APPENDIX A. SEARCH STRATEGIES

PubMed

((("Aspiration therapy"[Title/Abstract] OR AspireAssist[Title/Abstract] OR "Intragastric balloon"[Title/Abstract] OR "endoscopic sleeve gastroplasty"[Title/Abstract] OR "endoscopic sleeve"[Title/Abstract] OR "Endoscopic gastroplasty"[Title/Abstract] OR "primary obesity surgery endoluminal"[Title/Abstract] OR "Endoscopic gastric plication"[Title/Abstract] OR "gastric volume reduction"[Title/Abstract] OR OverStitch[Title/Abstract] OR ORBERA[Title/Abstract] OR Obalon[Title/Abstract] OR "Gastric Balloon"[Title/Abstract] OR Gastrostomy[Title/Abstract] OR Gastroplasty[Title/Abstract] OR "Collis Gastroplasty"[Title/Abstract] OR "Vertical Banded Gastroplasty"[Title/Abstract] OR "Gastrostomies"[Title/Abstract] OR "Gastric Bubble"[Title/Abstract] OR IGB[Title/Abstract] OR ESG [Title/Abstract])) OR ((Gastric Balloon [MeSH] OR Gastrostomy [MeSH] OR Gastroplasty [MeSH]))) AND (((("metabolic Surgery"[Title/Abstract] OR "Bariatric Surgery"[Title/Abstract] OR "Bariatric Surgical Procedure"[Title/Abstract] OR "Stomach Stapling"[Title/Abstract] OR "gastric bypass"[Title/Abstract] OR MGB[Title/Abstract] OR OAGB[Title/Abstract] OR lifestyle[Title/Abstract] OR "life style"[Title/Abstract] OR lifestyles[Title/Abstract] OR "life styles"[Title/Abstract] OR "Lifestyle therapy"[Title/Abstract])) OR (("Bariatric Surgery"[Mesh] OR "gastric bypass"[Mesh] OR Life Style[MESH])))

Filters: from 2014/1/1 - 2021/12/07 [1599]

AND

"endoscopic bariatric therapy"[Title/Abstract] Filters: from 2014/1/1 – 2022/01/23 [45]

Embase

('aspiration therapy':ab,ti OR aspireassist:ab,ti OR 'intragastric balloon':ab,ti OR 'endoscopic sleeve gastroplasty':ab,ti OR 'endoscopic sleeve':ab,ti OR 'endoscopic gastroplasty':ab,ti OR 'primary obesity surgery endoluminal':ab,ti OR 'endoscopic gastric plication':ab,ti OR 'gastric volume reduction':ab,ti OR overstitch:ab,ti OR orbera:ab,ti OR obalon:ab,ti OR 'gastric balloon':ab,ti OR gastrostomy:ab,ti OR gastroplasty:ab,ti OR 'collis gastroplasty':ab,ti OR 'vertical banded gastroplasty':ab,ti OR 'gastrostomies':ab,ti OR 'gastric bubble':ab,ti OR igb:ab,ti OR esg:ab,ti OR ("gastric balloon"/exp) OR 'gastrostomy'/exp OR 'gastroplasty'/exp) AND ('metabolic surgery':ab,ti OR 'bariatric surgery':ab,ti OR mgb:ab,ti OR oagb:ab,ti OR lifestyle:ab,ti OR 'life style':ab,ti OR lifestyles:ab,ti OR 'life styles':ab,ti OR 'lifestyle therapy':ab,ti OR 'endoscopic bariatric therapy':ab,ti OR (('bariatric surgery'/exp OR 'gastric bypass'/exp OR "life style"/exp))

Filters: from 2014/1/1 - 2021/12/07 [1533]

AND

'endoscopic bariatric therapy':ab,ti Filters: from 2014/1/1 – 2022/01/23 [36]

Cochrane

("Aspiration therapy" OR AspireAssist OR "Intragastric balloon" OR "endoscopic sleeve gastroplasty" OR "endoscopic sleeve" OR "Endoscopic gastroplasty" OR "primary obesity surgery endoluminal" OR "Endoscopic gastric plication" OR "gastric volume reduction" OR OverStitch OR ORBERA OR Obalon OR "Gastric Balloon" OR Gastrostomy OR Gastroplasty OR "Collis Gastroplasty" OR "Vertical Banded Gastroplasty" OR "Gastrostomies" OR "Gastric Bubble" OR IGB OR ESG) in Title Abstract Keyword OR (mh Gastroplasty OR mh Gastrostomy OR mh "Gastric Balloon") in All Text OR (mh "Bariatric Surgery" OR mh "gastric bypass" OR mh "Life Style") in All Text AND ("metabolic Surgery" OR "Bariatric Surgery" OR "Bariatric Surgical Procedure" OR "Stomach Stapling" OR "gastric bypass" OR MGB OR OAGB OR lifestyle OR "life style" OR lifestyles OR "life styles" OR "Lifestyle therapy") in Title Abstract Keyword - with Cochrane Library publication date Between Jan 2014 and Dec 1 [985]

AND

"endoscopic bariatric therapy" Between Jan 2014 and Jan 2022 [5]

APPENDIX B. PEER REVIEW COMMENTS/AUTHOR RESPONSES

Reviewer #	Reviewer Comment	Authors Responses		
1	Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked? Yes - Abu Dayyeh BK, Maselli DB, Rapaka B, Lavin T, Noar M, Hussan H, Chapman CG, Popov V, Jirapinyo P, Acosta A, Vargas EJ, Storm AC, Bazerbachi F, Ryou M, French M, Noria S, Molina D, Thompson CC. Adjustable intragastric balloon for treatment of obesity: a multicentre, open-label, randomised clinical trial. Lancet. 2021 Nov 27;398(10315):1965- 1973. doi: 10.1016/S0140-6736(21)02394-1. Epub 2021 Nov 15. Erratum in: Lancet. 2021 Nov 27;398(10315):1964. PMID: 34793746.	We have included this article in the updated search.		
2	Make sure that abbreviations are defined when first used. a. For example, ESG should be defined on page 6 before it is used on page 7	Completed.		
	Page 8: The following line seems a bit awkward. "There are no studies assessing the durability of the weight loss with endoscopic therapies, such as at 5 years or even 10 years following the intervention, as does exist for some established surgical weight loss therapies (such as gastric bypass)." a. Consider rephrasing the portion "such as at 5 year or even 10 years" It may be better to drop the "or even 10 years". I understand that you are trying to say that surgery has data out to 10 years, but the way it is written seems awkward.	Completed.		
	Page 17: there is an error: "Error!"	Thank you for this comment; there was a technical glitch and has been corrected.		
	Page 27, line 8: This statement about statistical significance is a bit confusing. Consider revising to include this information in the earlier sentences on that page. I presume the 7.9% less improvement is the result that has no confidence interval. Since the other result is presented as non-significant, I don't think that point merits repeating.	We adapted the description of these studies to make this more clear.		
	Page 28, line 47: It would help the reader if the 1 reintervention was put in the context of the overall sample size. Is this one out of 10 participants or 1 out of 100, etc.?	Fixed.		
	Page 28, lines 53-60 and all of page 29: Along the same lines, the discussion of abdominal pain and other adverse events is difficult to interpret without some information about the	We agree with the comments made by the reviewer. Most of the included studies do not detail severity or symptom specifics in		



Reviewer #	Reviewer Comment	Authors Responses	
	overall proportion and ideally, severity of the symptoms. a. Table 2 should be called out on the prior page as this would have helped answer my question. The table would benefit from changing "Total Complications" to "Any Complication" and clarification that these are risk differences, not absolute rates of nausea, etc. b. The analysis of adverse events doesn't delve into any issues of severity or duration of these events. Many of these symptoms may be transitory as the patient adapts to the intervention. If nausea and vomiting require removal of the device, then that is much more important than a day or two of nausea immediately following the initial intervention. Even if it is not feasible to detail the severity and duration of symptoms, it would seem appropriate to acknowledge this as a limitation of the review.	regards to abdominal discomfort. Therefore we are limited in our ability to further characterize abdominal pain in our review. We have added a statement regarding limitation of interpretation on page 28 as suggested.	
	Page 29, Figure 8: This is labelled as "Total Complications" but then presented as risk differences. This is a bit confusing because "Total" makes it seem like this is a count of complications, but I suspect you mean "Any Complication". As such, for the Thompson study, it would seem that almost 100% of the endoscopic group had a complication versus very few in the lifestyle group. Consider if there is a way to clarify this presentation through revision of the labels and/or adding explanatory text.	We have written a definition for total complications as a total of any complication in any patient.	
	Page 37, line 6: This should read "Primary Obesity Surgery Endoluminal (POSE)"	Complete.	
	Page 38, line 26: Consider revising as: "Financial impacts on closed"	Complete.	
	Page 39, line 47: The Conclusion states that endoscopic therapy is more effective than lifestyle, but has more complications. This is followed by a statement that surgery is probably more effective than endoscopy therapy but there is no mention of the increased risk of complications with surgery (ref 30). It would seem that this trade-off of risk/reward should also be clearly stated in the conclusion. This one aspect gives at least a hint of surgical bias in the presentation of the review.	We appreciate this input and have changed the sentence in conclusion to reflect the decreased relative adverse events rate of endoscopy as compared to surgery.	
3	Review for VA Evidence Synthesis Program Endoscopic bariatric interventions versus lifestyle interventions or surgery for weight loss in obese patients: A systematic review and meta-analysis Overall, based on the available evidence I	On the updated search following submission, we are including the data in regards to the newly FDA- approved Spatz balloon which will include the data as suggested by the reviewer.	



Reviewer #	Reviewer Comment	Authors Responses	
	agree with the conclusions of the report. The report is limited by not including some of the registry studies, which for US data includes the largest number of patients and are likely more representative of clinical practice. For example, Moore RL. SOARD. 2019; 15(3):417-423 included over 1300 patients from 108 practices with data collected and entered into the registry prospectively. However, I understand that the questions posed were specific to comparator groups, which is why registry data was not included. There were a few studies listed below that were not included in this analysis and there were some study populations that were reported more than once, which are outlined below. I would also highly recommend adding the data on safety included in FDA's Summary of Safety and Efficacy Data for the Spatz3 balloon, which is can be found on FDA's website (I can also provide you a PDF if you cannot find it). Although the data on non-serious adverse events wasn't included in the abstract, all of that data is included in the SSED and it would be good if that can be included in the analysis.	Completed.	
	patients with obesity instead of obese patients. This is the required terminology for most obesity and bariatric surgery related journals as well as The Obesity Society and ASMBS. Page 17 lines 20-21 include a grammatical error message,	Thank you for this comment; there was a technical glitch and has	
	Citations 14, 21, and 22 are from the same study population (IGB and control groups)	been corrected. These references were continuations of a similar study population, for which we only included additional data for later published studies with longer followup. We were cognizant to not double count any overlapping data.	
	Citations 31 and 33 are from the same patient population for ESG	These references were continuations of a similar study population, for which we only included additional data for later published studies with longer followup. We were cognizant to not double count any overlapping data.	
	Citations 27 and 34 are from the same patient population for ESG (This may or may not be an issue because the comparator groups are different)	These references had overlapping study populations but we were cognizant to not double count any overlapping data.	



Reviewer #	Reviewer Comment	Authors Responses	
	In table 2 and other points in the manuscript the Courcoulos 2017 study is incorrectly listed as Courcoulos 2005.	Complete.	
	No studies of the ReShape balloon were included in the analysis. This balloon is no longer commercially available, but both a pilot study and randomized sham-controlled study took place in the US leading to FDA approval. The data support the use of intragastric balloons for weight loss, but would not otherwise change your conclusions.	We include FDA approved and currently available devices/techniques in this review.	
	Randomized sham-controlled study design has been shown to reduce weight loss in endoscopic bariatric therapies (Swei E. The American Journal of Gastroenterology. 2021;116:S584). While this doesn't change your overall conclusions, it should be noted in your introduction and summary that this may limit the ability of this analysis to determine the full extent of efficacy since some of the studies included in this analysis were sham controlled.	We appreciate this insight and will address this in the methods.	
	There are 2 randomized controlled trials for Aspire Assist. You are missing: Sullivan S. Gastroenterology. 2013;145(6):1245-1252	This title was included in our updated search but has been excluded as it is a pilot study of a later Sullivan RCT of AspireAssist patients with likely patient overlap.	
	Reference 36 is not an RCT. It is a comparative analysis.	We have updated this in our study.	
	Page 28 line 19, this should be reference 36	We have confirmed that this reference is appropriate	
	Reference 26 is only an abstract. The full data can be seen on the FDA's Summary of Safety and Effectiveness Data report for the Spatz3 balloon, which is available publicly on line. I understand this got approval one week before completing this report. If possible this data should be included in all of the sections on AE outcomes in Key Question 2 indicating data is available for these outcomes in 3 studies.	We have added these data to our study.	
	Page 28 line 46 – I don't believe this is the correct reference.	We have changed the reference to the appropriate study.	
	Page 29 line 5, I believe 36 is the incorrect reference	We have changed the reference to the appropriate study.	
	Page 29 line 14. There was one bleeding event in the study of reference 23. That should be noted since the rate is 0.3% compared with 0%, which actually may not reach statistical significance.	Thank you for the reference and we have adjusted the results in the manuscript.	

Reviewer #	Reviewer Comment	Authors Responses		
	Page 32 paragraph 2. There is a comparative analysis of Obera vs Obalon balloon: Almuh aidb A. Comparison of the efficacy and safety of the FDA-Approved Intragastric Balloon systems in a clinical setting. Gastrointestinal Endoscopy. 2020;91(6):AB222.	We excluded studies that compared endoscopic to endoscopic therapies given that this was beyond the scope of this query.		
4	Very nicely done. This will be a helpful addition to the literature. Some suggestions for improvements:	Complete.		
	General - Many organizations and journals are trying to move away from the phrase "obese patients" or "obese adults" and instead use "patients with obesity." For example, in the title, would rephrase to "patients with obesity." There are numerous places in the manuscript too.			
	Terminology - Instead of "surgical bariatric therapy" would just say "bariatric surgery"; I get that you're drawing a comparison to "endoscopic bariatric therapy," but that term is awkward.	Complete.		
	Are you comparing endoscopy to surgery and "lifestyle modification" only? What about pharmacologic therapy? This typically would not be considered in the same boat as behavior weight management, which typically includes dietary and physicial activity changes. Would be clear about these therapies throughout. In my mind, there are 4 therapies: behavioral weight management, pharmacologic, endoscopic, and surgery. Also, would use the term "pharmacologic" since previous obesity workgroups (e.g., Weight Management SOTA in 2015) used the terminology "pharmacologic"	We agree that pharmacotherapy is a crucial part of management. We did not find any randomized or comparative studies directly studying endoscopic methods to pharmacotherapy in our search. This is a key question that should be explored further in future research.		
	Data abstraction - Who was involved in the "full group discussion"?	Phan, Shekelle, Weitzner, Gibbons, Girgis		
	Exec summary Intro - Is that economic burden in the US alone?	Yes the burden is in regards to the United States alone.		
	Rationale for excluding studies where similar mechanisms were compared to one another (balloon vs. balloon). Wouldn't data from those participants still be useful in a meta-analysis?	We agree that comparing similar mechanisms is valuable, as it warrants investigation in future papers. However, this was outside the scope of our paper for the purposes of TEP review.		
	I like including the main outcome as % TWL as opposed to another metric such as % EWL. The first figure is excellent.	We appreciate this feedback.		
	Key question 2 - "more total complications" in which group?	Completed.		
	Research gap - Can you be more specific about a "prior version of the gastric balloon." Are you referring to laparoscopic adjustable gastric	Thank you for the comments, clarification has been added to the research gaps.		



Reviewer #	Reviewer Comment	Authors Responses	
	banding or another type of endoscopically placed intra-gastric balloon? LAGB has not been "removed" although it is much lower in frequency than it was previously.		
	Literature flow - There is a comment that includes "Error!"	Thank you for this comment; there was a technical glitch and has been corrected.	
	The interpretation of Table 1 is challenging. It's not immediately clear what the mean difference in hemoglobin and QoL represents. For QoL, presumably a higher number means QoL is higher for IGB compared to lifestyle? It's not clear if these scales are all the same. For HgbA1c diff, a higher number would presumably be bad for IBG because it would imply that post-intervention HbgA1c is higher than that of lifestyle? The interpretation is quite challenging here. Would consider just describing this in the text.	We have clarified this for the reader.	
	Same with Table 2. I struggle with interpretability. Maybe it would be helpful to add a legend describing what a couple of numbers in the various cells means.	A legend has been added to help explain table values.	
	The authors note that "the history of weight loss interventions is one of innovation and dissemination prior to evaluation." This seems misleading and inaccurate. Yes, there are some examples that the authors highlight. There is also a 30+ year history of a lack of D&I of evidence-based obesity treatment - including the 2 gold standard operations (lap sleeve and lap bypass) and numerous FDA-approved obesity medications such that we're severely underutilizing evidence-based obesity treatments in the U.S. I think it's totally justifiable to cite those examples (VBG, LABG?, phenteramine) as interventions within the field where evidence was lacking prior to D&I, but would not characterize the entire field of obesity treatment (meds, bariatric surgery) as fitting that description.	Thank you for this comment; the statement has been rephrased.	
1	The authors are to be congratulated on this important and well-executed systematic review and meta-analysis. Given the rapid increase in obesity over the past few decades, and projected further increase in obesity, new interventions available to veterans are needed. Amongst the currently available options, bariatric surgery appears to be the most effective in reducing weight and improving metabolic comorbidities in the long term, however, its uptake is limited due to perceived surgical risks and limited access. A new class of interventions that are less invasive than	Thank you for this comment. We have included the Spatz balloon in our updated review after its approval.	

•

Reviewer #	Reviewer Comment	Authors Responses
	surgery, endoscopic bariatric therapies (EBTs), have become available to veterans in recent years. This systematic review focuses on a few specific questions related to the efficacy of FDA-approved EBTs, looking at studies published since 2014. These include two of the four FDA-approved intragastric balloons(IGBs), Orbera and Obalon; aspiration therapy, and endoscopic gastroplasty (not approved for treatment of obesity but device approved for use). Another balloon that was approved in 2015, the Reshape balloon, currently is not available in the US. A fourth balloon, the Spatz balloon, was approved in October 2021, but data was published after this review was completed. However, the pivotal trial results were presented as an abstract in 2018-2019, and likely should have been included. The FDA submission documents were also available for review since earlier in 2021. Overall, well-executed review looking at three questions: Key Question 1: What Is the Comparative Effectiveness Of Endoscopic Bariatric Interventions Versus Lifestyle Interventions Or Bariatric Surgery? Key Question 2: What Are the Comparative Harms Of Endoscopic Bariatric Interventions Versus Lifestyle Interventions Or Bariatric Surgery? Key Question 3: Do The Comparative Effectiveness And/Or Harms Vary By Patient Or Intervention Characteristics(ie, Age, BMI, Type Intragastric Balloon, Gastroplasty Technique, etc)?	
	Given the general lack of RCTs involving EBTs, I would recommend including the recently published high quality RCT of Spatz balloon in this meta-analysis. PMID 34793746	This study has been included in our updated search.
	The authors have used overlapping data of three presentations looking at the same IGB trial population: References 14,20,21 are all presentations of data from the Orbera pivotal trial, here presented as different studies. I would argue that this may be allowed if they document complimentary data, such as reporting different adverse events, but would not use them separately to report the same outcome measure such as weight loss or nausea, for example.	These references had overlapping study populations but we were cognizant to not double count any overlapping data.
	References 1 and 12 are the same.	Thank you for catching this error. The references have been changed.
	Additionally, ref 1/12 and 30 have overlapping patients; 1/12, 30 and 43 – same.	These references had overlapping study populations but we were



₩ 4

Reviewer #	Reviewer Comment	Authors Responses	
		cognizant to not double count any overlapping data.	
	Regarding Figures 2 and 6, I am not sure why the authors decided to pool both surgery and lifestyle as comparators to EBTs. I would argue that these should be two different figures : 2a and 2b, and 6a and 6b, with lifestyle and surgery, respectively.	The data are not pooled, just displayed on the same graph to allow better visual interpretation.	
	The adverse events associated with Orbera and Obalon differ widely, and one could argue that they should be analyzed separately and not pooled together. Rate of serious adverse events (SAE) with fluid-filled gastric balloons such as Spatz, Reshape and Orbera, is reported to be around 10%, while rate of SAE with Obalon(gas-filled) is 0.2%. To me, it is not clinically relevant to pool these together in the same meta-analysis. Rather, these should be discussed separately in comparison to lifestyle or surgery.	While each procedure has its own benefits and shortcomings, the scope of our review was to compare overall effects of treatment types in comparison to each other. Further studies can tease out these nuances.	
	Since the approval of semaglutide, weight loss medications have become a viable option for treatment of obesity, apparently similar in efficacy to the EBTs, with its own set of adverse events, cost issues, and attrition rate. Additionally, combination of GLP-1 and GIP- agonists are pending and expected next year. Thus, weight loss medications should be included in the discussion of future directions for studies.	We agree and have included the importance of pharmacotherapy in the future directions.	
	Some data from outside of the US points to a beneficial more sustained effect of EBTs in patients with lower BMIs in the overweight range. Thus, studies of early weight reduction interventions in patients who are overweight and at risk for metabolic decompensation could represent a future direction.	We agree, but aimed this review at those who qualify for procedures in the US. Future studies can address this.	
	Finally, in our experience, combination therapies involving EBTs and weight loss medications may be a viable long-term option for patients unwilling to undergo surgery. We use IGB of ESG as a tool for selected patients as part of a lifelong obesity therapy with an initial weight reduction that, in turn, could positively influences lifestyle choices and allow weight stabilization in the long term.	We agree and have expanded this in our discussion.	

APPENDIX C. COCHRANE RISK OF BIAS TOOL

The Cochrane Collaboration's Tool for Assessing Risk of Bias*

Domain	Support for judgment	Review authors' judgment				
Selection bias	Selection bias					
Random sequence generation	Describe the method used to generate the allocation Selection bias (bias sequence in sufficient detail to allow an assessment allocation to of whether it should produce comparable groups. interventions) due t inadequate generat of a randomised sequence.					
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	cation Selection bias (biased ether allocation to seen in interventions) due to inadequate concealment of allocations prior to assignment.				
Performance bias						
Blinding of participants and personnel Assessments should be made for each main outcome (or class of outcomes).	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.				
Detection bias						
Blinding of outcome assessment Assessments should be made for each main outcome (or class of outcomes).	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.				
Attrition bias						
Incomplete outcome data Assessments should be made for each main outcome (or class of outcomes).	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Attrition bias due to amount, nature or handling of incomplete outcome data.				
Reporting bias						
Selective reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.				

Other bias					
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Bias due to problems not covered elsewhere in the table.			

* http://handbook.cochrane.org/ in Table 8.5.a

APPENDIX D. RISK OF BIAS IN NON-RANDOMISED STUDIES – OF INTERVENTIONS (ROBINS-I)

Bias domains included in ROBINS-I

Pre-intervention	Risk of bias assessment is mainly distinct from assessments of randomised trials
Bias due to confounding	Baseline confounding occurs when one or more prognostic variables (factors that predict the outcome of interest) also predicts the intervention received at baseline ROBINS-I can also address time-varying confounding, which occurs when individuals switch between the interventions being compared and when post-baseline prognostic factors affect the intervention received after baseline
Bias in selection of participants into the study	When exclusion of some eligible participants, or the initial follow-up time of some participants, or some outcome events is related to both intervention and outcome, there will be an association between interventions and outcome even if the effects of the interventions are identical This form of selection bias is distinct from confounding—A specific example is bias due to the inclusion of prevalent users, rather than new users, of an intervention
At intervention	Risk of bias assessment is mainly distinct from assessments of randomised trials
Bias in classification of interventions	Bias introduced by either differential or non-differential misclassification of intervention status Non-differential misclassification is unrelated to the outcome and will usually bias the estimated effect of intervention towards the null Differential misclassification occurs when misclassification of intervention status is related to the outcome or the risk of the outcome, and is likely to lead to bias
Post-intervention	Risk of bias assessment has substantial overlap with assessments of randomised trials
Bias due to deviations from intended interventions	Bias that arises when there are systematic differences between experimental intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s) Assessment of bias in this domain will depend on the type of effect of interest (either the effect of assignment to intervention or the effect of starting and adhering to intervention).
Bias due to missing data	Bias that arises when later follow-up is missing for individuals initially included and followed (such as differential loss to follow-up that is affected by prognostic factors); bias due to exclusion of individuals with missing information about intervention status or other variables such as confounders
Bias in measurement of outcomes	Bias introduced by either differential or non-differential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects
Bias in selection of the reported result	Selective reporting of results in a way that depends on the findings and prevents the estimate from being included in a meta-analysis (or other synthesis)



APPENDIX E. QUALITY ASSESSMENT FOR INCLUDED RANDOMIZED CONTROLLED TRIALS

Author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data at 6, 12 months, longest	Selective reporting	Other sources of bias
Abu Dayyeh, 2015 ¹³	Unknown risk	Unknown risk	High risk	High risk	High risk (70- 75% follow up at 1 year)	Lowrisk	Moderate risk
Abu Dayyeh, 2019 ⁴⁹	Unknown risk	Unknown risk	High risk	High risk	Lowrisk	Low risk	Moderate risk
Chan, 2021 59	Unknown risk	Unknown risk	High risk	High risk	Moderate risk	Low risk	Lowrisk
				Unknown risk for weight	lowrisk at 9		
				Unclear how weight	months (80% follow up)		
Courcoulas, 2017 ²⁰	Low risk (Trial is FDA approved)	Unknown risk	High risk	Moderate risk for QOL	High risk at 12 months (75% follow up)	Low risk	Moderate risk
Fuller, 2013 27	Unknown risk	Unknown risk	High risk	Highrisk	Lowrisk	Low risk	Moderate risk
				Unknown risk for weight			
				Unclear how weight measured			
	Low risk			Moderate risk for QOL		High risk Weight is not primary	
Gomez, 2016 ²¹	(Trial is FDA approved)	Unknown risk	Highrisk	High risk for gastric emptying	Low risk (100% follow up)	endpoint of study	Moderate risk
Lee, 2012 ⁵⁸	Unknown risk	Unknown risk	Moderate risk	Moderate risk	Lowrisk	Lowrisk	Lowrisk

Author year	Random sequence	Allocation	Blinding of participants	Blinding of outcome	Incomplete outcome data at 6, 12 months,	Selective	Other sources
Aution, year	generation	conceannent	and personner	assessment	longest	reporting	UI DId5
3220 ³⁸	Unknown risk	Unknown risk	High risk	Moderate risk	Low risk	Low risk	Low risk
Ponce, 2013 ²⁶	Unknown risk	Unknown risk	Moderate risk	Moderate risk	Low risk	Low risk	Moderate risk
Ponce, 2015 28	Low risk	Low risk	Moderate risk	Moderate risk	Lowrisk	Low risk	Moderate risk
Raftoupoulos, 2019 ²⁴	Unknown risk	Unknown risk	High risk	High risk	High risk	Low risk	Lowrisk
Sullivan, 2012 ⁴¹	Unknown risk	Unknown risk	High risk	High risk	Lowrisk	Low risk	Lowrisk
Sullivan, 2017 ³¹	Low risk (Trial is FDA approved)	Unknown risk	Lowrisk	Unknown risk for weight Unclear how weight measured Moderate risk for QOL	Low risk	Low risk	Moderate risk
Sullivan, 2018 ²²	Low risk (Trial is FDA approved)	Unknown risk	Lowrisk	Unknown risk for weight Unclear how weight measured Moderate risk for QOL	Los risk	Low risk	Moderate risk
Thompson, 2017 ³⁹	Low risk (Trial is FDA approved)	Unknown risk	High risk	Unknown risk for weight Unclear how weight measured Moderate risk for QOL	High risk	Low risk	Moderate risk

₩ • •

Author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data at 6, 12 months, longest	Selective reporting	Other sources of bias
Thompson, 2019 ⁵²	Low risk (Trial is FDA approved)	Unknown risk	High risk	Unknown risk for weight Unclear how weight measured Moderate risk for QOL	High risk	Low risk	Moderate risk

APPENDIX F. QUALITY ASSESSMENT FOR INCLUDED OBSERVATIONAL STUDIES

Author, year	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported results
Abd El Mohsen, 2017 ³⁰	Unknown risk	Unknown risk	Lowrisk	Low risk	Low risk	Moderate risk	Lowrisk
Abeid, 2019 ⁴⁷	Low risk	Low risk	Low risk	Lowrisk	Low risk	Moderate risk	Lowrisk
Ahmed, 2019 ⁴²	Moderate risk	Moderate risk	Lowrisk	Lowrisk	Low risk	High risk	Low risk
Alqahtani, 2019	Low risk	Low risk	Low risk	Low risk	Low risk	Moderate risk	Lowrisk
Benias, 2020 ³⁷	Low risk	Moderate risk	Low risk	Lowrisk	Unknown risk	Moderate risk	Low risk
Cheskin, 2020 29	Low risk	Low risk	Low risk	Lowrisk	High risk	Moderate risk	Lowrisk
Espinet Coll, 2017 ⁴⁸	Low risk	Low risk	Lowrisk	Low risk	Low risk	Moderate risk	Lowrisk
Fayad, 2019 ³⁶	Moderate risk	Low risk	Lowrisk	Low risk	High risk	Moderate risk	Lowrisk
Fiorillo, 2020 ³⁴	Low risk	High risk	Lowrisk	Low risk	Low risk	Moderate risk	Low risk
Lopez-Nava, 2020 ³⁵	Low risk	Unknown risk	Lowrisk	Low risk	Low risk	Low risk	Lowrisk
Lopez-Nava, 2021 ³³	Low risk	High risk	Low risk	Low risk	Low risk	Moderate risk	Lowrisk
Mathus-Vliegen, 2015 45	Low risk	Moderate risk	Lowrisk	Low risk	Low risk	Moderate risk	Lowrisk
Novikov, 2018 32	High risk	High risk	Low risk	Lowrisk	Low risk	Moderate risk	Low risk
Raftopoulos, 2019 ²³	Moderate risk	Unknown risk	Low risk	Low risk	Unknown risk	Moderate risk	Lowrisk
Raftopoulos, 2019 ²⁴	Unknown risk	Unknown risk	Lowrisk	Lowrisk	Unknown risk	Moderate risk	Unknown risk
Sadek, 2017 43	Unknown risk	Unknown risk	Lowrisk	Lowrisk	Unknown risk	Moderate risk	Low risk
Salomone, 2021	Moderate risk	Lowrisk	Lowrisk	Lowrisk	Lowrisk	Moderate risk	Lowrisk



Author, year	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported results
Sander, 2017 53	Low risk	Moderate risk	Lowrisk	Low risk	Low risk	Moderate risk	Lowrisk
Wilson, 2018 40	Lowrisk	Moderate risk	Lowrisk	Lowrisk	Lowrisk	Moderate risk	Lowrisk

APPENDIX G. EVIDENCE TABLES

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Cha	aracteristics Preo	р			
				ESG	Balloon	AspireAssist	RYGB	LSG	Lifestyle
Cheskin, 2020 ²⁹	Obs/Y	Single	Yes	n: 105 Age: 47.58 (11.97) Female: 75 (71.42) BMI: 40.50 (7.89)					n: 281 Age: 48.17 (12.18) Female: 189 (67.26) BMI: 39.85 (7.62)
Courcoulas, 2017 ²⁰	RCT / Y	Multi	No		n: 125 Age: 38.7 (9.37) Race White: 101 (80.8) Black: 13 (11.2) Asian: 0 Hispanic: 9 (7.2) Female: 112 (89.6) BMI: <30: 2 (1.6) 30-35: 63 (50.4) 35-40: 56 (44.8) >40: 4 (3.2) EBW: 36# (11) DM: 9 (7) HTN: 33 (26)				n: 130 Age: 40.8 (9.61) Race White: 106 (81.5) Black: 15 (11.5) Asian: 0 Hispanic: 7 (5.4) Female: 117 (90.0) BMI: <30: 1 (0.8) 30-35: 57 (43.8) 35-40: 70 (53.8) >40: 2 (1.5) EBW: 36# (9) DM: 8 (6) HTN: 37 (28)
Fayad, 2019 36	Obs / Y	Single	Yes	n: 54 Age: 48 (24-72) Female: 57.4% BMI: median				n: 83 Age: 47 (30- 67) Female: 59 (71.1) BMI: 44.12 (29.73-64.46)	

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Cha	aracteristics Preop		
				BMI 43.07 DM: 3.7% HTN: 27.8%		DM: 20.48% HTN: 50.60%	
Fiorillo, 2020	Obs/N	Single	Yes	n: 23 Age: 41 (35-43) Female: 16 (30.4) BMI: 39.5 (36.7-44.7) DM: 2 (8.7) HTN: 3 (13)		n: 23 Age: 37 (25- 43) Female: 17 (73.9) BMI: 41 (38.3- 43.4) DM: 3 (13) HTN: 7 (30.4)	
Gomez, 2016	RCT / Y	Single	No		n: 15 Age: 38.1 (8.8) Race White: 60% Female: 87% BMI: 34.7 (3.42)		n: 14 Age: 38.2 (8.78) Race White: 85.7% Female: 93% BMI: 35.6 (2.84)
Lopez-Nava, 2021 ³³	Obs / N	Multi	No	n: 199 Age: 44.6 (10) Female: 141 (71) BMI: 39.4 (5.4)		n: 61 Age: 44.6 (11.2) Female: 36 (59) BMI: 40.1 (3.7)	
Novikov, 2018 ³²	Obs/Y	Single	No	n: 91 Age: 43.86 (11.26) Female: 62 (68.13) BMI: 38.61 (6.98)		n: 120 Age: 40.71 (11.95) Female: 94 (78.33) BMI: 47.22 (7.84)	

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Cha	racteristics Preop		
				DM: 20 (21.98) A1c: 5.82 (0.98) HTN: 18 (19.78)		DM: 31 (25.83) A1c: 6.3 (1.25) HTN: 61 (50.83)	
Sullivan, 2018 ²²	RCT / Y	Multi	No		n: 198 Age: 42.7 (9.6) Race White: 165 (83.3) Female: 171 (86.4) BMI: 35.2 (2.7) A1c: 5.3 (0.4) HTN: 31 (15.7)		n: 189 Age: 42.5 (9.3) Race White: 155 (82.0) Female: 170 (89.9) BMI: 35.5 (2.7) A1c: 5.3 (0.5) HTN: 28 (14.8)
Sullivan, 2017 ³¹	RCT / Y	Multi	No	n: 221 Age: 44.2 (8.6) Race White: 154 (71) Black: 61 (28.1) Female: 195 (88.2) BMI: 36.0 (2.4) EBW: 99.7 (12.2kg) DM: 17 (7.7) HTN: 100 (45.2)			n: 111 Age: 45.3 (9.1) Race White: 70 (64.8) Black: 34 (31.5) Female: 101 (91) BMI: 36.2 (2.2) EBW: 98.7 (11.6kg) DM: 11 (9.9) HTN: 42 (37.8)

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Characteristics Preop	
Thompson,				$\begin{array}{cccccccccccccccccccccccccccccccccccc$	3)
2017 39	RCI / Y	Multi	NO	(41.4) HTN: 24 (40.0) n: 111 Age: 42.4 (10.0) Race White: 63 n: 60 (56.8) n: 60 Black: 33 Age: 46.8 (11.6) (29.7) Race Hispanic: 11 White: 31 (51.7) (9.9) Black: 17 (28.3) Female: 96 Hispanic: 11 (86.5) (18.3) BMI: 42.0 Female: 53 (88.3) BMI: 42.0 Female: 53 (88.3)	3)
Thompson, 2018 ⁵²	RCT / Y	Multi	No	DM: 3 (2.7) A1c: 5.7 (0.6) DM: 8 (13.3) A1c: 5.8 (0.6) HTN: 24 (40.0)	

₩ • •

Study Design / US	Single vs Multi- center	Propensity Matching	Patient Characteristics Preop
			HTN: 46
			(41.4)

Lopez-Nava, 2020 ³⁵	Obs / N	Multi	No	n: 12 Age: 49.3 (2.4) Female: 9 (75) BMI: 38.3 (1.8) DM: 0 HTN: 2 (17)				n: 12 Age: 50.5 (1.9) Female: 9 (75) BMI: 39.2 (1.5) DM: 0 HTN: 9 (75)	
Raftopoulos, 2019 ²³	Obs/N	Single	Yes		n: 58 Age: 43.2 (11.8) Female: 70.7% BMI: 36.7 (5.7)				n: 413 Age: 48.3 (12.4) Female: 85.9% BMI: 36.8 (5.0)
Raftopoulos, 2019 ²⁴	Obs/N	Single	Yes		n: 79 Age: 43 (10.8) Female: 68.4% BMI: 36.2 (5.4)				n: 413 Age: 48.3 (12.4) Female: 85.9% BMI: 36.8 (5.0)
Abu Dayyeh, 2019 ⁴⁹	RCT / Y	Multi	No						
Wilson, 2018	Obs/N	Single	No			Unknown	Unknown		
Sadek, 2017	Obs / Y	Single	Unclear	n: 23				n: 277	

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Ch	aracteristics Preo	р			
Abd El Mohsen, 2017 ³⁰	Obs / Y	Multi	No	n: 5					n: 14
Abu Dayyeh, 2015 ¹³	RCT / Y	Multi	No		n: 137 Age: 38.7 (9.4) Female: (89.6) BMI: 35.2 (3.17) EBW: 28.4 (2.7)				n: 136 Age: 40.8 (9.6) Female: (90) BMI: 35.4 (2.7) EBW: 28.7 (8.1) kg
				ESG	Balloon	AspireAssist	RYGB	LSG	Lifestyle
Fuller, 2010	RCT / N	Sinale	No		n: 31 Age: 43 Female: (68) BMI: 36.0				n: 35 Age: 48 BMI: 36.7
Ponce, 2012	RCT / Y	Multi	No		n: 21 Age: 38.9 (9.1) White: (95) Female: (81) BMI: 34.7 (2.6)				n: 9 Age: 45.3 (6.6) White: (100) Female: (100) BMI: 35.6 (2.0)
Lee, 2012 ⁵⁸	RCT / N	Single	No		n: 8 Age: 43 (19.75) Female: 5 (62.5) BMI: 30.3 (4.22) Diabetes: 1 (12.5) NAFLD: 8 (100)				n: 10 Age: 47 (15) Female: 2 (20) BMI: 32.4 (6.66) Diabetes: 1 (10) NAFLD: 10 (100)
Ponce, 2015	RCT / Y	Multi	No		n: 187 Age: 43.8 (9.5) White: (81.8) Black: (13.4)				n: 139 Age: 44.0 (10.2) White: (85.6) Black: (11.5)



	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Characteristics Preop	
				Hispanic: (8)	Hispanic: (5.8)
				Female: (95.2)	Female: (95.0)
				BMI: 35.3 (2.8)	BMI: 35.4 (2.6)
				Diabetes: (7)	Diabetes: (7.2)
				HbA1c: 5.7 (0.7)	HbA1c: 5.7 (0.88)
				HTN: (28.9)	HTN: (35.3)
				n: 84	
				Age: 43.96	
				(8.98) Earris (54)	n [.] 44
				Female: (54)	Age: 42.65 (6.61)
				DIVII. 47.87 (1.08)	Female: (59)
Mohammed				EBW: 65 45	BMI: 47.46 (1.85)
2014 ³⁸	RCT / N	Single	No	(5.04)	EBW: 65.23 (6.77)
				n: 40	
				Female: 40	n: 40
Ahmed, 2019		_		(100)	Female: 40 (100)
42	Obs / N	Single	No	BMI: 36	BMI: 36.5
Sullivan.				n: 11	n: 7
2012 ⁴¹	RCT / Y	Single	No	BMI: 42 (4.7)	BMI: 43.4 (5.3)
				n: 26	
				Age: 53	
				Female: (31)	
				Diabetes: (38)	
				HbA1c: 7.5	
Salomone,				HTN: (65)	
2021 57	Obs/N	Single	No	NAFLD: 26 (100)	
				n: 26	n: 23
				Age: 38.1 (7.9)	Age: 35.3 (7.2)
Chan, 2021				Female (70)	Female: (75.5)
59	RCT / N	Multi	No	BMI: 30.2 (2.3)	BMI: 30.2 (2.1)



	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Ch	aracteristics Preop	
					n: 1600	
					Age: 34.1 (10.3)	
					Female: (77)	
					BMI: 40.3 (8.17)	
Abeid, 2019	Oha / N	Cinala	No		Diabetes: (6.8)	
-1/	UDS / N	Single	INO		HIN: (15.06)	
				n: 1000		
				Age: 34.4 (9.5)		
				(0.0) Female		
				(89.7)		
				BMI: 33.3 (4.5)		
				Diabetes:		
Alqahani,		_		(1.7)		
2019 50	Obs/N	Single	No	HTN: (2.8)		
					n: 815	
					Age: 36.5 (9.8)	
Mathus,		<u>.</u>			Diabetes: (2.3)	
2014 40	Obs / N	Single	No		HIN: (15.6)	
					n: 9763	
					Age: 31.13	
Sander, 2017		0:	N I -		Female: (78)	
	UDS / N	Single	INO		BMI: 33.42	
D : 0000				n: 14		p: 11
Benias, 2020	Obs / N	Single	No	Age: 39 (4.2)		Age: 47 (3.9)

	Study Design / US	Single vs Multi- center	Propensity Matching	Patient Characteristics Preop	
				n: 37	n: 37
				Age: 43.3 (9.4)	Age: 48.1 (7.3)
				White: (83.9)	White: (74.3)
Fuller, 2019				Female: (68)	Female: (66)
27	RCT / Y	Single	No	BMI: 36 (2.7)	BMI: 36.9 (2.7)
				n: 187	
				Age: 44.4 (8.9)	n: 101
				White: 132 (71)	Age: 44.0 (8.9)
				Black: 49 (26)	White: 72 (71)
				Asian: 1 (1)	Black: 26 (26)
				Female: 162	Asian: 1 (1)
				(87)	Female: 90 (89)
				BMI: 35.8 (2.6)	BMI: 35.8 (2.7)
Abu Dayyeh,				Diabetes: 13 (7)	Diabetes: 4 (4)
2021 ²⁵	RCT / Y	Single	No	HTN: 41 (22)	HTN: 32 (32)
				n: 1343	
				Age: 45.7 (10.8)	
				White: 897	
				(66.8)	
				Female: 1055	
Moore, 2019				(78.6)	
46	Obs/Y	Multi	No	BMI: 35.4 (5.4)	

APPENDIX H. OUTCOMES

Outcome	f/u Time (months)	# Studies	# RCTs	# nonRCTs
%TBWL	6	19	7	12
%TBWL	12	15	7	8
%EBWL	6	8	7	1
%EBWL	12	8	7	1
BMI	6	8	6	2
total complication	6	7	4	3
weight loss	6	7	6	1
weight loss	12	7	6	1
nausea/vomiting	12	6	3	3
total complication	12	6	3	3
BMI	12	5	3	2
QOL	6	5	3	2
infection	12	5	2	3
GERD	6	4	2	2
at least 10% total body weight	6	4	3	1
at least 5% total body weight	6	4	3	1
bleeding	12	4	2	2
dehydration	6	4	3	1
nausea/vomiting	6	4	3	1
%TBWL	24	3	0	3
30-day readmissions (time not specified)	6	3	1	2
30-day reintervention	12	3	1	2
QOL	12	3	3	0
at least 10% total body weight	12	3	3	0
at least 25% excess body weight	12	3	3	0
at least 5% total body weight	12	3	3	0

Outcome	f/u Time (months)	# Studies	# RCTs	#nonRCTs
bleeding	6	3	1	2
dehydration	12	3	1	2
dyspepsia/abdominal pain	6	3	3	0
dyspepsia/abdominal pain	12	3	2	1
gastric ulceration	6	3	3	0
HbA1C	6	3	3	0
HbA1C	12	3	2	1
30-day reintervention	6	2	1	1
BMI	24	2	0	2
GERD	12	2	2	0
at least 25% excess body weight	6	2	2	0
infection	6	2	1	1
mortality	12	2	1	1
weight loss	24	2	1	1
%EBWL	24	1	0	1
%EBWL	36	1	0	1
%TBWL	36	1	0	1
%TBWL	120	1	1	0
30-day readmissions (only know within 90 days though)	12	1	0	1
30-day readmissions (time not specified)	12	1	1	0
30-day reintervention (don't know time frame)	12	1	0	1
BMI	120	1	1	0
gastric ulceration	12	1	0	1
improvement of diabetes	12	1	1	0
improvement of hypertension	12	1	1	0
weight loss	60	1	1	0
weight loss	120	1	1	0

APPENDIX I. CITATIONS FOR EXCLUDED PUBLICATIONS

Adjunct Therapies, N = 8

- Badurdeen, D., et al., Endoscopic sleeve gastroplasty plus liraglutide versus endoscopic sleeve gastroplasty alone for weight loss. Gastrointestinal endoscopy, 2021.93(6): p. 1316-1324.e1.
- 2. Badurdeen, D., et al., ESG PLUS LIRAGLUTIDE IS SUPERIOR TO ESG ALONE FOR WEIGHT LOSS IN OVERWEIGHT AND OBESE PATIENTS. Gastrointestinal Endoscopy, 2020. 91(6): p. AB215.
- 3. Carolina Hoff, A., et al., SEMAGLUTIDE IN ASSOCIATION TO ENDOSCOPIC SLEEVE GASTROPLASTY: TAKING ENDOSCOPIC BATRIATRIC PROCEDURES OUTCOMES TO THE NEXT LEVEL. Gastrointestinal Endoscopy, 2021.93(6): p. AB6-AB7.
- 4. de Souza, T.F., et al., The First Study Evaluating Effectiveness and Safety of the Endoscopic Sleeve Gastroplasty in HIV Patients. Obesity surgery, 2020. 30(3): p. 1159-1162.
- 5. Hoff, A.C., et al., Endoscopic sleeve gastroplasty and liraglutide: Associating a GLP1analogue to potentialize weight loss. Digestive Endoscopy, 2020. 32((Hoff A.C.) Angioskope SP, Bariatric Endoscopy, São Paulo, Brazil): p. 14.
- 6. Kolli, S., et al., THE DUAL EFFICACY OF PHARMACOTHERAPY WITH INTRAGASTRIC BALLOONS FOR SUSTAINED WEIGHT LOSS – A RETROSPECTIVE ANALYSIS. Gastrointestinal Endoscopy, 2020. 91(6): p. AB227.
- 7. Peker, Y., et al., Comparison of results of laparoscopic gastric banding and consecutive intragastric balloon application at 18 months: a clinical prospective study. Journal of laparoendoscopic & advanced surgical techniques. Part a, 2011. 21(6): p. 471-475.
- 8. Russo, T., et al., BioEnterics Intragastric Balloon (BIB) versus Spatz Adjustable Balloon System (ABS): Our experience in the elderly. International journal of surgery (London, England), 2017. 38: p. 138-140.

Bridging Therapy, N = 1

1. Rzepa, A., et al. (2019). "Selected aspects of intra-gastric balloons use in patients undergoing surgery for morbid obesity." Obesity surgery 29(5): 551.

Duplicate Data, N = 3

- 1. Fuller, N., et al., A prospective, randomised, controlled trial of the BioEnterics® Intragastric Balloon (BIB) in the treatment of obese individuals with metabolic syndrome. Obesity reviews, 2010. 11: p. 436-.
- 2. Fuller, N.R., et al., An intragastric balloon produces large weight losses in the absence of a change in ghrelin or peptide YY. Clinical obesity, 2013.3(6): p. 172-179.
- 3. Klein, S., et al., Aspiration therapy: a novel endoscopic approach for treating obesity. Obesity facts., 2012. 5: p. 203.

Modified Procedures, N = 7

- Alasfar, F.S. and F. Alotaibi, A comparison between swallowable fluid filled and air filled gastric balloon: A single surgeon experience. Surgical Endoscopy, 2019. 33((Alasfar F.S.; Alotaibi F.) Department of Surgery, Faculty of Medicine, Kuwait University): p. S35.
- Barrichello, S.A., et al., ANALYSIS OF THE EFFICACY AND SYMPTOMATOLOGY OF THE BALLOON IN RELATION TO THE VOLUME OF THE ACCESSORY.
 "INTRAGASTRIC BALLOON - THE GREATER THE VOLUME, THE BETTER?". Gastrointestinal Endoscopy, 2019. 89(6): p. AB274-AB275.
- 3. Fittipaldi-Fernandez, R.J., et al., Randomized Prospective Clinical Study of Spatz3® Adjustable Intragastric Balloon Treatment with a Control Group: a Large-Scale Brazilian Experiment. Obesity surgery, 2021. 31(2): p. 787-796.
- 4. Folini, L., et al., Liver steatosis (LS) evaluated through chemical-shift magnetic resonance imaging liver enzymes in morbid obesity; effect of weight loss obtained with intragastric balloon gastric banding. Acta diabetologica, 2014. 51(3): p. 361-368.
- Malik, S., et al., INTRA-GASTRIC BALLOON FOR TREATMENT OF OBESITY: SAFETY ANALYSIS OF 2407 PATIENTS PERFORMED BY GASTROENTEROLOGISTS AND SURGEONS. Gastrointestinal Endoscopy, 2019. 89(6): p. AB271-AB272.
- 6. Mosli, M.M. and M. Elyas, Does combining liraglutide with intragastric balloon insertion improve sustained weight reduction? Saudi journal of gastroenterology : official journal of the Saudi Gastroenterology Association, 2017. 23(2): p. 117-122.
- Sadek, R. and A. Wassef, Comparative gastric balloon systems: Does size matter? endoscopic and percutaneous interventional procedures. Obesity Surgery, 2017. 27(1): p. 345.

No Data, N = 4

- 1. Nct, Efficacy and Safety of Endoscopic Sleeve Gastroplasty Versus Laparoscopic Sleeve Gastrectomy in Obese Subjects With NASH. https://clinicaltrials.gov/show/NCT04060368, 2019.
- 2. Pate, P., et al., Impact of combined medical weight loss and intra-gastric balloon therapy on body fat composition following completion of 6 months of treatment punam patel md, michael seger md, jennifer seger md, terive duperier md, richard englehardt md, allison arnett NP-BC, tamara deshazo np. Surgery for obesity and related diseases, 2017. 13(10): p. S198-S199.
- 3. Plua Marcillo, W., et al., Prospective analysis of results of laparoscopic gastric sleeve and intragastric ball in obese patients. Obesity Surgery, 2019. 29(5): p. 1112.
- 4. Solmaz, A., et al., Comparison of intragastric balloon and gastric plication. Obesity Surgery, 2015. 25(1): p. S262.

<u>Non-Bariatric Outcomes</u>, N = 5

- 1. Abu Dayyeh, B.K., et al., Baseline gastric emptying and its change in response to diverse endoscopic bariatric therapies predict weight change after intervention. Gastroenterology, 2016. 150(4): p. S86.
- Fayad, L., et al., ENDOSCOPIC BARIATRIC THERAPIES ASSOCIATED WITH LOWER RATE OF ADVERSE EVENTS AND LENGTH OF STAY THAN LAPAROSCOPIC BARIATRIC THERAPIES. Gastrointestinal Endoscopy, 2020. 91(6): p. AB223-AB224.
- 3. Goff, J.L., Gastroplasty with stomach plication gp associated with significant psychological support: A real alternative to the sleeve and gastric by-pass. Obesity Surgery, 2014. 24(8): p. 1245-1246.
- 4. Kolesnikov, E., et al., Comperative ph-monitoring studies after Roux-en-Y gastric bypass, sleeve gastrectomy operations and intragastric balloon insertion in morbidly obese patients. Obesity Surgery, 2015. 25(1): p. S274.
- 5. Wroblewski, E., et al., Variation in blood levels of hormones in obese patients following weight reduction induced by endoscopic and surgical bariatric therapies. Cytokine, 2016. 77: p. 56-62.

<u>Procedure Type Not Included</u>, N = 10

- 1. Cruz, J., et al. (2017). "Efficacy of weight reduction of endoscopic intrasgastric balloon (IGB) vs oral sibutramine in patients with class i obesity in an asian cohort-a randomized control trial with long term follow up. Surgery and strategies for low BMI." Obesity surgery 27(1): 235-.
- 2. Durmus, A., et al., The Efficacy Of Intragastric Balloon Versus Botulinum Toxin Injection In Obese Patients. Surgery for Obesity and Related Diseases, 2019. 15(10): p. S187-S188.
- 3. Familiari, P., et al., Transoral gastroplasty for morbid obesity: a multicenter trial with a 1year outcome. Gastrointestinal endoscopy, 2011. 74(6): p. 1248-1258.
- 4. Huberty, V., et al., Endoscopic sutured gastroplasty in addition to lifestyle modification: short-term efficacy in a controlled randomised trial. Gut, 2020.
- 5. Jonnalagadda, S.S., et al., Preliminary results of a randomized, blinded, sham-controlled trial of transoral gastroplasty for the treatment of morbid obesity. Gastroenterology, 2012. 142(5): p. S78-.
- 6. Lecumberri, E., et al., Effectiveness and safety of air-filled balloon heliosphere BAG in 82 consecutive obese patients. Obesity surgery, 2011. 21(10): p. 1508-1512.
- 7. Nanni, G., et al., Effectiveness of the transoral endoscopic vertical gastroplasty (TOGa): a good balance between weight loss and complications, if compared with gastric bypass and biliopancreatic diversion. Obesity surgery, 2012. 22(12): p. 1897-1902.
- 8. Popov, V., A. Ou, and C.C. Thompson, Intragastric balloons are effective at inducing weight loss: a systematic review and meta-analysis of randomized controlled trials. Gastroenterology, 2015. 148(4): p. S903-.
- 9. Rothstein, R.I., et al., TRANSPYLORIC SHUTTLE TREATMENT IMPROVES CARDIOMETABOLIC RISK FACTORS AND QUALITY OF LIFE IN PATIENTS WITH OBESITY: RESULTS FROM A RANDOMIZED, DOUBLE-BLIND, SHAM-CONTROLLED TRIAL. Gastroenterology, 2019. 156(6): p. S-237-.



10. Schouten, R., et al., Long-term results of bariatric restrictive procedures: a prospective study. Obesity surgery, 2010. 20(12): p. 1617-1626.

Sample Size, N = 6

- 1. IMPACT OF SINGLE FLUID-FILLED INTRAGASTRIC BALLOON ON METABOLIC PARAMETERS AND NONALCOHOLIC STEATOHEPATITIS: a PROSPECTIVE PAIRED ENDOSCOPIC ULTRASOUND GUIDED CORE LIVER BIOPSY AT THE TIME OF BALLOON PLACEMENT AND REMOVAL. Gastroenterology, 2018. 154(6): p. S-1360-.
- 2. Genco, A., et al., Safety and efficacy of a new swallowable intragastric ballon not needing endoscopy: earlyitalian experience. Gastrointestinal endoscopy, 2017. 85(5): p. AB271-.
- 3. Jagtap, N., et al., Endoscopic sleeve gastroplasty for non-alcoholic fatty liver disease. Endoscopy, 2021. 53(SUPPL 1): p. S21-.
- 4. Lopez-Nava, G., et al., Endoscopic Sleeve Gastroplasty for Obesity: a Multicenter Study of 248 Patients with 24 Months Follow-Up. Obesity surgery, 2017: p. 1-7.
- 5. Machytka, E., et al., Elipse, the first procedure less gastric balloon for weight loss: a prospective, observational, open-label, multicenter study. Endoscopy, 2016. (no pagination).
- 6. Maekawa, S., M. Niizawa, and M. Harada, A Comparison of the Weight Loss Effect between a Low-carbohydrate Diet and a Calorie-restricted Diet in Combination with Intragastric Balloon Therapy. Internal medicine (Tokyo, Japan), 2020. 59(9): p. 1133-1139.

Short Follow-Up, N = 4

- 1. Armijo, P.R., et al., Patients undergoing intra-gastric balloon achieve approximately 50% of their target weight loss in the first month postoperatively: a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program analysis. Surgery for Obesity and Related Diseases, 2018. 14(11): p. S63.
- Armijo, P.R., et al., Patients undergoing intragastric balloon achieve approximately 50% of their target weight loss in the first month postoperatively: an MBSAQIP analysis. Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery, 2019. 15(12): p. 2060-2065.
- 3. Behzadi, F., et al., Predictors of Early Reintervention Following Intragastric Balloon: An MBSAQIP Analysis. Surgery for Obesity and Related Diseases, 2019. 15(10): p. S74.
- 4. Jain, S., S. Rajput, and R.K. Jain, Endoscopic Sleeve gastroplasty is safe minimally invasive modality in treatment of obesity with good short term efficacy: Initial experience at single center. Journal of Gastroenterology and Hepatology, 2019. 34((Jain S.; Jain R.K.) Jainamshree Multispecialty Hospital, Bhopal, India): p. 454.

Study Design, N = 19

- 1. Abeid, M., et al., EFFICACY AND SAFETY OF INTRAGASTRIC BALLOON PLACEMENTS IN 1600 CASE, AN EXPERIENCE FROM THE MIDDLE EAST. Gastrointestinal Endoscopy, 2019. 89(6): p. AB263.
- 2. Deliopoulou, K., et al., The impact of weight loss on depression status in obese individuals subjected to intragastric balloon treatment. Obesity surgery, 2013. 23(5): p. 669-675.
- 3. Fayad, L., et al., Endoscopic sleeve gastroplasty versus intragastric balloon insertion: efficacy, durability, and safety. Endoscopy, 2019. 51(6): p. 532-539.
- 4. Fernandez, R.J.F., et al., Intragastric balloon: A critical view in non elective bariatric surgery patients. United European Gastroenterology Journal, 2017. 5(5): p. A830.
- 5. Fittipaldi-Fernandez, R., et al., Intragastric balloon: A critical view in non elective bariatric surgery patients endoscopic and percutaneous interventional procedures. Obesity Surgery, 2017. 27(1): p. 494-495.
- 6. Ienca, R., C. Giardiello, and R. Schiano, Virtual follow-up (FU) program enhances weight-loss results post Elipse balloon: an innovative, digital patient-friendly approach. Obesity facts, 2018. 11: p. 49-.
- Ienca, R., et al., Elipse® swallowable intragastric balloon + very low calorie ketogenic diet (VLCKD): a novel strategy to optimize weight-loss and minimize side effects. Obesity surgery, 2018. 28(1): p. S49-S50.
- Jaruvongvanich, V., et al., CHALLENGES AND SUCCESS OF INTRAGASTRIC BALLOON THERAPY IN LIVER TRANSPLANT CANDIDATES: A PROSPECTIVE STUDY WITH LONG-TERM FOLLOW-UP. Gastrointestinal Endoscopy, 2020. 91(6): p. AB211-AB212.
- 9. Lopez-Nava, G., et al., EUROPEAN ENDOSCOPIC SUTURING REGISTRY FOR TREATMENT OF OBESITY. Gastrointestinal Endoscopy, 2020. 91(6): p. AB62.
- Ohta, H., CAN INTRAGASTRIC BALLOON THERAPY NORMALIZE THE GUT DYSBIOSIS OF PATIENTS WITH OBESITY? Gastroenterology, 2019. 156(6): p. S-678.
- 11. Popov, V., et al., The impact of intragastric balloons on metabolic disease in veterans: Results of a 6-month pilot study. Gastroenterology, 2017. 152(5): p. S639.
- 12. Sander, B., et al., Brazilian multicenter study of endoscopic sleeve gastroplasty with over stitch use-initial results. United european gastroenterology journal, 2019. 7(8): p. 744-.
- Storm, A.C. and B.K. Abu Dayyeh, Endoscopic sleeve gastroplasty for obesity: defining the risk and reward after more than 1600 procedures. Gastrointestinal endoscopy, 2019. 89(6): p. 1139-1140.
- 14. Storm, A.C. and B.K. Abu Dayyeh, Metabolic function and weight loss after endoscopic sleeve gastroplasty: resistance is futile. Gastrointestinal endoscopy, 2021. 93(5): p. 1119-1120.
- 15. Suchartlikitwong, S., et al., Intragastric balloons in severe obesity: A new capability. Gastrointestinal Endoscopy, 2018. 87(6): p. AB605.
- 16. Sullivan, S. and S. Edmundowicz, Early Experience With Endoscopic Sleeve Gastroplasty and Hints at Mechanisms of Action. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association, 2017. 15(1): p. 44-45.

- 17. Vargas, E.J., et al., Effectiveness of Online Aftercare Programs Following Intragastric Balloon Placement for Obesity Is Similar to Traditional Follow-up: a Large Propensity Matched US Multicenter Study. Obesity surgery, 2019. 29(12): p. 4036-4042.
- 18. Wallstabe, I., et al., Endoscopic sleeve gastroplasty using the novel Endomina device for morbidly obese patients. 2018: Germany.
- 19. Wannhoff, A., et al., Endoscopic sleeve gastroplasty for severe obesity by full-thickness suturing using the GERDX device. 2019: Germany.

Unavailable, N = 11

- 1. Buzga, M., et al., Effect of endoscopic gastroplasty and surgical plication of the stomach on bodycomposition: Short term, 6 months study. Vnitrni Lekarstvi, 2017. 63(9): p. 2S47-2S48.
- 2. Dayyeh, B.A., et al., Laparoscopic greater curvature plication (LGCP) VS. Endoscopic Sleeve Gastroplasty (ESG): Similar efficacy with different physiology. Surgery for Obesity and Related Diseases, 2017. 13(10): p. S205.
- 3. Hollenbach, M., et al., Pre-Study protocol Weight-loss Endoscopy Trial (WET): A multicenter, randomized, controlled trial comparing weight loss in endoscopically implanted duodenal-jejunal bypass liners vs. intragastric balloons vs. a sham procedure. Zeitschrift fur Gastroenterologie, 2017. 55(8).
- 4. Kadouh, H., et al., Pharmacotherapy enhances weight loss maintenance after obesity treatment with the intragastric balloon. Surgery for Obesity and Related Diseases, 2017. 13(10): p. S209.
- 5. Ohta, H. and S. Katsuki, A new bariatric balloon capsule therapy without a filling tube indicates a reduction in visceral fat and insulin resistance. Gastroenterology, 2017. 152(5): p. S135.
- 6. Pryor, A., et al., A 6-month swallowable balloon system results in sustainable weight loss at 1 year: Results from a prospective, randomized sham-controlled trial. Surgery for Obesity and Related Diseases, 2016. 12(7): p. S26-S27.
- 7. Rodríguez, G., et al., A New Bariatric Procedure: The Stomach Sparing Gastric SleeveTM. Surgical technology international, 2015. 27: p. 116-122.
- 8. Sivero, L., et al., Treatment of morbid obesity with intragastric balloon: BioEnterics intragastric vs. Spatz adjustable balloon systems. Chirurgia (Turin), 2017. 30(2): p. 40-42.
- 9. Sullivan, S., et al., The obalon swallowable 6-month balloon system is more effective than moderate intensity lifestyle therapy alone: Results from a 6-month randomized sham controlled trial. Gastroenterology, 2016. 150(4): p. S1267.
- Thompson, C.C., et al., The aspireassist is an effective tool in the treatment of class ii and class iii obesity: Results of a one-year clinical trial. Gastroenterology, 2016. 150(4): p. S86.
- 11. Thompson, C.C., et al., Aspiration Therapy for the Treatment of Obesity: 2-4 Year Results of the PATHWAY Multicenter Randomized Controlled Trial. Surgery for Obesity and Related Diseases, 2018. 14(11): p. S4-S5.