Washington State Health Care Authority

Metabolic and Bariatric Surgery: New Populations and Procedures

Final Evidence Report

April 18, 2024

Health Technology Assessment Program (HTA)

Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712
(360) 725-5126
www.hca.wa.gov/hta
shtap@hca.wa.gov

Metabolic and Bariatric Surgery: New Populations and Procedures

Evidence Report

April 18, 2024

Prepared by:

Center for Evidence-based Policy
Oregon Health & Science University
3030 S Moody, Suite 250
Portland, OR 97201
Phone: 503-494-2182
Fax: 503-494-3807
CenterForEvidenceBasedPolicy.org

Authors:

Shannon Robalino, MSc, Shauna Durbin, MPH, Erin Young, MA, Susan Connor, PhD, Valerie King, MD, MPH, and Beth Shaw, MSc

The authors would like to acknowledge Judy Chen, MD; Eduardo Grunvald, MD; Marc Michalsky, MD; Derek Rogalsky, MD; Fatima Cody Stanford, MD; and Sevket Yigit, MD for their contributions to this report. The authors would also like to acknowledge Courtney Cooper, Amanda Delzer Hill, and Veronique Johnson from the Center for Evidence-based Policy for their contributions to this work.

This health technology assessment report is based on research conducted by the Center for Evidence-based Policy (Center) under contract to the Washington State Health Care Authority (HCA). This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the authors, who are responsible for the content. These findings and conclusions do not necessarily represent the views of the Washington HCA and thus, no statement in this report shall be construed as an official position or policy of the HCA.

The information in this assessment is intended to assist health care decision makers, clinicians, patients, and policymakers in making evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

About the Center for Evidence-based Policy

The Center is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

Conflict of Interest Disclosures: No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

AACE	American Association of Clinical Endocrinology
AAP	American Academy of Pediatrics
AGB	adjustable gastric band
ASMBS	American Society for Metabolic and Bariatric Surgery
BMI	body mass index
BPD	biliopancreatic diversion, with or without duodenal switch
Center	Center for Evidence-based Policy
CI	confidence interval
CMS	Centers for Medicare & Medicaid Services
CoE	certainty of evidence
CQ	contextual question
EAES	European Association for Endoscopic Surgery
ESG	endoscopic sleeve gastroplasty
EWL	excess weight loss
FDA	US Food and Drug Administration
GERD	gastroesophageal reflux disease
GI	gastrointestinal
GLP-1	glucagon-like peptide 1
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
HDL	high-density lipoprotein (cholesterol)
HERC	(Oregon) Health Evidence Review Commission
HbA1c	glycated hemoglobin (A1c)
HRQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
IFSO	International Federation for the Surgery of Obesity and Metabolic Disorders
IGB	intragastric balloon
IQR	interquartile range
IWQOL	Impact of Weight on Quality of Life survey
KQ	key question
LDL	low-density lipoprotein (cholesterol)
MBS	metabolic and bariatric surgery

MBSAQIP	Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program
MCID	minimal clinically important difference
MD	mean difference
MDC	multidisciplinary diabetes care
MetS	metabolic syndrome
NCD	National Coverage Determination
NICE	National Institute for Health and Care Excellence
NRS	nonrandomized study
OAGB	one-anastomosis gastric bypass
OP-14	Obesity-related Problems Scale
OR	odds ratio
ORC	obesity-related comorbidity
OSA	obstructive sleep apnea
PICOS	population, intervention, comparator, outcome, study design
QALY	quality-adjusted life year
QoL	quality of life
RCT	randomized controlled trial
RoB	risk of bias
RR	risk ratio (relative risk)
RYGB	Roux-en-Y gastric bypass
SADI-S	single-anastomosis duodenal ileostomy with sleeve gastrectomy
SF-36	36-item Short Form Health Survey (similar to RAND-36)
SG	sleeve gastrectomy
T2DM	type 2 diabetes mellitus
TPS	TransPyloric Shuttle
TWL	total weight loss
VBG	vertical banded gastroplasty
WHO	World Health Organization
WTP	willingness to pay

Executive Summary

Structured Abstract

Purpose

This health technology assessment evaluates the effectiveness (e.g., total weight loss, change in body mass index [BMI]), safety (e.g., reoperations, serious adverse events), and cost-effectiveness of metabolic and bariatric surgery (MBS) compared with nonsurgical interventions (e.g., exercise, medications) in adults and children with overweight or obesity. This report only covers MBS procedures or devices not reviewed or in populations not currently covered under the 2015 Washington coverage determination made by the Washington Health Technology Clinical Committee.

Methods

Data Sources

We conducted searches across multiple electronic databases and analyzed 30-day postsurgery patient-level data from the publicly available Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Registry.

Study and Guideline Selection

We conducted dual independent title and abstract screening and full-text article review for English-language randomized controlled trials (RCTs), nonrandomized studies, and economic evaluations of MBS in adults and children. We also selected and assessed relevant clinical practice guidelines using a similar process.

Data Extraction and Risk-of-Bias Assessment

We used standardized procedures to extract relevant data from each of the included trials and performed dual independent risk-of-bias assessment on the included studies and guidelines.

Data Synthesis and Analysis

We used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to rate the overall certainty of evidence (CoE) of selected measures of outcomes.

Results

We identified limited evidence on the effectiveness of adjustable gastric bands (AGBs) in adults who are not currently covered under the 2015 Washington coverage determination:

- AGBs are more effective than a very-low-calorie diet plus orlistat in adults with a BMI ≥ 30 to < 35 kg/m^2 and an obesity-related comorbidity (very low to moderate CoE; 1 RCT)
- AGBs are more effective than multidisciplinary care in adults with type 2 diabetes mellitus and a BMI ≥ 25 to < 30 kg/m^2 (very low to low CoE; 1 RCT)

We identified limited evidence on the effectiveness of MBS procedures and FDA-approved devices were not reviewed for the 2015 for the Washington coverage determination:

- One-anastomosis gastric bypass (OAGB) is similarly effective or more effective than Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG) in adults with a BMI of ≥ 30 kg/m^2, with or without an obesity-related comorbidity (moderate to high CoE; 3 RCTs)
- OAGB, the Orbera intragastric balloon (IGB), and endoscopic sleeve gastroplasty (ESG) are more effective than low-calorie diet and exercise lifestyle interventions in adults with a

BMI ≥ 30 to < 50 kg/m^2, with or without an obesity-related comorbidity (low to moderate CoE; 3 RCTs)
- IGBs (Obalon and TransPyloric Shuttle) are more effective than sham surgery, with or without a lifestyle intervention, in adults with a BMI ≥ 30 to < 40 kg/m^2 (moderate CoE; 2 RCTs)

We identified limited evidence on MBS in children and adolescents:
- AGBs, RYGB, and SG are more effective than reduced calorie intake, exercise, and behavior-therapy lifestyle interventions (very low to low CoE; 3 RCTs)

We did not identify any eligible comparative studies for biliopancreatic diversion (BPD) with or without duodenal switch, or single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S), for either children or adults.

Cost-Effectiveness Outcomes

Economic findings for MBS procedures not reviewed in 2015 and people not currently covered under the 2015 Washington coverage determination include:
- ESG was cost-effective for individuals with BMI ≥ 30 to < 35 kg/m^2, and SG was cost-effective for individuals with BMI ≥ 35 kg/m^2, compared with semaglutide and lifestyle interventions in individuals aged ≥ 40 (very low CoE; 1 cost-effectiveness analysis)
- IGBs were not cost-effective at any willingness-to-pay threshold for adults with overweight or obesity (i.e., BMI > 25 kg/m^2) compared with commercially available nonsurgical weight-loss interventions (moderate CoE; 1 cost-effectiveness analysis)

We did not identify any eligible cost-effectiveness analyses comparing MBS with other interventions for children and adolescents. We also did not identify any cost-effectiveness analyses involving 2 of the procedures (OAGB and SADI-S) not reviewed in 2015.

Clinical Practice Guidelines and Payer Policies

Overall, clinical practice guidelines recognize MBS as an effective intervention for weight loss and resolution of obesity-related comorbidities in eligible individuals. These recommendations are fairly consistent across personal characteristics (e.g., BMI, race or ethnicity, presence or absence of an obesity-related comorbidity). Some guidelines include recommendations for or against specific types of MBS in adult populations, with some acknowledgment of inconclusive evidence for relatively new procedures. The American Academy of Pediatrics recommends those aged 13 to 17 years be referred for evaluation for RYGB or SG at an MBS surgery center. A few guidelines also provide statements related to the eligibility of pediatric individuals with overweight or obesity, which are mixed overall. Payer policies varied in coverage decisions for MBS in adults and adolescents.

Conclusions

Metabolic and bariatric surgery is generally an effective and safe intervention for weight-loss and resolution of obesity-related comorbidities in eligible individuals when compared with nonsurgical interventions (e.g., diet, exercise, medication). The most common adverse events were nausea and vomiting. Deaths and complication-related reoperations were rare.

Background

Metabolic and bariatric surgery (MBS) is an umbrella term encompassing several surgeries and procedures that make changes to the digestive system to help people lose excess weight. These procedures may also be referred to as "weight-loss surgery" or "bariatric surgery," and can include weight-management devices regulated by the US Food and Drug Administration (FDA). Some weight-loss procedures may use a device (e.g., adjustable gastric band [AGB], intragastric balloon [IGB]) to decrease gastric capacity or emptying. An MBS is an important clinical intervention used when conventional treatments (e.g., diet, exercise, medication) have not resulted in desired weight loss or resolution of weight-related comorbidities.

Technology of Interest

The objective of this health technology assessment (HTA) is to evaluate the effectiveness, safety, and cost-effectiveness of MBS compared with nonsurgical interventions (e.g., exercise, medications) in adults and children with overweight or obesity. This report only covers procedures in specific populations not currently reflected in the 2015 Washington coverage determination, or using devices that have been approved by the FDA in the years since:

- AGB, biliopancreatic diversion (BPD; with or without duodenal switch), Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy (SG) for:
  - Children (< 18 years of age), with or without an obesity-related comorbidity
  - Adults with a body mass index (BMI) < 30 kg/m^2, with or without an obesity-related comorbidity
  - Adults with a BMI ≥ 30 to < 35 kg/m^2 without type 2 diabetes mellitus (T2DM)
- Endoscopic gastroplasty (ESG), IGB, one-anastomosis gastric bypass (OAGB), and single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S) for any individual with overweight or obesity, regardless of the presence or absence of an obesity-related comorbidity

This HTA only considers the effectiveness, safety, or cost-effectiveness of nonsurgical interventions when they have been directly compared with MBS.

Policy Context

In 2015, the Washington HTA Health Technology Clinical Committee made the following coverage determination:

- MBS (i.e., AGB, BPD, RYGB, SG) is a covered benefit for adults (aged ≥ 18 years) for the following conditions:
  - BMI ≥ 40 kg/m^2
  - BMI ≥ 35 to < 40 kg/m^2, and at least 1 obesity-related comorbidity
  - BMI ≥ 30 to < 35 kg/m^2, and T2DM
- When covered, individuals must abide by all other agency surgery-program criteria (e.g., specified centers or practitioners; preoperative psychological evaluation; participation in preoperative and postoperative multidisciplinary care programs)
- MBS is not covered for the following groups:
  - Children (aged < 18 years)
  - Adults with BMI < 30 kg/m^2
  - Adults with BMI ≥ 30 to < 35 kg/m^2 without T2DM

Methods

This evidence review is based on the final key questions (KQs) published on November 15, 2023. The draft KQs were available for public comment from October 18 to October 31, 2023, and appropriate revisions were made to the KQs based on the comments and responses. All public comments received and a table of responses can be found on the Washington HTA website. The draft report was available for public comment from March 1, 2024, through March 30, 2024, and appropriate revisions were made based on comments received, with the final report being posted to the program's website. This draft report was also peer-reviewed by subject matter experts, with appropriate revisions reflected in the final report. The PICO (population, intervention, comparator, outcome) details, along with the setting, study design, and publication factors that guided development of the KQs and study selection, are presented in Table 3 of the Technical Report. Full details of our methods can be found in Appendix A.

Contextual Questions

Contextual questions were not systematically reviewed and are not shown in the analytic framework. To address contextual questions, we relied on recent systematic reviews or a subset of the largest, most relevant recent primary research articles identified through our search.

CQ1. What is the overall effectiveness profile of nonsurgical weight management treatments (including antiobesity medications, diet-control programs, exercise, psychotherapy, and nutritional counseling)?

CQ2. What is the overall safety profile of previously reviewed MBS procedures (AGB, BPD, RYGB, and SG) in adults with overweight or obesity?

CQ3. What accreditation standards and center of excellence designations exist for MBS in the US, and what are the requirements of each?

CQ4. What are professional society or guideline criteria for revision or conversion of bariatric surgeries?

Key Questions

KQ1. What is the comparative clinical effectiveness of MBS procedures reviewed in 2015 (AGB, BPD, RYGB, and SG) vs. nonsurgical weight-loss management in people not currently covered under the 2015 Washington coverage determination? Specifically in:

- a. Adults (aged ≥ 18 years) with a BMI ≥ 35 to < 40 kg/m^2 without an obesity-related condition
- b. Adults (aged ≥ 18 years) with a BMI ≥ 30 to < 35 kg/m^2 without T2DM; or with or without any other obesity-related comorbidity
- c. Adults with a BMI < 30 kg/m^2, regardless of comorbidity status
- d. Children (aged ≤ 17 years) with overweight or obesity, on an overall basis and by specific age groups (e.g., 13 to 17, ≤ 12 years)

KQ2. What is the comparative clinical effectiveness of MBS procedures not reviewed (ESG, IGB, OAGB, and SADI-S) vs. nonsurgical weight-loss management, with or without obesity-related comorbid conditions in:

- a. Adults (aged ≥ 18 years) with overweight or obesity?

b. Children (aged ≤ 17 years) with overweight or obesity, on an overall basis and by specific age groups (e.g., 13 to 17, ≤ 12 years)?

KQ3. What is the potential short-term and long-term safety of MBS procedures, including rates of procedure-specific complications (including those requiring revision surgery), longer-term morbidity, and mortality in the populations specified in KQ1 and KQ2?

KQ4. What is the differential effectiveness and safety of MBS procedures according to patient and clinical factors, such as:

a. Age (chronological, physiologic, skeletal)
b. Sex
c. Race and ethnicity
d. BMI (assessed as both continuous and categorical variable)
e. Presence of comorbidities (e.g., hypertension, T2DM)
f. Prior medical event history (e.g., myocardial infarction, stroke)
g. Smoking status
h. Psychosocial health
i. Pre- and post-procedure adherence with program recommendations

KQ5. What are the costs and cost-effectiveness of the MBS procedures included in this evidence review?

Data Sources

We conducted searches of the peer-reviewed published literature using multiple electronic databases to identify randomized controlled trials (RCTs), nonrandomized studies (NRSs), and economic analyses. The time periods for searches were:

- Ovid MEDLINE All: from 1946 to November 10, 2023
- Cochrane Central Register of Controlled Trials (CENTRAL): from database inception to November 10, 2023

We also analyzed 30-day postsurgery patient-level data from the publicly available Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Registry for years 2016 through 2022. We excluded any studies and data in populations already covered under the 2015 Washington coverage determination.

Study and Guideline Selection

We independently screened titles and abstracts and reached agreement on exclusion through discussion. We performed dual full-text review for any study not excluded by review of title and abstract. Disagreements were managed by discussion; if consensus could not be reached, any remaining disagreements were settled by a third independent researcher. We also selected and assessed relevant clinical practice guidelines using a similar process.

Data Extraction and Risk-of-Bias Assessment

We used standardized procedures to extract relevant data from each of the included trials and fully cross-checked all entered data for accuracy. We evaluated each eligible study for methodological risk of bias (RoB) and held discussions to reach agreement on these assessments. Any remaining disagreement was settled by a third independent researcher. Each trial was

assessed using Center for Evidence-based Policy instruments adapted from national and international standards and assessments for RoB. A rating of high, moderate, or low RoB was assigned to each study based on adherence to recommended methods and the potential for internal and external biases.

We also evaluated the methodological quality of eligible clinical practice guidelines. Any remaining disagreement among these assessments was settled by a third independent researcher. We rated the methodological quality of clinical practice guidelines as good, fair, or poor.

Data Synthesis and Analysis

We assigned selected outcomes a summary judgment for the overall certainty of evidence (CoE) using the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group. We assessed the CoE for the following outcomes:

- Weight-related (i.e., excess weight loss or total weight loss)
- Cardiovascular risk factors (e.g., resolution of hypertension or T2DM, changes in high- or low-density lipoprotein)
- Health-related quality of life, using prespecified instruments
- Safety (e.g., proportion of individuals experiencing an adverse event, number of complications requiring reoperation)

Results

Our data collection, including from public comments and peer review, returned a total of 10,012 records. After duplicate records were removed, 7,560 remained for title and abstract screening. Of these, 476 required full-text review to determine eligibility. In total, 13 RCTs (in 21 publications) met the inclusion criteria for KQ1 through KQ4. In addition, a further 3 economic or cost-focused studies met the inclusion criteria for KQ5. We report below findings from our CQs, followed by the remaining evidence for the KQs, ongoing studies, and clinical practice guidelines.

Contextual Questions

Overall Effectiveness of Nonsurgical Weight Management (CQ1)

In adults with a BMI ≥ 25 kg/m2, nonsurgical interventions (e.g., lifestyle programs, medication) provide greater weight-loss and reductions in BMI than usual care, wait lists, or no intervention. The same results are seen in children and adolescents.

Overall Safety of MBS Procedures Reviewed in 2015 (CQ2)

Metabolic and bariatric surgical procedures reviewed in 2015 remain effective in reducing weight and weight-related outcomes and mortality for adults and adolescents, compared with standard medical treatment or lifestyle interventions. Surgery-related deaths are rare and the potential benefits of MBS outweigh the harms.

Accreditation Designations and Standards (CQ3)

The American Society for Metabolic and Bariatric Surgery (ASMBS) has 6 accreditation designations for inpatient MBS care, covering both adolescents and adults. Currently, there is 1 accreditation designation for outpatient MBS (i.e., ambulatory surgery centers), for adults only. Regardless of designation, all centers must demonstrate compliance with MBSAQIP standards, exclusively perform ASMBS-endorsed procedures (ASMBS approval can be sought for

nonendorsed procedures), successfully complete site visits, and enter data into the MBSAQIP registry. While national accreditation for MBS centers is voluntary, uptake has been robust driven in part by public and commercial payer coverage requirements for facility certification.

Criteria for Revision or Conversion of Bariatric Surgeries (CQ4)

See the Clinical Practice Guidelines section below for criteria related to MBS revision or conversion procedures.

Effectiveness and Safety of MBS in Adults (KQ1 to KQ4)

Based on the studies included in this review, we identified limited evidence on the effectiveness of adjustable gastric bands (AGBs) in adults who are not currently covered for MBS under the 2015 Washington coverage determination:

- AGBs are more effective than a very-low-calorie diet plus orlistat in adults with a BMI ≥ 30 to < 35 kg/m^2 and an obesity-related comorbidity (very low to moderate CoE; on 1 RCT)
- AGBs are more effective than multidisciplinary care in adults with T2DM and a BMI ≥ 25 to < 30 kg/m^2 (very low to low CoE; 1 RCT)

Based on the studies included in this review, we identified limited evidence on the effectiveness of MBS procedures not reviewed in 2015:

- One anastomosis gastric banding (OAGB) is similarly or more effective than Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG) in adults with a BMI ≥ 30 kg/m^2 with or without an obesity-related comorbidity (moderate to high CoE; 3 RCTs)
- OAGB, the Orbera intragastric balloon (IGB), and endoscopic sleeve gastroplasty (ESG) are more effective than the lifestyle interventions that include low-calorie diets and exercise, in adults with a BMI ≥ 30 to < 50 kg/m^2 with or without an obesity-related comorbidity (low to moderate CoE; 3 RCTs)
- IGBs (Obalon and TransPyloric Shuttle) are more effective than sham surgery, with or without a lifestyle intervention, in adults with a BMI ≥ 30 to < 40 kg/m^2 (moderate CoE; 2 RCTs)

Effectiveness and Safety of MBS in Children and Adolescents (KQ1 to KQ4)

Based on the studies included in this review, we identified limited evidence on MBS in children and adolescents:

- AGBs, RYGB, and SG are more effective than the lifestyle interventions that include reduced calorie intake, exercise, and behavior therapy (very low to low CoE; 3 RCTs)

No eligible studies included children under the age of 13 years. Furthermore, we did not identify any eligible comparative studies for BPD or SADI-S in children or adolescents.

30-Day Safety Outcomes (KQ3)

We conducted an independent analysis of 30-day safety outcomes from the MBSAQIP registry for nearly 1.1 million patients, for years 2016 through 2022. Most patients (75%) had at least 1 obesity-related comorbidity and underwent SG (71%) or RYGB (26%). The most common serious adverse events across all patients and procedures were deep vein thrombosis and pulmonary embolism (both < 1%). Deaths within the first 30-days postsurgery were uncommon (0.08%; n = 901). Some small, but significant, differences were seen in the proportion of patients

and types of adverse events between surgeries. Readmissions occurred in 3% of patients, most commonly for those who underwent ESG or SG.

Less than 1% of the patients were between the ages of 13 and 17 years (n = 2,164), and the majority underwent SG (90%) or RYGB (9%). The most common adverse events in adolescents were emergency department visits, readmission, and dehydration requiring treatment (all ≤ 5%). Only 2 deaths were recorded in the 30-days postsurgery. Readmissions and reoperations affected less than 1% and 6% of adolescent patients, respectively.

Cost-Effectiveness of MBS (KQ5)

Economic findings for MBS procedures not reviewed in 2015 and in populations not currently covered under the 2015 Washington coverage determination, include:

- ESG was cost-effective when compared with semaglutide and lifestyle interventions for individuals aged 40 with class 1 obesity (i.e., BMI > 30 to < 35 kg/m^2) and class 2 or 3 obesity (i.e., BMI ≥ 35 kg/m^2), respectively (very low; 1 cost-effectiveness analysis)
- SG was cost-effective when compared with semaglutide and lifestyle interventions for individuals aged ≥ 40 with a BMI ≥ 35 kg/m^2 (very low CoE; 1 cost-effectiveness analysis)
- IGBs were not cost-effective at any willingness-to-pay threshold for adults with overweight or obesity (i.e., BMI ≥ 25 kg/m^2) compared with commercially available, nonsurgical weight-loss interventions (moderate CoE; 1 cost-effectiveness analysis)

We did not identify any eligible cost-effectiveness analyses comparing MBS with other interventions for children and adolescents. Additionally, we did not identify any cost-effectiveness analyses comparing 2 of the procedures (OAGB or SADI-S) not reviewed in 2015, in any population.

Ongoing Studies

We identified 24 ongoing studies (17 RCTs and 7 prospective comparative NRS). These include:

- 11 RCTs and 3 NRS comparing procedures not reviewed in 2015 (e.g., SADI-S, ESG) with older procedures (e.g., RYGB, SG)
- 6 RCTs comparing MBS with a lifestyle intervention
- 4 NRSs comparing 1 or more MBS with a nonsurgical intervention
  - 2 include adolescents

We did not identify any ongoing RCTs that include children or adolescents.

Evidence Summary

Metabolic and bariatric surgery is generally a safe and effective intervention for weight-loss and resolution of obesity-related comorbidities (e.g., hypertension, T2DM) in eligible individuals when compared with nonsurgical interventions (e.g., diet, exercise, medication). We identified no eligible comparative studies for BPD or SADI-S for adults, or for children and adolescents. Only 1 study examined outcomes by baseline BMI and found no differences in outcomes; no other subgroups were reported in the included studies. As would be expected when comparing a surgical intervention with a nonsurgical one, some differences were seen in the number of individuals experiencing an adverse event and the severity of those events. The most common adverse events were nausea and vomiting. Complication-related reoperations were generally

rare, and surgery-related deaths were extremely rare. Metabolic and bariatric surgery is generally more cost-effective compared with nonsurgical interventions, though the eligible evidence was limited.

Clinical Practice Guidelines

Overall, clinical practice guidelines recognized MBS as an effective intervention for weight-loss and resolution of obesity-related comorbidities in eligible individuals. These recommendations are fairly consistent when considering personal characteristics (e.g., BMI, race or ethnicity, presence or absence of an obesity-related comorbidity). Some guidelines include recommendations for or against specific types of MBS in adult populations, with some acknowledgment of inconclusive evidence for relatively newer procedures.

Recommendations related to pediatric populations are scant; only 1 is focused on this population, from the American Academy of Pediatrics (AAP). The AAP recommends those aged 13 to 17 years be referred to an MBS surgery center for evaluation for MBS (usually RYGB or SG). A few other guidelines do provide mixed eligibility statements related to pediatric aged individuals living with overweight or obesity.

Revisional MBS (CQ4)

There is general agreement among professional societies that revisional MBS can refer to different types of procedures (i.e., conversion from 1 type of MBS to another; correction to enhance effects [e.g., adjusting band position]; reversal to restore normal anatomy [e.g., removal of gastric band or IGB]). General criteria for consideration of a revisional procedure are weight recurrence (i.e., weight regain) or nonresponse (i.e., inadequate weight loss); treatment of specific MBS-related complications (e.g., leaks, strictures); or insufficient improvement or the emergence of serious comorbidities like T2DM or gastroesophageal reflux disease. There is some guidance on when OAGB or SG are appropriate as revisional procedures (e.g., depending on the type of primary MBS, specific comorbidities). The SADI-S procedure has been highlighted as a conversion procedure following nonresponse to RYGB or SG, but there is a lack of high-quality comparative evidence.

Select Payer Coverage Determinations

Payer policies varied in coverage decisions for MBS in adults and adolescents. Most payers will cover MBS for individuals with a BMI ≥ 35 to < 40 kg/m^2 with at least 1 obesity-related comorbidity, and those with a BMI ≥ 40 kg/m^2 regardless of comorbidity status. Only private insurers cover revisional MBS.

Conclusions

Metabolic and bariatric surgeries continue to be a safe and effective intervention to reduce weight and resolve obesity-related comorbidities like hypertension and T2DM in adults with overweight or obesity. There remains limited published evidence for the use of MBS in children and adolescents, but the available evidence does support the use of these interventions in adolescents. Serious adverse events and deaths are relatively rare. Metabolic and bariatric surgeries are generally cost-effective compared with nonsurgical interventions. Many professional societies have recently updated their clinical practice guidelines by expanding eligibility criteria (e.g., lowering BMI thresholds and comorbidity status) as well as recognizing

that there are differences in BMI for different races and ethnicities (e.g., obesity is defined as a BMI ≥ 27 kg/m^2 in some Asian populations). Guidance related to revisional surgeries remains scant. Public and private payer policies vary, but generally cover individuals with BMI ≥ 35 to < 40 kg/m^2 (with a comorbidity) or all individuals with a BMI ≥ 40 kg/m^2.

Technical Report

Background

Technology of Interest

Metabolic and bariatric surgery (MBS) is an umbrella term that encompasses several types of surgeries and procedures that make changes to the digestive system to help people lose excess weight.[1,2] These procedures may also be referred to as "weight-loss surgery" or "bariatric surgery," and can include weight-management devices regulated by the US Food and Drug Administration (FDA).[1,3] Some weight-loss procedures may use devices (e.g., adjustable gastric bands [AGB], intragastric balloons [IGB]) to decrease gastric capacity or emptying.[3] MBS is an important clinical intervention used when conventional treatments (e.g., diet, exercise, medication) have not resulted in either weight loss, or improvement or resolution of weight-related comorbidities.[1]

Overweight and Obesity

Definitions

Obesity is a condition of excess body fat, which increases risk to health.[4] Obesity was declared a disease by the National Institutes of Health in 1998 and the American Medical Association in 2013.[5]

For adults, the World Health Organization (WHO) and the Centers for Disease Control and Prevention classify *overweight* as a body mass index (BMI) greater than or equal to 25 kg/m^2, and *obesity* as a BMI of greater than or equal to 30 kg/m^2.[4,6] Adult obesity is further subdivided into 3 classes[6]:

- Class 1: BMI of ≥ 30 to < 35 kg/m^2
- Class 2: BMI of ≥ 35 to < 40 kg/m^2
- Class 3: BMI of ≥ 40 kg/m^2

For children, the WHO classifies *overweight* and *obesity* as greater than 2 and 3 standard deviations from the WHO Growth Reference median, respectively.[4] The Centers for Disease Control and Prevention classifies *child obesity* as greater than the 95th percentile of age-specific and sex-specific percentile curves (see Appendix K for example growth curves).[7] Recently, the American Academy of Pediatrics (AAP) published an expanded definition of severe obesity in children[8]:

- Class 2: BMI ≥ 120% but < 140% of the 95th percentile, or BMI ≥ 35 to < 40 kg/m^2
- Class 3: BMI ≥ 140% of the 95th percentile, or BMI ≥ 40 kg/m^2

However, definitions of obesity that focus exclusively on BMI have long been criticized, because of the limited usefulness of BMI as an objective indicator of individual health status, and its lack of generalizability across different racial and ethnic groups, sexes, and ages.[9,10] In 2023, the American Medical Association adopted a new policy that acknowledged the problematic history of BMI use and suggested that BMI be used as one diagnostic tool among many to identify weight-related health risks, with other valid measures including body composition, relative fat mass, and waist-to-height ratios.[11] In light of the evolving recommendations to reconsider use of BMI as an individual health indicator, though it may be more appropriate to use at the

population-level, it is important to note that all of the included studies in this report defined study participant eligibility primarily on the basis of BMI.

Prevalence

In the US, the prevalence of obesity, as measured by BMI, between 2017 and March 2020 was 41.9% among adults and 19.7% among children and adolescents aged 2 to 19 years.[12,13] The US prevalence of overweight and obesity together for adults aged 20 years and over reached 73.6% in 2018, a nearly 30% increase since 1960 (estimated 45%).[14]

There are disparities in obesity prevalence among racial and ethnic groups in the US. Between 2017 and March 2020, the prevalence of obesity was 26.2% among Hispanic children, 24.8% among non-Hispanic Black children, 16.6% among non-Hispanic White children, and 9.0% among non-Hispanic Asian children.[13] The prevalence of adult obesity adjusted for age during the same period was 49.9% among non-Hispanic Black adults, 45.6% among Hispanic adults, 41.4% among non-Hispanic White adults, and 16.1% among non-Hispanic Asian adults.[12] Alaska Native and Pacific Islander communities also experience a higher prevalence of obesity than non-Hispanic White and Asian adults, but small sample sizes in national datasets limit the ability to examine these trends.[15]

In Washington, data from the 2022 Behavioral Risk Factor Surveillance System indicate the prevalence of adult obesity between 2020 and 2022 was 30% to 35%; individuals identifying as non-Hispanic American Indian or Alaska Native had an obesity prevalence of 40% to 45%.[16] According to the Healthy Youth Survey results in 2021, 16% and 17% of 8th graders in Washington were experiencing overweight or obesity, respectively; in the same year, 15% of 12th graders had overweight and another 15% had obesity.[17] Results from the 2016 Healthy Youth Survey suggest that American Indian/Alaska Native, Black, Hispanic, and Native Hawaiian/Pacific Islander populations in Washington experience a greater risk of overweight and obesity than White or Asian populations.[18]

Causes

Obesity is widely recognized as a condition with complex, multilevel causes.[19,20] While the most proximal cause of overweight and obesity is an imbalance between calories consumed and expended, underlying causes can include eating behaviors, physical inactivity, sleep habits, genetic and epigenetic factors, illnesses, medications, psychosocial stress, and the intrauterine environment.[19-21] Mutations in a single gene can also cause monogenic obesity, though this is relatively rare, accounting for less than 5% of all cases of severe obesity.[22]

In recent years, there has been increasing focus on systemic and environmental causes of obesity, such as the roles of the food system, political and economic policies, and other social determinants of health.[20,23] The relationship between obesity and income level is complex and may be bidirectional (i.e., low-income individuals may be more likely to develop subsequent obesity, and in turn, weight stigma and employment discrimination may constrain income).[24] Patterns of obesity rates by household income levels also vary by sex, race or ethnicity, and education level.[25] Communities of color in the US are more likely to experience obesogenic environments, where social and economic conditions interact to reinforce unhealthy elements

(such as limited access to grocery stores) that may increase an individual's risk of developing overweight and obesity.[15,26]

Consequences

People living with obesity are at increased risk for many chronic health conditions, including hypertension, type 2 diabetes (T2DM), obstructive sleep apnea (OSA), osteoarthritis, liver and kidney disease, non-alcoholic steatohepatitis (NASH), breast cancer, colon cancer, fertility challenges, and clinical depression and anxiety.[27-29] Childhood obesity has been associated with premature mortality in adulthood.[30] People living with obesity may also experience stigma and discrimination due to sociocultural stereotypes about body weight.[31] Stigma and weight bias internalization can negatively affect both psychological and physical health.[32,33] The growing prevalence of overweight and obesity is expected to continue to increase health spending in high-income countries, and also contribute to additional economic burdens by negatively affecting the health and productivity of the workforce.[27,34]

Metabolic and Bariatric Surgery

Treatment

Metabolic and bariatric surgery is widely recommended to treat obesity and weight-related comorbidities.[35-37] Several decades of research has produced evidence that MBS results in substantial weight loss and improvement or resolution of weight-related comorbidities,[36,38] which can in turn increase life expectancy[39,40] and improve health-related quality of life (HRQoL).[41-43] However, there are also risks of complications, reoperation, and procedure-related mortality.[38,44]

Nonsurgical weight-loss interventions are commonly used as the first line of treatment for overweight and obesity.[1] Nonsurgical weight-loss interventions include lifestyle changes (e.g., reduced-calorie diet, structured exercise programs), weight-loss medications, and behavioral therapy, either in isolation or in combination, at varying levels of intensity and duration.[45] While nonsurgical weight-loss interventions can be effective in the short term, the resulting weight loss is typically modest, and there is limited evidence of effectiveness over the long term.[45,46]

Glucagon-like peptide 1 (GLP-1) agonists[47] (e.g., semaglutide, liraglutide) are a class of medication that has recently generated significant attention for weight-loss outcomes following new FDA drug approvals. While GLP-1 agonists generally result in statistically significant differences in weight loss compared with placebo, they may also cause complications, such as nausea and vomiting, and long-term maintenance of weight loss is unclear.[48] Additionally, evidence suggests that GLP-1 agonists result in less weight loss than MBS, though effects on glycemic control may be similar.[49]

MBS is generally not intended to replace nonsurgical lifestyle interventions. Rather, MBS is commonly recommended with concurrent nonsurgical lifestyle interventions to sustain maximum weight loss and mitigate potential weight recurrence.[1,46,50,51] Furthermore, clinical guidelines have emphasized the importance of involving a multidisciplinary team in the management of obesity care.[52-54]

Additional details related to nonsurgical interventions for overweight and obesity are discussed under the section Effectiveness Profile of Nonsurgical Weight Management Treatments (CQ1).

Focus of Research

There has been a recent increase in MBS research, with randomized controlled trials (RCTs) registered around the world, and a growing interest in measuring particular outcomes, such as obesity-related comorbidities, body composition, and quality of life.[55,56] There also continue to be concerns and controversy about the potential risk of long-term nutritional deficiencies from certain surgical procedure types,[57-59] and possible negative effects on bone health following MBS.[60,61] Other areas of interest within MBS research include revision surgery for nonresponse,[62] implications for fertility and best practices for women of childbearing age,[63,64] and the effectiveness, safety, and ethics of MBS for children and adolescents.[65-68]

Types of MBS

There are several types of MBS procedures that modify the digestive system in different ways.[1,3] The American Society for Metabolic and Bariatric Surgery (ASMBS) currently endorses 8 MBS procedures, including revision procedures, and devices approved by the FDA[2] (see Table 1 for a full list of ASMBS-endorsed surgeries and FDA-approved devices). All MBS procedures decrease stomach volume to limit how much food and drink can be consumed at one time.[69] However, some procedures (e.g., Roux-en-Y gastric bypass [RYGB]) also make changes to the small intestine to reduce absorption of calories and alter gut hormones to help normalize hunger and satiety.[69] The metabolic mechanisms leading to weight loss are still not completely understood for some procedures.[37] While the body of evidence involving long-term follow-up is relatively robust for older procedures (e.g., RYGB), there is less evidence on the long-term benefits and harms of newer procedures, including single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S) and one-anastomosis gastric bypass (OAGB).[35,70]

Table 1. ASMBS-Endorsed Procedures and FDA-Approved Devices for MBS[2,3,71]

Procedure Name FDA-Approved Device (Approval Year)	Stomach Restriction	Bypass Procedure	Reversible?
Surgical procedures			
Adjustable gastric banding (AGB) Lap-Band (2001)	Adjustable silicone band is placed around the top of the stomach creating a small pouch; main stomach stays attached	N/A	Yes
Biliopancreatic diversion (with or without duodenal switch)	Similar to SG	The stomach sleeve is attached to the lower small intestine, bypassing 75% of the small intestine	No
One-anastomosis gastric bypass (OAGB)[a]	Similar to SG	The stomach sleeve is attached to a loop from the middle portion of the small intestine	No
Roux-en-Y gastric bypass (RYGB) • Apollo Revise (2022) • Apollo REVISE NXT (2023) • Apollo Revise Sx (2022)	Stomach is reduced to a pouch the size of an egg	The stomach pouch is attached to the middle of the small intestine, bypassing about 3 to 4 feet of small intestine and resembling a Y shape	No
Single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S)	Similar to SG	The stomach sleeve is attached to a loop of small intestine several feet from its end	No
Sleeve gastrectomy (SG)	80% of the stomach is removed, leaving a banana-shaped "sleeve"	N/A	No
Endoscopic procedures			
Endoscopic sleeve gastroplasty (ESG) • Apollo ESG (2022) • Apollo ESG NXT (2023) • Apollo ESG Sx (2022)	Sutures are placed with the endoscope to reduce the volume of the stomach, leaving it shaped like a tube or "sleeve"	N/A	No
Intragastric balloon (IGB) • Obalon (2016) • Orbera (2015)[b] • Spatz3 (2021) • TransPyloric Shuttle (2019)	Fluid-filled or gas-filled silicone balloons temporarily placed in the stomach, limiting amount of food one can eat	N/A	Yes

Notes. [a] Also known as mini gastric bypass or omega gastric bypass. [b] Formerly known as the BioEnterics Intragastric Balloon (BIB).
Abbreviations. ASMBS: American Society for Metabolic and Bariatric Surgery; FDA: Food and Drug Administration; MBS: metabolic and bariatric surgery; N/A: not applicable.

Though bariatric surgical procedures can occur through open surgery or laparoscopy, several clinical practice guidelines[35,37,72] recommend a preference for laparoscopic surgery over open surgery for its reduced risk of complications,[73] with exceptions made for complex cases that necessitate open surgery. The uptake of robotic MBS is also on the rise worldwide, representing about 17% of bariatric surgeries in the US in 2020.[74] While most bariatric procedures are surgeries, IGBs and endoscopic sleeve gastroplasty (ESG) are endoscopic procedures.[75] Intragastric balloons are usually placed for up to 6 months, but some can be placed for up to 12 months (Table 2).[76] Adjustable gastric bands and IGBs are considered reversible procedures, though scar tissue and changes to the gastric and esophageal physiology can be permanent[76,77]; other MBS procedures are considered nonreversible. Adjustable gastric bands and IGBs may be used independently or prior to another type of MBS to reduce weight to a level that is suitable for surgery.[76,77]

Table 2. Additional Details for Intragastric Balloon Devices[78]

Intragastric Device	Number of Balloons Implanted	Material (Fill)	Maximum Duration of Implantation	Insertion (Removal if Different)
Orbera	1	Silicone (saline)	6 months	Endoscopic
Obalon	Up to 3	Gelatin capsule (gas)	3 to 6 months	Oral (endoscopic)
Spatz3	1	Silicone (NR)	12 months	Endoscopic
TransPyloric Shuttle	1	Silicone (NR)	12 months	Endoscopic

Note. All devices are approved for individuals with a body mass index of ≥ 30 to < 40 kg/m^2.
Source. Adapted from Lari and colleagues (2021).[78]
Abbreviation. NR: not reported.

Disparities in Access to and Outcomes of MBS

MBS is not equally accessible to all patient populations. People who receive MBS are more likely to be female, non-Hispanic White, and privately insured.[79-81] The sex gap in MBS use is consistent across countries, with female patients undergoing the vast majority of MBS procedures.[74] Black males may be particularly disproportionately underrepresented in the MBS patient population in the US.[82] Mixed evidence at the state level suggests that patterns of disparities by sex or race and ethnicity may differ in various locales.[83,84]

Disparities in access to MBS have been attributed to insurance coverage policies, provider bias in referral patterns, obesity stigma, and patient perceptions of MBS.[31,85-87] Weight bias among health care professionals has generated particular attention.[88] Stigma may pose a barrier to high quality care because negative experiences in health care settings can undermine a patient's desire to seek care, as well as their trust in physicians.[89]

Adequate access to MBS for pediatric populations is also a concern.[90] Access for children is affected by attitudes among pediatric health care professionals towards MBS referral for adolescents[91,92] and potential barriers in seeking authorization from insurers.[93,94] Racial and ethnic disparities in access may exist for adolescents as well, with 1 study finding that White adolescents were more likely to undergo MBS than Hispanic and Black adolescents.[95]

There is also evidence of racial and ethnic disparities in MBS outcomes. Black and African American patients have higher rates of complications and hospital readmission following MBS.[96-98] Black patients also generally have less favorable weight-loss outcomes than Hispanic and non-Hispanic White patients.[82,99] However, there appears to be no association between race and comorbidity resolution following MBS.[99,100]

Medicaid Beneficiaries and MBS

Analysis of the Healthcare Cost and Utilization Project National Inpatient Sample found that Medicaid as the primary payer for the 2 most common types of MBS increased from 9% in 2012 to 19% in 2018.[101] There appear to be no significant differences in weight-loss outcomes between Medicaid and privately insured individuals following MBS.[102] However, Medicaid beneficiaries may have higher rates of hospital readmission or longer length of stay following MBS than individuals with private insurance.[102,103]

The proportion of publicly insured adolescents receiving MBS increased significantly between 2009 and 2017; however, the majority of adolescent bariatric patients remained privately insured.[104] The authors of a study on MBS among adolescents with Medicaid coverage from 2012 to 2018 suggest that the relatively small sample size identified in national Medicaid claims data implies that MBS is infrequently used as an intervention in this population, perhaps due to access barriers or uncertainty about its indication for adolescents.[105] Notably, 1 study of adolescents with severe obesity found that White adolescents with Medicaid coverage were more likely to undergo MBS than those with private insurance, while the reverse was true for adolescents of color: Black and Hispanic adolescents with Medicaid coverage were less likely to undergo MBS than those with private insurance.[81]

Policy Context

As the prevalence of overweight and obesity continues to rise in the US, so does the number of MBS procedures performed annually. Approximately 249,000 primary MBS procedures were performed in the US in 2022, up from 213,500 (an increase of nearly 16%) in 2019.[106] Sleeve gastrectomy and RYGB remain the most common procedures performed, accounting for 66% and 26% of annual procedures, respectively.[106] The number of newer procedures (e.g., OAGB, SADI-S) performed continue to increase, but make up less than 3% of all MBS procedures performed in the US.[106] The number of procedures performed is expected to continue to increase, particularly considering recently published guidelines from the ASMBS, International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), and AAP.

In October 2022, ASMBS and IFSO published a joint update to the 1991 National Institutes of Health indications for MBS.[36] Major changes to the 1991 guidance include[36]:

- Recommending MBS for individuals with a BMI ≥ 35 kg/m^2, regardless of the presence, absence, or severity of comorbidities
- Considering MBS for individuals with metabolic disease and a BMI of 30 to 34.9 kg/m^2
- Adjusting BMI thresholds in people of Asian descent (also recently re-endorsed by the American Diabetes Association[107])
    - A BMI ≥ 25 kg/m^2 suggests clinical obesity in this population
    - Individuals from this population with a BMI ≥ 27.5 kg/m^2 should be offered MBS

- Considering MBS for appropriately selected children and adolescents with:
  - A BMI > 140% of the 95th percentile (i.e., BMI ≥ 40)
  - A BMI > 120% of the 95th percentile (i.e., BMI ≥ 35 to < 40 kg/m^2) and a major comorbidity

Relatedly, in February 2023 the AAP published updated clinical practice guidelines and recommendations for the evaluation and treatment of children and adolescents with overweight and obesity.[108] The AAP recommends offering a referral to an appropriate surgery center for an evaluation for MBS for adolescents aged 13 years and older with severe obesity (i.e., BMI ≥ 120% of the 95th percentile, or BMI ≥ 35).[108]

In 2015, the Washington Health Technology Assessment Health Technology Clinical Committee made the following coverage determination based on a review of the 4 most common MBS procedures performed in the US (i.e., AGB, biliopancreatic diversion [BPD], RYGB, and SG)[109]:

- MBS is a covered benefit for adults (≥ 18 years of age) for the following conditions:
  - BMI ≥ 40 kg/m^2
  - BMI 35 to < 40 kg/m^2, and at least 1 obesity-related comorbidity
  - BMI 30 to < 35 kg/m^2, and T2DM
- When covered, individuals must abide by all other agency surgery program criteria (e.g., specified centers or practitioners; preoperative psychological evaluation; participation in preoperative and postoperative multidisciplinary care programs)
- MBS is not covered for the following groups:
  - Children (individuals < 18 years of age)
  - Adults with a BMI < 30 kg/m^2
  - Adults with a BMI 30 to < 35 kg/m^2, without T2DM

In 2023, this topic was selected for rereview based on medium concerns about safety and high concerns about effectiveness and cost.[110] The objective of the health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of MBS in adults and children with overweight or obesity. This evidence review will help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use of MBS in adults and pediatric populations. This evidence review focuses on MBS as compared with nonsurgical interventions for overweight and obesity. This review only considers the effectiveness, safety, or cost-effectiveness of nonsurgical interventions (e.g., diet, antiobesity medications) when they have been directly compared with MBS in studies deemed eligible for inclusion (see Table 3).

Washington State Utilization and Cost Data

State data to be added.

Methods

This evidence review is based on the final key questions (KQs) published on November 15, 2023.[111] The draft KQs were available for public comment from October 18 to October 31, 2023, and appropriate revisions were made to the KQs based on the comments and responses.[112] All public comments received, and a table of responses, can be found on the Washington Health Technology Assessment website.[113] The draft report was available for public comment from March 4 through April 1, 2024, but no public comments were received. The draft

report was also peer-reviewed by 6 subject matter experts, with appropriate revisions reflected in this final report. The PICOS (population, intervention, comparator, outcome, study design) details, along with the setting, sample size, and publication factors that guided development of the KQs and study selection, are presented in Table 3 below.

Contextual Questions

Contextual questions were not systematically reviewed and are not shown in the analytic framework (**Error! Reference source not found.**). To address contextual questions, we relied on r ecent systematic reviews or a subset of the largest, most relevant recent primary research articles identified through our search.

CQ1. What is the overall effectiveness profile of nonsurgical weight management treatments (including antiobesity medication, diet-control programs, exercise, psychotherapy, and nutritional counseling)?

CQ2. What is the overall safety profile of previously reviewed MBS procedures (i.e., AGB, BPD, RYGB, and SG) in adults with overweight or obesity?

CQ3. What accreditation standards and center of excellence designations exist for MBS in the US, and what are the requirements of each?

CQ4. What are professional society or guideline criteria for revision or conversion of bariatric surgeries?

Key Questions

KQ1. What is the comparative clinical effectiveness of MBS procedures reviewed in 2015 (i.e., AGB, BPD, RYGB, and SG) vs. nonsurgical weight-loss management in people not currently covered under the 2015 Washington coverage determination? Specifically in:

a. Adults (aged ≥ 18 years) with a BMI ≥ 35 to < 40 kg/m^2 without an obesity-related condition

b. Adults (aged ≥ 18 years) with a BMI ≥ 30 to < 35 kg/m^2 without T2DM; or with or without any other obesity-related comorbidity

c. Adults (aged ≥ 18 years) with a BMI < 30 kg/m^2, regardless of comorbidity status

d. Children (aged ≤ 17 years) with overweight or obesity, on an overall basis and by specific age groups (e.g., 13 to 17, ≤ 12 years)

KQ2. What is the comparative clinical effectiveness of MBS procedures not reviewed (i.e., ESG, IGB, OAGB, and SADI-S) vs. nonsurgical weight-loss management, with or without obesity-related comorbid conditions in:

a. Adults (aged ≥ 18 years) with overweight or obesity?

b. Children (aged ≤ 17 years) with overweight or obesity, on an overall basis and by specific age groups (e.g., 13 to 17, ≤ 12 years)?

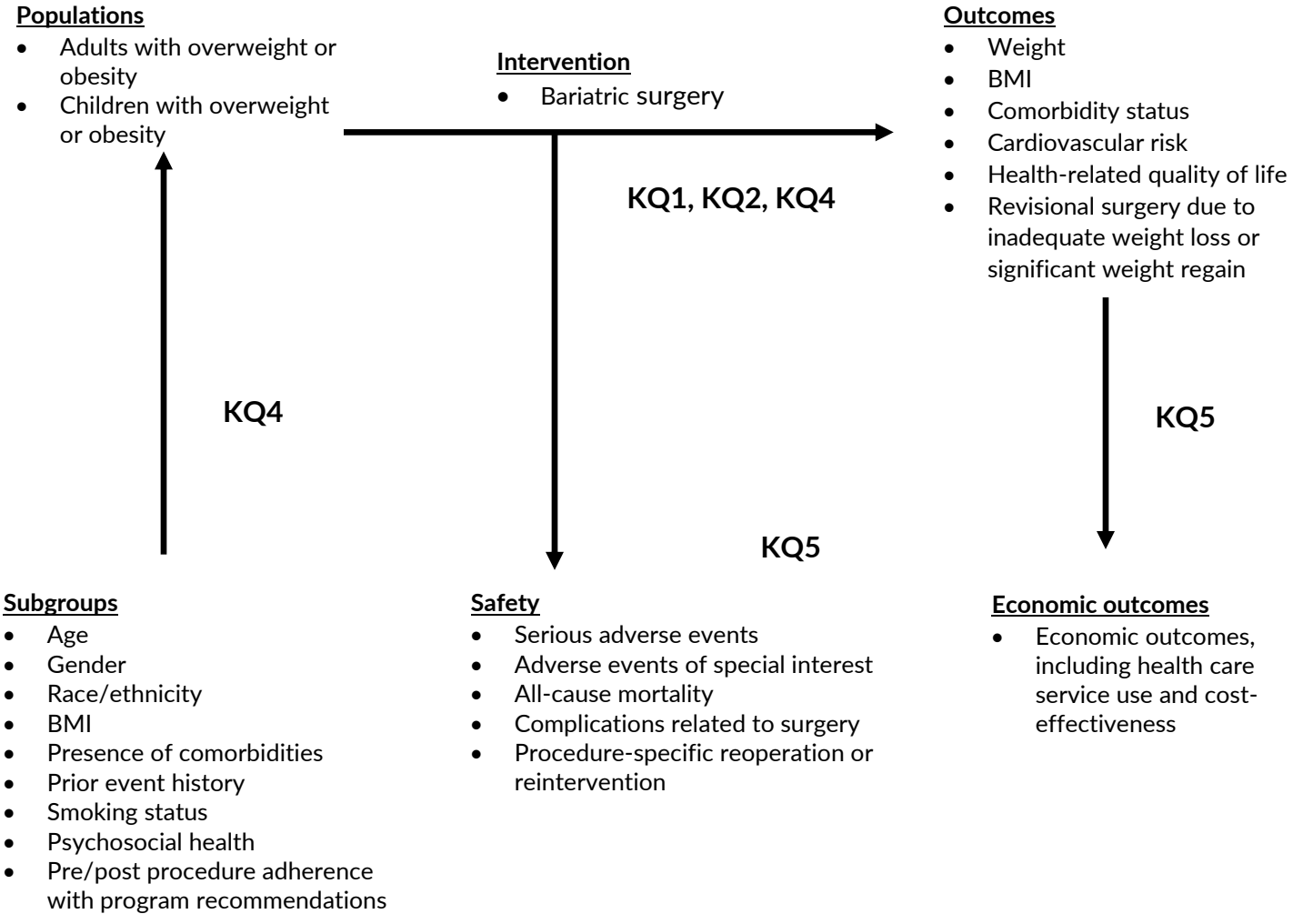
KQ3. What is the potential short-term and long-term safety of MBS procedures, including rates of procedure-specific complications (including those requiring revision surgery), longer-term morbidity, and mortality in the populations specified in KQ1 and KQ2?

KQ4. What is the differential effectiveness and safety of MBS procedures according to patient and clinical factors, such as:

a. Age (chronological, physiologic, skeletal)
b. Sex
c. Race and ethnicity
d. BMI (assessed as both continuous and categorical variable)
e. Presence of comorbidities (e.g., hypertension, T2DM)
f. Prior medical event history (e.g., myocardial infarction, stroke)
g. Smoking status
h. Psychosocial health
i. Pre- and post-procedure adherence with program recommendations

KQ5. What are the costs and cost-effectiveness of the MBS procedures included in this evidence review?

Figure 1. Analytic Framework



Abbreviations. BMI: body mass index; KQ: key question.

PICOS and Eligible Studies

Table 3 provides detailed information on the inclusion and exclusion criteria Center of Evidence-based Policy (Center) researchers applied to determine the eligibility of studies.

Table 3. Detailed Inclusion and Exclusion Criteria for Studies of MBS

Inclusion Criteria	Exclusion Criteria
Populations	
KQ1 • Adults with a BMI of ≥ 35 to < 40 without an obesity-related condition • Adults with a BMI of ≥ 30 to < 35 without T2DM; or with or without any other comorbidity • Adults with a BMI < 30, regardless of comorbidity status • Children and adolescents with overweight or obesity KQ2 • Adults with overweight or obesity • Children and adolescents with overweight or obesity	• Populations with overweight or obesity due to factors known to cause weight gain (e.g., pregnancy, substance misuse, some medications)
Interventions	
KQ1 • MBS procedures currently endorsed by the ASMBS[2] and FDA-approved devices,[3] alone or in combination with nonsurgical treatments (e.g., diet, exercise, medication) • Roux-en-Y gastric bypass • Adjustable gastric banding • Vertical sleeve gastrectomy • Biliopancreatic diversion (with or without duodenal switch) KQ2 • MBS procedures currently endorsed by the ASMBS[2] and FDA-approved devices,[3] alone or in combination with nonsurgical treatments (e.g., diet, exercise, medication) • Single-anastomosis duodenal ileostomy with sleeve gastrectomy • Intragastric balloon • One-anastomosis gastric bypass • Endoscopic sleeve gastroplasty	• Non-ASMBS endorsed procedures • Non-FDA approved devices • Procedures or devices that are outdated, rarely practiced, or are not available in the US
Comparators	
• Nonsurgical weight management treatments (including antiobesity medication, diet-control programs, exercise, psychotherapy, and nutritional counseling), alone or in combination • Sham procedures combined with a nonsurgical weight management treatment • Head-to-head studies in under 18s or for procedures listed in KQ2	• Treatments not available in the US (including outdated procedures [e.g., jejunoileal bypass] and devices [e.g., Garren-Edwards gastric bubble]) • Comparators other than those stated (e.g., comparison of different surgical techniques for the same procedure) • Pre- or post-operative protocols to reduce risk of complications and AEs (e.g., oxygenation, anesthesia, administration of medication) • Head-to-head studies unless otherwise noted

Inclusion Criteria	Exclusion Criteria
Outcomes[a,b]	
Efficacy and effectiveness • Weight • BMI • Comorbidity status (e.g., remission of T2DM) • Cardiovascular risk (e.g., major adverse cardiovascular event, blood pressure, HDL/LDL, triglycerides) • Health-related quality of life • Patient important outcomes (e.g., self-esteem, mobility, depression) using specific measurement tools as defined in 2022[114] • Revision or conversion surgery due to nonresponse (i.e., inadequate weight loss) or significant weight recurrence (i.e., regain) Safety • Serious AEs (SAEs) • AEs of special interest • Difficulty swallowing (dysphagia/regurgitation) • Micronutrient status (i.e., vitamin B12, vitamin D, or anemia) • All-cause mortality (30-day or longer term) • Complications related to surgery (e.g., intraoperative organ injury, hernia) • Any procedure-specific reoperation or reintervention and classification of severity (e.g., strictures, leaks) Economic outcomes • Health care service use • Costs • Cost-effectiveness	• Studies not reporting outcomes of interest • Outcomes with less than 12 months post-intervention data (unless otherwise noted) • Economic outcomes from studies performed in non-US countries • Economic outcomes from studies performed in the US that were published more than 5 years ago • Other outcomes not listed
Timing	
• Any point in the treatment pathway[c]	• None stated
Settings	
Any nonemergency clinical setting in: • Countries categorized as *very high* on the UN HDI[115] • Central America and the Caribbean • Top 10 countries with the highest number of immigrants to the US (i.e., Mexico, India, China [including Hong Kong and Macao], the Philippines, El Salvador, Vietnam, Cuba, the Dominican Republic, Guatemala, and Korea)[116]	• Nonclinical settings (e.g., animal models of disease) • Countries categorized as *high*, *medium*, or *low* on the UN HDI, unless otherwise noted
Study designs	
For KQ1 to KQ4 • RCTs (≥ 50 participants) • Prospective nonrandomized comparative studies for interventions where RCTs are not available (≥ 100 participants) • Large registry studies (≥ 1,000 individuals) for safety outcomes only For KQ5 • Comparative studies and economic evaluations • Cost-effectiveness analyses	• Abstracts, conference proceedings, posters, editorials, letters • Studies without a comparator • Placebo-controlled studies • Proof-of-principle studies (e.g., procedure development, technique modification) • Studies without extractable data • Uncontrolled studies

Inclusion Criteria	Exclusion Criteria
• Economic simulation modeling studies	• Retrospective studies unless otherwise noted
Sample sizes	

Minimum sample size of:
• 50 participants for RCTs
• 100 participants for nonrandomized comparative study designs
  ○ ≥ 50 participants if aged < 18 years (children and adolescents)
• 1,000 participants for registry studies
  ○ ≥ 500 participants if < 18 years (children and adolescents)
	• Studies that do not meet the minimum sample size

Publications	
• Peer-reviewed publications • Published in the English-language • Published from January 1, 2000, to present • Economic studies published from January 1, 2019	• Studies reported only as abstracts that do not allow study characteristics to be determined • Studies that cannot be found • Duplicate publications of the same study that do not report different outcomes or follow-up times, or single-site reports from published multicenter studies • Studies published in languages other than English • Studies that have not been formally peer reviewed (i.e., preprint publications)

Notes. [a] Published core outcome sets and multiperspective consensus statements were reviewed for clinical and patient-important outcomes.[114,117] [b] For studies examining intragastric balloons, 6-month outcomes are eligible, if they also report longer term outcomes, since these devices are generally removed no later than 6-months post-implantation. [c] The aim is to include studies regardless of any prior obesity-related treatments since presurgical requirements can vary across individual characteristics (e.g., age, severity of comorbidities), time periods, and geographical regions.
Abbreviations. AE: adverse event; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; FDA: US Food and Drug Administration; HDL: high-density lipoprotein (cholesterol); KQ: key question; LDL: low-density lipoprotein (cholesterol); MBS: metabolic and bariatric surgery; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus; UN HDI: United Nations Human Development Index.[115]

Data Sources and Searches

We ran a literature search using Ovid MEDLINE ALL and the Cochrane Central Register of Controlled Trials (CENTRAL) for any RCTs, comparative nonrandomized studies (NRSs), large registry studies, cost-effectiveness studies, and clinical practice guidelines analyzing a listed MBS intervention. We also conducted general internet searches in DuckDuckGo and Google Scholar, and reviewed reference lists of included studies and relevant systematic reviews to identify relevant publications that were not identified through the database searches. Searches for interventions were limited to January 1, 2000, to November 9, 2023, to capture relevant published studies. We also searched ClinicalTrials.gov, International Clinical Trials Registry Platform (WHO), and ScanMedicine for ongoing studies of listed interventions for primary MBS.

Screening, Data Abstraction and Quality Assessment

Screening of the literature search results, risk-of-bias (RoB) and methodological assessments, and data abstraction were performed in DistillerSR; artificial intelligence was used to aid in title and abstract screening.[118] Two independent researchers reviewed each unique citation and conducted RoB and methodological assessments; conflicts were handled through discussion, and any disagreements were resolved by a third independent senior researcher. Data was extracted by 1 researcher and checked by another for accuracy. We performed the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach on select outcomes: excess weight loss (EWL), total weight loss (TWL), and resolution of baseline comorbidities (e.g., metabolic syndrome [MetS], T2DM). Two independent researchers assigned GRADE certainty-of-evidence (CoE) ratings from *very low* to *high*; conflicts were handled through discussion, and any disagreements were resolved by a third independent senior researcher.

We included RCTs and comparative NRSs that evaluated a listed intervention. Additional eligibility criteria were studies on human participants, conducted in countries evaluated as *very high* on the United Nations Human Development Index, as well as the top 10 countries with the highest number of immigrants to the US (e.g., Mexico, India, China)[116] published between January 1, 2000, and November 10, 2023. Economic evaluations and clinical practice guidelines published from January 1, 2019, were also included; economic evaluations were required to have a US perspective. All included studies were published in the English language. Studies were excluded if data was not extractable or if we were unable to isolate data for populations of interest for this review. Refer to Table 3 for more detailed inclusion and exclusion criteria.

Registry Studies

Due to the volume of registry studies, particularly from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Registry, we excluded nearly all registry publications due to time constraints. However, we have conducted an original analysis of the publicly available MBSAQIP 30-day post-surgery patient-level data for years 2016 through 2022. Data was extracted for individuals undergoing their first MBS procedure or IGB procedure who had a full 30 days of follow up. Exclusion criteria included prior MBS, conversion or revision procedures, and emergency surgery. Adult and pediatric patients with missing values for height or weight, for whom BMI could not be calculated, were excluded. Analysis omits records for adult patients with biologically implausible values for height (< 48 or > 84 inches) or weight (< 75 pounds or > 800 pounds), as defined by Noel and colleagues.[119] Further details of this analysis are available in the section covering KQ3, and in Appendix L.

A full description of our methods can be found in Appendix A.

Overview of Key Outcome Measures

Table 4 summarizes the primary measures used for outcomes in the included studies, the interpretation of those measures, including categories or classes that are used clinically to determine treatment approaches, and change values determined as clinically meaningful. Minimal clinically important difference (MCID) values are defined as the smallest improvement in an outcome in response to treatment that in an individual patient would be identified as important, leading to a change in the patient's management[120] (also known as differences, or improvements, that are clinically meaningful). While these thresholds can offer valuable information about

effectiveness beyond statistical significance for responders and nonresponders, there is controversy around methods used and lack of standardization in the derivation of MCIDs.[121] MCIDs should not be applied and interpreted in isolation, but rather with consideration of the patient population, the individual patient, and other clinically relevant information.[121,122]

There are currently no MCIDs for common weight loss outcomes related to bariatric surgery. Several recent publications have suggested that, in general, a minimum reduction of 20% to 25% of baseline weight could be used to determine clinically meaningful response to MBS.[123-126] These suggestions note response to MBS will depend on several factors including baseline weight, BMI, the number and severity of comorbidities, and the type of MBS; therefore a reduction of 20% to 25% may not be universally achievable.[123-125] It has also been suggested that clinicians use calculators or other charts to predict patient-specific weight loss since these can account for individual characteristics (e.g., comorbidities, age, ethnicity) to more accurately predict patient-specific response to MBS.[124,127] Centile charts for weight loss trajectories for Asian patients have been suggested, but have not been adopted.[128]

Furthermore, controversy surrounds the commonly used percent EWL and percent TWL to determine response to MBS.[126,129] Researchers have suggested that TWL is the more appropriate metric because it is more consistent across the spectrum of baseline BMIs compared with EWL which may underestimate the benefits of MBS for individuals with a BMI ≥ 40 kg/m^2.[130-132]

Table 4. Summary of Key Outcomes for Studies of Metabolic and Bariatric Surgery

Measure	Description	Interpretation	MCID
Weight			
Percent total weight loss (%TWL)	$\left(\frac{baseline\ weight - post\text{-}treatment\ weight}{baseline\ weight}\right) x\ 100$	Assessment of proportion of weight lost over time (with intervention) For example, 20% weight loss in an individual with: • Baseline body weight of 135 kg (289 lbs): loss of 27 kg (58 lbs); post-treatment weight of 108 kg (231 lbs) • Baseline body weight of 80 kg (176 lbs): loss of 16 kg (35 lbs); post-treatment weight of 64 kg (141 lbs)	• No MCID identified in relation to MBS
Percent excess weight loss (%EWL)	$\left(\frac{baseline\ weight - post\text{-}treatment\ weight}{baseline\ weight - ideal\ weight}\right) x\ 100$	Assessment of proportion of weight lost over time (with intervention) with the goal to reach an ideal weight based on individual characteristics	• No MCID identified in relation to MBS
Percent change in body mass index (%BMI)	$\left(\frac{baseline\ BMI - post\text{-}treatment\ BMI}{baseline\ BMI - ideal\ BMI}\right) x\ 100$	Assessment of proportion of BMI change over time (with intervention) with the goal to reach an ideal BMI of 25 kg/m^2	• No MCID identified in relation to MBS
Comorbidity risk factors			
Systolic blood pressure (SBP)	• Represents the peak arterial force produced by the heart when pumping out blood to the body; Shown to predict cardiovascular risk better than DBP • Typically has linear relationship with DBP	Measured in millimeters (mm) of mercury (Hg) • Normal: < 120 mmHg • Elevated: 120 to 129 mmHg • Hypertension, stage 1: 130 to 139 mmHg • Hypertension, stage 2: ≥ 140 mmHg	• Reduction of 5 mmHg shown to reduce major cardiovascular event by 10%[133]

Measure	Description	Interpretation	MCID
Low-density lipoprotein (LDL) cholesterol	• Test for blood lipoproteins that transport cholesterol and fat around the body via the blood • The largest component of total blood cholesterol that can contribute to atherosclerosis if high	Measured in mg/dL or mmol/L (1 mmol/L = 38.7 mg/dL) • Normal: < 100 mg/dL • Near optimal: 100 to 129 mg/dL • Borderline high: 130 to 159 mg/dL • High: 160 to 189 mg/dL • Very high: ≥ 190 mg/dL	• 1 mmol/L (38.7 mg/dL) reduction associated with 23% to 25% risk reduction of major cardiovascular events[134] • Goal of statin therapy > 50% reduction in LDL cholesterol[135]
Quality of life			
Beck Youth Inventory[136]	• A self-report measure with 100 items that is designed to be used by children aged 7 to 18 • Includes 5 inventories with 20 items each that can be used individually or in combination • Inventories for anxiety, depression, anger, disruptive behavior, and self-concept • Scores are on a scale of 0 to 60	• Higher scores represent more symptoms (anxiety, depression, anger, and disruptive behavior) or higher self-concept. Positive change in self-concept score indicates improvement	• No MCID score identified
Impact of Weight on Quality of Life (IWQOL)[a] survey	• Clinical trials version is scaled and scored similarly to regular version • 20-item self-report survey to assess obesity-specific QoL in adults (-Lite) or adolescents (-Kids) • Consists of 5 domains (physical function, self-esteem, sexual life, public distress, work)	• Transformed scores (from raw scores) range from 0 to 100, with 100 representing the best QoL • Physical function score includes only the single domain, or component	• Increases of 7.7 to 12 points of total score[137] • No MCID for component score identified
OP-14 Scale[138,139]	• A self-assessment scale to evaluate the impacts of obesity on psychosocial functioning in daily life • Score is on a scale of 0 to 100	• Higher scores represent more impairment. A reduction in OP-14 score indicated improvement in obesity-related QoL	• No MCID score identified
SF-36/RAND-36[b]	• The physical functioning component of RAND-36 • Includes 10 of 36 items of a self-report survey	• Component scores range from 0 to 100 with higher scores indicating a more favorable QoL	• > 3.8 points for obesity health-related QoL[140]

Note. [a] Adult studies included here use the IWQOL-Lite version, while studies of adolescents us the IWQOL-Kids version. [b] SF-36 is the commercial version of RAND-36; there are minor differences between the clinical tools.
Abbreviations. BMI: body mass index; DBP: diastolic blood pressure; lbs: pounds; LDL: low-density lipoprotein; MBS: metabolic and bariatric surgery MCID: minimal clinically important difference; QoL: quality of life; SF-36: 36-item Short Form Health Survey.

Contextual Questions

Effectiveness Profile of Nonsurgical Weight Management Treatments (CQ1)

This section provides an overview of the current state of nonsurgical weight management treatments (e.g., medications, lifestyle programs) through examination of recent systematic reviews and other materials.

Nonsurgical Weight Management in Adults

A 2018 systematic review, in support of the US Preventive Services Task Force recommendations on behavioral and pharmacotherapy weight-loss interventions, examined over 124 studies (N = 62,533 participants in 122 RCTs and 2 observational studies) that compared behavior- or medication-based interventions with usual care, attention control, wait list, or placebo.[141] Participants in the behavior-based intervention studies generally had BMIs in the overweight (i.e., BMI > 25 kg/m^2 to < 30 kg/m^2) and class 1 obesity (i.e., BMI ≥ 30 kg/m^2 to < 35 kg/m^2) range than those in the medication-based studies who were more likely to have BMIs in the class 1 or class 2 (i.e., BMI > 35 to < 40 kg/m^2) range.[141] Follow up ranged from 1 year to 10.5 years with a mean of nearly 2 years.[141] Participants who received the behavior- or medication-based interventions generally lost more weight over 1 to 1.5 years than those in the control groups (pooled mean difference, −2.4 kg; range, −0.06 kg to −7.1 kg).[141] Cardiovascular risk factor outcomes were inconsistent across studies.[141]

In a 2022 systematic review and meta-analysis, in support of the American Gastroenterological Association's clinical practice guidelines on pharmaceutical interventions for adults with obesity and BMIs ≥ 30 kg/m^2 or ≥ 27 kg/m^2 and weight-related complications, FDA-approved antiobesity medications were compared with lifestyle interventions alone.[142] Total mean weight loss varied when compared with placebo, but ranged from 3.0% TWL for naltrexone-bupropion to 10.7% for semaglutide.[142]

Nonsurgical Weight Management in Children and Adolescents

In 2023, the AAP released a technical report regarding interventions (e.g., lifestyle counseling, medical management, surgery) for childhood obesity treatment; most studies examined lifestyle or dietary interventions.[143,144] Studies included children aged 2 to 17 years.[143,144] Most studies did not quantify dose of behavioral interventions (e.g., number and length of contact hours), however, there appeared to be a dose-response with more contact resulting in an increased likelihood of improved BMI and larger weight-loss up to 2 years postbaseline.[143,144] The greatest BMI changes (> 2 kg/m^2 reduction) were observed in trials of 52 contact hours or more, mostly delivered over 12 months, and were greater in older children and adolescents.[144]However, RCTs of pharmaceutical treatments demonstrated greater BMI reduction than lifestyle intervention alone.[144]

In 2024, Torbahn and colleagues published an update to the 2016 Cochrane systematic review on the use of medications for the treatment of obesity in children and adolescents.[145] Included RCTs had a minimum of 6 months treatment and compared an active treatment with placebo, most frequently in combination with a behavior change intervention (e.g., exercise, diet).[145] Active treatments included: exenatide, liraglutide, lorcaserin, metformin, orlistat, phentermine with topiramate, semaglutide, sibutramine, and topiramate.[146] Torbahn and colleagues found a moderate certainty of evidence that antiobesity medications, in combination with behavior

change interventions, resulted in a 1.71 kg/m^2 reduction in BMI for up to 2 years; when isolating these results to newer antiobesity medications, the reduction in BMI was 2.66 kg/m^2.[146] Similarly, a 2017 systematic review in support of the Endocrine Society's recommendations, combined interventions had stronger associations with weight reduction and improvement in metabolic outcomes than interventions focused on diet, education, or physical activity alone.[147]

There are currently 5 FDA-approved antiobesity medications for use in pediatric populations and that are recommended by the AAP[8,148]:

- Liraglutide and semaglutide (both GLP-1s) in adolescents aged ≥ 12 years
- Orlistat in adolescents aged ≥ 12 years
- Phentermine monotherapy in adolescents aged ≥ 16 years
- Phentermine-topiramate in adolescents aged ≥ 12 years
- Setmelanotide in children and adolescents aged ≥ 6 years

Safety Profile of Previously Reviewed MBS Procedures (CQ2)

See the Short-Term and Long-Term Safety section below for 30-day postoperative outcomes and select long-term outcomes.

Accreditation Standards and Center of Excellence Designations (CQ3)

National Accreditation

National accreditation for bariatric surgery centers began in 2004 with the launch of 2 accrediting programs: the American College of Surgeons Bariatric Surgery Center Network and the ASMBS Bariatric Surgery Centers of Excellence.[149,150] Although distinct certifications, these programs established similar practice standards related to surgical leadership, structural facility components, multidisciplinary care teams, and outcomes reporting with the goal of improving the safety of MBS procedures.[149,150]

In 2012, these programs were unified into the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), jointly administered by the American College of Surgeons and ASMBS, and operating as a single accrediting program for bariatric centers in the US and Canada.[150,151] There are currently 6 inpatient and 1 outpatient MBSAQIP accreditation designations that vary in terms of allowed procedures, treatment population, and procedural volume requirements (Table).[151] As of January 2024, there were 16 MBSAQIP-accredited bariatric surgery centers in Washington State, including all adult accreditation designations and 1 center with adolescent qualifications.[152]

Table 5. MBSAQIP Accreditation Designation Descriptions

Designation Type[a]	Bariatric Procedures	Populations	Annual Volume Requirements	Available in WA?
Inpatient designations				
Comprehensive Center	• ASMBS-endorsed procedures[b]	Adults	≥ 50 bariatric stapling procedures	Yes
Comprehensive Center with Adolescent Qualifications	• ASMBS-endorsed procedures[b]	Adults and adolescents	≥ 50 bariatric stapling procedures	Yes[c]
Comprehensive Center with Obesity Medicine Qualifications	• ASMBS-endorsed procedures[b]	Adults	≥ 50 bariatric stapling procedures	Yes
Comprehensive Center with Adolescent and Obesity Management Qualifications	• ASMBS-endorsed procedures[b]	Adults and adolescents	≥ 50 bariatric stapling procedures	Yes
Low Acuity Center	• ASMBS-endorsed primary procedures[b] • AGB replacement, positioning, or removal • Port revision or removal • Emergent revisional procedures[d]	Adults aged 18 to 65 BMI < 55 for males and < 60 for females No history of organ failure or current CVD	≥ 25 bariatric procedures	Yes
Adolescent Center	• ASMBS-endorsed procedures[b]	Adolescents	≥ 15 bariatric stapling procedures	No
Outpatient designations				
Ambulatory Surgery Center	• ASMBS-endorsed primary procedures[b] • AGB replacement, positioning, or removal • Port revision or removal • Emergent revisional procedures[d]	Adults aged 18 to 65 BMI < 55 for males and < 60 for females No history of organ failure or current CVD	≥ 25 bariatric procedures	Yes

Notes. [a] Regardless of designation, all centers must demonstrate compliance with MBSAQIP standards, successfully complete site visits, and enter data into the MBSAQIP registry. [b] MBSAQIP-accredited centers must receive approval from an Institutional Review Board to perform primary procedures not endorsed by the ASMBS. [c] This designation does not exist on its own in WA, but there is 1 comprehensive center with both adolescent and obesity medicine qualifications. [d] An emergent case is usually performed shortly after patient diagnosis or the onset of related preoperative symptomatology. Patient well-being and outcome is potentially threatened by unnecessary delay and the patient status could deteriorate unpredictably or rapidly.
Source. American College of Surgeons, 2022.[151,152]
Abbreviations. AGB: adjustable gastric banding; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; CVD: cardiovascular disease; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; WA: Washington State.

Programs seeking accreditation must demonstrate compliance with MBSAQIP standards regarding facility structures, staff competencies, and data reporting to provide quality metabolic and bariatric care.[151] These standards include[151]:

- A dedicated bariatric surgery committee consisting of a director, coordinator, clinical reviewer, pediatric medical advisor (if applicable), obesity medicine director (if applicable), clinical staff, and representative from the facility administration team. The committee is responsible for sharing best practices, discussing adverse events, and conducting quality improvement.
- Multidisciplinary teams capable of providing integrated preoperative, perioperative, and postoperative care for bariatric surgery patients. Programs must be able to provide access or referral to consistent and credentialed surgeons and operating teams, nursing staff, registered dieticians, and mental health professionals. Accredited adolescent centers must also have clinicians specializing in pediatrics for the treatment of pediatric obesity for both medical and behavioral domains.
- Facilities, equipment, and furniture that can accommodate all bariatric surgery candidates. This includes larger beds, wheelchairs, X-ray equipment, and weight-rated or supported toilets.
- Comprehensive patient education and care pathways for patient selection, preoperative behavioral and physical evaluation, nutritional support, and transition plans for pediatric patients to move from a pediatric specialist to an adult program over time.

Payer Accreditation Programs

Participation in national accreditation for bariatric centers is voluntary but has had robust uptake, driven in part by public and commercial payer facility certification coverage requirements.[150,153] In 2006, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) limiting Medicare coverage to accredited centers[154]; subsequently, by 2010 almost 90% of MBS procedures were performed in accredited centers.[150,153] Although CMS ultimately reversed the facility accreditation requirement in 2013, citing inconsistent outcomes at bariatric centers of excellence and concern regarding access limitations, participation in national accreditation has remained high.[150,153,155-157]

Despite the NCD reversal, several commercial payers have developed MBS accreditation programs required for participation in their networks, which include supplementary quality and cost criteria beyond national accreditation requirements (Table 6).[150]

Table 6. Commercial Payer Bariatric Accreditation Programs

Program Name (Payer)	Minimum MBSAQIP Designation Requirements	Summary of Supplemental Requirements
Institutes of Quality Bariatric Surgery network[158] (Aetna)	• Comprehensive center for inpatient facilities • Ambulatory surgery center for outpatient facilities	• Facilities and providers must be credentialed by Aetna and participate in their geographic provider network • At least 1 surgeon who has performed ≥ 100 bariatric procedures in 24 months • 12-month facility volume: ≥ 125 procedures for inpatient canters, ≥ 75 procedures for outpatient centers • Must meet outcome metrics for mortality, reoperations, SAE, revisions, hospital admissions

Program Name (Payer)	Minimum MBSAQIP Designation Requirements	Summary of Supplemental Requirements
3 Star Quality Bariatric Center[159] *or* Bariatric Center of Excellence[159] (Cigna)	• Comprehensive center[a,b] • Comprehensive center with adolescent qualifications[a,b]	• Active status with Cigna as a participating bariatric treatment center[a,b] • Receive 2 or 3 stars for cost efficiency[b,c] • Meet the minimum volume criteria for cost-efficiency evaluation in ≥ 50 inpatient bariatric procedures during assessment[b]
Blue Distinction Specialty Care Center for Bariatric Surgery[160] (BlueCross BlueShield)	• Comprehensive center for inpatient facilities • Ambulatory surgery center for outpatient facilities	• Facilities and providers must participate in the local Blue Plan BlueCard PPO Network • Must meet outcome metrics for mortality, re-operations, SAE, revisions, hospital admissions, and infections for each approved bariatric procedure type • Cost of care must be less than the national composite cost index threshold

Notes. [a] Cigna 3 Star Quality Bariatric Center [b] Cigna Bariatric Center of Excellence [c] Cigna's cost-efficiency score is a measure of a hospital's average cost for a particular procedure or condition that has been severity adjusted for national comparison. Two stars are awarded to programs with intermediate average cost (i.e., middle 33%) and three stars are awarded to programs with the lowest average cost (i.e., top 34%).
Abbreviations. MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; PPO: preferred provider organization.

Professional Guidance on Revision and Conversion of MBS (CQ4)

See the Clinical Practice Guidelines section below for criteria related to MBS revision or conversion procedures.

Evidence Summary

We identified 10,012 citations through bibliographic database (e.g., MEDLINE) searches and other search methods (e.g., reference list checking, internet searches). Following the removal of duplicate citations, 8,600 unique records were reviewed (**Error! Reference source not found.**). Ultimately, 13 RCTs (in 21 publications; total N = 2,121; range, 50 to 387) and 3 economic evaluations were included.[138,161-181]

Table 7 provides brief details of baseline characteristics.[138,161-181] Most studies (9 of 12) were conducted outside the US and enrolled mostly female participants (range, 60% to 93%). All but 1 study had a trial duration of 1 to 2 years with 4 studies reporting additional follow-up of 4 or 8 years[165,167,173,174]; 1 study had a trial duration of 5 years with an additional 5 years of follow-up.[173] We did not identify any eligible RCTs (i.e., those that met our population and other criteria defined in the PICOS section) for BPD or SADI-S procedures, though some 30-day outcomes are reported in our analysis of MBASQIP data.

We identified the following evidence for people not currently covered for MBS procedures under the 2015 Washington coverage determination:

- 2 RCTs in adults (total N = 131; mean age range, 41.2 to 53.0 years)
  - 1 comparing AGB with multidisciplinary diabetes care[173]
  - 1 comparing AGB with a lifestyle intervention plus the medication orlistat[167]

- 3 RCTs in children and adolescents (total N = 159; mean age range, 15.6 to 16.6 years)
  - 2 comparing AGB with a lifestyle intervention[161,168]
  - 1 compared RYGB (or SG) with a lifestyle intervention[138]

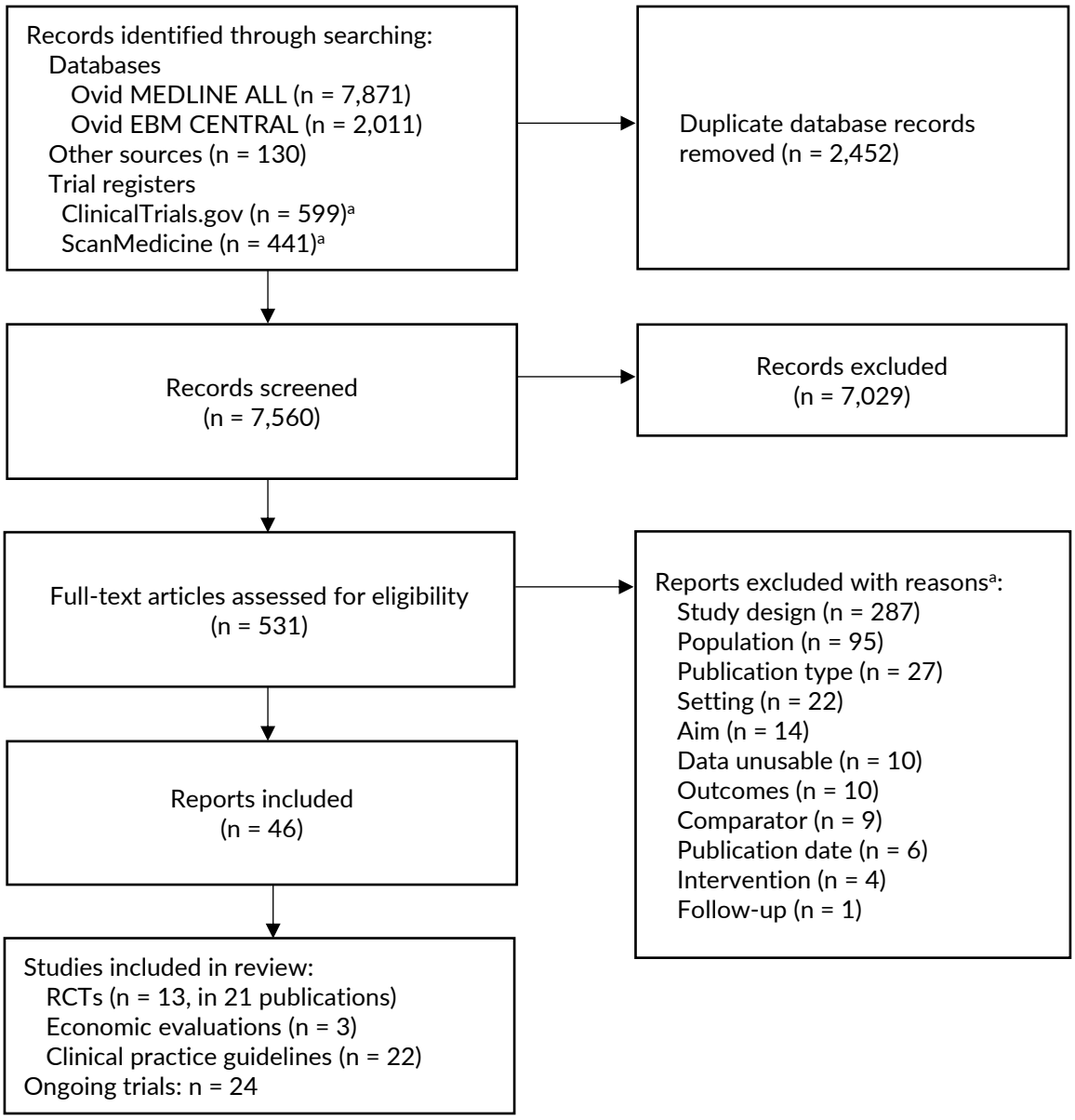
We identified the following evidence for procedures not reviewed for the 2015 Washington coverage determination:

- 8 RCTs in adults (total N = 1,575; range, 51 to 317; mean age range, 38.6 to 53 years)
  - 3 head-to-head RCTs comparing OAGB with RYGB or SG[169,170,174,176-178]
  - 3 comparing ESG, IGB, or OAGB with a lifestyle intervention[163-165,179]
  - 2 comparing 2 IGB devices (Orbera and TransPyloric Shuttle [TPS]) with sham surgery[171,175]

We identified 2 additional RCTs that appeared eligible for inclusion; however, they included mixed populations (e.g., BMI range, 27 to > 40; mean BMI > 35).[182,183] The results of these studies were not reported by baseline BMI, so Center researchers were unable to isolate data for populations of interest for this review. These study publications are listed in Appendix I.

The results of our review are presented by categories of adults, and children and adolescents. They are further presented by key question (KQ). Further details about the included studies are provided in each of the relevant sections.

Figure 2. Study Flow Diagram



Notes. Adapted from Page and colleagues.[184] [a] These numbers represent records identified through trials registries, which are not reflected in the remainder of the diagram.

Table 7. Summary of Inclusion Criteria and Baseline Characteristics for All Included RCTs of MBS

Study Details						Eligibility Criteria		Baseline Characteristics					
Study Name/Author, Year Trial Number	Includes US	N Randomized	MBS Type	Nonsurgical comparator	Duration + Follow-up, years	Age, years	BMI, kg/m^2	Mean Age, years[a]	Mean BMI, kg/m^2	Mean Weight, kg	Female, n (%)	Non-White, n (%)	Risk of Bias
Adults currently covered for MBS under the 2015 Washington coverage determination (for procedures reviewed in 2015)													
AMOS2[138,180] NCT02378259	X	50	• RYGB • SG	Lifestyle	2	13 to 16	≥ 35	15.7	42.6	122.6	37 (74.0)	NR	Mod
BASIC[161,162] NCT01172899	X	59	• AGB	Lifestyle	1	14 to 16	≥ 35[c]	15.7	44.1	128.8	47 (79.7)	NR	Mod
O'Brien, 2006[166,167] ACTRN012605000113651	X	80	• AGB	Lifestyle + orlistat	2 + 8	20 to 50	≥ 30 to < 35	41.2	33.6	94.8	61 (76.3)	NR	Mod
O'Brien, 2010[168] ACTRN12605000160639	X	50	• AGB	Lifestyle	2	14 to 18	> 35	16.5	41.3	118.0	34 (68.0)	NR	Mod
Wentworth, 2014[172,173] ACTRN012609000286246	X	51	• AGB + MDC	MDC	5 + 5	18 to 65	23 to < 30	53.0	29.0	82.0	36 (70.5)	NR	Low
MBS procedures not reviewed in 2015													
Head-to-head RCTs													
RYSA[169,170] NCT02882685	X	121	• OAGB • RYGB	N/A	1	≥ 18	≥ 35	46.5	43.8	126.9	84 (69.5)	NR	Mod
Seetharamaiah, 2017[176-178] NR	X	214	• OAGB • SG	N/A	1 + 4	18 to 64	> 30[b]	38.9	41.7	108.9	127 (59.3)	214 (100)	Mod
YOMEGA[174] NCT02139813	X	253	• OAGB • RYGB	N/A	2	18 to 65	≥ 35[c]	43.5	43.8	120.6	176 (69.5)	NR	Mod

Study Details						Eligibility Criteria		Baseline Characteristics					
Study Name/Author, Year Trial Number	Includes US	N Randomized	MBS Type	Nonsurgical comparator	Duration + Follow-up, years	Age, years	BMI, kg/m^2	Mean Age, years[a]	Mean BMI, kg/m^2	Mean Weight, kg	Female, n (%)	Non-White, n (%)	Risk of Bias
Compared with sham surgery or nonsurgical interventions													
ENDObesity II[175] NCT02518685	✓	270	• IGB	Sham surgery	1	22 to 60	≥ 30 to < 40[d]	43.3	36.6	100.4	252 (93.3)	74 (27.4)	Mod
IB-005[163] NCT00730327	✓	317	• IGB	Lifestyle	1	18 to 65	≥ 30 to < 40	32.0	35.6	78.8	229 (72.2)	48 (15.1)	High
LIFEXPE-RT[164,179] NCT03667469	X	60	• OAGB	Diet	1	18 to 65	≥ 35 to < 50	44.8	40.8	113.0	46 (76.7)	NR	Mod
MERIT[165] NCT03406975	✓	209	• ESG	Lifestyle	1 + 8	21 to 65	≥ 30 to < 40	41.5	31.9	88.4	160 (76.5)	72 (34.4)	Mod
SMART[171] NCT02235870	✓	387	• IGB	Sham surgery	1	20 to 64	≥ 30 to < 40	42.6	35.3	98.4	341 (88.1)	67 (17.3)	High

Notes. Shaded rows indicate studies conducted in children and adolescents. Lifestyle interventions were highly varied; see Appendix B for further details. [a] Mean age at baseline was calculated by Center for Evidence-based Policy researchers. [b] Those with a BMI of 30 to 31.9 were required to have ≥ 2 comorbidities; BMI of 32 to 34.9 with ≥ 1 comorbidity. [c] Those with a BMI of 35 to 39.9 were required to have ≥ 1 obesity-related comorbidity. [d] Those with a BMI of 30 to 34.9 were required to have ≥ 1 obesity-related comorbidity.

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MDC: multidisciplinary diabetes care; Mod: moderate; N/A: not applicable; NR: not reported; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Adults Not Currently Covered for MBS (KQ1a, KQ3, and KQ4)

History

The following section focuses on adult populations not currently covered for MBS procedures (e.g., AGB, RYGB) under the 2015 Washington coverage determination.[109] These populations are adults with overweight (BMI ≥ 23 to < 30 kg/m^2) or Class 1 obesity (BMI ≥ 30 to < 35 kg/m^2) without an obesity-related comorbidity with the exception of T2DM which qualifies individuals in these categories for MBS.

Study Characteristics

We identified 2 RCTs (in 4 publications) conducted among Australian adults with a BMI ≤ 35 kg/m^2; both studies measured outcomes up to 10 years post-baseline.[166,167,172,173] Both RCTs studied AGB compared with nonsurgical therapies; we did not identify any eligible studies for BPD, RYGB, or SG in patients with overweight or obesity, with or without an obesity-related comorbidity. For patients with a BMI ≥ 30 kg/m^2 and T2DM these procedures are already covered by the Washington coverage policy.

Adults With a BMI ≥ 30 to < 35 kg/m^2 and an Obesity-Related Issue or Comorbidity

We identified 1 RCT (in 2 publications) comparing AGB surgery with an intensive lifestyle intervention over a 10-year period.[166,167] We rated this study as having a moderate RoB due to concerns about financial disclosures and notable differences in attrition.

- O'Brien and colleagues (2006; N = 80; moderate RoB): AGB was compared with a lifestyle-plus-orlistat intervention in a 2-year RCT that enrolled individuals with a BMI of ≥ 30 to < 35 kg/m^2 who had an obesity-related issue (e.g., severe physical limitations) or an obesity-related comorbidity (e.g., T2DM); participants were followed for up to 8 years (Appendix B, Table B1).[166,167] After 2 years, those in the control group could crossover and receive an AGB.[166,167] Participants had a mean age of 41.2, mean BMI of 33.6 kg/m^2, and mean baseline weight of 94.8 kg.[167] Most participants were female (61 of 80; 76%); race and ethnicity were not reported.[167]

The lifestyle-plus-orlistat intervention continued over the 2-year initial study period, with patients seen at least every 6 weeks.[167] This program comprised behavioral modification, very-low-calorie diet, and pharmacotherapy with education and professional support on appropriate eating and exercise behavior and was delivered by trained physicians.[167] The program began with an intensive 6-month period of very-low-calorie diet (500 to 550 kcal per day), with liquid meal replacements for 12 weeks, followed by a transition phase leading to 120 mg of orlistat before all meals until the completion of the intensive phase.[167] Participants continued with additional courses of very-low-calorie diets or orlistat as tolerated, as well as continual behavioral, dietary, and exercise advice.[167]

Table 8Table 10. GRADE Summary of Findings: Adults With BMI ≥ 30 to < 35 kg/m^2 and an Obesity-Related Issue or Comorbidity: AGB vs. Lifestyle + Orlistat

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Weight			
N = 80 1 RCT[167]	After the initial 6 months, AGB associated with significantly greater EWL than intensive medical management (ranging from 79% to 87% EWL in AGB group vs. 22% to 41% in intensive medical management group) Difference maintained at the 10-year timepoint; both surgery and medical management associated with reduced weight from baseline.	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]
Cardiovascular risk factors			
N = 80 1 RCT[167]	AGB associated with significantly lower risk of MetS at 2 years than intensive medical management (2.6% vs. 24.2%; RR, 0.11; 95% CI, 0.01 to 0.80).	●○○○ Very low	Downgraded 3 levels • 3 for imprecision (i.e., small study size, wide CIs, and very small number of events)[a]
N = 80 1 RCT[167]	AGB associated with significantly greater changes in HDL and diastolic blood pressure Between-group differences not observed for changes in LDL, systolic blood pressure, or triglycerides.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not all risk factors changed)
Health-related quality of life			
N = 80 1 RCT[167]	All participants had some improvements in SF-36 subdomain scores, but the AGB group saw significantly greater improvements across the 8-domains.	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]
Safety			
N = 80 1 RCT[167]	AEs occurred in both AGB and intensive medical management groups with a higher proportion occurring in the medical group (58% vs. 18%).	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]

Note. [a] Inconsistency not assessed as only a single study.

Abbreviations. AE: adverse event; AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; LDL: low-density lipoprotein cholesterol; MetS: metabolic syndrome; RCT: randomized controlled trial; RR: risk ratio; vs.: versus; SF-36: 36-item Short Form Health Survey.

Weight

In the first 6 months, participants in both the AGB group and the intensive medical management group lost similar amounts of weight (a 13-kg loss from a 95-kg baseline, or a BMI reduction to approximately 30 kg/m^2 from 35 kg/m^2; Appendix B, Table B3).[167] However, from 12 months to 2 years, participants in the AGB group lost a significantly higher percentage of excess weight than participants in the intensive medical management group (ranging from 79% to 87% EWL in the AGB group vs. 22% to 41% in the intensive medical management group.[167] This difference was maintained at the 10-year timepoint; participants in both groups had reduced weight from baseline.[167] However, participants in both groups had gained weight since the 2-year assessment, although the gain did not reach baseline levels in either group.[167] At the end of 2 years, participants in the AGB group were significantly more likely to lose at least 25% of their body weight compared with the control group (98% vs. 35%).[167]

Cardiovascular Risk Factors

At the start of the study, 15 individuals in each group were living with MetS.[167] Metabolic syndrome resolution was significantly more likely in the AGB group compared with those in the intensive medical management group at 2 years, but not 10 years (risk ratio [RR], 2.0; 95% CI, 1.145 to 3.49; $P < .01$ vs. RR, 0.35; 95% CI, 0.09 to 1.358; $P > .05$, respectively; Appendix B, Table B4).[166,167] Full remission of MetS occurred in 93% of those in the AGB group compared with 47% in the intensive medical management group ($P < .01$) at 2 years.[167] At 10 years, there was no significant difference in the number of individuals living with MetS.[167]

At 2 years, participants in the AGB were more likely to have clinically significant improvements in HDL compared with those in the intensive lifestyle intervention group (increases of 30 mg/dL and 7 mg/dL, respectively; $P \leq .05$; Appendix B, Table B4).[167] Similar results were seen for reductions in triglycerides (−19 and −3.5 mg/dL reductions in AGB and control groups, respectively).[167] However, no between-group differences were observed for changes in LDL or systolic blood pressure.[167]

In general, participants initially randomized to the intensive medical management group who opted to undergo AGB surgery at the end of the first 2 years of the study had outcomes similar to those who had surgery at the start.[166]

We have not reported many of the 10-year results of this study because they report very small numbers of participants, particularly for the control group, as two-thirds opted to undergo AGB placement at the end of 2 years. Details of 10-year outcomes are available in Appendix B, Table B4.

Health-Related Quality of Life

The SF-36 (36-item Short Form Health Survey) was used to measure HRQoL across 8 domains. After 2 years, both groups saw significant improvements from baseline in scores for physical function, vitality, and mental health; the AGB group also had significant improvements across the other 5 domains.[167] When compared with the intensive lifestyle intervention, those in the AGB group were statistically more likely to have improvements in physical function, physical role, general health, energy, and emotional role scores.[166,167] No between-group differences were observed in the composite scores for physical or mental health at 2 and 10 years (Appendix B, Table B5).[166,167]

Safety

Overall, 7 (18%) participants in the AGB group and 18 (58%) participants in the intensive lifestyle group experienced an adverse event over the 2-year study period (Appendix B, Table B6).[167] The adverse events in the surgical group included[167]:

- 1 occurrence of 5 mm–port site infection, treated successfully with antimicrobial agents
- 1 case of acute gallbladder inflammation, requiring surgery
- 4 posterior prolapses, treated with laparoscopic revision

In the lifestyle plus orlistat group, adverse events included[167]:

- 1 case intolerance to a very-low-calorie diet
- 8 cases of intolerance to orlistat
- 4 cases of acute gallbladder inflammation, all requiring surgery

Furthermore, 3% of participants in the AGB group and 13% of participants in the lifestyle plus orlistat group were lost to follow-up.[167]

Adults With a BMI ≥ 25 to < 30 kg/m^2 and T2DM

We identified 1 RCT (in 3 publications) comparing AGB surgery with multidisciplinary diabetes care (MDC).[172,173,181]

- Wentworth and colleagues (N = 51; low RoB): Individuals with a BMI ≥ 23 kg/m^2 to < 30 kg/m^2 and T2DM were enrolled in a 5-year RCT comparing AGB plus MDC with MDC alone; participants were followed for a further 5 years (Appendix B, Table B7).[172,173] Participants had a mean age of 53 years, mean BMI of 29.0 kg/m^2, and mean baseline weight of 82 kg.[173] Most participants were female (36 of 51; 71%); race and ethnicity were not reported.[173]

Multidisciplinary diabetes care was delivered by an endocrinologist, with additional support from a physician and other members of the care team, as needed.[173] Participants were advised to do at least 150 minutes of moderate-intensity physical activity each week.[173] Participants were set a target HbA1c (glycated hemoglobin) of less than 7.0%, with pharmacological treatment (including metformin, sulfonylurea, sitagliptin and exenatide, with insulin if other therapies were not effective).[173] Blood pressure and cholesterol levels were also targeted and treated.[173] In addition, participants were advised by a dietitian to follow a calorie-restricted diet.[173]

Table 9. GRADE Summary of Findings: Adults With BMI ≥ 25 to < 30 kg/m^2 and T2DM: AGB vs. MDC

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Weight			
N = 48 1 RCT[173]	Participants in the AGB group lost significantly more weight than participants in the MDC group at 2, 5, and 10 years.	●●○○ Low	Downgraded 2 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest
Cardiovascular			
N = 48 1 RCT[173]	AGB was associated with an increased chance of remission from T2DM at 2 years; however, this was not maintained at 5- or 10 years.	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not maintained at all time points) • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest
N = 48 1 RCT[173]	AGB was associated with significantly greater improvements in diabetes control Between-group differences were not observed for changes in blood pressure or cholesterol, other than triglycerides	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not all risk factors changed) • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest
Health-related quality of life			
N = 48 1 RCT[173]	AGB was associated with a greater improvement in the SF-36 physical health composite score at 2 and 5 years.	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not maintained at all time points) • 1 for high RoB (i.e., serious issue with study design, funding, and investigator conflicts of interest
Safety			
N = 48 1 RCT[173]	AGB was associated with a higher rate of AEs at 2 years. At 5 and 10 years, the number of AEs was similar.	●○○○ Very low	Downgraded 3 levels: • 2 for imprecision (i.e., small study size, few events)[a] • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest

Note. [a] Inconsistency not assessed, as only a single study.
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; MDC: multidisciplinary diabetes care; RCT: randomized controlled trial; RoB: risk of bias; SF-36: 36-item Short Form Health Survey; T2DM: type 2 diabetes mellitus.

Weight

Participants in the AGB group lost a greater percentage of weight than participants in the MDC group (reported graphically; at 2 years, participants in the AGB lost 11.5 kg compared with 1.6 kg in the MDC group (between-group difference, −11.2 kg; 95% CI, −17.9 kg to −4.5 kg; $P = .003$).[173] Significant between-group differences in weight loss were maintained at 5 years (AGB, −9.1 kg vs. MDC, −1.9 kg; $P < .001$)[181] and 10 years (AGB, −8.5 kg vs. MDC, −4.7 kg; $P < .01$; Appendix B, Table B9).[172] A similar pattern was seen with reduction in BMI at 2 years (a decrease of −4.1 kg/m^2 vs. −0.5 kg/m^2; between-group difference, −3.0 kg/m^2; 95% CI, −5.0 kg/m^2 to −2 kg/m^2; $P < .001$).[173] At the end of 5 years, the AGB group had a BMI reduction of −3.3 kg/m^2 compared with −0.7 kg/m^2 in the MDC group, as compared with baseline measurements (between-group difference 2.2 kg/m^2; 95% CI, 0.8 to 3.7; $P = .003$)[181]; BMI was not reported at 10 years.

Cardiovascular Risk Factors

Very few between-group differences were observed at 2, 5, and 10 years (Appendix B, Table B10). Individuals who underwent placement of an AGB were 6.5 times more likely to experience full remission of T2DM after 2 years (AGB, 12 of 23 vs. MDC, 2 of 25; $P < .001$).[173] At 5 and 10 years, more people in the AGB surgery group sustained remission of T2DM than in the MDC group; however, the differences were small and not significant.[172,181] Glucose concentrations were more likely to be reduced in the AGB group (−1.0 mmol/L) compared with an increase in the MDC group (+0.1 mmol/L; $P < .01$) at 2 years,[173] but no differences were observed at 5 years.[181] Similarly, participants in the AGB group were more likely to see reductions in HbA1c compared with the MDC group (mean HbA1c, 6.1% vs. 7.3%, respectively; $P < .01$) at 2 years,[173] but no differences were observed at 5 or 10 years.[172,181] Participants in the AGB group were also more likely to achieve an HbA1c of less than 7% compared with the MDC group at 2 years (21 of 23 [91%] vs. 15 of 25 [60%], respectively; $P = .02$)[173] but no differences were observed at 5 or 10 years.[172,181] No differences in blood pressure were seen at any timepoint.[172,173,181] While more than 55% of participants in each group met the treatment targets for blood pressure at 2 and 5 years, differences between groups were not significant.[173,181]

No between-group differences in HDL were observed at 2 or 5 years (Appendix B, Table B10),[173,181] but at 10 years the AGB group had improvements in HDL concentrations compared with the MDC group ($P = .03$) though these differences were small.[172] No between-group differences in LDL were seen at any timepoint.[172,173,181]

Health-Related Quality of Life

SF-36 physical and mental health composite scores were reported at 2, 5, and 10 years (Appendix B, Table B11).[172,173,181] No between-group differences were observed in the mental health composite scores at any timepoint.[172,173,181] Clinically significant improvements[140] in the physical composite score were observed at 2 years (+7.7 points vs. −1.7 points) and 5 years (+5.6 points vs. −0.2 points) in the AGB group, but not at 10 years.[172,173,181]

Safety

The overall number of individuals who experienced at least 1 adverse event was not reported at 2 or 5 years.[173] At the end of the first 2 years, the number of adverse events was higher in the

surgical group (21 events), compared with the MDC group (8 events; Appendix B, Appendix B1).[173] The adverse events in the surgical group included[173]:

- 5 cases in 4 individuals of food intolerance that were resolved with an outpatient procedure to reduce the fluid volume in the band
- 5 cases in 4 individuals of unplanned procedures

In the MDC group, adverse events included[173]:

- 2 cases of retinal photocoagulation
- 1 unplanned knee arthroscopy
- 1 2-month hospitalization to manage eosinophilic fasciitis, possibly precipitated by the use of atorvastatin

After 5 years, both groups experienced a similar number of events (AGB, 63 events vs. MDC, 72 events) which included elective surgeries and hospitalizations unrelated to the interventions (Appendix B, Table B12).[181] Approximately 14% of individuals who received AGB reported difficulty swallowing (7 cases) compared with 30% (10 cases) in the MDC group.[181] Similar numbers of adverse events were reported at 10 years; details were not reported.[172]

Reoperations were rare, with 1 occurring between the start of the study and 2 years.[173] Between years 2 and 5, 2 reoperations were reported, but it is unclear whether this was 2 in a single individual or in 1 in each of 2 separate individuals.[181]

Note that this was a very small study (N = 50) and therefore these results may not be representative of the true effects.

MBS Procedures Not Reviewed in 2015 for Any Adult Population (KQ2a, KQ3, and KQ4)

History

Endoscopic sleeve gastroplasty (ESG), IGB, OAGB, and SADI-S were not included in the 2015 report because that report focused on the 4 most commonly performed MBS procedures in the US.[109] The following section covers these 4 procedures in adults with overweight or obesity regardless of the presence of obesity-related comorbidities.

Study Characteristics

We identified 8 RCTs (in 12 publications)[163-165,169,170,174,176-179] examining procedures not reviewed for the 2015 Washington coverage determination.[109] Mean age ranged from 27.8 to 64.9 years, with mean BMIs ranging from 31.9 to 43.8 kg/m^2, and mean weight ranging from 78.8 to 126.9 kg.[163-165,169,170,174,176-179] Between 78% and 90% of participants were female.[163-165,169,170,174,176-179] Specific study characteristics can be found in the sections below and in Appendix B.

We did not identify any eligible RCTs of SADI-S. For the other 3 surgeries, we found:

- 3 head-to-head RCTs comparing OAGB with RYGB or SG[169,170,174,176-178]
- 3 RCTs comparing ESG, IGB, or OAGB with a lifestyle intervention[163-165,179]
- 2 RCTs compared IGB with sham surgery[171,175]

MBS Procedures Not Reviewed in 2015, Compared to Previously Reviewed MBS Procedures, in Adults

We identified 3 RCTs (in 6 publications) comparing OAGB with previously reviewed MBS procedures.[169,170,174,176-178]

- RYSA (N = 121; moderate RoB): A 1-year noninferiority RCT conducted in Finland, comparing OAGB with RYGB in individuals with a BMI ≥ 35 kg/m^2.[169] Most participants were female (104 of 121; 86%); race and ethnicity were not reported.[169] Participants had a mean age of 46.5 years, mean BMI of 43.8 kg/m^2, and mean weight of 126.9 kg.[169] The inclusion criteria did not require the presence of an obesity-related comorbidity, but it appears that all participants had at least 1 of these conditions.[169]
- Seetharamaiah and colleagues (N = 214; moderate RoB): A 5-year RCT conducted in India, comparing OAGB with SG in adults with a BMI ≥ 30 kg/m^2.[176-178] Additional criteria included the presence of at least 1 obesity-related comorbidity in those with a BMI of ≥ 32 to < 35 kg/m^2, or abdominal obesity plus at least 2 obesity-related comorbidities in those with a BMI of ≥ 30 to < 32 kg/m^2.[176] Mean age ranged from 50 to 43 years, with a mean BMI of approximately 40 kg/m^2.[176] Approximately 60% of participants were female.[176]
- YOMEGA (N = 253; moderate RoB): A 2-year multicenter noninferiority RCT conducted in France, comparing OAGB with RYGB in individuals with a BMI ≥ 40 kg/m^2, or ≥ 35 kg/m^2 plus at least 1 obesity-related comorbidity.[174] Most participants were female (226 of 253; 89%); race and ethnicity were not reported.[174] Participants had a mean age of 43.5 years, a mean of BMI 43.9 kg/m^2, and mean weight of 120.5 kg; 27% of participants had T2DM.[174]

Table 10. GRADE Summary of Findings for MBS Procedures Not Reviewed in 2015 vs. Previously Reviewed MBS Procedures, in Adults

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
OAGB vs. RYGB or SG			
Weight			
N = 542 3 RCTs[169,174,176-178]	Total weight loss ranged from 25% to 37% 1 to 3 years post-surgery, regardless of surgical intervention (i.e., OAGB, RYGB, SG). Similarly, EWL ranged from 60% to 66% in the same time periods. One study showed EWL was maintained at years 4 and 5 for OAGB, but not for SG though the changes were small (a decrease of approximately 4% to 5% from year 3).[177,178]	●●●● High	• Not downgraded.
Cardiovascular risk factors			
N = 542 3 RCTs[169,174,176-178]	Rates of remission of obesity-related comorbidities (e.g., T2DM, hypertension) and changes to other cardiovascular risk factors (e.g., HDL, triglycerides) were similar up to 3 years (and in some cases up to 5 years) regardless of surgical intervention (i.e., OAGB, RYGB, SG).	●●●● High	• Not downgraded.
Health-related quality of life			
N = 126 1 RCT[174]	Improvements in HRQoL, as measured with IWQOL-Lite, were similar in individuals who underwent OAGB or RYGB. Clinically significant increases in the physical and self-esteem domains were observed for both groups (20 and 12 points, respectively).	●●●○ Moderate	Downgraded 1 level: • 1 for imprecision (i.e., small study size)
Safety			
N = 542 3 RCTs[169,174,176-178]	Reported safety outcomes varied across the studies, but most showed no differences (e.g., rates of anemia, vitamin deficiencies, complications related to surgery) between the surgical interventions. One study reported significantly more SAEs in participants who underwent OAGB compared with RYGB.	●●●○ Moderate	Downgraded 1 level: • 1 for inconsistency (i.e., different markers of safety reported across studies)

Abbreviations. EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; HRQoL: health-related quality of life; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SAE: serious adverse event; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Weight

All studies reported at least 1 measure of change in weight or BMI. All participants, regardless of surgery received, had decreases in their weight, BMI, or both. Generally, there were no significant between-group differences for any weight-related outcomes. Details of weight outcomes are available in Appendix B, Table B15.

The RYSA trial reported no between-group differences for BMI after 1 year; both groups had a BMI reduction of approximately 11 kg/m^2.[169] In the YOMEGA trial and trial by Seetharamaiah and colleagues, participants who underwent OAGB had much larger excess BMI losses compared with RYGB (88% vs. 86%, respectively; $P = .002$)[174] after 2 years, and with SG (62% vs. 51%, respectively; $P < .01$)[177] after 5 years. The differences in excess BMI losses between these studies is likely due to the additional 3 years of follow-up in the Seetharamaiah trial.

No between-group differences in EWL or TWL were noted at 1 year[169,176] or after 2 and 3 years.[176,177] However, Seetharamaiah and colleagues reported those who received OAGB were significantly more likely to maintain EWL after 4 and 5 years, compared with SG.[178] Participants who received OAGB in the YOMEGA study lost significantly more weight overall after 2 years compared with RYGB.[174] Furthermore, there were no between-group differences in the number of participants who achieved at least a 50% reduction in EWL or at least 10% TWL at 1 year in the RYSA study.[169]

Seetharamaiah and colleagues reported 1 revision surgery for nonresponse in a participant who received a SG; no revision surgeries were reported in those who received OAGB.[176]

Cardiovascular Risk Factors

After 5 years, 1 study reported significantly more individuals (85%) in the OAGB group no longer had T2DM, compared with 57% of those in the SG group (Appendix B, Table B16).[178] However, no other between-group differences in other cardiovascular risk factors (e.g., high cholesterol, hypertension) were observed at any time point.[169,174,176-178]

Health-Related Quality of Life

All participants in the YOMEGA study had improvements in their IWQOL-Lite subdomain scores after 2 years, but they were not significantly different between OAGB and RYGB (Appendix B, Table B17).[174] Improvements in the physical function and self-esteem subdomains were clinically significant[137] for both groups with improves of approximately 20 points and 12 points, respectively.[174] Participants who received RYGB had slightly larger improvements than those who received OAGB.[174]

Safety

The proportion of participants experiencing a safety-related event of any type (e.g., difficulty swallowing, reoperations, nutritional deficiencies) were similar across all groups at all reported timepoints (Appendix B, Table B18).[176-178] The proportion of participants overall who experienced at least 1 serious adverse event at 2 years was similar to the proportion overall who experienced a nonserious adverse event, but the number of serious events differed significantly between groups; many more events occurred in the OAGB group than the RYGB group (67 vs.

38 events, respectively).[174] The serious adverse events deemed related to surgery followed a similar pattern (OAGB, 42 events vs. RYGB, 24 events).[174]

Rates of the following harm outcomes were similar between the OAGB and RYGB or SG groups (Appendix B, Table B18):

- Anemia at 1 (13%), 2 (36%), and 5 years (8%)[169,174,178]
- GERD at 5 years (5%)[178]
- Vitamin deficiencies
  - Overall vitamin deficiency at 2 years (83%)[174]
  - No severe malnutrition events observed at 5 years[178]
- Complications related to surgery (e.g., GERD, hemorrhage, bowel injury) at 1, 2, and 5 years (approximately 5% at all time points)[174,176,178]
- Readmissions and reoperations within the first year (7%)[176]

Vitamin D deficiency was more likely after 1 year in those who underwent OAGB (43 of 57; 75%) than those in the RYGB group (21 of 51; 41%; $P < .001$).[169] Four participants underwent conversion from OAGB to RYGB at 2 years due to an anastomotic leak, Wernicke encephalopathy, and severe biliary reflux; no participants in the RYGB group required conversion to another bariatric procedure.[174]

Seetharamaiah and colleagues reported no deaths after 1 year, and 1 death in each group after 2 years.[176] The cause of death in the OAGB group was unknown, while the SG group had 1 death due to acute myocardial infarction.[176,177]

Loss to follow-up at 2 years was approximately 25% in the YOMEGA study, with slightly more participants lost in the RYGB group.[174] Seetharamaiah and colleagues reported minimal losses to follow-up during the first 3 years of their study, but at year 5 nearly 30% of participants in each group had been lost to follow-up.[176-178]

MBS Procedures Not Reviewed in 2015, Compared With a Lifestyle Intervention, in Adults

We identified 3 RCTs (IB-005,[163] LIFEXPE-RT,[164,179] and MERIT[165]) comparing ESG, IGB, or OAGB with a lifestyle intervention. We did not identify any eligible studies examining SADI-S.

- IB-005 (N = 317; high RoB): A 1-year, US-based, multicenter RCT comparing the Orbera IGB plus a lifestyle intervention with a lifestyle intervention alone.[163] The lifestyle intervention consisted of a low-calorie diet (1,000 to 1,500 calories per day), a daily food and exercise diary, encouragement to exercise, and visits with clinical staff approximately every other week throughout the trial.[163] Adults with a BMI of ≥ 30 to < 40 kg/m^2 with a minimum 2-year history of obesity were eligible to participant in IB-005; the presence of an obesity-related comorbidity was not a requirement.[163] Most participants were female (243 of 317; 77%); approximately 15% of participants identified as non-White, most often as Hispanic or as non-Hispanic Black.[163] Participants had a mean age of 31.9 years, mean BMI of 35 kg/m^2, and mean weight of 98 kg.[163]

- LIFEXPE-RT (N = 60; moderate RoB): A 1-year, 3-arm RCT conducted in Kazakhstan, comparing OAGB (with or without staples) with diet.[179] For each participant randomized to the control (diet) group, a low-calorie diet was customized, providing an energy deficit of 500

to 1,000 calories per day (i.e., 20 to 25 kcal/kg/day for ideal body weight).[179] Adults with a BMI of ≥ 35 to < 50 kg/m^2 with MetS were eligible to participate in LIFEXPE-RT.[179] Most participants were female (46 of 60; 77%); all were non-White.[179] Participants had a mean age of 44.8 years, mean BMI of 40.8 kg/m^2, and mean weight of 113.0 kg.[179]

- MERIT (N = 209; moderate RoB): A 2-year, US-based, multicenter RCT, with up to 8 years follow-up comparing ESG with a lifestyle intervention.[165] This moderate-intensity lifestyle intervention consisted of a low-calorie diet plan, 150 mins of aerobic exercise per week, 13 counseling visits, and assessments during the first year of the study.[165] Participants who were randomized to the lifestyle intervention and did not achieve at least 25% EWL by the end of the first year could opt for ESG while remaining in the study.[165] Most (179 of 209; 86%) participants were female and nearly 35% were non-White, identifying as African American, Hispanic, or Latino.[165] Participants had a mean age of 41.5 years, mean BMI 31.9 kg/m^2, and mean weight of 88.4 kg.[165]

Table 11. GRADE Summary of Findings for MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions, in Adults

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
MBS procedures not reviewed in 2015 vs. lifestyle interventions			
Weight			
N = 586 3 RCTs[163,165,179]	Participants who underwent a surgical intervention (i.e., ESG, IGB, OAGB) had significantly larger reductions in weight and BMI than those who received lifestyle interventions. Clinically significant improvements were also observed in favor of surgical interventions, as well as excess weight loss and excess BMI loss.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the largest study [N = 317] had a high RoB)
Cardiovascular risk factors			
N = 60 1 RCT[179]	Larger improvements in blood pressure and triglycerides were seen in those who received OAGB compared with diet alone. Additionally, remission of prediabetes or T2DM were achieved in 100% and 93% in the OAGB group, respectively; there were no remissions of these conditions for those who were treated with diet alone.	●●○○ Low	Downgraded 2 levels: • 2 for imprecision (i.e., single study with small study size, < 50% of participants with conditions)
Health-related quality of life			
No studies reported HRQoL.			
Safety			
N = 350 2 RCTs[163,179]	AEs and SAEs, and the total number of events, were much higher for IGB and ESG than for lifestyle interventions. The most common AEs were nausea, vomiting, and abdominal pain. SAEs (e.g., severe dehydration, surgery-related injuries) were experienced by 10% of those who underwent IGB; 20% had the IGB removed before 6-months.	●●●○ Moderate	Downgraded 1 level: • 1 for inconsistency (i.e., different markers of safety reported across studies)

Abbreviations. AE: adverse event; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HRQoL: health-related quality of life; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RoB: risk of bias; SAE: serious AE; T2DM: type 2 diabetes mellitus.

Weight

At least 1 weight-related outcome (e.g., EWL, change in BMI) was reported by each study. Individuals who received a surgical intervention (i.e., ESG, IGB, or OAGB) lost significantly more weight, resulting in larger reductions in BMI, compared with the lifestyle interventions at 6-months (IGBs only), and at 1-year (ESG and OAGB; most $P < .001$; see Appendix B, Table B21).[163,165,179] There were some notable differences among the surgical interventions in terms of the amount of weight loss after 1-year. The EWL was much larger in those who underwent ESG compared with IGB (14% vs. 45%, respectively).[163,165] Meanwhile, TWL was greatest in individuals who underwent OAGB (approximately 33%) or ESG (14%) compared with placement of an IGB (8%)[163,165,179]; however, it should be noted that the OAGB study had far fewer participants than the other studies, so these differences may be exaggerated.

After 1 year, the number of participants who achieved at least 10% EWL, a clinically important difference, was twice as likely for IGB (RR, 1.98; 95% CI, 1.24 to 3.16 $P < .01$) and 6.5 times more likely for ESG (RR, 6.48; 95% CI, 3.83 to 10.96; $P < .001$) compared with lifestyle interventions.[163,165] LIFEXPE-RT reported excess BMI loss at 1 year was significantly larger in the 2 OAGB arms (79% to 89%) compared with diet alone (12%; $P < .001$).[179] These differences equate to a decrease in BMI of 12 to 16 kg/m^2 in the OAGB groups and 3 kg/m^2 in the diet group.[179]

Cardiovascular Risk Factors

The LIFEXPE-RT study reported 1-year outcomes related to cardiovascular risk factors (Appendix B, Table B22).[179] Almost all individuals in the OAGB groups who entered the study with prediabetes or T2DM went into remission of these conditions (prediabetes, 100% [16 of 16]; T2DM, 93% [13 of 14]), compared with the diet-only group where none of the participants had resolution of prediabetes or T2DM.[179] Note that this was a very small 3-arm study (N = 60) and therefore these results may not be representative of the true effects.[179] Changes in systolic and diastolic blood pressure and decreases in triglycerides were more likely in the surgical group compared with the diet-only group (all, $P < .001$).[179]

Health-Related Quality of Life

HRQoL outcomes were not reported by any of the studies in this section.

Safety

Two studies, IB-005[163] and LIFEXPE-RT[179], reported safety outcomes during their 1-year study periods (Appendix B, Table B23). It is important to note that the number of surgical participants reported by authors of the IB-005 study was slightly larger than the original number randomized.[163] This difference is due to a change in the surgical technique that was piloted in 35 participants who weren't randomized but were followed through 1-year to observe safety outcomes.[163]

The number of participants who experienced at least 1 adverse event, and the number of events, was greater for IGB (RR, 2.37; 95% CI, 2.02 to 2.77; $P < .001$) and ESG (RR not reported), compared with lifestyle interventions (Appendix B, Table B23).[163,179] Nausea, vomiting, and abdominal pain were the most common adverse events reported by those who underwent surgery.[163,179] The IB-005 study reported 810 adverse events (in 160 IGB participants) compared

with 429 events in the lifestyle group (in 130 participants).[163] Device-related or procedure-related serious adverse events occurred in 10% of participants who had an IGB placement.[163] The most common serious adverse events were severe dehydration (2 participants) and procedure-related esophageal mucosal injuries (2 participants).[163] Furthermore, 20% (30 of 160) of those who had an IGB placed had the device removed before the 6-month mark when these devices are generally removed.[163] LIFEXPE-RT reported no cardiovascular events or deaths in either the OAGB or lifestyle groups, and no reoperations in the OAGB group, during the 1-year study.[179]

The MERIT study reported some surgical-related safety outcomes approximately 10 years after the start of the study, for the ESG group only (Appendix B, Table B23).[165] However, these outcomes include those who were initially randomized to the lifestyle intervention, but were given the option to undergo ESG after the first year of the study.[165] Most participants (92%) experienced at least 1 adverse event.[165] There were a total of 927 events recorded, the majority (612; 66%) of which were for accommodative gastrointestinal symptoms.[165] Only 6% (9 of 150) of participants experienced a serious adverse event.[165] These included 3 participants with device or procedure-related grade 3 events (i.e., abdominal abscess, upper gastrointestinal bleed, case of malnutrition requiring endoscopic reversal of the ESG) and 6 participants who required subsequent hospital admission for medical management of accommodative symptoms.[165]

MBS Procedures Not Reviewed in 2015, Compared With Sham Surgery, in Adults

We identified 2 RCTs comparing 2 types of IGBs with a sham surgery in adults with a BMI of ≥ 30 to < 40 kg/m^2.[171,175] We did not identify any eligible studies comparing other newer surgical techniques (i.e., ESG, OAGB, or SADI-S) with a sham surgery.[171,175] The IGBs are usually in place for no more than 6 months before they are removed; hence we have reported 6-month and 1-year outcomes when present.

- ENDObesity II (N = 270; moderate RoB): A 1-year US-based multicenter RCT comparing an IGB device, the TransPyloric Shuttle (TPS), to sham surgery in adults with a BMI of ≥ 35 to < 40 kg/m^2 or ≥ 30 to < 35 kg/m^2 with the presence of T2DM, controlled hypertension, or controlled high cholesterol.[175] Nearly all participants were female (98%; 265 of 270) and 27% were non-White. Participants had a mean age of 43.3 years, a mean BMI of 36.6 kg/m^2, and mean weight of 100.4 kg.[175]
- SMART (N = 430; high RoB): A 1-year, US-based, multicenter RCT compared the Obalon IGB with a sham surgery in adults with a BMI of ≥ 30 to < 40 kg/m^2, regardless of the presence of an obesity-related comorbidity; all participants also received a lifestyle intervention and consultations during the trial.[171] Those randomized to sham surgery were eligible to receive an IGB placement after the initial 6-month study period.[171] Most participants were female (341 of 387; 88%); less than 20% of participants were non-White.[171] Participants had a mean age of 42.6 years, mean BMI of 35.3 kg/m^2, and mean weight of 98.4 kg.[171]

Table 12. GRADE Summary of Findings: MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
MBS procedures not reviewed in 2015 vs. sham surgery			
Weight			
N = 657 2 RCTs[171,175]	Participants who had an IGB implanted (Obalon or TPS) had statistically significant improvements in BMI at 6 months. They also had significant improvements in EWL and TWL.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB)
Cardiovascular			
N = 657 2 RCTs[171,175]	Some very small statistically significant changes were observed in favor of the IGB devices (Obalon or TPS), but these were not clinically significant.	●●○○ Low	Downgraded 2 levels: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB) • 1 for inconsistency (i.e., conflicting results for CV risk factors)
Health-related quality of life			
N = 270 1 RCT[175]	Those who had the TPS device implanted had greater improvements in their total IWQOL-Lite score compared with the sham surgery group (+10.5 vs. +7.8 points, respectively). These improvements are considered clinically meaningful.	●●●○ Moderate	Downgraded 1 level: • 1 for imprecision (i.e., single study)
Safety			
N = 657 2 RCTs[171,175]	Any AE was common for all procedures (ranging from 94% to 100% in the IGB groups and 70% to 98% in the sham surgery groups), but this difference was significant in 1 study (n = 270; *P* < .001). SAEs were rare (2% to 3% of all participants). However, early removal of the TPS device occurred in 23% of participants.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB)

Abbreviations. AE: adverse event; BMI: body mass index; CV: cardiovascular; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; IGB: intragastric balloon; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; RCT: randomized controlled trial; RoB: risk of bias; SAE: serious AE; TPS: TransPyloric Shuttle; TWL: total weight loss.

Weight

At 6-months and 1-year, EWL was significantly larger in the IGB groups (range, 24% to 31%) than the sham surgery groups (10% to 12%; *P* < .001; Appendix B, Table B26).[171,175] In individuals who had the Obalon IGB placed, TWL after 1-year was greater than those who received sham surgery, around 9% and 3%, respectively (*P* < .001).[175] The SMART study found greater TWL in the TPS group (6%) compared with the sham surgery group (3%; *P* = .04), but the between-group difference was smaller than the between-group difference observed in the ENDObesity II study.[171] Proportionally, twice as many TPS participants (62%) achieved TWL of at least 5% compared with sham surgery (31%).[171] A small, but significant, reduction in BMI of 6% (2.3 kg/m^2) occurred in the TPS group compared with a 3% (1.2 kg/m^2) reduction in the sham surgery group (*P* < .001).[171]

The SMART study reported TWL by baseline BMI (i.e., ≥ 30 to < 35 kg/m^2 and ≥ 35 to < 40 kg/m^2).[171] The differences within and between classes was similar, indicating that individuals with in both obesity groups can expect similar weight loss results with the TPS device.[171]

Cardiovascular Risk Factors

For most cardiovascular risk factors measured by the ENDObesity II and SMART studies, significant improvements were observed in the IGB groups compared with sham surgeries.[171,175] Systolic blood pressure decreased by 3 to 3.4 mmHg at 6 months and 1 year, compared with sham surgery where an increase of 1 mmHg occurred at 6 months, but a decrease of 2.6 mmHg at 1 year (Appendix B, Table B27).[171,175] While these between-group differences were statistically significant (*P* < .01),[171,175] none were clinically meaningful (a reduction of ≥ 5 mmHg).[133] Both studies reported very small changes in diastolic blood pressure; the changes were inconsistent between studies. At 6-months, the SMART study reported small increases of 1 and 2 mmHg in the IGB and sham groups, respectively (*P* > .05).[171] At 1 year, ENDObesity II observed a decrease of 2 mmHg in the IGB group compared with an increase of 1 mmHg in the sham surgery group (*P* < .01).[171] It should be noted that, on average, participants in both studies had a baseline blood pressure that was in the elevated range.[171,175]

Some small but statistically significant between-group differences in LDL were observed at 1 year: a decrease of 2.9 mg/dL for Obalon IGB recipients compared with an increase of 3.9 mg/dL in the sham surgery participants (*P* = .03; Appendix B, Table B27).[175] ENDObesity II reported a decrease of 6 mg/dL occurred in TPS participants compared with no change from baseline of the sham surgery group (*P* < .001) after 6 months.[175] However, the changes observed in either study are not considered clinically meaningful (i.e., a 38.7 mg/dL reduction in LDL, associated with 23% to 25% risk reduction of major cardiovascular events) for any participants.[134] All participants had small increases of HDL (1.3 to 3 mg/dL in the IGB groups vs. 1 to 1.6 mg/dL in the sham surgery groups) but these were not significant between groups.[171,175] Conflicting results for changes in triglyceride concentration were reported. At 6 months, TPS recipients had a mean reduction of triglycerides of 15 mg/dL compared with a small increase of 3 mg/dL in the sham surgery group (*P* < .01).[175] However, at 1 year the Obalon and sham surgery group had reductions in their triglyceride concentrations of 15.8 and 8.1 mg/dL, respectively, though this was not statistically significant.[171]

Of note, the ENDObesity II authors found a larger magnitude of change in systolic and diastolic blood pressure and LDL in the minority of individuals who entered the study with abnormal measurements, though the latter still was not clinically meaningful.[175]

Health-Related Quality of Life

Health-related quality of life was measured with the IWQOL-Lite tool at multiple points during the 1-year ENDObesity II study.[175] The IGB and sham surgery groups achieved clinically meaningful improvements (i.e., an increase of 7.7 to 12 points)[137] at the end of the study year (Appendix B, Table B28).[175] The IGB group had a larger improvement in their total score (+10.5 points) compared with the sham surgery group (+7.8 points; $P < .01$).[175] The subdomain scores for physical function ($P < .001$), self-esteem ($P = .045$), and sexual life ($P = .02$) were also significantly different in favor of IGB[175]; we did not identify any published standards for a minimal clinically important difference for IWQOL-Lite subdomains.

Safety

Many types of adverse events were common, regardless of intervention received (Appendix B, Table B29).[171,175] The proportion of participants experiencing at least 1 adverse event ranged from 94% to 100% in the IGB groups and 70% to 98% in the sham surgery groups.[171,175] In the SMART study, a significantly larger proportion of individuals experienced at least 1 adverse event (TPS device, 94% vs. sham surgery, 70%; $P < .001$).[171] Additionally, the number of events in the TPS device group was almost triple (902 events) to what was recorded in the sham surgery group (358 events).[171] Across all groups and studies, the most common adverse events were nausea, vomiting, and abdominal pain.[171,175] In the ENDObesity II study, serious adverse events were rare, with 6 TPS-device individuals (3%) experiencing a surgical-related event (e.g., esophageal rupture with bilateral pneumothoraces, device impaction); the authors did not report for the sham surgery group.[175] A similar proportion of individuals experienced an any-cause serious adverse events during the 6-month SMART study (Obalon device, 5 vs. sham surgery 4, roughly 2% of participants in each group).[171]

Removal of the TPS device before the end of the 1-year study period occurred in 23% of participants.[175] No deaths were reported for either group in the ENDObesity study.[175]

MBS in Children and Adolescents (KQ1b, KQ2b, KQ3, and KQ4)

History

The following section focuses on children and adolescents, regardless of MBS procedure or patient characteristics (e.g., BMI, comorbidity status) as they are not currently covered for MBS under the 2015 Washington coverage determination.[109] This section reports RCTs conducted in a pediatric population for any ASMBS-endorsed procedure; there are no FDA-approved devices available for use in children or adolescents.

Study Characteristics

We identified 3 small RCTs (in 5 publications), comparing AGB or RYGB with a lifestyle intervention in adolescents with a BMI ≥ 35 kg/m^2.[138,161,162,168,180] We determined all studies to be of moderate RoB. We did not identify any eligible studies conducted in children and adolescents for BPD, OAGB, SADI-S, or SG; individuals with a BMI < 35 kg/m^2; or individuals under the age of 13 years.

- AMOS2 (N = 50; moderate RoB): A 2-year multicenter RCT in Sweden randomizing participants to RYGB, SG, or a lifestyle intervention (a diet of 1,500 calories per day, 60 minutes of moderate-to-vigorous physical activity per day, and monthly check-ins with clinical professionals).[138,180] A majority (23 of 25; 92%) of participants randomized to a surgical intervention underwent RYGB, so results for surgical interventions were reported as a single group; 2 participants received SG because of inflammatory bowel disease or hereditary alcohol use disorder.[138] Participants had a mean age of 15.7 years, a mean BMI of 42.6 kg/m^2, and mean weight of 122.6 kg.[138] Approximately 75% of participants were female; race and ethnicity were not reported.[138] We determined AMOS2 to have a moderate RoB, because outcome assessors were not blinded and because 20% of the control group participants opted to crossover to the surgical group at the end of the first year.[138]

- BASIC (N = 59; moderate RoB): A 1-year single-center RCT conducted in the Netherlands randomizing participants to AGB with a multidisciplinary lifestyle intervention, or the lifestyle intervention alone.[161,162] The lifestyle intervention consisted of regular dietary advice and monitoring from a certified dietician, regular exercise training, and behavioral therapy.[162] Participants had a mean age of 15.7 years, a mean BMI of 44.1 kg/m^2, and mean weight of 128.8 kg.[161] Nearly 80% of participants were female; race and ethnicity were not reported.[161] We assessed BASIC as having a moderate RoB because of some methodological concerns (e.g., lack of assessor blinding) and a differential loss to follow-up (20% in the lifestyle-alone group vs. no losses in the AGB group[161]).

- O'Brien and colleagues (2010; N = 50; moderate RoB): A 2-year RCT conducted in Australia randomizing participants to AGB or an individualized lifestyle intervention.[168] The lifestyle intervention consisted of a reduced energy intake (between 800 and 2,000 calories per day), a target of 10,000 steps per day, structured exercise of at least 30 minutes per day; all monitored with food diaries, step counts, and consultations with clinical staff.[168] Participants had a mean age of 16.5 years, a mean BMI of 41.3 kg/m^2, and mean weight of 118 kg.[168] Approximately 70% of participants were female; race and ethnicity were not reported.[168] We determined a moderate RoB was appropriate due to differential losses to follow-up (30% of lifestyle participants withdrew from the study[168]) and potential investigator conflicts of interest.

Table 13. GRADE Summary of Effectiveness for Weight-Related Outcomes in Adolescents

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Weight			
N = 149 3 RCTs[138,161,168]	Adolescents who underwent a RYGB or SG had significantly larger reductions in weight (mean total weight loss, 20 kg) and BMI (−1.71 kg/m^2) than those in receipt of a lifestyle intervention.	●●●○ Moderate	Downgraded 1 levels • 1 for imprecision (i.e., total N)
Cardiovascular risk factors			
N = 59[a] 3 RCTs[138,161,168]	Resolution of high cholesterol was significantly more likely in adolescents who underwent a surgical procedure. No between-group differences in the resolution of metabolic syndrome, T2DM, or hypertension were observed.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., not all comorbidities were resolved)
N = 149 3 RCTs[138,161,168]	No between-group differences in triglyceride concentrations were observed for RYGB or SG vs. a lifestyle intervention; a small, but not clinically significant, difference was seen when comparing AGB with a lifestyle intervention. No other between-group differences were observed for blood pressure, HDL, or LDL.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., other CV risk factors were inconsistent across studies)
Health-related quality of life			
N = 50 1 RCT[138,161,168]	No between-group differences were observed for depression, obesity-related problems (i.e., OP-14 scale), or in 6 of 7 subdomains of the RAND-36; only the general health score was significantly improved in those who received RYGB.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., not all comorbidities were resolved)
Safety			
N = 149 3 RCTs[138,161,168]	Safety outcomes were minimally reported. In 2 studies, only surgery-related outcomes were reported. In the third study, AEs occurred in similar proportions, but the types of events differed, and approximately half were unrelated to the interventions.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., small number of events)

Note. [a] Represents subset of participants with 1 of the comorbidities mentioned; participant may have ≥ 1.
Abbreviations. AE: adverse event; BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein (cholesterol); LDL: low-density lipoprotein (cholesterol); OP-14: Obesity-related Problems; RAND-36: 36-item Short Form Health Survey; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Weight

Adolescents who underwent MBS had significantly greater reductions in BMI and more total weight loss, and larger EWL (all $P < .001$; Appendix C, Table C3).[138,161,168] Changes in BMI were measured in a variety of ways, but ultimately those in the MBS groups reduced their BMI by approximately 12 kg/m^2 compared with an approximate reduction of 1 kg/m^2 in the lifestyle groups over a 1 to 2 year period.[138,161,168]

In the AMOS2 study, significantly more individuals (63%) who received MBS achieved a BMI of less than 30 compared with the lifestyle group (4%); final mean BMIs at 2 years were 30.2 kg/m^2 versus 42.1 kg/m^2 ($P < .001$; Table C3).[138] Note that AMOS2 was a very small study (N = 47) and may not be representative of the true effects.[138]

All 3 studies included all our weight-related outcomes of interest (e.g., EWL, TWL). All comparisons were statistically significant in favor of MBS (all $P < .001$).[138,161,168] Adolescents in the AGB group were significantly more likely to have greater EWL compared with the lifestyle group (79% vs. 13% EWL; between-group difference, 65.6; 95% CI, 50.2 to 80.9; $P < .001$) after 2 years.[168] Additionally, a greater proportion of those in the AGB group achieved EWL of over 50% at 2 years compared with the lifestyle group (84% vs. 12%).[168] Total weight loss at years 1 and 2 was greater in the MBS groups (range, 11% to 29% TWL) than the lifestyle groups (range, weigh gain of 2% to weight reduction of 3%; $P < .001$).[138,161,168] The AMOS2 study reported the proportion of participants who achieved at least 10% TWL was significantly greater in the RYGB group (92%; 22 of 24) than the lifestyle group (26%; 6 of 23) after 2 years ($P < .001$).[138]

Cardiovascular Risk Factors

While a few significant cardiovascular risk factor between-group differences were observed in these studies, we note that these studies were very small; for remission of baseline comorbidities (e.g., T2DM, MetS) these numbers were even smaller, as not all participants may have had a comorbidity at enrollment. Remission of high cholesterol was more likely in the RYGB group than the lifestyle group after 2 years (89% vs. 10%, respectively; $P = .03$; Appendix C, Table C4).[138] Nearly all adolescents who began the O'Brien and colleagues (2010) study with MetS achieved remission (RYGB, 100% vs. lifestyle, 78%); these differences were not significant.[168] No significant differences were observed in remission of T2DM at 1 year or hypertension at 2 years, with approximately 50% in each group achieving resolution of hypertension.[138,161]

There were no significant between-group differences observed in blood pressure, HDL, or LDL across the studies (Appendix C, Table C4).[138,161,168] However, conflicting results for triglyceride concentrations emerged when we evaluated the results from AMOS2 and BASIC. The AMOS2 trial found no significant differences in triglycerides (measured in mmol/L)[138], while BASIC found that individuals who received AGB experienced improvements in triglycerides (mean difference, −33.3 mg/dL; 95% CI, −64.3 to −2.4; $P = .04$).[161]

Health-Related Quality of Life

No significant between-group differences were observed in the Obesity-related Problems (OP-14) scale, any subdomain of the Beck Youth Inventory, or the majority (6 of 7) of the RAND-36 subdomains (Appendix C, Table C5).[138] Adolescents in the RYGB group were much more likely to

achieve clinically significant improvements in the RAND-36 general health score than the lifestyle group (+21 points vs. +5 points; $P < .03$).[138]

Safety

There was minimal reporting of safety outcomes in these studies, particularly for the control groups (Appendix C, Table C6). The proportion of surgery-related complications were similar in the BASIC and AMOS2 studies, at 1 and 2 years respectively, though the types and severity of the complications varied.[138,161] Most of the reported safety outcomes were considered mild or moderate (i.e., Clavien-Dindo grade I or II)[138,161]; 2 events requiring surgical interventions were considered serious (i.e., Clavien-Dindo grade III) in the BASIC trial.[161]

AMOS2 reported[138]:

- At 6 weeks, 3 events (2 minor wound complications and 1 gallbladder removal) were reported in 2 of 25 (8%) participants
- At 1 year, no surgery-related complications were reported
- At 2 years, 2 events (symptomatic gallstones and acute abdominal pain not requiring intervention) were reported in 2 of 25 (8%) participants

BASIC reported that at 1 year, 5 participants had experienced at least 1 adverse event (all were surgery-related)[161]:

- 3 of 29 (10%) participants experienced heartburn or peptic complaints, and were successfully treated with a short course of proton pump inhibitors
- 1 of 29 (3%) participants required reoperation for dislocation of the band access port
- 1 of 29 (3%) participants developed symptomatic gallstones requiring gallbladder removal

In the study by O'Brien and colleagues (2010), the proportion of participants who experienced at least 1 adverse event was similar in the AGB and lifestyle groups (48% vs. 44%, respectively); however, the specific events were different.[168] While there were more adverse events reported in the lifestyle group (18, vs. 13 in the AGB group), half were unrelated to the lifestyle intervention (i.e., 7 study withdrawal unrelated to adverse events, 2 unplanned pregnancies; Appendix C, Table C6).[168] A single participant in the lifestyle group accounted for 44% (8 of 18) of the adverse events (hospitalization for depression and intracranial hypertension).[168] Of the 13 adverse events in the AGB group, 6 were proximal gastric enlargements, 2 needle sticks to tubing (no further details supplied), and 1 gallbladder removal; the remaining 4 events were for unplanned pregnancy, hospitalization for depression, and loss to follow-up.[168]

Longer-Term Outcomes in Children and Adolescents

The following section summarizes longer-term (e.g., ≥ 3 years) outcomes from NRSs (which have not been assessed for RoB or GRADE CoE because they cover procedures already evaluated by RCTs).

We identified 2 NRSs (in 5 publications) of MBS in adolescents reporting relevant long-term outcomes.[185-189] Study characteristics and complete outcomes are available in Appendix C, Table C7 and Table C8, respectively.

- AMOS (N = 162)[188,189]: A 5-year prospective cohort NRS conducted in Sweden, assessing outcomes among adolescents (ages 13 to 18 years; mean age, 16.1 years) with a BMI ≥ 35 kg/m^2 who received RYGB, compared with a matched control group of adolescents (identified in the Swedish Childhood Obesity Treatment Register) who received conventional interventions (mean BMI, 43.8 kg/m^2 across groups).[189] Conventional interventions in Sweden can include family counseling, cognitive behavior therapy, low-calorie diet, and medication.[189] Most participants were female (61%).[189] The study also included a comparator group of adults treated with RYGB, but those results were not included in this review.

- Teen-LABS (N = 242)[185-187]: A multicenter 5-year prospective cohort NRS conducted in the US, comparing outcomes among adolescents (ages 13 to 19 years; mean age, 17 years) with a BMI ≥ 35 kg/m^2 who received RYGB, SG, or AGB (mean BMI, 53 kg/m^2 across groups).[186] Participants with AGB were excluded from the primary 3-year results due to the small group sample size (N = 14)[186], and 5-year results were limited to the subset of participants who underwent RYGB (N = 161).[185]

Weight Change

Long-term results from these studies showed that adolescents who underwent RYGB or SG experienced greater TWL from baseline (range, 26% to 28%) and BMI reductions (range, 13.0 to 15.0 kg/m^2) over 3 to 5 years follow-up (P < .001 for all; Appendix C, Table C8).[185,186,188] No significant differences of TWL were observed in Teen-LABS at 3 years within or between the RYGB and SG groups (27% TWL)[186]; at year 5, only results for the RYGB group were reported and they had maintained the weight loss observed at 3 years.[185] Subgroup analyses conducted among the 3-year cohort showed that weight loss outcomes did not vary significantly by baseline age group (i.e., 13–15 years vs. 16–19 years).[187] Similarly, at the AMOS 5-year follow-up, adolescents who underwent RYGB had 28% TWL compared with a 5% weight gain in the conventional treatment group.[189] At 5 years, the observed weight loss among the surgical group corresponded with a significant reduction in BMI (mean, −13.1 kg/m^2), while there was an increase in BMI of in the control group (mean, +3.3 kg/m^2; P < .001).[188] A significantly greater proportion of RYGB patients also achieved a BMI below the threshold for clinical obesity (.e., < 30 kg/m^2) compared with the control patients (37% vs. 3%; P < .001).[188]

Despite the significant long-term mean weight and BMI reductions observed for adolescents who underwent MBS, it is notable that a minority of participants in both studies (i.e., < 40%) had BMIs below the clinical threshold for obesity (< 30 kg/m^2) at long-term follow-up (Appendix C, Table C8).[186,188]

Cardiovascular Risk Factors

Remission of T2DM occurred in 86% to 100% of surgical participants with baseline diagnoses during long-term follow-up (Appendix C, Table C8). [185,186,188] Approximately 13% (29 of 225) of adolescents enrolled in Teen-LABS, across both groups, were living with T2DM at the time of enrollment though the majority (23 of 159) were in the RYGB group.[186] At the 3-year follow-up, subgroup analyses did not show any significant differences in rates of T2DM remission by surgical type (i.e., RYGB vs. SG).[186] At the 5-year follow-up, 86% (14 of 20) of participants who underwent RYGB had maintained remission of T2DM.[185] No comparative results were available for AMOS study; however, 100% (3 of 3) of RYGB participants with T2DM at baseline were in remission at 5 years.[188] Similar results were seen in the resolution of hypertension and high cholesterol at 3 and

5 years.[185,186,188] In Teen-LABS, 74% (56 of 76) of participants in the RYGB and SG groups with baseline hypertension or elevated blood pressure were in remission at the 3-year follow-up; remission rates did not vary by surgical type.[186] At 5 years, 70% (33 of 47) of RYGB participants who had had abnormal blood pressure at baseline were in remission.[185] A small proportion of adolescents entered the AMOS study with hypertension (12 participants in the RYGB group) and all were in remission at the 5-year follow-up, but no comparator group results were reported.[188]

Remission of dyslipidemia (i.e., elevated LDL or elevated triglycerides) occurred in 66% to 83% of surgical participants during long-term follow-up.[186,188] In Teen-LABS, 66% (84 of 128) of participants in the RYGB and SG groups who were available for the 3-year follow-up and had had study-defined dyslipidemia at baseline (N = 128) were in remission; remission rates did not vary significantly by surgery type or baseline age.[186,187] At the 5 year follow-up of the AMOS study, 83% (43 of 52) of participants who received RYGB were no longer living with dyslipidemia.[188] Moreover, all RYGB participants with elevated baseline LDL (n = 13) or triglycerides (n = 22) alone exhibited normal levels at the 5-year follow-up.[188] Dyslipidemia-related remission rates were not reported for the AMOS adolescents who received conventional treatment; however, surgical participants experienced significantly greater reductions in concentrations of triglycerides (−41.6 mg/dL; 95% CI, −62.0 to 17.7; *P* < .001) and LDL levels (mean difference, −34.0 mg/dL; 95% CI, −46.4 to −23.2; *P* < .001) compared with nonsurgical participants (Appendix C, Table C8).[188]

Quality of Life

Long-term weight-related QoL was reported in both adolescent NRSs. At the 3-year follow-up assessment, Teen-LABS participants who underwent RYGB or SG (N = 185) reported a statistically significant improvement in the effect of weight on their overall well-being including physical limitations, self-esteem, and interpersonal relationships (IWQOL-Kids scale: +20 points; 95% CI, 17.4 to 22.7; *P* < .001).[186] The magnitude of reported change in QoL did not vary significantly by surgical type or baseline age and all groups exceeded the clinically significant change threshold of 4.8 points.[186,187] Participants who received RYGB in AMOS reported a similar statistically significant reduction in weight-related distress during activities such as shopping, swimming, eating at restaurants, and intimate relations at the 5-year assessment (OP-14 scale: −13.0 points; 95% CI, -19.6 to -6.4; *P* < .001); however, mean surgical group scores did not differ significantly from control group scores (37.4 vs. 45.1 points; *P* = .22).[188]

AMOS also reported on several measures of overall QoL as measured by the SF-36 survey. Compared with the adolescent nonsurgical control group, adolescents with RYGB experienced differential improvements in 2 of the 10 assessed domains (physical function: +8.8 points; *P* = .05; and physical role limitations: +13.5 points; *P* = .02).[188]

Adverse Events

Additional abdominal surgeries were the most common long-term adverse events in AMOS and Teen-LABS, occurring in 13% to 25% of surgical participants (Appendix C, Table C8).[185,186,188] Most reported abdominal surgeries occurring outside of the perioperative period were cholecystectomies or hernia repair procedures, whereas the incidence of revisional MBS was not reported.[185,186,188] Other long-term adverse events included outpatient endoscopic procedures for upper gastrointestinal issues and anemia-related blood transfusions.[185,186,188] Deaths were uncommon, with no reported deaths in AMOS and only 4 reported deaths occurring over 5 years

of follow-up among the 242 participants enrolled in Teen-LABS.[185,186,188] None of the deaths in Teen-LABS were related to bariatric surgery; 2 deaths were attributed to drug overdose and 2 other deaths were attributed to hypoglycemic events (1 in a participant with type 1 diabetes, and 1 in a participant with suspected sepsis after an unrelated surgery).[185,186]

Reported rates of nutritional abnormalities in adolescents after MBS were high, with up to 22% having vitamin B12 deficiency, 63% having vitamin D deficiency, and 66% having low iron or ferritin levels at 3 or more years after SG or RYGB .[186,188] In the AMOS study, almost a third of participants (32%) were also found to have clinical anemia.[188] When compared with nonsurgical controls, AMOS participants with RYGB were significantly more likely to have vitamin B12 deficiency, low iron or ferritin, and clinical anemia at the 5-year follow-up, but did not differ in terms of vitamin D insufficiency.[188]

Short-Term and Long-Term Safety of MBS (KQ3 and CQ2)

Real-World Evidence Analysis of 30-Day Safety Outcomes (KQ3)

To assess the comparative safety profiles of MBS procedures for adults, we conducted a novel analysis of patient-level data from the MBSAQIP registry (Table 14). The data presented in Table 14 are select 30-day serious adverse event rates for 1,073,973 adult individuals (i.e., ≥ 18 years) with a baseline BMI of 30 kg/m^2 or greater, undergoing MBS as a primary surgery (i.e., not a revisional procedure) at an MBSAQIP-accredited center for years 2016 to 2022.[190] Only 2,127 MBS procedures of any type were recorded among adolescents. Among adults, the most common risk factors were hypertension (46%), sleep apnea (38%), GERD (30%) and T2DM (25%). The full 30-day perioperative safety profiles for all MBS procedures, including rates of specific adverse events, are detailed in Appendix L.

Table 14. Select 30-day SAE Rates from the MBSAQIP Registry for Adults, 2016 to 2022[190]

MBS Procedure	Select Serious Adverse Events, n %							
	Deaths		≥ 1 Hospital readmissions		≥ 1 ED visits		≥ 1 Reoperations	
	n	%	n	%	n	%	n	%
AGB N = 8,973	1	0.01	148	1.64	360	4.01	71	0.79
BPD N = 11,180	31	0.28	656	5.86	901	8.06	314	2.81
ESG N = 1,480	0	0	38	2.57	58	3.92	799	0.54
IGB N = 3,072	1	0.03	52	1.69	124	4.04	34	1.11
OAGB N = 7,630	13	0.17	403	5.28	820	10.75	140	1.83
RYGB N = 273,474	347	0.13	14,495	5.30	27,347	9.99	5,497	2.01
SADI-S N = 2,394	4	0.17	102	4.26	197	8.23	49	2.05
SG N = 765,770	462	0.06	19,834	2.59	50,464	6.59	5,590	0.73
Overall N = 1,073,973	859	0.08	35,728	3.33	80,271	7.47	12,494	1.16

Abbreviations. AGB: adjustable gastric banding; BPD: biliopancreatic diversion with or without duodenal switch; ED: emergency department; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SAE: serious adverse event; SG: sleeve gastrectomy.

Deaths

The rate of death from any cause occurring within 30 days of the primary MBS was less than 1% within individual procedure types (Table 14). Across all MBS procedure types, 859 (0.08%) deaths, from any cause, were reported for the first 30 days postsurgery. Proportionally, the highest rates of death occurred among adults undergoing BPD (31 of 11,180; 0.28%); the next highest rates of death were among those undergoing OAGB (13 of 7,630; 0.17%) or SADI-S (4 of 2,394; 0.17%). In adolescents, only 2 surgical-related deaths within 30 days of the primary MBS and both were among in adolescents who underwent SG (2 of 1,943; 0.10%).

The most common primary causes of death were pulmonary embolism, bleeding, abdominal sepsis, respiratory failure, and leaks at the site of anastomosis or stapling. Additionally, deaths were categorized as likely related or unrelated to the procedure in registry years 2016 to 2020, but not for years 2021 to 2022. Among the deaths recorded from 2016 to 2020, 58% were considered likely related to the procedure.

Hospital Readmissions

Overall, the proportion of individuals with 1 or more inpatient hospital readmissions (planned or unplanned) within 30 days of surgery was roughly 3% (N = 35,728; Table 14). When analyzed by procedure, the likelihood of having a 30-day hospital readmission was highest among individuals with BPD (656; 6%), RYGB (14,495; 5%), and OAGB (403; 5%).

According to the registry analysis, 95% of 30-day hospital readmissions were for unplanned interventions and the most common reasons readmission across all MBS types were dehydration-related (e.g., nausea and vomiting; 23%), abdominal pain (10%), and gastrointestinal (GI) tract stricture or obstruction (5%). Approximately 80% of hospital readmissions reported from 2016 through 2019 were related to specific procedures. Biliopancreatic diversion and RYGB had the highest procedure-related readmissions at 81% and 83%, respectively; the lowest rates were for AGB and SG (both 73%).

Emergency Department Admissions

The proportion of individuals with 1 or more emergency department visits within 30 days was 7.5% (N = 80,271) across all MBS types (Table 14). When analyzed by procedure, the likelihood of having a 30-day emergency department visit was highest among adults who underwent OAGB (11%), RYGB (10%), BPD (8%), or SADI-S (8%).

For registry years 2016 to 2019, no information was provided about the reason for emergency department visits; for registry years 2020 to 2021, however, the reason for each outpatient visit was available. For they yeas 2020 and 2021, the most common reasons for emergency department visits across MBS types were abdominal pain and dehydration-related symptoms (e.g., nausea and vomiting).

- Abdominal pain-related emergency department visits were highest among individuals who had OAGB (4%), RYGB (4%), or BPD (3%); all other procedures had rates of 1% to 2%.
- Dehydration-related emergency department visits were highest among individuals who had BPD, OAGB, or RYGB (all 3%); all other procedures had rates of 1% to 2%.

Reoperations

The 30-day reoperation rate among adults was 1% (N = 12,494) for all MBS types (Table 14). Reoperation was more likely for adults who underwent BPD (3%) and OAGB, RYGB, or SADI-S (2% each); all other procedures had reoperation rates of 1% or less. The 30-day reoperation rate was less than 1% in adolescents and was more likely to occur in those who underwent SG.

Repair of the primary surgery was the most common type of specified reoperation for adults who had a primary BPD, RYGB, or SG. In contrast, reversal was the most common reoperation among individuals with an AGB. Reoperations were primarily attributable to obstructions or bleeding in the GI tract or leaks at the internal surgical sites, but varied in frequency between MBS procedures. The top 3 reasons for reoperation, with 10 or more incidents recorded, were:

- BPD: anastomotic or staple line leak, GI tract stricture or obstruction, GI tract bleeding
- OAGB: GI tract stricture or obstruction
- RYGB: GI tract stricture or obstruction, anastomotic or staple line leak, GI tract bleeding
- SADI-S: anastomotic or staple line leak
- SG: GI tract bleeding, anastomotic or staple line leak, other bleeding

For AGB, ESG, and IGB, no incidents with 10 or more occurrences were reported.

Long-Term Safety and Effectiveness of MBS (CQ2)

Long-Term Outcomes in Adults

A 2020 systematic review and meta-analysis (N = 607,643) compared the long-term mortality of adults with class 3 obesity (i.e., BMI ≥ 40 kg/m^2) who underwent MBS (n = 72,267) compared with those who received standard medical care (n = 535,376).[40] The median follow-up was 8.7 years.[40] All-cause deaths occurred in 3% of adults with class 3 obesity who underwent MBS, compared with 13% standard medical care (odds ratio [OR], 0.29; 95% CI, 0.17 to 0.49; $P < .001$).[40] When deaths were examined by age, the review found people aged 39 and older (the median age) who underwent MBS were significantly less likely to die than those who received standard medical care (OR, 0.23; 95% CI, 0.12 to 0.44; $P < .001$); however, this difference was not seen in the younger cohort (aged under 39, OR, 0.78; 95% CI, 0.57 to 1.06; $P < .001$).[40] Deaths related to cancer, cardiovascular disease, or diabetes were reduced by 65% to 75% compared with standard treatment (all, $P < .05$).[40]

Long-Term Outcomes in Adolescents

A 2023 systematic review and meta-analysis of MBS in children and adolescents (N = 4,970; 29 NRSs) with a mean age range of 12 to 19 years reported long-term weight and comorbidity-related outcomes; follow-up periods ranged from 5 to 15 years.[66] Participant mean preoperative BMI range was 38.9 kg/m^2 to 58.5 kg/m^2.[66] Obesity-related comorbidities were common (total, 3,309) with high cholesterol being most common (37%) followed by hypertension (28%); T2DM and OSA each account for approximately 16%, and asthma less than 2% (note individuals could have more than 1 obesity-related comorbidity).[66] Approximately 70% of the 5,000 procedures were SG followed by RYGB (20%), AGB (9%), and other procedures (1%; i.e., BPD, OAGB).[66] The meta-analysis found MBS provided a mean reduction in BMI of 13.1 kg/m^2 (95% CI,

11.75 to 14.43; *P* < .001) with postoperative BMIs ranging from 25.9 kg/m^2 to 50 kg/m^2. Subgroup analyses found greater reductions in BMI[66]:

- In those who underwent SG (mean difference [MD], 15.27 kg/m^2; 95% CI, 12.68 to 17.85; *P* < .001) vs. reductions of 12.9 kg/m^2 and 7.6 kg/m^2 for RYGB and AGB, respectively (both, *P* ≤ .001)
- For patients aged < 17 years (MD, 13.10 kg/m^2; 95% CI, 12.36 to 13.8; *P* = .26) compared with those ≥ 17 years (MD, 12.6; *P* < .001; between-group differences not reported)

Remission of obesity-related comorbidities was high. The meta-analyses found resolution rates for[66]:

- T2DM of 90% (95% CI, 83.2 to 95.6; *P* not reported)
- High cholesterol of 77% (95% CI, 62.0 to 88.9; *P* < .001)
    - Remission was more likely for RYGB procedures (88%) vs. SG (60%) and those < 17 years (89%; all, *P* < .001)
- Hypertension of 81% (95% CI, 71.5 to 88.8; *P* < .001)
    - Remission was more likely with RYGB (92%) vs. AGB (84%) and in those < 17 years (88%; all *P* < .001)

All-cause mortality was reported in less than 1% of adolescents who underwent MBS; other adverse events were not addressed in the review. Reported deaths included[66]:

- 1 from suicide nearly 4 years after MBS, due to bipolar disorder
- 1 from myocardial infarction 4.5 years after MBS
- 1 from infectious colitis approximately 3 years after MBS
- 1 from hypoglycemic episodes 3 years after MBS
- 2 overdoses 4 years after MBS
- 4 deaths deemed unrelated to MBS, timepoints not stated

Economic Outcomes (KQ5)

We identified 3 eligible studies (2 in adults and 1 in children and adolescents)[191-193] reporting economic outcomes (health care resource use or costs) or the results of an economic model from a US perspective (Table 15). We focused on economic studies that compared noncovered procedures (e.g., OAGB) or covered procedures in noncovered populations (e.g., BMI < 30 kg/m^2) with other interventions aimed at managing obesity. We focused on economic studies for noncovered populations and procedures because there is already significant published evidence that MBS procedures covered 2015 Washington coverage policy (e.g., RYGB, SG) are generally cost-effective.

Table 15. Summary Study Characteristics of Economic Studies of Bariatric Surgery

Study Details				Cohort Characteristics		Model Characteristics					
Study Reference	US Costs	MBS Type	Comparator	Age, years	BMI	Type of Analysis	Perspective	Time Horizon	Discount Rate	US dollar year	Risk of Bias
Adults											
Finkelstein and colleagues, 2019[191]	✓	• IGB (Orbera)	• Commercial lifestyle modification programs • Commercial food replacement programs • Medication[a]	≥ 18	• ≥ 25 kg/m^2	Cost-effectiveness	Payer	4 years	3.5%	2018	High
Saumoy and colleagues, 2023[192]	✓	• SG • ESG	• Semaglutide • Lifestyle intervention	40	• 33 kg/m^2 • 37 kg/m^2 • 44 kg/m^2	Cost-effectiveness	Health care sector	30 years	3%	2021	Mod
Children and adolescents											
Kyler and colleagues, 2019[193]	✓	• Bariatric surgery (no restriction)	• No comparator	10 to 18	NR	Cost analysis	NA	NA	NA	2016	High

Note. [a] *Medication included orlistat, phentermine-topiramate, naltrexone-bupropion, lorcaserin, and liraglutide.*
Abbreviations. ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; Mod: moderate; NA: not applicable; NR: not reported; SG: sleeve gastrectomy.

GRADE Summary of Findings

Table 16. GRADE Summary of Findings: Cost-Effectiveness of MBS

Number of Studies	Findings	Certainty of Evidence	Rationale
MBS in adults			
ESG and SG vs. semaglutide and lifestyle intervention			
1 cost-effectiveness analysis[192]	• ESG was cost-effective, with an ICER of $4,105 per QALY gained for adults aged 40 with a BMI of 33 kg/m^2 • SG was cost-effective, with an ICER of $5,883 per QALY gained for adults aged 40 with a BMI of 37 kg/m^2 • SG was cost-effective, with an ICER of $7,821 per QALY gained for adults aged 40 with a BMI of 44 kg/m^2 • Both procedures were cost-effective when compared individually with lifestyle intervention • Semaglutide was less effective and more costly (i.e., dominated) than another intervention	●○○○ Very low	Downgraded 1 level each for RoB, imprecision (i.e., model sensitivity to the cost of the procedure)[a], and indirectness (i.e., only adults aged 40)
IGB vs. commercially available nonsurgical weight-loss interventions			
1 cost-effectiveness analysis[191]	• IGB were not cost-effective for adults with overweight or obesity (BMI ≥ 25 kg/m^2) when compared with other nonsurgical options at any WTP threshold • Other interventions were less costly and more effective	●●○○ Low	Downgraded 2 levels for RoB (i.e., very limited reporting of methods)[a]
MBS in children and adolescents			
No eligible cost-effectiveness analyses comparing MBS with other interventions were identified in the populations of interest			
Comparison of MBS procedures in adults and children			
No eligible cost-effectiveness analyses comparing different MBS procedures were identified in the populations of interest			

Note. [a] *Inconsistency not assessable due to only 1 study.*
Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; ICER: incremental cost-effectiveness ratio; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; QALY: quality-adjusted life year; SG: sleeve gastrectomy; WTP: willingness-to-pay.

Costs of Bariatric Surgery vs. Other Weight Management Interventions

Endoscopic Sleeve Gastroplasty and Sleeve Gastrectomy in Adults

We identified 1 eligible cost-effectiveness analysis of 2 MBS techniques (ESG and SG) compared with semaglutide and with lifestyle intervention.[192] The base case included 3 hypothetical cohorts:

- Adults aged 40 with a BMI of 33 kg/m^2 (class 1 obesity)
- Adults aged 40 with a BMI of 37 kg/m^2 (class 2 obesity)
- Adults aged 40 with a BMI of 44 kg/m^2 (class 3 obesity)

The model took a health care sector perspective over a 30-year time horizon.[192] Costs were based on 2021 Medicare national average costs from the CMS, costs from the authors' own institution's endoscopy center, average wholesale costs for semaglutide, and the Medical Expenditure Panel Survey.[192] All costs were adjusted to 2021 $US, and both costs and utilities were discounted by 3% per year.[192] Other estimates of transition probabilities and utilities were based on published literature; where this was not available, expert opinion was used.[192] The willingness-to-pay (WTP) threshold was $100,000.[192]

Key assumptions were that each patient was only eligible for 1 treatment option, patients who discontinued semaglutide were not eligible to restart it, all patients would receive lifestyle intervention in addition to any active treatment (surgery or medication), and that patients could not regain more than 10% of their initial bodyweight.[192]

For each of the 4 strategies, patients lost weight over the first 1 to 2 years, followed by progressive weight gain over the 30-year period.[192] The model used estimates from the published literature; where only short-term data was available, the model assumed that a proportion of people had weight gain and the remainder of the cohort had a natural increase of 0.47 kg per year.[192] The model also assumed highest weight loss in the SG cohort (approximately 22% to 28% of initial body weight) and lowest weight loss in the lifestyle intervention cohort (approximately 4% to 9% of initial body weight).[192] Long-term adherence to semaglutide was assumed to be 50% (range, 20% to 100%) and the probability of intolerance was assumed to be around 6%.[192]

Baseline costs for each of the strategies were:

- $13,000 for ESG (range, $7,000 to $21,000), plus additional costs for medication in 25% people who gained weight or did not lose sufficient weight with surgery alone and for repeat surgery for 11% of people
- $26,696 for SG (range, $15,000 to $100,000)
- $21,045 per year for semaglutide (range, $200 to $40,000)
- $182 to $1,826 per year for lifestyle intervention (range, $100 to $4,000)

For adults aged 40 with a BMI of 33 kg/m^2, the intervention with the lowest cost was lifestyle intervention, with a cost of $124,195.[192]

- When all strategies were compared:
  - ESG was cost-effective, with an incremental cost-effectiveness ratio (ICER) of $4,105 per quality-adjusted life year (QALY) gained.
  - SG was not cost-effective compared with ESG, with an ICER of $110,325 per QALY gained.
- When all interventions were compared individually with lifestyle intervention:
  - Both ESG and SG were cost-effective with ICERs of $4,105 per QALY gained and $21,377 per QALY gained, respectively.
  - Semaglutide was not cost-effective, with an ICER of $508,414 per QALY gained.

For adults aged 40 with a BMI of 37 kg/m^2, the intervention with the lowest cost was lifestyle intervention, with a cost of $142,606.[192]

- When all strategies were compared:
  - SG was cost-effective, with an ICER of $5,883 per QALY gained.
  - ESG and semaglutide were both dominated (i.e., another intervention was either more effective with a lower cost or had a lower ICER).
- When all interventions were compared individually with lifestyle intervention:
  - Both ESG and SG were cost-effective with ICERs of $11,411 per QALY gained and $5,833 per QALY gained, respectively.
  - Semaglutide was not cost-effective, with an ICER of $420,483 per QALY gained.

For adults aged 40 with a BMI of 44 kg/m^2, the intervention with the lowest cost was lifestyle intervention, with a cost of $177,449.[192]

- When all strategies were compared:
  - SG was cost-effective, with an ICER of $7,821 per QALY gained.
  - ESG and semaglutide were both dominated (i.e., another intervention was either more effective with a lower cost or had a lower ICER).
- When all interventions were compared individually with lifestyle intervention:
  - Both ESG and SG were cost-effective with ICERs of $8,213 per QALY gained and $7,821 per QALY gained, respectively.
  - Semaglutide was not cost-effective, with an ICER of $350,637 per QALY gained.

In sensitivity analyses, each of the 3 models were sensitive to the costs of SG and semaglutide.[192] Probabilistic sensitivity analysis showed[192]:

- In class 1 obesity, SG was cost-effective for 56% of all iterations, and ESG was cost-effective for 31% of iterations at a WTP of US$100,000 per QALY gained.
- In class 2 obesity, SG was cost-effective for 79% of all iterations, and ESG was cost-effective for 14% of iterations at a WTP of US$100,000 per QALY gained.
- In class 3 obesity, SG was cost-effective for 85% of all iterations, and ESG was cost-effective for 13% of iterations at a WTP of US$100,000 per QALY gained.

Overall, the authors concluded that ESG was cost-effective for class 1 obesity (BMI of 33 kg/m^2) and SG was cost-effective for classes 2 and 3 obesity (BMIs of 37 kg/m^2 and 44 kg/m^2) in adults aged 40.[192] However, they did highlight that semaglutide may be cost-effective at a much lower cost, and given a higher service use with medication compared with surgery, may have the potential to provide the largest reduction in obesity-related mortality at the population level.[192]

Intragastric Balloons in Adults

We identified 1 eligible cost-effectiveness analysis of commercially available, evidence-based nonsurgical weight-loss interventions for adults with excess weight (defined as a BMI above 25 kg/m^2).[191] Although MBS was explicitly excluded from the analysis, an IGB (specifically Orbera) was included as an intervention of interest.[191] The cost-effectiveness analysis was conducted from the payer perspective over a 4-year time horizon, with costs being incurred only in the first year and benefits assumed to continue over the remaining 3 years after intervention.[191] The analysis included 4 types of intervention[191]:

- Commercial lifestyle modification programs
  - Weight Watchers Online
  - Weight Watchers meetings
- Commercial food replacement programs
  - Jenny Craig
- Branded medications
  - Over-the-counter orlistat (Alli)
  - Prescription orlistat (Xenical)
  - Phentermine-topiramate (Qsymia)
  - Naltrexone-bupropion (Contrave)
  - Lorcaserin (Belviq)
  - Liraglutide (Saxenda)
- IGB systems
  - Saline-filled balloon in the stomach (Orbera)

Effect estimates were based on a meta-analysis of 21 RCTs; 9 of the 10 interventions resulted in a statistically significant weight loss at 12 months, with a mean loss of[191]:

- 3.17 kg (95% CI, 2.22 to 4.05) with Weight Watchers meetings
- 7.43 kg (95% CI, 5.81 to 8.98) with Jenny Craig
- 2.45 kg (95% CI, 1.51 to 3.42) with orlistat (over the counter, 60 mg 3 times a day)
- 3.04 kg (95% CI, 2.43 to 3.60) with orlistat (prescription, 120 mg 3 times a day)
- 6.70 kg (95% CI, 6.11 to 7.28) with phentermine-topiramate
- 4.62 kg (95% CI, 4.24 to 4.98) with naltrexone-bupropion
- 3.23 kg (95% CI, 2.64 to 3.82) with lorcaserin
- 5.54 kg (95% CI, 5.15 to 5.91) with liraglutide
- 4.43 kg (95% CI, 3.04 to 5.78) with IGB (Orbera)

Only Weight Watchers Online showed no significant reduction in weight at 12 months and was excluded from further cost-effectiveness analysis.[191]

Direct medical costs for each intervention were identified from online sources in 2018.[191] Costs included[191] program fees and food costs (if any) for the commercial weight programs; medication costs and physician visit costs for the pharmaceutical interventions; and balloon costs and physician costs for the IGB.[191] Total costs for the first 12 months were calculated, and adjusted for people who did not continue with the program or medication (full 12-month costs were assumed for IGB because this was a one-time cost, regardless of continuation). The adjusted first 12-month costs were[191]:

- $424 (95% CI, $321 to $533) for Weight Watchers meetings
- $3,301 (95% CI, $2,499 to $4,101) with Jenny Craig
- $615 (95% CI, $470 to $764) with orlistat (over the counter, 60 mg 3 times a day)
- $6,164 (95% CI, $4,538 to $7,601) with orlistat (prescription, 120 mg 3 times a day)
- $2,194 (95% CI, $1,627 to $2,743) with phentermine-topiramate
- $2,498 (95% CI, $1,921 to $3,140) with naltrexone-bupropion
- $2,658 (95% CI, $2,054 to $3,295) with lorcaserin
- $11,644 (95% CI, $8,820 to $14,322) with liraglutide
- $6,500 (95% CI, $4,867 to $8,081) with IGB (Orbera)

Based on the calculated ICERs:

- Weight Watchers meetings were associated with a cost of $134 per kg lost and $30,071 per QALY gained.[191] This was the only intervention below a WTP threshold of $50,000.[191]
- Phentermine-topiramate was associated with a cost of $501 per kg lost and $117,219 per QALY gained.[191]
- Jenny Craig meal replacements were associated with a cost of $1,516 per kg lost and $369,000 per QALY gained.[191]
- All other interventions, (specifically orlistat [over-the-counter and prescription], naltrexone-bupropion, lorcaserin, liraglutide, and the IGB system) were more expensive and less effective than the next most expensive intervention (i.e., dominated) for both cost per kg lost and cost per QALY gained.[191]

Similar findings were seen in the sensitivity analyses.[191] Based on the probabilistic sensitivity analysis at lower WTP thresholds, Weight Watchers meetings were most likely to be cost-effective, with phentermine-topiramate being most likely to be cost-effective at higher WTP thresholds; IGB remained very unlikely to be cost-effective at any WTP threshold.[191] Furthermore, Finkelstein and colleagues estimated that the cost of the IGB system would have to be reduced from $6,500 to $694 for the intervention to be cost-effective at the WTP of $50,000.[191]

Children and Adolescents

We identified 1 eligible study reporting on costs related to MBS in children and adolescents.[193] We did not assess the CoE for outcomes from this study, as cost-effectiveness was not evaluated.

Kyler and colleagues[193] aimed to describe the trends in surgery volume and resource utilization in MBS for children and adolescents. Using data from a large database covering 90 pediatric hospitals in the US, 859 children and adolescents aged 10 to 18 who had MBS in the study period were identified.[193] The authors estimated this represented around 20% to 25% of all eligible pediatric admissions in the US. [193] Overall, the majority were older children (50% aged 17 to 18 years), female (73%), non-Hispanic White (50%) and had at least 1 comorbidity (55%).[193] Also, the majority were insured through a government-paid program (53%).[193]

The majority of the procedures were SG, with the total volume of this procedure increasing from 53% to 78% from 2012 to 2016.[193] Median length of stay was 2 days (interquartile range [IQR], 2 to 3) over the study period; however, the median length of stay decreased significantly over time (from 3 days in 2012 to 2 days in 2016; $P < .05$).[193] The majority of patients stayed in the hospital for 2 to 3 days (68.1% overall) and with a small proportion staying for 7 days or more (5.6% overall).[193]

Hospital costs decreased significantly over time, from $19,537 in 2012 (IQR, $15,187 to $27,372) to 15,143 in 2016 (IQR, $11,766 to $20,017; $P < .05$). However, 30-day hospital readmission rates remained stable over time, from 8.7% in 2012 to 7.7% in 2016 ($P = .08$); however, there was substantial variation, ranging from 3.9% to 12% across the years.[193]

Summary

Based on the evidence reviewed in this report:

- SG and ESG may be cost-effective interventions for adults with BMIs < 40 kg/m^2, compared with a lifestyle intervention, regardless of comorbid status (very low CoE, based on 1 cost-effectiveness analysis).
- IGBs are unlikely to be cost-effective for adults with overweight or obesity (BMI > 25 kg/m^2) when compared with other nonsurgical options (moderate CoE, based on 1 cost-effectiveness analysis).

We did not identify any cost-effectiveness evidence directly comparing MBS in adult populations currently not covered under the existing coverage determination (i.e., BMI < 30 kg/m^2, BMI ≥ 30 to < 35 kg/m^2 without T2DM), evaluating newer procedures in adults (e.g., SADI-S), or the cost-effectiveness of MBS in children and adolescents.

Ongoing Studies

We identified 24 ongoing studies (17 RCTs and 7 prospective comparative NRSs; Table 17)[194-217]; study sizes range from 24 to 500. Four NRSs[211,213,215,217] include individuals under 18 years old, including 3 studies[211,213,217] exclusively enrolling adolescents aged 12 to 19 years. No studies are enrolling children under the age of 12. Notably, none of the ongoing RCTs we identified include children or adolescents. Seventeen studies[194-201,204-208,210,212,214,215] are examining populations and procedures not currently covered under the Washington State coverage policy. Almost all studies report weight loss or change in BMI, except 1 study focused on comorbidity resolution in adolescents.[213] Briefly, we identified the following:

Head-to-Head Studies

- 11 RCTs with primary completion dates ranging from 2021 to 2027[195-201,204,205,207,210]
  - Study sizes ranging from 30 to 500
  - 4 include OAGB as a procedure of interest, compared with RYGB in 2 studies,[198,210] with SADI-S in 1 study,[205] and with SADI-S and BPD in 1 study[207]
  - 6 include SADI-S as a procedure of interest, compared with RYGB in 1 study,[201] with OAGB in 1 study,[205] with BPD only in 3 studies,[195,200,204] and with OAGB and BPD in 1 study[207]
  - 2 include ESG as a procedure of interest, compared with SG in 1 study[196] and with IGB in 1 study[199]
  - 2 include IGB as a procedure of interest, compared with ESG in 1 study[199] and 1 study comparing adjustable IGB to nonadjustable IGB[197]
  - 2 studies are located in Canada[195,200] and 9 are located in Europe[196-199,201,204,205,207,210]
  - 1 study exclusively enrolled individuals with liver disease[196]
  - 4 studies have a follow-up period of 1 to 2 years,[196,197,201,210] 5 studies have a follow-up of 4 to 5 years,[195,199,200,205,207] and 2 studies have a 10-year follow-up[198,204]

- 3 NRSs with primary completion dates ranging from 2024 to 2029[214,215,217]
  - Study sizes ranging from 50 to 248
  - 1 study compares OAGB and RYGB,[214] 1 study compares OAGB, SG, and RYGB,[215] and 1 study compares RYGB and SG in adolescents[217]
  - 1 study is located in China[215] and 2 are located in Europe[214,217]

- 1 study exclusively enrolled individuals with liver disease[215]
- Follow-up periods are 2 years,[215] 5 years,[217] and 7 years[214]

MBS Compared With a Lifestyle Intervention

- 6 RCTs with primary completion dates ranging from 2020 to 2026 compare 1 or more MBS procedures with a nonsurgical lifestyle intervention or usual care[194,202,203,206,208,209]
  - Study sizes range from 24 to 100
  - 2 studies are located in the US,[206,208] 2 in Asia,[202,203] and 2 in Europe[194,209]
  - 3 exclusively enrolled individuals with liver disease[203,208,209] and 1 exclusively enrolled individuals with T2DM[202]
  - 1 includes semaglutide as the nonsurgical comparator[208]
  - 2 involve 2 surgical procedures (RYGB and SG)[203,209]
  - 4 involve a single bariatric procedure, including ESG in 3 studies[194,206,208] and SG in 1 study[202]
  - Most studies (4 of 6) have a follow-up period of 1 year,[202,203,206,208] 1 study has a follow-up of 3 years,[194] and 1 study has a follow-up of 5 years[209]

- 4 NRSs with primary completion dates ranging from 2023 to 2029 compare 1 or more bariatric procedures with a nonsurgical lifestyle intervention or usual care[211-213,216]
  - Study sizes range from 75 to 480
  - 2 studies are located in the US[212,213] and 2 are located in Europe[211,216]
  - 1 exclusively enrolled individuals with T2DM[213]
  - 2 involve 2 or more surgical procedures: 1 study compares IGB and ESG to an intensive lifestyle intervention[212] and 1 study compares RYGB, SG, and AGB to an intensive lifestyle intervention and usual care[216]
  - 2 involve a single bariatric procedure, including RYGB in 1 study[211] and SG in 1 study[213]; both studies exclusively enrolled adolescents
  - 3 studies have follow-up periods of 6 months to 3 years[212,213,216] and 1 study has a follow-up period of 10 years[211]

Further characteristics of ongoing studies are available in Table 17 below, and Appendix D.

Table 17. Ongoing Studies of Metabolic and Bariatric Surgery

Study Characteristics						Inclusion Criteria		Outcomes			
Study Name Trial Number	Includes US	Follow-up, years	Expected Enrollment	Surgical Intervention(s)	Nonsurgical Comparator(s)	Age, years	BMI, kg/m^2	Cardiovascular Risk Factors	AEs[a]	QoL	Primary Completion Date
RCTs											
ESGORT[194] NCT04200144	X	3	60	• ESG (Overstitch)	• ILI	20 to 65	• 30 to 45	✓	✓	X	December 2020
DSvsSADI[195] NCT02692469	X	5	140	• BPD • SADI-S	N/A	18 to 70	• ≥ 40 • ≥ 35 with ORC • ≥ 30 with T2DM	✓	✓	X	April 2021
TESLA-NASH[196] NCT04060368	X	2	30	• ESG (Overstitch) • SG	N/A	18 to 60, with NASH	• 35 to 45 • 30 to 35 with T2DM	✓	✓	X	June 2022
NCT04800835[197]	X	1	44	• IGB (Spatz3) • Nonadjustable IGB	N/A	18 to 65	• ≥ 27	X	X	X	July 2022
OAGBvsLLbypass[198] NCT04812132	X	10	500	• OAGB • RYGB	N/A	18 to 60	• ≥ 40 • ≥ 35 with ORC	✓	✓	X	January 2023
NCT04854317[199]	X	4	150	• IGB • ESG • EVG • POSE-2	N/A	≥ 18	• > 30	X	✓	✓	June 2023
NCT04767490[200]	X	5	120	• BPD • SADI-S	N/A	18 to 60	• ≥ 40 • ≥ 35 with ORC	✓	✓	✓	September 2023
SADISLEEVE[201] NCT03610256	X	2	382	• RYGB • SADI-S	N/A	18 to 65	• ≥ 40 • ≥ 35 with ORC	✓	✓	✓	October 2023
[b]UMIN000038432[202]	X	1	60	• SG	• MWM	18 to 50, with T2DM	• 27.5 to 35	✓	✓	✓	November 2023
[b]NCT03875625[203]	X	1	80	• RYGB • SG	• ILI • Usual care	18 to 65, with NAFLD	• ≥ 35 • ≥ 30 with MetS • 25 to 30	✓	X	X	December 2023

Study Characteristics						Inclusion Criteria		Outcomes			
Study Name Trial Number	Includes US	Follow-up, years	Expected Enrollment	Surgical Intervention(s)	Nonsurgical Comparator(s)	Age, years	BMI, kg/m^2	Cardiovascular Risk Factors	AEs[a]	QoL	Primary Completion Date
TORSBY I[204] NCT03938571	X	10	56	• BPD • SADI-S	N/A	≥ 18	• > 45	✓	✓	X	January 2024
OASIS[205] NCT05948852	X	5	96	• OAGB • SADI-S	N/A	18 to 65	• ≤ 50	X	✓	✓	July 2024
NCT05739162[206]	✓	1	24	• ESG	• ILI	22 to 69	• 30 to 50	X	✓	X	January 2025
BAR-3[207] NCT04861961	X	5	186	• BPD • OAGB • SADI-S	N/A	18 to 65	• 50 to 60	✓	✓	✓	April 2025
NCT06138821[208]	✓	1	30	• ESG • ESG + semaglutide	• Semaglutide	21 to 65, with NAFLD	• 30 to 40	✓	X	✓	July 2025
NASHSURG[209] NCT03472157	X	5	100	• RYGB • SG	• ILI	18 to 65, with NASH	• ≥ 30	✓	X	✓	March 2026
YOMEGA-2[210] NCT06057597	X	2	368	• OAGB • RYGB	N/A	18 to 65	• ≥ 40 • ≥ 35 with ORC	✓	✓	✓	October 2027
Prospective nonrandomized comparative studies											
4XL[211] NCT00923819	X	10	120	• RYGB	• Usual care	13 to 18	• ≥ 40 • ≥ 35 with ORC	X	✓	✓	August 2023
NCT04306445[212]	✓	0.5	75	• ESG • IGB (Obalon)	• ILI	22 to 65	• 30 to 40	✓	X	X	March 2024
ST2OMP[213] NCT04128995	✓	2	100	• SG + MWM	• MWM	13 to 19, with T2DM	• ≥ 35 or > 120% of 95th percentile	✓	X	X	September 2024
YOMEGA 5-7y[214] NCT05549271	X	7	248	• OAGB • RYGB	N/A	18 to 65	• ≥ 40 • ≥ 35 with ORC	X	X	X	September 2024
[b]Base-NAFLD[215] NCT04366999	X	2	150	• OAGB • RYGB • SG	N/A	16 to 65, with NAFLD	• ≥ 32.5 • ≥ 27.5 with ORC • ≥ 25 with T2DM	✓	X	X	December 2024

Study Characteristics						Inclusion Criteria		Outcomes			
Study Name Trial Number	Includes US	Follow-up, years	Expected Enrollment	Surgical Intervention(s)	Nonsurgical Comparator(s)	Age, years	BMI, kg/m^2	Cardiovascular Risk Factors	AEs[a]	QoL	Primary Completion Date
NCT01344525[216]	X	3	480	• AGB • RYGB • SG	• ILI • Usual care	18 to 65	• > 30	X	✓	✓	May 2029
ROSA[217] NCT03203161	X	5	50	• RYGB • SG	N/A	12 to 17	• ≥ 40 • ≥ 35 with ORC	✓	✓	✓	September 2029

Notes. Shaded rows indicate studies that include pediatric populations. ✓denotes yes; X denotes no. [a] This column includes AEs, mortality, surgical complications, GERD, and micronutrient status. [b] Indicates studies conducted in Asian countries or populations of Asian descent, and therefore the BMI inclusion criteria are lower.

Abbreviations. AE: adverse event; AGB: adjustable gastric banding; BMI: body mass index; BPD: biliopancreatic diversion; ESG: endoscopic sleeve gastroplasty; EVG: endoluminal vertical gastroplasty; IGB: intragastric balloon; ILI: intensive lifestyle intervention; MetS: metabolic syndrome; MWM: medical weight management; N/A: not applicable; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; OAGB: one-anastomosis gastric bypass (aka mini gastric bypass); ORC: obesity-related comorbidity; POSE-2: primary obesity surgical endoluminal 2; QoL: quality of life; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Clinical Practice Guidelines

We identified 22 clinical practice guidelines published since 2019.[8,35-37,50,51,53,54,70,72,218-229] Eight are US guidelines.[8,36,50,51,72,218,219,224] Two guidelines are exclusively focused on the pediatric population,[8,227] 3 guidelines contain recommendations relevant to both adults and children,[36,53,220] and the remaining 17 guidelines contain recommendations only specific to adults. Of these 17 guidelines, 2 explicitly state that the recommendations are not applicable to children,[35,228] 4 specify that the recommendations are for adults,[37,50,219,222] and the remaining 11 are ambiguous about their applicability to the pediatric population.

Metabolic and Bariatric Surgery in Adults

Eligibility Criteria

Guidelines generally consider adults to be eligible for MBS with the following criteria (see Appendix G, Table G1 for full details):

- With or without a comorbidity:
  - BMI ≥ 40 (recommended by 9 guidelines[35-37,50,53,72,219,222,223])
  - BMI ≥ 35 (recommended by 1 guideline[36])
  - Lower BMI threshold for people of Asian background with or without a comorbidity, ranging from BMI ≥ 30 to ≥ 37.5 (recommended by 4 guidelines[36,53,72,220])
- With at least 1 comorbidity:
  - BMI ≥ 35 (recommended by 11 guidelines[35-37,50,53,72,218,219,222,223,229])
  - BMI ≥ 30 (recommended by 2 guidelines[37,218])
  - Lower BMI threshold for people of Asian background with at least 1 comorbidity, ranging from BMI ≥ 27.5 to ≥ 32.5 (recommended by 5 guidelines[36,53,72,218,220])
- With T2DM:
  - BMI ≥ 30 (recommended by 8 guidelines[35-37,50,53,72,218,222])
  - Lower BMI threshold for people of Asian background with T2DM, generally BMI ≥ 27.5 (recommended by 6 guidelines[36,53,72,218,220,222])

Summary of Recommendations

Overall, the guidelines recognized MBS as an effective intervention for weight loss and resolution of obesity-related comorbidities in eligible patients. Seventeen guidelines include recommendations for or against specific types of MBS in adult populations, with some acknowledgment of inconclusive evidence for relatively newer procedures. Some recommendations focus on individuals with particular obesity-related comorbidities (e.g., liver disease,[72,218,223] OSA,[72,219] and T2DM[35-37,50,53,72,220-222,229]). Six guidelines recommend a lower BMI threshold for consideration of MBS eligibility for people of Asian background,[36,53,72,218,220,222] with 1 guideline applying lower BMI thresholds to people of other ethnicities as well: "people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African–Caribbean background."[53] See Appendix G, Table G2 for a complete list of relevant recommendations for MBS in adults.

Metabolic and Bariatric Surgery in Children and Adolescents

Eligibility Criteria

Children are generally considered eligible for referral to MBS at the following criteria[8,36,220,227] (see Appendix G, Table G3 for full details):

- With or without a comorbidity

  - BMI ≥ 40 or 140% of the 95th percentile
- With at least 1 comorbidity
  - BMI ≥ 35 to 39.9 or 120% of the 95th percentile

Three non-US pediatric guidelines suggest that MBS should be limited in children who have not completed growth and puberty.[53,220,227] Two pediatric guidelines do not specify growth and puberty completion as prerequisites for MBS referral[8,36]; 1 of these guidelines limits its recommendation for referral to children aged 13 years or older.[8] Two guidelines explicitly state that MBS should be considered for children only after nonsurgical interventions have failed.[220,227]

Recommendations

Only 1 guideline (from the AAP) references specific MBS procedures for adolescents: RYGB and SG.[8] The AAP guideline acknowledges that safety and effectiveness have not been established for lower ages due to limited data in populations under the age of 13 years.[108] All 5 guidelines for pediatric populations recommend adolescents receive care from a multidisciplinary team.[8,36,53,220,227] This includes 1 National Institute for Health and Care Excellence (NICE) guideline that is currently in draft and out for consultation and therefore has not been finalized.[53] For a complete list of relevant recommendations for MBS in adolescents see Appendix G, Table G4.

Professional Guidance on Revision and Conversion of MBS (CQ4)

Revisional MBS Criteria from Clinical Practice Guidelines

We identified 4 evidence-based clinical practice guidelines representing 11 relevant professional societies with criteria pertaining to revisional MBS:

- The 2023 NICE draft guideline on overweight and obesity management[53]
- A joint 2022 guideline on indications for MBS issued by the American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)[36]
- A 2020 update of the European Association for Endoscopic Surgery (EAES) guidelines on bariatric surgery[35]
- A 2019 clinical practice guideline for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures commissioned by the American Association of Clinical Endocrinologists/American College of Endocrinology (AACE) and cosponsored by the Obesity Society, ASMBS, Obesity Medicine Association, and American Society of Anesthesiologists [72]

Across the guidelines there was general agreement that revisional MBS is a broad term that may refer to several types of procedures[35,36,53,72]:

- Conversion from one kind of MBS to another (e.g., receiving RYGB after a primary AGB)
- Corrective procedures to enhance effects or treat complications of a primary MBS (e.g., adjusting the band position after initial AGB placement)
- Reversal of the primary procedure to restore normal anatomy (e.g., removing a gastric band)

The guidelines also agreed on the following indications for revisional MBS[35,36,53,72]:

- Weight recurrence or nonresponse (i.e., inadequate weight loss)
- Treatment of certain MBS-related complications (e.g., leaks, strictures)

- Insufficient improvement or emergence of serious comorbidities (e.g., T2DM, GERD)

The guidelines additionally noted that revisional MBS is associated with increased mortality and a higher risk of perioperative complications and subsequently emphasized the need for robust multidisciplinary assessment, including shared decision-making between patients and providers, before proceeding to revisional procedures.[35,36,53,72]

Although the guidelines exhibited a high level of agreement regarding the definition and indications for revisional MBS, several included additional or refined criteria recommendations:

- NICE specified that revisional MBS should only be undertaken by surgeons with extensive experience and occur exclusively in specialist centers[53]
- The EAES proposed the following criteria for clinical nonresponders after primary MBS[35]:
  - Patient response should be evaluated no sooner than 18 to 24 months following the primary bariatric procedure to allow for weight stabilization
  - Primary nonresponse defined as: 1) weight loss less than 10% of total baseline body weight; 2) weight loss insufficient to not qualify for bariatric surgery based on BMI; or 3) inadequate control of baseline comorbidities with medical therapy
  - Secondary nonresponse defined as: 1) ongoing progressive weight gain; 2) weight recurrence sufficient to re-qualify for bariatric surgery based on BMI; 3) weight recurrence and inadequate control of baseline comorbidities with medical therapy
- AACE made several procedure-specific revision recommendations[72]:
  - Conversion to RYGB may be considered for patients with a primary SG who develop medical treatment-resistant GERD with severe symptoms
  - Conversion to SG or RYGB may be considered in cases of persistent vomiting, regurgitation, and upper-gastrointestinal obstruction due to AGB-related complications (e.g., band slippage)

Procedure-specific Guidance

We identified several position statements and expert consensus publications describing recommended revisional criteria for specific bariatric surgery types, including SADI-S, SG, and OAGB.

SADI-S

Two position statements regarding indications for the SADI-S procedure issued by ASMBS[224] and IFSO[54] did not provide any revision-related guidance citing a lack of high-quality comparative evidence.[54,224] However, both organizations acknowledged that SADI-S has been evaluated as a conversion procedure after nonresponse to RYGB in uncontrolled studies with limited sample sizes.[54,224] The ASMBS position statement additionally noted that SADI-S has been advocated as a conversion procedure following nonresponse to SG.[224]

SG

An international committee of clinicians with metabolic and bariatric expertise issued a consensus document reflecting expert opinion concerning the application of SG across the care pathway, including several consensus statements regarding revisional MBS in the context

of SG.[230] The committee achieved consensus agreement (i.e. ≥ 70% agree), on the following indications and preferred revisional procedures following a primary SG[230]:

- Conversion to RYGB for treatment of SG-related symptomatic GERD, strictures, or leaks
- Conversion to OAGB, BPD, RYGB, or SADI-S for SG patients seeking greater metabolic and bariatric benefits

The committee also agreed that SG itself was a suitable revisional procedure for patients with[230]:

- Primary AGB seeking greater metabolic and bariatric benefits in the absence of severe GERD
- Severe reactive hypoglycemia after RYGB

In contrast, the committee achieved consensus disagreement (i.e., ≥ 75% disagree) regarding the use gastric plication as a revision procedure for SG patients.[230] Finally, the committee was unable to achieve consensus as to whether a re-sleeve procedure was an acceptable revisional MBS after an SG for patients with a large residual sleeve who are seeking greater metabolic and bariatric benefits.[230]

OAGB

In 2024, the ASMBS released an updated position statement for the endorsement of OAGB as a primary and revision procedure based on additional evidence, including longer term outcomes.[231] Two consensus documents reflecting the clinical opinion of international committees of MBS experts detailed guidance regarding revisional surgery in the context of OAGB.[232,233] Using a modified Delphi methodology, the committees agreed (i.e., ≥ 70% consensus) that OAGB is a suitable revisional procedure in the following circumstances:

- As a mainstream, standalone revisional MBS
- Nonresponse or weight recurrence after AGB,[232,233] SG,[232,233] ESG,[232] IGB,[232] or gastric plication[232]
- As the planned second stage of a 2-stage procedure after SG for patients with very high BMI (> 50 kg/m^2)[232]
- As a salvage procedure during a planned SADI-S in cases of a duodenal perforation or anastomotic leak[232]

One committee additionally agreed that patients with primary OAGB may consider conversion to a RYGB in instances of[233]:

- Persistent ulcers or strictures
- Dyspeptic symptoms from alkaline gastritis with no meaningful clinical improvement after 6 months of medical treatment
- Uncontrolled GERD despite optimal medical treatment
- Leaks from the gastric pouch or anastomosis

Only 1 committee reported consensus disagreements; they agreed that OAGB was not a suitable revisional procedure the following circumstances[232]:

- Weight recurrence after a primary RYGB
- Leak in a primary SG

The committees were not able to come to consensus regarding whether OAGB is a suitable procedure in the following circumstances:

- As 2-stage conversion procedure in very high BMI patients (i.e., ≥ 50)[232]
- Treatment for symptomatic GERD after primary SG,[232,233] vertical banded gastroplasty (VBG),[232] gastric plication,[232] or AGB[232]

Selected Payer Coverage Determinations

We identified coverage policies related to bariatric surgery from Medicare,[154] Oregon Medicaid,[234] Aetna,[235] Cigna,[236] and Regence BlueCross BlueShield (Regence).[237] Key coverage criteria regarding approved populations, approved procedures, and other administrative or clinical requirements are summarized in Table 18.

Table 18. Summary of Coverage Criteria for MBS by Payer

Coverage Criteria	Medicare	Oregon Medicaid	Aetna	Cigna	Regence
Approved populations					
BMI < 30 (any circumstances)	X	X	X	X	X
BMI 30 to 34.9 only with comorbidities	X	✓	X	X	X
BMI 35 to 39.9 only with comorbidities	X	X	✓	✓	✓
BMI ≥ 35 only with comorbidities	✓	X	X	X	X
BMI ≥ 30	X	X	X	X	X
BMI ≥ 35	X	✓	X	X	X
BMI ≥ 40	X	X	✓	✓	✓
Adolescents (age < 18 years)	*N/A*	✓	✓	✓	✓
Approved procedures					
AGB	✓	X	✓	✓	X
BPD	✓	✓	✓	✓	✓
Gastric plication[a]	X	X	X	X	X
IGB[a]	X	X	X	X	X
OAGB[a]	X	✓	X	X	X
RYGB	✓	✓	✓	✓	✓
SADI-S[a]	X	✓	✓	✓	X
SG	✓	✓	✓	✓	✓
VBG[a]	X	X	✓	✓	X
Revisional MBS	X	X	✓	✓	✓
Other requirements					
Trial of medical weight-loss program	✓	X	✓	✓	✓
MBSAQIP accreditation	X	✓	X	X	X
Multidisciplinary evaluation	X	✓	✓	✓	✓

Notes. ✓ denotes yes; X denotes no. [a] These MBS procedures are not covered by the 2015 Washington coverage policy.

Abbreviations. AGB: adjustable gastric banding; BMI: body mass index; BPD: biliopancreatic diversion with or without duodenal switch; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; N/A: not applicable; OAGB: one-anastomosis gastric bypass; Regence: Regence BlueCross BlueShield; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy; VBG: vertical banded gastroplasty.

Medicare

We identified 1 NCD for Medicare related to MBS that has been in effect since 2013 (Table 18).[154] We did not identify an additional local coverage determination for contractors with Medicare clients in Washington State.

The Medicare NCD specifies the following criteria for coverage of bariatric surgery[154]:

- BMI ≥ 35 with at least 1 comorbidity (e.g., T2DM)
- Documentation of an unsuccessful trial of medical treatment for obesity
- Covered procedures include:
  - Open and laparoscopic RYGB
  - Open and laparoscopic BPD or gastric reduction duodenal switch
  - Laparoscopic AGB
  - Laparoscopic SG

The Medicare NCD additionally specifies that the following are not covered[154]:

- MBS for the treatment of obesity alone
- Open AGB, open SG, open and laparoscopic vertical banded gastroplasty, intestinal bypass surgery, and IGB

The NCD did not describe any coverage criteria related to OAGB, SADI-S, or revisional MBS.

Medicare allows coverage for MBS procedures that are not explicitly identified as covered or not covered in the NCD (e.g., OAGB, SADI-S) through local coverage determinations, provided that the beneficiary meets the clinical criteria for coverage specified in the NCD.[154]

Medicaid

The Oregon Health Evidence Review Commission (HERC) issued a coverage determination about bariatric procedures after an evidence review completed in 2023 (Table 18).[234]

In the new guidance document, HERC recommended coverage for certain MBS procedures, including RYGB, SG, BPD, OAGB, and SADI-S, but did not recommend coverage for AGB or IGB citing a lack of evidence of long-term benefit.[234] HERC's recommendations apply to adult and adolescent Oregon Medicaid members when a range of clinical and administrative criteria are satisfied.[234]

Approved MBS procedures are covered for <u>adults</u> under the following conditions[234]:

- Age ≥ 18 years
- BMI 30 to 34.9 kg/m^2 with diagnosed T2DM that has not met glycemic targets after trials of 2 diabetic medications, <u>*or*</u>
- BMI ≥ 35 kg/m^2 with or without comorbidities
- Multidisciplinary evaluation in an MBSAQIP-accredited program
- Free from substance use disorder or active use of combustible cigarettes
- Not currently pregnant and counseled on the need for contraceptive use for at least 18 months postoperatively, where indicated
- Agree to adhere to all post-surgical evaluations and care recommendations

Approved MBS procedures are covered for adolescents when all of the following criteria are met[234]:

- Age 13 to 17 years
- BMI > 35 kg/m^2 or 120% of the 95th percentile for age and sex AND a clinically significant comorbid condition, *or*
- BMI > 40 kg/m^2 or 140% of the 95th percentile for age and sex
- Multidisciplinary evaluation in an MBSAQIP-accredited program with Adolescent accreditation
- Agree to adhere to all post-surgical evaluations and care recommendations

The coverage guidance did not describe any criteria associated with revisional MBS.

Private Payers

Coverage criteria for MBS procedures is similar across the Aetna, Cigna and Regence policies, and a summary of these criteria is detailed in Table 18.

Adults

Private payer policies generally indicate coverage of MBS for adults under the following criteria[235-237]:

- BMI ≥ 40 *or* BMI ≥ 35 to 39.9 with a serious obesity-related comorbidity (e.g., T2DM, OSA)
- Unsuccessful trial of a medical weight-loss program
- Presurgical evaluation by a multidisciplinary team
- BPD, RYGB, or SG for primary MBS
- Revisional MBS due to complications from the primary procedure or in instances of weight recurrence or nonresponse

The policies also overlap in the following experimental or investigational (i.e., not covered) criteria[235-237]:

- IGB and OAGB for primary or revisional MBS
- MBS for the primary treatment of any condition except for obesity

Beyond the common criteria described above, each policy details slightly different requirements (e.g., lengths of time, type of documentation) for a presurgery, structured medical weight-loss intervention overseen by medical professionals. In general, the beneficiary is required to have failed to lose a clinically important amount of weight during the course of that intervention prior to being eligible for MBS.[235-237]

All private payers require surgical candidates to undergo a preoperative multidisciplinary assessment, including medical and psychiatric evaluations.[235-237] Common examples of contraindications for MBS include an ongoing substance use disorder, medically correctable cause of obesity, inability to adhere to post-operation care and lifestyle requirements (determined from psychiatric or medical assessment), or current pregnancy (or pregnancy planned within a year of the operation).[235-237]

Policies vary in terms of covered primary procedure types: all 3 payers cover BPD, SG, and RYGB,[235-237] whereas Aetna and Cigna additionally cover AGB, SADI-S, and VBG.[235,236] Similarly, policies vary in which procedures are considered experimental or investigational: all 3 payers

categorize IGB and OAGB as investigational,[235-237] whereas Cigna additionally does not cover gastric plication procedures,[236] and Regence does not cover AGB, gastric plication, primary endoscopic procedures, SADI-S, VBG, or planned 2-stage procedures.[237] All policies cover revisions and reoperations for either development of complications or medical necessity resulting from a failure to lose sufficient weight.[235-237]

In contrast to the Oregon HERC coverage determination, the policies for Aetna, Cigna, and Regence consider MBS as a treatment for T2DM in patients with a BMI < 35 to be investigational and experimental.[235-237] However, the coverage policy for Cigna states that an altered threshold for BMI be used for individuals whose providers attest they are of Asian race or ethnicity with a BMI ≥ 37.5 without a comorbidity, or a BMI ≥ 32.5 with a comorbidity.[236]

Adolescents

Among the private payers, policies related to MBS for adolescents have different eligibility criteria than policies for adults.

These policies generally require that adolescents meet the following criteria[235-237]:

- Achievement of skeletal maturity
- BMI ≥ 40 or ≥ 140% of the 95th percentile for age and sex *or* BMI ≥ 35 or ≥ 120% of the 95th percentile for age and sex and a clinically significant comorbid condition (e.g., T2DM, OSA)
- Unsuccessful trial of a medical weight-loss program
- Presurgical evaluation by a multidisciplinary team
- RYGB or SG for primary MBS procedures
- Revisional MBS due to complications from the primary procedure or in instances of weight recurrence or nonresponse

Compared with adults, fewer types of MBS are approved for adolescents. Cigna and Regence currently only approve RYGB or SG for primary MBS in adolescents and Aetna recommends RYGB (although others may be covered with provider documentation).[235-237] All policies cover revisional MBS to treat the development of complications or medical necessity resulting from a failure to lose sufficient weight.[235-237]

The evaluation, documentation, and surgical contraindication criteria are similar to those for adults, with the exception of the skeletal maturity requirement. While Aetna and Cigna only require documentation of completed bone growth during the preoperative evaluation, Regence additionally requires documentation of Tanner 4 or 5 pubertal development.[235-237]

Discussion

Summary

We found that, in general, MBS performed in patients with BMI ≥ 25 kg/m^2 (or ≥ 23 kg/m^2 in some non-White populations), with or without an obesity-related comorbidity or issue, resulted in greater weight-loss, greater reductions in BMI, and greater improvements in cardiovascular risk factors (e.g., resolution of MetS, increase in HDL) compared with nonsurgical interventions (e.g., diabetes care, lifestyle interventions). When comparing procedures currently covered under the Washington coverage determination with those that are not (e.g., OAGB vs. RYGB), there

were no differences in outcomes. Health-related quality of life was rarely reported, and the observed results were mixed.

While adverse events were common, and more so in some types of MBS, most adverse events were mild or moderate and resolved without further intervention. Few reoperations due to adverse events occurred; deaths were also infrequent. There is some evidence from the MBSAQIP registry that non-White patients experience higher rates of adverse events, including emergency department visits, readmissions, and reoperations within the first 30 days postsurgery.

Professional organizations and societies continue to update their clinical practice guidelines to reflect the current body of evidence around eligibility criteria, which may include personal characteristics related to age, BMI, weight, comorbidities, prior nonsurgical weight-loss attempts, as well as adherence to any pre- or postsurgical requirements (e.g., reduced calorie diets, physical activity level). Some of these organizations and societies are also adopting varying BMI thresholds to align with the natural variance among some racial and ethnic minorities, and adjusting comorbidity requirements (e.g., patients with BMI ≥ 30 to < 35 kg/m^2 without T2DM may be eligible) to reflect risks related to overweight and obesity.

Limitations

There are a number of limitations of this health technology assessment (HTA). Few RCTs report outcomes beyond 1 to 2 years; therefore, it is difficult to know the durability of these interventions for long-term weight-loss (i.e., ≥ 5 years) and the impact on related comorbidities. Per the scope of this HTA, we prioritized RCTs over other types of study designs for evidence on effectiveness and harms, with some included RCTs reporting outcomes 3 years or more from baseline. However, there are likely NRSs that have reported on longer-term weight, HRQoL, and safety outcomes that are not included in this report. Additionally, several studies allowed participants in the control group to undergo MBS after the primary study period (generally 6 months for IGBs and 1 year for all other procedures) while remaining in the study. This often resulted in very small numbers of participants when outcomes were measured beyond the initial period, within already small studies, making the results unreliable. Validated clinical tools to measure HRQoL in MBS populations exist, and are part of published reporting standards for MBS, but these do not appear to be frequently used by researchers. Furthermore, we were unable to identify any eligible studies for SADI-S, and limited evidence for ESG.

While we had planned to include registry-based studies, the volume of literature surrounding registries was substantial. Given our resources (i.e., time and staffing constraints) and the need to focus on key evidence to inform committee decision making, we elected to instead conduct an original analysis of the US-based MBSAQIP registry to report 30-day safety-related outcomes.

Studies, particularly RCTs, enrolling patients under the age of 18 remain uncommon. We attempted to complement the lack of RCT evidence in the pediatric population with evidence from long-term NRSs. In the adult populations, despite studies enrolling patients up to age 65, the mean age was closer to 40 to 45 years, resulting in patients over the age of 50 not being well represented in the current evidence.

The evidence we reviewed lacks analysis by subgroups (e.g., race or ethnicity, age, comorbidity), thereby making it difficult to determine whether there are different efficacy, effectiveness, and safety profiles among patient groups and procedures.

Finally, the landscape surrounding pharmacotherapies for obesity has rapidly changed in the last few years. We did not identify any eligible studies that compared the effectiveness of MBS with newer pharmacotherapies (e.g., semaglutide, liraglutide); therefore we could not provide comparative clinical effectiveness between MBS procedures and these therapies.

Conclusions

Metabolic and bariatric surgeries continue to be a safe and effective intervention to reduce weight and resolve obesity-related comorbidities like hypertension and T2DM in adults with overweight or obesity. There remains limited published evidence for the use of MBS in children, adolescents, and individuals over the age of 50, but the available evidence does support the use of these interventions in adolescents. Serious adverse events and deaths are relatively rare in both adults and adolescents. Metabolic and bariatric surgeries are generally cost-effective compared with nonsurgical interventions. Many professional societies have recently updated their clinical practice guidelines by expanding eligibility criteria (e.g., lowering BMI thresholds and comorbidity status) as well as recognizing that there are differences in BMI for different races and ethnicities (e.g., obesity is defined as a BMI ≥ 27 kg/m^2 in some Asian populations). Guidance related to revisional surgeries remains scant. Public and private payer policies vary, but generally cover individuals with BMI ≥ 35 to < 40 kg/m^2 (with a comorbidity) or individuals with a BMI ≥ 40 kg/m^2 regardless of comorbidity status.

References

1. Mayo Clinic. Bariatric surgery: overview. 2023; https://www.mayoclinic.org/tests-procedures/bariatric-surgery/about/pac-20394258. Accessed January 16, 2024.

2. American Society for Metabolic and Bariatric Surgery. ASMBS endorsed procedures and FDA approved devices. 2022; https://asmbs.org/resources/endorsed-procedures-and-devices. Accessed October 12, 2023.

3. US Food and Drug Administration. Weight-loss and weight-management devices. 2023; https://www.fda.gov/medical-devices/products-and-medical-procedures/weight-loss-and-weight-management-devices. Accessed October 12, 2023.

4. World Health Organization. Obesity and overweight. 2021; https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight. Accessed January 14, 2024.

5. Kyle TK, Dhurandhar EJ, Allison DB. Regarding obesity as a disease: evolving policies and their implications. *Endocrinol Metab Clin North Am.* 2016;45(3):511-520. doi: 10.1016/j.ecl.2016.04.004.

6. Centers for Disease Control and Prevention. Defining adult overweight & obesity. 2022; https://www.cdc.gov/obesity/basics/adult-defining.html. Accessed January 16, 2024.

7. Centers for Disease Control and Prevention. Defining child BMI categories. 2023; https://www.cdc.gov/obesity/basics/childhood-defining.html. Accessed January 14, 2024.

8. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. *Pediatrics.* 2023;151(2). doi: 10.1542/peds.2022-060640.

9. Nuttall FQ. Body mass index: obesity, BMI, and Health: a critical review. *Nutr Today.* 2015;50(3):117-128. doi: 10.1097/NT.0000000000000092.

10. Gutin I. In BMI we trust: reframing the body mass index as a measure of health. *Soc Theory Health.* 2018;16(3):256-271. doi: 10.1057/s41285-017-0055-0.

11. American Medical Association. AMA adopts new policy clarifying role of BMI as a measure in medicine. 2023; https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine. Accessed January 14, 2024.

12. Centers for Disease Control and Prevention. Adult obesity facts. 2022; https://www.cdc.gov/obesity/data/adult.html. Accessed January 16, 2024.

13. Centers for Disease Control and Prevention. Childhood obesity facts. 2022; https://www.cdc.gov/obesity/data/childhood.html. Accessed January 16, 2024.

14. National Center for Health Statistics Home. Obesity and overweight. Centers for Disease Control and Prevention; 2023; https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Accessed October 12, 2023.

15. Waidmann TA, Waxman E, Pancini V, Gupta PK, Tabb LP. Obesity across America: geographic variation in disease prevalence and treatment options. Urban Institute; 2022; https://www.urban.org/sites/default/files/2022-02/obesity-across-america.pdf. Accessed January 18, 2024.

16. Centers for Disease Control and Prevention. Adult obesity maps. 2023; https://www.cdc.gov/obesity/data/prevalence-maps.html#overall. Accessed October 13, 2020.

17. Washington State Healthy Youth Survey. HYS fact sheets. 2021; https://www.askhys.net/SurveyResults/FactSheets. Accessed January 18, 2024.

18. Washington State Department of Health. Obesity data. https://doh.wa.gov/data-and-statistical-reports/diseases-and-chronic-conditions/obesity. Accessed February 2, 2024.

19. Masood B, Moorthy M. Causes of obesity: a review. *Clin Med (Lond).* 2023;23(4):284-291. doi: 10.7861/clinmed.2023-0168.

20. Centers for Disease Control and Prevention. Causes of obesity. 2022; https://www.cdc.gov/obesity/basics/causes.html. Accessed January 16, 2024.

21. Apovian CM. Obesity: definition, comorbidities, causes, and burden. *Am J Manag Care.* 2016;22(7 Suppl):s176-185.

22. Ranadive SA, Vaisse C. Lessons from extreme human obesity: monogenic disorders. *Endocrinol Metab Clin North Am.* 2008;37(3):733-751, x. doi: 10.1016/j.ecl.2008.07.003.

23. Bluher M. Obesity: global epidemiology and pathogenesis. *Nat Rev Endocrinol.* 2019;15(5):288-298. doi: 10.1038/s41574-019-0176-8.

24. Kim TJ, von dem Knesebeck O. Income and obesity: what is the direction of the relationship? a systematic review and meta-analysis. *BMJ Open.* 2018;8(1):e019862. doi: 10.1136/bmjopen-2017-019862.

25. Ogden CL, Fakhouri TH, Carroll MD, et al. Prevalence of obesity among adults, by household income and education - United States, 2011-2014. *MMWR Morb Mortal Wkly Rep.* 2017;66(50):1369-1373. doi: 10.15585/mmwr.mm6650a1.

26. Bower KM, Thorpe RJ, Jr., Rohde C, Gaskin DJ. The intersection of neighborhood racial segregation, poverty, and urbanicity and its impact on food store availability in the United States. *Prev Med.* 2014;58:33-39. doi: 10.1016/j.ypmed.2013.10.010.

27. Centers for Disease Control and Prevention. Consequences of obesity. 2022; https://www.cdc.gov/obesity/basics/consequences.html. Accessed January 16, 2024.

28. National Institute of Diabetes and Digestive and Kidney Diseases. Health risks of overweight & obesity. 2018; https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks. Accessed January 14, 2024.

29. Censin JC, Peters SAE, Bovijn J, et al. Causal relationships between obesity and the leading causes of death in women and men. *PLoS Genet.* 2019;15(10):e1008405. doi: 10.1371/journal.pgen.1008405.

30. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and adolescence on morbidity and premature mortality in adulthood: systematic review. *Int J Obes (Lond).* 2011;35(7):891-898. doi: 10.1038/ijo.2010.222.

31. Washington TB, Johnson VR, Kendrick K, et al. Disparities in access and quality of obesity care. *Gastroenterol Clin North Am.* 2023;52(2):429-441. doi: 10.1016/j.gtc.2023.02.003.

32. Wu YK, Berry DC. Impact of weight stigma on physiological and psychological health outcomes for overweight and obese adults: a systematic review. *J Adv Nurs.* 2018;74(5):1030-1042. doi: 10.1111/jan.13511.

33. Hilbert A, Braehler E, Haeuser W, Zenger M. Weight bias internalization, core self-evaluation, and health in overweight and obese persons. *Obesity (Silver Spring).* 2014;22(1):79-85. doi: 10.1002/oby.20561.

34. Vuik S, Lerouge A, Guillemette Y, Feigl A, Aldea A. The economic burden of obesity. OECD Health Policy Studies; 2019; https://www.oecd-ilibrary.org/sites/6cc2aacc-en/index.html?itemId=/content/component/6cc2aacc-en. Accessed January 14, 2024.

35. Di Lorenzo N, Antoniou SA, Batterham RL, et al. Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP. *Surg Endosc.* 2020;34(6):2332-2358. doi: 10.1007/s00464-020-07555-y.

36. Eisenberg D, Shikora SA, Aarts E, et al. 2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) indications for metabolic and bariatric surgery. *Obes Surg.* 2023;33(1):3-14. doi: 10.1007/s11695-022-06332-1.

37. Biertho L, Hong D, Gagner M. Bariatric surgery: surgical options and outcomes. 2020; https://obesitycanada.ca/wp-content/uploads/2021/05/13-Bariatric-Surgery-Surgical-Options-and-Outcomes-v6-with-links.pdf.

38. Chang SH, Stoll CR, Song J, Varela JE, Eagon CJ, Colditz GA. The effectiveness and risks of bariatric surgery: an updated systematic review and meta-analysis, 2003-2012. *JAMA Surg.* 2014;149(3):275-287. doi: 10.1001/jamasurg.2013.3654.

39. Carlsson LMS, Sjoholm K, Jacobson P, et al. Life expectancy after bariatric surgery in the Swedish Obese Subjects study. *N Engl J Med.* 2020;383(16):1535-1543. doi: 10.1056/NEJMoa2002449.

40. Pontiroli AE, Ceriani V, Tagliabue E. Compared with controls, bariatric surgery prevents long-term mortality in persons with obesity only above median age of cohorts: a systematic review and meta-analysis. *Obes Surg.* 2020;30(7):2487-2496. doi: 10.1007/s11695-020-04530-3.

41. Bout-Tabaku S, Gupta R, Jenkins TM, et al. Musculoskeletal pain, physical function, and quality of life after bariatric surgery. *Pediatrics.* 2019;144(6):12. doi: 10.1542/peds.2019-1399.

42. Ebell MH. Bariatric surgery improves quality of life and results in more weight loss than intensive medical therapy. *Am Fam Physician.* 2017;95(12):805.

43. Driscoll S, Gregory DM, Fardy JM, Twells LK. Long-term health-related quality of life in bariatric surgery patients: a systematic review and meta-analysis. *Obesity (Silver Spring).* 2016;24(1):60-70. doi: 10.1002/oby.21322.

44. Kim JC, Kim MG, Park JK, et al. Outcomes and adverse events after bariatric surgery: an updated systematic review and meta-analysis, 2013-2023. *J Metab Bariatr Surg.* 2023;12(2):76-88. doi: 10.17476/jmbs.2023.12.2.76.

45. Twells LK, Harris Walsh K, Blackmore A, et al. Nonsurgical weight loss interventions: a systematic review of systematic reviews and meta-analyses. *Obes Rev.* 2021;22(11):e13320. doi: 10.1111/obr.13320.

46. Kheniser K, Saxon DR, Kashyap SR. Long-term weight loss strategies for obesity. *J Clin Endocrinol Metab.* 2021;106(7):1854-1866. doi: 10.1210/clinem/dgab091.

47. Cleveland Clinic. GLP-1 agonists. 2023; https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists. Accessed February 2, 2024.

48. Vosoughi K, Atieh J, Khanna L, et al. Association of glucagon-like peptide 1 analogs and agonists administered for obesity with weight loss and adverse events: a systematic

review and network meta-analysis. *EClinicalMedicine*. 2021;42:101213. doi: 10.1016/j.eclinm.2021.101213.

49. Sarma S, Palcu P. Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: a systematic review and meta-analysis. *Obesity (Silver Spring)*. 2022;30(11):2111-2121. doi: 10.1002/oby.23563.

50. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of adult overweight and obesity. 2020; https://www.healthquality.va.gov/guidelines/CD/obesity/VADoDObesityCPGFinal5087242020.pdf. Accessed October 19, 2023.

51. Muniraj T, Day LW, Teigen LM, et al. AGA clinical practice guidelines on intragastric balloons in the management of obesity. *Gastroenterology*. 2021;160(5):1799-1808. doi: 10.1053/j.gastro.2021.03.003.

52. Sharaiha RZ, Shikora S, White KP, Macedo G, Toouli J, Kow L. Summarizing consensus guidelines on obesity management: a joint, multidisciplinary venture of the International Federation for the Surgery of Obesity & Metabolic Disorders (IFSO) and World Gastroenterology Organisation (WGO). *J Clin Gastroenterol*. 2023;57(10):967-976. doi: 10.1097/MCG.0000000000001916.

53. National Institute for Health and Care Excellence. Guideline: overweight and obesity management: draft for consultation. 2023; https://www.nice.org.uk/guidance/indevelopment/gid-ng10182/consultation/html-content-2. Accessed October 20, 2023.

54. Brown WA, de Leon Ballesteros GP, Ooi G, et al. Single anastomosis duodenal-ileal bypass with sleeve gastrectomy/one anastomosis duodenal switch (SADI-S/OADS) IFSO Position Statement-Update 2020. *Obes Surg*. 2021;31(1):3-25. doi: 10.1007/s11695-020-05134-7.

55. Rives-Lange C, Poghosyan T, Rassy N, et al. The future of bariatric surgery research: a worldwide mapping of registered trials. *Obes Rev*. 2022;23(6):e13433. doi: 10.1111/obr.13433.

56. Rives-Lange C, Rassy N, Carette C, et al. Seventy years of bariatric surgery: a systematic mapping review of randomized controlled trials. *Obes Rev*. 2022;23(5):e13420. doi: 10.1111/obr.13420.

57. Stein J, Stier C, Raab H, Weiner R. Review article: the nutritional and pharmacological consequences of obesity surgery. *Aliment Pharmacol Ther*. 2014;40(6):582-609. doi: 10.1111/apt.12872.

58. Lewis CA, de Jersey S, Seymour M, Hopkins G, Hickman I, Osland E. Iron, vitamin B(12), folate and copper deficiency after bariatric surgery and the impact on anaemia: a systematic review. *Obes Surg.* 2020;30(11):4542-4591. doi: 10.1007/s11695-020-04872-y.

59. Zolfaghari F, Khorshidi Y, Moslehi N, Golzarand M, Asghari G. Nutrient deficiency after bariatric surgery in adolescents: a systematic review and meta-analysis. *Obes Surg.* 2024;34(1):206-217. doi: 10.1007/s11695-023-06955-y.

60. Kim J, Nimeri A, Khorgami Z, et al. Metabolic bone changes after bariatric surgery: 2020 update, American Society for Metabolic and Bariatric Surgery Clinical Issues Committee position statement. *Surg.* 2021;17(1):1-8. doi: 10.1016/j.soard.2020.09.031.

61. Stein EM, Silverberg SJ. Bone loss after bariatric surgery: causes, consequences, and management. *Lancet Diabetes Endocrinol.* 2014;2(2):165-174. doi: 10.1016/S2213-8587(13)70183-9.

62. Axer S, Szabo E, Naslund I. Non-response after gastric bypass and sleeve gastrectomy-the theoretical need for revisional bariatric surgery: Results from the Scandinavian Obesity Surgery Registry. *Obes Surg.* 2023;33(10):2973-2980. doi: 10.1007/s11695-023-06783-0.

63. Giouleka S, Tsakiridis I, Koutsouki G, et al. Obesity in pregnancy: a comprehensive review of influential guidelines. *Obstet Gynecol Surv.* 2023;78(1):50-68. doi: 10.1097/OGX.0000000000001091.

64. Shawe J, Ceulemans D, Akhter Z, et al. Pregnancy after bariatric surgery: consensus recommendations for periconception, antenatal and postnatal care. *Obes Rev.* 2019;20(11):1507-1522. doi: 10.1111/obr.12927.

65. de la Cruz-Munoz N, Xie L, Quiroz HJ, et al. Long-term outcomes after adolescent bariatric surgery. *J Am Coll Surg.* 2022;235(4):592-602. doi: 10.1097/XCS.0000000000000325.

66. Wu Z, Gao Z, Qiao Y, et al. Long-term results of bariatric surgery in adolescents with at least 5 years of follow-up: a systematic review and meta-analysis. *Obes Surg.* 2023;33(6):1730-1745. doi: 10.1007/s11695-023-06593-4.

67. Haddad A, Kow L, Herrera MF, et al. Innovative bariatric procedures and ethics in bariatric surgery: the IFSO Position Statement. *Cas Lek Cesk.* 2023;161(7-8):285-295.

68. Malhotra S, Czepiel KS, Akam EY, et al. Bariatric surgery in the treatment of adolescent obesity: current perspectives in the United States. *Expert Rev Endocrinol Metab.* 2021;16(3):123-134. doi: 10.1080/17446651.2021.1914585.

69. Mayo Clinic. Bariatric surgery. 2022; https://www.mayoclinic.org/tests-procedures/bariatric-surgery/about/pac-20394258. Accessed October 13, 2023.

70. Carrano FM, Iossa A, Di Lorenzo N, et al. EAES rapid guideline: systematic review, network meta-analysis, CINeMA and GRADE assessment, and European consensus on bariatric surgery-extension 2022. *Surg Endosc.* 2022;36(3):1709-1725. doi: 10.1007/s00464-022-09008-0.

71. American Society for Metabolic and Bariatric Surgery. Bariatric surgery procedures. 2021; https://asmbs.org/patients/bariatric-surgery-procedures/. Accessed January 16, 2024.

72. Mechanick JI, Apovian C, Brethauer S, et al. Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures - 2019 Update: cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. *Obesity (Silver Spring).* 2020;28(4):O1-O58. doi: 10.1002/oby.22719.

73. Reoch J, Mottillo S, Shimony A, et al. Safety of laparoscopic vs open bariatric surgery: a systematic review and meta-analysis. *Arch Surg.* 2011;146(11):1314-1322. doi: 10.1001/archsurg.2011.270.

74. Brown WA, Shikora S, Liem R, et al. 7th IFSO global registry report. The International Federation for the Surgery of Obesity and Metabolic Disorders; 2022; https://www.ifso.com/pdf/ifso-7th-registry-report-2022.pdf. Accessed January 18, 2024.

75. Johns Hopkins Medicine. Endoscopic options for weight loss. https://www.hopkinsmedicine.org/health/wellness-and-prevention/endoscopic-options-for-weight-loss. Accessed January 18, 2024.

76. Crossan K, Sheer AJ. Intragastric balloon. StatPearls; 2023; https://www.ncbi.nlm.nih.gov/books/NBK578184/. Accessed October 13, 2023.

77. Seeras K, Acho R, Prakash S. Laparoscopic gastric band placement. StatPearls; 2023; https://www.ncbi.nlm.nih.gov/books/NBK526062/. Accessed October 13, 2023.

78. Lari E, Burhamah W, Lari A, Alsaeed T, Al-Yaqout K, Al-Sabah S. Intra-gastric balloons - the past, present and future. *Ann Med Surg (Lond).* 2021;63:102138. doi: 10.1016/j.amsu.2021.01.086.

79. Bhogal SK, Reddigan JI, Rotstein OD, et al. Inequity to the utilization of bariatric surgery: a systematic review and meta-analysis. *Obes Surg.* 2015;25(5):888-899. doi: 10.1007/s11695-015-1595-9.

80. Wallace AE, Young-Xu Y, Hartley D, Weeks WB. Racial, socioeconomic, and rural-urban disparities in obesity-related bariatric surgery. *Obes Surg.* 2010;20(10):1354-1360. doi: 10.1007/s11695-009-0054-x.

81. Perez NP, Westfal ML, Stapleton SM, et al. Beyond insurance: race-based disparities in the use of metabolic and bariatric surgery for the management of severe pediatric obesity. *Surg.* 2020;16(3):414-419. doi: 10.1016/j.soard.2019.11.020.

82. Sudan R, Winegar D, Thomas S, Morton J. Influence of ethnicity on the efficacy and utilization of bariatric surgery in the USA. *J Gastrointest Surg.* 2014;18(1):130-136. doi: 10.1007/s11605-013-2368-1.

83. Clapp B, Barrientes A, Dodoo C, et al. Disparities in access to bariatric surgery in Texas 2013-2017. *JSLS.* 2020;24(2). doi: 10.4293/JSLS.2020.00016.

84. Birkmeyer NJ, Gu N. Race, socioeconomic status, and the use of bariatric surgery in Michigan. *Obes Surg.* 2012;22(2):259-265. doi: 10.1007/s11695-010-0210-3.

85. Johnson-Mann C, Hassan M, Johnson S. Improving equity and access to bariatric surgery. *Lancet Gastroenterol Hepatol.* 2023;8(12):1068-1070. doi: 10.1016/S2468-1253(23)00277-7.

86. Funk LM, Jolles S, Fischer LE, Voils CI. Patient and referring practitioner characteristics associated with the likelihood of undergoing bariatric surgery: a systematic review. *JAMA Surg.* 2015;150(10):999-1005. doi: 10.1001/jamasurg.2015.1250.

87. Johnson-Mann C, Martin AN, Williams MD, Hallowell PT, Schirmer B. Investigating racial disparities in bariatric surgery referrals. *Surg.* 2019;15(4):615-620. doi: 10.1016/j.soard.2019.02.002.

88. Lawrence BJ, Kerr D, Pollard CM, et al. Weight bias among health care professionals: a systematic review and meta-analysis. *Obesity (Silver Spring).* 2021;29(11):1802-1812. doi: 10.1002/oby.23266.

89. Phelan SM, Burgess DJ, Yeazel MW, Hellerstedt WL, Griffin JM, van Ryn M. Impact of weight bias and stigma on quality of care and outcomes for patients with obesity. *Obes Rev.* 2015;16(4):319-326. doi: 10.1111/obr.12266.

90. Steinhart A, Tsao D, Pratt JSA. Pediatric metabolic and bariatric surgery. *Surg Clin North Am.* 2021;101(2):199-212. doi: 10.1016/j.suc.2020.12.007.

91. Vanguri P, Lanning D, Wickham EP, Anbazhagan A, Bean MK. Pediatric health care provider perceptions of weight loss surgery in adolescents. *Clin Pediatr (Phila).* 2014;53(1):60-65. doi: 10.1177/0009922813500848.

92. Woolford SJ, Clark SJ, Gebremariam A, Davis MM, Freed GL. To cut or not to cut: physicians' perspectives on referring adolescents for bariatric surgery. *Obes Surg.* 2010;20(7):937-942. doi: 10.1007/s11695-010-0152-9.

93. Inge TH, Boyce TW, Lee M, et al. Access to care for adolescents seeking weight loss surgery. *Obesity (Silver Spring).* 2014;22(12):2593-2597. doi: 10.1002/oby.20898.

94. Gebran SG, Knighton B, Ngaage LM, et al. Insurance coverage criteria for bariatric surgery: a survey of policies. *Obes Surg.* 2020;30(2):707-713. doi: 10.1007/s11695-019-04243-2.

95. Nunez Lopez O, Jupiter DC, Bohanon FJ, Radhakrishnan RS, Bowen-Jallow KA. Health disparities in adolescent bariatric surgery: nationwide outcomes and utilization. *J Adolesc Health.* 2017;61(5):649-656. doi: 10.1016/j.jadohealth.2017.05.028.

96. Hui BY, Roberts A, Thompson KJ, et al. Outcomes of bariatric surgery in African Americans: an analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) data registry. *Obes Surg.* 2020;30(11):4275-4285. doi: 10.1007/s11695-020-04820-w.

97. O'Neill SM, Needleman B, Narula V, Brethauer S, Noria SF. An analysis of readmission trends by urgency and race/ethnicity in the MBSAQIP registry, 2015-2018. *Surg.* 2022;18(1):11-20. doi: 10.1016/j.soard.2021.10.018.

98. Rahimi AO, Soliman D, Hsu C-H, Ghaderi I. The impact of gender, race, and ethnicity on bariatric surgery outcomes. *Surg.* 2024. doi: 10.1016/j.soard.2023.12.020.

99. Zhao J, Samaan JS, Abboud Y, Samakar K. Racial disparities in bariatric surgery postoperative weight loss and co-morbidity resolution: a systematic review. *Surg.* 2021;17(10):1799-1823. doi: 10.1016/j.soard.2021.06.001.

100. Ng J, Seip R, Stone A, Ruano G, Tishler D, Papasavas P. Ethnic variation in weight loss, but not co-morbidity remission, after laparoscopic gastric banding and Roux-en-Y gastric bypass. *Surg.* 2015;11(1):94-100. doi: 10.1016/j.soard.2014.07.013.

101. Jackson TN, Grinberg G, Khorgami Z, Shiraga S, Yenumula P. Medicaid expansion: the impact of health policy on bariatric surgery. *Surg.* 2023;19(1):20-26. doi: 10.1016/j.soard.2022.08.017.

102. Takemoto E, Andrea SB, Wolfe BM, Nagel CL, Boone-Heinonen J. Weighing in on bariatric surgery: effectiveness among Medicaid beneficiaries-limited evidence and future research needs. *Obesity (Silver Spring).* 2018;26(3):463-473. doi: 10.1002/oby.22059.

103. Liu N, Venkatesh M, Hanlon BM, et al. Association between Medicaid status, social determinants of health, and bariatric surgery outcomes. *Ann Surg Open.* 2021;2(1):e028. doi: 10.1097/AS9.0000000000000028.

104. Bouchard ME, Tian Y, Linton S, et al. Utilization trends and disparities in adolescent bariatric surgery in the United States 2009-2017. *Child Obes.* 2022;18(3):188-196. doi: 10.1089/chi.2021.0201.

105. Howard R, Yang J, Thumma J, et al. Health care use and adverse events after sleeve gastrectomy and gastric bypass among adolescents with severe obesity insured by Medicaid. *JAMA.* 2022;328(19):1972-1974. doi: 10.1001/jama.2022.14843.

106. Clapp B, Ponce J, Corbett J, et al. American Society for Metabolic and Bariatric Surgery 2022 estimate of metabolic and bariatric procedures performed in the United States. *Surg.* 2024;01:01. doi: 10.1016/j.soard.2024.01.012.

107. ElSayed NA, Aleppo G, Aroda VR, et al. 2. Classification and diagnosis of diabetes: standards of care in diabetes-2023. *Diabetes Care.* 2023;46(Suppl 1):S19-S40. doi: 10.2337/dc23-S002.

108. Hampl SE, Hassink SG, Skinner AC, et al. Executive summary: clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. *Pediatrics.* 2023;151(2). doi: 10.1542/peds.2022-060641.

109. Health Technology Clinical Committee. Findings and decision: bariatric surgery. Washington State Health Care Authority; 2015; https://www.hca.wa.gov/assets/program/bariatric_final_findings_decision_071015.pdf. Accessed October 13, 2023.

110. Washington State Health Care Authority. Health Technology Assessment Program: selected technologies 2023. 2023; https://www.hca.wa.gov/assets/program/Director-topic-selection-2023.pdf. Accessed October 13, 2023.

111. Bariatric surgery: final key questions. Washington State Health Care Authority; 2023; https://www.hca.wa.gov/assets/program/bariatric-surgery-final-key-questions-November-2023.pdf. Accessed February 16, 2024.

112. Bariatric surgery: draft key questions for public comment. Washington State Health Care Authority; 2023; https://www.hca.wa.gov/assets/program/bariatric-surgery-comment-response-KQ-November-2023.pdf. Accessed February 16, 2024.

113. Bariatric surgery. Washington State Health Care Authority; 2024; https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/bariatric-surgery. Accessed February 16, 2024.

114. de Vries CEE, Terwee CB, Al Nawas M, et al. Outcomes of the first global multidisciplinary consensus meeting including persons living with obesity to standardize patient-reported outcome measurement in obesity treatment research. *Obes Rev.* 2022;23(8):e13452. doi: 10.1111/obr.13452.

115. United Nations Development Programme. Human Development Report 2021-22. 2022; http://report.hdr.undp.org. Accessed November 13, 2023.

116. Ward N, Batalova J. Frequently requested statistics on immigrants and immigration in the United States: immigrants now and historically. Migration Information Source; Washington, DC; 2023; https://www.migrationpolicy.org/article/frequently-requested-statistics-immigrants-and-immigration-united-states#immigrants_now_historically. Accessed October 12, 2023.

117. Coulman KD, Hopkins J, Brookes ST, et al. A core outcome set for the benefits and adverse events of bariatric and metabolic surgery: the BARIACT project. *PLoS Med.* 2016;13(11):e1002187. doi: 10.1371/journal.pmed.1002187.

118. DistillerSR, Inc. DistillerSR [cloud-based systematic review software]. 2024; https://www.distillersr.com/.

119. Noel PH, Copeland LA, Perrin RA, et al. VHA corporate data warehouse height and weight data: opportunities and challenges for health services research. *J Rehabil Res Dev.* 2010;47(8):739-750. doi: 10.1682/jrrd.2009.08.0110.

120. McGlothlin AE, Lewis RJ. Minimal clinically important difference: defining what really matters to patients. *JAMA.* 2014;312(13):1342-1343. doi: 10.1001/jama.2014.13128.

121. Cook CE. Clinimetrics corner: the minimal clinically important change score (MCID): a necessary pretense. *J Man Manip Ther.* 2008;16(4):E82-83. doi: 10.1179/jmt.2008.16.4.82E.

122. Sedaghat AR. Understanding the minimal clinically important difference (MCID) of patient-reported outcome measures. *Otolaryngol Head Neck Surg.* 2019;161(4):551-560. doi: 10.1177/0194599819852604.

123. Grover BT, Morell MC, Kothari SN, Borgert AJ, Kallies KJ, Baker MT. Defining weight loss after bariatric surgery: a call for standardization. *Obes Surg.* 2019;29(11):3493-3499. doi: 10.1007/s11695-019-04022-z.

124. Park JY. Weight loss prediction after metabolic and bariatric surgery. *J Obes Metab Syndr.* 2023;32(1):46-54. doi: 10.7570/jomes23008.

125. Horn DB, Almandoz JP, Look M. What is clinically relevant weight loss for your patients and how can it be achieved? A narrative review. *Postgrad Med.* 2022;134(4):359-375. doi: 10.1080/00325481.2022.2051366.

126. van de Laar AW, van Rijswijk AS, Kakar H, Bruin SC. Sensitivity and specificity of 50% excess weight loss (50%EWL) and twelve other bariatric criteria for weight loss success. *Obes Surg.* 2018;28(8):2297-2304. doi: 10.1007/s11695-018-3173-4.

127. van de Laar AW, Nienhuijs SW, Apers JA, van Rijswijk AS, de Zoete JP, Gadiot RP. The Dutch bariatric weight loss chart: a multicenter tool to assess weight outcome up to 7 years after sleeve gastrectomy and laparoscopic Roux-en-Y gastric bypass. *Surg.* 2019;15(2):200-210. doi: 10.1016/j.soard.2018.11.024.

128. Tan SYT, Syn NL, Lin DJ, et al. Centile charts for monitoring of weight loss trajectories after bariatric surgery in Asian patients. *Obes Surg.* 2021;31(11):4781-4789. doi: 10.1007/s11695-021-05618-0.

129. Ching SS, Lee PC, Lim CH, et al. Study on weight loss outcomes after bariatric surgery to determine a metric least influenced by preoperative BMI. *Int J Obes (Lond).* 2023;47(10):993-999. doi: 10.1038/s41366-023-01349-7.

130. van Rijswijk AS, van Olst N, Schats W, van der Peet DL, van de Laar AW. What is weight loss after bariatric surgery expressed in percentage total weight loss (%TWL)? A systematic review. *Obes Surg.* 2021;31(8):3833-3847. doi: 10.1007/s11695-021-05394-x.

131. Corcelles R, Boules M, Froylich D, et al. Total weight loss as the outcome measure of choice after Roux-en-Y gastric bypass. *Obes Surg.* 2016;26(8):1794-1798. doi: 10.1007/s11695-015-2022-y.

132. van de Laar AW, Emous M, Hazebroek EJ, Boerma EJ, Faneyte IF, Nienhuijs SW. Reporting weight loss 2021: position statement of the Dutch Society for Metabolic and Bariatric Surgery (DSMBS). *Obes Surg.* 2021;31(10):4607-4611. doi: 10.1007/s11695-021-05580-x.

133. Blood Pressure Lowering Treatment Trialists' Collaboration. Pharmacological blood pressure lowering for primary and secondary prevention of cardiovascular disease across different levels of blood pressure: an individual participant-level data meta-analysis. *Lancet.* 2021;397(10285):1625-1636. doi: 10.1016/S0140-6736(21)00590-0.

134. Silverman MG, Ference BA, Im K, et al. Association between lowering LDL-C and cardiovascular risk reduction among different therapeutic interventions: a systematic

review and meta-analysis. *JAMA.* 2016;316(12):1289-1297. doi: 10.1001/jama.2016.13985.

135. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. *J Am Coll Cardiol.* 2019;73(24):3168-3209. doi: 10.1016/j.jacc.2018.11.002.

136. Child Outcomes Research Consortium. Beck Youth Inventory (BYI). 2024; https://www.corc.uk.net/outcome-experience-measures/beck-youth-inventory-byi/. Accessed February 9, 2024.

137. Crosby RD, Kolotkin RL, Williams GR. An integrated method to determine meaningful changes in health-related quality of life. *J Clin Epidemiol.* 2004;57(11):1153-1160. doi: 10.1016/j.jclinepi.2004.04.004.

138. Jarvholm K, Janson A, Peltonen M, et al. Metabolic and bariatric surgery versus intensive non-surgical treatment for adolescents with severe obesity (AMOS2): a multicentre, randomised, controlled trial in Sweden. *Lancet Child Adolesc Health.* 2023;7(4):249-260. doi: 10.1016/S2352-4642(22)00373-X.

139. Wadden TA, Phelan S. Assessment of quality of life in obese individuals. *Obes Res.* 2002;10 Suppl 1:50S-57S. doi: 10.1038/oby.2002.190.

140. Warkentin LM, Majumdar SR, Johnson JA, et al. Weight loss required by the severely obese to achieve clinically important differences in health-related quality of life: two-year prospective cohort study. *BMC Med.* 2014;12:175. doi: 10.1186/s12916-014-0175-5.

141. LeBlanc ES, Patnode CD, Webber EM, Redmond N, Rushkin M, O'Connor EA. Behavioral and pharmacotherapy weight loss interventions to prevent obesity-related morbidity and mortality in adults: updated evidence report and systematic review for the US Preventive Services Task Force. *JAMA.* 2018;320(11):1172-1191. doi: 10.1001/jama.2018.7777.

142. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterology.* 2022;163(5):1198-1225. doi: 10.1053/j.gastro.2022.08.045.

143. Skinner AC, Staiano AE, Armstrong SC, et al. Appraisal of clinical care practices for child obesity treatment. Part II: comorbidities. *Pediatrics.* 2023;151(2). doi: 10.1542/peds.2022-060643.

144. Skinner AC, Staiano AE, Armstrong SC, et al. Appraisal of clinical care practices for child obesity treatment. Part I: interventions. *Pediatrics.* 2023;151(2). doi: 10.1542/peds.2022-060642.

145. Axon E, Atkinson G, Richter B, et al. Drug interventions for the treatment of obesity in children and adolescents. *Cochrane Database Syst Rev.* 2016;11(11):CD012436. doi: 10.1002/14651858.CD012436.

146. Torbahn G, Jones A, Griffiths A, et al. Pharmacological interventions for the management of children and adolescents living with obesity-an update of a Cochrane systematic review with meta-analyses. *Pediatr Obes.* 2024:e13113. doi: 10.1111/ijpo.13113.

147. Rajjo T, Mohammed K, Alsawas M, et al. Treatment of pediatric obesity: an umbrella systematic review. *J Clin Endocrinol Metab.* 2017;102(3):763-775. doi: 10.1210/jc.2016-2574.

148. Prevention and management of childhood obesity in the primary care setting. UpToDate; 2024; https://www.uptodate.com/contents/prevention-and-management-of-childhood-obesity-in-the-primary-care-setting. Accessed April 1, 2024.

149. Blackstone R, Dimick JB, Nguyen NT. Accreditation in metabolic and bariatric surgery: pro versus con. *Surg.* 2014;10(2):198-202. doi: 10.1016/j.soard.2014.01.012.

150. DeMaria EJ, El Chaar M, Rogers AM, et al. American Society for Metabolic and Bariatric Surgery position statement on accreditation of bariatric surgery centers endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons. *Surg.* 2016;12(5):946-954. doi: 10.1016/j.soard.2016.04.020.

151. American College of Surgeons. Optimal resources for metabolic and bariatric surgery: standards manual. 2022; www.facs.org/quality-programs/accreditation-and-verification/metabolic-and-bariatric-surgery-accreditation-and-quality-improvement-program/standards/. Accessed April 15, 2024.

152. American College of Surgeons. Hospitals and facilities - bariatric surgery centers: Washington state. 2024; https://www.facs.org/hospital-and-facilities/?searchTerm=&institution=BariatricSurgeryCenter&address=WA&sort=a-z&page=1. Accessed January 17, 2024.

153. Gebhart A, Young M, Phelan M, Nguyen NT. Impact of accreditation in bariatric surgery. *Surg.* 2014;10(5):767-773. doi: 10.1016/j.soard.2014.03.009.

154. Centers for Medicare & Medicaid Services. Bariatric surgery for treatment of comorbid conditions related to obesity. 2013; https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=57. Accessed June 30, 2022.

155. Jacques L, Syrek Jensen T, Schafer J, Paserchia L, O'Connor D. Proposed decision memo for bariatric surgery for the treatment of morbid obesity–facility certification requirement (CAG-00250R3). CMS.gov; 2013; https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-

memo.aspx?proposed=Y&NCAId=266&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+-+Facility+Certification+Requirement&TimeFrame=7&DocType=All&bc=AQAAIAAACAAAAA%3D%3D&. Accessed January 18, 2024.

156. Ibrahim AM, Ghaferi AA, Thumma JR, Dimick JB. Variation in outcomes at bariatric surgery centers of excellence. *JAMA Surg.* 2017;152(7):629-636. doi: 10.1001/jamasurg.2017.0542.

157. Centers for Medicare & Medicaid Services. Bariatric surgery for the treatment of morbid obesity: facility certification requirement (CAG-00250R3). 2013; https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=266. Accessed January 24, 2024.

158. Aetna. Aetna institutes of quality bariatric surgery summary of criteria facility requirements for consideration. 2022; https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/individuals-families-health-insurance/document-library/Bariatric-IOQ-Program-Requirements.pdf. Accessed January 18, 2024.

159. Cigna. Cigna centers of excellence 2023 methodology. 2023; https://static.cigna.com/assets/chcp/pdf/resourceLibrary/medical/commit2Quality/cigna-centers-of-excellence-program-2023-methodology.pdf. Accessed January 18, 2024.

160. BlueCross BlueShield Association. Blue distinction specialty care centers for bariatric surgery: program selection criteria. 2020; https://www.bcbs.com/sites/default/files/file-attachments/page/Selection%20Criteria_2020%20Bariatric%20Surgery.pdf. Accessed January 18, 2024.

161. Roebroek YGM, Paulus GF, Talib A, et al. Weight loss and glycemic control after bariatric surgery in adolescents with severe obesity: a randomized controlled trial. *J Adolesc Health.* 2024;74(3):597-604. doi: 10.1016/j.jadohealth.2023.10.024.

162. Roebroek YGM, Paulus GF, van Mil E, et al. Bariatric surgery in adolescents: a prospective randomized controlled trial comparing laparoscopic gastric banding to combined lifestyle interventions in adolescents with severe obesity (BASIC trial). *BMC Pediatr.* 2019;19(1):34. doi: 10.1186/s12887-019-1395-9.

163. Courcoulas A, Abu Dayyeh BK, Eaton L, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. *Int J Obes (Lond).* 2017;41(3):427-433. doi: 10.1038/ijo.2016.229.

164. Ospanov O, Yeleuov G, Kadyrova I, Bekmurzinova F. The life expectancy of patients with metabolic syndrome after weight loss: study protocol for a randomized clinical trial (LIFEXPE-RT). *Trials.* 2019;20(1):202. doi: 10.1186/s13063-019-3304-9.

165. Abu Dayyeh BK, Bazerbachi F, Vargas EJ, et al. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. *Lancet.* 2022;400(10350):441-451. doi: 10.1016/S0140-6736(22)01280-6.

166. O'Brien PE, Brennan L, Laurie C, Brown W. Intensive medical weight loss or laparoscopic adjustable gastric banding in the treatment of mild to moderate obesity: long-term follow-up of a prospective randomised trial. *Obes Surg.* 2013;23(9):1345-1353. doi: 10.1007/s11695-013-0990-3.

167. O'Brien PE, Dixon JB, Laurie C, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. *Ann Intern Med.* 2006;144(9):625-633. doi: 10.7326/0003-4819-144-9-200605020-00005.

168. O'Brien PE, Sawyer SM, Laurie C, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. *JAMA.* 2010;303(6):519-526. doi: 10.1001/jama.2010.81.

169. Heinonen S, Saarinen T, Merilainen S, et al. Roux-en-Y versus one-anastomosis gastric bypass (RYSA study): weight loss, metabolic improvements, and nutrition at 1 year after surgery, a multicenter randomized controlled trial. *Obesity (Silver Spring).* 2023;31(12):2909-2923. doi: 10.1002/oby.23852.

170. Saarinen T, Merilainen S, Koivukangas V, Pietilainen KH, Juuti A. Prospective randomized controlled trial comparing the efficacy and safety of Roux-en-Y gastric bypass and one-anastomosis gastric bypass (the RYSA trial): trial protocol and interim analysis. *Trials.* 2019;20(1):803. doi: 10.1186/s13063-019-3898-y.

171. Sullivan S, Swain J, Woodman G, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss. *Surg.* 2018;14(12):1876-1889. doi: 10.1016/j.soard.2018.09.486.

172. Qi QYD, Playfair J, Brown WA, Burton P, O'Brien PE, Wentworth JM. Long-term impact of weight loss for people with overweight but not obesity, and with type 2 diabetes: 10-year outcomes of a randomized trial of gastric band surgery. *Diabetes Obes Metab.* 2023;25(6):1464-1472. doi: 10.1111/dom.14992.

173. Wentworth JM, Playfair J, Laurie C, et al. Multidisciplinary diabetes care with and without bariatric surgery in overweight people: a randomised controlled trial. *Lancet Diabetes Endocrinol.* 2014;2(7):545-552. doi: 10.1016/S2213-8587(14)70066-X.

174. Robert M, Espalieu P, Pelascini E, et al. Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial. *Lancet.* 2019;393(10178):1299-1309. doi: 10.1016/S0140-6736(19)30475-1.

175. Rothstein RI, Kopjar B, Woodman GE, et al. Randomized double-blind sham-controlled trial of a novel silicone-filled endoscopically placed device for weight loss. *Tech Innov Gastrointest Endosc.* 2024;26(1):21-29. doi: 10.1016/j.tige.2023.10.002.

176. Seetharamaiah S, Tantia O, Goyal G, et al. LSG vs OAGB-1 year follow-up data-a randomized control trial. *Obes Surg.* 2017;27(4):948-954. doi: 10.1007/s11695-016-2403-x.

177. Shivakumar S, Tantia O, Goyal G, et al. LSG vs MGB-OAGB-3 year follow-up data: a randomised control trial. *Obes Surg.* 2018;28(9):2820-2828. doi: 10.1007/s11695-018-3255-3.

178. Jain M, Tantia O, Goyal G, et al. LSG vs MGB-OAGB: 5-year follow-up data and comparative outcome of the two procedures over long term-results of a randomised control trial. *Obes Surg.* 2021;31(3):1223-1232. doi: 10.1007/s11695-020-05119-6.

179. Ospanov O, Akilzhanova A, Buchwald JN, et al. Stapleless vs stapled gastric bypass vs hypocaloric diet: a three-arm randomized controlled trial of body mass evolution with secondary outcomes for telomere length and metabolic syndrome changes. *Obes Surg.* 2021;31(7):3165-3176. doi: 10.1007/s11695-021-05454-2.

180. Janson A, Jarvholm K, Gronowitz E, et al. A randomized controlled trial comparing intensive non-surgical treatment with bariatric surgery in adolescents aged 13-16 years (AMOS2): rationale, study design, and patient recruitment. *Contemp Clin Trials Commun.* 2020;19:100592. doi: 10.1016/j.conctc.2020.100592.

181. Wentworth JM, Burton P, Laurie C, Brown WA, O'Brien PE. Five-year outcomes of a randomized trial of gastric band surgery in overweight but not obese people with type 2 diabetes. *Diabetes Care.* 2017;40(4):e44-e45. doi: 10.2337/dc16-2149.

182. Liang Z, Wu Q, Chen B, Yu P, Zhao H, Ouyang X. Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: a randomized controlled trial. *Diabetes Res Clin Pract.* 2013;101(1):50-56. doi: 10.1016/j.diabres.2013.04.005.

183. Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med.* 2012;366(17):1567-1576. doi: 10.1056/NEJMoa1200225.

184. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ.* 2021;372:n71. doi: 10.1136/bmj.n71.

185. Inge TH, Courcoulas AP, Jenkins TM, et al. Five-year outcomes of gastric bypass in adolescents as compared with adults. *N Engl J Med.* 2019;380(22):2136-2145. doi: 10.1056/NEJMoa1813909.

186. Inge TH, Courcoulas AP, Jenkins TM, et al. Weight loss and health status 3 years after bariatric surgery in adolescents. *N Engl J Med.* 2016;374(2):113-123. doi: 10.1056/NEJMoa1506699.

187. Ogle SB, Dewberry LC, Jenkins TM, et al. Outcomes of bariatric surgery in older versus younger adolescents. *Pediatrics.* 2021;147(3):03. doi: 10.1542/peds.2020-024182.

188. Olbers T, Beamish AJ, Gronowitz E, et al. Laparoscopic Roux-en-Y gastric bypass in adolescents with severe obesity (AMOS): a prospective, 5-year, Swedish nationwide study. *Lancet Diabetes Endocrinol.* 2017;5(3):174-183. doi: 10.1016/S2213-8587(16)30424-7.

189. Olbers T, Gronowitz E, Werling M, et al. Two-year outcome of laparoscopic Roux-en-Y gastric bypass in adolescents with severe obesity: results from a Swedish Nationwide Study (AMOS). *Int J Obes (Lond).* 2012;36(11):1388-1395. doi: 10.1038/ijo.2012.160.

190. Quality programs: participant use data file (PUF). American College of Surgeons; 2024; https://www.facs.org/quality-programs/accreditation-and-verification/metabolic-and-bariatric-surgery-accreditation-and-quality-improvement-program/participant-use-data-file-puf/. Accessed February 27, 2024.

191. Finkelstein EA, Verghese NR. Incremental cost-effectiveness of evidence-based non-surgical weight loss strategies. *Clin Obes.* 2019;9(2):e12294. doi: 10.1111/cob.12294.

192. Saumoy M, Gandhi D, Buller S, et al. Cost-effectiveness of endoscopic, surgical and pharmacological obesity therapies: a microsimulation and threshold analyses. *Gut.* 2023;72(12):2250-2259. doi: 10.1136/gutjnl-2023-330437.

193. Kyler KE, Bettenhausen JL, Hall M, Fraser JD, Sweeney B. Trends in volume and utilization outcomes in adolescent metabolic and bariatric surgery at children's hospitals. *J Adolesc Health.* 2019;65(3):331-336. doi: 10.1016/j.jadohealth.2019.02.021.

194. ClinicalTrials.gov. NCT04200144. Endoscopic sleeve gastroplasty for obesity and microbiota randomized trial (ESGORT). 2019; https://clinicaltrials.gov/study/NCT04200144. Accessed December 15, 2023.

195. ClinicalTrials.gov. NCT02692469. Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy vs laparoscopic duodenal switch (DSvsSADI). 2016; https://clinicaltrials.gov/study/NCT02692469. Accessed December 15, 2023.

196. ClinicalTrials.gov. NCT04060368. Efficacy and safety of endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy in obese subjects with NASH (TESLA-NASH). 2019; https://clinicaltrials.gov/study/NCT04060368. Accessed January 2, 2024.

197. ClinicalTrials.gov. NCT04800835. A study to compare the 12-month Spatz3 adjustable balloon with a 6-month non adjustable balloon. 2021; https://clinicaltrials.gov/study/NCT04800835. Accessed January 2, 2024.

198. ClinicalTrials.gov. NCT04812132. RCT comparing OAGB and long limb Roux gastric bypass (OAGBvsLLbypass). 2021; https://clinicaltrials.gov/study/NCT04812132. Accessed December 15, 2023.

199. ClinicalTrials.gov. NCT04854317. Bariatric endoscopy for treatment of obesity. 2021; https://clinicaltrials.gov/study/NCT04854317. Accessed December 15, 2023.

200. ClinicalTrials.gov. NCT04767490. Single anastomosis versus standard duodenal switch. 2021; https://clinicaltrials.gov/study/NCT04767490. Accessed January 2, 2024.

201. ClinicalTrials.gov. NCT03610256. Single-anastomosis duodeno ileal bypass (SADI) versus Roux-en-Y gastric bypass (SADISLEEVE). 2018; https://clinicaltrials.gov/study/NCT03610256. Accessed December 15, 2023.

202. UMIN Trial Registry. UMIN000038432. Bariatric surgery vs intensive medical therapy in mildly obese Japanese patients with early onset type 2 diabetes mellitus. 2019; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000043792. Accessed January 2, 2024.

203. ClinicalTrials.gov. NCT03875625. Change of adipose tissues and triglyceride after bariatric surgery or life-style intervention. 2019; https://clinicaltrials.gov/study/NCT03875625. Accessed December 15, 2023.

204. ClinicalTrials.gov. NCT03938571. Standard duodenal switch vs. single anastomosis duodeno-ileostomy duodenal switch. 2019; https://clinicaltrials.gov/study/NCT03938571. Accessed December 15, 2023.

205. ClinicalTrials.gov. NCT05948852. Two hypoabsorption techniques for the treatment of type III obesity (OASIS). 2023; https://clinicaltrials.gov/study/NCT05948852. Accessed December 15, 2023.

206. ClinicalTrials.gov. NCT05739162. A study of endoscopic sleeve gastroplasty for obesity in ulcerative colitis. 2023; https://clinicaltrials.gov/study/NCT05739162. Accessed December 15, 2023.

207. ClinicalTrials.gov. NCT04861961. Comparison of three hypoabsortive surgical techniques for treatment of Type IV morbid obesity (BAR-3). 2021; https://clinicaltrials.gov/study/NCT04861961. Accessed December 15, 2023.

208. ClinicalTrials.gov. NCT06138821. ESG vs GLP-1RA vs ESG + GLP-1RA in patients with obesity, NAFLD and advanced fibrosis: a randomized controlled trial. 2023; https://clinicaltrials.gov/study/NCT06138821. Accessed December 15, 2023.

209. ClinicalTrials.gov. NCT03472157. A randomized controlled study evaluating bariatric surgery as a treatment for severe NASH with advanced liver fibrosis in non-severe obese patients (NASHSURG). 2018; https://clinicaltrials.gov/study/NCT03472157. Accessed December 15, 2023.

210. ClinicalTrials.gov. NCT06057597. Omega gastric bypass (150cm) compared to the Roux-en-Y gastric bypass (YOMEGA-2 multicentric trial). 2023; https://clinicaltrials.gov/study/NCT06057597. Accessed December 15, 2023.

211. ClinicalTrials.gov. NCT00923819. 4XL study—obesity surgery in adolescence. 2009; https://clinicaltrials.gov/study/NCT00923819. Accessed December 15, 2023.

212. ClinicalTrials.gov. NCT04306445. How gas-filled intragastric balloons or endoscopic sleeve gastroplasty affect hunger, hunger hormones, and gastric emptying compared to meal replacements. 2020; https://clinicaltrials.gov/study/NCT04306445. Accessed December 15, 2023.

213. ClinicalTrials.gov. NCT04128995. Surgical or medical treatment for pediatric type 2 diabetes. 2019; https://clinicaltrials.gov/study/NCT04128995. Accessed December 15, 2023.

214. ClinicalTrials.gov. NCT05549271. 5 and 7-year follow-up of the YOMEGA trial cohort (YOMEGA 5-7y). 2022; https://clinicaltrials.gov/study/NCT05549271. Accessed December 15, 2023.

215. ClinicalTrials.gov. NCT04366999. Bariatric surgery effect nonalcoholic fatty liver disease. 2020; https://clinicaltrials.gov/study/NCT04366999. Accessed December 15, 2023.

216. ClinicalTrials.gov. NCT01344525. Pilot project on interdisciplinary therapy of obesity. 2011; https://clinicaltrials.gov/study/NCT01344525. Accessed December 15, 2023.

217. ClinicalTrials.gov. NCT03203161. A prospective observational cohort study collecting coordinated clinical, epidemiological, and behavioural data to assess safety and efficacy of surgical treatment in adolescent morbid obese patients. 2017; https://clinicaltrials.gov/study/NCT03203161. Accessed December 15, 2023.

218. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology clinical practice guideline for the diagnosis and management of nonalcoholic fatty liver disease in primary care and endocrinology clinical settings: co-sponsored by the American Association for the Study of Liver Diseases (AASLD). *Endocr Pract*. 2022;28(5):528-562. doi: 10.1016/j.eprac.2022.03.010.

219. Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2021;17(12):2499-2505. doi: 10.5664/jcsm.9592.

220. Kim KK, Haam JH, Kim BT, et al. Evaluation and treatment of obesity and its comorbidities: 2022 update of clinical practice guidelines for obesity by the Korean Society for the Study of Obesity. *J Obes Metab Syndr.* 2023;32(1):1-24. doi: 10.7570/jomes23016.

221. Sasaki A, Yokote K, Naitoh T, et al. Metabolic surgery in treatment of obese Japanese patients with type 2 diabetes: a joint consensus statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity. *Diabetol Int.* 2022;13(1):1-30. doi: 10.1007/s13340-021-00551-0.

222. Ministry of Public Health Qatar. National clinical guideline: bariatric & metabolic surgery in adults. 2021; https://www.moph.gov.qa/english/OurServices/eservices/Pages/Clinical-Guidelines.aspx. Accessed October 19, 2023.

223. Bischoff SC, Barazzoni R, Busetto L, et al. European guideline on obesity care in patients with gastrointestinal and liver diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology guideline. *United European Gastroenterol J.* 2022;10(7):663-720. doi: 10.1002/ueg2.12280.

224. Kallies K, Rogers AM, American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery updated statement on single-anastomosis duodenal switch. *Surg.* 2020;16(7):825-830. doi: 10.1016/j.soard.2020.03.020.

225. De Luca M, Piatto G, Merola G, et al. IFSO update position statement on one anastomosis gastric bypass (OAGB). *Obes Surg.* 2021;31(7):3251-3278. doi: 10.1007/s11695-021-05413-x.

226. Ciangura C, Coupaye M, Deruelle P, et al. Clinical practice guidelines for childbearing female candidates for bariatric surgery, pregnancy, and post-partum management after bariatric surgery. *Obes Surg.* 2019;29(11):3722-3734. doi: 10.1007/s11695-019-04093-y.

227. Yi DY, Kim SC, Lee JH, et al. Clinical practice guideline for the diagnosis and treatment of pediatric obesity: recommendations from the Committee on Pediatric Obesity of the Korean Society of Pediatric Gastroenterology Hepatology and Nutrition. *Pediatr Gastroenterol Hepatol Nutr.* 2019;22(1):1-27. doi: 10.5223/pghn.2019.22.1.1.

228. National Institute for Health Care Excellence. Endoscopic sleeve gastroplasty for obesity: interventional procedures guidance. 2024; https://www.nice.org.uk/guidance/ipg783. Accessed February 26, 2024.

229. MacKay D, Chan C, Dasgupta K, et al. Remission of type 2 diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group. *Can J Diabetes.* 2022;46(8):753-761 e758. doi: 10.1016/j.jcjd.2022.10.004.

230. Mahawar KK, Omar I, Singhal R, et al. The first modified Delphi consensus statement on sleeve gastrectomy. *Surg Endosc.* 2021;35(12):7027-7033. doi: 10.1007/s00464-020-08216-w.

231. Ghiassi S, Nimeri A, Aleassa EM, et al. American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass. *Surg.* 2024;20(4):319-335. doi: 10.1016/j.soard.2023.11.003.

232. Kermansaravi M, Parmar C, Chiappetta S, et al. Patient selection in one anastomosis/mini gastric bypass-an expert modified delphi consensus. *Obes Surg.* 2022;32(8):2512-2524. doi: 10.1007/s11695-022-06124-7.

233. Ramos AC, Chevallier JM, Mahawar K, et al. IFSO (International Federation for Surgery of Obesity and Metabolic Disorders) consensus conference statement on one-anastomosis gastric bypass (OAGB-MGB): results of a modified delphi study. *Obes Surg.* 2020;30(5):1625-1634. doi: 10.1007/s11695-020-04519-y.

234. Oregon Health Authority. Health Evidence Review Commission coverage guidance: bariatric procedures. 2023; https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/Coverage%20Guidance%20-%20Bariatric%20Procedures_as-approved-5-18-23.pdf. Accessed January 24, 2024.

235. Aetna. Obesity surgery medical clinical policy bulletin 0157. 2023; https://www.aetna.com/cpb/medical/data/100_199/0157.html#policy. Accessed January 24, 2024.

236. Cigna Healthcare. Bariatric surgery and procedures (policy number 0051). 2023; https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0051_coveragepositioncriteria_bariatric_surgery.pdf. Accessed January 24, 2024.

237. Regence BlueCross BlueShield. Bariatric surgery. 2024; https://blue.regence.com/trgmedpol/surgery/sur58.pdf. Accessed January 24, 2022.

238. Scottish Intercollegiate Guidelines Network. Methodology checklist 2: randomised controlled trials. 2015; https://www.sign.ac.uk/what-we-do/methodology/checklists/. Accessed October 30, 2020.

239. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ.* 2013;346:f1049. doi: 10.1136/bmj.f1049.

240. Evers S, Goossens M, de Vet H, van Tulder M, Ament A. Criteria list for assessment of methodological quality of economic evaluations: consensus on health economic criteria. *Int J Technol Assess Health Care.* 2005;21(2):240-245.

241. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ.* 2010;182(18):E839-842. doi: 10.1503/cmaj.090449.

242. Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 2: assessment of validity of items and tools to support application. *CMAJ.* 2010;182(10):E472-478. doi: 10.1503/cmaj.091716.

243. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ.* 2008;336(7650):924-926. doi: 10.1136/bmj.39489.470347.AD.

244. Schünemann H, Brozek J, Guyatt G, Oxman A, (editors). GRADE handbook: a handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013. The GRADE Working Group; 2014; http://gdt.guidelinedevelopment.org/app/handbook/handbook.html. Accessed December 6, 2023.

245. Dean A, Sullivan K, Soe M. OpenEpi: open source epidemiologic statistics for public health, version 3.01. 2024; https://www.openepi.com/Menu/OE_Menu.htm. Accessed January 26, 2024.

246. Shah AS, Helmrath MA, Inge TH, et al. Study protocol: a prospective controlled clinical trial to assess surgical or medical treatment for paediatric type 2 diabetes (ST(2)OMP). *BMJ Open.* 2021;11(8):e047766. doi: 10.1136/bmjopen-2020-047766.

247. Kim BK, Seo KW. Changes of guidelines in the management of obese patients with diabetes in the metabolic surgery perspective. *J Metab Bariatr Surg.* 2022;11(2):13-19. doi: 10.17476/jmbs.2022.11.2.13.

248. National Institute for Health Care Excellence. Interventional procedures consultation document: endoscopic sleeve gastroplasty for obesity. 2023; https://www.nice.org.uk/guidance/indevelopment/gid-ipg10300/consultation/html-content. Accessed October 20, 2023.

Appendix A. Clinical Evidence Methods

Search Strategy

We searched select clinical bibliographic databases (Table A1.) and gray literature clinical evidence sources to identify randomized controlled trials (RCTs), comparative nonrandomized studies (NRSs), large registry studies, cost-effectiveness studies, and clinical practice guidelines analyzing a listed metabolic and bariatric surgery (MBS) or related device of interest including the terms: *Roux-en-Y*, *intragastric balloon*, *bariatric surgery*, *sleeve gastrectomy*, *SADI-S*, *OAGB*, *overweight*, *obese*, and *body mass index* (see below for full search strategies). We limited records retrieved to those studies focused on human subjects and published in the English language after January 1, 2000. We also used study design and publication type (e.g., RCT, economic evaluation) filters to limit records retrieved. Systematic reviews were used for reference list searching and not as evidence sources. Searches were conducted on November 9 and 10, 2023.

Table A1. Bibliographic Databases Searched

Database	Platform	Issue/Version	Total Number of Records Retrieved
CENTRAL	Wiley	Issue 10 of 12, October 2023	2,011
MEDLINE ALL	Ovid	1946 to November 8, 2023	7,871

Abbreviation. CENTRAL: Cochrane Central Register of Controlled Trials.

Gray Literature Sources

- Agency for Healthcare Research and Quality (AHRQ)
  - Effective Health Care (EHC) Program
  - Evidence-based Practice Centers (EPC) Reports
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Oregon Health Evidence Review Commission (HERC)
- Institute for Clinical and Economic Review (ICER)/California Technology Assessment Forum (CTAF)
- International Health Technology Assessment (HTA) Database
- Veterans Administration Evidence-based Synthesis Program (VA-ESP)

We searched Medicare,[154] Oregon Medicaid,[234] Aetna,[235] Cigna,[236] and Regence BlueCross BlueShield (Regence)[237] and used general internet searches in DuckDuckGo and Google Scholar for background and gray literature searches. We also searched AHRQ, CADTH, HERC, ICER/CTAF, International HTA database, and VA-ESP. to identify systematic reviews and gray literature using the following search terms: *Roux-en-Y*, *intragastric balloon*, *bariatric surgery*, *sleeve gastrectomy*, *SADI-S*, *OAGB*, *overweight*, *obese*, and *body mass index*.

Ovid MEDLINE ALL Search Strategy

1. *Overweight/
2. Overweight.ti,ab,kf.
3. *Obesity/ or *Obesity, Morbid/ or *Pediatric Obesity/
4. (obese or obesity or superobes* or super-obes*).ti,ab,kf.

5. ((body mass index or bmi) adj2 ("85th percentile" or "90th percentile" or "94th percentile" or "95th percentile" or "96th percentile" or "97th percentile" or "98th percentile" or "99th percentile" or "120%" or "130%" or "140%" or "150%" or "160%")).ti,ab,kf.
6. ((body mass index or bmi) adj2 (24* or 25* or 26* or 27* or 28* or 29*)).ti,ab,kf.
7. ((body mass index or bmi) adj2 (30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*)).ti,ab,kf.
8. ((body mass index or bmi) adj2 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*)).ti,ab,kf.
9. ((body mass index or bmi) adj1 (50* or 51* or 52* or 53* or 54* or 55* or 56* or 57* or 58* or 59*)).ti,ab,kf.
10. ((body mass index or bmi) adj1 (60* or 65*)).ti,ab,kf.
11. ((body mass index or bmi) adj2 ("> 24*" or "≥ 24*" or " = 24*" or "> 25*" or "≥ 25*" or " = 25*" or "> 27.5*" or "≥ 27.5*" or " = 27.5*" or "> 29*" or "≥ 29*" or " = 29*")).ti,ab,kf.
12. ((body mass index or bmi) adj2 ("> 30*" or "≥ 30*" or "< 30*" or " ≤ 30*" or " = 30*" or "> 35*" or "≥ 35*" or "< 35*" or " ≤ 35*" or " = 35*" or "< 39*" or " ≤ 39*" or "> 39*" or "≥ 39*" or " = 39*")).ti,ab,kf.
13. ((body mass index or bmi) adj2 ("< 40*" or "> 40*" or "≥ 40*" or "< 40*" or " ≤ 40*" or " = 40*" or "> 45*" or "≥ 45*" or "< 45*" or " ≤ 45*" or " = 45*" or "< 49*" or " ≤ 49*" or "> 49*" or "≥ 49*" or " = 49")).ti,ab,kf.
14. ((body mass index or bmi) adj2 ("< 50*" or "> 50*" or "≥ 50*" or "< 50*" or " ≤ 50*" or " = 50*" or "> 55*" or "≥ 55*" or "< 55*" or " ≤ 55*" or " = 55*" or "< 59*" or " ≤ 59*" or "> 59*" or "≥ 59*" or " = 59")).ti,ab,kf.
15. ((body mass index or bmi) adj2 ("< 60*" or "> 60*" or "≥ 60*" or "< 60*" or " ≤ 60*" or " = 60*" or "> 65*" or "≥ 65*" or "< 65*" or " ≤ 65*" or " = 65*")).ti,ab,kf.
16. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (24* or 25* or 26* or 27* or 28* or 29*)).ti,ab,kf.
17. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*)).ti,ab,kf.
18. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*)).ti,ab,kf.
19. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (50* or 51* or 52* or 53* or 54* or 55* or 56* or 57* or 58* or 59*)).ti,ab,kf.
20. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (60* or 61* or 62* or 63* or 64* or 65* or 66* or 67* or 68* or 69*)).ti,ab,kf.
21. or/1-20
22. Obesity/su
23. Bariatric Surgery/
24. (bariatric adj2 (surger* or surgical or procedure* or operat*)).ti,ab,kf,kw.
25. (metabolic* adj2 (surger* or surgical)).ti,ab,kf,kw.

26. Biliopancreatic Diversion/
27. ((Biliopancr* or Bilio-pancr* or Bilio pancr*) adj2 (diversion* or bypass*)).ti,ab,kf,kw.
28. Gastric Bypass/
29. ((Gastric* or Gastroileal* or Gastro-ileal* or Gastro ileal* or intragastric* or intra gastric or intra-gastric*) adj2 (band* or bypass*)).ti,ab,kf,kw.
30. (Gastrojejunostom* or Gastro-jejunostom* or Gastro jejunostom*).ti,ab,kf,kw.
31. Gastroplasty/
32. (Gastroplast* or Gastro-plast* or Gastro plast*).ti,ab,kf,kw.
33. Anastomosis, Roux-en-Y/
34. (Roux en Y or Roux-en-Y or "Roux in Y" or Roux-in-Y or RYGB).ti,ab,kf,kw.
35. Gastrectomy/
36. gastrectom*.ti,ab,kf,kw.
37. ((gastric or intragastric or intra gastric or intra-gastric or stomach) adj2 stapl*).ti,ab,kf,kw.
38. Gastric Balloon/
39. ((Gastric* or Gastroileal* or Gastro-ileal* or Gastro ileal* or intragastric* or intra gastric or intra-gastric*) adj2 balloon*).ti,ab,kf,kw.
40. duoden* switch.ti,ab,kw,kf.
41. (((single-anastomosis duoden*-ileal or single anastomosis duoden* ileal) adj2 (bypass* or sleeve*)) or SADI-S).ti,ab,kf,kw.
42. ((single-anastomosis sleeve* or single anastomosis sleeve*) adj2 (bypass* or ileal)).ti,ab,kf,kw.
43. (One anastomosis gastric* bypass* or One-anastomosis gastric* bypass* or OAGB).ti,ab,kf,kw.
44. (Transoral gastric outlet reduction or Trans-oral gastric outlet reduction or transoral Outlet Reduction or trans-oral Outlet Reduction).ti,ab,kf,kw.
45. (Apollo ESG* or Apollo ESG Sx* or Apollo Revise* or Apollo Revise Sx* or Lap-Band* or Orbera* or Obalon*).mp.
46. or/22-45
47. random*.ti,ab. or ("clinical trial" or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or "multicenter study" or "randomized controlled trial").pt. or double-blind method/ or clinical trials as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or early termination of clinical trials as topic/ or multicenter studies as topic/ or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single* or doubl* or tripl* or treb* or quad*) adj1 (blind* or mask*))).ti,ab,kw. or ("2 arm" or "two arm" or "3 arm" or "three arm" or "4 arm" or "four arm" or "5 arm" or "five arm").ti,ab,kw. or quasi*.ti,ab.

48. (phase 3* or phase iii* or phase 4* or phase iv*).ti,ab. or (head-to-head or (compar* adj3 (effectiveness or efficacy))).ti,ab,kf. or Comparative Effectiveness Research/ or (active adj1 (comparator* or control$1 or treatment*)).ti,ab,kf.
49. (sham adj2 (procedure* or surger* or surgical or operation*)).ti,ab.
50. or/47-49
51. 21 and 46 and 50
52. Medicaid*.ti,kf. or (Medicaid/ or Dual MEDICAID MEDICARE Eligibility/)
53. 21 and 46 and 52
54. exp Intraoperative Complications/ or exp Postoperative Complications/
55. (adverse adj2 (event* or effect*)).ti,ab,kf.
56. (complication* or safe* or harm*).ti,ab,kf.
57. ((serious or rare) adj2 (reaction$1 or side effect*)).ti,ab,kf.
58. negative effect*.ti,ab,kf.
59. ((treatment-induced or treatment-related or treatment-associated) adj2 (reaction$1 or side effect*)).ti,ab,kf.
60. ((treatment induced or treatment related or treatment associated) adj2 (reaction$1 or side effect*)).ti,ab,kf.
61. ((surg*-induced or surg*-related or surg*-associated) adj2 (reaction$1 or side effect*)).ti,ab,kf.
62. ((surg* induced or surg* related or surg* associated) adj2 (reaction$1 or side effect*)).ti,ab,kf.
63. (Revision* or conversion* or reoperat* or re-operat* or re-intervention).ti,kf.
64. Deglutition Disorders/
65. deglutition disorder*.ti,ab,kf.
66. (swallow* adj2 (disorder* or difficult*)).ti,ab,kf.
67. dysphagi*.ti,ab,kf.
68. Malabsorption Syndromes/
69. (micronutrient* adj3 (status or absorption or absorb* or deficienc*)).ti,ab,kf.
70. (malnutrition or nutri* deficienc* or malabsor*).ti,ab,kf.
71. Gastroesophageal Reflux/ or Laryngopharyngeal Reflux/ or "Respiratory Aspiration of Gastric Contents"/
72. (((Gastr*-Esophageal or Gastr* Esophageal or Gastr*-oesophageal or Gastroesophageal or Supraesophageal Gastric or Supra-esophageal Gastric or Supra esophageal Gastric or Esophageal or oesophageal or Laryngopharyngeal) adj1 Reflux) or GERD).ti,ab,kf.
73. ((respiratory or pulmonary) adj2 aspiration).ti,ab,kf.
74. regurgitation.ti,ab,kf.
75. Esophageal Achalasia/

76. (Achalasia* or cardiospasm* or Megaesophagus).ti,ab,kf.
77. (death* or mortality).ti,ab,kf.
78. exp "Quality of Life"/ or Patient Reported Outcome Measures/
79. (HRQOL or quality of life or patient important outcome* or patient reported outcome* or patient-important outcome* or patient-reported outcome*).ti,ab,kf.
80. or/54-79
81. *cohort studies/ or *longitudinal studies/ or *follow-up studies/ or *prospective studies/ or *retrospective studies/ or cohort*.ti. or longitudinal*.ti. or long-term*.ti. or prospective*.ti. or retrospective*.ti.
82. *Case-Control Studies/ or *Control Groups/ or *Matched-Pair Analysis/ or ((case* adj5 control*) or (case adj3 comparison*) or control group*).ti.
83. Registries/ or (registr* or register$1 or national database*).ti,kw,kf.
84. or/81-83
85. 21 and 46 and 80 and 84
86. 21 and 46 and 84
87. limit 86 to adverse effects - surgical interventions
88. ("Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program*" or MBSAQIP*).mp.
89. (exp Animals/ not Humans/) or (baboon$1 or bovine$1 or canine$1 or cat$1 or chimpanzee$1 or cow$1 or dog$1 or feline$1 or fish or goat$1 or hens or macque$1 or mice or monkey$1 or mouse or murine$1 or ovine or pig$1 or porcine or primate$1 or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent$1 or zebrafish).ti.
90. (recommend* or consensus or guideline* or guidance or position* or society or coverage or standard$1).ti,kf.
91. (((clinical or care or treatment) adj3 pathway*) or (practice adj3 parameter*)).ti,ab,kw. or algorithms/ or clinical protocols/ or Consensus/ or Consensus Development Conference.pt. or Consensus Development Conference, NIH.pt. or Consensus Development Conferences as Topic/ or Consensus Development Conferences, NIH as Topic/ or critical pathway/ or guidelines as topic/ or practice guidelines as topic/ or Health Planning Guidelines/ or practice guideline/
92. or/90-91
93. 21 and 46 and 92
94. limit 93 to (english language and yr = "2019 -Current")
95. exp Cost-Effectiveness Analysis/ or exp Health Care Costs/ or exp Health Expenditures/ or "Costs and Cost Analysis"/
96. (cost or costs or cost-effective* or cost-utilit* or economic*).ti,kf.
97. or/95-96
98. 21 and 46 and 97
99. limit 98 to (english language and yr = "2019 -Current")

CENTRAL via Ovid

EBM Reviews – Cochrane Central Register of Controlled Trials (CENTRAL)

1. Overweight/
2. Overweight.ti,ab,kw.
3. Obesity/ or Obesity, Morbid/ or Pediatric Obesity/
4. (obese or obesity or superobes* or super-obes*).ti,ab,kw.
5. ((body mass index or bmi) adj2 ("85th percentile" or "90th percentile" or "94th percentile" or "95th percentile" or "96th percentile" or "97th percentile" or "98th percentile" or "99th percentile" or "120%25" or "130%25" or "140%25" or "150%25" or "160%25")).ti,ab,kw.
6. ((body mass index or bmi) adj2 (24* or 25* or 26* or 27* or 28* or 29*)).ti,ab,kw.
7. ((body mass index or bmi) adj2 (30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*)).ti,ab,kw.
8. ((body mass index or bmi) adj2 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*)).ti,ab,kw.
9. ((body mass index or bmi) adj1 (50* or 51* or 52* or 53* or 54* or 55* or 56* or 57* or 58* or 59*)).ti,ab,kw.
10. ((body mass index or bmi) adj1 (60* or 65*)).ti,ab,kw.
11. ((body mass index or bmi) adj2 ("> 24*" or "≥ 24*" or " = 24*" or "> 25*" or "≥ 25*" or " = 25*" or "> 27.5*" or "≥ 27.5*" or " = 27.5*" or "> 29*" or "≥ 29*" or " = 29*")).ti,ab,kw.
12. ((body mass index or bmi) adj2 ("> 30*" or "≥ 30*" or "< 30*" or " ≤ 30*" or " = 30*" or "> 35*" or "≥ 35*" or "< 35*" or " ≤ 35*" or " = 35*" or "< 39*" or " ≤ 39*" or "> 39*" or "≥ 39*" or " = 39*")).ti,ab,kw.
13. ((body mass index or bmi) adj2 ("< 40*" or "> 40*" or "≥ 40*" or "< 40*" or " ≤ 40*" or " = 40*" or "> 45*" or "≥ 45*" or "< 45*" or " ≤ 45*" or " = 45*" or "< 49*" or " ≤ 49*" or "> 49*" or "≥ 49*" or " = 49")).ti,ab,kw.
14. ((body mass index or bmi) adj2 ("< 50*" or "> 50*" or "≥ 50*" or "< 50*" or " ≤ 50*" or " = 50*" or "> 55*" or "≥ 55*" or "< 55*" or " ≤ 55*" or " = 55*" or "< 59*" or " ≤ 59*" or "> 59*" or "≥ 59*" or " = 59")).ti,ab,kw.
15. ((body mass index or bmi) adj2 ("< 60*" or "> 60*" or "≥ 60*" or "< 60*" or " ≤ 60*" or " = 60*" or "> 65*" or "≥ 65*" or "< 65*" or " ≤ 65*" or " = 65*")).ti,ab,kw.
16. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (24* or 25* or 26* or 27* or 28* or 29*)).ti,ab,kw.
17. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (30* or 31* or 32* or 33* or 34* or 35* or 36* or 37* or 38* or 39*)).ti,ab,kw.
18. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (40* or 41* or 42* or 43* or 44* or 45* or 46* or 47* or 48* or 49*)).ti,ab,kw.
19. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (50* or 51* or 52* or 53* or 54* or 55* or 56* or 57* or 58* or 59*)).ti,ab,kw.

20. ((bmi or body mass index) adj2 (over or above or greater* or excess* or "equal to" or less* or below) adj2 (60* or 61* or 62* or 63* or 64* or 65* or 66* or 67* or 68* or 69*)).ti,ab,kw.
21. or/1-20
22. Obesity/su
23. Bariatric Surgery/
24. (bariatric adj2 (surger* or surgical or procedure* or operat*)).ti,ab,kw.
25. (metabolic* adj2 (surger* or surgical)).ti,ab,kw.
26. Biliopancreatic Diversion/
27. ((Biliopancr* or Bilio-pancr* or Bilio pancr*) adj2 (diversion* or bypass*)).ti,ab,kw.
28. Gastric Bypass/
29. ((Gastric* or Gastroileal* or Gastro-ileal* or Gastro ileal* or intragastric* or intra gastric or intra-gastric*) adj2 (band* or bypass*)).ti,ab,kw.
30. (Gastrojejunostom* or Gastro-jejunostom* or Gastro jejunostom*).ti,ab,kw.
31. Gastroplasty/
32. (Gastroplast* or Gastro-plast* or Gastro plast*).ti,ab,kw.
33. Anastomosis, Roux-en-Y/
34. (Roux en Y or Roux-en-Y or "Roux in Y" or Roux-in-Y or RYGB).ti,ab,kw.
35. Gastrectomy/
36. gastrectom*.ti,ab,kw.
37. ((gastric or intragastric or intra gastric or intra-gastric or stomach) adj2 stapl*).ti,ab,kw.
38. Gastric Balloon/
39. ((Gastric* or Gastroileal* or Gastro-ileal* or Gastro ileal* or intragastric* or intra gastric or intra-gastric*) adj2 balloon*).ti,ab,kw.
40. duoden* switch.ti,ab,kw.
41. (((single-anastomosis duoden*-ileal or single anastomosis duoden* ileal) adj2 (bypass* or sleeve*)) or SADI-S).ti,ab,kw.
42. ((single-anastomosis sleeve* or single anastomosis sleeve*) adj2 (bypass* or ileal)).ti,ab,kw.
43. (One anastomosis gastric* bypass* or One-anastomosis gastric* bypass* or OAGB).ti,ab,kw.
44. (Transoral gastric outlet reduction or Trans-oral gastric outlet reduction or transoral Outlet Reduction or trans-oral Outlet Reduction).ti,ab,kw.
45. (Apollo ESG* or Apollo ESG Sx* or Apollo Revise* or Apollo Revise Sx* or Lap-Band* or Orbera* or Obalon*).mp.
46. or/22-45
47. ("Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program*" or MBSAQIP*).mp.
48. (21 and 46) or 47

49. (exp Animals/ not Humans/) or (baboon$1 or bovine$1 or canine$1 or cat$1 or chimpanzee$1 or cow$1 or dog$1 or feline$1 or fish or goat$1 or hens or macque$1 or mice or monkey$1 or mouse or murine$1 or ovine or pig$1 or porcine or primate$1 or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent$1 or zebrafish).ti.
50. (conference proceeding or dissertation thesis or trial registry record).pt.
51. or/49-50
52. 48 not 51
53. limit 52 to (yr = "2000 -Current" and english language)

Gray Literature Search Terms

- Adjustable gastric band
- Bariatric surgery
- Biliopancreatic diversion
- BPD
- Endoscopic sleeve gastroplasty
- ESG
- IGB
- Intragastric balloon
- Intragastric balloon
- OAGB
- Obalon
- One-anastomosis gastric bypass
- Orbera
- Roux-en-Y
- RYGB
- SADI-S
- Single-anastomosis duodenal ileostomy with sleeve gastrectomy
- Sleeve gastrectomy

Ongoing Studies

We searched the following sources for ongoing studies using the search terms:

- ClinicalTrials.gov
- ScanMedicine
- US Food and Drug Administration (FDA)

Clinical Practice Guidelines

We searched clinical practice guideline sources and performed general internet searches using DuckDuckGo to identify guidelines using the search terms: *Roux-en-Y*, *intragastric balloon*, *bariatric surgery*, *sleeve gastrectomy*, *SADI-S*, and *OAGB*. We searched the following sources for clinical practice guidelines published in the last 5 years:

- American Society for Metabolic and Bariatric Surgeons (ASMBS)
- Canadian Medical Association
- Guidelines International Network (GIN)
- National Institute for Health and Care Excellence (NICE)

- Ovid MEDLINE ALL
- Scottish Intercollegiate Guidelines Network (SIGN)
- US Preventive Services Task Force (USPSTF)
- Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guidelines

Inclusion and Exclusion Criteria

Table A2. Detailed Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Populations	
KQ1 • Adults with a BMI of ≥ 35 to < 40 without an obesity-related condition • Adults with a BMI of ≥ 30 to < 35 without T2DM • Adults with a BMI < 30 • Children and adolescents with overweight or obesity KQ2 • Adults with overweight or obesity • Children and adolescents with overweight or obesity	• Populations with overweight or obesity due to obesogenic factors (e.g., pregnancy, substance misuse, medication)
Interventions	
KQ1 • MBS procedures currently endorsed by the ASMBS[2] and FDA-approved devices,[3] alone or in combination with nonsurgical treatments (e.g., diet, exercise, medication) • Roux-en-Y gastric bypass • Adjustable gastric banding • Vertical sleeve gastrectomy • Biliopancreatic diversion (with or without duodenal switch) KQ2 • MBS procedures currently endorsed by the ASMBS[2] and FDA-approved devices,[3] alone or in combination with nonsurgical treatments (e.g., diet, exercise, medication) • Single-anastomosis duodenal ileostomy with sleeve gastrectomy • Intragastric balloon • One anastomosis gastric bypass • Endoscopic sleeve gastroplasty	• Non-ASMBS endorsed procedures • Non-FDA approved devices • Procedures or devices that are outdated and rarely practiced
Comparators	
• Nonsurgical weight management treatments (including antiobesity medication, diet-control programs, exercise, psychotherapy, and nutritional counseling), alone or in combination • Sham procedures combined with a nonsurgical weight management treatment • Head-to-head studies in children/adolescents (< 18) or for procedures listed in KQ2	• Treatments not available in the US (including outdated procedures [e.g., jejunoileal bypass] and devices [e.g., Garren-Edwards gastric bubble]) • Comparators other than those stated (e.g., comparison of different surgical techniques for the same procedure) • Pre- or post-operative protocols to reduce risk of complications and AEs (e.g., oxygenation, anesthesia, administration of medication) • Head-to-head studies unless otherwise noted

Inclusion Criteria	Exclusion Criteria
Outcomes[a,b]	
Efficacy and effectiveness • Weight • BMI • Comorbidity status (e.g., remission of T2DM) • Cardiovascular risk (e.g., major adverse cardiovascular event, blood pressure, HDL/LDL, triglycerides) • Health-related quality of life • Patient important outcomes (e.g., self-esteem, mobility, depression) using specific measurement tools as defined in 2022[114] • Revision or conversion surgery due to nonresponse (i.e., inadequate weight loss) or significant weight recurrence (i.e., regain) Safety • Serious AE (SAEs) • AEs of special interest • Difficulty swallowing (dysphagia/regurgitation) • Micronutrient status (i.e., vitamin B12, vitamin D, or anemia) • All-cause mortality (30-day or longer term) • Complications related to surgery (e.g., intraoperative organ injury, hernia) • Any procedure-specific reoperation or reintervention and classification of severity (e.g., strictures, leaks) Economic outcomes • Health care service use • Costs • Cost-effectiveness	• Studies not reporting outcomes of interest • Outcomes with less than 12 months post-intervention data (unless otherwise noted) • Economic outcomes from studies performed in non-US countries • Economic outcomes from studies performed in the US that were published more than 5 years ago • Other outcomes not listed
Timing	
• Any point in the treatment pathway[c]	• None stated
Setting	
Any nonemergency clinical setting in: • Countries categorized as very high on the UN HDI[115] • Central America and the Caribbean • Top 10 countries with the highest number of immigrants to the US (e.g., Mexico, China, India)[115]	• Nonclinical settings (e.g., animal models of disease) • Countries categorized as high, medium, or low on the UN HDI, unless otherwise noted
Study design	
For KQ1 to KQ4 • RCTs (≥ 50 participants) • Prospective comparative NRSs for interventions where RCTs are not available (≥ 100 participants) • Large registry studies (≥ 1,000 individuals) for safety outcomes only For KQ5 • Comparative studies and economic evaluations • Cost-effectiveness analyses • Economic simulation modeling studies	• Abstracts, conference proceedings, posters, editorials, letters • Studies without a comparator • Placebo-controlled studies • Proof-of-principle studies (e.g., procedure development, technique modification) • Studies without extractable data • Uncontrolled studies • Retrospective studies unless otherwise noted

Inclusion Criteria	Exclusion Criteria
Sample size	

Minimum sample size of:
• 50 participants for RCTs
• 100 participants for comparative NRS designs
  ○ ≥ 50 participants if aged < 18 years (children and adolescents)
• 1,000 participants for registry studies
  ○ ≥ 500 participants if < 18 years (children and adolescents)
	• Studies that do not meet the minimum sample size

Publication	
• Peer-reviewed publications • Published in the English-language • Published from January 1, 2000, to present • Economic studies published from January 1, 2019	• Studies reported only as abstracts that do not allow study characteristics to be determined • Studies that cannot be found • Duplicate publications of the same study that do not report different outcomes or follow-up times, or single-site reports from published multicenter studies • Studies published in languages other than English • Studies that have not been formally peer reviewed (i.e., preprint publications)

Notes. [a] Published core outcome sets and multiperspective consensus statements were reviewed for clinical and patient-important outcomes.[114,117] [b] For studies examining intragastric balloons, 6-month outcomes are eligible, if they also report longer term outcomes, since these devices are generally removed no later than 6-months post-implantation. [c] The aim is to include studies regardless of any prior obesity-related treatments since presurgical requirements can vary across individual characteristics (e.g., age, severity of comorbidities), time periods, and geographical regions.
Abbreviations. AE: adverse event; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; FDA: US Food and Drug Administration; HDL: high-density lipoprotein (cholesterol); KQ: key question; LDL: low-density lipoprotein (cholesterol); MBS: metabolic and bariatric surgery; NRS: nonrandomized study; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus; UN HDI: United Nations Human Development Index.[115]

Screening

Two experienced researchers independently screened all titles and abstracts of identified documents. In cases in which there was disagreement about eligibility, a third experienced researcher resolved the disagreement. This method was repeated for full-text review of documents that could not be excluded by title and abstract screening.

Data Abstraction

One experienced researcher abstracted and entered data from eligible studies in a standardized way using DistillerSR.[118] A second experienced researcher reviewed all the data entered. We attempted to resolve discrepancies through discussion. When discussion did not resolve the issue, a third experienced researcher settled disagreements.

Participant Characteristics and Association with Outcomes

When discussing risk and protective factors or variables in statistical models in Center for Evidence-based Policy research products, in almost all cases, we are referring to associations of participant characteristics with outcomes, and not causation of outcomes. This is important because participant characteristics, such as race and ethnicity, serve as proxy or surrogate measures for underlying etiological factors not measured or evaluated in analyses. Etiological factors that might cause differences in outcomes for subgroups of participants could include systemic racism or other forms of systemic discrimination, stress, poverty, housing instability, or epigenetics. For example, by describing any differences in outcomes by race and ethnic groups, we are noting observed associations; these associations are not caused by biological determinants of being Black, White, or Hispanic.

Risk-of-Bias Assessment

We assessed the risk of bias of the included RCTs, economic analyses, and clinical practice guidelines using standard instruments developed and adapted by DERP that are modifications of instruments used by national and international standards for quality.[238-240] Two experienced researchers independently rated all included studies. In cases in which there was disagreement about the risk of bias of a study, a third rater resolved the disagreement.

Randomized Controlled Trials

Low-risk-of-bias randomized controlled trials include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Low-risk-of-bias randomized controlled trials also have low potential for bias from conflicts of interest and funding source(s). Moderate-risk-of-bias randomized controlled trials have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. High-risk-of-bias randomized controlled trials have clear flaws that could introduce significant bias.

Clinical Practice Guidelines

We assessed the methodological quality of the guidelines using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration.[241,242]. Each rater assigned the study a rating of good, fair, or poor based on its adherence to recommended methods and potential for biases. A good-quality guideline fulfills all or most of the criteria outlined in the instrument. A fair-quality guideline fulfills some of the criteria, and its unfulfilled criteria are not likely to alter the recommendations. A poor-quality guideline met few or none of the criteria.

Certainty of Evidence Assessment

We assigned each outcome a summary judgment for the overall certainty of evidence based on the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation Working Group (GRADE).[243,244] Two independent experienced researchers assigned ratings, with disagreements resolved by a third rater. The GRADE system defines the overall certainty of a body of evidence for an outcome in the following manner:

- **High:** Raters are very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect. Typical sets of studies are randomized controlled trials with few or no limitations, and the estimate of effect is likely stable.
- **Moderate:** Raters are moderately confident in the estimate of the effect of the intervention on the outcome. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is different. Typical sets of studies are randomized controlled trials with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.
- **Low:** Raters have little confidence in the estimate of the effect of the intervention on the outcome. The true effect may be substantially different from the estimate of the effect. Typical sets of studies are randomized controlled trials with serious limitations or nonrandomized studies without special strengths.
- **Very low:** Raters have no confidence in the estimate of the effect of the intervention on the outcome. The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.
- **Not applicable:** Researchers did not identify any eligible articles.

Additional Methods

Table A3. Risk-of-Bias Assessment: Randomized Controlled Trials

Domain	Domain Elements[a]
Randomization	• An appropriate method of randomization is used to allocate participants or clusters to groups, such as a computer random number generator • Baseline characteristics between groups or clusters are similar
Allocation concealment	• An adequate concealment method is used to prevent investigators and participants from influencing enrollment or intervention allocation
Intervention	• Intervention and comparator intervention applied equally to groups • Co-interventions appropriate and applied equally to groups • Control selected is an appropriate intervention
Outcomes	• Outcomes are measured using valid and reliable measures • Investigators use single outcome measures and do not rely on composite outcomes, or outcome of interest can be calculated from composite outcome • The trial has an appropriate length of follow-up and groups are assessed at same time points • Outcome reporting of entire group or subgroups is not selective
Masking (blinding) of investigators and participants	• Investigators and participants are unaware (masked or blinded) of intervention status
Masking (blinding) of outcome assessors	• Outcome assessors are unaware (masked or blinded) of intervention status
Intention-to-treat analysis	• Participants are analyzed based on random assignment (intention-to-treat analysis)
Statistical analysis	• Participants lost to follow-up unlikely to significantly bias results (i.e., complete follow-up of ≥ 80% of participants overall and nondifferential, ≤ 10% difference between groups) • The most appropriate summary estimate (e.g., risk ratio, hazard ratio) is used • Paired or conditional analysis used for crossover RCT • Clustering appropriately accounted for in a cluster-randomized trial (e.g., use of an intraclass correlation coefficient)
Other biases (as appropriate)	• List others in table footnote and describe, such as: • Sample size adequacy • Interim analysis or early stopping • Recruitment bias, including run-in period used inappropriately • Use of unsuitable crossover intervention in a crossover RCT
Interest disclosure	• Disclosures of interest are provided for authors/funders/commissioners of study • Interests are unlikely to significantly affect study validity
Funding	• There is a description of source(s) of funding • Funding source is unlikely to have a significant impact on study validity

Note. [a] *The elements included in each domain are assessed and rated as* Yes, No, Unclear, *or* Not Applicable *based on performance and documentation of individual elements in each domain. The overall risk of bias for study is assessed as* High, Moderate, *or* Low *based on assessment of how well overall study methods and processes were performed to limit bias and ensure validity.*
Abbreviation. RCT: randomized controlled trial.

Table A4. Risk-of-Bias Assessment: Economic Modeling Studies

Domain	Domain Elements[a]
Target population	• Target population and care setting described • Describe and justify basis for any target population stratification, identify any previously identifiable subgroups • If no subgroup analyses were performed, justify why these were not required
Perspective	• State and justify analytic perspective (e.g., societal, payer, etc.)
Time horizon	• Describe and justify time horizon(s) used in analysis
Discount rate	• State and justify discount rate used for costs and outcomes
Comparators	• Describe and justify selected comparators • Competing alternatives appropriate and clearly described
Modeling	• Model structure (e.g., scope, assumptions made) is described and justified • Model diagram provided, if appropriate • Model validation is described (may involve validation of different aspects such as structure, data, assumptions, and coding and different validation models such as comparison with other models) • Data sources listed and assumptions for use justified • Statistical analyses are described
Effectiveness	• Estimates of efficacy/effectiveness of interventions are described and justified • The factors likely to have an impact on effectiveness (e.g., adherence, diagnostic accuracy, values, and preferences) are described and an explanation of how these were factored into analysis is included • The quality of evidence for relationship between intervention and outcomes, and any necessary links, is described
Outcomes	• All relevant outcomes are identified, measured, and valued appropriately (including harms/adverse events) for each intervention, and justification for information/assumptions is given • Any quality of life measures used in modeling are described and use justified • Any other outcomes that were considered but rejected are described with rationale for rejection • Ethical and equity-related outcomes are considered and included when appropriate
Resource use/costs	• All resources used are identified, valued appropriately, and included in analyses • Methods for costing are reporting (e.g., patient level) • Resource quantities and unit costs are both reported • Methods for costing time (e.g., lost time, productivity losses) are appropriate and a justification is provided if time costs are not considered
Uncertainty	• Sources of uncertainty in analyses are identified and justification for probability distributions used in probabilistic analyses are given • For scenario analyses, values and assumptions tested are provided and justified
Results	• All results are presented in a disaggregated fashion, by component, in addition to an aggregated manner • All results are presented with undiscounted totals before discounting and aggregation • Natural units are presented along with alternative units (e.g., QALYs) • The components of incremental cost-effectiveness ratio (ICER) are shown (e.g., mean costs of each intervention in numerator and mean outcomes of each intervention in denominator) • Results of scenario analyses, including variability in factors such as practice patterns and costs, are reported and described in relation to reference (base) case

Domain	Domain Elements[a]
Interest disclosure	• Disclosures of interest are provided for authors/funders/commissioners of study • Interests are unlikely to significantly affect study validity
Funding source	• There is a description of source(s) of funding • Funding source is unlikely to have a significant impact on study validity

Note. [a] *The elements included in each domain are assessed and rated as Yes,* No, Unclear, *or* Not Applicable *based on performance and documentation of individual elements in each domain. The overall risk of bias for study is assessed as* High, Moderate, *or* Low *based on assessment of how well overall study methods and processes were performed to limit bias and ensure validity.*
Abbreviation. QALY: quality-adjusted life year.

Table A5. Risk-of-Bias Assessment: Clinical Practice Guidelines

Domain	Domain Elements[a]
Rigor of development: Evidence	• Systematic literature search meets quality standards for a systematic review (i.e., comprehensive search strategy with, at a minimum, 2 or more electronic databases) • The criteria used to select evidence for inclusion is clear and appropriate • The strengths and limitations of individual evidence sources is assessed and overall quality of body of evidence assessed
Rigor of development: Recommendations	• Methods for developing recommendations clearly described and appropriate • There is an explicit link between recommendations and supporting evidence • The balance of benefits and harms is considered in formulating recommendations • The guideline has been reviewed by external expert peer reviewers • The updating procedure for guideline is specified in guideline or related materials (e.g., specialty society website)
Editorial independence	• There is a description of source(s) of funding and views of funder(s) are unlikely to have influenced content or validity of guideline • Disclosures of interests for guideline panel members are provided and are unlikely to have a significant impact on overall validity of guideline (e.g., a process for members to recuse themselves from participating on recommendations for which a significant conflict is provided)
Scope and purpose	• Objectives specifically described • Health question(s) specifically described • Target population(s) for guideline recommendations is specified (e.g., patients in primary care) and target users for guideline (e.g., primary care clinicians)
Stakeholder involvement	• Relevant professional groups represented • Views and preferences of target population(s) sought (e.g., clinicians and patients)
Clarity and presentation	• Recommendations are specific and unambiguous • Different management options are clearly presented • Key recommendations are easily identifiable
Applicability	• Provides advice and/or tools on how recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered • Criteria for implementation monitoring, audit, and/or performance measures based on guideline are presented

Note. [a] *Assessment indicates how well guideline methodology and development process were performed to limit bias and ensure validity for elements in domain (each domain rated as* Good, Fair, *or* Poor *overall based on performance and documentation of elements).*

Appendix B. Full Evidence Tables for Studies Conducted in Adults

Adults Currently Covered for MBS Procedures Under the 2015 Washington Coverage Determination

Table B1. Study Details, RCTs for BMI ≥ 30 to < 35 kg/m^2 and an Obesity-Related Issue or Comorbidity in Adults[166,167]

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
O'Brien, 2006 ACTRN012605000113651 Australia, New Zealand 2000 to 2011	To ascertain whether surgical therapy for obesity with AGB achieves better weight loss, health, and quality of life than nonsurgical therapy.	• AGB • Lifestyle + orlistat	N = 80 2 years + 8 years Eligibility • BMI ≥ 30 to < 35 kg/m^2 • Age, 20 to 50 years	With identifiable problems, including an obesity-related comorbid condition (such as hypertension, dyslipidemia, T2DM, OSA, or GERD), severe physical limitations, or clinically significant psychosocial problems associated with their obesity; at least 1 attempt to reduce weight over the previous 5 years	History of bariatric surgery; medical problems that contraindicated treatment with bariatric surgery, such as impaired mental status, drug or alcohol addiction, or portal hypertension; past participation in an intensive, physician-supervised program that used very-low-calorie diets or pharmacotherapy; failure to attend the 2 initial patient information visits

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; GERD: gastroesophageal reflux disease; OSA: obstructive sleep apnea; T2DM: type 2 diabetes mellitus.

Table B2. Full Baseline Characteristics, BMI ≥ 30 to < 35 kg/m^2 and an Obesity-Related Issue or Comorbidity in Adults[166,167]

Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)[b]
O'Brien, 2006	AGB	41.8 (6.4)	30 (75.0)	NR	33.7 (1.8)	96.1 (11.2)	• Hypertension: 9 (22.5) • Metabolic syndrome: 15 (37.5) • Coronary artery disease: 0
	Lifestyle	40.7 (7.0)	31 (87.5)	NR	33.5 (1.4)	93.6 (11.9)	• Hypertension: 7 (17.5) • Metabolic syndrome: 15 (37.5) • Coronary artery disease: 0

Note. [a] Details of non-White population were not reported. [b] Current medications for comorbidities were not reported.
Abbreviations. BMI: body mass index; NR: not reported; SD: standard deviation.

Table B3. Weight Outcomes, BMI ≥ 30 to < 35 kg/m^2 and an Obesity-Related Issue or Comorbidity in Adults[166,167]

Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline, or Proportion	Between-Group Differences	*P* Value
Excess weight loss							
O'Brien, 2006	EWL, % (SD)	1	AGB	40	78.6 (95% CI, 69.2 to 88.1)	NR	*P* < .001
			Lifestyle + orlistat	40	41.1 (95% CI, 31.2 to 50.9)		
		1.5	AGB	40	83.6 (95% CI, 74.2 to 93.1)		
			Lifestyle + orlistat	40	29.0 (95% CI, 19.0 to 38.9)		
		2	AGB	40	87.2 (95% CI, 77.7 to 96.6)		
			Lifestyle + orlistat	40	21.8 (95% CI, 11.9 to 31.6)		
		10[a]	AGB	40	48.85 (SD, 44.78)		
			Lifestyle + orlistat	40	11.38 (SD, 40.70)		
O'Brien, 2006	EWL ≥ 25%, n (%)	2	AGB	40	39 (97.5)		
			Lifestyle + orlistat	40	14 (35.0)		
O'Brien, 2006	EWL ≥ 50%, n (%)		AGB	39	33 (84.6)		
			Lifestyle + orlistat	31	8 (25.8)		
Total weight loss							
O'Brien, 2006	TWL, % (SD)	2	AGB	40	21.6 (95% CI, 19.3 to 23.9)	NR	*P* < .001
			Lifestyle + orlistat	40	5.5 (95% CI, 3.2 to 7.9)		
Weight loss							
O'Brien, 2006	Weight loss, % (SD)	2	AGB	39	20.5 (6.4)	MD, NR (95% CI, −18.9 to −11.6)	NR
			Lifestyle	31	6.1 (8.5)		

Note. [a] *O'Brien and colleagues completed an intention-to-treat analysis at 10 years.*

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; EWL: excess weight loss; MD: mean difference; NR: not reported; SD: standard deviation; TWL: total weight loss.

Table B4. Cardiovascular Outcomes, BMI ≥ 30 to < 35 kg/m^2 and Obesity-Related Issue or Comorbidity in Adults[166,167]

Author, Year	Specific Outcome	Timepoint, years	Intervention			Comparator			Between-group comparisons	*P* Value
			Intervention Group	N Reported	Mean Change from Baseline, or Proportion	Comparator Group	N Reported	Mean Change from Baseline, or Proportion		
Comorbid conditions										
O'Brien, 2006	Active metabolic syndrome, n (%)	2	AGB	39	1 (2.7)	Lifestyle	33	8 (24.2)	NR	*P* = .006
O'Brien, 2006	Active metabolic syndrome, n (%)	10	AGB	27	3 (11.1)	Lifestyle without crossovers	10	4 (40.0)	NR	NR
O'Brien, 2006	Resolution of metabolic syndrome, n (%)	2	AGB	15	14 (93.3)	Lifestyle	15	7 (46.7)	NR	NR
Cholesterol-related										
O'Brien, 2006	HDL, mg/dL (SD)	2	AGB	39	30.0 (28.9)	Lifestyle	31	6.9 (18.9)	95% CI, 10.6 to 35.4	*P* < .05
O'Brien, 2006	Total cholesterol, mg/dL change (SD)	2	AGB	39	−0.4 (18.1)	Lifestyle	31	−3.0 (17.0)	95% CI, −25.7 to −4.7	*P* > .05

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; HDL: high-density lipoprotein cholesterol; NR: not reported; SD: standard deviation.

Table B5. HRQoL Outcomes, BMI ≥ 30 to < 35 kg/m^2 and Obesity-Related Issue or Comorbidity in Adults[166,167]

Author, Year	Domain	Timepoint, years	Intervention	N Reported	Mean Score	Between-group comparisons	*P* Value
SF-36							
O'Brien, 2006	Mental health composite score, points (SD)	2	AGB	22	50.75 (5.59)	NR	*P* < .05
			Lifestyle without crossovers	8	47.82 (6.84)		
		10	AGB	22	50.77 (6.27)		
			Lifestyle without crossovers	8	49.59 (5.71)		
	Physical composite score, points (SD)	2	AGB	28	53.93 (5.21)		
			Lifestyle without crossovers	10	54.32 (7.88)		
		10	AGB	28	48.00 (10.53)		
			Lifestyle without crossovers	10	52.76 (3.90)		

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; HRQoL: health-related quality of life; NR: not reported; SD: standard deviation; SF-36: (RAND-36) 36-item Short-Form Health Survey.

Table B6. Safety Outcomes, BMI ≥ 30 to < 35 kg/m^2 and Obesity-Related Issue or Comorbidity in Adults[166,167]

Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Proportion	Most Common Adverse Events, n (%)
Adverse events						
O'Brien, 2006	≥ 1 adverse event, n (%)	AGB	2	39	7 (18.0)	• Revision due to prolapse: 4 (10.0) • Operative interventions: 5 (13.0) • Gallbladder inflammation: 1 (2.6) • Port site infection: 1 (2.6)
		Lifestyle	2	31	18 (58.0)	• Intolerance to orlistat: 8 (26.0) • Acute gallbladder inflammation: 4 (13.0) • Operative interventions: 4 (13.0)
		AGB	10	57 (includes crossovers)	NR	• Proximal gastric enlargements: 17 (29.8) • Port or tubing events: 4 (7.0) • Explantation of band: 7 (12.3)
	Number of events	AGB	10	57 (includes crossovers)	31 events	• Proximal Gastric enlargements: 20 events (in 17 patients; 30.0) • Port or tubing events: 4 of 57 (7.0) • Explantation of band: 7 of 57 (12.0)
Reoperations						
O'Brien, 2006	Patients requiring reoperation, n (%)	AGB	10	57 (includes crossovers)	17 (29.8)	• All for proximal gastric enlargements
	Number of reoperations				24 events	• Proximal gastric enlargement events: 20 • Port or tubing events: 4

Note. 10-year outcomes for the intensive lifestyle group were not reported. [a] These results include all participants who had an AGB placed regardless of which group they were initially randomized to.
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; NR: not reported.

Table B7. Study Details, RCTs of MBS for BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
Wentworth, 2014 ACTRN12609000286246 Australia, New Zealand 2009 to 2021	To establish whether laparoscopic AGB had a similar effect on glucose control in people with T2DM who were overweight but not obese	• AGB • Lifestyle	N = 51 5 years + 5 years Eligibility • BMI 25 to 30 kg/m^2 • Age, 18 to 65 years	Diabetes duration < 5 years, willingness to be randomized to either study group, and ability to comply with the treatment protocol	Positive glutamic acid decarboxylase autoantibody titer, pancreatic disease, previous bariatric surgery, or contraindication to laparoscopic AGB

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; T2DM: type 2 diabetes mellitus.

Table B8. Full Baseline Characteristics, BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)	Current Medications for Comorbidities, n (%)	Notes
Wentworth 2014	AGB	53 (6)	19 (76)	NR	29 (1)	81 (10)	T2DM: 25 (100)	Insulin: 4 (16)	• Mean T2DM duration (months): 26 (20) • Mean HbA1c: 6.9% (1.2)
	MDC	53 (7)	17 (65)	NR	29 (1)	83 (12)	T2DM: 26 (100)	Insulin: 1 (4)	• Mean T2DM duration (months): 33 (22) • Mean HbA1c: 7.2% (1.1)

Note. [a] Details of non-White population were not reported.
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; HbA1c: glycated hemoglobin; MDC: multidisciplinary diabetes care; NR: not reported; T2DM: type 2 diabetes mellitus.

Table B9. Weight Outcomes, BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Mean Change From Baseline	Between-Group Comparisons	*P* Value
BMI							
Wentworth, 2014	Change in BMI, kg/m^2	AGB	2	23	−4.1 (−5.1 to −3.2)	3 (2 to 5)	*P* < .001
		MDC		25	−0.5 (−1.3 to 0.3)		
		AGB	5	22	−3.3 (95% CI, −4.3 to −2.3)	2.2 (95% CI, 0.8 to 3.7)	*P* = .003
		MDC		23	−0.7 (95% CI, −1.6 to 0.1)		
Weight							
Wentworth, 2014	Weight loss, kg	AGB	2	23	−11.5 (−14.1 to −8.9)	11.2 (4.5 to 17.9)	*P* = .001
		MDC		25	−1.6 (−4.3 to 1.0)		
		AGB	5	22	−9.1 (95% CI, −12.0 to 6.3)	−7.8 (95% CI, −10.75 to −3.65)	*P* < .001
		MDC		23	−1.9 (95% CI, −4.3 to 0.5)		
		AGB	10	21	−8.5 (95% CI, −13.1 to −5.4)	NR	*P* < .01
		MDC		20	−4.7 (95% CI , −5.9 to −3.1)		
	Weight loss, %	AGB	5	22	11.2 (95% CI, 7.8 to 14.5)	−8.6 (95% CI, −13.0 to −4.2)	*P* < .001
		MDC		23	2.6 (95% CI, −0.4 to 5.6)		
		AGB	10	21	9.8 (95% CI, 6.7 to 16.3)	NR	*P* < .01
		MDC		20	5.6 (95% CI, 3.4 to 7.6)		

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; MDC: multidisciplinary diabetes care; NR: not reported; T2DM: type 2 diabetes mellitus.

Table B10. Cardiovascular Outcomes, BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
Cardiovascular risk factors							
Wentworth, 2014	Resolution of T2DM, n (%)	2	AGB	23	12 (52)	RR, 6.52 (95% CI, 1.63 to 26.07)	*P* < .001
			MDC	25	2 (8)		
		5	AGB	22	5 (23)	RR, 2.61 (95% CI, 0.56 to 12.09)	*P* > .05
			MDC	23	2 (9)		
		10	AGB	21	5 (24)	RR, 10.50 (95% CI, 0.62 to 178.40]	*P* > .05
			MDC	20	0 (0)		
	Glucose, mmol/L	2	AGB	23	−1.0 (95% CI, −1.7 to −0.3)	1.9 (95% CI, 0.6 to 3.1)	*P* < .01
			MDC	25	0.1 (95% CI, −1.2 to 1.4)		
		5	AGB	22	−0.14 (95% CI, −1.07 to 0.79)	1.11 (95% CI, −0.41 to 2.41)	*P* > .05
			MDC	23	0.24 (95% CI, −1.13 to 1.61)		
	HbA1c, % (SD)	2	AGB	23	6.1 (1.0); mean CFB, −0·8 (95% CI, −1·1 to −0·5)	13 (5 to 21)	*P* < .01
			MDC	25	7·3 (1·4); mean CFB, 0·0 (95% CI, −0·5 to 0·5)		
		5	AGB	21	6.6 (1.0); mean CFB, −0.44 (95% CI, −0.87 to −0.01	0.48 (−0.24 to 1.21)	*P* > .05
			MDC	20	7.1 (1.4); mean CFB, −0.27 (95% CI, −0.80 to 0.27)		
		10	AGB	21	7.0 (95% CI, 6.2 to 7.8)	NR	*P* > .05
			MDC	20	7.9 (95% CI, 6.7 to 9.0)		

Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
Proportion of participants who met treatment targets							
Wentworth, 2014	HbA1c < 7% (i.e., 54 mmol/mol), n (%)	2	AGB	23	21 (91); an increase of 9 participants	Proportional difference, 0.31 (95% CI, 0.05 to 0.58)	*P* = .02
			MDC	25	15 (60); an increase of 1 participant		
		5	AGB	22	17 (77); an increase of 7 participants	Proportional difference, −0.25 (95% CI, −0.02 to 0.52)	*P* > .05
			MDC	23	12 (52); no change		
	HbA1c < 6.5% (i.e., 48 mmol/mol), n (%)	10	AGB	21	5 (24)	NR	*P* > .05
			MDC	20	0 (0)		
	Blood pressure, n (%)	2	AGB	23	12 (68%); an increase of 5 participants	MD, 0.1 (95% CI, −0.20 to 0.40)	*P* > .05
			MDC	25	16 (64%); a decrease of 2 participants		
		5	AGB	22	12 (55%); an increase of 3 participants	MD, 0.02 (95% CI, −0.27 to 0.31)	*P* > .05
			MDC	23	13 (57%); an increase of 4 participants		
Cholesterol							
Wentworth, 2014	HDL, mmol/L	2	AGB	23	0.30 (95% CI, 0.19 to 0.41)	−0.26 (95% CI, −0.53 to 0.01)	*P* > .05
			MDC	25	0.05 (95% CI, −0.10 to 0.20)		
		5	AGB	22	0.26 (95% CI, 0.14 to 0.37)	−0.24 (95% CI, −0.48 to 0.01)	*P* > .05
			MDC	23	0.01 (95% CI, −0.08 to 0.09)		
	HDL concentration, mmol/L	10	AGB	21	1.2 (95% CI, 1.0 to 1.7)	NR	*P* = .03

Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
			MDC	20	1.1 (95% CI, 0.8 to 1.3)		
	LDL, mmol/L	2	AGB	23	−0.3 (−0.9 to 0.3)	−0.1 (−0.6 to 0.4)	*P* > .05
			MDC	25	−0.6 (−1.1 to −0.04)		
		5	AGB	22	−0.48 (95% CI, −0.83 to −0.12)	−0.29 (95% CI, −0.76 to −0.17)	*P* > .05
			MDC	23	−0.65 (95% CI, −1.16 to −0.12(		
	LDL concentration, mmol/L	10	AGB	21	2.0 (95% CI, 1.3 to 2.7)	NR	*P* > .05
			MDC	20	1.9 (95% CI, 1.4 to 2.9)		
	Triglycerides, mmol/L	2	AGB	23	−0.5 (95% CI, −1.0 to −0.1)	−0.5 (−0.9 to −0.1)	*P* < .01
			MDC	25	−0.5 (95% CI, −0.9 to −0.1)		
		5	AGB	22	−0.29 (95% CI, −0.76 to 0.18)	0.65 (95% CI, 0.02 to 1.28)	*P* = .04
			MDC	23	−0.13 (95% CI, −0.50 to 0.24)		
		10	AGB	21	1.4 (95% CI, 1.1 to 2.0)	NR	*P* > .05
			MDC	20	1.8 (95% CI, 1.3 to 2.7)		

Notes. RRs were calculated by Center for Evidence-based Policy researchers using OpenEpi.[245]
Abbreviations.[245]
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CFB: change from baseline; CI: confidence interval; HbA1c: glycated hemoglobin; HDL: high-density lipoprotein; LDL: low-density lipoprotein; MD: mean difference; MDC: multidisciplinary diabetes care; RR: risk ratio; T2DM: type 2 diabetes mellitus.

Table B11. HRQoL, BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Author, Year	Timepoint, years	Intervention	N Reported	Mean Change From Baseline or Total Score, points	Between-Group Comparisons	*P* Value
SF−36						
Mental health component score						
Wentworth, 2014	2	AGB	23	−0.13 (95% CI, −6.8 to 6.5)	−2 (95% CI, −9 to 6)	*P* > .05
		MDC	25	−0.82 (95% CI, −5.2 to 3.6)		
	5	AGB	22	5.0 (95% CI, 0.1 to 9.8)	−6.5 (95% CI, −13.0 to 0.1)	*P* = .053
		MDC	23	−0.4 (95% CI, −5.0 to 4.3)		
	10	AGB	21	53.97 (95% CI, 45.40 to 58.86)	NR	*P* > .05
		MDC	20	52.28 (95% CI, 44.00 to 59.28)		
Physical component score						
Wentworth, 2014	2	AGB	23	+7.7 (95% CI, 5.0 to 10.4)	−10 (95% CI, −14 to −5)	*P* < .001
		MDC	25	−1.7 (95% CI, −5.3 to 1.9)		
	5	AGB	22	+ 5.6 (95% CI, 1.8 to 9.3)	−6.0 (95% CI, −11.2 to −0.8)	*P* = .02
		MDC	23	−0.2 (95% CI, −4.3 to 3.9)		
	10	AGB	21	50.44 (95% CI, 45.56 to 58.10)	NR	*P* > .05
		MDC	20	47.89 (95% CI, 41.16 to 55.41)		

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; HRQoL: health-related quality of life; NR: not reported; SF-36: RAND-36 Short-Form Health Survey, 36 questions; T2DM: type 2 diabetes mellitus.

Table B12. Safety Outcomes, BMI ≥ 25 to < 30 kg/m^2 and T2DM in Adults[172,173,181]

Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Proportion	Most Common Adverse Events, n (%)
Adverse Events						
Wentworth, 2014	≥ 1 adverse event, (%)	AGB	10	21	15 (71.4)	NR
		MDC	10	20	13 (65.0)	
	Number of events	AGB	2	25	21 events	• Food intolerance that required a reduction of the fluid volume in the band as outpatients: 5 events (4 people) • Unplanned surgical procedures[a]: 5 events (4 people)
		MDC	2	23	8 events	• Retinal photocoagulation: 2 events (2 people) • Unplanned surgical procedure: 1 event • Hospitalization for 2 months to manage eosinophilic fasciitis, possibly precipitated by atorvastatin: 1 event
		AGB	5	22	63 events	• Elective surgery unrelated to AGB: 8 events (4 people) • Acute hospitalization unrelated to AGB: 12 events (7 people) • Swallowing difficulty: 7 events (3 people)
		MDC	5	23	72 events	• Musculoskeletal pain: 17 events (10 people) • Elective surgery unrelated to AGB: 12 events (8 people) • Infections: 10 events (7 people)
		AGB	10	21	63	NR
		MDC	10	20	60	
Adverse events of special interest						
Wentworth, 2014	Difficulty swallowing, n (%)	AGB	2	25	4 (17.0)	N/A
		AGB	5	23	3 (13; 7 events)	
Reoperations						
Wentworth, 2014	Number of events	AGB	2	25	1 (4)	N/A
		AGB	5	22	2 events in 2 people	

Note. [a] Unplanned surgical procedures in the AGB group were knee arthroscopy, uterine curettage, inguinal hernia repair, gallbladder removal, and transurethral resection of prostate. [b] The unplanned surgical procedure in the lifestyle group was knee arthroscopy.
Abbreviations: AGB: adjustable gastric band; BMI: body mass index; MDC: multidisciplinary diabetes care; N/A: not applicable; NR: not reported; T2DM: type 2 diabetes mellitus.

MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults With Overweight or Obesity

Table B13. Study Details, RCTs of MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
RYSA[170] NCT02882685 Western Europe 2016 to 2022	To provide evidence on whether OAGB is metabolically superior to the "gold standard," i.e., RYGB	• OAGB • RYGB	N = 121 1 year[a] Eligibility • BMI ≥ 35 kg/m^2 • Age, ≥ 18 years	Eligible for gastric bypass surgery according to national treatment guidelines	Anemia; Pregnancy or lactation; For MRI/MRS imaging: metal objects in the body or claustrophobia; Endoscopic evidence of hiatal hernia, reflux esophagitis or Barret's esophagus; Any other condition that, in the opinion of the investigator, could create a hazard for the safety of the participant, endanger the study procedures or interfere with the interpretation of study results
Seetharamaiah, 2017[176] NR South Asia 2013 to 2019	This study aims at comparing the 1-year follow-up results of OAGB and SG in terms of excess weight loss, complications, resolution of comorbidities, and quality of life.	• OAGB • SG	N = 214 1 year + 4 years Eligibility • BMI ≥ 30 to < 60 kg/m^2 • Age, 18 to 60 years	People with Asian ethnicity with: • BMI ≥ 35 kg/m^2 with or without comorbidities • BMI ≥ 32 to < 35 kg/m^2 with comorbidities • BMI ≥ 30 to < 32 kg/m^2 if they have abdominal obesity along with ≥ 2 of the additional criteria for MetS: raised triglycerides, reduced HDL cholesterol levels, high blood pressure and raised	Previous bariatric or stomach surgery, pregnancy, associated psychiatric illness, BMI > 60 kg/m^2, and patients who either chose their surgical procedure or did not wish to be a part of the study and who could not complete 1-year follow-up

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
				fasting plasma glucose levels	
YOMEGA[174] NCT02139813 Western Europe 2014 to 2018	To compare the omega loop to the validated RYGB	• OAGB • RYGB	N = 253 2 years Eligibility • BMI ≥ 35 kg/m^2 • Age, 18 to 65 years	BMI ≥ 40 kg/m², or ≥ 35 kg/m² with the presence of ≥ 1 comorbidity (e.g., T2DM, high blood pressure, OSA, dyslipidemia, or arthritis)	History of esophagitis, severe GERD resistant to proton-pump inhibitors, Barrett's esophagus, and previous bariatric surgery

Notes. [a] The primary outcome is weight loss after 2 years, but results have not yet been published. The study plan includes 10 years of follow-up.
Abbreviations. BMI: body mass index; GERD: gastroesophageal reflux disease; HDL: high-density lipoprotein; MetS: metabolic syndrome; MRI/MRS: magnetic resonance imaging/magnetic resonance spectroscopy; NR: not reported; OAGB: one-anastomosis gastric bypass; OSA: obstructive sleep apnea; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table B14. Full Baseline Characteristics, MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)	Comorbidity-Related Medications, n (%)
RYSA[169,170] Heinonen, 2023	OAGB	46.6 (95% CI, 44.5 to 48.6)	41 (68.3)	NR	44.6 (95% CI, 43 to 46.1)	128.4 (95% CI, 122.4 to 134.4)	• T2DM: 27 (45) • HTN: 36 (60) • Dyslipidemia: 47 (78.3) • Hypercholesterolemia: 34 (56.7) • Hypertriglyceridemia: 16 (26.1)	• T2DM meds: 24 of 27 (88.9) • Insulin: 5 of 27 (18.5) • HTN meds: 32 of 36 (88.9) • Lipid meds: 14 of 47 (29.8)
	RYGB	47.1 (95% CI, 45.0 to 49.2)	43 (72)	NR	43.8 (95% CI, 42.2 to 45.3)	127.5 (95% CI, 122.9 to 132.1)	• T2DM: 26 (44.8) • HTN: 42 (71.2) • Dyslipidemia: 44 (74.6) • Hypercholesterolemia: 34 (57.6) • Hypertriglyceridemia: 16 (27.1)	• T2DM meds: 23 of 26 (88.5) • Insulin: 4 of 26 (15.4) • HTN meds: 36 of 42 (85.7) • Lipid meds: 16 or 44 (36.4)
Seetharamaiah, 2017[176-178]	OAGB	42.89 (14.02)	39 (62)	101 (100)	44.32 (7.88)	114.39 (22.51)	• T2DM: 49 (49) • HTN: 53 (53) • OSA: 24 (24)	• NR
	SG	39.89 (11.75)	35 (65)	100 (100)	44.57 (7.16)	117.64 (25.97)	• T2DM: 47 (47) • HTN: 56 (56) • OSA: 18 (18)	• NR
YOMEGA[174] Robert, 2019	OAGB	44.4 (11.4)	85 (73)	NR	43.8 (6.1)	121.2 (24.4)	• T2DM: 28 (26) • Hypertension: 38 (33) • High cholesterol: 22 (19) • Sleep apnea: 60 (54)	• Oral antidiabetic drugs: 21 (88)
	RYGB	42.6 (10.2)	91 (78)	NR	43.9 (5.1)	119.91 (18.7)	• T2DM: 30 (29) • Hypertension: 33 (28) • High cholesterol: 20 (17) • Sleep apnea: 68 (59)	• Oral antidiabetic drugs: 22 (92) • On insulin: 8 (33)

Note. [a] No studies reported details about their non-White participants.
Abbreviations. BMI: body mass index; CI: confidence interval; HTN: hypertension; NR: not reported; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; OSA: obstructive sleep apnea; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table B15. Weight Outcomes, MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Change From Baseline (unless otherwise noted)	Between−Group Differences	*P* Value
BMI							
RYSA Heinonen, 2023[169]	1	BMI, kg/m^2	OAGB	60	−11.80 (95% CI, 10.34 to 13.25)	NR	*P* > .05
			RYGB	56	−10.42 (95% CI, 9.05 to 11.80)		
Seetharamaiah, 2017[176]	5	EBMIL, % (SD)	OAGB	73	62.1 (12.72)	NR	*P* < .001
			SG	71	50.6 (26.04)		
YOMEGA Robert, 2019[174]	2	EBMIL, % (SD)	OAGB	117	87.9 (23.6)	MD, −3.3 (90% CI, −9.1 to 2.6)	*P* = .002
			RYGB	117	85.8 (23.1)		
EWL							
RYSA Heinonen, 2023[169]	1	EWL, % (SD)	OAGB	60	63.4 (95% CI, 57.9 to 68.8)	NR	*P* > .05
			RYGB	56	60.1 (95% CI, 55.2 to 66.6)		
Seetharamaiah, 2017[176]	1	EWL, % (SD)	OAGB	101	66.87 (10.87)		
			SG	100	63.97 (13.24)		
	2		OAGB	97	64.77 (17.30)		
			SG	95	62.79 (21.10)		
	3		OAGB	93	66.48 (15.72)		
			SG	92	61.15 (25.27)		
	4		OAGB	82	67.18 (11.62)	NR	*P* ≤ .01
			SG	80	58.46 (26.79)		
	5		OAGB	73	65.28 (13.98)		
			SG	71	55.94 (27.01)		
RYSA Heinonen, 2023[169]	1	EWL ≥ 50%, n (%)	OAGB	60	43 (71.7)	NR	*P* > .05
			RYGB	56	40 (71.4)		
TWL							
RYSA Heinonen, 2023[169]	1	TWL, % (SD)	OAGB	60	26.1 (95% CI, 24.2 to 28.0)	NR	*P* > .05
			RYGB	56	25.4 (95% CI, 23.4 to 27.5)		
Seetharamaiah, 2017[176]	2	TWL, % (SD)	OAGB	97	29.65 (10.19)	NR	*P* > .05
			SG	95	28.58 (8.82)		
	3		OAGB	93	29.99 (9.51)		

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Change From Baseline (unless otherwise noted)	Between–Group Differences	*P* Value
			SG	92	27.59 (10.24)		
YOMEGA Robert, 2019[174]	2	TWL, % (SD)	OAGB	117	37.1 (10.3)	MD, −1.4 (90% CI, −3.7 to 1.0)	*P* < .001
			RYGB	117	35.4 (8.1)		
RYSA Heinonen, 2023[169]	1	TWL ≥ 10%, n (%)	OAGB	60	59 (98.3)	NR	*P* > .05
			RYGB	56	55 (98.2)		
Revision for nonresponse (i.e., inadequate weight loss)							
Seetharamaiah, 2017[176]	2	Proportion, n (%)	OAGB	97	0 (0)	NR	NR
			SG	95	1 (1.0)		
Weight loss							
RYSA Heinonen, 2023[169]	1	Weight, kg	OAGB	60	−33.3 kg (95% CI, −30.4 to −36.1)	NR	*P* > .05
			RYGB	56	−31.7 kg (95% CI, −28.8 to −34.6)		

Abbreviations. BMI: body mass index; CI: confidence interval; EBMIL: excess body mass index loss; EWL: excess weight loss; MBS: metabolic and bariatric surgery; MD: mean difference; NR: not reported; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; SG: sleeve gastrectomy; TWL: total weight loss.

Table B16. Cardiovascular Outcomes, MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline, or Proportion	Between-Group Differences	*P* Value
Full remission of baseline comorbidity							
RYSA Heinonen, 2023[169]	Dyslipidemia, n (%)	1	OAGB	47	27 (57.5)	NR	*P* > .05
			RYGB	44	25 (56.8)		
	Hypercholesterolemia, n (%)		OAGB	34	19 (55.9)		
			RYGB	34	21 (61.8)		
	Hypertension, n (%)		OAGB	36	9 (25.0)		*P* = .053
			RYGB	42	23 (54.8)		
Seetharamaiah, 2017[176]	Hypertension, n (%)	1	OAGB	53	33 (64.15)	NR	*P* > .05
			SG	56	37 (66.07)		
		2	OAGB	53	35 (67.31)		
			SG	56	38 (67.86)		
		3	OAGB	50	37 (74.0)		
			SG	54	39 (72.22)		
		5	OAGB	37	24 (70.27)		
			SG	45	21 (46.67)		
RYSA Heinonen, 2023[169]	Hypertriglyceridemia, n (%)	1	OAGB	16	15 (93.8)	NR	*P* > .05
			RYGB	16	14 (87.5)		
Seetharamaiah, 2017[176]	Obstructive sleep apnea, n (%)	5	OAGB	16	12 (75.0)	NR	*P* > .05
			SG	11	7 (63.64)		
RYSA Heinonen, 2023[169]	T2DM, n (%)	1	OAGB	27	22 (81.5)	NR	*P* > .05
			RYGB	26	24 (92.3)		
Seetharamaiah, 2017[176]		1	OAGB	49	41 (83.63)		
			SG	47	36 (76.58)		
YOMEGA Robert, 2019[174]		2	OAGB	20	12 (60.0)		
			RYGB	16	6 (37.5)		
Seetharamaiah, 2017[176]		2	OAGB	49	43 (87.76)		
			SG	45	37 (85.22)		
		3	OAGB	46	41 (89.13)		
			SG	44	36 (81.82)		
		5	OAGB	40	34 (85.0)	NR	*P* = .02
			SG	37	21 (56.76)		

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline, or Proportion	Between-Group Differences	*P* Value
Blood pressure							
RYSA Heinonen, 2023[169]	Systolic, mmHg	1	OAGB	57	−9.95 (95% CI, 5.13 to 14.77)	NR	*P* > .05
			RYGB	50	−8.04 (95% CI, 2.52 to 13.56)		
	Diastolic, mmHg		OAGB	55	−8.18 (95% CI, 4.81 to 11.54)		
			RYGB	50	−7.67 (95% CI, 3.95 to 11.38)		
Cholesterol-related							
RYSA Heinonen, 2023[169]	HDL, mmol/L	1	OAGB	55	0.23 (95% CI, −0.30 to −0.16)	NR	*P* > .05
			RYGB	58	0.20 (95% CI, −0.28 to −0.13)		
YOMEGA Robert 2019[174]		2	OAGB	55	+0.3 (SD, 0.3)		
			RYGB	50	+0.3 (SD, 0.3)		
RYSA Heinonen, 2023[169]	LDL, mmol/L (SD)	1	OAGB	55	−0.59 (95% CI, 0.40 to 0.77)		
			RYGB	58	−0.46 (95% CI, 0.28 to 0.65)		
YOMEGA Robert, 2019[174]		2	OAGB	53	−0.4 (SD, 1.1)		
			RYGB	49	−0.4 (SD, 1.0)		
RYSA Heinonen, 2023[169]	Total cholesterol, mmol/dL (SD)	1	OAGB	55	−0.39 (95% CI, 0.12 to 0.67)		
			RYGB	58	−0.54 (95% CI, 0.31 to 0.78)		
YOMEGA Robert, 2019[174]		2	OAGB	58	−0.7 (SD, 1.5)		
			RYGB	49	−0.6 (SD, 0.62)		
RYSA Heinonen, 2023[169]	Triglycerides, mmol/L	1	OAGB	55	−0.55 (95% CI, 0.37 to 0.72)		
			RYGB	58	−0.71 (95% CI, 0.32 to 1.10)		

Abbreviations. CI: confidence interval; HDL: high-density lipoprotein; LDL: low-density lipoprotein; MBS: metabolic and bariatric surgery; NR: not reported; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table B17. HRQoL Outcomes, MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Author, Year	Timepoint, years	Subdomain	Intervention	N Reported	Change From Baseline, points	Between-Group Differences	*P* Value
IWQOL-Lite							
YOMEGA Robert, 2019[174]	2	Physical function	OAGB	63	+20.4 (11.9)	NR	*P* > .05
			RYGB	63	+21.5 (8.4)		
		Self-esteem	OAGB	63	+11.2 (9.3)		
			RYGB	63	+12.1 (6.8)		
		Public distress	OAGB	63	+5.5 (6.2)		
			RYGB	63	+6.1 (3.8)		
		Working conditions	OAGB	63	+4.0 (3.2)		
			RYGB	63	+4.7 (3.3)		

Abbreviations. IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; MBS: metabolic and bariatric surgery; NR: not reported; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass.

Table B18. Safety Outcomes, MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Proportion, n (%)	Most Common Adverse Events, n (%)
Anemia						
RYSA Heinonen, 2023[169]	1	Anemia, n (%)	OAGB	58	8 (13.8)	N/A
			RYGB	56	7 (12.5)	
Seetharamaiah, 2017[176]	5		OAGB	73	7 (9.6)	
			SG	71	4 (5.6)	
YOMEGA Robert, 2019[174]	2		OAGB	60	17 (28.3)	
			RYGB	58	21 (36.2)	
Difficulty swallowing						
Seetharamaiah, 2017[176]	5	GERD, n (%)	OAGB	73	3 (4.1)	N/A
			SG	71	4 (5.6)	
Vitamin deficiency						
RYSA Heinonen, 2023[169]	1	Vitamin B12, n (%)	OAGB	57	0	N/A
			RYGB	54	0	
		Vitamin D, n (%)	OAGB	57	43 (75.4)	
			RYGB	51	21 (41.2)	
Seetharamaiah, 2017[176]	5	Severe malnutrition, n (%)	OAGB	73	0 (0)	
			SG	71	0 (0)	
YOMEGA Robert, 2019[174]	2	Vitamin deficiency, n (%)	OAGB	58	49 (84.5)	
			RYGB	48	40 (83.3)	
Complications related to surgery						
Seetharamaiah, 2017[176]	1	Complications related to surgery , n (%)	OAGB	101	7 (7.0)	• Hemorrhage: 3 (3) • Marginal ulcer: 2 (2) • GERD: 2 (2)
			SG	101	8 (7.0)	• Hemorrhage: 4 (4) • Leak: 1 (1) • GERD: 3 (3)

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Proportion, n (%)	Most Common Adverse Events, n (%)
YOMEGA Robert, 2019[174]	2	Complications related to surgery , n (%)	OAGB	117	8 (7.0)	• Hemorrhage: 4 (50) • Bowel injury: 2 (25) • Stapling of the nasogastric tube: 2 (25)
			RYGB	117	4 (3.0)	• Hemorrhage: 3 (75) • Bowel injury: 1 (25)
Seetharamaiah, 2017[176]	5		OAGB	73	3 (4.1)	• Gall stone (minor): 3 (4.1)
			SG	71	3 (4.2)	• Port site hernia (minor): 2 (2.8) • Gall stone (minor): 1 (1.4)
Deaths						
Seetharamaiah, 2017[176]	1	Deaths, n (%)	OAGB	101	0	N/A
			SG	100	0	
	2		OAGB	97	1 (0.9)	• Unknown cause
			SG	95	1 (1.0)	• Acute myocardial infarction
SAEs						
YOMEGA Robert, 2019[174]	2	Number of events, n	OAGB	117	67 events	NR
	2		RYGB	117	38 events	
	2	Experienced an SAE, n (%)	OAGB	129	28 (22)	
	2		RYGB	124	19 (15)	
	2	Number of surgery-related events, n	OAGB	117	42 events	• Nutritional complications: 9 (21) • Vesicular lithiasis: 8 (19) • Diarrhea or anal fissures: 6 (14)
	2		RYGB	117	24 events	• Abdominal pain: 5 (21) • Vesicular lithiasis: 5 (21) • Abdominal wall hematoma or abscess: 3 (13) • Anastomotic ulcer: 3 (13) • Bowel obstruction: 3 (13)

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Proportion, n (%)	Most Common Adverse Events, n (%)
Readmissions						
Seetharamaiah, 2017[176]	1	> 30 days post-surgery, n (%)	OAGB	101	5 (5.0)	• Nausea and vomiting: 1 (0.9) • Marginal perforation: 1 (0.9) • Symptomatic gallstones: 3 (3)
			SG	100	4 (3.0)	• Nausea and vomiting: 2 (2) • Symptomatic gallstones: 2 (2)
		≤ 30 days post-surgery, n (%)	OAGB	101	7 (6.9)	• Wound infection: 4 (3.9) • Nausea and vomiting: 2 (2) • Bleeding: 1 (0.9)
			SG	100	10 (10.0)	• Wound infection: 6 (6) • Nausea and vomiting: 2 (2) • Leak: 1 (1) • Bleeding: 1 (1)
Reoperations						
Seetharamaiah, 2017[176]	1	Reoperations, n (%)	OAGB	101	10 (9.9)	• Wound infection: 4 (4) • Nausea and vomiting: 3 (3) • Bleeding: 1 (0.9) • Marginal ulcer perforation: 1 (0.9) • Marginal ulcer bleed: 1 (0.9)
			SG	100	12 (12.0)	• Wound infection: 6 (6) • Nausea and vomiting: 4 (4) • Leak: 1 (1) • Bleeding: 1 (1)
YOMEGA Robert, 2019[174]	2		OAGB	127	4 (3.0)	• Conversion to RYGB: • Anastomotic leak: 1 • Wernicke encephalopathy: 2 • Severe biliary reflux: 1
			RYGB	NR	NR	NR

Abbreviations. AE: adverse event; GERD: gastroesophageal reflux disease; MBS: metabolic and bariatric surgery; MD: mean difference; N/A: not applicable; NR: not reported; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SAE: serious AE; SG: sleeve gastrectomy.

MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions, in Adults With Overweight or Obesity

Table B19. Study Details, RCTs of MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions, in Adults

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
IB-005[163] NCT00730327 US 2008 to 2011	To study the safety and effectiveness of the IGB for weight loss among individuals in the US with class I and II obesity (BMI 30 to 40 kg/m^2).	• IGB • Lifestyle	N = 317 6 months + 6 months Eligibility • BMI ≥ 30 to < 40 kg/m^2 • Age, 18 to 65 years	Eligible subjects had a history of obesity for≥ 2 years with failed conservative weight loss attempts, such as supervised diet, exercise, and behavioral modification programs	A history of foregut or gastrointestinal (GI) surgery (except uncomplicated cholecystectomy or appendectomy), GI obstruction, adhesive peritonitis, or clinically significant hiatal hernia
LIFEXPE-RT[164] NCT03667469 Central Asia 2018 to 2020	To compare the treatment modalities in terms of changes in BMI and telomere length (as a possible biomarker of life expectancy) and resolution of MetS components.	• OAGB • Diet	N = 60 1 year Eligibility • BMI ≥ 35 to < 50 kg/m^2 • Age, 18 to 65 years	Had MetS with adiposity and ≥ 2 of the following MetS components: elevated fasting plasma glucose levels detected before T2DM or prediabetes, previously diagnosed T2DM, arterial hypertension, elevated triglyceride levels, and low levels of HDL cholesterol.	Patients were excluded if they had a drug or alcohol addiction, were immobilized (paralysis), a history of bariatric surgery, insulin-dependent T2DM, serious mental disorders, were socially vulnerable (according to ethical principles)
MERIT[165] NCT03406975 US 2017 to 2019	To explore the efficacy and safety of ESG in the multidisciplinary approach to obesity care	• ESG • Lifestyle	N = 209 1 year + 1 year Eligibility • BMI ≥ 30 to < 40 kg/m^2 • Age, 21 to 65 years	With a history of failure with non-surgical weight loss methods, and who agreed to comply with the lifelong dietary restrictions required by the procedure.	Individuals with a history of GI surgery and any inflammatory disease in the GI tract.

Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GI: gastrointestinal; HDL: high-density lipoprotein; IGB: intragastric balloon; MetS: metabolic syndrome; OAGB: one-anastomosis gastric bypass; T2DM: type 2 diabetes mellitus.

Table B20. Full Baseline Characteristics, MBS Procedures Not Reviewed in 2015 vs. Lifestyle Intervention, in Adults

Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Details of Non-White Population, n (%)	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)	Current Medications for Comorbidities, n (%)
IB-005[163] Courcoulas, 2017	IGB	38.7 (9.4)	112 (89.6)	24 (19.2)	• Hispanic: 9 (7.2) • Black (not of Hispanic origin): 14 (11.2) • Asian: 0 (0) • Other: 1 (0.8)	NR	98 (15)	• T2DM: 9 (7) • HTN: 33 (26) • Dyslipidemia: 49 (39)	NR
	Lifestyle	40.8 (9.6)	117 (90.0)	24 (18.5)	• Hispanic: 7 (5.4) • Black (not of Hispanic origin): 15 (11.5) • Asian: 0 (0) • Other: 2 (1.5)	NR	98 (12)	• T2DM: 8 (6) • HTN: 37 (28) • Dyslipidemia: 39 (30)	
LIFEXPE-RT[164] Ospanov, 2021	OAGB-Stapleless	38.6 (6.9)	18 (90)	NR	NR	39.88 (5.8)	108.95 (15.69)	• Prediabetes: 7 (35) • Diabetes 7 (35)	NR
	OAGB-Stapled	48.7 (8.5)	15 (75)	NR	NR	45.9 (5.5)	129.0 (23.7)	• Prediabetes 9 (45) • Diabetes 7 (35)	
	Diet	47.3 (9.9)	13 (65)	NR	NR	36.5 (8.1)	101.1 (26.1)	• Prediabetes 11 (55) • Diabetes: 6 (30)	

Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Details of Non-White Population, n (%)	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)	Current Medications for Comorbidities, n (%)
MERIT[165] Abu Dayyeh, 2022	ESG	47.3 (9.3)	68 (88)	24 (31)	• African American: 11 (14) • Asian: 0 (0) • Hispanic or Latino: 11 (14) • Other: 1 (1) • Deferred: 1 (1)	35.5 (2.6)	98.4 (12.3)	• Diabetes: 18 (23) • HTN: 38 (49)	• Diabetes-related: 17 (22) • Anti-HTN: 40 (52) • Lipid-lowering: 13 (17)
	Lifestyle	45.7 (10.0)	92 (84)	48 (44)	• African American: 14 (13) • Asian: 3 (3) • Hispanic or • Latino:18 (16) • Other: 9 (8) • Deferred: 4 (4)	35.7 (2.6)	99.1 (12.8)	• Diabetes: 36 (33) • HTN: 58 (53)	• Diabetes-related: 38 (35) • Anti-HTN: 66 (60) • Lipid-lowering: 27 (25)

Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; HTN: hypertension; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; NR: not reported; OAGB: one-anastomosis gastric bypass; SD: standard deviation; T2DM: type 2 diabetes mellitus.

Table B21. Weight Outcomes, MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions, in Adults

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
EWL							
IB-005 Courcoulas, 2017[163]	6 months	EWL, % (SD)	IGB + Lifestyle	119	26.5 (95% CI, 23.6 to 29.3)	MD, 17.0 (95% CI, 13.0 to 21.0)	*P* < .001
			Lifestyle	121	9.5 (95% CI, 6.7 to 12.3)		
	1		IGB + Lifestyle	98	23.2 (95% CI, 20.3 to 26.0)	MD, 13.8 (95% CI, 9.8 to 17.8)	*P* < .001
			Lifestyle	93	9.4 (95% CI, 6.6 to 12.2)		
MERIT Abu Dayyeh, 2022[165]	1	EWL, % (SD)	ESG	77	49.2 (32.0)	MD, 44.7 (95% CI, 37.5 to 51.9)	*P* < .001
			Lifestyle	110	3.2 (18.6)		
IB-005 Courcoulas, 2017[163]	6 months	EWL ≥ 10%, n (%)	IGB + Lifestyle	125	58 (46.4)	Risk difference, 34.9 (95% CI, 24.5 to 45.2)	*P* < .001
			Lifestyle	130	15 (11.5)		
	1		IGB + Lifestyle	125	40 (32.0)	Risk difference, 15.9 (95% CI, 5.5 to 26.2)	*P* < .01
			Lifestyle	130	21 (16.2)		
MERIT Abu Dayyeh, 2022[165]	1	EWL ≥ 25%, n (%)	ESG	77	59 (77)	NR	*P* < .001
			Lifestyle	110	13 (12)		
TWL							
IB-005 Courcoulas, 2017[163]	6 months	TWL, % (SD)	IGB + Lifestyle	119	9.1 (95% CI, 8.2 to 10.1)	MD, 5.8 (95% CI, 4.5 to 7.1)	*P* < .001
			Lifestyle	121	3.3 (95% CI, 2.4 to 4.3)		
	1		IGB + Lifestyle	98	7.9 (95% CI, 7.0 to 8.9)	MD, 4.6 (95% CI, 3.3 to 6.0)	*P* < .001
			Lifestyle	93	3.3 (95% CI, 2.4 to 4.2)		
LIFEXPE-RT Ospanov, 2021[179]	1	TWL, % (SD)	OAGB-stapled[a]	20	34.75 (16.67)	NR	*P* < .001
			OAGB-stapleless[a]	20	30.34 (10.4)	NR	*P* < .001
			Diet	20	1.96 (4.45)	N/A	N/A

Study Name Author, Year	Timepoint, years	Specific Outcome	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
MERIT Abu Dayyeh, 2022[165]	1	TWL, % (SD)	ESG	77	13.6% (8.0)	MD, 12.6% (95% CI, 10.7 to 14.5)	*P* < .001
			Lifestyle	110	0.8% (5.0)		
		TWL ≥ 10%, n (%)	ESG	77	48 (62)	NR	NR
			Lifestyle	110	6 (5.0)		
BMI							
LIFEXPE-RT Ospanov, 2021[179]	1	EBMIL, % (SD)	OAGB-stapled[a]	20	78.75 (39.12)	NR	*P* < .001
			OAGB-stapleless[a]	20	89.23 (36.0)	NR	*P* < .001
			Diet	20	11.94 (14.78	N/A	N/A
		BMI kg/m^2	OAGB-stapled[a]	20	−16.04 (95% CI, −11.7 to −20.37)	NR	*P* = .02
			OAGB-stapleless[a]	20	−12.137 (95% CI, −8.34 to −15.93)	NR	*P* = .01
			Diet	20	−2.76 (95% CI, −3.84 to −9.36)	N/A	N/A

Note. [a] *These differences are compared with diet alone.*
Abbreviations. BMI: body mass index; CI: confidence interval; EBMIL: excess body mass index loss; ESG: endoscopic sleeve gastroplasty; EWL: excess weight loss; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MD: mean difference; N/A: not applicable; NR: not reported; OAGB: one-anastomosis gastric bypass; SD: standard deviation; TWL: total weight loss.

Table B22. Cardiovascular Outcomes, MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions, in Adults

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
Full remission of baseline comorbidity							
LIFEXPE-RT Ospanov, 2021[179]	Prediabetes, n (%)	1	OAGB-stapled	9	9 (100)	NR	NR
			OAGB-stapleless	7	7 (100)		
			Diet	11	0 (0)		
	T2DM, n (%)		OAGB-stapled	7	7 (100)		
			OAGB-stapleless	7	6 (86.0)		
			Diet	6	0 (0)		
Cardiovascular risk[b]							
LIFEXPE-RT Ospanov, 2021[179]	Cardiovascular risk[b], CFB (SD)	1	OAGB-stapled	20	−2.8 (95% CI, −1.48 to −4.11)[a]	NR	*P* < .001
			OAGB-stapleless	20	−3.82 (95% CI, −2.35 to −5.28)[a]		
			Diet	20	−1.48 (95% CI, −0.2 to −3.17)		
Blood pressure							
LIFEXPE-RT Ospanov, 2021[179]	Diastolic, mmHg	1	OAGB-stapled	20	−18.25 (95% CI, −15.15 to −21.35)[a]	NR	*P* < .001
			OAGB-stapleless	20	−17.7 (95% CI, −14.38 to −21.02)[a]		
			Diet	20	−5.80 (95% CI, −3.22 to −8.38)		
LIFEXPE-RT Ospanov, 2021[179]	Systolic, mmHg	1	OAGB-stapled	20	−23.4 (95% CI, −11.66 to −35.14)[a]		
			OAGB-stapleless	20	−20.3 (95% CI, −15.99 to −24.61)[a]		
			Diet	20	−8.10 (95% CI, −0.65 to −15.55)		
Cholesterol-related outcomes							
LIFEXPE-RT Ospanov, 2021[179]	Triglycerides, mg/dL	1	OAGB-stapled	20	−0.70 mg/dL (95% CI, −0.35 to −1.05)[a]	NR	*P* < .001
			OAGB-stapleless	20	−0.77 mg/dL (95% CI, −0.51 to −1.03)[a]		
			Diet	20	−0.04 mg/dL (95% CI, −0.30 to −0.38)		

Note. [a] *These differences are compared with diet alone.* [b] *Authors defined cardiovascular risk as the normal ratio total cholesterol/HDL < 4*
Abbreviations. CI: confidence interval; HDL: high-density lipoprotein; MBS: metabolic and bariatric surgery; NR: not reported; OAGB: one-anastomosis gastric bypass; SD: standard deviation; T2DM: type 2 diabetes mellitus.

Table B23. Safety Outcomes, MBS Procedures Not Reviewed in 2015 vs. Lifestyle Intervention, in Adults

Study Name Author, Year	Intervention	Timepoint, years	N Reported	Proportion, n (%)	Top 3 AEs, n (%)	Notes
Any adverse event (AE)						
IB-005 Courcoulas, 2017[163]	IGB + lifestyle	1	160	157 (98.1)	• Nausea: 139 (86.9) • Vomiting: 121 (75.6) • Abdominal pain: 92 (57.5)	IGB vs. ILI: Risk difference, 27.4% (95% CI, 19.3% to 35.5%); *P* NR RR, 2.37 (95% CI, 2.02 to 2.77); *P* < .001 ≥ 1 AE; includes 35 run-in patients who followed study procedures but were not part of the randomized population.
	Lifestyle	1	130	92 (70.8)	• Sinusitis: 19 (14.6) • Upper respiratory tract infection: 13 (10.0) • Bronchitis: 11 (8.5)	N/A
LIFEXPE-RT Ospanov, 2021[179]	OAGB-stapled	1	20	8 (40.0)	• Moderate bile reflux from distal gastritis (Clavien-Dindo grade I): 6 • Protein malnutrition (Clavien-Dindo grade II): 2	N/A
	OAGB-stapleless	1	20	2 (10.0)	• Abdominal pain (Clavien-Dindo grade II): 1 • Nausea and vomiting (Clavien-Dindo grade II): 1	
	Diet	1	20	0 (0)	N/A	
IB-005 Courcoulas, 2017[163]	IGB + lifestyle	1	160	810 events	NR	≥ 1 device-related AE in 157 IGB participants; includes 35 run-in patients who followed study procedures but were not part of the randomized population.
	Lifestyle	1	130	429 events	NR	≥ 1 device-related AE in 130 ILI participants
MERIT Abu Dayyeh, 2022[165]	ESG including crossovers	8.6	150	138 (92.0) 927 events	Accommodative gastrointestinal symptoms: 612 (66.0)	Includes abdominal pain, heartburn, nausea, and vomiting

Study Name Author, Year	Intervention	Timepoint, years	N Reported	Proportion, n (%)	Top 3 AEs, n (%)	Notes
Serious adverse events (SAEs)						
IB-005 Courcoulas, 2017[163]	IGB + lifestyle	1	160	16 (10.0)	• Severe dehydration: 2 (12.5) • Procedure-related esophageal mucosal injuries: 2 (12.5) • Laryngospasm during placement: 1 (6.25) • Gastric outlet obstruction: 1 (6.25) • Gastric perforation with sepsis: 1 (6.25) • Aspiration pneumonia: 1 (6.25)	Device- or procedure-related SAE; includes 35 run-in patients who followed study procedures but were not part of the randomized population.
	Lifestyle	1	130	8 (6.1)	NR	Device- or procedure-related SAE
MERIT Abu Dayyeh, 2022[165]	ESG including crossovers	8.6	150	9 (6.0)	N/A	SAEs, surgery-related, n (%) 3 participants with device or procedure-related grade 3 events: abdominal abscess, upper gastrointestinal bleed, case of malnutrition requiring endoscopic reversal of the ESG 6 participants required subsequent hospital admission for medical management of accommodative symptoms
Cardiovascular events						
LIFEXPE-RT Ospanov, 2021[179]	OAGB-stapled	1	20	0 (0)	N/A	
	OAGB-stapleless	1	20	0 (0)		
	Diet	1	20	0 (0)		
Deaths						
LIFEXPE-RT Ospanov, 2021[179]	OAGB-stapled	1	20	0 (0)	N/A	
	OAGB-stapleless	1	20	0 (0)		
	Diet	1	20	0 (0)		

Study Name Author, Year	Intervention	Timepoint, years	N Reported	Proportion, n (%)	Top 3 AEs, n (%)	Notes
Early IGB removal						
IB-005 Courcoulas, 2017[163]	IGB + lifestyle	6 months	160	30 (18.8)	• Participant request: 15 (50.0) • Device intolerance (considered an SAE: 8 (26.7) • AE (e.g., abdominal pain): 7 (23.3)	IGB removed before 6-months; includes 35 run-in patients who followed study procedures but were not part of the randomized population.
Reoperations						
LIFEXPE-RT Ospanov, 2021[179]	OAGB-stapled	1	20	0 (0)	N/A	Under AEs section, authors state: There were no conversions of operative procedures.
	OAGB-stapleless		20	0 (0)		
	Diet		20	0 (0)		

Abbreviations. AE: adverse event; CI: confidence interval; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; ILI: intensive lifestyle intervention; MBS: metabolic and bariatric surgery; N/A: not applicable; NR: not reported; OAGB: one-anastomosis gastric bypass; RR: risk ratio; SAE: serious AE.

MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Table B24. Study Details, RCTs of MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
ENDObesity II[175] NCT02518685 US 2015 to 2018	To assess safety and efficacy of the current TPS for treatment of weight loss in patients with Class I and Class II obesity.	• IGB • Sham	N = 270 1 year Eligibility • BMI > 30 to < 40 kg/m^2 • Age, 22 to 60 years	≥ 2-year history of obesity and a history of failure of past weight loss attempts. Patients with BMI > 30 to < 35 kg/m^2 were required to have T2DM, controlled hypertension, or controlled hyperlipidemia.	Previous abdominal surgery or endoscopic intervention that had altered the esophageal, gastric, or duodenal anatomy; treatment with an IGB; use of antiobesity medications in the previous 6 months; and treatment with an NSAID or anticoagulant that could not be stopped for the duration of the trial
SMART[171] NCT02235870 US 2015 to 2016	To determine the safety and efficacy of an IGB system for weight loss	• IGB • Sham	N = 387 6 months + 6 months Eligibility • BMI > 30 to < 40 kg/m^2 • Age, 22 to 64 years	Adults who were weight stable for 12 months who made ≥ 1 attempt to lose weight through a medically or nonmedically supervised weight loss program without success	Failure to swallow a test placebo capsule, use of medications known to cause weight loss or weight gain, use of NSAIDS, history of structural or functional disorders of the esophagus, prior foregut surgery, hiatal hernia > 2 cm diagnosed on upper GI series imaging, peptic ulcer disease, T1DM or T2DM requiring oral medications or insulin, poorly controlled HTN, and severe organ dysfunction

Abbreviations. BMI: body mass index; GI: gastrointestinal; HTN: hypertension; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; NSAID: nonsteroidal anti-inflammatory drug; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; TPS: TransPyloric Shuttle.

Table B25. Full Baseline Characteristics, MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Author, Year	Intervention	Mean Age, years (SD)	Females, n (%)	Non-White, n (%)[a]	Details of Non-White Population, n (%)	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)
ENDObesity II[175] Rothstein, 2023	IGB	43.0 (8.9)	169 (93.4)	50 (27.6)	• Black/African American: 32 (17.7) • Asian: 1 (0.6) • American Indian/Alaska Native: 1 (0.6) • Native Hawaiian/Other Pacific Islander: 1 (0.6) • Hispanic or Latino: 13 (7.2) • Other: 2 (1.1)	36.8 (2.2)	101.5 (11.9)	• HTN: 46 (25.4) • Hyperlipidemia: 39 (21.6) • Diabetes: 11 (6.1) • ≥ 1 comorbidity: 117 (64.6) • ≥ 2 comorbidities: 42 (23.2)
	Sham	43.9 (8.5)	83 (93.3)	24 (27.0)	• Black/African American: 13 (14.6) • Asian: 0 (0) • American Indian/Alaska Native: 0 (0) • Native Hawaiian/Other Pacific Islander: 1 (1.1) • Hispanic or Latino: 6 (6.7) • Other: 4 (4.5)	36.1 (2.4)	98.1 (10.9)	• HTN: 26 (29.2) • Hyperlipidemia: 21 (23.6) • Diabetes: 5 (5.6) • ≥ 1 comorbidity: 63 (70.8) • ≥ 2 comorbidities: 20 (22.5)
SMART[171] Sullivan, 2018	IGB	42.7 (9.6)	171 (86.4)	33. (16.7)	NR	35.2 (2.7)	98.1 (13.2)	• Prediabetes: 3 (1.5) • HTN: 31 (15.7) • OSA: 7 (3.5) • Current smoker: 11 (5.6)
	Sham	42.5 (9.3)	170 (89.9)	34 (18.0)	NR	35.5 (2.7)	98.8 (11.9)	• Prediabetes: 0 (0) • HTN: 28 (14.8) • OSA: 5 (2.6) • Current smoker: 13 (6.9)

Abbreviations. BMI: body mass index; HTN: hypertension; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MetS: metabolic syndrome; NR: not reported; OSA: obstructive sleep apnea; SD: standard deviation.

Table B26. Weight Outcomes, MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline	Between-Group Differences	*P* Value
BMI							
SMART Sullivan, 2018[171]	BMI, kg/m^2 (SD)	6 months	IGB (Obalon)	198	−2.3 (1.8)	−1.1 (95% CI, −0.8 to− 1.5)	*P* < .001
			Sham surgery	189	−1.2 (1.8)		
EWL							
ENDObesity II Rothstein, 2023[175]	EWL, % (SD)	1	IGB (TPS)	168	30.9 (NR)	NR	*P*< .001
			Sham surgery	89	9.8 (NR)		
SMART Sullivan, 2018[171]	EWL, % (SD)	6 months	IGB (Obalon)	198	23.9 (19.2)	MD, 11.5 (95% CI, 7.8 to 15.3)	*P* < .001
			Sham surgery	189	12.4 (18.8)		
TWL							
ENDObesity II Rothstein, 2023[175]	TWL, %	1	IGB (TPS)	168	9.5 (95% CI, 8.2 to 10.8)	NR	*P* < .001
			Sham surgery	89	2.8 (95% CI, 1.1 to 4.1)		
			IGB (TPS)	171	9.3 (95% CI, 8.1 to 10.6)	NR	*P* < .001
			Sham surgery	89	2.8 (95% CI, 1.1 to 4.1)		

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline	Between-Group Differences	*P* Value
SMART Sullivan, 2018[171]	TWL, % (SD)	6 months	IGB (Obalon)	198	6.6 (5.1)	MD, 3.2 (95% CI, 2.2 to 4.2)	*P* = .04
			Sham surgery	189	3.4 (5.0)		
			IGB (Obalon; baseline BMI 30 to 34.9 kg/m^2)	97	6.8 (95% CI, 5.8 to 7.9)	MD, 3.3 (95% CI, 1.8 to 4.8)	*P* < .001
			Sham surgery (baseline BMI 30 to 34.9)	83	3.6 (95% CI, 2.4 to 4.7)		
			IGB (Obalon; baseline BMI 35 to 40)	101	6.4 (95% CI, 5.3 to 7.4)	MD, 3.1 (95% CI, 1.7 to 4.5)	*P* < .001
			Sham surgery (baseline BMI 35 to 40)	106	3.3 (95% CI, 2.3 to 4.3)		
			IGB (Obalon; any weight loss at 24 weeks)	151	6.9 (4.4)	NR	NR
			Sham surgery-crossover (any weight loss at 24 weeks)	128	7.0 (6.2)		
SMART Sullivan, 2018[171]	TWL > 5%, n (%)	6 months	IGB (Obalon)	198	123 (62.1)	NR	NR
			Sham surgery	189	58 (30.7)		
Weight change							
SMART Sullivan, 2018[171]	Weight, kg (SD)	6 months	IGB (Obalon)	198	−6.6 (5.3)	−3.2 (95% CI, −2.2 to − 4.2)	*P* < .001
			Sham surgery	189	−3.3 (5.1)		

Abbreviations. BMI: body mass index; CI: confidence interval; EWL: excess weight loss; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MD: mean difference; N/A: not applicable; NR: not reported; SD: standard deviation; TPS: TransPyloric Shuttle; TWL: total weight loss.

Table B27. Cardiovascular Risk Factors, MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline	Between-Group Differences	*P* Value	Notes
Blood pressure								
ENDObesity II Rothstein, 2023[175]	Systolic, mmHg (SD)	1	IGB (TPS)	171	−3.4 (0.9)	LS MD, −3.7 (SE, 1.0; 95% CI, −5.8 to −1.7)	*P* < .001	The magnitude of these changes was higher in those with abnormal baseline measurements: LSM, −7.8 (95% CI, −12.2 to −3.4); *P* < .01
			Sham surgery	89	− 2.6 (1.3)			
SMART Sullivan, 2018[171]		6 months	IGB (Obalon)	198	−3 (95% CI, −5 to −1)	MD, −4 (95% CI, −7 to −2)	*P* = .002	N/A
			Sham surgery	189	1 (95% CI, −1 to 3)			
ENDObesity II Rothstein, 2023[175]	Diastolic, mmHg (SD)	1	IGB (TPS)	171	−1.9 (0.7)	LS MD, −3.0 (SE, 1.1; 95% CI, −5.2 to −0.8)	*P* < .01	The magnitude of these changes was higher in those with abnormal baseline measurements: LSM, −4.5 (95% CI, −7.3 to −1.6); *P* < .01
			Sham surgery	89	1.1 (0.9)			
SMART Sullivan, 2018[171]		6 months	IGB (Obalon)	198	1 (95% CI, −1 to 2)	MD, −1 (95% CI, −3 to 1)	*P* = .34	N/A
			Sham surgery	189	2 (95% CI, 0 to 3)			
Cholesterol-related outcomes								
ENDObesity II Rothstein, 2023[175]	HDL, mg/dL (SD)	1	IGB (TPS)	171	1.3 (0.7)	LS MD, −0.3 (SE, 1.2; 95% CI, −2.7 to 2.1)	*P* > .05	N/A
			Sham surgery	89	1.6 (1.0)			
SMART Sullivan, 2018[171]		6 months	IGB (Obalon)	198	3 (95% CI, 1 to 4)	MD, 1 (95% CI, 0 to 3)	*P* = .08	
			Sham surgery	189	1 (95% CI, −1 to 2)			

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change From Baseline	Between-Group Differences	*P* Value	Notes
ENDObesity II Rothstein, 2023[175]	LDL, mg/dL (SD)	1	IGB (TPS)	171	−2.9 (1.9)	LS MD, −6.8 (SE, 3.2; 95% CI, −13.0 to −0.6)	*P* = .03	The magnitude of these changes was higher in those with abnormal baseline measurements: LSM, −16.7 (95% CI, −29.1 to −4.7); *P* < .01
			Sham surgery	89	3.9 (2.5)			
SMART Sullivan, 2018[171]		6 months	IGB (Obalon)	198	−6 (95% CI, −10 to −3)	MD, −5 (95% CI, −10 to 1)	*P* = .08	N/A
			Sham surgery	189	0 (95% CI, −5 to 5)			
ENDObesity II Rothstein, 2023[175]	Triglycerides, mg/dL (SD)	1	IGB (TPS)	171	−15.8 (3.6)	LS MD, −7.8 (SE, 6.0; 95% CI, −19.6 to 4.1)	*P* > .05	N/A
			Sham surgery	89	−8.1 (4.8)			
SMART Sullivan, 2018[171]		6 months	IGB (Obalon)	198	−15 (95% CI, −23 to −7)	MD, −15 (95% CI, −25 to −5)	*P* = .005	
			Sham surgery	189	3 (95% CI, −5 to 10)			

Abbreviations. CI: confidence interval; HDL: high-density lipoprotein; IGB: intragastric balloon; LDL: low-density lipoprotein; LS MD: least squares mean difference; LSM: least squares mean; MBS: metabolic and bariatric surgery; MD: mean difference; N/A: not applicable; NR: not reported; SD: standard deviation; SE: standard error; TPS: TransPyloric Shuttle.

Table B28. HRQoL Outcomes, MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Study Name Author, Year Study Timepoint	Subdomain	Intervention	N Reported	Mean Change From Baseline, LSM (SD)	Between-Group Differences	*P* Value
IWQOL-Lite						
ENDObesity II Rothstein, 2023[175] 1 year	Total score	IGB (TPS)	167	81.1 (14.0)	NR	*P* < .01
		Sham surgery	89	75.2 (15.2)		
	Physical function	IGB (TPS)	167	83.3 (13.63)		*P* < .001
		Sham surgery	89	75.7 (18.8)		
	Public distress	IGB (TPS)	167	88.2 (16.2)		*P* > .05
		Sham surgery	89	89.6 (12.46)		
	Self-esteem	IGB (TPS)	167	65.5 (23.8)		*P* = .045
		Sham surgery	89	56.8 (23.3)		
	Sexual life	IGB (TPS)	167	81.83 (22.7)		*P* = .02
		Sham surgery	89	76.47 (22.6)		
	Working conditions	IGB (TPS)	167	92.1 (14.4)		*P* > .05
		Sham surgery	89	87.24 (14.9)		

Abbreviations. HRQoL: health-related quality of life; IGB: intragastric balloon; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; LSM: least squares mean; MBS: metabolic and bariatric surgery; NR: not reported; SD: standard deviation; TPS: TransPyloric Shuttle.

Table B29. Safety Outcomes, MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Study Name Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Proportion	Most Common Adverse Events	Notes
Any adverse events (AEs)							
ENDObesity II[175] Rothstein, 2024	≥ 1 AE, n (%)	IGB (TPS)	1	203	203 (100.0)	• Nausea : 131 (64.5) • Abdominal pain, upper: 128 (63.1) • Vomiting: 126(62.1)	AEs that are not SAEs reported in ≥ 10% of patients
		Sham surgery		89	87 (97.8)	• Oropharyngeal pain: 44 (49.4) • Abdominal pain, upper: 37 (41.6) • Nausea: 35 (39.3)	
SMART[171] Sullivan, 2018	≥ 1 AE, n (%)	IGB (Obalon)	6 months	198	187 (94.4)	• Abdominal pain: 148 (74.7) • Nausea: 110 (55.6) • Dyspepsia: 37 (18.7)	Between-group difference, *P* < .001
		Sham surgery		189	132 (69.8)	• Abdominal pain: 48 (25.4) • Nausea: 34 (18.0) • Constipation: 32 (16.9)	
SMART[171] Sullivan, 2018	Number of AEs	IGB (Obalon)	6 months	198	902 events	• Abdominal pain: 299 events • Nausea: 186 events • Dyspepsia: 43 events	N/A
		Sham surgery		189	358 events	• Abdominal pain: 62 events • Nausea: 34 events • Constipation: 41 events	
Deaths							
ENDObesity II[175] Rothstein, 2024	Deaths, n (%)	Sham surgery	1	89	0 (0)	N/A	N/A
		IGB (TPS)		203	0 (0)		

Study Name Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Proportion	Most Common Adverse Events	Notes
IGB removal							
ENDObesity II[175] Rothstein, 2024	Early IGB removal, n (%)	IGB (TPS)	1	168	39 (23.0)	• Device impaction: 7 (3.4); 4 considered SAEs • Abdominal pain, upper: 6 (3.0); 1 considered SAE • Gastric ulcer: 1 (0.5); considered SAE • Vomiting: 8 (3.9); 1 considered SAE • Nausea: 3 (1.5) • Meningioma: 1 (0.5); considered SAE not related to device • Abdominal discomfort, diarrhea, dyspepsia, dysphagia, fatigue, and gastroenteritis all had 1 each	7 appear to have not been related to AEs or SAEs.
Serious adverse events (SAEs)							
ENDObesity II[175] Rothstein, 2024	Participants who experienced a surgery-related SAE, n (%)	IGB (TPS)	1	213	6 (2.8)	• Esophageal rupture with bilateral pneumothoraces, 1 • Upper abdominal pain, 1 • Vomiting and device impaction, 1 • Device intolerance and device impaction, 1 • Gastric ulcer and device impaction, 1 • Device impaction, 1	Esophageal rupture with bilateral pneumothoraces occurred in association with unsuccessful TPS deployment; patient had surgical repair of esophagus. Other 5 patients resolved after device removal.

Study Name Author, Year	Specific Outcome	Intervention	Timepoint, years	N Reported	Proportion	Most Common Adverse Events	Notes
SMART[171] Sullivan, 2018	Participants who experienced an SAE, n (%)	IGB (Obalon)	6 months	198	5 (2.5)	• 5 events, 1 each: • Abnormal pap smear • Cancer • Infection • Lower body injury/pain • Peptic ulcer disease (bleeding)	N/A
		Sham surgery		189	4 (2.1)	• 3 types of events: • Foot injury/pain (n = 1) • Infection (n = 2) • Sepsis (n = 1)	

Abbreviations. AE: adverse event; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; N/A: not applicable; SAE: serious AE; TPS: TransPyloric Shuttle.

Appendix C. Full Evidence Tables for Studies Conducted in Children and Adolescents

Table C1. Study Details, RCTs of MBS in Children and Adolescents

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
AMOS2[138] NCT02378259 Northern Europe 2014 to 2017	To evaluate the efficacy and safety of MBS in adolescents aged 13 to 16 years with severe obesity compared with intensive non-surgical treatment.	• RYGB • SG • Lifestyle (diet)	N = 50 2 years Eligibility • BMI ≥ 35 kg/m^2 • Age, 13 to 16 years	Attended treatment for obesity for at least 1 year, including at least 6 months at a specialized pediatric obesity unit. Participants were required to pass assessments by a pediatric psychologist and a pediatrician, have a Tanner pubertal stage of at least 3, and were required to show a positive attitude to long-term follow-up.	Monogenic or syndromic obesity, major psychiatric illness, regular self-induced vomiting, ongoing substance use, severe pervasive developmental disorder, and previous major gastrointestinal surgery
BASIC[161] NCT01172899 Western Europe 2011 to 2019	To assess the efficacy and safety of bariatric surgery in adolescents without sufficient weight loss after lifestyle intervention for severe obesity.	• AGB • Lifestyle	N = 59 1 year Eligibility • BMI ≥ 35 kg/m^2 • Age, 14 to 16 years	With obesity mediated comorbidities; participation in a lifestyle intervention for ≥ 12 months without at least 5% TWL	Eating disorders; lack of understanding of surgical treatment and risks; inadequate family/social support; skeletal or developmental immaturity; severe cardiorespiratory impairment; syndromic disorders causing obesity; unwillingness to adhere to follow-up procedures

Study Name Trial Number Location(s) Study Period	Trial Aim	Interventions	Randomized (N) Study Duration Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
O'Brien, 2010[168] ACTRN12605000160639 Australia, New Zealand 2005 to 2008	To compare the outcomes of gastric banding with an optimal lifestyle program on adolescent obesity	AGB Lifestyle	N = 50 2 years Eligibility • BMI ≥ 35 kg/m^2 • Age, 14 to 18 years	Identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; physical limitations such as an inability to play a sport, difficulties with activities of daily living; or psychosocial difficulties such as isolation or low self-esteem, subject to bullying that stems from obesity, and evidence of attempts to lose weight by lifestyle means for > 3 years	Intellectual disability, Prader Willi syndrome

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; BP: blood pressure; MBS: metabolic and bariatric surgery; MDC: multidisciplinary diabetes care; MetS: metabolic syndrome; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus; TWL: total weight loss.

Table C2. Full Baseline Characteristics, RCTs of MBS in Children and Adolescents

Study Name Author, Year	Intervention	Mean Age, years (SD)	Female, n (%)	Non-White, n (%)[a]	Mean BMI, kg/m^2 (SD)	Mean Weight, kg (SD)	Comorbidities, n (%)	Current Medications for Comorbidities, n (%)
AMOS2 Jarvholm, 2023[138]	RYGB	15.6 (1.1)	19 (76)	NR	42.9 (5.0)	124.3 (16.9)	• Dyslipidemia: 9 of 23 (23) • Raised BP: 8 of 25 (32) • Smoking: 1 of 24 (4.0) • T2DM: 0 (0)	NR
	Lifestyle	15.9 (0.8)	18 (72)	NR	42.3 (5.5)	120.9 (21.6)	• Dyslipidemia: 12 of 24 (50) • Raised BP: 10 of 24 (42) • Smoking: 0 of 24 (0) • T2DM: 0 (0)	NR
BASIC Roebroek, 2024[161]	AGB	15.9 (1.0)	23 (79.3)	NR	43.9 (5.6)	129.0 (18.5)	• T2DM: 3 (10.3)	Diabetes-related: 3 (10.3)
	Lifestyle	15.6 (1.0)	24 (80.0)	NR	44.3 (5.6)	128.6 (21.3)	• T2DM: 3 (10.0)	Diabetes-related: 2 (8.3)
O'Brien, 2010[168]	AGB	16.5 (1.4)	16 (64.0)	NR	42.3 (6.1)	120.7 (25.3)	• MetS: 9 (36)	NR
	Lifestyle	16.6 (1.2)	18 (72.0)	NR	40.4 (3.1)	115.4 (14.0)	• MetS: 10 (40)	NR

Note. [a] Details of non-White populations were not reported.
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; BP: blood pressure; MBS: metabolic and bariatric surgery; MetS: metabolic syndrome; NR: not reported; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table C3. Weight Outcomes, MBS vs. Lifestyle Interventions in Children and Adolescents

Study Name Author, Year	Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
BMI							
AMOS2 Jarvholm, 2023[138]	Achieved BMI < 30, n (%)	2	RYGB	24	15 (63.0)	NR	NR
			Lifestyle	23	1 (4.0)		
BASIC Roebroek, 2024[161]	zScore, (SD)	1	AGB	29	3.11 (0.56)	MD, −0.43 (95% CI, −0.59 to −0.26)	*P* < .001
			Lifestyle	23	3.58 (0.36)		
O'Brien, 2010[168]		2	AGB	25	1.08 (95% CI, 0.86 to 1.31)	NR	NR
			Lifestyle	25	0.23 (95% CI, 0.05to 0.39)		
AMOS2 Jarvholm, 2023[138]	BMI change, % (SD)	2	RYGB	24	29.3 (NR)	NR	*P* < .001[a]
			Lifestyle	23	0.4 (NR)		
	BMI change, kg/m^2 (SD)	2	RYGB	24	−12.6 (NR)	MD, −12.4 (95% CI, −15.5 to −9.3)	
			Lifestyle	23	−0.2 (NR)		
O'Brien, 2010[168]		2	AGB	25	−12.7 (95% CI, −14.2 to −11.3)	NR	*P* < .001
			Lifestyle	25	−1.3 (95% CI, −2.9 to 0.4)		
AMOS2 Jarvholm, 2023[138]		2	RYGB	24	30.2 (95% CI, 27.6 to 32.9)	NR	*P* < .001[a]
			Lifestyle	23	42.1 (95% CI, 39.4 to 44.7)		
EWL							
O'Brien, 2010[168]	EWL, % (SD)	2	AGB	25	78.8% (95% CI, 66.6 to 91.0)	MD, 65.60 (95% CI, 50.25 to 80.95)[b]	*P* < .001
			Lifestyle	25	13.2% (95% CI, 2.6 to 21.0)		
	EWL ≥ 50%, n (%)		AGB	25	21 (84)		NR
			Lifestyle	25	3 (12)		

Study Name Author, Year	Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
TWL, % (SD)							
BASIC Roebroek, 2024[161]	TWL, % (SD)	1	AGB	29	11.23 (7.76)	MD, 13.10 (95% CI, 17.49 to 8.72)	*P* < .001
			Lifestyle	23	−1.74 (8.05)		
AMOS2 Jarvholm, 2023[138]		2	RYGB	24	28.7 (95% CI 23.8 to 33.6)	MD, 29.10 (95% CI, 22.48 to 35.72)	*P* < .001[a]
			Lifestyle	23	−0.4 (95% CI −4.6 to 5.4)		
O'Brien, 2010[168]		2	AGB	25	28.3 (95% CI, 24.9 to 31.7)	MD, 24.20 (95% CI, 21.11 to 29.29)	*P* < .001
			Lifestyle	25	3.1 (95% CI, 0.7 to 6.8)		
AMOS2 Jarvholm, 2023[138]	TWL ≥ 10%, n (%)	2	RYGB	24	22 (92.0)	NR	*P* < .001
			Lifestyle	23	6 (26.0)		

Notes. The AMOS study reported positive results using negative numbers (e.g., −28.7% EWL) and negative results as positive (e.g., +0.4% EWL); we have converted these values to align with the conventions as reported by other studies. [a] *Adjusted for stratifying variables (sex and study center).*
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; CI: confidence interval; EWL: excess weight loss; MBS: metabolic and bariatric surgery; MD: mean difference; NR: not reported; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; TWL: total weight loss.

Table C4. Cardiovascular Outcomes, MBS vs. Lifestyle Interventions in Children and Adolescents

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
Full remission of baseline comorbidity							
AMOS2 Jarvholm, 2023[138]	Dyslipidemia, n (%)	2	RYGB	9	8 (89.0)	RR, 1.648 (95% CI, 0.989 to 2.747)[b]	*P* > .05[c]
			Lifestyle	10	1 (10.0)		
	Hypertension, n (%)		RYGB	7	4 (57.0)	RR, 0.124 (95% CI, 0.019 to 0.793)[b]	*P* < .001[c]
			Lifestyle	8	4 (50.0)		
O'Brien, 2010[168]	Metabolic syndrome, n (%)	2	RYGB	24	24 (100)	RR, 0.027 (95% CI, 0 to 13.67)[b]	*P* = .025
			Lifestyle	18	14 (77.8)		
BASIC Roebroek, 2024[161]	T2DM, n (%)	1	AGB	3	1 (33.3)	RR, 0.857 (95% CI, 0.285 to 2.577)[b]	*P* > .05[c]
			Lifestyle	3	0		
Blood pressure							
AMOS2 Jarvholm, 2023[138]	Systolic, mmHg (SD)	2	RYGB	25	−4.50 (95% CI, −9.30 to 0.30)	MD, −0.90 (95% CI, −7.90 to 6.10)	*P* = .08[a]
			Lifestyle	25	−3.60 (95% CI, −8.70 to 1.40)		
BASIC Roebroek, 2024[161]		1	AGB	27	125 (16)	MD, −2 (95% CI, −9 to 5)	*P* = .56
			Lifestyle	21	123 (10)		
O'Brien, 2010[168]		2	AGB	24	−12.5 (17.6)	MD, 7.8 (−4.5 to 20.1)	*P* > .05
			Lifestyle	18	−20.3 (21.7)		
AMOS2 Jarvholm, 2023[138]	Diastolic, mmHg (SD)	2	RYGB	25	−6.20 (95% CI, −10.40 to −2.00)	MD, −2.40 (95% CI, −8.50 to 3.80)	*P* = .45[a]
			Lifestyle	25	−3.80 (95% CI, −8.30 to 0.60)		
BASIC Roebroek, 2024[161]		1	AGB	27	72 (29)	MD, −2 (95% CI, −7 to 2)	*P* = .34
			Lifestyle	21	68 (9)		

Study Name Author, Year	Specific Outcome	Timepoint, years	Intervention	N Reported	Mean Change from Baseline, or Proportion	Between-Group Differences	*P* Value
O'Brien, 2010[168]		2	AGB	24	−6.0 (9.4)	MD, 0.9 (95% CI, −5.9 to 7.7)	*P* > .05
			Lifestyle	18	−6.9 (12.5)		
Cholesterol-related outcomes							
BASIC Roebroek, 2024[161]	HDL	1	AGB	29	43.6 mg/dL (SD, 12.4)	MD, 0.9 (95% CI, −3.6 to 5.5)	*P* = .69
			Lifestyle	23	40.5 (SD, 9.4)		
AMOS2 Jarvholm, 2023[138]		2	RYGB	25	1.7 mmol/L (95% CI, 1.6 to 1.8)	NR	*P* > .05[a]
			Lifestyle	25	1.1 mmol/L (95% CI, 1.0 to 1.2)		
O'Brien, 2010[168]		2	AGB	24	+9.3 mg/dL (SD, 14.7)	MD, 5.4 (95% CI, 3.5 to 14)	*P* > .05
			Lifestyle	18	+3.9 mg/dL (SD, 6)		
AMOS2 Jarvholm, 2023[138]	LDL	2	RYGB	25	2.1 mmol/L (95% CI, 1.9 to 2.3)	NR	*P* > .05[a]
			Lifestyle	25	2.6 mmol/L (95% CI, 2.4 to 2.9)		
AMOS2 Jarvholm, 2023[138]	Triglycerides	2	RYGB	25	0.8 mmol/L (95% CI, 0.6 to 1.0)	NR	*P* > .05[a]
			Lifestyle	25	1.3 mmol/L (95% CI, 1.1 to 1.5)		
BASIC Roebroek, 2024[161]		1	AGB	29	126.0 mg/dL (SD, 38.9)	MD, −33.3 (95% CI, −64.3 to −2.4)	*P* = .04
			Lifestyle	23	143.0 mg/dL (SD, 63.3)		

Notes. [a] *Adjusted for stratifying variables (sex and study center).* [b] *Calculated by Center for Evidence-based Policy researchers.*
Abbreviations. AGB: adjustable gastric band; CI: confidence interval; HDL: high-density lipoprotein (cholesterol); LDL: low-density lipoprotein (cholesterol); MBS: metabolic and bariatric surgery; MD: mean difference; NR: not reported; RYGB: Roux-en-Y gastric bypass; SD: standard deviation; T2DM: type 2 diabetes mellitus.

Table C5. HRQoL Outcomes, MBS vs. Lifestyle Interventions, in Children and Adolescents

Study Name Author, Year	Timepoint, years	Subdomain	Intervention	N Reported	Mean Change from Baseline, points (95% CI)	Between-Group Differences	*P* Value
Beck Youth Inventory							
AMOS2[138] Jarvholm, 2023	2	Self-concept	RYGB	25	8.50 (95% CI, 4.10 to 12.80)	MD, 4.20 (95% CI, −2.20 to 10.60)	*P* > .05
			Lifestyle	25	4.30 (95% CI, −0.50 to 9.00)		
		Anxiety	RYGB	25	−4.80 (95% CI, −9.40 to −0.20)	MD, −1.40 (95% CI, −8.10 to 5.40)	
			Lifestyle	25	−3.40 (95% CI, −8.30 to 1.50)		
		Depression	RYGB	25	−3.50 (95% CI, −8.50 to 1.50)	MD, −4.90 (95% CI, −12.30 to 2.50)	
			Lifestyle	25	1.40 (95% CI, −4.10 to 6.80)		
		Anger	RYGB	25	−6.00 (95% CI, −9.70 to −2.30)	MD, −0.90 (95% CI, −6.40 to 4.70)	
			Lifestyle	25	−5.10 (95% CI, −9.20 to −1.10)		
		Disruptive behavior	RYGB	25	−2.30 (95% CI, −4.00 to −0.60)	MD, −2.00 (95% CI, −4.50 to 0.50)	
			Lifestyle	25	−0.30 (95% CI, −2.20 to 1.50)		
OP-14 Scale							
AMOS2[138] Jarvholm, 2023	2	Obesity-related problems	RYGB	25	−24.30 (95% CI, −35.30 to −13.10)	MD, −6.70 (95% CI, −23.10 to 9.60)	*P* > .05
			Lifestyle	25	−17.60 (95% CI, −29.50 to −5.70)		
RAND-36							
AMOS2[138] Jarvholm, 2023	2	Bodily pain	RYGB	25	+8.60 (95% CI, 0.50 to 16.80)	MD, 4.30 (95% CI, −7.70 to 16.30)	*P* > .05
			Lifestyle	25	+4.40 (95% CI, −4.40 to 13.20)		
		Emotional role functioning	RYGB	25	+3.60 (95% CI, −9.20 to 16.40)	MD,1.90 (95% CI, −16.90 to 20.70)	
			Lifestyle	25	+1.70 (95% CI, −12.10 to 15.50)		
		Emotional well-being	RYGB	25	+7.80 (95% CI, −1.10 to 16.70)	MD, 8.00 (95% CI, −4.90 to 21.00)	
			Lifestyle	25	−0.20 (95% CI, −9.70 to 9.20)		
		Energy or fatigue	RYGB	25	+8.30 (95% CI, −2.80 to 19.40)	MD, 6.90 (95% CI, −9.20 to 23.10)	
			Lifestyle	25	+1.30 (95% CI, −10.40 to 13.00)		
		General health perceptions	RYGB	25	+20.90 (95% CI, 11.70 to 30.20)	MD, 15.60 (95% CI, 2.10 to 29.10)	*P* < .03
			Lifestyle	25	+5.30 (95% CI, −4.50 to 15.20)		
		Physical role functioning	RYGB	25	+33.00 (95% CI, 15.30 to 50.60)	MD, 25.20 (95% CI, −0.40 to 50.70)	*P* = .053
			Lifestyle	25	+7.80 (95% CI, −10.60 to 26.20)		
		Social role functioning	RYGB	25	+11.40 (95% CI, −7.60 to 30.40)	MD, 9.30 (95% CI, −18.40 to 37.00)	*P* > .05
			Lifestyle	25	+2.00 (95% CI, −18.10 to 22.20)		

Abbreviations. CFB: change from baseline; CI: confidence interval; HRQoL: health-related quality of life; MBS: metabolic and bariatric surgery; MD: mean difference; NR: not reported; OP-14: Obesity-related Problems Scale; RYGB: Roux-en-Y gastric bypass; SF-36/RAND-36: 36-item Short-Form Health Survey.

Table C6. Safety Outcomes, MBS vs. Lifestyle Interventions, in Children and Adolescents

Author, Year Study Name	Outcome	Intervention	Timepoint, years	N Reported	Proportion, n (%)	Top 3 Adverse Events, n (%)
Surgery-related complications						
AMOS2 Jarvholm, 2023[138]	Complications	RYGB	6 weeks	25	2 (8.0; 3 events)	• Minor wound complications, grade I: 2 (100) ○ 1 of these participants also underwent cholecystectomy at 6 weeks post-surgery.
			2		2 (8.0; 2 events)	• Symptomatic gallstones: 1 (50.0) • Acute abdominal pain without diagnosis or intervention: 1 (50.0)
BASIC Roebroek, 2023[161]	Reoperation	AGB	1	29	1 (3.4; 1 event)	• Band access port dislocation requiring reintervention: 1 participant
	Surgery-related SAEs				2 (6.9; 2 events)	• Band access port dislocation requiring intervention: 1 participant • Gallbladder removal: 1 participant
Overall adverse events (AEs)						
O'Brien, 2010[168]	N/A	AGB	2	25	12 (48; 13 events)	• Proximal gastric enlargements: 6 (24) • Needle stick injury to tubing: 2 (8) • Cholecystectomy: 1 (4)
		Lifestyle		25	11 (44; 18 events)	• Hospital admission for depression and intracranial hypertension: 1 (4) • Cholecystectomy: 1 (4)
BASIC Roebroek, 2023[161]	N/A	AGB	1	29	5 (17.2; 5 events)	• Heartburn or peptic complaints: 3 • Band access port dislocation: 1 • Acute gallbladder disease: 1

Abbreviations. AE: adverse event; AGB: adjustable gastric band; MBS: metabolic and bariatric surgery; N/A: not applicable; RYGB: Roux-en-Y gastric bypass; SAE: serious adverse event.

Table C7. Summary of Inclusion Criteria and Baseline Characteristics, NRSs of MBS in Adolescents

Study Details						Eligibility Criteria		Baseline Characteristics			
Study Name Author, Year	Location	Number Enrolled	MBS Type(s)	Control Group	Max Follow-up, years	Age Range, years	BMI, kg/m^2	Mean Age, years	Mean BMI, kg/m^2	Female, %	Non-White, %
AMOS Olbers, 2012[189]	Sweden	162	• RYGB	Lifestyle	5	13 to 18	≥ 35	16.5	46.0	65.0%	NR
Teen-LABS Inge, 2016[186]	US	242	• AGB[a,b] • RYGB • SG[b]	None	5	13 to 19	≥ 35	17.1	50.5	75.6	28.1

Notes. [a] *Not included in 3-year analysis.* [b] *Not included in 5-year analysis.*
Abbreviations. AGB: adjustable gastric banding; BMI: body mass index; MBS: metabolic and bariatric surgery; NR: not reported; NRS: nonrandomized study; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Table C8. Selected Long-Term Outcomes, NRSs of MBS in Adolescents

Outcome	Teen-LABS[185-187]		AMOS[188,189]
	3 years; N = 228 (SG and RYGB)	5 years; N = 161 (RYGB only)	5 years; N = 153
Weight-related outcomes			
Total weight loss, %	Overall: 27% (95% CI, 25 to 29) • RYGB: 28% • SG: 26%	26% (95% CI, 23 to 29)	• RYGB: 28% (NR) • Control: 5% weight gain
BMI mean change from baseline, kg/m^2	Overall: −15 (95% CI, −16 to −13) • RYGB: −15 • SG: −13	−12.7 (95% CI, −14.2 to −11.2)	• RYGB: −13.1 (95% CI −14.5 to −11.8) • Control: +3.3 (95% CI +1.1 to +4.8) • *P* < .001
BMI < 30 kg/m^2, n (%)	Overall: 26%	NR	• RYGB: 37% • Control: 3% • *P* < .001
Comorbidities and cardiovascular risk factors			
T2DM remission, n (%)	19 of 20 (95.0)	12 of 14 (85.7)	• RYGB: 3 of 3 (100) • Control: NR
Hypertension remission, n (%)	56 of 76 (74.0)	33 of 47 (70.2)	• RYGB: 12 of 12 (100) • Control: NR
Dyslipidemia resolution, n (%)	84 of 128 (66)	NR	• RYGB: 43 of 52 (83) • Control: NR
Adverse events			
Vitamin B12 deficiency, n (%)	13 of 160 (8.0)	NR	• RYGB: 16 of 73 (22) • Control: 2 of 31 (6) • *P* = .05
Vitamin D insufficiency, n (%)	74 of 172 (43)	NR	• RYGB: 46 of 73 (63) • Control: 20 of 35 (57) • *P* = .67
Low iron or ferritin, n (%)	43 of 171 (57)	NR	• RYGB: 51 of 77 (66) • Control: 12 of 42 (29) • *P* < .001
Anemia, n (%)	NR	NR	• RYGB: 25 of 77 (32.5) • Control: 3 of 42 (7) • *P* < .001

Outcome	Teen-LABS[185-187]		AMOS[188,189]
	3 years; N = 228 (SG and RYGB)	5 years; N = 161 (RYGB only)	5 years; N = 153
Serious adverse events (SAEs)			
Additional abdominal operations (surgical groups only), n (%)	30 of 228 participants (13.2) 47 events (22.3 per 300 PY)	32 of 161 participants (20) 46 events (19.5 per 500 PY)	• 20 of 80 participants (25) • 21 events
Death, n (%)	1 of 228 participants (0.4) • Hypoglycemic event	3 of 161 participants (1.9) • Suspected sepsis (1) • Overdose (2)	• No deaths

Note. [a] *Surgical groups only.*
Abbreviations. BMI: body mass index; CI: confidence interval; MBS: metabolic and bariatric surgery; NR: not reported; NRS: nonrandomized study; PY: person years; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Appendix D. Full Details of Ongoing Studies

Table D1. Details of Ongoing Studies of MBS

Study Name Trial Number Location(s)	Expected Enrollment Eligibility Criteria Age	Procedure Type Comparators	Follow-up	Outcome Measures	Primary Completion Date
RCTs					
ESGORT[194] NCT04200144 Italy	N = 60 BMI ≥ 30 to < 45 20 to 65 years	• ESG (Overstitch) • MWM	3 years	• GERD • Liver disease • Weight loss	December 2020
DSvsSADI[195] NCT02692469 Canada	N = 140 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity or BMI ≥ 30 with T2DM 18 to 70 years	• SADI-S • BPD	Up to 5 years	• BMI • Complications • Hypertension • Micronutrients (ferritin, vit B12, vit D) • T2DM • Weight loss	April 2021
TESLA-NASH[196] NCT04060368 Spain	N = 30 BMI ≥ 35 to < 45; or BMI ≥ 30 to < 35 with T2DM; NASH 18 to 60 years	• ESG (Overstitch) • SG	96 weeks	• AEs • Complications • Liver fibrosis • T2DM • Weight loss	June 2022
NCT04800835[197] Czechia	N = 44 BMI ≥ 27 18 to 65 years	• Adjustable IGB (Spatz3) • Nonadjustable IGB	1 year	• Weight loss	July 2022
OAGBvsLLbypass[198] NCT04812132 Estonia	N = 500 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 18 to 60 years	• OAGB • RYGB	10 years	• Cholesterol • CVD • GERD • Micronutrients (ferritin, vit B12) • T2DM • Weight loss	January 2023

Study Name Trial Number Location(s)	Expected Enrollment Eligibility Criteria Age	Procedure Type Comparators	Follow-up	Outcome Measures	Primary Completion Date
NCT04854317[199] Italy	N = 150 BMI > 30 ≥ 18 years	• IGB • ESG • EVG • POSE-2	Up to 4 years	• BMI • Complications • Liver disease • QoL • Weight loss	June 2023
NCT04767490[200] Canada	N = 120 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 18 to 60 years	• SADI-S • BPD	5 years	• BMI • Complications • CVD • GERD • Micronutrients • Mortality • QoL • T2DM • Weight loss	September 2023
SADISLEEVE[201] NCT03610256 France	N = 382 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 18 to 65 years	• SADI-S • RYGB	2 years	• BMI • Cholesterol • Complications • GERD • Hypertension • Micronutrients (ferritin, iron, vit B12, vit D) • QoL • T2DM • Weight loss	October 2023
UMIN000038432[202] Japan	N = 60 BMI ≥ 27.5 to < 35; T2DM 18 to 50 years	• SG • MWM	1 year	• Cholesterol • Complications • CVD • Hypertension • QoL • T2DM • Weight loss	November 2023

Study Name Trial Number Location(s)	Expected Enrollment Eligibility Criteria Age	Procedure Type Comparators	Follow-up	Outcome Measures	Primary Completion Date
NCT03875625[203] China	N = 80 BMI ≥ 35 or BMI ≥ 30 with metabolic syndrome or BMI ≥ 25-30; NAFLD 18 to 65 years	• Bariatric surgery (RYGB or SG) • Dietitian led lifestyle intervention groups • Usual care	1 year	• BMI • Cholesterol • Hypertension • Liver disease • T2DM • Weight loss	December 2023
TORSBY I[204] NCT03938571 Sweden	N = 56 (actual) BMI > 45 ≥ 18 years	• SADI-S • BPD	10 years	• Complications • Hypertension • Micronutrients (vit B12, vit D) • T2DM • Weight loss	January 2024
OASIS[205] NCT05948852 Spain	N = 96 BMI ≤ 50 18 to 65 years	• SADI-S • OAGB	5 years	• Complications • GERD • Micronutrients (iron, vit B12) • Mortality • QoL • Weight loss	July 2024
NCT05739162[206] US	N = 24 BMI ≥ 30 to < 50 22 to 69 years	• ESG • Lifestyle intervention	1 year	• Complications • GERD • SAEs • Weight loss	January 2025
BAR-3[207] NCT04861961 Spain	N = 186 BMI ≥ 50 to < 60 18 to 65 years	• SADI-S • OAGB • BPD	5 years	• Complications • GERD • Hypertension • Mortality • QoL • Revisional surgery • T2DM • Weight loss	April 2025
NCT06138821[208] US	N = 30 BMI ≥ 30 to < 40; NAFLD 21 to 65 years	• ESG only • ESG + semaglutide • Semaglutide only	1 year	• Liver fibrosis • QoL • Weight loss	July 2025

Study Name Trial Number Location(s)	Expected Enrollment Eligibility Criteria Age	Procedure Type Comparators	Follow-up	Outcome Measures	Primary Completion Date
NASHSURG[209] NCT03472157 France	N = 100 BMI ≥ 30; NASH 18 to 65 years	• RYGB or SG • Lifestyle therapy	5 years	• Cholesterol • Complications • Mortality • NASH • QoL • T2DM • Weight loss	March 2026
YOMEGA-2[210] NCT06057597 France	N = 368 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 18 to 65 years	• OAGB • RYGB	2 years	• BMI • Cholesterol • Complications • GERD • Hypertension • Micronutrients (ferritin, iron, vit B12, vit D) • QoL • T2DM • Weight loss	October 2027
Prospective comparative NRSs					
4XL[211] NCT00923819 Norway	N = 120 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 13 to 18 years	• RYGB • Usual care	10 years	• BMI • Complications • QoL • Weight loss	August 2023
NCT04306445[212] US	N = 75 BMI ≥ 30 to < 40 22 to 65 years	• IGB (Obalon) • ESG • Lifestyle intervention	6 months	• T2DM • Weight loss	March 2024
ST2OMP[213] NCT04128995 US	N = 100 BMI ≥ 35; or > 120% of 95th percentile and youth-onset T2DM[246] 13 to 19 years	• SG + MWM • MWM only • SG only	2 years	• Hypertension • Liver disease • T2DM	September 2024

Study Name Trial Number Location(s)	Expected Enrollment Eligibility Criteria Age	Procedure Type Comparators	Follow-up	Outcome Measures	Primary Completion Date
YOMEGA 5-7y[214] NCT05549271 France	N = 248 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 18 to 65 years	• OAGB • RYGB	7 years	• BMI • Weight loss	September 2024
Base-NAFLD[215] NCT04366999 China	N = 150 BMI ≥ 32.5 or BMI ≥ 27.5 with obesity-related comorbidity or BMI ≥ 25 with T2DM; NAFLD 16 to 65 years	• OAGB • SG • RYGB	2 years	• NAFLD • T2DM • Weight loss	December 2024
NCT01344525[216] Germany	N = 480 BMI > 30 18 to 65 years	• SG • AGB • RYGB • Diet-based lifestyle intervention • Usual care	3 years	• BMI • Hypertension • Micronutrients (Vit B12) • QoL • Weight loss	May 2029
ROSA[217] NCT03203161 Belgium	N = 50 BMI ≥ 40 or BMI ≥ 35 with obesity-related comorbidity 12 to 17 years	• RYGB • SG	5 years	• AEs • BMI • Comorbidities • Micronutrients • Mortality • QoL • Weight loss	September 2029

Note. Shaded rows indicate studies that include pediatric populations.
Abbreviations. AE: adverse event; AGB: adjustable gastric banding; BMI: body mass index; BPD: biliopancreatic diversion (with or without duodenal switch); CVD: cardiovascular disease; ESG: endoscopic sleeve gastroplasty; EVG: endoluminal vertical gastroplasty; GERD: gastroesophageal reflux disease; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MWM: medical weight management; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; NRS: nonrandomized study; OAGB: one-anastomosis gastric bypass (aka mini gastric bypass); POSE-2: primary obesity surgical endoluminal 2; QoL: quality of life; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SAE: serious AE; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus; vit: vitamin.

Appendix E. Full Risk-of-Bias and Methodological Quality Assessment Tables

Table E1. Risk-of-Bias Assessments for Included RCTs of MBS

Study Name Author, Year	Randomization	Allocation Concealment	Masking	Follow-Up	Outcome Measures	Intention to Treat Analysis	Statistical Analysis	Sample Baseline Characteristics	Attrition < 20%	Interest Disclosure	Funding	Applicability	Crossover Trial	Overall RoB Assessment
AMOS2 Jarvholm, 2023[138]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Mod
BASIC Roebroek, 2023[161]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Mod
ENDObesity II Rothstein, 2023[175]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Mod
IB-005 Courcoulas, 2017[163]	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	No	No	Yes	No	High
LIFEXPE-RT Ospanov, 2021[179]	Yes	Yes	Yes	No	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	No	No	Mod
MERIT Abu Dayyeh, 2022[165]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Mod
O'Brien, 2006[167]	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	No	Mod
O'Brien, 2010[168]	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Mod
RYSA Heinonen, 2023[169]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Mod
Seetharamaiah, 2017[176]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	Mod
SMART Sullivan, 2018[171]	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	High
Wentworth, 2014[173]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Low
YOMEGA Robert, 2019[174]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	Mod

Abbreviations. MBS: metabolic and bariatric surgery; Mod: moderate; RCT: randomized controlled trial; RoB: risk of bias.

Table E2. Risk of Bias: Economic Modeling Studies of MBS

Author, Year	Target Population	Perspective	Time Horizon	Discount Rate	Comparators	Modeling	Effectiveness	Outcomes	Resource Use/Costs	Uncertainty	Results	Interest Disclosure	Funding Source	Overall RoB Assessment
Finkelstein and Verghese, 2019[191]	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No	Yes	Unclear	Yes	High
Kyler, 2019[193]	No	No	Unclear	No	No	No	No	No	No	No	No	Yes	Yes	High
Saumoy, 2023[192]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Mod

Abbreviations. MBS: metabolic and bariatric surgery; Mod: moderate; RCT: randomized controlled trial; RoB: risk of bias.

Table E3. Methodological Quality of Included Clinical Practice Guidelines for MBS

Guideline Developer, Year	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
US guidelines								
American Academy of Pediatrics, 2023[8]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
American Academy of Sleep Medicine, 2021[219]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
American Association of Clinical Endocrinology American Association for the Study of Liver Diseases, 2022[218]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
American Association of Clinical Endocrinology American College of Endocrinology The Obesity Society American Society for Metabolic and Bariatric Surgery (ASMBS) Obesity Medicine Association American Society of Anesthesiologists, 2020[72]	No	Yes	No	Yes	Yes	Yes	No	Fair
American Gastroenterological Association, 2021[51]	Yes	Yes	No	Yes	Yes	Yes	Yes	Good
American Society for Metabolic and Bariatric Surgery (ASMBS) International Federation for Surgery of Obesity and Metabolic Disorders (IFSO), 2023[36]	No	No	No	No	No	Yes	No	Poor

Guideline Developer, Year	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
American Society for Metabolic and Bariatric Surgery (ASMBS), 2020 [statement on SADI-S][224]	No	No	Unclear	Yes	No	No	No	Poor
Veterans Affairs, Department of Defense, 2020[50]	Yes	Yes	Yes	Yes	Yes	Yes	No	Good
International guidelines								
Ciangura, 2019[226]	No	Yes	No	Yes	Yes	Yes	Yes	Poor
Diabetes Canada, 2022[229]	Yes	Yes	No	Yes	Yes	Yes	Yes	Fair
European Association for Endoscopic Surgery, 2022 [rapid guideline][70]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
European Society for Clinical Nutrition and Metabolism, United European Gastroenterology, 2022[223]	No	Yes	Yes	Yes	No	Yes	No	Fair
International Federation for Surgery of Obesity and Metabolic Disorders, 2021 [statement on OAGB][225]	No	No	No	Unclear	Unclear	No	No	Poor
International Federation for Surgery of Obesity and Metabolic Disorders, 2021 [for SADI-S][54]	No	No	No	Yes	Unclear	No	No	Poor
Japanese Society for Treatment of Obesity Japan Diabetes Society Japan Society for the Study of Obesity, 2022[247]	No	No	Yes	Unclear	No	Yes	No	Poor

Guideline Developer, Year	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
Korean Society of Pediatric Gastroenterology Hepatology and Nutrition, 2019[227]	No	No	No	Yes	Yes	Yes	No	Poor
Korean Society for the Study of Obesity, 2023[220]	No	No	Yes	Yes	Unclear	No	No	Poor
Ministry of Public Health Qatar, 2021[222]	No	No	Unclear	Yes	Yes	Yes	Yes	Good
National Institute for Health and Care Excellence (NICE), *2024* [for overweight and obesity][228]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
National Institute for Health and Care Excellence (NICE), *Expected 2024* [for ESG][248]	No	No	Yes	Yes	Yes	Yes	No	Fair
Obesity Canada, The Canadian Association of Bariatric Physicians and Surgeons, 2020[37]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Abbreviations. ESG: endoscopic sleeve gastroplasty; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy.

Appendix F. Full GRADE Certainty of Evidence Tables

Table F1. GRADE Profile: BMI ≥ 30 to < 35 kg/m^2 and Obesity-Related Issue or Comorbidity: AGB vs. Lifestyle + Orlistat

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Weight								
N = 80 1 RCT[167]	No serious	Not assessable (single study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size	After the initial 6 months, AGB associated with significantly greater EWL than intensive medical management (ranging from 79% to 87% EWL in AGB group vs. 22% to 41% in intensive medical management group) Difference maintained at the 10-year timepoint; both surgery and medical management associated with reduced weight from baseline.	●●●○ Moderate
Cardiovascular risk factors								
N = 80 1 RCT[167]	No serious	Not assessable (single study)	No serious	Very serious (downgraded 3 levels)	Not assessed	Small study size, wide CIs, and very small number of events.	AGB associated with significantly lower risk of MetS at 2 years than intensive medical management (2.6% vs. 24.2%; RR, 0.11; 95% CI, 0.01 to 0.80).	●○○○ Very low
N = 80 1 RCT[167]	No serious	Serious (downgraded 1 level for	No serious	Serious (downgraded 1 level)	Not assessed	Small study size; not all risk factors	AGB associated with significantly greater	●●○○ Low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
		inconsistency within study)				changed showing lack of internal consistency.	changes in HDL and diastolic blood pressure Between-group differences not observed for changes in LDL, systolic blood pressure, or triglycerides.	
Safety								
N = 80 1 RCT[167]	No serious	Not assessable (single study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size	Adverse events occurred in both the AGB and intensive medical management groups with a higher proportion occurring in the medical group (58% vs. 18%) All were treated successfully	●●●○ Moderate

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein (cholesterol); LDL: low-density lipoprotein (cholesterol); MetS: metabolic syndrome; RCT: randomized controlled trial; RR: risk ratio.

Table F2. GRADE Profile: BMI ≥ 25 to < 30 kg/m^2 and T2DM: AGB vs. MDC

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Weight								
N = 48 1 RCT[173]	Serious (downgraded 1 level)	Not assessable (single study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size; serious issue with study design, funding and investigator conflicts of interest	Participants in the AGB group lost significantly more weight than participants in the MDC group at 2, 5, and 10 years.	●●○○ Low
Cardiovascular								
N = 48 1 RCT[173]	Serious (downgraded 1 level)	Serious (downgraded 1 level for inconsistency within study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size; serious issue with study design, funding and investigator conflicts of interest; inconsistency within study as effect not maintained at all time points	AGB was associated with an increased chance of remission from T2DM at 2 years; however, this was not maintained at 5- or 10 years.	●○○○ Very low
N = 48 1 RCT[173]	Serious (downgraded 1 level)	Serious (downgraded 1 level for inconsistency within study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size; serious issue with study design, funding and investigator conflicts of interest;	AGB was associated with significantly greater improvements in diabetes control Between-group differences were not observed for changes in blood pressure or	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
						inconsistency within study as not all risk factors changed	cholesterol, other than triglycerides	
Health-related quality of life (HRQoL)								
N = 48 1 RCT[173]	Serious (downgraded 1 level)	Serious (downgraded 1 level for inconsistency within study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size; inconsistency within study as changes were not maintained at all points; serious issue with study design, funding and investigator conflicts of interest;	AGB was associated with a greater improvement in the SF-36 physical health composite score at 2 and 5 years.	●○○○ Very low
Safety								
N = 48 1 RCT[173]	Serious (downgraded 1 level)	No serious	No serious	Very serious (downgraded 2 levels)	Not assessed	Small study size; serious issue with study design, funding and investigator conflicts of interest;	AGB was associated with a higher rate of AEs at 2 years. At 5 and 10 years, the number of AEs was similar.	●○○○ Very low

Abbreviations. AE: adverse event; AGB: adjustable gastric band; BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; LDL: low-density lipoprotein cholesterol; RCT: randomized controlled trial; SF-36: 36-item Short-Form Health Survey.

Table F3. GRADE Summary of Findings: MBS Procedures Not Reviewed vs. Procedures Reviewed in 2015, in Adults

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
OAGB vs. RYGB or SG								
Weight								
N = 542 3 RCTs[169,174,176-178]	No serious	No serious	No serious	No serious	Not assessed	Not downgraded	Total weight loss ranged from 25% to 37% 1 to 3 years post-surgery, regardless of surgical intervention (i.e., OAGB, RYGB, SG). Similarly, excess weight loss ranged from 60% to 66% in the same time periods. One study showed excess weight loss was maintained at years 4 and 5 for OAGB, but not for SG though the changes were small (a decrease of approximately 4% to 5% from year 3).[177,178]	●●●● High
Cardiovascular								
N = 542 3 RCTs[169,174,176-178]	No serious	No serious	No serious	No serious	Not assessed	Not downgraded	Rates of remission of obesity-related comorbidities (e.g., T2DM, hypertension) and changes to other cardiovascular risk factors (e.g., HDL, triglycerides) were similar up to 3 years (and in some cases up to 5 years) regardless of surgical intervention (i.e., OAGB, RYGB, SG).	●●●● High

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Health-related quality of life (HRQoL)								
N = 126 1 RCT[174]	No serious	Not assessable (single study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size	Improvements in HRQoL, as measured with IWQOL-Lite, were similar in individuals who underwent OAGB or RYGB.	●●●○ Moderate
Safety								
N = 542 3 RCTs[169,174,176-178]	No serious	Serious (downgraded 1 level)	No serious	No serious	Not assessed	Different markers of safety reported across studies	Reported safety outcomes varied across the studies, but most showed no differences (e.g., rates of anemia, vitamin deficiencies, complications related to surgery) between the surgical interventions. One study reported significantly more serious adverse events in participants who underwent OAGB compared with RYGB.	●●●○ Moderate

Abbreviations. BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; HRQoL: health-related quality of life; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; OAGB: one anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table F4. GRADE Summary of Findings: MBS Procedures Not Reviewed in 2015 vs. Lifestyle Intervention, in Adults

Number of Participants (N) Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Weight								
N = 586 3 RCTs[163,165,179]	Serious (downgraded 1 level)	No serious	No serious	No serious	Not assessed	the largest study [N = 317] had a high RoB	Participants who underwent a surgical intervention (i.e., ESG, IGB, OAGB) had significantly larger reductions in weight and BMI than the lifestyle interventions. Clinically significant improvements were also observed in favor of surgical interventions, as well as excess weight loss and excess BMI loss.	●●●○ Moderate
Cardiovascular								
N = 60 1 RCT[179]	No serious	Not assessable (single study)	Serious (downgraded 1 level)	Serious (downgraded 1 level)	Not assessed	Single study with small study size, conducted in Kazakhstan	Larger improvements in blood pressure and triglycerides were seen in those who received OAGB compared with diet alone. Additionally, remission of prediabetes or T2DM were achieved in 100% and 93% in the OAGB group,	●●○○ Low

Number of Participants (N) Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
							respectively; there were no remissions of these conditions for those who were treated with diet alone.	
Health-related quality of life (HRQoL)								
No studies reported HRQoL.								
Safety								
N = 350 2 RCTs[163,179]	No serious	Serious (downgraded 1 level)	No serious	No serious	Not assessed	Different markers of safety reported across studies	Adverse events and serious adverse events, and the total number of events, were much higher for IGB and ESG. The most common adverse events were nausea, vomiting, and abdominal pain. Serious adverse events (e.g., severe dehydration, surgery-related injuries) were experienced by 10% of those who underwent IGB; 20% had the IGB removed before 6-months.	●●●○ Moderate

Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HRQoL: health-related quality of life; IGB: intragastric balloon; OAGB: one anastomosis gastric bypass; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus.

Table F5. GRADE Summary of Findings: MBS Procedures Not Reviewed in 2015 vs. Sham Surgery, in Adults

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Weight								
N = 657 2 RCTs[171,175]	Serious (downgraded 1 level)	No serious	No serious	No serious	Not assessed	The larger study (N = 387) had a high RoB and the other had a moderate RoB)	Participants who had an IGB implanted (Obalon or TPS) had statistically significant improvements in BMI at 6 months. They also had significant improvements in EWL, TWL, and the proportion who achieved a clinically meaningful reduction of ≥ 5% TWL.	●●●○ Moderate
Cardiovascular								
N = 657 2 RCTs[171,175]	Serious (downgraded 1 level)	Serious (downgraded 1 level)	No serious	No serious	Not assessed	The larger study (N = 387) had a high RoB and the other had a moderate RoB); conflicting results for CV risk factors	Some very small statistically significant changes were observed in favor of the IGB devices (Obalon or TPS), but these were not clinically significant.	●●○○ Low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Health-related quality of life								
N = 270 1 RCT[175]	No serious	Not assessable (single study)	No serious	Serious (downgraded 1 level)	Not assessed	Small study size	Those who had the TPS device implanted had greater improvements in their total IWQOL-Lite score compared with the sham surgery group (+10.5 vs. +7.8 points, respectively). These improvements are considered clinically meaningful.	●●●○ Moderate
Safety								
N = 657 2 RCTs[171,175]	Serious (downgraded 1 level)	No serious	No serious	No serious	Not assessed	The larger study (N = 387) had a high RoB and the other had a moderate RoB)	Any AE was common for all procedures (ranging from 94% to 100% in IGB groups and 70% to 98% in sham surgery groups), but difference was significant in 1 study (n = 270; *P* < .001). SAEs were rare (2% to 3% of all participants). However, early removal of TPS device occurred in 23% of participants.	●●●○ Moderate

Abbreviations. AE: adverse event; BMI: body mass index; CV: cardiovascular; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; IGB: intragastric balloon; IWQOL Lite: Impact of Weight on Quality of Life-Lite survey; RCT: randomized controlled trial; RoB: risk of bias; SAE: serious AE; TPS: TransPyloric Shuttle; TWL: total weight loss.

Table F6. GRADE Summary of Effectiveness: Weight-Related Outcomes in Adolescents

Number of Participants (N) Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
Weight								
N = 149 3 RCTs[138,161,168]	No serious	No serious	No serious	Very serious (downgraded 21 levels)	Not assessed	Total N; non-US population	Adolescents who underwent a RYGB or SG had significantly larger reductions in weight (mean total weight loss, 20 kg) and BMI (−1.71 kg/m^2) than those in receipt of a lifestyle intervention.	●●○○ Low
Cardiovascular risk factors								
N = 59[a] 3 RCTs[138,161,168]	No serious	Serious (downgraded 1 level)	No serious	Very serious (downgraded 2 levels)	Not assessed	Small sample size; resolution of comorbidities inconsistent.	Resolution of high cholesterol was significantly more likely in adolescents who underwent a surgical procedure. No between-group differences in the resolution of metabolic syndrome, T2DM, or hypertension were observed.	●○○○ Very low
N = 149 3 RCTs[138,161,168]	No serious	Serious (downgraded 1 level)	No serious	Very serious (downgraded 2 levels)	Not assessed	Small sample size; changes in other CV risk factors were inconsistent across studies.	No between-group differences in triglyceride concentrations were observed for RYGB or SG vs. a lifestyle intervention; a small, but not clinically	●○○○ Very low

Number of Participants (N) Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Certainty of Evidence Rating
							significant, difference was seen when comparing AGB with a lifestyle intervention. No other between-group differences were observed for blood pressure, HDL, or LDL.	
Safety								
N = 149 3 RCTs[138,161,168]	No serious	Serious (downgraded 1 level)	No serious	Very serious (downgraded 2 levels)	Not assessed	Small sample size; small number of events.	Safety outcomes were minimally reported. In 2 studies, only surgery-related outcomes were reported. In the third study, AEs occurred in similar proportions, but the types of events differed, and approximately half were unrelated to the interventions.	●○○○ Very low

Note. [a] This represents the subset of participants who had 1 of the comorbidities mentioned; an individual may have had ≥ 1 comorbidity.
Abbreviations. AE: adverse event; BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein; LDL: low-density lipoprotein; OP 14: Obesity-related Problems scale; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table F7. GRADE Summary of Evidence: Cost-Effectiveness of MBS

Number of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Quality of Evidence Rating
MBS in adults								
ESG and SG vs semaglutide and lifestyle intervention								
1 cost-effectiveness analysis[192]	Serious (downgraded 1 level)	Not assessable (single study)	Serious (downgraded 1 level)	Serious (downgraded 1 level)	Not assessed	(i.e., model sensitivity to the cost of the procedure; only adults aged 40)	• ESG was cost-effective, with an ICER of $4,105 per QALY gained for adults aged 40 with a BMI of 33 kg/m^2. • SG was cost-effective, with an ICER of $5,883 per QALY gained for adults aged 37 with a BMI of 33 kg/m^2. • SG was cost-effective, with an ICER of $7,821 per QALY gained for adults aged 37 with a BMI of 44 kg/m^2. • Both procedures were cost-effective when compared individually with lifestyle intervention. • Semaglutide was less effective and more costly than another intervention (i.e., dominated)	●○○○ Very low

Number of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Comments	Effect	Overall Quality of Evidence Rating
IGB vs commercially available, nonsurgical weight loss interventions								
1 cost-effectiveness analysis[191]	Very serious (downgraded 2 levels)	Not assessable (single study)	No serious	No serious	Not assessed		• IGB were not cost-effective for adults who are overweight or obese (BMI ≥ 25 kg/m^2) when compared with other nonsurgical options at any WTP threshold.	●●●○ Moderate
MBS in children and adolescents								
No eligible cost-effectiveness analyses comparing MBS with other interventions were identified in the populations of interest.								
Comparison of different MBS procedures in adults and children								
No eligible cost-effectiveness analyses comparing different bariatric procedures were identified in the populations of interest.								

Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; ICER: incremental cost-effectiveness ratio; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; QALY: quality-adjusted life year; SG: sleeve gastrectomy; WTP: willingness-to-pay.

Appendix G. Full Clinical Practice Guidelines Tables

Table G1. Clinical Practice Guidelines: MBS Criteria for Adults

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
US guidelines										
• American Association of Clinical Endocrinology[218] • American Association for the Study of Liver Diseases	2022	Fair	NR	NR	NR	✓[b]	✓[b]	≥ 32.5[b]	✓	≥ 27.5[b]
• American Academy of Sleep Medicine[219]	2021	Good	✓[c]	X	NR	✓[c]	X	NR	NR	NR
• American Gastroenterological Association[51]	2021	Good	NR							
• Department of Defense[50] • Veterans Affairs	2020	Good	✓	X	NR	✓	X	NR	✓	NR
• American Association of Clinical Endocrinology[72] • American College of Endocrinology • American Society of Anesthesiologists • American Society for Metabolic and Bariatric Surgery (ASMBS) • Obesity Medicine Association • The Obesity Society	2020	Fair	✓	X	≥ 35	✓	X	≥ 30	✓	≥ 27.5
• American Society for Metabolic and Bariatric Surgery (ASMBS)[36] • International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	2023	Poor	✓	✓	≥ 30	✓	✓	≥ 27.5	✓	≥ 27.5

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
• American Society for Metabolic and Bariatric Surgery (ASMBS)[224] [for SADI-S]	2020	Poor	NR							
International guidelines										
• Korean Society for the Study of Obesity[220]	2023	Poor	NR	NR	≥ 35	NR	NR	≥ 30	NR	≥ 27.5
• International Federation for Surgery of Obesity and Metabolic Disorders (IFSO)[225] [for OAGB]	2021	Poor	NR							
• International Federation for Surgery of Obesity and Metabolic Disorders[54] [for SADI-S]	2021	Poor	NR							
• Japanese Society for Treatment of Obesity[221] • Japan Diabetes Society • Japan Society for the Study of Obesity	2022	Poor	NR	NR	NR	NR	NR	NR	NR	≥ 32[d]
• Ministry of Public Health Qatar[222]	2021	Good	✓	X	NR	✓	X	NR	✓	≥ 27.5
• European Association for Endoscopic Surgery[35]	2020	Good	✓	X	NR	✓	X	NR	✓	NR
• National Institute for Health and Care Excellence (NICE)[53] [for overweight and obesity]	*Expected 2024*	Good	✓	X	≥ 37.5	✓	X	≥ 32.5	✓	≥ 27.5
• National Institute for Health and Care Excellence (NICE)[228] [for ESG]	2024	Fair	✓	X	✓	✓	NR	✓	NR	≥ 27.5

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
• European Society for Clinical Nutrition and Metabolism[223] • United European Gastroenterology	2022	Fair	✓[e]	X	NR	✓[e]	X	NR	NR	NR
• BARIA-MAT (France)[226]	2019	Poor	NR							
• Obesity Canada[37] • The Canadian Association of Bariatric Physicians and Surgeons	2020	Good	✓	X	NR	✓	✓[f]	NR	✓	NR
• Diabetes Canada[229]	2022	Fair	NR	NR	NR	✓[d]	X	NR	X	NR

Notes. ✓ denotes yes; X denotes no. [a] Severe obesity-related comorbidities include T2DM, poorly controlled hypertension, NAFLD, OSA, and osteoarthritis, among others. [b] This guideline is specific to adults with obesity and NAFLD or NASH. [c] This guideline is specific to adults with obesity and OSA. [d] These guidelines are specific to adults with obesity and T2DM. [e] This recommendation is specific to patients with irritable bowel syndrome or disease, gastroesophageal reflux disease, and liver disease. [f] This guideline suggests that individuals with Class 1 obesity may be considered for MBS for weight loss or control of comorbidity when medical and behavioral interventions have been insufficient.
Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; MBS: metabolic and bariatric surgery; N/A: not applicable; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; NR: not reported; OAGB: one-anastomosis gastric bypass; OSA: obstructive sleep apnea; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Table G2. Clinical Practice Guideline Recommendations: MBS in Adults

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
US guidelines			
American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (2022)[218]	ESG, IGB	"Endoscopic [MBS] therapies and orally ingested devices should not be recommended in persons with NAFLD due to insufficient evidence"	Grade C; Intermediate/ Weak strength of evidence; BEL 2
	Eligibility criteria	"Clinicians should consider [MBS] as an option to treat NAFLD (Grade B; Intermediate/Weak Strength of Evidence; BEL 2) and improve cardiometabolic health (Grade A; High/Intermediate Strength of Evidence; BEL 2; upgraded based on the cardiometabolic and all-cause mortality benefits in all persons with or without NAFLD) in persons with NAFLD and a BMI ≥ 35 kg/m^2 (≥ 32.5 kg/m^2 in Asian populations), particularly if T2DM is present"	As stated at left
	Eligibility criteria	"[MBS] should also be considered an option in those with a BMI of ≥ 30 to 34.9 kg/m^2 (≥ 27.5 to 32.4 kg/m^2 in Asian populations)"	Grade B; Intermediate/ Weak Strength of Evidence; BEL 2
Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)[219]	Eligibility criteria	"We recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class 2/3, BMI ≥ 35) who are intolerant or unaccepting of [positive airway pressure] as part of a patient-oriented discussion of alternative treatment options"	Strong
American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)[51]	IGB	"In individuals with obesity seeking a weight-loss intervention who have failed a trial of conventional weight-loss strategies, AGA suggests the use of IGB therapy with lifestyle modification over lifestyle modification alone"	Conditional recommendation, moderate certainty
VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)[50]	Eligibility criteria	"We suggest offering the option of [MBS], in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥ 30 kg/m^2 and T2DM"	Weak; We suggest offering this option.
	Eligibility criteria	"We suggest offering the option of [MBS], in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a BMI ≥ 40 kg/m^2 or those with BMI ≥ 35 kg/m^2 with obesity-associated condition(s)"	Weak; We suggest offering this option.

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
	IGB	"We suggest offering [IGB] in conjunction with a comprehensive lifestyle intervention to patients with obesity (BMI ≥ 30 kg/m^2) who prioritize short-term (up to 6 months) weight loss"	Weak; We suggest offering this option.
	IGB	"There is insufficient evidence to recommend for or against [IGBs] for long-term weight loss to support chronic weight management or maintenance"	Neither for nor against
Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/ American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists (2020)[72]	Eligibility criteria	"Patients with a BMI ≥ 40 kg/m^2 without coexisting medical problems and for whom [MBS] would not be associated with excessive risk are eligible for [MBS]"	Grade A; BEL 1
	Eligibility criteria	"Patients with a BMI ≥ 35 kg/m^2 and 1 or more severe ORCs remediable by weight loss, including T2DM, high risk for T2DM (insulin resistance, prediabetes, and/or MetS), poorly controlled HTN, NAFLD or NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure. Patients with the following comorbidities and BMI ≥ 35 kg/m^2 may also be considered for [MBS], though the strength of evidence is more variable: obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial HTN; GERD; severe venous stasis disease; impaired mobility due to obesity; and considerably impaired QoL"	Grade C; BEL 3
	Eligibility criteria	"Patients with BMI ≥ 30 to 34.9 kg/m^2 and T2DM with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for [MBS]; current evidence is insufficient to support recommending [MBS] in the absence of obesity"	Grade B; BEL 2
	Eligibility criteria	"The BMI criterion for [MBS] should be adjusted for ethnicity (e.g., ≥ 18.5 to 22.9 kg/m^2 is normal range, ≥ 23 to 24.9 kg/m^2 is overweight, and ≥ 25 kg/m^2 obesity for Asians)"	Grade D
	Eligibility criteria	"[MBS] should be considered to achieve optimal outcomes regarding health and QoL when the amount of weight loss needed to prevent or treat clinically significant ORCs cannot be obtained using only structured lifestyle change with medical therapy"	Grade B; BEL 2

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
	AGB, BPD, RYGB, SG	"Laparoscopic AGB, laparoscopic SG, laparoscopic RYGB, and laparoscopic BPD, or related procedures should be considered as primary [MBS] procedures performed in patients requiring weight loss and/or amelioration of ORCs"	Grade A; BEL 1
	BPD	"Physicians must exercise caution when recommending BPD, BPD, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine"	Grade A; BEL 1
	ESG, IGB	"Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy"	Grade C; BEL 3
2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)[36]	Eligibility criteria	"MBS is recommended for individuals with BMI > 35 kg/m^2, regardless of presence, absence, or severity of co-morbidities."	NR
	Eligibility criteria	"MBS is recommended in patients with T2DM and BMI > 30 kg/m^2." "MBS should be considered in individuals with BMI of 30 to 34.9 kg/m^2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods."	NR
	Eligibility criteria	"Clinical obesity in the Asian population is recognized in individuals with BMI > 25 kg/m^2. Access to MBS should not be denied solely based on traditional BMI risk zones"	NR
American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)[224]	SADI-S	SADI-S is "endorsed by ASMBS as an appropriate [MBS] procedure"	NR
American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass (2024)[231]	OAGB	"The ASMBS endorses OAGB as a metabolic and bariatric procedure."	NR
International guidelines			
Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical	Eligibility criteria	"[MBS] should be considered in Korean adults with a BMI ≥ 35 kg/m^2, or a BMI ≥ 30 kg/m^2 or more with obesity-related	Grade IIa, level of evidence B

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)[220]		comorbidities, who have failed to lose weight with nonsurgical treatment"	
	Eligibility criteria	"[MBS] should be considered in individuals with T2DM with a BMI ≥ 27.5 kg/m^2 and a blood sugar level that is not properly controlled with nonsurgical treatment"	Grade IIa, level of evidence B
	AGB, BPD, RYGB, SG	"It is recommended to choose from among standard procedures that have been proven to be effective and safe, such as SG, RYGB, AGB, and BPD, taking into account the individual's status"	Grade I, level of evidence A
Metabolic Surgery in Treatment of Obese Japanese Patients with Type 2 Diabetes: A Joint Consensus Statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity (2022)[221]	SG	"SG is recommended for obese patients with T2DM with a short duration of diabetes and a well-retained insulin secretory capacity"	Recommendation
	Eligibility criteria	"[MBS] is recommended as a treatment option regardless of glycemic control if the patient has T2DM with BMI ≥ 35 kg/m^2 at the time of consultation and the BMI ≥ 35 kg/m^2 persists despite treatments by a diabetologist or obesity specialist for≥ 6 months."	Recommendation
	Eligibility criteria	"[MBS] should be considered a treatment option if the patient has T2DM with BMI ≥ 32 kg/m^2 at the time of consultation and has not achieved≥ 5% weight loss or has achieved it but continues to have poor glycemic control (HbA1c > 8.0%) despite treatments by a diabetologist or obesity specialist for≥ 6 months"	Consideration
	RYGB	"Because the remission rate of diabetes is higher in the cases with a surgery that add the malabsorptive procedure such as gastrointestinal bypass, it is advisable to consider carrying out the gastrointestinal bypass surgery for patients with reduced insulin secretory capacity."	Consideration
European Guideline on Obesity Care in Patients with Gastrointestinal and Liver Diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology Guideline (2022)[223]	Eligibility criteria	"In patients with [irritable bowel disease] and BMI > 40 kg/m^2 or > 35 kg/m^2 with obesity-related comorbidities and previous failed nonsurgical weight-loss attempts can be offered [MBS], preferably considering non-malabsorptive procedures not involving the small bowel"	Grade of recommendation 0 - Strong consensus
	Eligibility criteria	"Patients with [irritable bowel syndrome] and BMI > 40 kg/m^2 or > 35 kg/m^2 with obesity-related comorbidities can be	Grade of recommendation: GPP (Good practice

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		offered [MBS] provided that serious attempts to lose weight with nonsurgical methods have been made"	points/expert consensus); Strong consensus
	Eligibility criteria	"Patients with [chronic liver disease] (NAFLD or NASH) with BMI > 35 kg/m^2 unresponsive to multimodality treatment should be considered for [MBS]"	Grade of recommendation B; Strong consensus
	Eligibility criteria; RYGB	"In patients with GERD and BMI ≥ 40 kg/m^2 or ≥ 35 kg/m^2 with obesity-related comorbidities, [MBS] can be considered to achieve weight reduction if nonsurgical interventions failed to achieve the goals. The preferred procedure is RYGB"	Grade of recommendation 0; Strong consensus
	RYGB, SG	"RYGB or laparoscopic SG should be preferred as [MBS] procedures in patients with obesity and NAFLD"	Grade of recommendation B; Strong consensus
IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (2021)[225]	OAGB	"The outcomes from OAGB are promising…and appear at least equivalent to other [MBS] procedures"	NR
Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020 (2021)[54]	SADI-S	"Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure"	NR
	SADI-S	"IFSO supports the SADI-S/OADS as a recognized [MBS], but highly encourages RCTs in the near future"	NR
Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020 Endorsed by IFSO-EC, EASO and ESPCOP[35]	Eligibility criteria	"Laparoscopic [MBS] should be considered for patients with BMI ≥ 40 kg/m^2 and for patients with BMI ≥ 35 to < 40 kg/m^2 with associated comorbidities that are expected to improve with weight loss"	Strong recommendation
	Eligibility criteria	"Laparoscopic [MBS] should be considered for patients with ≥ BMI ≥ 30 to 35 kg/m^2 and T2DM and/or arterial hypertension with poor control despite optimal medical therapy"	Strong recommendation
	AGB	"AGB surgeries are associated with a high rate of reoperations for complications or conversion to another bariatric procedure for insufficient weight loss in the long term"	Position statement
	AGB, SG	"SG may be preferred over adjustable gastric banding for weight loss and control/resolution of metabolic comorbidities"	Conditional recommendation

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
	AGB, RYGB	"RYGB should be preferred over [AGB]"	Strong recommendation
	BPD, SG	"No recommendation for either BPD or SG can be made on the basis of available comparative evidence"	Conditional recommendation
	BPD, RYGB	"With regard to mid-term weight loss there is no difference between BPD and RYGB. BPD is superior to RYGB for control/ remission of T2DM. Long-term comparative data are, however, lacking"	Position statement
	OAGB	"OAGB may offer greater short-term weight loss compared to RYGB, gastric plication, AGB and SG. Long-term comparative data are, however, lacking. The effect on nutritional deficiencies remains controversial."	Position statement
	SADI-S	"No recommendation on SADI-S compared with OAGB, BPD, RYGB or SG can be made on the basis of available evidence"	Conditional recommendation
Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery (2019)[226]	Eligibility criteria	"A minimal interval of 12 months between BS [bariatric surgery] and pregnancy is recommended to allow the weight of the patient to stabilize."	Grade C
	SG	"Available data on pregnancy after sleeve gastrectomy are insufficient to recommend this intervention over others."	Grade C
	BPD, OAGB, SADI-S	BPD, OAGB, and SADI-S "should be considered with caution" for women of a childbearing age "given the nutritional deficiencies and cases of undernutrition associated with these procedures"	Grade C
	AGB	"AGB deflation is associated with higher maternal weight gain, and thus systematic deflation is not recommended during pregnancy"	Grade C
	AGB	"AGB inflation is not recommended either throughout pregnancy and rapid deflation is indicated if digestive symptoms appear"	Grade C
Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)[37]	Eligibility criteria	"[MBS] can be considered for people with BMI ≥ 40 kg/m^2, or BMI ≥ 35 kg/m^2 with at least one adiposity-related disease"	Level 4, Grade D, Consensus
	Eligibility criteria	"[MBS] should be considered in patients with poorly controlled T2DM and Class 1 obesity (BMI ≥ 30 to < 35 kg/m^2) despite optimal medical management"	Level 1a; Grade A

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
	Eligibility criteria	"[MBS] may be considered for weight loss and/or to control adiposity-related diseases in persons with Class 1 obesity, in whom optimal medical and behavioral management have been insufficient to produce significant weight loss"	Level 2a, Grade B
	BPD, RYGB, SG	"We suggest the choice of [MBS] (SG, gastric bypass or duodenal switch) be decided according to the patient's need, in collaboration with an experienced interprofessional team"	Level 4, Grade D, Consensus
	OAGB	"We suggest that [OAGB] not be routinely offered, due to long-term complications in comparison with standard RYGB"	Level 4, Grade D,
	AGB	"We suggest that AGB not be offered due to unacceptable complications and long-term failure"	Level 4, Grade D
Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)[229]	Eligibility criteria	"[MBS] should be recommended to nonpregnant adults with T2DM and a BMI ≥ 35 kg/m^2 as an option to potentially induce T2DM remission"	Grade A, Level 1A
	Eligibility criteria	"[MBS] for diabetes remission cannot be recommended at this time in those with preoperative BMI ≥ 30 to < 35 kg/m^2 because of limitations of current evidence on the relative remission rates with different types of [MBS] procedures and the balance of potential risks and long-term effects of [MBS] in individuals with T2DM with nonsevere obesity"	NR
Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)[222]	IGB	"Endoscopic [MBSs] are indicated in the following patients: BMI ≥ 27 kg/m^2 with obesity-related complications; BMI ≥ 30 kg/m^2 without obesity-related complications; BMI ≥ 40 kg/m^2. When the patient prefers nonsurgical management, there is a contraindication to surgery. Preoperative weight loss as a 'bridge therapy' to safe surgery is required"	Recommended best practice on the basis of the clinical experience of the Guideline Development Group members
	Eligibility criteria	"[MBS] is indicated in the following patients: • BMI ≥ 30 to 34.9 kg/m^2 with uncontrollable T2DM: The patient should be assessed, and their comorbidity management optimized, prior to surgery. Consider surgery at a lower BMI (≥ 27.5 kg/m^2) after MDT assessment for people of South Asian family origin, who have diabetes. • BMI ≥ 35 to 39.9 kg/m^2 with obesity-related complications. • BMI ≥ 40 kg/m^2 without obesity-related complications.	Recommended best practice on the basis of the clinical experience of the Guideline Development Group members

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		• Special populations, e.g.: Waiting for organ transplantation with a BMI ≥ 30 kg/m^2 and demonstrated lack of response to specialist medical weight management. • Post-renal transplant with a BMI ≥ 30 kg/m^2 and an uncontrollable obesity complication"	
NICE Guideline: Overweight and Obesity Management: Draft for Consultation (*Expected 2024*)[53]	Eligibility criteria	"Offer adults a referral for a comprehensive assessment by specialist overweight and obesity management services providing multidisciplinary management of obesity, to see whether [MBS] is suitable for them if they: have a BMI ≥ 40 kg/m^2, BMI ≥ 35 kg/m^2 to 39.9 kg/m^2 with a significant health condition that could be improved if they lost weight and agree to the necessary long-term follow up after surgery (for example, lifelong annual reviews)"	NR
	Eligibility criteria	"Offer an expedited assessment for [MBS] to people: with a BMI ≥ 35 kg/m^2 who have recent-onset (diagnosed within the past 10 years) T2DM and as long as they are also receiving, or will receive, assessment in a specialist overweight and obesity management service"	NR
	Eligibility criteria	"Consider an expedited assessment for [MBS] for people: with a BMI of ≥ 30 to 34.9 kg/m^2 who have recent-onset (diagnosed within the past 10 years) T2DM and who are also receiving, or will receive, assessment in a specialist overweight and obesity management service"	NR
	Eligibility criteria	"Consider an expedited assessment for [MBS] for people of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African–Caribbean background using a lower BMI threshold (reduced by 2.5 kg/m^2) than in [the previous recommendations], to account for the fact that these groups are prone to central adiposity and their cardiometabolic risk occurs at lower BMI"	NR
NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)[228]	ESG	"ESG for obesity may be used if standard arrangements are in place for clinical governance, consent and audit"	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022[70]	SG; RYGB; AGB; BPD	"We suggest SG or laparoscopic RYGB over AGB, BPD with duodenal switch, and gastric plication for the management of severe obesity and associated metabolic diseases"	NR
	OAGB; SADI-S	"OAGB and SADI-S are suggested as alternatives, although evidence on benefits and harms, and specific selection criteria is limited compared to SG and RYGB"	NR

Note. Readers should visit the full reference to determine how each guideline defines the strength of recommendations and quality of evidence. Abbreviations. AGB: adjustable gastric banding; BEL: best evidence level; BMI: body mass index; BPD: biliopancreatic diversion with or without duodenal switch; EASO: European Association for the Study of Obesity; ESG: endoscopic sleeve gastroplasty; ESPCOP: European Society for the Peri-operative Care of the Obese Patient; GERD: gastroesophageal reflux disease; IFSO: International Federation for the Surgery of Obesity and Metabolic Disorders; IFSO-EC: IFSO, European Chapter; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; MetS: metabolic syndrome; NAFLD: nonalcoholic fatty liver disease; NICE: National Institute for Health and Care Excellence; NR: not reported; OAGB: one-anastomosis gastric bypass; OAGB/MGB: one-anastomosis gastric bypass/mini gastric bypass; ORC: obesity-related comorbidity; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SADI-S/OADS: single-anastomosis duodenal ileostomy with sleeve gastrectomy/one anastomosis duodenal switch; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus; VA/DoD: US Veterans Affairs/Department of Defense.

Table G3: Clinical Practice Guidelines: MBS Criteria for Children and Adolescents

Institution(s) Issuing Guideline or Consensus Statement	Year Published	140% of the 95th Percentile or BMI ≥ 40	120% of 95th Percentile or 35 to 39.9 BMI and ≥ 1 Severe ORC[a]	Only After Nonsurgical Interventions	Only After Completion of Growth and Puberty	Multidisciplinary Care	Methodological Quality
US guidelines							
• American Academy of Pediatrics[8]	2023	✓	✓	NR	X[b]	✓	Good
• American Society for Metabolic and Bariatric Surgery[36] • International Federation for Surgery of Obesity and Metabolic Disorders	2023	✓	✓	NR	X	✓	Poor
International guidelines							
• Korean Society for the Study of Obesity[220]	2023	✓	✓	✓	✓	✓	Poor
• Korean Society of Pediatric Gastroenterology Hepatology and Nutrition[227]	2019	✓	✓	✓	✓	✓	Poor
• National Institute for Health and Care Excellence (NICE)[53]	Expected 2024	NR	NR	NR	✓	✓	Good

Notes. ✓ denotes yes; X denotes no. [a] Severe obesity-related comorbidities include T2DM, poorly controlled hypertension, NAFLD, OSA, or osteoarthritis, among others. [b] The recommendation from this guideline is intended for adolescents aged ≥ 13 years.
Abbreviations. BMI: body mass index; NAFLD: nonalcoholic fatty liver disease; NR: not reported; ORC: obesity-related comorbidity; OSA: obstructive sleep apnea; T2DM: type 2 diabetes mellitus

Table G4. Clinical Practice Guideline Recommendations: MBS in Children and Adolescents

Title (Year Issued)	Focus	Recommendations	Strength of Recommendations
American Academy of Pediatrics Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity (2023)[8]	Eligibility criteria	"Pediatricians and other PHCPs should offer referral for adolescents 13 y and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for [MBS] to local or regional comprehensive multidisciplinary pediatric [MBS] centers"	Grade C; moderate strength
	RYGB; SG	"Referral for evaluation to a comprehensive pediatric [MBS] center may result in the determination of eligibility for laparoscopic RYGB or vertical SG"	N/A
	Qualifying note	"Intentional vagueness: This action statement does not recommend surgery for all who have severe obesity but rather the opportunity for children, adolescents, and families to consider and undergo evaluation"	N/A
2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)[36]	Eligibility criteria	"Children and adolescents with BMI > 120% of the 95th percentile and a major co-morbidity, or a BMI > 140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center."	NR
NICE Guideline: Overweight and Obesity Management: Draft for Consultation (2023)[53]	NR	"Surgery for obesity is not generally recommended in children or young people."	
		"Surgery for obesity may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity."	
Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)[220]	Eligibility criteria	"In cases where weight gain and obesity-related comorbidities are sustained even with intensive multidisciplinary treatment and pharmacotherapy for obesity, surgical therapy may be considered in limited cases, only after completion of growth and puberty."	Grade IIb; Level of evidence: C
		"In pediatric and adolescent cases, surgery may be considered if the BMI ≥ 35 kg/m^2, the BMI is higher than 120% of the 95th percentile, and there are obesity-related comorbidities or if BMI ≥ 40 kg/m^2 or exceeds 140% of the 95th percentile."	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendations
Clinical Practice Guideline for the Diagnosis and Treatment of Pediatric Obesity: Recommendations from the Committee on Pediatric Obesity of the Korean Society of Pediatric Gastroenterology Hepatology and Nutrition (2019)[227]	Eligibility criteria	"We recommend that pharmacotherapy and [MBS] be considered only in patients with morbid obesity with major comorbidities after a formal program of intensive lifestyle modification has failed."	Strength of evidence: V; grade of recommendation: A
		"We recommend that [MBS] be an appropriate option to improve health when adolescents with a BMI > 40 kg/m^2 or > 35 kg/m^2 and obesity-related comorbidities fail to respond to behavioral interventions (with or without pharmacotherapy) for sufficient weight loss to achieve targeted health outcome goals and when they attain Tanner 4 or 5 pubertal development and final or near-final adult height."	Strength of evidence, V; grade of recommendation, A

Note. Readers should visit the full reference to determine how each guideline defines the strength of recommendations and quality of evidence.
Abbreviations. BMI: body mass index; MBS: metabolic and bariatric surgery; N/A: not applicable; NICE: National Institute for Health and Care Excellence; NR: not reported; PHCP: primary health care provider; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Appendix H. Bibliography of Included Studies

The following is a list of the primary publications (along with any ancillary publications) for the randomized controlled trials presented in this review. They are arranged alphabetically by study name (or first author, when no study name was given).

AMOS2

Jarvholm K, Janson A, Peltonen M, et al. Metabolic and bariatric surgery versus intensive non-surgical treatment for adolescents with severe obesity (AMOS2): a multicentre, randomised, controlled trial in Sweden. *Lancet Child Adolesc Health*. 2023;7(4):249-260. doi: 10.1016/S2352-4642(22)00373-X.

Janson A, Jarvholm K, Gronowitz E, et al. A randomized controlled trial comparing intensive non-surgical treatment with bariatric surgery in adolescents aged 13-16 years (AMOS2): rationale, study design, and patient recruitment. *Contemp Clin Trials Commun*. 2020;19:100592. doi: 10.1016/j.conctc.2020.100592.

BASIC

Roebroek YGM, Paulus GF, Talib A, et al. Weight loss and glycemic control after bariatric surgery in adolescents with severe obesity: a randomized controlled trial. *J Adolesc Health*. 2023. doi: 10.1016/j.jadohealth.2023.10.024.

Roebroek YGM, Paulus GF, van Mil E, et al. Bariatric surgery in adolescents: a prospective randomized controlled trial comparing laparoscopic gastric banding to combined lifestyle interventions in adolescents with severe obesity (BASIC trial). *BMC Pediatr*. 2019;19(1):34. doi: 10.1186/s12887-019-1395-9.

ENDObesity II

Rothstein RI, Kopjar B, Woodman GE, et al. Randomized double-blind sham-controlled trial of a novel silicone-filled endoscopically placed device for weight loss. *Tech Innov Gastrointest Endosc*. 2023. doi: 10.1016/j.tige.2023.10.002.

IB-005

Courcoulas A, Abu Dayyeh BK, Eaton L, et al. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. *Int J Obes (Lond)*. 2017;41(3):427-433. doi: 10.1038/ijo.2016.229.

LIFEXPE-RT

Ospanov O, Akilzhanova A, Buchwald JN, et al. Stapleless vs stapled gastric bypass vs hypocaloric diet: a three-arm randomized controlled trial of body mass evolution with secondary outcomes for telomere length and metabolic syndrome changes. *Obes Surg*. 2021;31(7):3165-3176. doi: 10.1007/s11695-021-05454-2.

Ospanov O, Yeleuov G, Kadyrova I, Bekmurzinova F. The life expectancy of patients with metabolic syndrome after weight loss: study protocol for a randomized clinical trial (LIFEXPE-RT). *Trials*. 2019;20(1):202. doi: 10.1186/s13063-019-3304-9.

MERIT

Abu Dayyeh BK, Bazerbachi F, Vargas EJ, et al. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. *Lancet*. 2022;400(10350):441-451. doi: 10.1016/S0140-6736(22)01280-6.

O'Brien, 2006

O'Brien PE, Dixon JB, Laurie C, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. *Ann Intern Med*. 2006;144(9):625-633. doi: 10.7326/0003-4819-144-9-200605020-00005.

O'Brien PE, Brennan L, Laurie C, Brown W. Intensive medical weight loss or laparoscopic adjustable gastric banding in the treatment of mild to moderate obesity: long-term follow-up of a prospective randomised trial. *Obes Surg*. 2013;23(9):1345-1353. doi: 10.1007/s11695-013-0990-3.

O'Brien, 2010

O'Brien PE, Sawyer SM, Laurie C, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. *Jama*. 2010;303(6):519-526. doi: 10.1001/jama.2010.81.

RYSA

O'Brien PE, Sawyer SM, Laurie C, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. *Jama*. 2010;303(6):519-526. doi: 10.1001/jama.2010.81.

Seetharamiah

Seetharamaiah S, Tantia O, Goyal G, et al. LSG vs OAGB-1 Year follow-up data-a randomized control trial. *Obes Surg*. 2017;27(4):948-954. doi: 10.1007/s11695-016-2403-x.

Jain M, Tantia O, Goyal G, et al. LSG vs MGB-OAGB: 5-year follow-up data and comparative outcome of the two procedures over long term-results of a randomised control trial. *Obes Surg*. 2021;31(3):1223-1232. doi: 10.1007/s11695-020-05119-6.

Jain M, Tantia O, Goyal G, et al. LSG vs OAGB: 7-Year Follow-up Data of a Randomised Control Trial and Comparative Outcome Based on BAROS Score. *Obes Surg*. 2024;01:01. doi: 10.1007/s11695-024-07114-7.

Shivakumar S, Tantia O, Goyal G, et al. LSG vs MGB-OAGB-3 year follow-up data: a randomised control trial. *Obes Surg*. 2018;28(9):2820-2828. doi: 10.1007/s11695-018-3255-3.

Wentworth

Wentworth JM, Playfair J, Laurie C, et al. Multidisciplinary diabetes care with and without bariatric surgery in overweight people: a randomised controlled trial. *Lancet Diabetes Endocrinol*. 2014;2(7):545-552. doi: 10.1016/S2213-8587(14)70066-X.

Qi QYD, Playfair J, Brown WA, Burton *P* , O'Brien PE, Wentworth JM. Long-term impact of weight loss for people with overweight but not obesity, and with type 2 diabetes: 10-year outcomes of a randomized trial of gastric band surgery. *Diabetes Obes Metab*. 2023;25(6):1464-1472. doi: 10.1111/dom.14992.

Wentworth JM, Playfair J, Laurie C, et al. Gastric band surgery leads to improved insulin secretion in overweight people with type 2 diabetes. *Obes Surg*. 2015;25(12):2400-2407. doi: 10.1007/s11695-015-1716-5.

YOMEGA

Robert M, Espalieu *P* , Pelascini E, et al. Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial. *Lancet*. 2019;393(10178):1299-1309. doi: 10.1016/S0140-6736(19)30475-1.

Appendix I. Eligible RCTs With a Mixed Population and Mean BMI > 35

The 2 studies, and related publications, listed below met the PICOS criteria, but were conducted in a mixed–body mass index (BMI) population, and results were reported as a single group. For example, a trial comparing Roux-en-Y gastric bypass (RYGB) with usual care, in individuals with type 2 diabetes mellitus (T2DM) and a BMI ≥ 25 kg/m^2, when those with T2DM and a BMI > 30 kg/m^2 are already eligible for MBS under the 2015 Washington coverage determination. All studies had a mean BMI > 35 kg/m^2.

NCT01435980

RYGB compared with usual care plus exenatide or usual care alone in Chinese individuals with a BMI > 28 kg/m^2.

Liang Z, Wu Q, Chen B, Yu *P* , Zhao H, Ouyang X. Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: a randomized controlled trial. *Diabetes Res Clin Pract.* 2013;101(1):50-56. doi: 10.1016/j.diabres.2013.04.005.

STAMPEDE (NCT00432809)

RYGB or sleeve gastrectomy plus medical therapy, compared with intensive medical therapy alone, in individuals with a baseline BMI range of 27 to 43 kg/m^2.

Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med.* 2012;366(17):1567-1576. doi: 10.1056/NEJMoa1200225.

Kashyap SR, Bhatt DL, Wolski K, et al. Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. *Diabetes Care.* 2013;36(8):2175-2182. doi: 10.2337/dc12-1596.

Kashyap SR, Bhatt DL, Schauer PR; STAMPEDE Investigators. Bariatric surgery vs. advanced practice medical management in the treatment of type 2 diabetes mellitus: rationale and design of the surgical therapy and medications potentially eradicate diabetes efficiently trial (STAMPEDE). *Diabetes Obes Metab.* 2010;12(5):452-454. doi: 10.1111/j.1463-1326.2009.01172.x.

Schauer PR, Bhatt DL, Kirwan JP, et al. Bariatric surgery versus intensive medical therapy for diabetes--3-year outcomes. *N Engl J Med.* 2014;370(21):2002-2013. doi: 10.1056/NEJMoa1401329.

Schauer PR, Bhatt DL, Kirwan JP, et al. Bariatric surgery versus intensive medical therapy for diabetes - 5-year outcomes. *N Engl J Med.* 2017;376(7):641-651. doi: 10.1056/NEJMoa1600869.

Aminian A, Kashyap SR, Wolski KE, et al. Patient-reported outcomes after metabolic surgery versus medical therapy for diabetes: insights from the STAMPEDE randomized trial. *Ann Surg.* 2021;274(3):524-532. doi: 10.1097/SLA.0000000000005003.

Appendix J. Bibliography of Excluded Studies, With Reasons

See attachment for a list of excluded studies, with reason for exclusion (pages J1 to J27).

Appendix K. Example Growth Curves for Children and Adolescents

See attachment for 2 example growth curve charts from the Centers for Disease Control and Prevention (pages K1 to K3).

Appendix M. MAUDE and Medical Device Recall Reports

See attachment for results from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) and Medical Device Recalls databases (pages M1 to M135).