnea	<input type="text"/>	<input type="text"/>	<input type="text"/>
Osteoarthritis	<input type="text"/>	<input type="text"/>	<input type="text"/>	Depression	<input type="text"/>	<input type="text"/>	<input type="text"/>	GERD	<input type="text"/>	<input type="text"/>	<input type="text"/>
Elevated lipids	<input type="text"/>	<input type="text"/>	<input type="text"/>	Metabolic syndrome	<input type="text"/>	<input type="text"/>	<input type="text"/>				
Oth	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Study Characteristics

Surgery type ☐ LABG ☐ RYGB ☐ Sleeve ☐ BPD ☐ Other Surgical ☐ Other non-Surgical

If RYGB, characterize the type:

- ☐ Lap
☐ Open
☐ Mixed
☐ Unknown
☐ Other

Duration

Study

Outcomes

Outcomes	Arm	Baseline t0	1st Follow-up t1	2nd Follow-up t2	3rd Follow-up t3	4th Follow-up t4	5th Follow-up t5	6th Follow-up t6	Units <input type="button" value="Select an Answer"/>
N	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
N	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
BMI	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
BMI	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Weight	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
Weight	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
HbA1c	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
HbA1c	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Fasting Glucose	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
Fasting Glucose	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
% on Diabetes meds	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
% on Diabetes meds	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Cholesterol	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
Cholesterol	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
Hypertension	Arm 1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
Hypertension	Arm 2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
<input type="text"/>	Select an Answer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
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<input type="text"/>	Select an Answer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
<input type="text"/>	Select an Answer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer
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<input type="text"/>	Select an Answer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an Answer

	Select an Answer								Select an Answer
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And finally, please do not forget to answer these last questions:

Does this study report adverse events?

- ☐ Yes
- ☐ No

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Bariatric surgery & metabolic conditions
Author, year _____
ID _____

AMSTAR Quality Assessment ANSWER EACH QUESTION

A/1 Was an 'a priori' design provided?

Yes 1
No 2
Not reported 8
Not applicable 9

A/2 Was there duplicate study selection and data extraction?

Yes 1
No 2
Not reported 8
Not applicable 9

A/3 Was a comprehensive literature search performed?

Yes 1
No 2
Not reported 8
Not applicable 9

A/4 Was the status of publication (i.e. grey literature)
used as an inclusion criterion?

Yes 1
No 2
Not reported 8
Not applicable 9

A/5 Was a list of included studies provided?

Yes 1
No 2
Not reported 8
Not applicable 9

A/6 Were the characteristics of the included studies provided?

Yes 1
No 2

Not reported 8
Not applicable 9

A/7 Was the scientific quality of the included studies
assessed and documented?

Yes 1
No 2
Not reported 8
Not applicable 9

A/8 Was the scientific quality of the included studies used
appropriately in formulating conclusions?

Yes 1
No 2
Not reported 8
Not applicable 9

A/9 Were the methods used to combine the findings of
studies appropriate?

Yes 1
No 2
Not reported 8
Not applicable 9

A/10 Was the likelihood of publication bias assessed?

Yes 1
No 2
Not reported 8
Not applicable 9

A/11 Was the conflict of interest stated?

Yes 1
No 2
Not reported 8
Not applicable 9

Appendix C. Evidence Tables

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Schauer 2012 ³⁷ US	RCT	50 T2DM patients with mean age 48.3 (SD=8.4), BMI 37.0 (SD=3.3)	RYGB	Mean Weight (kg): 12mths: 77.3 (SD=13.0) Mean BMI: 3mth: 31.8 (SD NR) 6mths: 28.2 (SD NR) 9mths: 26.9 (SD NR) 12mths: 26.8 (SD NR)	Fasting plasma glucose, mg/dl: 3mths: 109(SD NR) 6mths: 96 (SD NR) 9mths: 96 (SD NR) 12mths: 99 (SD NR) HbA1c, %: 3mths: 6.8 (SD NR) 6mths: 6.3 (SD NR) 9mths: 6.4 (SD NR) 12mths: 6.4 (SD=0.9) HbA1c<6.0%: 12mths: 42% HbA1c<6.0%, no meds: 12mths: 42% # of DM meds: Baseline: 2.6 (SD NR) 3mths: 1.1 (SD NR) 6mths: 0.6 (SD NR) 9mths: 0.4 (SD NR) 12mths: 0.3 (SD NR)	Median Percentage Change in: Triglyceride level: -44 (IQR -65- to -16) Mean Percentage Change in: HDL cholesterol level: -28.5 (SD=22.7)	

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Schauer 2012 ³⁷ US	RCT	50 T2DM patients with mean age 47.9 (SD=8.0), BMI 36.2 (SD=3.9)	Sleeve	Mean Weight (kg): 12mths: 75.5 (SD=12.9) Mean BMI: 3mth: 31.3 (SD NR) 6mths: 28.3 (SD NR) 9mths: 27.3 (SD NR) 12mths: 27.2 (SD NR)	Fasting plasma glucose, mg/dl: 3mths: 118(SD NR) 6mths: 104 (SD NR) 9mths: 102 (SD NR) 12mths: 97 (SD NR) HbA1c, %: 3mths: 7.1 (SD NR) 6mths: 6.7 (SD NR) 9mths: 6.7 (SD NR) 12mths: 6.6 (SD=1.0) HbA1c<6.0%: 12mths: 37% HbA1c<6.0%, no meds: 12mths: 27% # of DM meds: Baseline: 2.4 (SD NR) 3mths: 1.1 (SD NR) 6mths: 0.9 (SD NR) 9mths: 0.8 (SD NR) 12mths: 0.9 (SD NR)	Median Percentage Change in: Triglyceride level: -42 (IQR -56- to 0) Mean Percentage Change in: HDL cholesterol level: 28.4 (SD=21.9)	

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Schauer 2012 ³⁷ US	RCT	50 T2DM patients with mean age 49.7 (SD=7.4), BMI 36.8 (SD=3.0)	Medical Therapy	Mean Weight (kg): 12mths: 99.0 (SD=16.4) Mean BMI: 3mth: 35.4 (SD NR) 6mths: 34.8(SD NR) 9mths: 34.5 (SD NR) 12mths: 34.4 (SD NR)	Fasting plasma glucose, mg/dl: 3mths: 122(SD NR) 6mths: 113 (SD NR) 9mths: 120 (SD NR) 12mths: 120 (SD NR) HbA1c, %: 3mths: 7.7 (SD NR) 6mths: 7.1 (SD NR) 9mths: 7.4 (SD NR) 12mths: 7.5 (SD=1.8) HbA1c<6.0%: 12mths: 12% HbA1c<6.0%, no meds: 12mths: 0% # of DM meds: Baseline: 2.8 (SD NR) 3mths: 3.1 (SD NR) 6mths: 3.1 (SD NR) 9mths: 3.0 (SD NR) 12mths: 3.0 (SD NR)	Median Percentage Change in: Triglyceride level: -14 (IQR -40- to 3) Mean Percentage Change in: HDL cholesterol level: 11.3 (SD=25.7)	
Dixon 2008 ⁴² Australia/ New Zealand	RCT	30 T2DM patients with mean age 46.6 (SD=7.4), BMI 36.9 (SD NR)	LABG	Mean Weight (kg): 24mths: 84.6 (SD=15.8) Mean BMI: 24mths: 29.4 (SD NR)	Fasting blood glucose, mg/dL: 24mths: 105.6 (SD=30.3) HbA1c, %: 24mths: 6.0 (SD=0.8) HbA1c<6.2%: 24mths: 80% Taking DM meds, %: Baseline: 28/30 (93.3%) 24mths: 4/30 (13.3%) Metabolic Syndrome, %: Baseline: 29/30 (96.7%) 24mths: 9/30 (30.0%)	Blood pressure, mm Hg: Systolic: 130.4 (SD=19.0) Diastolic: 85.4 (SD=7.0) Total Cholesterol, mg/dL:205.4 (SD=46.6) Triglycerides, mg/dL:118.9 (SD=79.7) HDL-C, mg/dL: 59.7 (SD=13.6)	GI: Feeding difficulties, 1/30 (3.3%) Other, 1/30 (3.3%) Hepatobiliary: Acute cholecystitis or CBD obstruction, 4/40 (10%) Metabolic: Hypoglycemia, 1/30 (3.3%) Other: Constitutional, 1/30 (3.3%) Pouch/anastomosis: Pouch dilation: 2/30 (6.7%) Wound: Infection: 1/30 (3.3%)

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Dixon 2008 ⁴² Australia/ New Zealand	RCT	30 T2DM patients with mean age 47.1(SD=8.7), BMI 37.1 (SD NR)	Non-surgical treatment- Diet, pharmacotherapy & lifestyle change	Mean Weight (kg): 24mths: 104.8 (SD=15.3) Mean BMI: 24mths: 36. (SD NR)	Fasting blood glucose, mg/dL: 24mths: 139.6 (SD=38.1) HbA1c, %: 24mths: 7.2 (SD=1.4) HbA1c<6.2%: 24mths: 20% Taking DM meds, %: Baseline: 26/30 (86.7%) 24mths: 22/30 (73.3%) Metabolic Syndrome, %: Baseline: 29/30 (96.7%) 24mths: 26/30 (86.7%)	Blood pressure, mm Hg: Systolic: 132.6 (SD=17.7) Diastolic: 83.1 (SD=8.5) Total Cholesterol, mg/dL:197.8 (SD=59.3) Triglycerides, mg/dL:186.7 (SD=127.2) HDL-C, mg/dL: 50.7 (SD=12.1)	GI: Diarrhea, 1/30 (3.3%) Feeding difficulties, 2/30 (6.7%) Other, 2/30 (6.7%) Hepatobiliary: Acute cholecystitis or CBD obstruction, 4/40 (10%) Metabolic: Hypoglycemia, 1/30 (3.3%) Other: Constitutional, 1/30 (3.3%) TIA, 1/30 (3.3%)
O'Brien 2006 ⁴⁰ Australia/ New Zealand	RCT	40 patients with mean age 41.8 (SD=6.4), BMI 33.7 (32.9-34.4) kg/m2	LAGB	Mean Weight (kg): 6mth: 81.6 (79.4-83.7) 12mths: 76.3 (74.1-78.5) 18mths: 75.2 (73.1-77.4) 24mths: 74.5 (72.4-76.7) Mean BMI: 1mth: 28.9 (28.1-29.7) 12mths: 27.0 (26.2-27.8) 18mths: 26.7 (25.9-27.5) 24mths: 26.4 (25.6-27.2) Mean EWL, %: 1mth: 57.2 (47.8-66.6) 12mths: 78.6 (69.2-88.1) 18mths: 83.6 (74.2-93.1) 24mths: 87.2 (77.7-96.6)	Metabolic Syndrome, %: Baseline: 15/40 (37.5%) 24mths: 1/39 (2.7%)	Percentage Change in: Systolic BP: -10.8 (SD=10.8) Diastolic BP: -10.9 (SD=12.5) Total cholesterol level: -0.4 (SD=18.1) Triglyceride level: -19.1 (SD=35.7) HDL cholesterol level: 30.0 (SD=28.9) LDL cholesterol level: -6.5 (19.0)	Band related: Band slippage, 4/40 (10%) Port infection, 1/40 (2.5%) Hepatobiliary: Acute cholecystitis or CBD obstruction, 1/40 (2.5%) Major surgical complications: NOS, 5/40 (12.5%)

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
O'Brien 2006 ⁴⁰ Australia/ New Zealand	RCT	40 patients with mean age 40.7 (SD=7.0), BMI 33.5(32.7-34.3) kg/m ²	Non-surgical treatment- Diet, pharmacotherapy & lifestyle change	Mean Weight (kg): 6mth: 81.6 (79.4-83.7) 12mths: 85.3 (83.0-87.5) 18mths: 87.7 (79.9-83.0) 24mths: 89.5 (80.5-83.6) Mean BMI: 1mth: 28.7 (27.9-29.6) 12mths: 29.9 (29.1-30.8) 18mths: 30.9 (30.0-31.8) 24mths: 31.5 (30.6-32.4) Mean EWL, %: 1mth: 57.4 (47.6-66.4) 12mths: 41.1 (31.1-50.9) 18mths: 29.0 (19.0-38.9) 24mths: 21.8 (11.9-31.6)	Metabolic Syndrome, %: Baseline: 15/40 (37.5%) 24mths: 8/33 (24.0%)	Percentage Change in: Systolic BP: -7.2 (SD=9.7) Diastolic BP: -1.6 (SD=11.2) Total cholesterol level: -3.0 (SD=17.0) Triglyceride level: -3.7 (SD=39.4) HDL cholesterol level: 6.9 (SD=18.9) LDL cholesterol level: -5.2 (21.6)	GI: Feeding difficulties, 1/40 (2.5%) Other, 8/40 (20.0%) Hepatobiliary: Acute cholecystitis or CBD obstruction, 4/40 (10%) Major surgical complications: NOS, 4/40 (10%)
Chiellini, 2009 ⁴⁸ Western Europe	Matched Cohort	5 T2DM patients with mean age 48 years (SE=3), BMI 30.9 (SE=1.1) kg/m ²	Non-surgical treatment- Diet, pharmacotherapy & lifestyle change	Mean Weight (kg): 1mth: 92.6 (SE=6.4) 12mths: 77.8 (SE=3.5) 18mths: 76.8 (SE=3.0) Mean BMI: 1mth: 30.0(SE=0.8) 12mths: 25.4 (SE=0.01) 18mths: 25.1 (SE=0.01)	2 hr Fasting Blood Glucose,mmol/L: 1mth: 6.2 (SE=0.5) HbA1c, %: 1mth: 7.2 (SE=0.3) 12mth: 5.6 (SE=0.2) 18mth: 5.7 (SE=0.2)		No Mention of Adverse Events
Chiellini, 2009 ⁴⁸ Western Europe	Matched Cohort	7 T2DM patients with mean age 51 years (SE=3), BMI 30.0 (SE=1.7) kg/m ²	Non-surgical treatment- Diet	Mean Weight (kg): 1mth: 83.7 (SE=5.5) Mean BMI: 1mth: 29.2 (SE=1.8)	2 hr Fasting Blood Glucose, mmol/L: 1mth: 15.2 TO 6.2 HbA1c, %: 1mth: 8.6 (SE=0.3)		No Mention of Adverse Events

Appendix C Evidence Tables For Surgical Treatment v. Non-Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Serrot, 2011 ³⁸ US	Cohort	17 T2DM patients with median age 56.0 years (IQR=7.0), median BMI 34.6 (IQR=0.8) kg/m ²	RYGB	Median BMI: 12mths: 25.8 (IQR=2.5) %EWL: 12mths: 70 (IQR=21) %WL: 12mths: 25 (IQR=6)	Median HbA1c,%: 12mths: 6.1 (IRQ=2.7) Off anti-diabetic meds: 12mths: 9/17 (52.9%) Resolution of DM: 12mths: 11/17 (64.7%)	Systolic blood pressure,mm Hg: 12mths: 132 (IQR=27)) LDL,mg/dL: 12mths: 92 (IQR=62))	Other major surgical complications Incisional hernia 2/17 (11.8%) Metabolic: Hypoglycemia, 0/17 (0%) GI: Ulcers, 2/17 (11.8%) Death: NOS, 0/17 (0%)
Serrot, 2011 ³⁸ US	Cohort	17 T2DM patients with median age 62.0 years (IQR=12.0), median BMI 34.0 (IQR=1.0) kg/m ²	Non-surgical treatment - routine medical management	Median BMI: 12mths: 34.2 (IQR=2.1) %EWL: 12mths: -4 (IQR=10) %WL: 12mths: -1 (IQR=4)	Median HbA1c,%: 12mths: 7.1 (IRQ=1.8) Off anti-diabetic meds: 12mths: 0/17 (0%)	Systolic blood pressure,mm Hg: 12mths: 124 (IQR=26)) LDL,mg/dL: 12mths: 100 (IQR=66))	Death: NOS, 0/17 (0%)

Appendix C Evidence Tables For Surgical Treatment v. Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
DeMaria, 2010 ²⁸ US	Cohort	109 T2DM patients with mean age 52.8 years (SD=9.5), BMI 33.7 (SE=1.1) kg/m ²	RYGB	Mean BMI: 0-3mths: 30.6(SD=3.0) 3-6mths: 27.2(SD=3.8) 6-12mths: 27.1(SD=4.5) 12-24mths: 23.0(SD=2.0) % EBW: 0-3mths: 41.7(SD=15.0) 3-6mths: 26.8(SD=17.4) 6-12mths: 26.9(SD=19.7) 12-24mths: 7.6(SD=7.6)	Number of T2DM meds: 0-3mths: 0.8(SD=1.0) 3-6mths: 0.4(SD=0.7) 6-12mths: 0.5(SD=0.7) 12-24mths: 0(SD=0) % off T2DM meds: 0-3mths: 37.5 3-6mths: 50.0 6-12mths: 55.2 12-24mths: 75.0	Number of meds: 0-3mths: 3.9(SD=3.2) 3-6mths: 3.5(SD=3.2) 6-12mths: 3.0(SD=2.5) 12-24mths: 1.5(SD=1.9)	Bleeding/hematoma: Band slippage, 1/109 (0.9%) Cardiovascular/Respiratory: Arrhythmia, 1/109 (0.9%) Atelectasis, 1/109 (0.9%) Pneumonia, 2/109 (1.8%) Death: NOS, 0/40 (0%) GI: Feeding difficulties, 1/109 (0.9%) Vomitting and/or nausea, 4/109 (3.7%) Hepatobiliary: Acute cholecystitis or CBD obstruction, 1/109 (0.9%) Major Surgical Complications: Internal hernia, 1/109 (0.9%) Metabolic: Vitamin def, 1/109 (0.9%) Other: NOS, 1/109 (0.9%) Pouch/anastomosis: Anastomotic leak, 1/109 (0.9%) Stricture, 4/109 (3.7%) Wound: Infection, 1/109 (0.9%)
DeMaria, 2010 ²⁸ US	Cohort	109 T2DM patients with mean age 52.0 years (SD=11.2), BMI 33.9 (SE=1.1) kg/m ²	LABG	Mean BMI: 0-3mths: 31.6(SD=2.5) 3-6mths: 31.0(SD=2.7) 6-12mths: 30.9(SD=2.9) 12-24mths: 29.9(SD=2.2) % EBW: 0-3mths: 40.6(SD=46.8) 3-6mths: 45.5(SD=12.9) 6-12mths: 45.4(SD=13.6) 12-24mths: 41.8(SD=10.2)	Number of T2DM meds: 0-3mths: 1.0(SD=1.1) 3-6mths: 0.8(SD=1.0) 6-12mths: 0.6(SD=0.8) 12-24mths: 0.8 (SD=1.1) % off T2DM meds: 0-3mths: 21.1 3-6mths: 31.8 6-12mths: 27.5 12-24mths: 36.4	Number of meds: 0-3mths: 4.2(SD=3.8) 3-6mths: 3.5(SD=3.7) 6-12mths: 3.1(SD=3.7) 12-24mths: 3.0(SD=3.3)	Band related: Band slippage, 1/109 (0.9%) Death: NOS, 0/40 (0%) GI: Ileus, 1/109 (0.9%) Vomitting and/or nausea, 1/109 (0.9%)

Appendix C Evidence Tables For Surgical Treatment v. Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Frenken, 2011 ³² Western Europe	Case Series	4 T2DM patients with mean age 50 years (range 37-63), BMI 32 (range 31-34) kg/m ²	RYGB	Mean BMI: 12mths: 27 (range 26-28)	HbA1c, %: 12mth: 6.7 (range 5.8-7.8)		GI: Anorexia/excessive weight loss, 0/4 (0%)
Frenken, 2011 ³² Western Europe	Case Series	12 T2DM patients with mean age 57.3 years (range 36-68), BMI 32 (range 26-34.5) kg/m ²	BPD	Mean BMI: 12mths: 24.6(range 19-30)	HbA1c, %: 12mth: 5.2 (range 4.1-6.4)		GI: Anorexia/excessive weight loss, 0/12 (0%)
Lee, 2011 ³⁴ Taiwan	RCT	30 T2DM patients with mean age 45 years (range 34-58), BMI 30.3 (range 25.0-34.0) kg/m ^{2*}	RYGB	Mean BMI: 12mths: 22.8(SD=2.2) Weight, kg: 12mths: 60.7(SD=10.1) % EWL: 12mths: 94.4(SD=33.1)	Remission of DM: 12mths: 28/30 (93%) Successful treatment of DM: 12mths: 17/30 (57%) Metabolic syndrome: 12mths: 2/30 (7%)	C-peptides: 12 mths: 1.6(SD=1.1) Systolic BP: 12 mths: 119.6 (SD=17.3) Diastolic BP: 12 mths: 74.2(SD=12.3) Total cholesterol: 12 mths: 162.2(SD=26.6) Triglycerides: 12 mths: 104.9(SD=62.0) HDL-C: 12 mths: 49.3(SD=7.7) LDL-C: 12 mths: 96.9(SD=21.5)	Death: NOS, 0/30 (0%) Major surgical complications: NOS, 0/30 (0%) Other: Minor surgical complications 3/30 (10%) Readmission: Conservative treatment, 1/30 (3.3%)

Appendix C Evidence Tables For Surgical Treatment v. Surgical Treatment Trials

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Lee, 2011 ³⁴ Taiwan	RCT	30 T2DM patients with mean age 45 years (range 34-58), BMI 30.3 (range 25.0-34.0) kg/m ² *	Sleeve	Mean BMI: 12mths: 24.4(SD=2.4) Weight, kg: 12mths: 65.7(SD=7.9) % EWL: 12mths: 76.3(SD=38.9)	Remission of DM: 12mths: 14/30 (47%) Successful treatment of DM: 12mths: 0 (0%) Metabolic syndrome: 12mths: 18 (60%)	C-peptides: 12 mths: 1.6(SD=0.5) Systolic BP: 12 mths: 123.5(SD=9.8) Diastolic BP: 12 mths: 75.4(SD=8.5) Total cholesterol: 12 mths: 207.8(SD=67.0) Triglycerides: 12 mths: 144.2(SD=58.9) HDL-C: 12 mths: 45.4(SD=7.9) LDL-C: 12 mths: 136.6(SD=40.8)	Death: NOS, 0/30 (0%) Major surgical complications: NOS, 0/30 (0%) Other: Minor surgical complications 3/30 (10%) Readmission: Conservative treatment, 1/30 (3.3%)

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Boza, 2011 ³⁰ South America	Cohort	80 T2DM patients with mean age 47.7 years (SD=8.9), BMI 33 (SD=1.4) kg/m ² *	RYGB	% EWL: 6mths: 93.8(SD=25.4) 12mths: 103.2(SD=29.4) 24mths: 112.3(SD=30.5)	% Resolution of DM: 12mths: 61/80 (76%)	Resolution of Hypertension: 12mths: 46.7% Resolution of Dyslipidemia: 12mths: 80.1%	Other major surgical complication: Reoperation,0/80 (0%) Pouch/anastomosis: Stricture, 9/80 (12.3%) Leak, 0/80 (0%) Death: NOS,0/80 (0%)
Cohen, 2006 ²⁶ South America	Case Series	37 T2DM patients with mean age 34 years (range 28-45), BMI 32.5 (range 23.4-34.9) kg/m ² *	RYGB	%EWL: 6mths: 44 (SD NR) 12mths: 71.6 (SD NR) 18mths: 78.4 (SD NR) 36mths: 77 (SD NR) 48mths: 81 (SD NR)	% off DM meds: 20mths: 37/37 (100%) % DM Remission: 6mths: 36/37 (97.29%) Mean Fasting Glucose, mg/dL: 20mths: 88 (range 60-94)	Cholesterol,mg/dL: 20mths: 172 (range 161-190) Triglycerides,mg/dL: 20mths: 156 (range 172-163) LDL,mg/dL: 20mths: 115 (range 101-127) HDL men,mg/dL: 20mths: 41 (range 40-51) HDL women,mg/dL: 20mths: 50 (range 49-58)	Death: NOS,0/37 (0%) GI: GERD, 0/37 (0%)
de Sa, 2011 ³¹ South America	Cohort	27 T2DM patients with mean age 50.3 years (SD=8.3), BMI 33.6 (SD=1.5) kg/m ² *	RYGB	Mean BMI: 20mths: 25.7(SD=2.9) Weight, kg: 20mths: 68.5(SD=12.4)	Mean Fasting Glucose, mg/dL: 20mths: 93.9 (SD=17.0) Mean HbA1c: 20mths: 6.0 (SD=0.7) % Resolution of DM: 20mths: 13/27 (48.1%) % Glycemic Control without Medication: 20mths: 20/47 (74.1%)		Major surgical complication: NOS,0/27 (0%) Pouch/anastomosis: Stricture, 1/27 (3.7%) Death: NOS,0/27 (0%) Metabolic: Malnutrition,0/27 (0%) Wound: Seroma,4/27 (14.8%) Infection/abscess, 2/27 (7.4%)
Huang, 2011 ³³ Asia	Case Series	22 T2DM patients with mean age 47 years (range 28-63), BMI 30.8 (SD=2.9) kg/m ²	RYGB	Mean BMI: 6mths: 24.4 (SD=2.6) 12mths: 23.7 (SD=1.6)	% off DM meds: 12mths: 20/22 (90.3%) % Remission of DM: 12mths: 14/22 (63.6%) Fasting plasma glucose,mg/dL 6mths: 113.5 (SD=42.5) 12mths: 103.5 (SD=27.6)) HbA1c,%: 6mths: 6.3 (SD NR) 12mths: 5.9 (SD NR)	Fasting C-peptide, ng/ml (for 10 patients with mean BMI 29.4): 1mth: 1.94 (SD=1.29) 3mths: 1.90 (SD=0.92) 6mths: 1.88 (SD=0.82) 12mths: 1.88 (SD=1.07)	Death: NOS,0/22 (0%) GI: Diarrhea, 1/22 (4.6%) Bleeding/hematoma: Anastomotic hemorrhage: 1/22 (4.6%)

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Lee, 2008 ²⁷ Asia	Cohort	44 T2DM patients with mean age 39.0 years (SD=8.9), BMI 31.7 (SD=2.7) kg/m ² *	RYGB	Change in BMI: 12mths: 8.5 (SD=2.2) Change in Body Weight,kg: 12mths: 23.1 (SD=6.7)	% Metabolic Syndrome: 12mths: 42.7% Change in Glucose,mg/dl: 12mths: 80.1 (SD=56.2) Change in Insulin,pmol/l: 20.6 (SD=27.1) Change in HbA1c: 1.7 (SD=2.3)	Change in HDL-C, mg/dl: 8.3 (SD=11.2) Change in LDL,mg/dl: 53.8 (SD=29) Triglyceride,mg/dl: 147.4 (SD=150.4) C-peptide,mmol/l: 2.6 (SD=2.3)	Death: NOS, 0/44, (0%) Other: Morbidity major, 2/44, (4.6%)
Lee, 2011 ³⁵ Asia	Case Series	62 T2DM patients with mean age 43.1 years (SD=10.8), BMI 30.1 (SD=3.3) kg/m ² *	RYGB	Mean BMI: .25mths: 28.9 (SD=3.1) 1mths: 26.7 (SD=2.9) 3mths: 23.4 (SD=2.6) 6mths: 23.8 (SD=2.4) 12mths: 22.6 (SD=2.3) 24mths: 23.0 (SD=2.7) %EWL: .25mths: 22.9(SD=30.2) 1mths: 47.9 (SD=36.1) 3mths: 78.2 (SD=41.2) 6mths: 102.5 (SD=71.3) 12mths: 113 (SD=37.3) 24mths: 82.8 (SD=28.8)	Blood glucose level,mg/dL: .25mths: 168.9 (SD=52.0) 1mths: 140.2 (SD=41.6) 3mths: 116.6 (SD=25.9) 6mths: 103.2 (SD=19.2) 12mths: 100.2 (SD=19.4) 24mths: 106.3 (SD=18.8) Insulin, uIU/mL: .25mths: 4.6(SD=3.2) 1mths: 4.5(SD=2.6) 3mths: 5.0 (SD=3.1) 6mths: 5.2 (SD=4.7) 12mths: 4.6 (SD=3.8) 24mths: 2.8 (SD=1.6) Mean HbA1c: .25mths: 9.1 (SD=1.1) 1mths: 7.2 (SD=1.2) 3mths: 6.0 (SD=0.8) 6mths: 5.7 (SD=0.6) 12mths: 5.8 (SD=0.5) 24mths: 5.9 (SD=0.5) % DM Remission: .25mths: 0/62 (0%) 1mths: 7/62 (11%) 3mths: 17/45 (37%) 6mths: 21/40 (53%) 12mths: 17/30(57%) 24mths: 11/20 (55%)		Other major surgical: NOS, 0/62, (0%) Minor surgical: NOS, 7/62, (11.3%)
Ramos, 2011 ³⁶ South America	Cohort	147 T2DM patients with mean age 46.9 years (range 34-60), BMI 29.1 (range	RYGB	Not Reported	HbA1c,%: 18mths: 6.4 (SD=range 5.4-7.2), 31 patients % T2DM Control (no med + glucose control): 18mths: 124/147 (84.3%) % on oral diabetes meds ONLY: 18mths: 23/147 (15.6%)		Pouch/anastomosis: Stricture, 3/147 (2.0%) Fistula, 1/147 (0.7%) Death: NOS,0/147 (0%)

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
		26-33) kg/m ²					
Shah, 2010 ²⁹ India	Case Series	15 T2DM patients with mean age 45.6 years (SD=12), BMI 28.9 (SD=4.0) kg/m ² *	RYGB	Mean BMI: 9mths: 23.0 (SD=3.6) Mean Body Weight,kg: 62.7 (SD NR)	% off DM meds: 1mths: 12/15 (80%) 3mths: 15/15 (100%) 6mths: 15/15 (100%) 9mths: 15/15 (100%) Fasting blood glucose,mg/dL: 1mths: 106.7 (SD NR) 3mths: 112.3 (SD NR) 6mths: 100.2 (SD NR) 9mths: 89.2 (SD=12) Mean HbA1c,%: 1mths: 8.3 (SD NR) 3mths: 7.4 (SD NR) 6mths: 6.6 (SD NR) 9mths: 6.1 (SD=0.6)	Systolic blood pressure,mm Hg: 9mths: 116 (SD NR) Total cholesterol,mg/dL: 9mths: 135 (SD NR) High-density lipoprotein,mg/dL: 9mths: 50 (SD NR)	Death: NOS, 0/15 (0%) Major surgical complications: NOS, 0/15 (0%) GI: Anorexia/excessive weight loss, 0/15 (0%)
Angrisani, 2004 ³⁹ Western Europe	Cohort	210 patients (1.9% with DM) with mean age 38.2 years (range 17-66), BMI 33.9 (range 25.1-35.0) kg/m ² *	LAGB	Mean BMI: 6mths: 31.1(SD=2.2) 12mths: 29.7(SD=2.2) 24mths: 28.7(SD=3.8) 36mths: 26.7(SD=4.3) 48mths: 27.9(SD=3.2) 60mths: 28.2(SD=0.9) % EWL: 6mths: 28.1(SD=20.7) 12mths: 52.5(SD=13.2) 24mths: 61.3(SD=14.7) 36mths: 64.7(SD=12.2) 48mths: 68.8(SD=15.3) 60mths: 71.9(SD=10.7)	Resolution of DM: 12mths: 210/210 (100%)	Hypertension: Baseline: 9/210 (4.3%) 12mth: 1/210 (0.5%) GERD: Baseline: 5/210 (2.4%) 12mth: 0/210 (0%)	Band related: Band slippage, 2/210 (1.0%) Port tube leak, 4/210 (1.9%) Removal, 7/210 (3.3%) Death: Band related - gastric perforation, 1/210 (0.5%) Pouch/anastomosis: Pouch dilation, 11/210 (5.2%)

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Choi, 2010 ⁴⁴ US	Cohort	66 patients (6.5% with T2DM) with mean age 40.7 years (SD=11.0), BMI 36.1 (SD=2.6) kg/m ^{2*}	LABG	% EWL: 3mths: 20.3 (SD=9.0) 6mths: 28.5 (SD=14.0) 12mths: 44.7 (SD=19.3) 18mths: 42.2 (33.7)	DM improved/resolved: 12mths: 22/66 (33.3%)	Hypertension Improved/resolved: 28.6% Hyperlipidemia improved/resolved: 15.4% Apnea improved/resolved: 33.3% Arthritis improved/resolved: 36.7% GERD improved/resolved: 31.3% Stress incontinence improved/resolved: 46.6%	Band related: Band slippage, 2/66 (3.0%) Erosion, 1/66 (1.5%) Port site seroma, 1/66 (1.5%) Death: NOS, 0/66 (0%)
Parikh 2006 ⁴¹ Australia/ New Zealand	Case Series	93 patients (8.6% with T2DM) with mean age 44.6 years (range 16-76), BMI 32.7 (range 30-34) kg/m ^{2*}	LABG	Mean BMI: 12mths: 27 (SD=2) 24mths: 27 (SD=3) 36mths: 27 (SD=3) %EWL: 12mths: 58 (SD=24) 24mths: 57 (SD=29) 36mths: 54 (SD=32)	% off DM meds: Pre-op 8/93 took DM meds, Post-op 0/93 needed meds (100%)	Asthma Meds: Pre-op 5/93, Post-op 1/93 Depression Meds: Pre-op 11/93, Post-op 7/93 no meds, 4/93 improved Hypertension Meds: Pre-op 8/93, Post-op 2/93 Sleep apnea Meds: Pre-op 7/93, Post-op 1/93 Arthritis Meds: Pre-op 9/93, Post-op 8/93 improved	Band Related: Band slippage, 3/93 (3.2%) Port leak, 1/93 (1.1%) Death: NOS, 0/93, (0%) GI: Hiatal hernia, 2/93, (2.2%)
Sultan, 2009 ⁴³ US	Case Series	53 patients (28.3% with T2DM) with mean age 46.9 years (range 16-68), BMI 33.1 (range 28.2-35) kg/m ^{2*}	LABG	Mean BMI: 6mths: 28.1 (SD=2.4) 12mths: 25.8 (SD=2.9) 24mths: 25.8 (SD=3.1) %EWL: 6mths: 48.3 (SD=17.6) 12mths: 69.9 (SD=28.0) 24mths: 69.7 (SD=31.7)	% off & improved DM meds: Pre-op 15/53 took DM meds, Post-op 50% meds resolved & improved	Asthma Meds: Pre-op 8/53, Post-op 66.7% resolved, 0% improved Depression Meds: Pre-op 15/53, Post-op 25% resolved, 37.5% improved Hypercholesteremia Meds: Pre-op 25/53, Post-op 33.3% resolved, 0% improved Hypertension Meds: Pre-op 21/53, Post-op 45.5% resolved, 27.3% improved Hypertriglyceridemia Meds: Pre-op 11/53, Post-op 40% resolved, 20% improved Obstructive sleep apnea Meds: Pre-op 19/53, Post-op 50% resolved, 30% improved Osteoarthritis Meds: Pre-op 11/53, Post-op 100% resolved, 0% improved	Band Related: Band slippage, 1/53 (1.9%) Port leak, 2/53 (3.8%) Death: NOS, 0/53, (0%) GI: Esophagitis 2/53 (3.8%) Feeding difficulties 2/53 (3.8%)

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Lembach, 2011 ⁴⁵ South America	Cohort	12 patients with T2DM with mean age NR, BMI 35.8 kg/m ² (SD NR); And 9 Insulin Resistant patients with mean age NR, BMI 33.6 kg/m ² (SD NR)	Sleeve	Mean BMI: 12mths,T2DM: 28.2 (SD NR) 12mths,IR: 23.4 (SD NR)	Blood glucose level,mg/dL: 12mths,T2DM: 88(SD NR) 12mths,IR: 76 (SD NR) Mean HbA1c: 12mths,T2DM: 4.1 (SD NR)	Triglyceride,mg/dl: 12mths,T2DM: 150 (SD NR) 12mths,IR: 88 (SD NR)	No Mention of Adverse Events
Noya, 1998 ⁴⁶ Western Europe	Case Series	10 T2DM patients with mean age 52.1 years (range 40-62), BMI 33.2 (range 24-39) kg/m ^{2*}	BPD	Mean BMI: 7mths: 27.2 (SD=3.6) Mean Excess Weight,kg: 7mths: 11.9 (SD=7.9)	% off DM meds: 8mths: 9/10 (90%)	Cholesterol: 7mths: 165.1 (sd=8.7)	Cardiovascular: PE,1/10 (10%) Major surgical complications Reoperation NOS 1/10 (10%)
Scopinaro , 2007 ⁴⁷ Western Europe	Case Series	7 T2DM patients with mean age 49 years (range 39-60), BMI 33.4 (range 32.0-34.6) kg/m ^{2*}	BPD	Mean Weight, kg: 12mths: 71.2 (SD=9.5) 24mths: 74.7 (SD=9.8) Mean BMI: 12mths: 26.2 (SD=2.1) 24mths: 26.9 (SD=2.1)	Mean serum glucose: 12mths: 87.0 (SD=8.1) 24mths: 90.4 (SD=7.4) % off DM meds: 24mths: 7/7 (100%)	Triglycerides: 12mths: 156.5 (SD=67.5) 24mths: 144.1 (SD=62.2) Cholesterol: 12mths: 140.5 (SD=38.3) 24mths: 138.3 (SD=18.0)	No Mention of Adverse Events

Appendix C Evidence Tables For Observational Studies and Controlled Trials with 1 surgical arm**

Author, Year	Study Design	Patient Population	Procedures	Weight Loss Outcomes	Resolution or improvement in diabetes	Other Outcomes	Adverse Events
Scopinaro , 2011 ⁴⁹ Western Europe	Case Control	15 T2DM obese (OB) patients with mean age 55.1 years (SD=8.0), BMI 33.1 (SD=1.5) kg/m2; And 15 T2DM overweight (OW) patients with mean age 57.8 years (SD=6.7), BMI 28.0 (SD=1.3) kg/m2	BPD	Mean BMI, OB: 1mth: 29.1(SD=2.4) 4mths: 27.2(SD=1.6) 8mths: 26.9(SD=2.3) 12mths: 26.4(SD=2.4) 24mths: 27.4(SD=2.3) Mean BMI, OW: 1mth: 24.3(SD=0.9) 4mths: 24.2(SD=1.0) 8mths: 24.3(SD=1.3) 12mths: 24.2(SD=1.6) 24mths: 24.6(SD=1.8) Weight, kg, OB: 1mth: 78.2(SD=9.9) 4mths: 73.2(SD=9.1) 8mths: 72.4(SD=10.4) 12mths: 71.1(SD=10.4) 24mths: 73.7(SD=10.5) Weight, kg, OB: 1mth: 70.4(SD=8.7) 4mths: 70.0(SD=9.5) 8mths: 70.0(SD=8.2) 12mths: 70.3(SD=9.2) 24mths: 70.9(SD=9.6)	Mean fasting serum glucose, mg/dL,OB: 1mth: 154(SD=49) 4mths: 129(SD=32) 8mths: 133(SD=39) 12mths: 131(SD=32) 24mths: 134(SD=41) Mean fasting serum glucose, mg/dL,OW: 1mth: 176(SD=75) 4mths: 165(SD=58) 8mths: 171(SD=42) 12mths: 167(SD=48) 24mths: 154(SD=41) HbA1c,%, OB: 1mth: 7.3(SD=1.1) 4mths: 6.3(SD=0.8) 8mths: 5.9(SD=1.1) 12mths: 5.9(SD=0.6) 24mths: 5.9(SD=0.9) HbA1c,%, OW: 1mth: 7.3(SD=1.2) 4mths: 7.3(SD=1.3) 8mths: 6.9(SD=1.1) 12mths: 7.1(SD=1.1) 24mths: 6.9(SD=1.1) % Patients HbA1c<=7%, OB: 1mth: 8/15 (53%) 4mths: 13/15 (87%) 8mths: 13/15 (87%) 12mths: 15/15 (100%) 24mths: 12/15 (80%) % Patients HbA1c<=7%,OW: 1mth: 4/15 (27%) 4mths: 9/15 (60%) 8mths: 11/15 (73%) 12mths: 10/15 (67%) 24mths: 9/15 (60%)	Serum Triglyceride,mg/dL, OB: 1mth: 223(SD=258) 4mths: 174(SD=85) 8mths: 208(SD=123) 12mths: 181(SD=123) 24mths: 177(SD=82) Serum Triglyceride,mg/dL, OW: 1mth: 137(SD=52) 4mths: 240(SD=170) 8mths: 222(SD=85) 12mths: 227(SD=104) 24mths: 225(SD=116) Serum Total Cholesterol,OB: 1mth: 134(SD=35.4) 4mths: 138(SD=33.8) 8mths: 146(SD=35.5) 12mths: 153(SD=35) 24mths: 156(SD=28) Serum Total Cholesterol, OW: 1mth: 116(SD=31) 4mths: 158(SD=40) 8mths: 150(SD=29) 12mths: 141(SD=36) 24mths: 146(SD=29) Serum HDL Cholesterol,OB: 1mth: 37(SD=8.8) 4mths: 36(SD=6.6) 8mths: 39(SD=6.9) 12mths: 47(SD=10.4) 24mths: 47(SD=10.1) Serum HDL Cholesterol, OW: 1mth: 29(SD=8.1) 4mths: 38(SD=7.2) 8mths: 41(SD=6) 12mths: 41(SD=16) 24mths: 38(SD=7.3)	Bleeding/hematoma: Intraperitoneal bleeding, 1/30 (3.3%) Other major surgical complications NOS 0/30 (0%) GI: Gastroplegia, 4/30 (13.3%) Revision secondary to diarrhea, 1/30 (3.3%) Death: Sudden cardiac, 0/30 (0%)

* Demographic characteristics only reported overall, not for each group. No statistically significant differences found between demographic characteristics.

**Comparison arm did not receive non-surgical treatment

Appendix D. Excluded Studies

Reject Background:

1. Blackburn GL, Wollner SB, Jones DB. Bariatric surgery as treatment for type 2 diabetes. *Curr Diab Rep.* 2010 Aug;10(4):261-3. PMID 20440583.
2. Caballero MG. [Surgery of type 2 diabetes mellitus: the great discovery of bariatric surgery]. *Nutr Hosp.* 2010 Sep-Oct;25(5):693-4. PMID 21336421.
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5. Cummings DEF, D. R. Gastrointestinal surgery as a treatment for diabetes. *JAMA.* 2008 Jan 23;299(3):341-3. PMID 18212321.
6. Deitel M. Surgery for diabetes at lower BMI: some caution. *Obes Surg.* 2008 Oct;18(10):1211-4. PMID 18758867.
7. Ferrannini EM, G. Impact of different bariatric surgical procedures on insulin action and beta-cell function in type 2 diabetes. *Diabetes Care.* 2009 Mar;32(3):514-20. PMID 19246589.
8. Gagner M. Laparoscopic sleeve gastrectomy with ileal interposition (SGIT): a modified duodenal switch for resolution of type 2 diabetes mellitus in lesser obese patients (BMI < 35). *World J Surg.* 2011 Jan;35(1):109-10. PMID 21052995.
9. Gagner M. Surgical treatment of nonseverely obese patients with type 2 diabetes mellitus: sleeve gastrectomy with ileal transposition (SGIT) is the same as the neuroendocrine brake (NEB) procedure or ileal interposition associated with sleeve gastrectomy (II-SG), but ileal interposition with diverted sleeve gastrectomy (II-DSG) is the same as duodenal switch. *Surg Endosc.* 2011 Feb;25(2):655-6. PMID 20614137.
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11. Gill RS, Sharma AM, Al-Adra DP, et al. The impact of bariatric surgery in patients with type-2 diabetes mellitus. *Curr Diabetes Rev.* 2011 May;7(3):185-9. PMID 21488837.
12. Inabnet WB. Comment on: Prospective randomized controlled trial comparing 2 versions of laparoscopic ileal interposition associated with sleeve gastrectomy for patients with type 2 diabetes with BMI 2134 kg/m². *Surgery for Obesity and Related Diseases.* 2010;6(3):304-5.
13. Keating CLD, J. B. Moodie, M. L. Peeters, A. Playfair, J. O'Brien, P. E. Cost-efficacy of surgically induced weight loss for the management of type 2 diabetes: a randomized controlled trial. *Diabetes Care.* 2009 Apr;32(4):580-4. PMID 19171726.
14. Lautz D, Halperin F, Goebel-Fabbri A, et al. The great debate: Medicine or surgery: What is best for the patient with type 2 diabetes? *Diabetes Care.* 2011;34(3):763-70.

15. Lynis Dohm G, Pories WJ. Bypass of metabolic diseases with surgery. *Obesity*. 2011;19(7):1323-4.
16. Nathan DMB, M. Trials that matter: rosiglitazone, ramipril, and the prevention of type 2 diabetes. *Ann Intern Med*. 2007 Mar 20;146(6):461-3. PMID 17371892.
17. Pories WJ, Mehoff JH, Staton KM. The surgical treatment of type two diabetes mellitus. *Surg Clin North Am*. 2011 Aug;91(4):821-36. PMID 21787970.
18. Shikora SA. Comment on: diabetes remission and reduced cardiovascular risk after gastric bypass in Asian Indians with body mass index <35 kg/m(2). *Surg Obes Relat Dis*. 2010 Jul-Aug;6(4):338-9. PMID 19914146.
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Reject Case Report:

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