THE AGA INSTITUTE

AGA Statement to the MedCAC on Health Outcomes After Bariatric Surgical Therapies in the Medicare Population

Founded in 1897, the American Gastroenterological Association (AGA) is the trusted voice of the gastroenterology community that has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. As internists, specialists in digestive disorders, and endoscopists, gastroenterologists are uniquely positioned to play an important role in the multidisciplinary treatment of obesity.

The AGA is leading a multidisciplinary initiative to guide gastroenterologists in the comprehensive care of patients with obesity. Our Practice guide on Obesity and Weight management, Education and Resources, known as POWER, provides physicians with an evidence-based comprehensive, multi-disciplinary process to guide and personalize innovative obesity care for safe and effective weight management.[1] It is vital to understand the importance of embracing obesity as a chronic, relapsing disease that requires a long-term multidisciplinary approach to management. Patients who are overweight or obese present to gastroenterology clinics daily with obesity related gastroesophageal reflux disease, and its associated risks of Barrett's esophagus and esophageal cancer, gallstone disease, nonalcoholic fatty liver disease steatohepatitis, and an increased risk for colon polyps and cancer. Because gastrointestinal disorders resulting from obesity are frequent and often present sooner than type 2 diabetes mellitus and cardiovascular disease, gastroenterologists should be on the front line in providing effective therapy. We appreciate the opportunity to provide feedback on health outcomes after bariatric and endoscopic surgical therapies in the Medicare population.

There is rich scientific evidence supporting improved health outcomes after treatment with non-surgical endoscopic bariatric therapies (EBT) which are provided by gastrointestinal endoscopists in patients which include the Medicare population that other presenters will provide in detail. A systematic review and meta-analysis performed by the American Society for Gastrointestinal Endoscopy determined endoscopic bariatric therapies provide

[1] Acosta, Andres, MD, Sarah Streett, MD, et al. "POWER — Practice Guide on Obesity and Weight Management, Education and Resources." *Clinical Gastroenterology and Hepatology* 15, no. 5 (May 2017): 631-49. Accessed July 26, 2017. http://www.cghjournal.org/article/S1542-3565(16)30988-0/fulltext

an effective, minimally invasive alternative for treating obesity.[2] In addition, the AGA's POWER white paper and Episode-of-Care Framework for the Management of Obesity provide ample evidence that EBT intervention benefits outweigh harm and highlights the necessity of using these tools as part of a comprehensive support program to provide long-term benefit.[3] Instead of a linear care pathway, the POWER program care cycle is circular to represent the fact that obesity is a chronic disease that requires a lifelong multidisciplinary approach for effective, long-term therapy.[4] Given the challenges of both achieving weight loss and sustained weight maintenance, approaches that combine therapies can improve clinical efficacy.

While bariatric surgery is an option for patients who meet Medicare's criteria, low adoption demonstrates that patients often have a psychological bias against anatomy altering surgery, its associated risks, and potential costs. To reach more Medicare beneficiaries with obesity, MedCAC should consider coverage of EBT for patients who are unwilling to undergo life-altering surgery who may find a non-surgical approach more acceptable or for patients with multiple comorbidities who are not good candidates for bariatric surgery. Additionally, the truly minimally invasive approach of EBT may also allow for earlier interventions at lower class levels of obesity. The POWER program provides physicians with a comprehensive, multi-disciplinary process to guide and personalize obesity care that incorporates concomitant use of obesity therapies based on individual patient's comorbidities and goals.

EBT has proven successful when supported by comprehensive obesity care support, however, there are barriers to widespread adoption. Barriers to care include the 1987 National Coverage Determination (NCD) for Gastric Balloon for Treatment of Obesity (100.11) which established non-coverage of gastric balloon devices. Gastric balloons in use today are both safe and effective as demonstrated in pivotal FDA trials; however, the NCD has not been updated since its implementation 30 years ago. We ask CMS and MedCAC to consider retiring NCD 100.11.

Given the crisis of the obesity epidemic, the profound costs to patient health and health care spending, EBTs are effective therapies that can safely improve the treatment of obesity, and are an important advancement to the existing therapeutic options.

Thank you for the opportunity to provide input to MedCAC on scientific evidence for health outcomes from EBT.

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[2] Dayyeh, Barham K. Abu, Nitin Kumar et al. "ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies." *Gastrointestinal Endoscopy* 82, no. 3 (September 2015): 425-38. doi:10.1016/j.gie.2015.03.1964.

[3] Brill, Joel V., Jamile A. Ashmore, et al. "White Paper AGA: An Episode-of-Care Framework for the Management of Obesity—Moving Toward High Value, High Quality Care: A Report From the American Gastroenterological Association Institute Obesity Episode of Care and Bundle Initiative Work Group." *Clinical Gastroenterology and Hepatology* 15, no. 5 (May 2017): 650-64. doi:10.1016/j.cgh.2017.02.002.

[4] http://www.gastro.org/patient-care/conditions/obesity/POWER-care_cycle_FINAL.jpg.jpeg.pdf. Accessed July 26, 2017

WRITTEN COMMENTS:
Evidence for Health Outcomes in the Medicare Population for Surgical and Endoscopic Procedures for Weight Loss

The Binge Eating Disorder Association (BEDA) appreciates the opportunity to provide written comments in advance of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting to be held on August 30, 2017 regarding the state of evidence for health outcomes in the Medicare population for surgical and endoscopic procedures for weight loss.

BEDA focuses its comments on the first "Additional Discussion Topics" identified as follows: Discuss important evidence gaps that have not been previously or sufficiently addressed.

In the United States, an estimated 32 million individuals suffer from eating disorders, with anorexia nervosa having the highest mortality rate of any other mental health disorder. The majority of those with eating disorders live in normal or higher weight bodies and are desperate to lose weight.

BEDA is especially concerned that professionals performing pre-surgical evaluations, performing surgical and endoscopic procedures for weight loss, and those tasked with follow up after such procedures, including registered dietitians, have not received adequate training in screening for eating disorders, counseling patients about the potential risks of such procedures relative to their eating disorder, and providing evidence-based treatment interventions for patients developing eating pathology after such procedures.

The collection of data regarding eating disorder history, meeting current criteria for an eating disorder diagnosis, or being at increased risk of developing an eating disorder post-procedure, and the evaluation of that by those with expertise in eating disorders, is of paramount importance to insure the health and safety of those within the Medicare population who might be considered for surgical or endoscopic procedures for weight loss.

BEDA intends to initiate further discussions with CMS about the issue of eating disorders generally, and more specifically in relation to weight loss procedures. Please do not hesitate to contact Joslyn Smith, Director of Policy & Government Affairs, at (607) 280-6488 or joslyn@bedaonline.com with any questions or comments.

The Binge Eating Disorder Association (BEDA) is a national non-profit organization that provides leadership in the recognition, prevention, and treatment of Binge Eating Disorder (BED) and associated weight stigma. Through outreach, education and advocacy, BEDA will increase awareness and proper diagnosis of BED, while promoting excellence in care for those living with and those treating BED and its associated conditions. BEDA promotes cultural acceptance of, and respect for, the natural diversity of sizes, as well as promoting a goal of improved health, which may or may not include weight change. For more information, visit www.bedaonline.com

July 28, 2017

ATTN: CMS' Medicare Evidence Development & Coverage Advisory Committee

RE: Health outcomes in the Medicare population for surgical & endoscopic procedures for weight loss

The Obesity Care Continuum (OCC) is pleased to provide the following comments as the Centers for Medicare & Medicaid Services' (CMS) Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) develops recommendations regarding the appraisal of the state of evidence for health outcomes in the Medicare population for surgical and endoscopic procedures for weight loss. We appreciate this opportunity to provide feedback to MEDCAC regarding these important issues.

In 2006, bariatric surgery became a Medicare covered benefit. In the 11 years following that national coverage decision, bariatric surgery has now become a covered benefit under the Federal Employees Health Benefits Program, TRICARE, the overwhelming majority of state employee health plans, almost every state Medicaid plan, 23 state essential health benefit benchmark plans and majority of large employer health plans. Despite the broad coverage of bariatric surgery and the significant scientific evidence surrounding its profound impact on type 2 diabetes and numerous other serious chronic conditions, many health plans continue to discriminate against this range of surgical interventions for millions of Americans affected by severe obesity.

We are pleased that MEDCAC is examining the underlying evidence surrounding surgical and endoscopic procedures for the treatment of obesity. The OCC fully supports tracking long-term outcomes and accreditation that are clinically based and quality oriented to maintain accurate and current evidence for bariatric surgery outcomes. A Qualified Clinical Data Registry (QCDR) such as the American College of Surgeons/American Society for Metabolic and Bariatric Surgery's Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database is one of several available reporting mechanisms for satisfactory Merit-Based Incentive Payment System (MIPS) participation in 2017 and is the only national QCDR for bariatric surgery. Major private insurers like Blue Cross, United/Optum, Cigna and Aetna all require MBSAQIP accreditation to meet quality goals and network participation.

Since 1991, when the National Institutes of Health (NIH) declared obesity to be a multi-factorial chronic disease, the obesity community has been working to educate patients, healthcare professionals and policymakers that our country must take a comprehensive approach to both prevent and treat obesity. Science has proven that obesity is associated with numerous related conditions such as type 2 diabetes, hypertension, heart disease, lipid disorders, certain cancers, sleep apnea, arthritis and mental illness. Therefore, care should not be viewed as simply having the goal of reducing body weight, but should additionally be focused on improving overall health and quality of life. As with any other health concern, intervention at an earlier stage is met with better outcomes and we endorse treatment for those in need -- particularly patients with diabetes and early stage obesity.

Just as those affected by heart disease receive their care through a coordinated multidisciplinary treatment team, those affected by obesity should also follow a similar continuum of coordinated care. Because of the complex nature of obesity and its variety of impacts on both physical and mental health, effective treatment requires the coordinated services of providers from several disciplines and professions (both physician and non-physician) within both these treatment areas.

I**t is imperative that the August 30th MEDCAC panel acknowledge the impact that obesity is having on the health of our nation and support a disease model approach to obesity that incorporates a continuum of care based on the stage of disease from counseling, to FDA-approved medications and devices, to bariatric surgery**. Furthermore, OCC believes that the panel discussions should examine both the risk/benefit analysis of different treatment options as well as the consequences of ineffective treatment options or not treating the disease at all.

In examining these issues, we would hope that the panel would urge CMS to develop a robust public awareness campaign that both details the health consequences of obesity and promotes patient access to all available evidence-based treatments – including FDA-approved medications and devices and bariatric surgery. Finally, OCC supports a national quality metric that would require a physician-patient discussion of obesity treatment options or referral for treatment for every patient with obesity.

Again, we appreciate the opportunity to provide these comments. Should you have any questions or need additional information, please contact me via email at chris@potomaccurrents.com or telephone at 571-235-6475. Thank you.

Chris Gallagher
Washington Coordinator
Obesity Care Continuum

About the Obesity Care Continuum:
The leading obesity advocate groups founded the Obesity Care Continuum (OCC) in 2010 to better influence the healthcare reform debate and its impact on those affected by overweight and obesity. Currently, the OCC is composed of the Obesity Action Coalition (OAC), the Obesity Society (TOS), the Academy of Nutrition and Dietetics (AND), the American Society for Metabolic and Bariatric Surgery (ASMBS), and the Obesity Medicine Association (OMA). With a combined membership of more than 125,000 patient and healthcare professional advocates, the OCC covers the full scope of care from nutrition, exercise and weight management through pharmacotherapy to device and bariatric surgery. Members of the OCC also challenge weight bias and stigma-oriented policies – whenever and wherever they occur.

Johnson & Johnson MEDICAL DEVICES

July 28, 2017

Maria Ellis
Executive Secretary for MEDCAC
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: The August 30, 2017 meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) to examine currently available evidence on the health outcomes after bariatric surgical therapies in the Medicare population.

Dear Ms. Ellis:

On behalf of Ethicon, Inc., a member of the Johnson & Johnson Family of Companies, I am pleased to submit information to assist the MEDCAC in the evaluation of the currently available evidence on the health outcomes after bariatric surgical therapies in the Medicare population. Please include these comments in the public record made available to the MEDCAC panel.

Ethicon is committed to the fight against obesity and metabolic diseases and helping to elevate the standard of care through research and evidence, best-in-class education and training, innovative products, and expanding patient access to care. We support global initiatives, including clinical research, to demonstrate that, for the right patient, bariatric and metabolic surgery can be a long-term effective treatment for weight loss and obesity-related health conditions. We work together with thought leaders and experts to enable patients to live longer, more fulfilling lives.

We strongly support CMS's goal of evaluating the available evidence to ensure appropriate and safe use of bariatric surgical therapies in the Medicare population. To support CMS's effort to evaluate the currently available evidence, the attachment to this letter summarizes the comparative clinical evidence for obesity treatment strategies.

Summary of Key Points

- The burden of obesity, including its comorbidities and complications, is substantial in the Medicare population and demands consideration of a full range of interventions.[1-6]
  - Approximately two-thirds of Medicare bariatric surgery recipients are under age 65 (eligible due to disability), and nearly half are less than 55 years old.[7]
  - Comparative effectiveness evidence for laparoscopic surgical obesity treatments is applicable across a wide age range, including those over age 65, based on primary data analyses, systematic reviews, and technology assessments conducted by academic researchers, key clinical opinion leaders, the Agency for Healthcare Research and Quality (AHRQ),[8,9] the Institute for Clinical and Economic Review (ICER),[10] the Washington State Health Care Authority (HCA),[11] the Cochrane Collaboration,[12,13] and the California Technology Assessment Forum (CTAF).[10] Based on the current evidence of clinical effectiveness, cost-effectiveness and safety, laparoscopic bariatric surgery should remain as a treatment option for the elderly population.[10-12,14,15] In addition, recent evidence (within the last 9-12 months) for the effectiveness of bariatric surgery in the older population continues to mount.[17-28] These studies concluded that in older patients, the benefit-risk balance is acceptable and surgery should not be rejected on the sole argument of age age.[17-28]
  - Laparoscopic bariatric surgery produces marked weight loss in patients of all ages (30%-40% of total bodyweight[11]), and results in greater sustained weight loss vs. conventional weight-loss

management.[8,10,13,16] Outcomes of bariatric surgery in older patients are comparable to those in a younger population, independent of the type of procedure.[13] Weight loss has been shown to persist at 10 years after surgery (14-25% below baseline).[29,30]

- Studies assessing laparoscopic bariatric surgery in patients ≥65 years have concluded that laparoscopic bariatric surgery has an acceptable safety profile.[13,16,29] The complication rates of bariatric surgery in patients >60 years old have been found to be comparable to those in a younger population, independent of the type of procedure performed.[13]
- Five-year randomized control trial (RCT) data showed that, among patients with T2D and a BMI of 27 to 43, laparoscopic bariatric surgery with intensive medical therapy was more effective vs. intensive medical therapy alone in decreasing or resolving hyperglycemia.[32] Another recent RCT found that diabetes remission at 1 year was 60.0% with Roux-en-Y gastric bypass vs 5.9% with the most rigorous intensive lifestyle and medical intervention tested against surgery in an RCT.[33] T2D remission rates, antidiabetic durability, and other cardiovascular risk factor benefits from bariatric/metabolic surgery were comparable among patients with a BMI below or above 35 kg/m^2.[9,11,34] The overall odds of T2D remission were found to be 76.4 times greater with surgery compared with non-surgical interventions.[35] Among patients ≥65 years of age, pooled diabetes resolution was 54.5% at 1-year follow-up.[13]
- Laparoscopic bariatric surgery enhances future cardiovascular health for obese individuals,[11,36,37] including the elderly.[36] It has also been shown to resolve or reduce obstructive sleep apnea,[38,39] improve gait biomechanics,[40] reduce osteoarthritic pain,[40,41] and improve joint function.[40,41]
- Regardless of age, improved mobility, reduced comorbidities, pain reduction, and enhanced psychological functioning such as improvements in mood, self-esteem, social functioning, and sexuality led to improved quality of life enrichment in laparoscopic bariatric surgery patients.[29]
- Laparoscopic bariatric surgery is a cost-effective treatment.[11] In some obese populations, the reduction in comorbidities as a result of surgery may lead to a net cost savings.[42] Cost savings with bariatric surgery in older adults (>60 years old) start accruing within 3 months of surgery.[29]

➢ The American Diabetes Association (ADA),[43] the 2nd Diabetes Surgery Summit (DSS-II),[44] the American Association of Clinical Endocrinologists,[45] the Obesity Society,[45] the American Society for Metabolic and Bariatric Surgery (ASMBS),[45,46] the American Heart Association (AHA),[47] and the National Institute for Health and Care Excellence (NICE)[19,48] all support laparoscopic bariatric surgery as an obesity treatment without age restrictions in adults.

Conclusions:

Laparoscopic bariatric surgery is a cost-effective treatment, results in marked weight loss in patients of all ages, results in greater sustained weight loss vs. conventional weight-loss management, has an acceptable safety profile in patients ≥65 years, and has been shown to resolve or improve other medical issues such as metabolic conditions, cardiovascular conditions, sleep apnea, and joint function. In addition, quality of life improvements has been demonstrated with laparoscopic bariatric surgery. Based on this evidence, we believe Medicare patients should continue to have access to laparoscopic bariatric surgery.

Thank you for your consideration of our comments and recommendations.

Sincerely,

Christina Farup, MD, MS
Vice President, Health Economics and Market Access, Americas
Johnson & Johnson Medical Devices

Thank you for this opportunity to provide feedback on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) recommendations regarding the appraisal of the state of evidence for health outcomes of surgical and endoscopic procedures for obesity in aged and/or disabled individuals enrolled in Medicare. Ethicon, Inc. recognizes that providing effective and cost-effective therapies is important to individual patients, clinicians, payers, the health system, and society, and appreciates MEDCAC's contributions. We have provided our perspective regarding this appraisal of the state of evidence in the following pages.

Summary of Key Points

- The burden of obesity, including its comorbidities and complications, is substantial in the Medicare population and demands consideration of a full range of interventions.[1-6] Most Medicare bariatric surgery recipients are <65 years old (eligible due to disability), and nearly half are <55 years old.[7]
- Comparative effectiveness evidence for laparoscopic surgical obesity treatments is applicable across a wide age range, including those over age 65, based on primary data analyses, systematic reviews, and technology assessments conducted by academic researchers, key clinical opinion leaders, the Agency for Healthcare Research and Quality (AHRQ),[8,9] the Institute for Clinical and Economic Review (ICER),[10] the Washington State Health Care Authority (HCA),[11] the Cochrane Collaboration,[12,13] and the California Technology Assessment Forum (CTAF).[10] Based on the current evidence of clinical effectiveness, cost-effectiveness and safety, laparoscopic bariatric surgery should remain as a treatment option for the elderly population.[10-12,14,15] In addition, recent evidence (within the last 9-12 months) for the effectiveness of bariatric surgery in the older population continues to mount. The studies concluded that in older patients, the benefit-risk balance is acceptable and surgery should not be rejected on the sole argument of age.[17-28]
  - Laparoscopic bariatric surgery produces marked weight loss in patients of all ages (30%-40% of total bodyweight[11]), and results in greater sustained weight loss vs. conventional weight-loss management.[8,10,13,16] Outcomes of bariatric surgery in older patients are comparable to those in a younger population, independent of the type of procedure.[13] Weight loss has been shown to persist at 10 years after surgery (14-25% below baseline).[29,30]
  - Studies assessing laparoscopic bariatric surgery in patients ≥65 years have concluded that laparoscopic bariatric surgery has an acceptable safety profile.[13,16,19,29,31] The complication rates of bariatric surgery in patients >60 years old have been found to be comparable to those in a younger population, independent of the type of procedure performed.[13,19,20]
  - Five-year randomized control trial (RCT) data showed that, among patients with T2D and a BMI of 27 to 43, laparoscopic bariatric surgery with intensive medical therapy was more effective vs. intensive medical therapy alone in decreasing or resolving hyperglycemia.[20,32] Another recent RCT found that diabetes remission at 1 year was 60.0% with Roux-en-Y gastric bypass vs 5.9% with the most rigorous intensive lifestyle and medical intervention tested against surgery in an RCT.[33] T2D remission rates, antidiabetic durability, and other cardiovascular risk factor benefits from bariatric/metabolic surgery were comparable among patients with a BMI below or above 35 kg/m^2.[9,11,34] The overall odds of T2D remission were 76.4 times greater with surgery compared with non-surgical interventions.[20,21,35] Among patients ≥65, pooled diabetes resolution was 54.5% at 1-year follow-up.[13]
  - Laparoscopic bariatric surgery enhances future cardiovascular health for obese individuals,[11,36,37] including the elderly.[36] It has also been shown to resolve or reduce obstructive sleep apnea,[21,22,38,39] improve gait biomechanics,[40] reduce osteoarthritic pain,[40,41] and improve joint function.[23,40,41]
  - Regardless of age, improved mobility, reduced comorbidities, pain reduction, and enhanced psychological functioning such as improvements in mood, self-esteem, social functioning, and sexuality led to improved quality of life enrichment in laparoscopic bariatric surgery patients.[25,29]
  - Laparoscopic bariatric surgery is a cost-effective treatment.[11,26] In some obese populations, the reduction in comorbidities as a result of surgery may lead to a net cost savings.[27,42] Cost savings with bariatric surgery in older adults (>60 years old) start accruing within 3 months of surgery.[28,29]
- The American Diabetes Association (ADA),[43] the 2nd Diabetes Surgery Summit (DSS-II),[44] the American Association of Clinical Endocrinologists,[45] the Obesity Society,[45] the American Society for Metabolic and Bariatric Surgery (ASMBS),[45,46] the American Heart Association (AHA),[47] and the National Institute for Health and Care Excellence (NICE)[19,48] all support laparoscopic bariatric surgery as an obesity treatment without age restrictions in adults.

The Burden of Obesity in Aged and/or Disabled Individuals Enrolled in Medicare

Obesity is an important public health priority in the United States. Obese individuals have emerged in recent years as a distinctive, concerning category in the Medicare and Medicaid programs because of the high costs of treating related health problems.[49]

- An AHRQ analysis of Medicare Beneficiary data from 2006-2009 showed that most Medicare bariatric surgery recipients were under age 65 (eligible due to disability), and that nearly half were less than 55 years old:[7]
    - 22.2% were age 18-24;[7]
    - 24.1% were age 45-54;[7]
    - 25.8% were age 55-64;[7] and
    - 27.9% were 65 years old or greater.[7]
- These findings are consistent with an analysis of 2014 Healthcare Cost and Utilization Project (HCUP) data which showed:
    - Of 13,020 Medicare patients who received a laparoscopic sleeve gastrectomy, 64.3% were <65 years old:
        - 17.8% were 18-44 years of age;
        - 46.5% were 45-64 years of age;
        - 35.6% were >65 years of age.
        - The mean age was 56.4 years old.[50]
    - Of 48,390 Medicare who received laparoscopic Roux-en-Y gastric bypass, 65.6% of Medicare patients were <65 years old:
        - 19.2% were 18-44 years of age;
        - 46.4% were 45-64 years of age;
        - 34% were >65 years of age;
        - The mean age was 56.2 years old.[50]
- Since >60% of the Medicare population is under the age of 65, evidence available on bariatric surgery in the younger population may be applicable to the Medicare population. In addition, evidence suggests a similar response in younger and older populations.
- The proportion of recipients over age 65 has increased over time.[7]
- Medicare beneficiaries under age 65 with disabilities have more cognitive and mental impairment and report poor health status.[51] Approximately 31% of the disabled Medicare population have 5 or more chronic conditions.[51]
- In 2002, it was estimated that 39.3% of disabled Medicare beneficiaries were obese.[52]
- Of adults aged 65 and over, 34.6% were obese in 2007–2010, representing over 8 million adults aged 65–74, and almost 5 million adults aged 75 and over.[2,4]
- By 2050, the number of U.S. adults age 65 and over is expected to more than double, rising from 40.2 million to 88.5 million.[3]
- The rate of type 2 diabetes (T2D) in Americans age 65 and older is 25.9%.[1]
- Both aging and obesity contribute to increased use of health care services[5,6] and an increase in the proportion of older adults will compound the burden and spending on health care services.[4,15]
- In 2006, the estimated additional Medicare spending for seniors due to obesity was more than $1,700 per beneficiary in inflation-adjusted dollars.[49] At the same time, Medicaid spending for the poor due to obesity was measured at $1,021 per beneficiary when adjusted for inflation.[49] The large percentage of cases of obesity combined with the generally high costs to Medicaid and Medicare for treatment translates into $91.6 billion a year in federal expenditures on obesity.[53]

Given the demographic changes forecasted, and the potential clinical and economic burden of obesity, it is important to identify and examine the full range of effective and cost-effective obesity treatment strategies.

Comparative Effectiveness Evidence for Obesity Treatment Strategies

Laparoscopic surgery results in greater improvement in weight loss outcomes and weight-associated comorbidities compared with non-surgical interventions, regardless of the type of procedures used (i.e., laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), biliopancreatic diversion with duodenal switch (BDDS), laparoscopic isolated sleeve gastrectomy (LISG)).[10,12] Comparative effectiveness evaluations and health technology assessments conducted by academic researchers, key clinical opinion leaders, government agencies, and non-profit, non-governmental organizations advocate for surgery in obese patients of all ages.[13,16,29,8,9,11,54,30,55]

Based on the current evidence of clinical effectiveness, cost-effectiveness and safety, laparoscopic bariatric surgery should remain as a treatment option for the elderly population.[10-12,14,15] Maintaining life span and quality of life remains a valid aim of surgery in older individuals.[14] Surgery can be an effective way of restoring both length and quality of life to older people.[14] Minimally invasive techniques and improved anesthesia make fewer demands on geriatric physiology.[14] Age makes only a partial contribution to the risk of bariatric surgery,[56] with postoperative morbidity often reflecting overall pre-operative health status. Recent evidence (within the last 9-12 months) for the effectiveness of bariatric surgery in the older population continues to mount.[17-28] These studies concluded that in older patients, the benefit-risk balance is acceptable and surgery should not be rejected on the sole argument of age.[17-28]

1. Weight Loss

Laparoscopic bariatric surgery is effective in producing marked weight loss in patients of all ages, and results in greater sustained weight loss compared to conventional weight-loss management.[8,10,13,16] The outcomes of bariatric surgery in patients >60 years old are comparable to those in a younger population, independent of the type of procedure performed.[13] Surgery can offer patients an effective and long-lasting treatment for obesity and related diseases, with weight loss persisting at 10 years after surgery.[29,30]

Two systematic reviews have summarized the evidence for weight loss with bariatric/metabolic surgery in the older population.

- Chow et al. (2016)[16] included 8 studies with a total of 1,835 patients aged ≥65 years old.
  - Mean excess weight loss at study endpoint was 66.2%.[16]
  - The authors concluded that bariatric surgery is effective in producing marked weight loss in patients ≥ 65 years old.[16]
- Giordano et al. (2015)[13] included 26 articles encompassing 8,149 patients >60 years old.
  - At 1-year follow-up, pooled mean excess weight loss was 53.8%.[13]
  - The authors concluded that outcomes of bariatric surgery in patients >60 years old are comparable to those in a younger population, independent of the type of procedure performed.[13]
- Studies of LSG and laparoscopic RYGB in older patients that were conducted after these systematic reviews showed weight loss consistent with these results after 3-4 years follow-up.[19,21,24]

Marihart et al. (2014)[29] conducted a narrative literature review of 349 articles that referred to bariatric surgery in older adults (>60 years old).

- The authors concluded that surgery can offer patients an effective and long-lasting treatment for obesity and related diseases.[13,29,37,54]
- They found that there was not any one bariatric procedure that is recommended for older adults, so individual needs should be taken into consideration when exploring options.[29]

The 2015 ***Washington State Health Care Authority (HCA)*** and ***the Institute for Clinical and Economic Review (ICER)*** Evidence Report found that:[11,54]

- For patients with a body mass index (BMI) of 35 or greater, data from 14 higher-quality randomized controlled trials (RCTs) demonstrated that bariatric surgery resulted in greater sustained weight loss (on average, 7-8 kg/m^2, or 30%-40% of total bodyweight) over 1 to 2 years of follow-up compared to conventional weight-loss management.[11]

The 2012 ***Agency for Healthcare Research and Quality (AHRQ)*** assessment of the association between bariatric surgery vs nonsurgical treatments and weight loss among patients with diabetes or impaired glucose tolerance and BMI of 30 to 35 concluded the following:[8,9]

- Surgery was associated with greater weight loss (range, 14.4-24 kg) during 1 to 2 years of follow- up than nonsurgical treatment.[8,9] Indirect comparisons of evidence from observational studies of bariatric procedures (n= 600 patients) and meta-analyses of nonsurgical therapies (containing more than 300 RCTs) support this finding at 1 or 2 years of follow-up.[8,9]

A 2014 ***Cochrane Collaboration review*** assessed the effects of bariatric surgery for overweight and obesity.[12,37]

- Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.[12,37,54]
- Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.[12]
- All seven RCTs comparing surgery with non-surgical interventions found benefits of surgery on measures of weight change at one to two years follow-up.[12]

The Swedish Obese Subjects (SOS) study,[30] which followed 4,047 patients for over 15 years, reported that weight increases did occur 1-2 years after surgery but eventually leveled off. After ten years, weight loss remained 25% and 14% below baseline weight for the subgroups of patients who underwent RYGB and LAGB, respectively (**Table 1**).[30]

Table 1. Weight change over time in patients from the Swedish Obese Subjects (SOS) Study

	% Weight Loss	
	1-2 years	After 10 years
RYGB	32%	25%
LAGB	20%	14%

A 2015 publication of the SOS study reporting on 3,485 patients divided into 5 baseline BMI categories (<35, 35-40, 40-45 or ≥ 45) showed that the favorable effect of weight reduction on T2D was independent of initial BMI.[55]

2. Postoperative Complications

Studies assessing laparoscopic bariatric surgery in patients ≥ 65 years old have concluded that bariatric surgery has an acceptable safety profile.[13,16,29] The complication rates of bariatric surgery in patients >60 years old have been found to be comparable to those in a younger population, independent of the type of procedure performed.[13]

The two systematic reviews in the older population also summarized the evidence for complications with bariatric/metabolic surgery.

- Chow et al. (2016)[16] included 8 studies with a total of 1,835 patients aged ≥65 years old:
  - Mean total post-operative complication rate was 21.1%, with wound infections being the most common (7.6%), followed by cardiorespiratory complications (3.0%). Mean 30-day mortality was 0.14%.[16]
  - The authors concluded that bariatric surgery in patients ≥ 65 years old has an acceptable safety profile.[16]
- Giordano et al. (2015)[13] included 26 articles encompassing 8,149 patients >60 years:
  - The overall complication rate was 14.7%. Mean 30-day mortality was 0.01%.[13]
  - The authors concluded that complication rates of bariatric surgery in patients >60 years old are comparable to those in a younger population, independent of the type of procedure performed.[13]
- Studies of LSG and laparoscopic RYGB in older patients that were conducted after these systematic reviews reported comparable or lower complication rates after 3-4 years follow-up.[19,21,24]

Marihart et al. (2014)[29] conducted a narrative literature review of 349 articles that referred to bariatric surgery in older adults (>60 years old).

- The authors concluded that a number of studies demonstrated that bariatric surgery was safe for the aging population and that comorbidities improve.[29]

An analysis of 30-day morbidity and mortality associated with LSG and RYGB in patients aged 65 years and over from the National Surgical Quality Improvement Program (NSQIP) database was conducted by Spaniolas et al. (2014).[57] Thirty-day complication rates in this cohort were not significantly different between patients who underwent laparoscopic RYGB and LSG: mortality 0.6% versus 0.6%, OR 1.1, 95% CI 0.11-9.49; serious morbidity 5.2% versus 5.6%, OR 0.91, 95% CI 0.42-0.96; and overall morbidity 9% versus 9.1%, OR 1.0, 95% CI 0.55-1.81 were similar.[57]

The 2015 ***Washington State HCA*** and ***ICER*** Evidence Report[11] identified a total of 28 RCTs and prospective cohort studies that met their criteria for good or fair quality and reported on complications of the four bariatric surgery procedures of interest.

- They found that the overall complication rate was comparable between RYGB and LAGB (19.4% vs 17.9% for LAGB), but the reoperation rate was higher for LAGB (14.8% vs 6.2%), which also had the highest rate of reoperations across all procedures.[11]
- Vertical sleeve gastrectomy (VSG) was associated with the fewest overall complications (9.5%) and reoperations (2.0%), and biliopancreatic diversion (BPD) had the highest complication rate (31.6%) and a revision rate of 13.0%.[11]
- The authors also commented that the studies were small and underpowered to detect any statistical differences between procedures for adverse events.[11]

The 2012 ***Agency for Healthcare Research and Quality (AHRQ)*** assessment of bariatric surgery in patients with diabetes or impaired glucose tolerance and BMI of 30 to 35 found that short-term rates of adverse events associated with bariatric surgery were relatively low.[9] One death, a case of sepsis at 20 months in an LAGB patient, was reported.[9] Short-term complications were minor and tended not to require major intervention.[9] Due to the dearth of long-term studies of bariatric surgery in this particular target population, few data exist about long-term adverse effects.[9]

The 2014 ***Cochrane Collaboration review*** identified five RCTs that report data on mortality, and no deaths occurred.[12] Serious adverse events (SAEs) were reported in four studies were similar across surgery and non-surgical groups, and ranged from 0% to 37% in the surgery groups and 0% to 25% in the no surgery groups.[12] Between 2% and 13% of surgery participants required reoperations over 12 to 24 months in the five studies that reported these data.[12]

A Nationwide US analysis assessed the safety of bariatric surgery in 1300 patients with T2D and a BMI ≥25 but <35 kg/m^2 from the database of the American College of Surgeons–National Surgical Quality Improvement Program.[58]

- The mean operative time and length of hospital stay were 109.4±58.3 minutes and 1.9±1.5 days, respectively.[58]
- The incidence of all individual major complications was ≤0.5%, except for postoperative bleeding (1.7%).[58]
- Thirty-day postoperative composite morbidity, serious morbidity, and mortality rates for the total cohort were 4.2%, 0.7%, and 0.15%, respectively.[58]
- Smoking (odds ratio = 2.75, 95% CI: 1.34–5.64) and COPD (odds ratio = 4.05, 95% CI 1.51–10.88) were predictors of composite morbidity, however age was not a predictor.[58]

3. Diabetes and Metabolic Outcomes

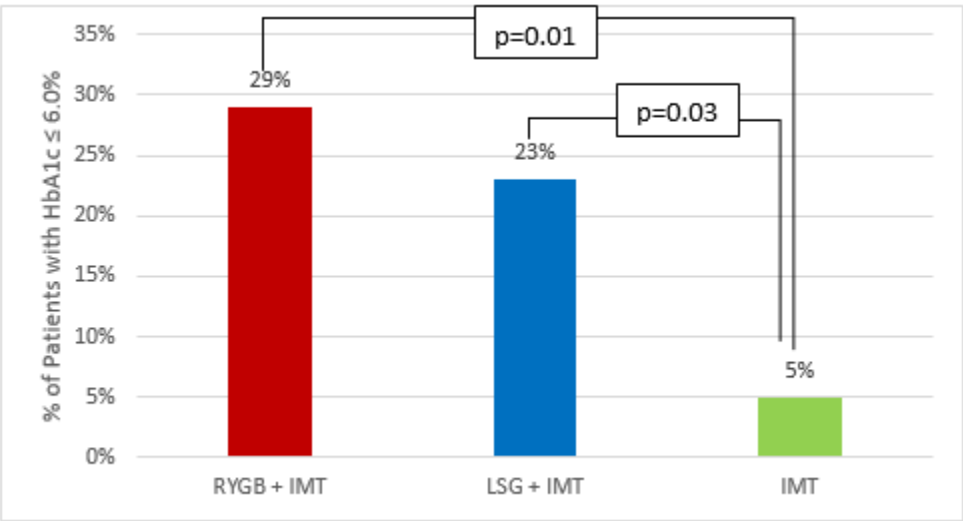
Five-year RCT data showed that, among patients with T2D and a BMI of 27 to 43, laparoscopic bariatric surgery (RYGB and LSG) plus intensive medical therapy was more effective than intensive medical therapy alone in decreasing, or in some cases resolving, hyperglycemia.[32] Another recent RCT found that diabetes remission at 1 year was 60.0% with RYGB vs 5.9% with the most rigorous intensive lifestyle and medical intervention yet tested against surgery in an RCT.[33] T2D remission rates, antidiabetic durability, and benefits on other cardiovascular risk factors from bariatric/metabolic surgery are comparable among patients with a BMI below or above 35 kg/m^2.[9,11,34] The overall odds of T2D remission were found to be 76.4 times greater with

surgery compared with non-surgical interventions.[35] Among patients ≥65 years of age, pooled diabetes resolution was 54.5% at 1-year follow-up.[13]

Long-term results from the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) RCT that compared intensive medical therapy (IMT) alone with laparoscopic surgical therapy plus IMT in patients with T2D and a BMI of 27 to 43 have recently been published by Schauer et al. (2017).[32]

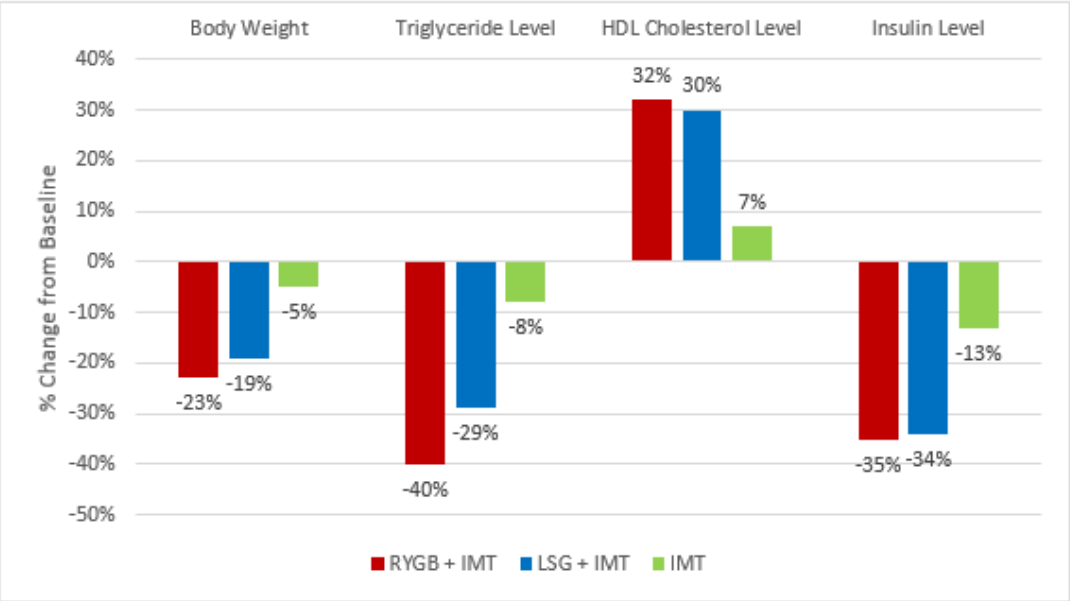
- At 5 years, the criterion for the primary end point (HbA1c ≤6.0% with or without the use of diabetes medications) was met by 2 of 38 patients (5%) who received IMT alone vs 14 of 49 patients (29%) who underwent RYGB with IMT(unadjusted p=0.01, adjusted p=0.03, p=0.08 in the intention-to-treat analysis) and 11 of 47 patients (23%) who underwent LSG with IMT (unadjusted p=0.03, adjusted p=0.07, p=0.17 in the intention-to-treat analysis) (**Figure 1**).[32]

Figure 1. Long-term results from the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) RCT at 5 years



- Patients who underwent laparoscopic procedures in addition to intensive medical therapy had a greater mean percentage reduction from baseline in glycated hemoglobin level than did patients who received intensive medical therapy alone at 5 years (2.1% vs 0.3%, p=0.00).[32]
- At 5 years, changes from baseline observed in the groups treated with RYGB and LSG combined with IMT were superior to the changes seen in the IMT only group with respect to body weight (-23%, -19%, and -5% in the RYGB + IMT, LSG + IMT, and IMT only groups, respectively), triglyceride level (-40%, -29%, and -8%), high-density lipoprotein cholesterol level (32%, 30%, and 7%), and use of insulin (-35%, -34%, and -13%) (**Figure 2**).[32]

Figure 2. Body weight, triglyceride level, HDL cholesterol level, and insulin level changes from baseline observed in the groups treated with RYGB and LSG plus intensive medical therapy and IMT only in the Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) RCT at 5 years



Results from another recent RCT by Cummings et al. (2016)[33] found that:

- Compared with the most rigorous intensive lifestyle and medical intervention tested against surgery in an RCT, laparoscopic RYGB yielded greater T2D remission in mild-to moderately obese patients.[33]
- Diabetes remission at 1 year was 60.0% with RYGB vs 5.9% with intensive lifestyle and medical intervention (p=0.002).[33]
- While the HbA1c decline over 1 year was only modestly more after laparoscopic RYGB than intensive lifestyle and medical intervention: from 7.7 ± 1.0% (60.7 mmol/mol) to 6.4 ± 1.6% (46.4 mmol/mol) vs 7.3 ± 0.9% (56.3 mmol/mol) to 6.9 ± 1.3% (51.9 mmol/mol), respectively (p=0.04) this drop occurred with significantly fewer or no diabetes medications after laparoscopic RYGB.[33]

A 2016 meta-analysis of 11 published RCTs directly comparing bariatric/metabolic surgery versus a variety of medical/lifestyle interventions for T2D provides level 1A evidence that surgery is superior for T2D remission, glycemic control, and HbA1c lowering in patients whose baseline BMI is below or above 35 kg/m^2.[34] The T2D remission rates, safety, antidiabetic durability, and benefits on other cardiovascular risk factors from bariatric/metabolic surgery appear roughly comparable among patients with a BMI below or above 35 kg/m^2.[34]

The 2015 ***Washington State HCA*** and ***ICER*** Evidence Report[11] found that:

- For patients with a BMI of 35 or greater, data from 14 higher-quality RCTs demonstrated that bariatric surgery resulted in greater resolution of comorbidities (primarily T2D) over 1 to 2 years of follow-up compared to conventional weight-loss management.[11] Data from high-quality observational studies suggested that surgery resulted in 20-40% reductions in all-cause mortality over 7 to 15 years of follow-up compared to conventional weight loss.[11]
- Higher-quality studies of bariatric surgery in patients with a BMI of 30.0 to 34.9 (7 RCTs and 3 observational studies) were conducted almost entirely among patients who also have T2D, and have focused on T2D resolution as the primary outcome.[11] The meta-analysis of the percentage of individuals with BMI of 30.0 to 34.9 achieving T2D resolution indicated that surgery was nearly 4 x more likely to result in complete resolution of T2D than conventional weight-loss management (odds ratio [OR], 3.6; 95% CI, 2.5-4.7).[11]

The 2012 ***Agency for Healthcare Research and Quality (AHRQ)*** assessment of bariatric surgery in patients with diabetes or impaired glucose tolerance and BMI of 30 to 35 found that surgery was associated with greater glycemic control (range, 0.9-1.43 point improvements in hemoglobin A1c levels) during 1 to 2 years of follow-up than nonsurgical treatment.[9] Indirect comparisons of evidence from observational studies of bariatric procedures (n= 600 patients) and meta-analyses of nonsurgical therapies (containing more than 300 RCTs) support this finding at 1 or 2 years of follow-up.[9]

A ***Cochrane Collaboration review*** assessed the effects of bariatric surgery for the control of comorbidities.[12]

- Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.[12]
- Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.[12]
- Improvements for T2D were found in five RCTs.[12]

In a 2013 publication of the SOS study, patients with BMI <35 kg/m^2 with comorbidities and patients with BMI 35-40 kg/m^2 without comorbidities were compared to 'eligible' patients and non-surgical patients.[59]

- Bariatric surgery reduced diabetes incidence by 73% in SOS individuals with BMI <35 kg/m^2 with comorbidities and by 67% in individuals with BMI 35-40 kg/m^2 without comorbidities after 15 years of follow-up.[59]
- Cardiovascular risk factors were significantly improved in both surgical groups after 10 years of follow-up.[59]
- Surgery reduced the diabetes incidence in both the BMI <35 (adjusted hazard ratio 0.33 [95% CI 0.13-0.82], p=0.017) and BMI 35-40 (0.27 [0.22-0.33], p<0.001) groups.[59]
- There was no difference in the effect of surgery between the groups (adjusted interaction p=0.713).[59]

Yan et al. (2016)[35] conducted a systematic literature review and meta-analysis of RCTs evaluating RYGB surgery versus medical treatment for T2D in obese patients. The authors found that the overall odds of T2D remission were 76.4 times greater with surgery compared with non-surgical interventions.[35]

A systematic review and meta-analysis by Chen et al. (2015)[60] showed that T2D remission was more likely in patients with smaller waist circumference, lower total cholesterol, lower triglycerides, lower low-density lipoprotein levels, higher high-density lipoprotein levels, shorter cardiovascular disease history, and less preoperative prevalence of hypertension.

Among patients ≥65 years of age, pooled diabetes resolution was 54.5% at 1-year follow-up.[13]

4. Cardiovascular Outcomes

Bariatric surgery enhances future cardiovascular health for obese individuals,[11,36,37,61] including the elderly.[36]

The effect of bariatric surgery on cardiometabolic risk in elderly patients (n=40) was evaluated in an observational cohort study by Batsis et al. (2016).[36]

- One-year after bariatric surgery, the prevalence of several cardiovascular risk factors decreased, including diabetes (57.5% to 22.5%; p<0.03), hypertension 87.5% to 73.7% (p=0.003), dyslipidemia (80% to 42.5%; p<0.001) and sleep apnea (62.5% to 23.7%; p<0.001).[36]
- Metabolic syndrome prevalence decreased from 80% to 45% (p<0.002).[36]
- Baseline risk using the Framingham risk score was 14.1%, which decreased at follow up to 8.2%.[36]

Vest et al. (2012)[37] conducted a systematic review of the impact of bariatric surgery on cardiovascular risk factors, and on cardiac structure and function.

- Seventy-three cardiovascular risk factor studies involving 19,543 subjects were included (mean age 42 years, 76% female).[37]
- Baseline prevalence of hypertension, diabetes and hyperlipidemia were 44%, 24%, and 44%, respectively.[37]

- Mean follow-up was 57.8 months (range 3-176) and average excess weight loss was 54% (range 16-87%).[37]
- Postoperative resolution/improvement of hypertension occurred in 63% of subjects, of diabetes in 73% and of hyperlipidemia in 65%.[37]
- Echocardiographic data from 713 subjects demonstrated statistically significant improvements in left ventricular mass, E/A ratio, and isovolumic relaxation time postoperatively.[37]

A recent study by Benotti et al. (2017)[54] evaluated the relationship between metabolic surgery and long-term cardiovascular events.

- A cohort of RYGB patients was tightly matched by age, BMI, sex, Framingham Risk Score, smoking history, use of antihypertension medication, diabetes mellitus status, and calendar year with a concurrent cohort of nonsurgical control patients (n=1,724 in each cohort).[54]
- The primary study end points of major cardiovascular events (myocardial infarction, stroke, and congestive heart failure) were evaluated using Cox regression. Secondary endpoints of longitudinal cardiovascular risk factors were evaluated using repeated-measures regression.[54]
- The RYGB and matched controls (N=1,724 in each cohort) were followed for up to 12 years after surgery (overall median of 6.3 years).[54]
- Kaplan-Meier analysis revealed a statistically significant reduction in incident major composite cardiovascular events (p=0.017) and congestive heart failure (p=0.008) for the RYGB cohort.
- Adjusted Cox regression models confirmed the reductions in severe composite cardiovascular events in the RYGB cohort (hazard ratio=0.58, 95% CI=0.42-0.82).[54]
- Improvements of cardiovascular risk factors (e.g., 10-year cardiovascular risk score, total cholesterol, high-density lipoprotein, systolic blood pressure, and diabetes mellitus) were observed within the RYGB cohort after surgery.[54]

Arterburn et al. (2016)[62] evaluated long-term survival in a large Veterans Affairs (VA) retrospective cohort study.

- Patients who underwent bariatric surgery (n=2,500) had lower all-cause mortality at 5 years and up to 10 years following the procedure compared with matched control patients who did not have surgery (n=7,462).[62]
- The mean (standard deviation) age for two cohorts evaluated was 52 (8.8) years for surgical patients and 53 (8.7) years for matched control patients.[62] Seventy-four percent of patients in both cohorts were male.[62]
- The results provide further evidence for the beneficial relationship between surgery and survival that has been demonstrated in younger, predominately female populations.[62]

5. Respiratory Outcomes

Obstructive sleep apnea (OSA) is frequently observed in morbidly obese patients undergoing bariatric surgery and tends to be severe in this patient population.[38] Dyslipidemia and BMI have been demonstrated to be associated factors for severity of OSA in this population.[38] Bariatric surgery either resolves OSA or results in significant improvement in OSA.[11,38,39]

A recent systematic review assessing and characterizing the impact that different types of bariatric surgery had on obese OSA patients included 22 articles with stated preoperative apnea-hypopnea index (AHI), apnea index (AI), or respiratory disturbance index (RDI).[39] Results showed:

- In addition to the expected reduction in BMI, significant improvement in AHI/AI/RDI occurred after surgery.[39]
- Furthermore, almost every study stated a postoperative reduction of the AHI to <20/hour and/or a >50% postoperative reduction of AHI.[39]

The 2015 ***Washington State HCA*** and ***ICER*** Evidence Report[11] identified three good- or fair-quality studies of the effects of bariatric surgery on sleep apnea.

- One was a good-quality RCT of 60 patients who were randomized to receive LAGB or conventional weight-loss treatment and were followed for two years.[11]

- Sleep apnea, defined as reductions in the number of events per hour on the AHI, improved in both groups and did not statistically differ between them.
- The prevalence of sleep apnea was reduced significantly in 30 patients with T2D who received VSG and were followed for 18 months in a prospective cohort (from 15% at baseline to 3% at end of follow-up, p=0.03); unfortunately, this measure was not reported for the control group receiving intensive medical therapy.[11]
- Resolution of sleep apnea also did not statistically differ between groups in a prospective cohort of 179 patients receiving RYGB or one of three nonsurgical options: a residential program, a commercial weight-loss camp, and a hospital outpatient program.[11]

6. Musculoskeletal Outcome

Obesity accelerates osteoarthritis of the knee and hip by exerting deleterious effects on joints through biomechanical and systemic inflammatory changes.[40] Recent evidence has demonstrated that bariatric surgery improves gait biomechanics, and improves pain and joint function.[40,41,63]

A recent literature review (Springer et al., 2017)[40] evaluated the impact of obesity on lower limb biomechanics and total joint arthroplasty outcomes, as well as weight changes after joint arthroplasty and the role of bariatric surgery among patients requiring joint arthroplasty.

- The authors found that weight loss increases swing time, stride length, gait speed, and lower extremity range of motion.[40]
- Total joint arthroplasty improves pain and joint function, but does not induce significant weight loss in the majority of patients. Bariatric surgery improves gait biomechanics, and in the severely obese patient with osteoarthritis, improves pain and joint function.[40]

A 2016 prospective cohort study in JAMA of 2,221 patients found that 77% of patients with knee pain and 79% of those with hip pain had significant pain relief after bariatric surgery.[41]

A 2016 analysis of a New York Statewide database matched 2,636 total knee arthroplasty (TKA) patients who received prior bariatric surgery to 2,636 morbidly obese patients who did not, and 792 total hip arthroplasty (THA) patients who received prior bariatric surgery were matched to 792 morbidly obese patients who did not.[63]

- Bariatric surgery lowered the comorbidity burden prior to total joint arthroplasty (TKA p<0.0001; THA p<0.005).[63]
- Risks for in hospital complications were lower for THA and TKA patients receiving bariatric surgery prior to TJA (odds ratio [OR]=0.25, p<0.001; and OR=0.69, p=0.021, respectively).[63]
- Risks for 90-day complications were lower for TKA (OR=0.61, p=0.002).[63]
- Revision risks were not different for either THA (p=0.634) or TKA (p=0.431), nor was THA dislocation risk (p=1.000).[63]

7. Patient-Reported Outcomes (Quality of Life) with Bariatric/Metabolic Surgery

The importance of the patient perspective in the treatment of disease has increasingly been recognized, and more emphasis is being placed on patient-reported outcomes (PROs) to capture the full impact of disease. PRO measurements such as health-related quality of life (HRQoL) can provide critically important information, complementing and supporting the meaningfulness of more traditional clinical outcomes. Regardless of age, improved mobility, reduced comorbidities, pain reduction, and enhanced psychological functioning such as improvements in mood, self-esteem, social functioning, and sexuality led to improved quality of life enrichment in bariatric surgery patients.[29]

- The narrative literature review by Marihart et al. (2014)[29] found that, regardless of age, improved mobility, reduced comorbidities, pain reduction, enhanced psychological functioning such as

improvements in mood, self-esteem, social functioning, and sexuality led to improved HRQoL enrichment in bariatric patients.
  - Ten years after weight loss surgery, patients had significantly better health perceptions, social interactions, psychosocial functioning, and reduced depression.[29]
  - Improved mobility and fewer medications alone led many participants who underwent bariatric surgery to state they had experienced improved mood, regardless of whether all weight-loss goals were met, and would opt to have the surgery again.[29]
  - Wheelchair-bound older patients were often fully ambulatory within months post-surgery.[29]
  - Even modest weight-loss improved overall physical functioning of older adults. For example, patients with lower extremity arthritis experienced reduced knee and hip pain.[29]
  - Many obese patients who have T2D experience normalization of blood sugars within days post-surgery.[29] Patients could frequently stop taking diabetes medications before leaving the hospital after surgery.[29] Being able to reduce or eliminate daily diabetes glucose testing and insulin injections leads to improved HRQoL.[29]
  - The authors also pointed out that nutrient deficiencies negatively affect HRQoL by requiring extra doctor visits, vitamin supplements, iron infusions, B-12 injections, and physical symptoms of lower energy.[29]

- Short- to mid-term (<5 years) HRQoL post-surgery has been well-documented, with significant improvement in physical health scores often reaching population normative values.[64]
- A meta-analysis conducted by Driscoll et al. (2015)[64] assessed the quality of evidence and effectiveness of surgery on HRQoL ≥5 years.
  - The meta-analysis provided evidence that bariatric surgery significantly improves long-term (≥5 years) physical and mental HRQoL; the forest plots favored ($p<0.05$) the surgical group for 3 out of 4 physical domain scores and 4 out of 4 mental domain scores on the 36-Item Short Form Health Survey (SF-36).[64]

- A ***Cochrane Collaboration review*** assessed the effects of bariatric surgery for overweight and obesity, including the control of comorbidities.[12]
  - Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.[12]
  - Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.[12]
  - The two RCTs that compared HRQoL with surgery vs. non-surgical interventions found benefits for some aspects of HRQoL.[12]

8. Overall Clinical and Economic Value

Laparoscopic bariatric surgery is a cost-effective treatment.[11] In some obese populations, the reduction in comorbidities as a result of surgery may lead to a net cost savings.[42] Cost savings with bariatric surgery in older adults (>60 years old) start accruing within 3 months of surgery.[29]

A 2015 ***Washington State HCA*** and ***ICER*** Evidence Report[11] noted the following findings regarding bariatric surgery costs and cost-effectiveness:

- Published evidence accumulated to date suggests that bariatric surgery meets commonly-accepted thresholds for cost-effectiveness in comparison to standard care across multiple BMI categories, time horizons, and procedure types.[11]
- Findings from the ***Washington State HCA*** and ***ICER*** decision model confirmed this, with results that were robust to even extreme assumptions about the durability of treatment effect and the impact of bariatric surgery on mortality.[11]
  - Cost-effectiveness estimates for bariatric surgery ranged from $23,784 to $63,011, suggesting that bariatric surgery for the treatment of obesity is cost-effective in comparison to well-accepted benchmarks (i.e., $50,000-$100,000 per QALY gained).[11]
  - More favorable cost-effectiveness estimates for bariatric surgery were found among patients with higher BMI (i.e., BMI ≥40) compared to those with lower BMI levels.[11]

- Two of the 21 higher-quality studies included in the ***Washington State HCA*** and ***ICER*** evaluation examined patients over the age of 65.[11]

ICER developed an evidence report, including a systematic review of the literature, a cost-effectiveness model, and a budgetary impact analysis, to support a public meeting of the ***California Technology Assessment Forum (CTAF)*** on July 14, 2015.[10]

- The results suggested that bariatric surgery provides substantial clinical benefit over 1 to 2 years of follow-up compared with conventional weight-loss management in patients with class 2 or 3 obesity.[10] More recent data suggest that these benefits accrue to patients with class 1 obesity and D2M as well.[10]
- Among the key votes at the public meeting, the CTAF Panel found the evidence inadequate to distinguish the clinical effectiveness of four different weight-loss drugs.[10]
- The vote was split nearly evenly on whether the evidence was adequate to demonstrate that the vBloc device was better than usual care.[10]
- However, for patients with class I obesity (BMI between 30 and 35) who also have T2D, the CTAF Panel voted unanimously that the evidence is adequate to demonstrate the superiority of bariatric surgery over conventional weight-loss management.[10] The CTAF Panel's vote reflected the growing body of evidence that surgery may not only reduce weight but also improve or resolve T2D for patients with a class I obesity.

Evidence has shown that, in some obese populations, the reduction in comorbidities as a result of bariatric surgery may lead to a net cost savings.[42]

- A study by Finkelstein et al. (2013)[42] estimated the net costs of bariatric surgery and the time to break-even costs (i.e., the time at which bariatric surgery begins to provide an overall net savings) for various obese populations. Findings showed that:
  - For all LAGB patients, the time to breakeven costs is 5.25 (CI: 4.25 to 10+) years. For all LRYGB patients, the time to breakeven costs exceeds 10 years.[42]
  - For a subsample of morbidly obese patients, costs for LAGB and LRYGB are recovered in 1.5 (CI: 1.45 to 1.55) and 2.25 years (CI: 2.07 to 2.43), respectively.[42] Five-year savings are $78,980 (CI: $62,320 to $100,550) for LAGB and $61,420 (CI: $44,710 to $82,870) for LRYGB.[42]
- A study by Warren et al. (2015)[65] suggested that bariatric surgery is underused as a cost-effective intervention for patients who have a BMI ≥40 kg/m^2 and T2DM.
  - The break-even return-on-investment for treating T2DM through surgical intervention occurred at year 4.[65]
  - Considering only the direct medical costs of T2DM, the aggregate cost savings of undergoing bariatric surgery were estimated to be $2.7 million per 1000 patients by the end of 10 years when compared with medical management.[65]
  - The total direct and indirect cost savings of undergoing bariatric surgery were estimated to be $5.4 million per 1000 patients by the end of 10 years when compared with medical management.[65]

In a recent retrospective analysis of a large real-world claims database by Dawson et al. (2017),[66] patients who had laparoscopic bariatric surgery incurred lower medication costs for the treatment of T2D, dyslipidemia, and hypertension compared to medically-managed controls up to 5 years post-surgery.

Recent cost-effectiveness evaluations have also shown that bariatric surgery was cost-effective in specific obese patient populations:

- A study by McLawhorn et al. (2016)[67] showed that morbidly obese patients undergoing total knee arthroplasty alone had lower quality-adjusted life-years (QALYs) gained than patients who underwent bariatric surgery two years prior to the total knee arthroplasty. The incremental cost-effectiveness ratio for bariatric surgery was $13,910/QALY, well below the threshold of accepted willingness-to-pay.[67]

- Neff et al. (2015)[68] estimated the cost-effectiveness of bariatric surgery in women with low risk stage I endometrial cancer and BMI≥40kg/m^2. Bariatric surgery had an incremental cost-effectiveness ratio of $26,080/QALY compared to routine care.[68]

The literature review of 349 articles by Marihart et al. (2014)[29] estimated that savings with bariatric surgery in older adults (>60 years old) start accruing within 3 months of surgery, making bariatric surgery a possible cost-saving treatment.[29]

Clinical Practice Guidelines and Position Statements

Recent Clinical Practice Guidelines and Position Statements have summarized the growing body of evidence that surgery may be appropriate in patients with moderate or severity obesity, as well as in patients with class I obesity. The American Diabetes Association (ADA),[43] the 2nd Diabetes Surgery Summit (DSS-II),[44] the American Association of Clinical Endocrinologists,[45] the Obesity Society,[45] the American Society for Metabolic and Bariatric Surgery (ASMBS),[45,46] the American Heart Association (AHA),[47] and the National Institute for Health and Care Excellence (NICE)[48] all support laparoscopic bariatric surgery as an obesity treatment without age restrictions in adults.

- A multidisciplinary group of ***48 international clinicians/scholars (75% nonsurgeons)***, including representatives of leading diabetes organizations, participating in the ***2nd Diabetes Surgery Summit (DSS-II)***, an international consensus conference convened in collaboration with leading diabetes organizations to develop global guidelines to inform clinicians and policymakers about benefits and limitations of metabolic surgery for T2D, concluded the following:[44]
  - Given its role in metabolic regulation, the gastrointestinal tract constitutes a meaningful target to manage T2D.[44]
  - Numerous RCTs, albeit mostly short/midterm, demonstrate that metabolic surgery achieves excellent glycemic control and reduces cardiovascular risk factors.[44]
  - On the basis of such evidence, metabolic surgery should be recommended to treat T2D in patients with class III obesity (BMI ≥40 kg/m^2) and in those with class II obesity (BMI 35.0–39.9 kg/m^2) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy.[44]
  - Surgery should also be considered for patients with T2D and BMI 30.0–34.9 kg/m^2 if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications.[44]
  - These BMI thresholds should be reduced by 2.5 kg/m^2 for Asian patients.[44]

- In 2013, the ***American Association of Clinical Endocrinologists***, the ***Obesity Society***, and the ***American Society for Metabolic and Bariatric Surgery (ASMBS)*** issued a guideline that recommended weight loss (bariatric) surgery for all patients with a BMI of 40 kg/m^2 or higher and for those with a BMI of 35 kg/m^2 or greater in the presence of at least 1 obesity-related comorbidity.[45]
  - The guideline points out that, although prospective data collected from a single academic center demonstrated that patients age ≥55 years old had a 3-fold mortality compared with younger patients, recent American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) data of 48,378 patients failed to reveal advanced age to be associated with statistically significant mortality compared with controls.[45] Although many bariatric programs have established arbitrary cutoff levels for age at 65–70 years, other programs primarily consider overall health risks and physiological status.[45]

- The ***ASMBS*** also recommends bariatric surgery should be an available option for patients with BMI 30–35 kg/m^2 who do not achieve substantial and durable weight and co-morbidity improvement with nonsurgical methods,.[46]
  - The guideline states that the existing cut-off of BMI which excludes those with Class 1 obesity was established arbitrarily nearly 20 years ago.
  - There is no current justification on grounds of evidence of clinical effectiveness, cost-effectiveness, ethics or equity that this group should be excluded from life-saving treatment.[46]

- In its 2011 Scientific Statement, the ***American Heart Association (AHA)***, after summarizing the National Institute of Health (NIH) consensus, which indicates surgical therapy for patients with BMI >40 kg/m^2 or >35 kg/m^2 with serious comorbidities—recommended bariatric surgery for patients with severe obesity who failed medical therapy.[47] The statement also mentioned that additional long-term data were needed before surgery in patients with BMI <35 kg/m^2 becomes standard practice.[47]

- In regards to the diabetic subpopulation, the ***American Diabetes Association (ADA)*** states that metabolic surgery should be recommended to treat T2D in appropriate surgical candidates with BMI ≥40 kg/m^2 (BMI ≥37.5 kg/m^2 in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens (Evidence Grade A).[43] Metabolic surgery should be recommended to treat T2D in appropriate surgical candidates in adults with BMI 35.0–39.9 kg/m^2 (32.5–37.4 kg/m^2 in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy (Evidence Grade A).[43] Metabolic surgery should be considered for adults with T2D and BMI 30.0–34.9 kg/m^2 (27.5–32.4 kg/m^2 in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin) (Evidence Grade B).[43]

- The ***National Institute for Health and Care Excellence (NICE)*** states that bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled: (1) The person has a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (for example, T2D or high blood pressure) that could be improved if they lost weight.; (2) All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.; (3) The person has been receiving or will receive intensive management in a tier 3 service.; (4) The person is generally fit for anesthesia and surgery.; and (5) The person commits to the need for long-term follow-up.[48]

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