



Research Review Disposition of Comments Report

March 13, 2018

Research Review Title: Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population.

Draft review available for public comment from July 17, 2017 to August 16, 2017.

Research Review Citation: Panagiotou O, Markozannes G, Kowalski R, Gazula A, Di M, Bond D, Ryder B, Adam G, Trikalinos T. Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population. Technology Assessment Program Project ID: OBST0816 (Prepared by the Brown Evidence-based Practice Center under Contract No. HHS A2902015000051.) Rockville, MD: Agency for Healthcare Research and Quality. October 2009. Available at: <http://www.ahrq.gov/research/findings/ta/index.html>.

Comments to Research Review

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Comments on draft reviews and the authors' responses to the comments are posted for public viewing on the Web site approximately 3 months after the final research review is published. Comments are not edited for spelling, grammar, or other content errors. Each comment is listed with the name and affiliation of the commentator, if this information is provided. Commentators are not required to provide their names or affiliations in order to submit suggestions or comments.

The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General Comments	This technology assessment was designed to examine outcomes after bariatric procedures for Medicare patients. The review is overall well done, unfortunately it is somewhat limited by the lack of high quality data on this study group available in the literature. Unfortunately, no study data is available on endoscopic therapies for obesity therefore the review is limited to bariatric surgery.	We would like to thank the reviewer for their comments. In the updated literature search, we identified a very limited number of studies on endoscopic procedures which we have now included in the updated version of the report.
Peer Reviewer #1	General Comments	Overall, I do think that the report is clinically meaningful as it does summarize the available literature looking at the effects and complications in this study group. The target population is well defined and the key questions are appropriate and mostly well-stated.	Thank you. We appreciate your feedback.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General Comments	While the authors clearly state that the data available is limited by the lack of randomized trials they fail to adequately discuss the strength of the various studies that are included in this review. Primarily, they seem to ignore the importance of study size. Certainly, a large prospectively done study is more meaningful than a small retrospective study even if it is not randomized. In this assessment very large studies are described in equal detail to much smaller studies and in most cases when describing a study in their review they fail to provide the reader with the number of patients in the study making it hard for the reader to understand the importance of the results.	We agree with the reviewer that sample size is critical for interpreting the relevant evidence. To assess the strength of evidence, we followed the established guidelines by AHRQ based on which we assessed the precision of the studies. In addition, report relevant sample sizes in the appendix table. In the revised version, we included sample sizes in tables and text in the main report.
Peer Reviewer #1	General Comments	I think that a major point that needs to be addressed are the tables and figures included in the study - many of which are very confusing and appear to add no significant value. More specific details are included below.	We have added further clarifications for the tables and figures.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	General Comments	While the authors choose not to perform meta - analyses of data because of multiple factors which limit the effectiveness I do think that some pooling of the data should be done. It would be helpful for the reader to understand how many patients overall have been studied for different outcomes in this population and some general data on overall weight loss and complications.	A formal statistical synthesis (meta-analysis) would not be informative or appropriate because of the clinical heterogeneity across studies. This heterogeneity is due to differences in comorbid conditions; limited number of similar enough studies that have measured the same outcome for the same procedure; differences in the follow-up times reported for weight loss outcomes combined with the lack of relevant reported data.
Peer Reviewer #1	General Comments	There should be some data given on expected outcomes in younger patients such that the reader can compare the information provided on Medicare patients. Some formal analysis comparing results in Medicare patients to younger patients would also be helpful.	We agree that a comparison between younger patients and Medicare patients would be helpful. However, formal inferences for such comparisons require access to individual-patient data and were beyond the scope of the current systematic review.
Peer Reviewer #1	Executive Summary	In the introduction part of the executive summary it is not accurate to say that "most non-surgical treatments fail to achieve long-term weight control". Need to focus the statement on severe obese and more on effect of weight loss .	We have revised the relevant sentence. It now reads "Most non-surgical treatments for obesity fail to achieve long-term weight loss, particularly among patients with severe obesity".



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	For question KQ3 the authors should provide a definition for minimal weight loss.	During topic refinement with the partners (AHRQ, CMS, TEP members) it became obvious that the review should not be restrictive by setting a specific definition of minimal weight loss. Instead, we considered that it would be more helpful for stakeholders and decision-maker if we included (as we did) any definition of minimal weight loss that has been used in the literature.
Peer Reviewer #1	Executive Summary	In terms of the study eligibility criteria I question the use of only including studies with a mean age >55. It may be worthwhile to look at any study that includes any patients whose age is greater than 65 and look at subgroup analyses to see the effect on patients in the Medicare population. In particular looking at any randomized studies that include some patients over 65 years old. May also be helpful to look at comparisons between the effects on patients over 65 and under 65 to see if any treatment effect difference is seen. If the treatment effect appears to be similar between >65 and < 65 then much can be inferred from the data on younger patients.	The age criterion of 55 years or older was applied either to the whole study population or to reported subgroup analyses. As a result, we have included studies that reported subgroup analyses in Medicare-eligible patients even if the total study population was not eligible. We have clarified this eligibility criterion better in the Methods section. As mentioned above, we agree that a comparison between younger patients and Medicare patients would be helpful. However, formal inferences for such comparisons require access to individual-patient data and were beyond the scope of the current systematic review.
Peer Reviewer #1	Executive Summary	Page ES-4 line 2 is missing the work "as".	Corrected.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	Would remove "restricting the diameter of the stomach's esophageal orifice" from ES-4 as this is confusing.	Corrected.
Peer Reviewer #1	Executive Summary	Is unclear what table A is demonstrating. Are these the number of studies which looked at these types of surgeries?	As specified in the footnote, the numbers represent study arms. We have now added this in the table title.
Peer Reviewer #1	Executive Summary	Figure A should be re-done in a different format. Currently it is very unclear what information the authors are trying to convey. I think that a pooling of adverse events across studies and providing a percentage would be more helpful.	We have revised the headings for all figures to clarify what these figures show. Because of overlap and clinical heterogeneity, we cannot statistically combine the results across studies. Studied sample sizes are reported in detail in Appendix tables.
Peer Reviewer #1	Executive Summary	Figure B is similarly confusing to Figure A and should be re-done in a different format.	We have revised the headings for all figures to clarify what these figures show. Because of overlap and clinical heterogeneity, we cannot statistically combine the results across studies. Studied sample sizes are reported in detail in Appendix tables.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page ES-10 the paragraph on Weight loss outcomes is confusing. The authors should make it very clear when they are reporting the results of a single study vs. pooled results. If possible, it would be best to report pooled results. They state that there are three studies comparing different bariatric surgeries but the second study they describe seems to compare sleeve gastrectomy to standard of care. Should also clarify that these are the only studies in the Medicare population specifically.	We have rewritten this paragraph to better reflect the three studies and the respective treatment arms. We have also added that "Although 2 studies reported estimates of weight changes at 12 months after surgery for SG versus LAGB and for RYGB versus LAGB, the clinical and methodological heterogeneity introduced by the different modeling strategies and the different covariates in these two studies do not allow for a meaningful statistical synthesis of the results."
Peer Reviewer #1	Executive Summary	Table B is overly complex for the question that it is addressing particularly given that there is only 1 study looking at it. The four outcomes are essentially the same - all are different ways of tracking "weight loss". Would be unusual for one surgery to result in more excess weight loss but another surgery to result in lower BMI. Not clear to me that a table is needed to demonstrate this.	This table is the standard table to summarize the strength of the evidence (SOE) for a particular outcome used in AHRQ reports. The SOE does not consider only the magnitude of effect but also elements related to risk of bias, precision, directness of the evidence and other methodological study design issues of the included studies. Whenever, one study was available all outcomes were given the same SOE unless if special analytical considerations applied to a particular outcome within this study



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page ES-11 the authors describe the strength of various models for weight loss. The authors need be clarify here or somewhere in the paper further what they mean by "models". Particularly, they must describe who the patients were that were used to develop these models.	We have now clarified that these are "predictive models of weight loss outcomes". Because this is the Executive Summary, we could not include the table describing the populations that were used for these models but this information is shown in detail in the main report and in the appendix.
Peer Reviewer #1	Executive Summary	On page ES-12 the authors state that the "second study" shows lower mortality but none of the reported outcomes had a statistically significant p value - should describe differently.	The term "lower mortality" was used to describe the direction of the effect estimate without any reference to hypothesis testing accompanying this estimate. We have now added that "these differences did not achieve statistical significance".
Peer Reviewer #1	Executive Summary	On page ES-12 what are the control groups for the studies on post-op complications?	We have now clarified what the control groups in these two studies are.
Peer Reviewer #1	Executive Summary	On page ES-13 the authors should clarify in the first paragraph that these are the results of a single study.	We have now added this clarification.
Peer Reviewer #1	Executive Summary	When summarizing the results of a single study the authors should provide the number of patients involved in that study (N= ???). This will help the reader understand the significance of this result.	We have added sample sizes in the text and tables as applicable.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On ES-13 under orthopedic outcomes the first paragraph is very confusing. The authors need to state that these are the results of a single study. Also, please explain how RYGB has no effect on BMI?	We have now revised this paragraph to reflect. The reporting of the paper does not make it clear which variables (except for hyperparathyroidism) are outcome variables and which are baseline covariates.
Peer Reviewer #1	Executive Summary	On ES-13 in the first paragraph under polypharmacy the authors again need to specify that this is the result of one study.	We have now added this clarification.
Peer Reviewer #1	Executive Summary	Under polypharmacy I would remove the section on warfarin dosing. This not a clinically important result.	We now removed the section on warfarin dosing.
Peer Reviewer #1	Executive Summary	On page ES-15 line 47 - please clarify this sentence - is not clear what outcomes being "reduced" means.	We have replaced "reduced" with "improved" to better characterize the changes in the outcomes.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page 14 line 35 can the authors provide more useful information than the range of mean BMIs across the studies? Perhaps an overall mean BMI or median?	These values pertain to baseline characteristics of patients in the eligible studies. It is highly uncommon for baselines to be statistically synthesized across studies in a meta-analysis. Baseline characteristics are reported using descriptive statistics such as mean, median, ranges, and interquartile range. Moreover, because of clinical differences in the studied populations, a meta-analysis that would result in an average mean BMI would not be appropriate or meaningful (e.g. if we were to combine the mean BMI from a study where all patients had heart failure with the mean BMI from a study where all patients had diabetes).



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page 14 - similar to point 20 above - can the authors provide more useful information than the ranges of studies? Overall rates of comorbidities would be more useful. Some type of comparison between the studied patients and typical Medicare patients would also be helpful. Are the patients in the reported studies representative of typical Medicare morbidly obese patients?	A formal statistical synthesis (meta-analysis) of rates would not be clinically informative or appropriate because of the clinical heterogeneity across studies. This heterogeneity is due to differences in comorbid conditions; limited number of similar enough studies that have measured the same outcome for the same procedure; differences in the follow-up times reported for weight loss outcomes combined with the lack of relevant reported data. In many instances, we are also limited by the lack of relevant data being reported (e.g. standard error or standard deviations) in addition to our concerns of clinical heterogeneity. Finally, based on our eligibility criteria we believe that included studies adequately capture the characteristics of patients in the Medicare program. A formal (statistical) testing of this assumptions requires individual-patient data and, although particularly intriguing, was beyond the scope of this systematic review.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page 17 - figure 3 is very unclear in terms of the information it is conveying - should be redone in another format (similar to Figure 1 and 2)	We have revised the headings for all figures to clarify what these figures show. Because of overlap and clinical heterogeneity, we cannot statistically combine the results across studies. Studied sample sizes are reported in detail in Appendix tables.
Peer Reviewer #1	Executive Summary	On page 19 and 21 - Figures 4-5 - see comments for figures 1-3 above. This format is not effective.	We have revised the headings for all figures to clarify what these figures show. Because of overlap and clinical heterogeneity, we cannot statistically combine the results across studies. Studied sample sizes are reported in detail in Appendix tables.
Peer Reviewer #1	Executive Summary	On page 22 - Table 2 - similar to table 1 - is very unclear what information this table is conveying. Are the N number of studies or number of overall events? Should be redone.	We have now clarified that "The numbers correspond to the study arms across all eligible studies."



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page 37 table 7 - similarly overly complex to table B - see comments above.	This table is the standard table to summarize the strength of the evidence (SOE) for a particular outcome used in AHRQ reports. The SOE does not consider only the magnitude of effect but also elements related to risk of bias, precision, directness of the evidence and other methodological study design issues of the included studies. Whenever, one study was available all outcomes were given the same SOE unless if special analytical considerations applied to a particular outcome within this study
Peer Reviewer #1	Executive Summary	On page 38 Line 25 - suggest removing this entire sentence. Is not a meaningful result - this states that patients who are lighter to start the study get to a BMI of 35 faster than those who are heavier - this seems like an obvious result.	We agree that this is a self-evident result but because it was reported by the original study, it is necessary to also report it because it meet our eligibility criteria.
Peer Reviewer #1	Executive Summary	On page 40 - the entire section on KQ C does not actually provide any answer to the question asked. The authors go into great detail describing the statistical analyses done but provide no useful results or analysis.	KQ 3c was about identifying and describing predictive models of weight loss. Our results (text and tables) include characteristics of model performance as these were reported in the primary studies as well as predictors included in the different models.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #1	Executive Summary	On page 48 line 23 - it states that Age is a significant predictor. Suggest going into more detail about this given the goals of this document.	We have now clarified that "with younger patients being able to lose more weight than older ones". This is based on studies which used age as a continuous predictors of weight loss.
Peer Reviewer #1	Executive Summary	On page 48 line 37 - suggest removing the line about 3 patients undergoing revision as this is not a meaningful result.	Revision was an outcome of both the primary study therefore as explained above it is necessary that we report in our systematic review. In addition, during topic refinement, we considered the need for revisional surgery a relevant outcome as it would indicate failure of the primary procedure.
Peer Reviewer #1	Executive Summary	On page 50 - suggest providing time frames when discussing rates of mortality	We have now clarified that these mortality outcomes refer to the time period after 90 days from bariatric surgery.
Peer Reviewer #1	Executive Summary	On page 60 line 6 - missing word "non" before weight loss outcomes.	Corrected.
Peer Reviewer #1	Executive Summary	ON page 60 line 14 - take out the word "surgery"	Corrected.
Peer Reviewer #1	Executive Summary	on page 62 line 34 - remove "most" and replace with "least"	Corrected.
Peer Reviewer #1	Executive Summary	In the discussion of the level of evidence would discuss not just the "number of trials" but discuss the number of patients included in the trials. One observational study with 10000 patients is likely more useful than a randomized trial with 20. What is the overall N in the studies included in this paper?	The sample sizes for each eligible were previously reported in the Appendix. We have now moved this information to the main report as Table 1.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	General Comments	Generally well done. Urge adoption of people first language throughout document. This is now the standard of language use (AMA just reconfirmed this at their annual meeting earlier this year). For example severely obese Medicare recipients would be rewritten as Medicare recipients with severe obesity. Suggest replacing all references to obese (with the exception of titles in journal/research papers).	We have now used people-first language as suggested by the reviewer and also in accordance with AMA.
Peer Reviewer #2	Introduction	Suggest striking reference to sibutramine (line 10 page 13) as it was removed from the market in the US. Appropriate replacements might be Phentermine, Locaserin, Liraglutide, etc.	Replaced with "phentermine".
Peer Reviewer #2		Line 27 and 28 might benefit from a reference that while large number of folks are eligible for bariatric surgery utilization is very low.	This is a very good suggestion. We have added a reference to low utilization of bariatric surgery.
Peer Reviewer #2		Reference to the fact that nearly twice as many women than men meet criteria for bariatric surgery might also be a good addition (and partially explain why some studies are female dominant later).	We have added a reference regarding the 2:1 ratio between women and men.
Peer Reviewer #2	Methods	As patient advocate these questions are outside my scope of expertise. Section was easy to understand.	Thank you. We tried to write this section in plain terms so that it can be understood by non-technical experts and non-methodologists.
Peer Reviewer #2	Results	Section well done.	Thank you.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #2	Discussion/ Conclusion	Missing in the discussion was a reference to what services Medicare currently covers under its national coverage decision (gastric bypass, adjustable gastric banding, duodenal switch) or allows to be covered by local coverage decision (sleeve gastrectomy and revisions.) Balloons, MGB and several other procedures are outright excluded. Important to recognize that as in many studies of bariatric surgery, patients insurance is still required to pay for bariatric surgery procedure. Might also be worth noting that many payors (including CMS) have criteria that limit access to bariatric surgery based on co-morbidities. Some require severe co-morbidities to allow coverage and others are less restrictive. Population entering these studies can vary based on these restrictions that are set by the insurers and not the researchers.	We agree with these insightful comments and we have accordingly revised the Discussion section. Unfortunately, due to these restrictions, published studies with routinely collected health data are scarce. Yet, our scope in this report was to review and appraise the current evidence base rather than comment on policies.
Peer Reviewer #2	Clarity and Usability	Well structured and organized. Language use should be improved throughout document. See general comments. People have obesity they are not obese.	We have now used people-first language as suggested by the reviewer and also in accordance with AMA.
Peer Reviewer #3	General Comments	The methodology utilized for this technology assessment of bariatric surgery in the Medicare population utilizes well-developed, well-described, and standardized methodology by AHRQ.	As the reviewer mentioned, we did follow the methodology used by AHRQ.



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Peer Reviewer #3	General Comments	<p>The report emphasizes the limitations in the peer-reviewed published literature regarding bariatric surgery in the Medicare-eligible population. One limitation that is minimally addressed and certainly not emphasized is the lack of published literature on the population of Medicare beneficiaries who are less than 65 years of age but are disabled. No reference is made to the proportion of Medicare beneficiaries who, in fact, have undergone bariatric surgery who are in this less-than-65 years of age population. In the entire review, I found just one reference to this population, a reference to Scott on page 83. I found no other reference to this population. In the past, this disabled population has constituted the majority of Medicare beneficiaries who have received bariatric surgery, such that this population is clearly of greater importance than the report indicates. Many, if not the majority, of the citations of the studies utilized in this report are based on age greater than 60. The extent to which the population, age 60-65, represents the Medicare eligible population is unclear. Reference is made at several points to the limitations to applying data accumulated on unrestricted age populations to the greater-than-65 population. To a lesser but similar extent, the population aged 60-65 is a limitation.</p>	<p>As we state in our eligibility criteria, in addition to including studies in patients >55 years of age, we also included studies in younger patients if these individuals were eligible for Medicare benefits (e.g. disabled, patients with end-stage renal disease). In Appendix Table, we specify which these studies are. We have now made this more clear in the main report as well. Because patients younger than 55 years of age who do not meet any Medicare eligibility criteria are very different from those who do meet them in terms of comorbid conditions, healthcare needs etc. including young non-Medicare eligible patients would not allow valid extrapolation of findings to those who are Medicare eligible. We have now clarified this point in the Discussion section and we also added in the same section (Discussion) that the results of studies in younger patients can be generalized to Medicare in cases when health practitioners and decision-makers believe that this Medicare patient is represented by (is exchangeable with) the average non-Medicare patient.</p>



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #3	Introduction	Page 13, line 14: "...and probably reduces morbidities." The word "probably" is inappropriate in this sentence and is not consistent with the body of the report.	We removed the word "probably".
Peer Reviewer #3	Introduction	Page 16, line 18: There is no bariatric surgical procedure at present which restricts the "stomach's esophageal orifice." This could be deleted as restricting the stomach's effective volume is sufficient and correct.	Corrected.
Peer Reviewer #3	Introduction	Page 16, line 22: I suggest deleting reference to malabsorption. Later in the report, the issue of malabsorption is addressed wherein it is recognized that malabsorption is not a mechanism by which present bariatric surgical procedures described in this report accomplish weight loss.	Corrected.
Peer Reviewer #3	Introduction	Page 16, line 34: Issue of the effect of bariatric surgical procedures on energy expenditure is controversial. There clearly is a species problem in relating energy expenditure in rodent models to humans. Several studies have demonstrated diminished energy expenditure following bariatric surgically induced weight loss. When corrected for changes in body composition, the energy expenditure may be unchanged.	We have removed the reference to energy expenditure.
Peer Reviewer #3	Introduction	Page 16, line 40: The units for BMI are kg/m ² , not percent (%).	Corrected.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #3	Methods	Page 24, line 53: While the effect of surgically induced weight loss on HDL is variable, the majority of reports indicate HDL increases. Reference is: Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. Circulation. 2013 Jan 1:01-cir.	The AHA/ACC/TOS guidelines conclude low strength of evidence, which is in agreement with our findings.
Peer Reviewer #3	Methods	Page 34, line 38, 44: As previously mentioned, deletion of reference to the esophageal orifice and malabsorption would be appropriate.	Corrected.
Peer Reviewer #3	Discussion/ Conclusion	Page 86, line 30: Respiratory disease. This is one example where it may be useful to repeatedly indicate that the limited evidence refers to the Medicare-eligible population, as there is substantial evidence regarding the effect of weight loss on respiratory disease in the population of all ages.	We have now explicitly mentioned that these results refer to the Medicare-eligible population.
Peer Reviewer #3	Discussion/ Conclusion	Page 87: The same statement can be made for cancer.	We have now explicitly mentioned that these results refer to the Medicare-eligible population.
Peer Reviewer #3	Discussion/ Conclusion	I have no disagreement with any of the conclusions or observations made. Thank you for the opportunity to review this important report.	Thank you for your time reviewing the report and for providing helpful and constructive comments.
Peer Reviewer #4	General comments	Thank you to the authors of this well written and researched paper.	Thank you.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	General comments	The report is clinically meaningful and points to the knowledge gaps and lack of RCT in bariatric surgery. The key questions are thoughtful and ask questions that clinicians struggle with and are not always easily explained in research.	Thank you.
Peer Reviewer #4	General comments	The Medicare guidelines for criteria for bariatric surgery are vague at best and may prevent some patients from undergoing surgery. A Bariatric Center risks non-payment for the procedure if a patient has comorbidities/ findings that don't fall within the Medicare criteria, for example fatty infiltration of the liver by ultrasound with abnormal LFTs, suggesting NASH. There is no method available for a clinician to speak with a Medicare representative to discuss the case prior to surgery since approval is made only after the surgery has been done.	Thank you, we acknowledge these issues whenever applicable in the report. We would like to take the opportunity here and clarify that the purpose of our systematic review was to review and appraise the existing evidence; commenting on coverage policies was outside the scope of the review. Comments about specific coverage policies should be addressed to Medicare.
Peer Reviewer #4	introduction	Should the 2013 ACC/AHA/ TOS Guideline for the Management of Overweight and Obesity be included in the discussion?	Many thanks for your suggestion. We have explained in the Discussion how our findings agree with AHA/ACC/TOS guidelines.
Peer Reviewer #4	introduction	On page 13. starting at line 29, "The effectiveness of bariatric procedures.... the primary insurer of elderly. (should also be mention of the other Medicare population- the disabled?)	We have revised this sentence to reflect other populations insured by Medicare.
Peer Reviewer #4	methods	Inclusion and exclusion criteria are justifiable.	Thank you.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	methods	The search strategies are explicitly stated and logical.	Thank you.
Peer Reviewer #4	methods	The definitions/ diagnostic criteria for outcome measures are appropriate.	Thank you.
Peer Reviewer #4	methods	I am not qualified to respond to the appropriateness of the statistical methods used.	We tried to write this section in plain terms so that it can be understood by non-technical experts and non-methodologists.
Peer Reviewer #4	results	There is sufficient detail in the results section. The characteristics of the studies are clearly described. the key messages are explicit and applicable.	Thank you.
Peer Reviewer #4	results	The figures, tables and appendices are outstanding, easy to read and provided excellent information and detail.	Thank you.
Peer Reviewer #4	results	On page 85 line 5, discussion regarding "no evidence of lower levels of LDL cholesterol, high- density lipoprotein cholesterol etc. (the desired effect would be an increased high density lipoprotein) (Given that LDL abbreviation was used, should high density lipoprotein also have an abbreviation listed (HDL)?	We added "HDL" to abbreviate "high-density lipoprotein-cholesterol".
Peer Reviewer #4	results	Question on Figure B lines 13 and 14- what was the difference between "revisional surgery" and "revisional bariatric surgery"? (Also in Figure 5 on page 54 lines 13 and 14)	The two lines reflect the outcome of revisional surgery and have now been merged into one.
Peer Reviewer #4	discussion/ Conclusion	The implications of the major findings are clearly stated. the limitations of the review are well described.	Thank you.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	discussion/ Conclusion	A significant limitation in long term follow up in the elderly population and disabled population is compliance to follow up due to multiple factors including transportation and financial barriers.	Thank you. We have discussed these limitations in the Discussion section.
Peer Reviewer #4	discussion/ Conclusion	Patients who do not return regularly for follow up are removed from MBSAQIP data collection. Some patients may never return for follow up, or return after their case has been excluded from data collection, which creates a loss of meaningful data. The data available is based on patients returning for follow up only- what are the outcomes of those who are lost to follow up?	Unfortunately, at the level of the systematic review, there is no way to capture data for those that do not return to follow-up visits if these are not reported in the primary studies. This is something that we expect to see from high-quality observational studies, which should not remove patients with missing follow-up but include all available data from eligible patients.
Peer Reviewer #4	discussion/ Conclusion	There are limitations to studies based on treatment outcomes, such as hyperlipidemia, GERD and hypertension. Patients may remain on antihypertensive medications at low doses for renal protection or chronic migraine headache for example, rather than HTN, or statins due to age or cardiac risk, who have normal lipid profiles or take prophylactic proton pump inhibitor therapy due to Barrett's esophagus or NSAID use.	We agree with the reviewers comments, and when applicable, we included these limitations in the report.
Peer Reviewer #4	discussion/ Conclusion	The future research section is clear and may easily translated into new research although that task will not be easily accomplished.	Thank you.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	clarity and Usability	The report, despite its complexity and length, is well structured and organized. The main points are clearly presented. the conclusions are relevant to policy and practice decisions, by acknowledging the limited high quality data and RCTs available, and in understanding the complexity of bariatric surgery outcomes.	Thank you.
Peer Reviewer #4	clarity and Usability	Hopefully this study will raise the bar for future studies and a core of clinically meaningful and standardized definitions such as post op weight loss (instead of various terms used currently like EWL, WL, EBML) will be developed	Thank you. We hope that our work will lead to meaningful and standardized definitions such as post op weight loss. There are ongoing initiatives towards this direction. One such initiative is the Core variable Assessment Towards a National Evaluation Program (CATNIP) project of the Medical Device Epidemiology Network (MDEpiNet), a public-private partnership supported by the U.S. Food and Drug Administration funding to advance the nation's approaches to the evaluation of medical devices.
Peer Reviewer #4	clarity and Usability	Perhaps this study can be an opportunity for NSQIP and MBSAQIP review of current data collected and make additions such as outcomes with regard to Medicare recipients age >65 and those with Medicare disability status, psychiatric, ESRD or other cause of early disability.	We will be glad to see that our work can be the starting point for NSQIP and MBSAQIP to identify missed opportunities and review of current data collected and make additions such as outcomes with regard to Medicare recipients age >65 and those with Medicare disability status, psychiatric, ESRD or other cause of early disability.



Commentator & Affiliation	Section	Comment	Response
Peer Reviewer #4	clarity and Usability	There are many unanswered questions with regard to benefits of surgery in the senior and disabled populations. Further study may provide some clarify as well as provide data for informed decision making in the Medicare population.	We agree that more studies particular to the Medicare population are needed to inform decision making.
Public Reviewer #1, Kay Sadik on behalf of Ethicon, Inc., Johnson & Johnson Medical Devices	General Comments	See PDF and answering letter. The submitted comments can be summarized as follows: Studies conducted in patients with a mean and/or median age of 55 or less should be considered in this assessment	We have added a detailed explanation in the Methods section regarding eligibility criteria. We have also added in the Discussion section how studies from younger patients may be applicable to the Medicare population and can inform the decision making process between patients and clinicians. In addition, many recent studies cited by the reviewer were published after our last search for the draft report; these studies were identified in the updated search and included in the revised report (except for the study by Hayashi et al. who only included 3 individuals >60 years of age).
Public Reviewer #2, Mary Fearon, The Association of periOperative Nurses, Denver, CO	General Comments	The evidence review is thorough and presented clearly.	Thank you for providing comments and for your positive review of the report.



Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2, Mary Fearon, The Association of periOperative Nurses, Denver, CO	Tables	The bubble graph is difficult to follow.	We have revised the headings for all figures to clarify what these figures show. We have added further clarifications for the tables and figures in the "Results" section.

Comments on the Draft Technology Assessment “Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population”

1. General

On behalf of Ethicon, Inc., a member of the Johnson & Johnson Family of Companies, I am pleased to submit comments on the draft AHRQ Technology Assessment “Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population” dated July 17, 2017. These comments are being timely filed by the August 15, 2017, 5 pm est deadline.

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 AHRQ’s goal of evaluating the available evidence to ensure appropriate and safe use of bariatric surgical therapies in the Medicare population. To support AHRQ’s effort to evaluate the currently available evidence, the comments provided summarize the comparative clinical evidence for obesity treatment strategies.

Summary of Key Points in Our Response

- 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
- The eligibility criteria for published scientific literature stated that: “Because the interest is in Medicare eligible individuals, eligible studies were those whose population resembled Medicare beneficiaries. Medicare beneficiaries are people age 65 years and older as well as people younger than 65 who are disabled or have a diagnosis of end-stage renal disease. Therefore, we excluded studies in pediatric populations (ages 0-18 years) as well as studies on pregnant women. Because studies that are conducted exclusively in adults age 65 years and older are uncommon, eligible for inclusion in our systematic review were studies with a mean and/or median age of 55 years or above.”
- However, we feel studies conducted in patients with a mean and/or median age of 55 or less should be considered in this assessment:
 - An AHRQ analysis of Medicare Beneficiary data from 2006-2009 showed that approximately two-thirds of Medicare bariatric surgery recipients are under age 65 (eligible due to disability), and nearly half were less than 55 years old.⁷
 - The restriction to studies where the mean and/or median age cut-off was 55 years or above is arbitrary, and may result in misleading conclusions about the strength of available evidence.
 - In addition, particular attention needs to be made to different value propositions for different subgroups of patients, however given that age was only a component in risk assessments for bariatric surgery (with postoperative morbidity often reflecting overall pre-operative health status),⁸ stratifying by patient age is likely an over-simplification for identifying patients appropriate for this treatment option.
- 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),^{9,10} the Institute for Clinical and Economic Review (ICER),¹¹ the Washington State Health Care Authority (HCA),¹² the Cochrane Collaboration,^{13,14} and the California Technology Assessment Forum (CTAF).¹¹ Given the current evidence of clinical effectiveness, cost-effectiveness, and safety, laparoscopic bariatric surgery should remain as a treatment option for the elderly population.^{11-13,15,16} In addition, recent evidence

(within the last 9-12 months) for the effectiveness of bariatric surgery in the older population continues to mount.¹⁷⁻²⁵ 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.¹⁷⁻²⁵

- Laparoscopic bariatric surgery produces marked weight loss in patients of all ages (30%-40% of total bodyweight¹²), and results in greater sustained weight loss vs. conventional weight-loss management.^{9,11,14,26} Outcomes of bariatric surgery in older patients are comparable to those in a younger population, independent of the type of procedure.¹⁴ Weight loss has been shown to persist at 10 years after surgery (14-25% below baseline).^{27,28}
- Studies assessing laparoscopic bariatric surgery in patients ≥ 65 years have concluded that laparoscopic bariatric surgery has an acceptable safety profile.^{14,26,27} 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.¹⁴
- 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.²⁹ 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.³⁰ 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/m².^{10,12,31} The overall odds of T2D remission were found to be 76.4 times greater with surgery compared with non-surgical interventions.³² Among patients ≥ 65 years of age, pooled diabetes resolution was 54.5% at 1-year follow-up.¹⁴
- Laparoscopic bariatric surgery enhances future cardiovascular health for obese individuals,^{12,33,34} including the elderly.³³ It has also been shown to resolve or reduce obstructive sleep apnea,^{35,36} improve gait biomechanics,³⁷ reduce osteoarthritic pain,^{37,38} and improve joint function.^{37,38}
- 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.²⁷
- Laparoscopic bariatric surgery is a cost-effective treatment.¹² In some obese populations, the reduction in comorbidities as a result of surgery may lead to a net cost savings.³⁹ Cost savings with bariatric surgery in older adults (>60 years old) start accruing within 3 months of surgery.²⁷

The American Diabetes Association (ADA),⁴⁰ the 2nd Diabetes Surgery Summit (DSS-II),⁴¹ the American Association of Clinical Endocrinologists,⁴² the Obesity Society,⁴² the American Society for Metabolic and Bariatric Surgery (ASMBS),^{42,43} the American Heart Association (AHA),⁴⁴ and the National Institute for Health and Care Excellence (NICE)^{19,45} all support laparoscopic bariatric surgery as an obesity treatment without age restrictions in adults.

Conclusions:

Studies have shown that 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 have been demonstrated with laparoscopic bariatric surgery. Based on this evidence, we believe Medicare patients should continue to have access to laparoscopic bariatric surgery. Current practice guidelines support laparoscopic bariatric surgery as an obesity treatment in adults without age restrictions.

2. Executive Summary

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 therefore clinical studies of bariatric surgery in patients of all ages are relevant for consideration. The key messages in the Executive Summary were derived based on published studies with a mean and/or median age of 55 years or above. This study inclusion criterion could be added to qualify the key message statements.

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.^{11-13,15,16} Maintaining life span and quality of life remains a valid aim of surgery in older individuals.¹⁵ Surgery can be an effective way of restoring both length and quality of life to older people.¹⁵ Minimally invasive techniques and improved anesthesia make fewer demands on geriatric physiology.¹⁵ Age makes only a partial contribution to the risk of bariatric surgery,⁸ 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.¹⁷⁻²⁵ 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.¹⁷⁻²⁵

3. Introduction/Background

- 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.⁴⁶
 - 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.⁴⁶
- Since >60% of the Medicare population is under the age of 65, evidence available on bariatric surgery in the younger population is applicable to the Medicare population. In addition, evidence suggests a similar response in younger and older populations.

4. Methods

Given that the AHRQ analysis of Medicare Beneficiary data from 2006-2009 showed that nearly half of Medicare bariatric surgery recipients were less than 55 years old (eligible due to disability),⁷ we do not agree with restricting the eligibility criteria to studies where the mean and/or median patient age was 55 years or above.

- The Evidence-Based Practice Center Technology Assessment Protocol for Short- and Long-Term Outcomes after Bariatric Therapies in the Medicare Population (published on November 9, 2016) stated that: “Because the interest is in Medicare-eligible individuals, we will exclude studies in pediatric populations (ages 0-18 years) and of the remaining we will further exclude those studies with no Medicare-eligible participants (i.e. age 65 or older; disabled) and studies on pregnant women.”
- The restriction to studies where the mean and/or median age cut-off was 55 years or above is arbitrary, and may result in misleading conclusions about the strength of available evidence.
- Inferences are based on linking together findings from an array of studies that deliver a preponderance of evidence. Therefore, a robust number of studies is needed to collectively provide evidence for a diverse Medicare population.
- Particular attention needs to be made to different value propositions for different subgroups of patients, however given that age was only a component in risk assessments for bariatric surgery (with postoperative morbidity often reflecting overall pre-operative health status),⁸ stratifying by patient age is likely an over-simplification for identifying patients appropriate for this treatment option.

5. Results

Given that nearly half of Medicare bariatric surgery recipients were less than 55 years old, studies conducted in patients with a mean and/or median age of 55 or less should be considered in this assessment.

The sections below present a summary of the comparative effectiveness evidence for laparoscopic bariatric surgery in obese patients of all ages.

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.^{9,11,14,26} 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.¹⁴ Surgery can offer patients an effective and long-lasting treatment for obesity and related diseases, with weight loss persisting at 10 years after surgery.^{27,28}

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

- Chow et al. (2016)²⁶ included 8 studies with a total of 1,835 patients aged ≥65 years old.
 - Mean excess weight loss at study endpoint was 66.2%.²⁶
 - The authors concluded that bariatric surgery is effective in producing marked weight loss in patients ≥ 65 years old.²⁶
- Giordano et al. (2015)¹⁴ included 26 articles encompassing 8,149 patients >60 years old.
 - At 1-year follow-up, pooled mean excess weight loss was 53.8%.¹⁴
 - 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.¹⁴
- 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)²⁷ 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.^{14,27,34,47}
- 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.²⁷

The 2015 **Washington State Health Care Authority (HCA)** and **the Institute for Clinical and Economic Review (ICER)** Evidence Report found that:^{12,47}

- 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/m², or 30%-40% of total bodyweight) over 1 to 2 years of follow-up compared to conventional weight-loss management.¹²

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:^{9,10}

- Surgery was associated with greater weight loss (range, 14.4-24 kg) during 1 to 2 years of follow-up than nonsurgical treatment.^{9,10} 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.^{9,10}

A 2014 **Cochrane Collaboration review** assessed the effects of bariatric surgery for overweight and obesity.^{13,34}

- Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.^{13,34,47}
- Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.¹³
- 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.¹³

The Swedish Obese Subjects (SOS) study,²⁸ 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**).²⁸

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.⁴⁸

2. Postoperative Complications

Studies assessing laparoscopic bariatric surgery in patients ≥ 65 years old have concluded that bariatric surgery has an acceptable safety profile.^{14,26,27} 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.¹⁴

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

- Chow et al. (2016)²⁶ 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%.²⁶
- The authors concluded that bariatric surgery in patients ≥ 65 years old has an acceptable safety profile.²⁶
- Giordano et al. (2015)¹⁴ included 26 articles encompassing 8,149 patients >60 years:
 - The overall complication rate was 14.7%. Mean 30-day mortality was 0.01%.¹⁴
 - 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.¹⁴
- 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)²⁷ 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.²⁷

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).⁴⁹ 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.⁴⁹

The 2015 **Washington State HCA** and **ICER** Evidence Report¹² 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.¹²
- 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%.¹²
- The authors also commented that the studies were small and underpowered to detect any statistical differences between procedures for adverse events.¹²

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.¹⁰ One death, a case of sepsis at 20 months in an LAGB patient, was reported.¹⁰ Short-term complications were minor and tended not to require major intervention.¹⁰ Due to the dearth of long-term studies of bariatric surgery in this particular target population, few data exist about long-term adverse effects.¹⁰

The 2014 **Cochrane Collaboration review** identified five RCTs that report data on mortality, and no deaths occurred.¹³ 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.¹³ Between 2% and 13% of surgery participants required reoperations over 12 to 24 months in the five studies that reported these data.¹³

A Nationwide US analysis assessed the safety of bariatric surgery in 1300 patients with T2D and a BMI ≥ 25 but <35 kg/m² from the database of the American College of Surgeons–National Surgical Quality Improvement Program.⁵⁰

- The mean operative time and length of hospital stay were 109.4 \pm 58.3 minutes and 1.9 \pm 1.5 days, respectively.⁵⁰
- The incidence of all individual major complications was $\leq 0.5\%$, except for postoperative bleeding (1.7%).⁵⁰

- Thirty-day postoperative composite morbidity, serious morbidity, and mortality rates for the total cohort were 4.2%, 0.7%, and 0.15%, respectively.⁵⁰
- 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.⁵⁰

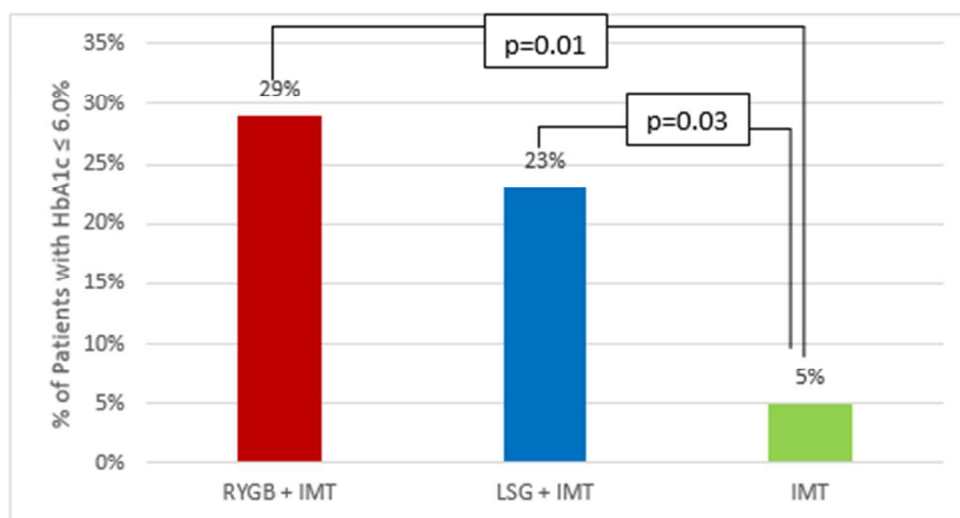
3. Diabetes and Metabolic-Related Outcomes

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.²⁹ 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.³⁰ 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/m².^{10,12,31} The overall odds of T2D remission were found to be 76.4 times greater with surgery compared with non-surgical interventions.³² Among patients ≥65 years of age, pooled diabetes resolution was 54.5% at 1-year follow-up.¹⁴

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).²⁹

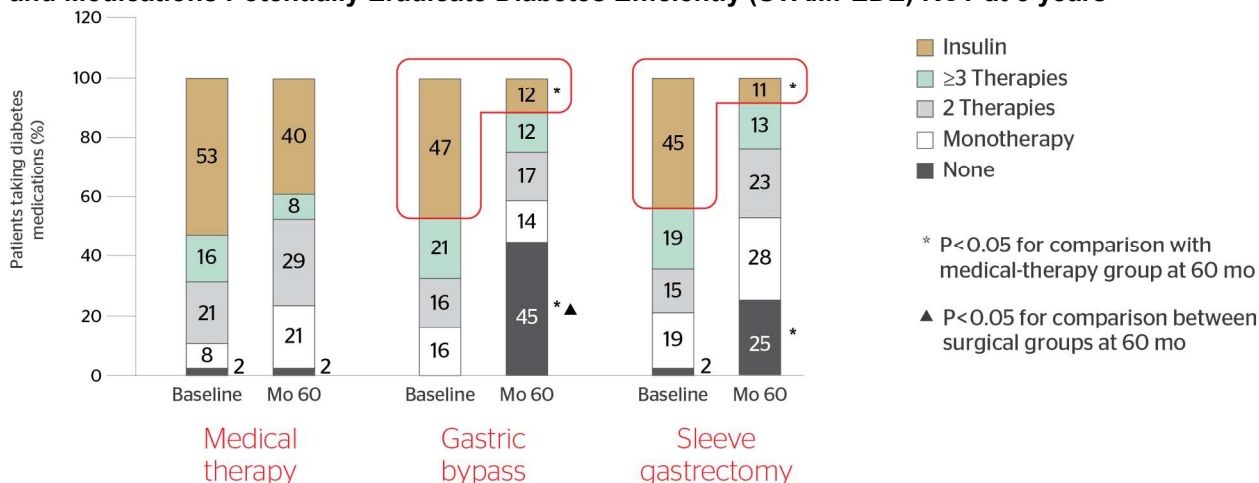
- At 5 years, the criterion for the primary end point (HbA1c ≤6.0% with or without the use of diabetes medications) was met by 2 of 38 patients (5%) who received IMT alone vs 14 of 49 patients (29%) who underwent RYGB with IMT (unadjusted p=0.01, adjusted p=0.03, p=0.08 in the intention-to-treat analysis)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

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



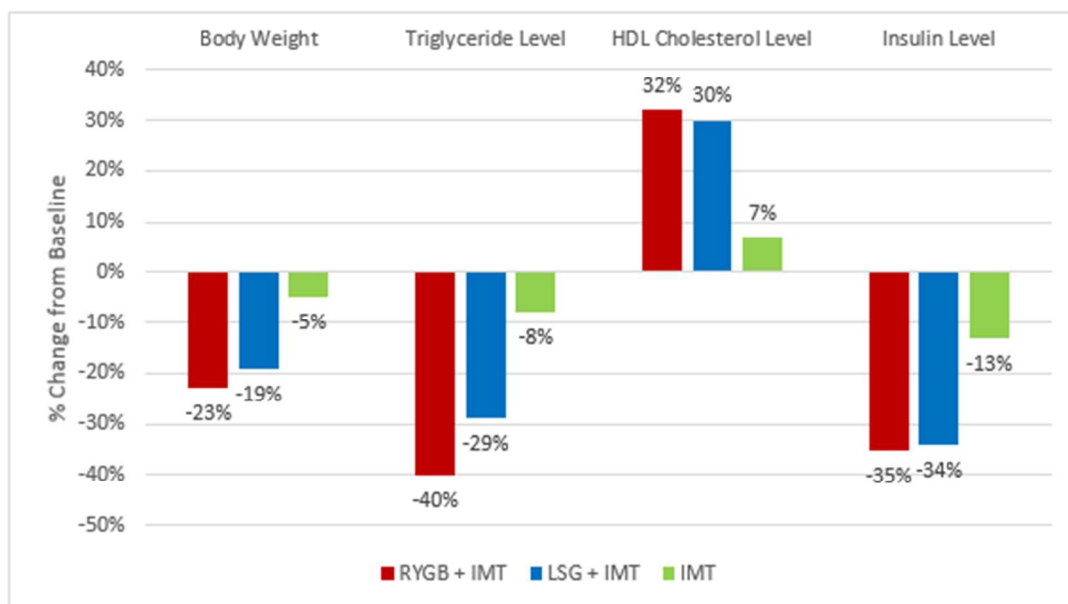
- 75% of patients requiring insulin therapy prior to surgery were able to forego insulin therapy for at least 5 years after surgery (Figure 2)²⁹. Insulin-dependent patients present the highest cost burden in type 2 diabetes⁴⁶, and surgery is the only alternative to continued insulin dependency.

Figure 2. Anti-hyperglycemic therapy 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



- 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%, $p=0.00$).²⁹
- 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 3).²⁹

Figure 3. 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)³⁰ 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.³⁰
- Diabetes remission at 1 year was 60.0% with RYGB vs 5.9% with intensive lifestyle and medical intervention ($p=0.002$).³⁰
- While the HbA1c decline over 1 year was only modestly more after laparoscopic RYGB than intensive lifestyle and medical intervention: from $7.7 \pm 1.0\%$ (60.7 mmol/mol) to $6.4 \pm 1.6\%$ (46.4 mmol/mol) vs $7.3 \pm 0.9\%$ (56.3 mmol/mol) to $6.9 \pm 1.3\%$ (51.9 mmol/mol), respectively ($p=0.04$) this drop occurred with significantly fewer or no diabetes medications after laparoscopic RYGB.³⁰

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 .³¹ 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 .³¹

The 2015 **Washington State HCA** and **ICER** Evidence Report¹² 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.¹² 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.¹²
- 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.¹² 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).¹²

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.¹⁰ 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.¹⁰

A **Cochrane Collaboration review** assessed the effects of bariatric surgery for the control of comorbidities.¹³

- Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.¹³
- Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.¹³
- Improvements for T2D were found in five RCTs.¹³

In a 2013 publication of the SOS study, patients with BMI $<35 \text{ kg/m}^2$ with comorbidities and patients with BMI $35\text{-}40 \text{ kg/m}^2$ without comorbidities were compared to 'eligible' patients and non-surgical patients.⁵¹

- Bariatric surgery reduced diabetes incidence by 73% in SOS individuals with BMI $<35 \text{ kg/m}^2$ with comorbidities and by 67% in individuals with BMI $35\text{-}40 \text{ kg/m}^2$ without comorbidities after 15 years of follow-up.⁵¹
- Cardiovascular risk factors were significantly improved in both surgical groups after 10 years of follow-up.⁵¹
- 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 $35\text{-}40$ (0.27 [0.22-0.33], $p<0.001$) groups.⁵¹
- There was no difference in the effect of surgery between the groups (adjusted interaction $p=0.713$).⁵¹

Yan et al. (2016)³² 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.³²

A systematic review and meta-analysis by Chen et al. (2015)⁵² 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.¹⁴

4. Cardiovascular Outcomes

Bariatric surgery enhances future cardiovascular health for obese individuals,^{12,33,34,53} including the elderly.³³

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).³³

- 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%; $p < 0.001$).³³
- Metabolic syndrome prevalence decreased from 80% to 45% ($p < 0.002$).³³
- Baseline risk using the Framingham risk score was 14.1%, which decreased at follow up to 8.2%.³³

Vest et al. (2012)³⁴ 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).³⁴
- Baseline prevalence of hypertension, diabetes and hyperlipidemia were 44%, 24%, and 44%, respectively.³⁴
- Mean follow-up was 57.8 months (range 3-176) and average excess weight loss was 54% (range 16-87%).³⁴
- Postoperative resolution/improvement of hypertension occurred in 63% of subjects, of diabetes in 73% and of hyperlipidemia in 65%.³⁴
- Echocardiographic data from 713 subjects demonstrated statistically significant improvements in left ventricular mass, E/A ratio, and isovolumic relaxation time postoperatively.³⁴

A recent study by Benotti et al. (2017)⁴⁷ 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).⁴⁷
- 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.⁴⁷
- 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).⁴⁷
- 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).⁴⁷
- 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.⁴⁷

Arterburn et al. (2016)⁵⁴ 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).⁵⁴
- 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.⁵⁴ Seventy-four percent of patients in both cohorts were male.⁵⁴
- The results provide further evidence for the beneficial relationship between surgery and survival that has been demonstrated in younger, predominately female populations.⁵⁴

5. Respiratory Disease

Obstructive sleep apnea (OSA) is frequently observed in morbidly obese patients undergoing bariatric surgery and tends to be severe in this patient population.³⁵ Dyslipidemia and BMI have been demonstrated to be associated factors for severity of OSA in this population.³⁵ Bariatric surgery either resolves OSA or results in significant improvement in OSA.^{12,35,36}

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).³⁶ Results showed:

- In addition to the expected reduction in BMI, significant improvement in AHI/AI/RDI occurred after surgery.³⁶
- Furthermore, almost every study stated a postoperative reduction of the AHI to <20/hour and/or a >50% postoperative reduction of AHI.³⁶

The 2015 **Washington State HCA** and **ICER** Evidence Report¹² 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.¹²
- 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.¹²
- 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.¹²

6. Orthopedic/Musculoskeletal Outcome

Obesity accelerates osteoarthritis of the knee and hip by exerting deleterious effects on joints through biomechanical and systemic inflammatory changes.³⁷ Recent evidence has demonstrated that bariatric surgery improves gait biomechanics, and improves pain and joint function.^{37,38,55}

A recent literature review (Springer et al., 2017)³⁷ 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.³⁷

- 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.³⁷

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.³⁸

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.⁵⁵

- Bariatric surgery lowered the comorbidity burden prior to total joint arthroplasty (TKA $p < 0.0001$; THA $p < 0.005$).⁵⁵
- 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).⁵⁵
- Risks for 90-day complications were lower for TKA (OR=0.61, $p = 0.002$).⁵⁵
- Revision risks were not different for either THA ($p = 0.634$) or TKA ($p = 0.431$), nor was THA dislocation risk ($p = 1.000$).⁵⁵

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.²⁷

- The narrative literature review by Marihart et al. (2014)²⁷ 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.²⁷
 - 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.²⁷
 - Wheelchair-bound older patients were often fully ambulatory within months post-surgery.²⁷
 - Even modest weight-loss improved overall physical functioning of older adults. For example, patients with lower extremity arthritis experienced reduced knee and hip pain.²⁷
 - Many obese patients who have T2D experience normalization of blood sugars within days post-surgery.²⁷ Patients could frequently stop taking diabetes medications before leaving the hospital after surgery.²⁷ Being able to reduce or eliminate daily diabetes glucose testing and insulin injections leads to improved HRQoL.²⁷
 - 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.²⁷
- 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.⁵⁶
- A meta-analysis conducted by Driscoll et al. (2015)⁵⁶ 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).⁵⁶
- A **Cochrane Collaboration review** assessed the effects of bariatric surgery for overweight and obesity, including the control of comorbidities.¹³
 - Twenty-two trials with 1,798 participants were included; sample sizes ranged from 15 to 250.¹³
 - Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years.¹³
 - The two RCTs that compared HRQoL with surgery vs. non-surgical interventions found benefits for some aspects of HRQoL.¹³

6. Discussion/Conclusions

- The conclusions were derived based on published studies with a mean and/or median age of 55 years or above. This study inclusion criterion should be added to qualify the conclusions along with noting that randomized studies where the mean patient age is less than 55 is available, and that these randomized studies where the mean age is less than 55 support effectiveness.

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