Do Endoscopic Bariatric Procedures Improve Postprocedural Quality of Life and Mental Health? A Systematic Review and Meta-analysis

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Do endoscopic bariatric procedures improve postprocedural quality of life and mental health? A systematic review and meta-analysis

Running heading: QoL after bariatric procedures

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Key words: Quality of life, intragastric balloon, endoscopic bariatric therapy, mental health, obesity, transpyloric shuttle, primary obesity surgery endoluminal, endoscopic sleeve gastroplasty, aspiration therapy, trans-oral gastroplasty, duodenal bypass liner

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Conflict of interest

The authors declare there are no conflict of interest.

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Abstract

Quality of life and mental health are important outcomes of bariatric therapy. This review aimed to determine endoscopic bariatric procedures impact on postprocedural quality of life and mental health. Four electronic databases were systematically searched. Studies with adults ≥18 years who underwent an endoscopic bariatric procedure and reported pre- and postprocedural quality of life and/or mental health using a validated tool were included. Meta-analyses were conducted RevMan and study quality was assessed. Twenty studies evaluating five different endoscopic procedures were included (N=876 total sample size). Intragastric balloon placement was associated with a large improvement in postprocedural quality of life and mental health. Endoscopic bariatric therapies may improve short term quality of life and mental health alongside weight loss and comorbidity improvement.

Keywords:

Quality of life, mental health, endoscopic, bariatric.

Introduction

Global obesity rates have nearly tripled since 1975 and have been associated with increased incidence of chronic diseases including type 2 diabetes, sleep apnoea, and cardiovascular disease [1]. Obesity and obesity-related stigmatisation also negatively impact on mental health and quality of life (QoL), particularly self-esteem, depression, anxiety, and fear of criticism by others [2, 3]. Weight loss options include traditional lifestyle approaches and bariatric surgeries, such as the gastric bypass, and more recently endoscopic weight loss procedures. These non-surgical procedures have increased from 2% to 4% of all bariatric procedures from just 2014 to 2016 [4]. Whilst bariatric surgery has emerged as the most effective long-term method for weight loss, some adults do not prefer this option which is associated with surgical complications (up to 15%), morbidity (3-20%), and mortality (0.1-0.5%) [5]. Furthermore, some adults with obesity are ineligible for surgery due to operative risks, cardiovascular complications, or a BMI of $\leq$35 kg/m^2 without comorbidities [6-8]. The rise in popularity of endoscopic bariatric procedures reflects their ability to meet such gaps [9, 10].

Endoscopic devices currently approved by the United States Food and Drug Administration include gastric balloon (IGB) systems, gastric emptying devices, and other space occupying devices [11]. Other endoscopic bariatric therapies reported in the literature include the transoral gastroplasty, duodenal-jejunal bypass liner, and endoscopic sleeve gastroplasty (ESG) [9, 12, 13]. Mechanisms of action of these endoscopic therapies and devices include gastric restriction, malabsorption, and/or delayed gastric emptying [14].

The weight loss and medical benefits of endoscopic devices have been reported; however, the impacts of endoscopic bariatric procedures on the patient-centred outcomes QoL and mental health are not as well understood [15-19]. The impact of weight loss procedures on QoL is seen by patients as a vital to a successful outcome [3]. The concept of quality

of life encompasses the physical body as well as emotional and social functioning, linking it inherently to mental health [20].

As the use of endoscopic bariatric therapies is increasing internationally, there is a need to understand their full impact on candidates by looking beyond weight loss to quality of life and mental health [16, 21]. Such evidence could enhance the patient-centredness of procedure selection, care planning, and outcome evaluation [22].

Research question

What is the effect of endoscopic bariatric procedures on postprocedural QoL and mental health of adult patients?

Method and Materials

Protocol and registration

A systematic review of literature was undertaken and reported according to the PRISMA guidelines [23]. The protocol was prospectively registered with the International Prospective Register for Systematic Reviews (PROSPERO number: CRD42020159822).

Eligibility criteria

Studies which included adults ≥18 years who elected an endoscopic bariatric procedure were eligible if they measured pre- and postprocedural QoL or mental health via a validated tool. The following endoscopic bariatric therapies were included in this review: ESG, IGB, transpyloric shuttle (TPS), primary obesity surgery endoluminal (POSE), duodenal-jejunal bypass liner (DJBL), aspiration therapy, duodenal mucosal resurfacing, incisionless anastomosis, overstitching endoscopic suturing system, transoral gastroplasty, and transoral endoscopic restrictive implant system. Studies were excluded when endoscopic therapy data was merged with excluded therapies including medical, lifestyle, and/or surgical weight loss. This review considered original research studies

including prospective and retrospective observational studies and intervention studies; studies were not limited by publication date. Each eligible arm of an intervention study was considered alone (i.e. not in relation to the comparator group) as representing prospective cohort data. Intervention study arms (whether comparator or intervention) which provided additional counselling and/or postprocedural variations in support beyond usual care, which would affect QoL and mental health outcomes, were excluded. Studies were sourced in any language if they could be translated to English using Google Translate [24]. Excluded publication types were conference abstracts or papers, reviews, study protocols, cross-sectional studies, and qualitative studies.

Search strategy and study selection

Studies were searched in the electronic databases: EMBASE, Medline, CINAHL, and PsycINFO. The search strategy comprised a combination of controlled vocabulary and keywords (Table S1). The search strategy was designed in PubMed and translated into other databases using the Systematic Review Accelerator Polyglot Search [25]. A structured sensitivity analysis of the search strategy was undertaken in EMBASE and CINAHL. When studies were irretrievable corresponding authors were contacted. Alerts for new studies were set up across databases, with any new eligible studies included up until 21st March 2020. Reference lists of relevant papers were hand searched to identify additional studies. Systematic search results were de-duplicated with Systematic Review Accelerator De-Duplicate software [25, 26]. Covidence software was utilized for screening of title/abstract and full text and was undertaken independently by two reviewers (AM and NG) [27]. A third reviewer (SM) assisted with eligibility disagreements. Corresponding authors were contacted for studies requiring further information to determine eligibility.

Outcomes

Outcomes were QoL, depression, anxiety, and mood. Outcomes which were considered as confounding variables on the primary outcomes included: changes in body composition (excess weight loss [EWL], body mass index [BMI], total body weight, fat mass, or waist circumference), changes in incidence or prevalence of comorbidities, and peri- and postprocedural adverse events.

Data extraction

Data were extracted a single investigator (AM or NG) and checked for accuracy by a second (JH, BFK, or IM). Any corrections to extracted data by the second reviewer were verified by a third investigator (NG or AM). For studies with missing data, corresponding authors were contacted. Where data on the same study variable was reported in multiple publications, the data extracted comprised either the most complete data (e.g. that which reported variance), data representing intention to treat analysis, or the largest sample size. Data reported in graphical form was extracted via Web Plot Digitizer software [28].

Quality assessment and risk of bias

Included articles were critically appraised by two investigators independently (AM and NG) using the Academy of Nutrition and Dietetics Quality Criteria Checklist [29]. Studies were rated as positive, neutral, or negative quality based on the internal risk of bias. Disagreements were resolved through discussion until consensus was reached and decision making was reviewed by a third authors (SM).

GRADEpro software was used to rate the confidence in the body of evidence for all studies with a primary outcome. Confidence in the body of evidence considered study design, risk of bias, consistency, directness, publication bias, effect sizes, and precision according to the Grading of Recommendations Assessment, Development and Evaluation

methodology (GRADE) approach (Table S4) [30]. GRADE was completed initially by AM and through consensus of three authors (AM, NG, SM).

Meta-analytical approach

Ccontinuous data were pooled using the inverse variance test using RevMan (Review Manager 5, Version 5.3) [31]. The total QoL score was prioritized and when not available, general health domain was used. When standard deviations were not reported, a calculation was made using the RevMan Calculator (Review Manager 5, Version 5.3). If data were presented as median (interquartile range), the distance between the interquartile range was assumed to be 1.35 standard deviations [32]. Outcomes were reported as standardized mean differences (SMD) to account for the different tools used to measure each construct. A random effects model was used across all meta-analytical models representing the substantial clinical heterogeneity expected. Studies were assessed for statistical consistency using the I^2 statistic. High levels of statistical inconsistency were explored using confounding variables, outlier results, or sample characteristics in a sensitivity analysis.

Results

Search results and study characteristics

The search strategy retrieved 5,959 records, 338 records were full text screened for eligibility, and 20 papers were included (Figure 1). Two additional records were identified through snowballing. The main reason for exclusion was study design (n=146) and surgical bariatric therapy (n=134).

The 20 studies were published between 2008 and 2019 with a total number of 876 patients (77% female). Intragastric balloons were the predominant endoscopic therapy (n=14) [2, 20, 33-45], followed by aspiration therapy (n=2) [46, 47], TOGA (n=2) [12, 48], ESG (n=1) [13], and TPS (n=1) [49] (Table S2).

Most studies were observational studies (n=15), with the remainder being randomised controlled trials (RCTs) (n=5). All studies were rated as positive quality (n=9) or neutral quality (n=11) (Table S3). The most common reasons for downgrading the quality of studies were failing to report eligibility criteria or sampling method, insufficient duration of intervention, or failure to account for confounding factors in the statistical analysis. The overall GRADE for QoL and mental health was "low" and "very low" due to the majority of the studies using a prospective observational design as opposed to randomised controlled trials, some risk of bias, and statistical inconsistency (Table S4).

Endoscopic bariatric therapies' impact on quality of life

All but one study measured QoL (n=19 studies) using a range of tools (Table 1). Eighteen studies reported a statistically significant improvement in QoL from baseline to follow-up, with only one study showing no change [44]. Interestingly, three studies appear to have misinterpreted their QoL results [36, 39, 42].

Nine studies with a total of 371 participants (n=350 at follow-up) who underwent IGB (6- to 76-month follow-up) were included via meta-analysis. Intragastric balloon placement was associated with a significant improvement in QoL (SMD:0.78; 95%CI: 0.56,1.00; P=0.05; I^2: 48%). A sensitivity analysis identified that results from De Castro et al 2010 [44] impacted on the overall I^2 and was removed in sensitivity analysis on the basis of QoL construct differences. Specifically, De Castro et al 2010 [44] used the GIQLI tool which assesses gastrointestinal-related QoL whereas other studies assessed general health-related QoL. Following sensitivity analysis, IGB placement was associated with a large improvement in postprocedural QoL (SMD: 0.85; 95%CI: 0.69, 1.02; P<0.00001; I^2: 7%; Figure 2). Insufficient data prevented other endoscopic bariatric therapies' impact on QoL being pooled via meta-analysis. It was not possible to assess publication bias due to small number of studies included in the meta-analysis.

Endoscopic bariatric therapies' impact on mental health

Depression, anxiety, and/or mental health including psychological or emotional health were assessed in seven studies, six of which excluded patients with psychiatric disorders or those taking anti-depressants [2, 41, 42, 45-47]. (Table S2). All studies reported a statistically significant postprocedural improvement in mental health. Five IGB studies were pooled via meta-analysis (n=367 participants at 6 to 76-months follow-up), finding that IGB was associated with a large improvement in the mental health, depression, or anxiety (SMD: 0.86; 95%CI: 0.29, 1.42; P=0.003; I^2=92%; Figure 3). Insufficient data prevented other endoscopic bariatric therapies' impact on mental health being pooled via meta-analysis. It was not possible to assess publication bias due to small number of studies included in the meta-analysis.

Impact of confounding factors on quality of life and mental health

All studies in the meta-analysis were neutral quality except two studies [2, 20]. Studies reporting the most significant changes in QoL and mental health were rated neutral [34, 40]. All studies reported a significant decrease in weight as changes to total body weight, BMI, TBWL%, or EWL%. The two studies (Guedes et al 2019 and Deliopoulo et al 2013) with the largest improvements in mental health also had the greatest weight loss [40, 43]; however, associations with strength of weight loss and change in mental health were not consistent thereafter. The largest improvements in QoL did not coincide with the highest mean weight loss. Guedes et al 2019 [40] reported the largest weight loss but only a small improvement in QoL. However, Tayyem et al 2014 [34] and Fuller et al 2013 [42] had slightly less but very similar weight loss to Guedes et al 2019 [40] and reported the most significant improvements in QoL.

Improvements in one or more comorbidities at follow-up were reported in nine studies including significant improvements and/or remission of type II diabetes mellitus,

hypertension, obstructive sleep apnoea, and metabolic syndrome [12, 13, 20, 33, 39-41, 46-48]. Studies that reported comorbidity risk factors (blood pressure, HbA1c, triglycerides, or LDL cholesterol) also reported improvements (Table S2). Three studies did not report follow-up comorbidity data (34, 40, 48). No association was seen between improvements in comorbidities and improvements in QoL or mental health.

Adverse events were reported categorically as ordinal or nominal variables or as a reason for study withdrawal in 13 studies [2, 20, 33, 36-39, 41, 42, 44, 46-49]. The most common adverse events were nausea and vomiting. Early balloon removal occurred in three studies: 1.2% in Alfredo et al 2014 [41], 3.4% in Mui et al 2010 [20] and 22% in Guedes et al 2017 [2]. Although the impact of adverse events on QoL in De Castro et al 2010 [44] was evident, there was no other clear associations found between adverse events and mental health or QoL.

The amount and type of multidisciplinary support provided to patients varied and was only reported in 10 of the 20 studies [2, 20, 37-39, 41-43, 46, 47]. Types of support included: unlimited 24 hour phone support [43], follow-up with a dietitian [2, 20, 41, 43], nutrition counselling [38, 39, 47], cognitive behavioural therapy [47], and/or a lifestyle modification program [42, 46]. Studies with the most significant improvements in mental health and QoL provided patients with the most support [2, 20, 42, 43]

Discussion

This systematic review and meta-analysis evaluated the effects of endoscopic bariatric procedures on postprocedural QoL and mental health using mostly observational evidence. Qualitative synthesis found strong and consistent improvements in QoL (95% of studies) and mental health (100% of studies). Meta-analyses of IGB studies also showed large statistically significant improvements in QoL and mental health. Pooled findings showed strong consistency for QoL; however, there was statistical inconsistency

in pooled effects on mental health, likely due to slight differences in the concepts included in mental health assessment tools. Although pooled effect sizes were large for the impact of IGB on postprocedural QoL and mental health; confidence in the body of evidence was low and very low respectively, where main reasons for downgrading were related to risk of bias in the included studies and the observational study design, highlighting the need for further RCTs.

A systematic review by Lindekilde et al [50] evaluated the impact of any bariatric procedure (mostly surgical, two were endoscopic), reporting similar improvements in postprocedural QoL. The previous review found an association of positive changes in QoL with higher weight loss [50]. However, the current review did not find a consistent positive association between weight loss and quality of life. The drivers of improvements in QoL following endoscopic bariatric procedures may be necessarily be due to the amount of weight loss alone and is likely to also reflect changes in physical appearance and physical function, general health through improvements in comorbidities, and social functioning due to increased confidence [12, 35]. Although this study did not identify an association between quality of life or mental health with improved comorbidities, this is likely a reflection of comorbid outcomes being inconsistently measured. Gastrointestinal-related QoL seems to differ from other postprocedural QoL domains. This review found much smaller and/or no improvements in gastrointestinal-related QoL, likely related to commonly reported gastrointestinal adverse events by studies using endoscopic bariatric procedures [50].

The reported improvements in mental health found in this review also align with the findings of Dawes et al [51], which evaluated the impact of bariatric surgery on mental health. Spirou et al [16] also found similar results at six-months postoperative; although, results at ≥36-months showed a reduction in mental health improvements. These findings suggested that QoL and mental health improvements may not be retained long-term and

may be due to a 'psychological honeymoon period' due to initial weight loss [16]. This may be translatable to endoscopic bariatric procedures, many of which are temporary. An association with weight change and mental health was identified in this review, which is inconsistent with previous research. Results suggest the amount of weight lost positively impacted participants mental health change; each study displayed a significant decrease in weight following endoscopic procedures. Canetti et al [52] analysed the change in mental health and QoL in Silastic Ring Vertical Banded Gastroplasty (laparoscopic) patients. Findings showed even though weight loss at 10-years was maintained, improvements in mental health were not.

The study with the most significant improvement in mental health and weight loss offered 24-hour telephone support and monthly dietitian follow-ups. A recent systematic review and meta-analysis found that compared with standard multidisciplinary care, intensive pre- and/or postoperative psychological intervention resulted in significantly improved postoperative symptoms of depression and anxiety [53]. This suggests that while bariatric procedures, whether endoscopic or surgical, may improve mental health at least temporarily, the greatest improvements are seen with intensive multidisciplinary support, aligning with bariatric clinical practice guidelines [54].

Limitations

Meta-analysis was limited by the number of diverse endoscopic procedures which have measured and adequately reported postprocedural QoL and mental health. Conclusions are also limited by the short duration of follow-up; meaning results cannot be interpreted to represent long-term outcomes. The meta-analysis was unable to control for variations of the effect of the procedure and confounding characteristics [55]. The exclusion of patients with psychiatric disorders or those taking anti-depressants limits the generalisability of the findings on mental health. Confidence that the estimated pooled means reflect the true change in QoL and mental health is low and very low. Therefore,

findings must be interpreted with the understanding that they may change with the availability of higher quality evidence, such as that from well conducted RCTs with adequate blinding and length of follow-up.

Implications for future practice and research

Health professionals should recognise the importance of QoL and mental health to patients and provide multidisciplinary support in line with the latest clinical practice guidelines [55], which includes dietetic and psychological intervention. Future research should be improved by strengthening the reporting of methods and results by utilising validated checklists such as the STROBE checklist for observational studies [56]. Studies should also seek to always contain patient-centred outcomes such as QoL, mental health, and the effects of weight stigmatisation in addition to clinical weight loss and medical outcomes. Consideration should be given to the reporting of results, including the reporting of baseline, change, and follow up measures of central tendency and variance, and not report results only graphically. Future research should incorporate QoL and mental health as an integral outcome of therapy success with further examination of weight-stigma.

Conclusion

Endoscopic bariatric procedures, particularly IGB, may improve postprocedural QoL and mental health alongside weight loss and comorbidity improvements; however, their effect on long term QoL and mental health is unknown. Multidisciplinary support by dietitians and/or psychologists is important for optimising QoL and mental health outcomes. Further research is required to understand the impact of diverse types endoscopic bariatric procedures on QoL and mental health in the long term.

Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

Conflict of interest

The authors declare there are no conflict of interest.

Abbreviations

BAROS, Bariatric Analysis and Reporting Outcome System

BQL, Body Quality of Life

DJBL, Duodenal-jejunal bypass liner

ESG, Endoscopic Sleeve Gastroplasty

EWL, Excess Weight Loss

FDA, Food and Drug Administration

GIQLI, Gastrointestinal Quality of Life

IGB, Intragastric Balloon

OR, Odds Ratio

POSE, Primary obesity surgery and endoluminal

QoL, Quality of life

SF-36, Short Form Health Survey

SMD, Standardised Mean Difference

TPS, Transpyloric Shuttle

Conflict of interest

The authors declare there are no conflict of interest.

Ethical approval statement

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Informed consent.

Informed consent does not apply.

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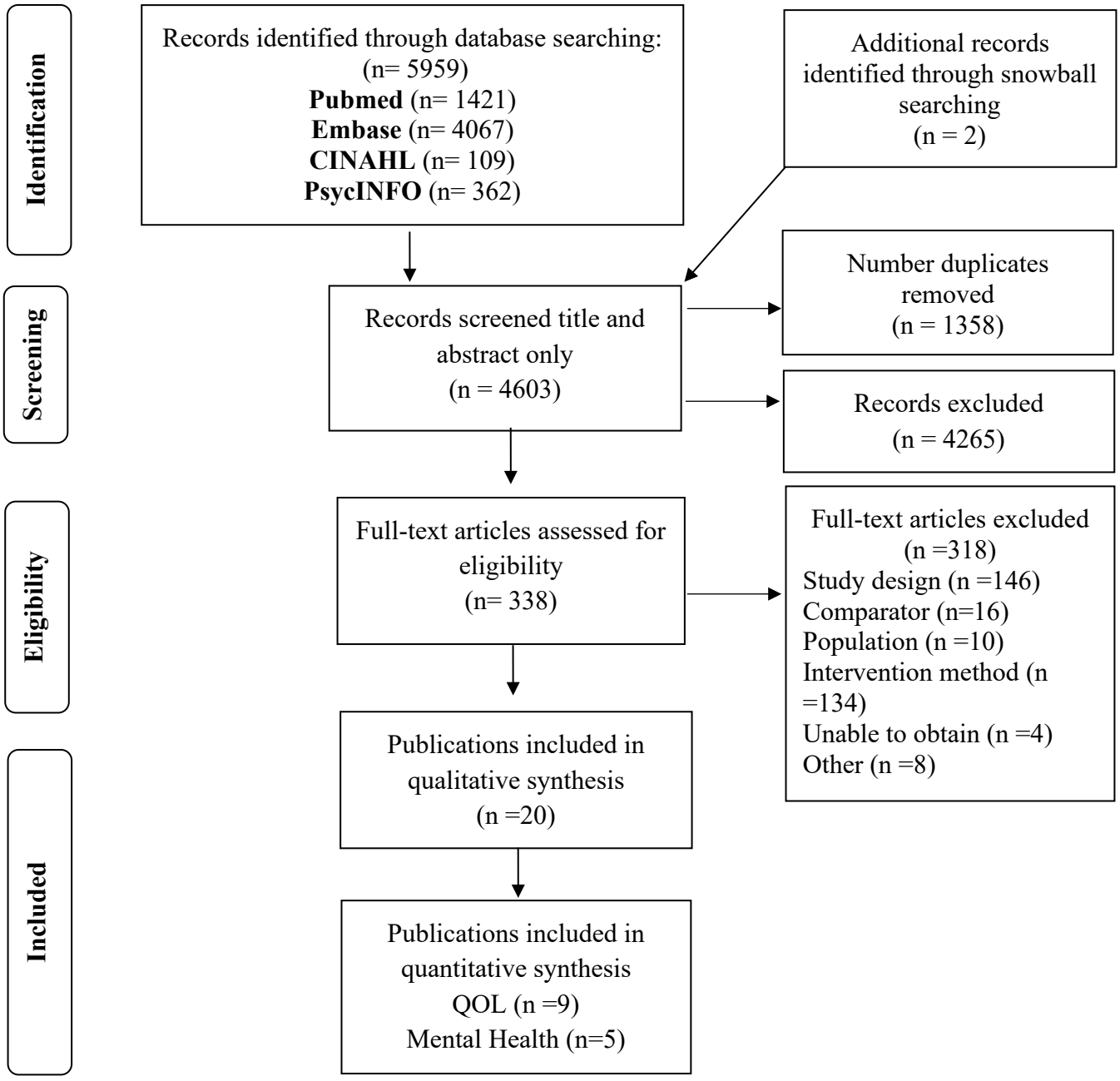

Figure 1: PRISMA diagram for the study

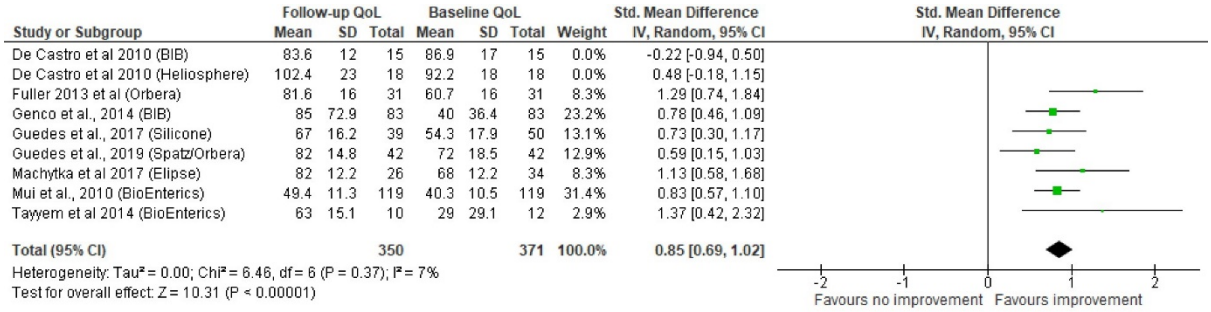

Figure 2. Pooled effects of intragastric balloon placement on pre- to postprocedural quality of life.

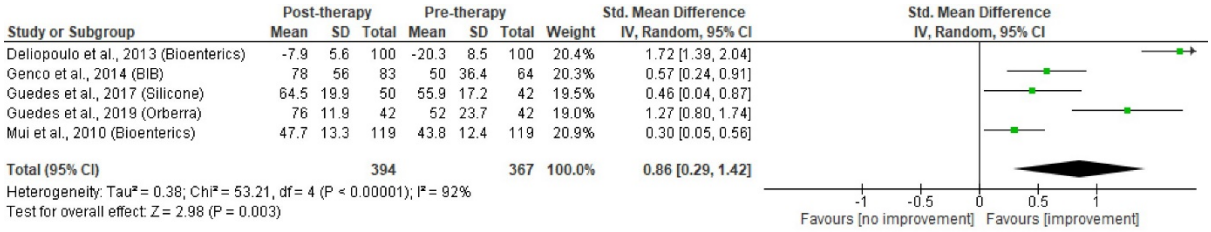

Figure 3. Pooled effects of intragastric balloon placement on pre- to postprocedural mental health

Table 1. Characteristics and outcomes of the 20 included publications which reported quality of life and/or mental health pre and post endoscopy bariatric therapies in adults.

Study design, setting and participants	Endoscopic therapy	Outcomes
Ahmed et al, 2019 [45]; Prospective study-; 2008-12; Iraq; BIB: n= 40, 100%F, µ27y (range: 20-39y), BMI µ36 (range: 31–39.9) kg/m^2, 0% attrition.	BIB; Duration of Tx: 6m; Method: inserted under sedation, 600mL saline containing 10% methyl blue; Follow-up: d7, d14, then monthly.	**Quality of life (6m follow-up):** EQ-5D: NR.
De Castro et al 2010 [44]; Prospective study; 2006-9; Spain; BIB: n=15, 67%F, µ45.4±8y, BMI µ44.2±6 kg/m2. Heliosphere IGB: n=18, 72%F, µ42.7±12y, BMI µ44.2±5 kg/m^2, 18% attrition.	BIB; Duration of Tx: 6m; Method: inserted under conscious sedation, 700ml saline containing methylene blue; Follow-up: monthly.	**Quality of life (6m follow-up):** GIQLI score: baseline µ86.9±17. Follow-up: µ83.6 ±12. Calculated change: -3.3.
	Heliosphere IGB; Duration of Tx: 6m; Method: 960cm^3 air; Follow-up: monthly.	**Quality of life (6m follow-up):** GIGLI score: baseline µ92.2+18. Follow-up: µ102.4 ±23. Calculated change: +10.2.
Deliopoulo et al, 2013 [43]; Prospective study-; 2009–2010; Greece; IGB: n=100; Depressed group: n=65, 100%F, µ37.52 + 11.77y [median: 37, range: 19-61], µ43.5 + 9.5 kg/m2. Non-depressed group: n=35, 100%F, 33.89 + 11.50y [33,18-63], BMI 41.9 + 7.4 kg/m^2, 0% attrition.	BioEnterics IGB; Duration of Tx: 6m; Method: inserted under sedation; Follow-up: monthly + 24h telephone helpline.	**Depression symptoms (6m follow-up):** BDI-II baseline: µ20.3 + 8.5 [range: 10-54]. Follow-up: µ7.9 + 5.6 [range: 0-26], p<0.0001. Calculated change = -12.4.
Familiari et al, 2011. [12]; Prospective study-; 2007-2010; Italy & Belgium; TOGA: n=67; follow-up n=53; 70%F, µ41.0+9.7y, BMI µ41.5+3.6 kg/m^2, 21% attrition.	TOGA sleeve stapler & restrictor systems; Method: inserted under sedation, sleeve stapler device; Follow-up: monthly.	**Quality of Life (12m follow-up):** SF-36v2 & IWQOL-Lite: p= < 0.001.
Fiorillo et al, 2020 [13]; Retrospective study; 2016-2018; France; ESG: n=84;; 70%F, µ41y (range: 35-43y), BMI µ39.5 (range: 36.7-44.7) kg/m^2, 50% attrition.	OverStitch, Apollo Endo-surgery; Method: flexible endoscopic suturing system; Follow-up: 6m.	**Quality of Life (6m follow-up):** GIQLI scores: Baseline: 105. Follow-up: 119. Calculated change: +14 (range: 3-24). Data reported graphically.
Fuller et al, 2013 [42]; RCT-; 2008-2010; Australia; Treatment: IGB: n= 31, 68% F, µ43y, 36 kg/m2. Control: Lifestyle modification n=35, 66% F, µ48.1y, 36.7 kg/m^2, 26% attrition (ITT used)	Orbera; Duration of Tx: 12m; Method: inserted using standard protocol [57], 450-700ml saline; Follow-up: 6m, every 3m.	**Quality of Life (6m follow-up):** IWQOL-Lite: Baseline: 60.7+16. Calculated change: 20.9.
Alfredo et al, 2014 [41]; Prospective study; Italy; IGB: n=83, 77%F, µ37.4y, BMI 43.74 kg/m^2, 41% attrition.	BIB; Duration of Tx: 6m; Method: Propofol sedation, 500mL saline. Multiple IGB: Reintroduced after weight gain ≥50%, n=83 had 2nd IGB, n=22 (18%) had 3rd IGB, n=1 (1.2%) had 4th IGB; Follow-up: 12m, 6y.	**Quality of life (76m follow-up) n=64/83:** SF-12: Baseline: Physical: µ40 + SE (4), Mental health: µ50 + SE (4). Follow-up: Physical: µ85 + SE (8), calculated change: +45, Mental health: µ78 + SE (7), calculated change: +28, p=<0.001. Data reported graphically.

Guedes et al, 2019. [40]; Prospective study-; 2016-2018; Brazil; IGB: n=42; 76%F, µ37.60±1.28y, BMI µ35.15±0.41kg/m^2, 0% attrition.	Orbera or Spatz; Duration of Tx: 6m; Method: inserted under sedation, 600-700mL saline, containing 4% methylene blue; Follow-up: 6m, monthly.	**Quality of Life (6m follow-up):** SF-36 mean + IQR score: Baseline: general health: (72, 57-82), MH (52, 40-72). Follow-up: general health (82, 72-92, p=0.0002), MH (76, 68-84, p=0.0003). Calculated change: general health: +10, MH: +24.
Marinos et al, 2014. [49]; Prospective study; Australia; Transpyloric shuttle 3m: n=10, 90%F, µ36.3+11.4y, BMI µ34+1.3kg/m2. Transpyloric Shuttle 6m: n=10, 90%F, µ45+8.3y, BMI µ37.9+7.3kg/m^2, 0% attrition.	TransPyloric Shuttle; Duration of Tx: 3m; Method: inserted under sedation; Follow-up: 6m	**Quality of Life (6m follow-up):** IWQOL-Lite score: Calculated change: +20.4+14.2.
	TransPyloric Shuttle; Duration of Tx: 6m; Follow-up: 6m	**Quality of Life (6m follow-up):** IWQOL-Lite score: Calculated change: + 23.3±20.5.
Machytka et al, 2017 [39]; Prospective study-; 2014-2015; Czech Republic & Greece; IGB: n=34; 67%F, 42+11y (range: 18-59y), BMI 34.8+3.7kg/m2 (range: 27-40kg/m^2), 6% attrition.	Elipse device; Duration of Tx: 4m (range: standard 117-141d; experimental 30-141); Method: IGB inside capsule, attached to catheter via a patented self-sealing valve and swallowed, 550mL of fluid (n=28); Follow-up: fortnightly.	**Quality of Life (4m follow-up):** IWQoL total score (n=26): Baseline: µ68. Follow-up µ82±12.2. Calculated change: -14.
Moreno et al, 2008 [48]; Prospective study; Belgium; TOGA: n=11, 64%F, µ44.2+10.7y, BMI µ41.6+4.3kg/m^2, 0% attrition.	TOGA System sleeve stapler; Method: inserted under sedation; Follow-up: monthly.	**Quality of Life (6m follow-up):** SF-36 total score: Baseline: 96. Follow-up: 49.9. Calculated change: -46; IWQOL-Lite domain scores: general health (40.4), MH (40). Follow-up: general health (56.7), MH (50). Calculated change: general health: +16.3, MH: +10.
Mui et al, 2010 [20]; Prospective study; 2005-2006; China; IGB: n=119, 72%F, µ37.8+10y, BMI: µ38.4+8.0 kg/m2, (range: 26.5 - 69.1kg/m^2), 0% attrition.	BioEnterics IGB; Duration of Tx: 6m; Method: inserted & removed by surgical team, µ542.7+28.2mL; Follow-up: weekly with dietitian for 1m, then monthly.	**Quality of life (6m follow-up):** SF-36: (Chinese Version): General health baseline: µ 40.3+10.5, follow-up: 49.4+11.3, calculated change: µ-9.1. MH: baseline: µ43.8+12.4, follow-up: µ47.7+13.3, calculated change: µ3.9, (p>0.014).
Norén& Forssell 2016 [47]; Prospective study; 2012-2013; Sweden; Aspiration Therapy: n=25, 92%F, µ48y, (range: 33-65y), BMI µ39.8+4.3 kg/m^2, 20% attrition.	Aspire Assist System; Duration of Tx: 12m (optional additional 12m); Method: custom gastrostomy tube percutaneously inserted during gastroscopy under sedation. Drainage & irrigation of stomach 3x/day; Follow-up: 4 in 3m, then every 3m.	**Quality of life (12m follow-up):** EQ-5D baseline: µ0.7±0.3, follow-up: µ0.9+0.1 (p<0.01), VAS baseline: µ63+15, follow-up: µ83+14, (p<0.01).
Ponce et al, 2012 [38]; RCT; 2010- 2011; USA; IGB: n=21, 81%F, µ38.9+9.1y, BMI µ34.7+2.6kg/m^2, 5% attrition.	ReShape Duo IGB System; Duration of Tx: 6m; Method: 900mL saline; Follow-up: monthly-6m, bi-weekly-48weeks.	**Quality of Life (6m follow-up):** SF-36 domain scores: baseline general health (73.9), MH (87.3). Follow-up: general health (80.7), MH (86.1). Calculated change: general health +6.8, MH -1.2.
Reimao, 2018 [37]; Prospective observational study-; 2014-2016; Brazil; IGB: n=40, 78%F, µ45.3+7.6y (range: 25-57y), BMI µ32.9+2.0 kg/m^2, 10% attrition.	Orberra IGB; Duration of Tx: 6m; Method: inserted under general anaesthesia, 600mL saline and methylene blue dye; Follow-up: monthly (nutritionist).	**Quality of life (6m follow-up):** SF-36 (validated Portuguese version) General Health (%) baseline: µ43, follow-up: µ68, calculated change: +25. MH (%) baseline: µ62, follow-up: µ79, calculated change: +17. Data reported graphically.

Raftopoulos et al, 2017. [36]; Prospective observational, nonrandomised study; Greece; IGB: n=12, 58%F, µ41y (range: 18-59y), BMI µ36.1+3.2kg/m^2, 8% attrition	Elipse Balloon; Duration of Tx: 4m; Method: insertion via swallow with water, 550mL water containing citric acid/potassium sorbate preservative; Follow-up: fortnightly.	**Quality of Life (12m follow-up):** IWQOL-Lite score: Baseline 65. Follow-up: 58. Calculated change: -7.
Guedes et al 2017[2], Guedes et al 2016 [35]; Prospective observational study-; 2011-2012; Brazil; IGB: n=50, 80%F, µ34.6+7.1y, BMI µ40+6.3 kg/m^2, 22% attrition.	Silmed Silicone IGB; Duration of Tx: 6m; Method: inserted under sedation, 650mL saline solution (0.9%) and 20mL methylene blue solution; Follow-up: weeks 0, 8,16 & 24.	**Quality of life (6m follow-up):** WHOQOL-BREF Physical domain baseline; µ54.3±17.9, follow-up; µ67.0±16.2, p<0.01, Psychological domain baseline; µ55.9±17.2, follow-up; µ64.5±19.9, p 0.03. Calculated change: physical: +12.7, psychological: +8.6.
		Depression/Anxiety (6m follow-up): *BDI: Baseline: µ16 (median), (range: 1-32), follow-up; µ6, (range: 0-45), change: µ4.57±10.6, (p=0.0019); HADS-D baseline: µ7 (range: 1-14), follow-up: 4 (0-18), change: 1.82±5.16, (p=0.0345).
Tayyem et al, 2014 [34]; Single centre, prospective study-; 2010-2010; Scotland; IGB: n=12, 62%F, µ40y, BMI µ55.9kg/m^2, attrition unclear.	BioEnterics IGB (BIB) System; Duration of Tx: 6m; Method: inserted under sedation, 600mL saline containing methylene blue.	**Quality of Life:** SF-36 domain scores: Baseline general health: 29. Follow-up: general health: 63. Calculated change: general health: +34.
Tayyem et al, 2011 [33]; Prospective study; 2008-2010; IGB: n=17, 65%F, µ40.9y, BMI µ61.4+8.3 kg/m^2, 0% attrition.	BioEnterics IGB (BIB) System; Duration of Tx: 6m; Method: inserted under sedation, 600mL saline containing methylene blue; Follow-up: quarterly.	**Quality of Life (9m follow-up):** SF-36 domain scores: Baseline general health: 28. Follow-up: general health: 70. Calculated change: general health: +42, p<0.021. Data reported graphically.
Thompson et al, 2017 [46]; RCT-; 2012-2015; USA; Aspiration therapy: n=111, 83%F, µ43.5+10.2y, BMI µ42.4+5.0 kg/m^2, 26% attrition.	Aspire Assist System; Duration of Tx: 52w; Method: Endoscopically placed percutaneous gastrostomy tube, external device for drainage 20mins post-meal; Follow-up: week 0, 2,6,10,14,20,24,28,32,36,40,44,48 & 52.	**Quality of life (12m follow-up):** IWQOL Total Score change: µ6.2+13.4.

BDI: Beck Depression Inventory; **BDI-II;** Beck Depression Inventory II; **BFM:** Body fat mass; **BMI:** body mass index; **BW**: Body weight; **CRP:** C-reactive Protein; **DBP:** Diastolic blood pressure; **DLD:** dyslipidaemia; **DM:** diabetes mellitus; **ED:** Eating disorder; **EQ-5D:** European Quality of life measurement questionnaire; **ESL:** English as a second language; **EW:** Excess weight; **EWL:** excess weight loss; **FBGL:** Fasting blood glucose; **GIQLI:** Gastrointestinal Quality of Life Index; **Hx:** history; **HDAS-A:** Hospital Anxiety and Depression Scale (Anxiety score); **HDAS-D:** Hospital Anxiety and Depression Scale (Depression Score); **HTN:** hypertension; **IBD:** inflammatory bowel disease; **IGB:** intragastric balloon; **IQR**: interquartile range; **ITT,** intention to treat; **IWQOL-Lite:** Impact of Weight on QOL-Lite; **LDL:** low density lipoprotein; **MH**: mental health; **MI:** myocardial infarction; **MS:** Metabolic Syndrome; **NR:** not reported; **QOL**: quality of life; **SBP:** Systolic blood pressure; **SD**: standard deviation; **SF-12:** Quality Metric's Short Form; **SF-36:** 36-Item Short-Form Health Survey; **TBWL:** Total body weight loss; **TC:** Total Cholesterol; **TG:** Triglycerides; **TOGA:** transoral gastroplasty; **VAS:** Visual Analogue Scale; **WC:** Waist circumference; **WL:** Weight loss.

BDI: score decreases [58]
BDI-II: score decreases [59]
EQ-5D: score increases[60].
GIQLI: score increases. 4 is the most desirable option, 0 is the least desirable option [61]
HDAS: score decreases[62] **IWQOL-BREF:** A higher score indicates an improved quality of life [63]

IWQOL-Lite: score increases. Scores range from 0 to 100, with 100 representing the best quality of life [64]
IWQOL: higher scores indicated lower levels of functioning and QOL [65]
SF-12: score decreases [66]
SF-36: A higher score indicates a better health status [67]

Table S1: Systematic search strategy

MEDLINE (via PubMed) was searched 21st October 2019 using keywords (title and abstract) and MeSH Terms. Result = 1421 records

((((("Obesity, Morbid /surgery"[Mesh] OR ("morbid obesity"[tiab] AND surgery[tiab])) OR "Obesity, Morbid /therapy"[Mesh]) OR ("Morbid obesity"[tiab] AND therapy[tiab]))) OR ((((((((((((((((((((((((Gastroplasty[Mesh]) OR Gastroplasty[tiab]) OR "Single-Balloon Enteroscopy"[Mesh]) OR "Single-balloon enteroscopy"[tiab]) OR "Double-Balloon Enteroscopy"[Mesh]) OR "Double-balloon enteroscopy"[tiab]) OR "Double-balloon enteroscopy"[tiab]) OR Bioenterics[tiab]) OR Orbera[tiab]) OR Spatz[tiab]) OR "transpyloric shuttle"[tiab]) OR "endoscopic sleeve gastroplasty"[tiab]) OR "aspire assist"[tiab]) OR ((incisionless[tiab]) AND "anastomosis, surgical"[Mesh])) OR "anastomotic system"[tiab]) OR "Balloon Enteroscopy"[Mesh]) OR "balloon enteroscopy"[tiab]) OR "Gastric balloon"[tiab]) OR "intragastric balloon*"[tiab]) OR BIB[tiab]) OR IB[tiab]) OR "ESG bariatric"[tiab]) OR "gastric bubble"[tiab]) OR "intragastric bubble"[tiab])AND (((((("Quality of life"[Mesh]) OR "quality of life"[tiab]) OR hrql[tiab]) OR qol[tiab]) OR hrqol[tiab])

CINAHL (via Ebscohost) was searched on 21st October 2019 using keywords and CINAHL Headings. Results = 109 records

TI (hrqol) OR AB (hrqol) OR TI (hrql) OR AB (hrql) OR TI ("Quality of Life") OR AB ("Quality of Life") OR MH "Quality of Life" AND TI ("gastric bubble") OR AB ("gastric bubble") OR TI (BIB) OR AB (BIB) OR TI ("double-balloon enteroscopy") OR AB ("double-balloon enteroscopy") OR TI ("Single-balloon enteroscopy") OR AB ("Single-balloon enteroscopy") OR TI ("intragastric balloon") OR AB ("intrgastric balloon") OR TI ("gastric balloon") OR AB ("gastric balloon") OR TI ("aspire assist") OR AB ("aspire assist") OR TI ("endoscopic sleeve gastroplasty") OR AB ("endoscopic sleeve gastroplasty") OR TI ("transpyloric shuttle") OR AB ("transpyloric shuttle") OR TI (spatz) OR AB (spatz) OR TI (orbera) OR AB (orbera) OR TI (Bioenterics) OR AB (Bioenterics) OR TI ("balloon enteroscopy") OR AB ("balloon enteroscopy") OR MH "Balloon Enteroscopy" OR TI (gastroplasty) OR AB (gastroplasty) OR MH "Gastroplasty" AND (TI ("morbid obesity") OR AB ("morbid obesity")) OR (TI (surgery) OR AB (surgery)) OR MH "Obesity, Morbid" AND (TI ("therapy") OR AB ("therapy"))

EMBASE was searched 21st October 2019 for citations from both Embase and MEDLINE using keywords (abstract and title) and Emtree terms Results = 4066 records

hrqol:ab,ti OR hrql:ab,ti OR 'quality of life'/exp OR 'quality of life':ab,ti AND bib:ab,ti OR 'gastric bubble':ti,ab OR 'esg bariatric':ti,ab OR ib:ti,ab OR 'stomach bypass device':ti,ab OR 'intragastric balloon':ti,ab OR 'gastric balloon'/exp OR 'gastric balloon':ti,ab OR 'balloon enteroscopy':ti,ab OR 'balloon enteroscopy'/exp OR 'aspire assist':ti,ab OR 'transpyloric shuttle':ti,ab OR orberra:ti,ab OR spatz:ti,ab OR bioenterics.ti,ab OR 'double balloon enteroscopy':ti,ab OR 'single balloon enteroscopy':ti,ab OR 'single balloon enteroscopy'/exp OR 'endoscopic sleeve gastroplasty'/exp OR 'endoscopic sleeve gastroplasty':ti,ab OR 'obesity therapy':ti,ab OR 'obesity therapy'/exp OR 'stomach bypass device'/exp OR 'morbid obesity':ab,ti OR 'surgery'/exp OR 'bariatric surgery'/exp OR 'anastomotic system':ti,ab OR 'anastomosis, surgical':ti,ab OR 'anastomosis and surgical':ti,ab OR incisionless:ti,ab

PsycINFO was searched 22nd October 2019 using keywords (title and abstract) and PsycINFO Terms. Result = 362 records

exp Obesity/ and exp Surgery/ OR "morbid obesity".ab,ti. OR surgery.ab,ti. OR therapy.ab,ti OR gastroplasty.ab,ti. OR "Single-Balloon Enteroscopy".ab,ti. OR "Double-Balloon Enteroscopy".ab,ti. OR Bioenterics.ab,ti. OR Orbera.ab,ti. OR Spatz.ab,ti. OR "transpyloric shuttle".ab,ti. OR "endoscopic sleeve gastroplasty".ab,ti. OR "aspire assist".ab,ti. OR incisionless.ab,ti. OR "anastomosis, surgical".ab,ti. OR "anastomotic system".ab,ti. OR "Balloon Enteroscopy".ab,ti. OR "Gastric balloon".ab,ti. OR "intragastric balloon".ab,ti. OR BIB.ab,ti. OR IB.ab,ti. OR "ESG bariatric".ab,ti. OR "gastric bubble".ab,ti. OR "intragastric bubble".ab,ti. AND exp *"Quality of Life"/ OR hrql.ab,ti. OR hrqol.ab,ti. OR qol.ab,ti.	
Total	5958 records

Table S2: Extended version of characteristics and outcomes of the 20 included publications which reported quality of life and/or mental health pre and post endoscopy bariatric therapies in adults.

Study design, setting and participants	Endoscopic therapy	Outcomes	Comment
Ahmed et al 2019 (56) Prospective 2-arm (1=endoscopic; 1=Atkins diet) randomised descriptive longitudinal study-; 2008-12. Exclusion: psychological problems, taking psychotropic drugs, previous IB or bariatric surgery, peptic ulcers, binge eating disorders. Iraq BIB: n= 40, 100%F, µ27y (range: 20-39y), BMI µ36 (range: 31–39.9) kg/m2.	BIB Duration of Tx: 6m Method: inserted under sedation, 600mL saline containing 10% methyl blue. Follow-up: d7, d14, then monthly.	Quality of life (6m follow-up): EQ-5D: NR. Weight loss: EWL%: 31-35kg (47.5%), p=0.00001	No funding received. Author contacted about type of QOL tool used; could not provide data. Participants reported daily teasing prior to therapy, afraid of media stating risks of obesity, obesity made participants uneasy socialising with friends – narrowed social circles and weight as an obstacle to obtaining a job.
De Castro et al 2010 (55) Prospective 2-arm (2=endoscopic) double-blinded study; 2006-9. Exclusion: disease of upper GIT, hiatus hernia >3cm, anti-inflammatory agents, anticoagulants. Spain. BIB: n=15, 67%F, µ45.4±8y, BMI µ44.2±6 kg/m2. Heliosphere IGB: n=18, 72%F, µ42.7±12y, BMI µ44.2±5 kg/m2.	BIB Duration of Tx: 6m Method: inserted under conscious sedation, 700ml saline containing methylene blue. Follow-up: monthly.	Quality of life (6m follow-up): GIQLI score: baseline µ86.9±17. Follow-up: µ83.6 ±12. Calculated change: -3.3. Weight loss: Baseline: µ121+18kg. Calculated change: -13kg. EWL%: µ30.2±19%. Adverse events: n=3/15 continuous vomiting and dehydration.	Funded by a FISS grant.
	Heliosphere IGB Duration of Tx: 6m Method: 960cm3 air Follow-up: monthly.	Quality of life (6m follow-up): GIGLI score: baseline µ92.2+18. Follow-up: µ102.4 ±23. Calculated change: +10.2. Weight loss: Baseline: µ119+17kg. Calculated change: -13kg. EWL%: µ27±16.	
Deliopoulo et al 2013 (54) Prospective study-; 2009–2010. Exclusion: no alcohol, drug problems or active psychosis. Greece IGB: n=100	BioEnterics IGB Duration of Tx: 6m Method: inserted under conscious or unconscious sedation under endoscopic vision.	Depression symptoms (6m follow-up): BDI-II baseline: µ20.3 + 8.5 [range: 10-54]. Follow-up: µ7.9 + 5.6 [range: 0-26], p<0.0001. Calculated change = -12.4. Weight loss (kg): Baseline: µ124.7 + 32.3kg. Follow up: µ103.7 + 30.1kg, p= 0.983. Calculated change: -21kg.	No funding received. Authors contacted about brand of balloon & funding source. Theorised self-esteem and subjective well-being are influenced by poor self-

Depressed group: n=65 (mild-26, moderate-21, severe-18), 100%F, µ37.52 + 11.77y [median: 37, range: 19-61], µ43.5 + 9.5 kg/m2. Non-depressed group: n=35, 100%F, 33.89 + 11.50y [33,18-63], BMI 41.9 + 7.4 kg/m2.	Follow-up: monthly. Dietitian and 24h telephone helpline available for support.	EWL%: µ39.6%. Weight loss (kg): Baseline: µ122.3 + 24.2kg. Follow up: µ103.6 + 24.1kg. Calculated change = -18.7kg. EWL%: µ36.1kg.	reported physical health and body image" than body weight itself.
Familiari et al. 2011. (13) Prospective single-arm study-; 2007-2010. Exclusion: BMI >55kg/m2, hiatus hernia >2cm, previous bariatric surgery, inflammatory disease of GIT, pregnancy or breast feeding, HIV, esophagitis, alcohol/drug addiction, present infection, thyroid disease, hx of scleroderma. Italy & Belgium. TOGA: n=67; follow-up n=53; 70%F, µ41.0+9.7y, BMI µ41.5+3.6 kg/m2.	TOGA sleeve stapler & restrictor systems. Method: inserted under sedation, sleeve stapler device. Follow-up: monthly.	Quality of Life (12m follow-up): SF-36v2 & IWQOL-Lite: p= < 0.001. Weight loss: Baseline: µ116.6+18.5kg. Calculated change: -19+8.5kg. EWL%: µ38.7+ 7.1%. Comorbidities: Baseline: DM n=4/67. Follow-up: DM n=3/53 (p=0.0005).	Funding by Satiety Inc. n=2 underwent laparoscopic bariatric procedures within 12m-post TOGA.
Fiorillo et al. 2020 (14) Retrospective single-centre study-; 2016-2018. France ESG: n=42; follow-up n=23; 16F (69.6%), µ41y (range: 35-43y), BMI µ39.5 (range: 36.7-44.7) kg/m2.	OverStitch, Apollo Endo-surgery. Method: flexible endoscopic suturing system. Follow-up: 6m.	QOL (6m follow-up): GIQLI scores: Baseline: 105. Follow-up: 119. Calculated change: +14 (range: 3-24). Data reported graphically. Weight loss: Baseline: µ115.5+29.6kg. EWL%: 39.9 (range: 17.5-58.9) %. Comorbidities: Baseline: DM: n=2/23, HTN n=3/23, OSA n=5/23. Follow-up: DM n=1/23, HTN n=2/23, OSA n=2/23.	
Fuller et al 2013 (53) RCT-; 2008-2010. Exclusion: Conditions increasing the risks associated with endoscopy or insertion of IGB, inflammation of GIT, upper GI bleeding conditions, hx of symptoms of oesophageal or GI	Orbera. Duration of Tx: 12m Method: inserted using standard protocol (61), 450-700ml saline. Follow-up: 6m, every 3m. 12m behavioural modification program (diet and exercise).	QOL (6m follow-up): IWQOL-Lite: Baseline: 60.7+16. Calculated change: 20.9. Weight loss: Baseline: µ104.6kg. Calculated change: -14.4kg. %EWL: µ50.3%. Adverse events:	Funded by a grant to the Boden Institute by Allergan Australia Pty Ltd.

motility disorders, hiatus hernia >5cm, structural abnormality of the GI tract, prior gastric surgery or IGB, or major surgery within 3m, cerebrovascular or cardiopulmonary disease, uncontrolled BP (>160/95 mmHG), epilepsy, T1DM, undiagnosed thyroid disease or hypothyroidism in which the dose of thyroxine replacement has not been stable for at least 3m, hepatic or renal insufficiency, psychiatric disorder or pregnancy. Australia Treatment: IGB: n= 31, 68% F, µ43y, 36 kg/m2. Control: Lifestyle modification n=35, 66% F, µ48.1y, 36.7 kg/m2.	Control Group T2DM Lifestyle Intervention Program. 12 months, 3 months	75% nausea/vomiting, 39% reflux, 33% lethargy, 55% abdominal pain/cramping in week 1. Comorbidities: Baseline: metabolic syndrome: 31/31. Follow-up: metabolic syndrome: 15/31.	
Alfredo et al, 2014 (52) Prospective 6y follow-up study. Exclusion: Weight loss >5% or medication causing weight gain (e.g. glucocorticoids or second generation anti-psychotic medication). Italy IGB: n=83, follow-up: n=49, 64F (77%), µ37.4y, BMI 43.74 kg/m2.	BIB Duration of Tx: 6m Method: Propofol sedation administered by an anaesthetist, 500mL saline. Multiple IGB: Reintroduced after weight gain >50%, n=83 had 2nd IGB, n=22 (18%) had 3rd IGB, n=1 (1.2%) had 4th IGB. Follow-up: 12m, 6y. Low-calorie diet provided by dietitian.	Weight loss (12m follow-up) BMI: 35.9kg/m2, (change: -7.8kg/m2), p=<0.001. Quality of life (76m follow-up) n=64/83 SF-12: Baseline: Physical: µ40 + SE (4), Mental health: µ50 + SE (4). Follow-up: Physical: µ85 + SE (8), calculated change: +45, Mental health: µ78 + SE (7), calculated change: +28, p=<0.001. Data reported graphically. Comorbidities: Baseline: T2DM: 33/83, HTN: 58/83, OSA: 16/83, p=0.02. Follow-up: T2DM: 14/49, HTN: 17/49, OSA: 5/49. Data reported graphically. Adverse Events: 1st IGB placement: Nausea, vomiting and epigastric pain µ2.5 d, 2nd IGB placement: Nausea, vomiting & epigastric pain µ4 d. No major complications, IGB removal: n=1 for intolerance.	
Guedes et al., 2019. (51) Prospective observational study-; 2016-2018. Exclusion: endocrine (DM, hypothyroidism, PCOS), AIDS, inflammatory conditions, malignant	Orbera or Spatz Duration of Tx: 6m Method: inserted under sedation by anesthesiologist, 600-700mL saline. containing 4% methylene blue. Follow-up: 6m, monthly.	Quality of Life (6m follow-up): SF-36 mean + IQR score: Baseline: general health: (72, 57-82), MH (52, 40-72), functional capacity (60, 40-85). Follow-up: general health (82, 72-92, p=0.0002), MH (76, 68-84, p=0.0003), functional capacity (90, 85-95, p=0.0001). Calculated change: general health: +10, MH: +24, functional capacity: +30.	

diseases, autoimmune diseases, CKD, HF, hepatic failure disorders, medications interfering with weight. Brazil IGB: n=42; 0% attrition, 76%F, µ37.60±1.28y, BMI µ35.15±0.41kg/m2.	Individualised low-calorie diet provided by dietitian.	Weight loss: Baseline: µ96±1.9kg. Follow-up: 80.6±2.0kg. Calculated change: -15.4+1.5kg. EWL%: 56.04±4.90%, p= <0.0001. Comorbidities: Baseline: HTN: n=6/42, dyslipidaemia: n=32/42.	
Marinos et al., 2014. (60) Prospective open-label study. Exclusion: positive helicobacter pylori, insulin-dependent DM, active gastric ulcer. Australia. Transpyloric shuttle 3m: n=10, 90%F, µ36.3+11.4y, BMI µ34+1.3kg/m2. Transpyloric Shuttle 6m: n=10, 90%F, µ45+8.3y, BMI µ37.9+7.3kg/m2.	TransPyloric Shuttle Duration of Tx: 3m Method: inserted under sedation. Follow-up: 6m	Quality of Life (6m follow-up): IWQOL-Lite score: Calculated change: +20.4+14.2. Weight loss: Baseline: µ98+8.1kg. EWL%: 25.1+14%.	Funding by BAROnova Inc. Author contacted about QOL data – awaiting response.
	TransPyloric Shuttle Duration of Tx: 6m Follow-up: 6m	Quality of Life (6m follow-up): IWQOL-Lite score: Calculated change: + 23.3+20.5. Weight loss: Baseline: µ103.8+28.3kg. EWL%: 41+21.1%. Adverse events: Mucosal erosion: n=15/20, gastric ulcers: n=10/20.	Funding by BAROnova Inc. Author contacted about QOL data – awaiting response.
Machytka, E et al, 2017 (50) Prospective, observational and open label design-; 2014-2015. Exclusion: small bowel obstruction, signs or symptoms of oesophageal, gastric or intestinal disease, IBD, cancer or a known large hiatal hernia. More than 1 laparoscopic or abdominal surgery and surgery in >12m, hx of smoking. Czech Republic & Greece. IGB: n=34; follow-up n=32, 23F (67%), 42+11y (range: 18-59y), BMI 34.8+3.7kg/m2 (range: 27-40kg/m2).	Elipse device Duration of Tx: 4m (range: standard 117-141d; experimental 30-141). Method: IGB folded inside capsule, attached to catheter via a patented self-sealing valve and swallowed, 550mL of fluid (n=28). Experimental IGB made from radiopaque film, slightly smaller capsules for ease of swallowing (n=6). Follow-up: fortnightly. Nutritional counselling fortnightly & encouraged to follow a high protein 1000-1200 Calories/day diet.	Quality of Life (4m follow-up): IWQoL total score (n=26): Baseline: µ68. Follow-up µ82+12.2. Calculated change: -14. Physical: baseline: µ68+12.9 follow-up: µ82, calculated change: +14. Weight loss (n=26): BMI: Follow-up: µ-3.9+3.1kg/m2 (-5.2 CL, -2.6 CI), p<0.001. TBWL%: follow-up µ10+6.6%, (7.3, 12.7), p<0.001. Adverse events (n=26): n=24/26, abdominal distension: n=1/26, abdominal pain: n=7/26, constipation: n=5/26, diarrhea: n=4/26, GERD: n=3/26, nausea: 15/26, vomiting: n=18/26. Comorbidities (change at follow-up) (n=26): HBA1c (mg/dL): µ -0.2+0.2% (-0.2,-0.009), LDL: - µ9.7+27.6 (-21.4,2.0), TG: µ-16.4+50.9 (-37.9, 5.1), SBP: µ-9.6+16.1 (-16.2, -2.9), DBP:µ-5.8+7.9 (-9.0,-2.5).	Two authors received consulting fees from Allurion Technologies, 1 author is a consultant and 3 authors are shareholders in the company.
Moreno et al., 2008(59) Prospective single-arm study.	TOGA System sleeve stapler. Method: inserted under sedation.	Quality of Life (6m follow-up):	Funding by Satiety Inc.

Exclusion: hx of IBD, pregnancy, cancer, etc. Belgium TOGA: n=11, 64%F, µ44.2+10.7y, BMI µ41.6+4.3kg/m2.	Follow-up: monthly. Diet and exercise guideline booklet provided at follow-up.	SF-36 total score: Baseline: 96. Follow-up: 49.9. Calculated change: -46. IWQOL-Lite domain scores: physical function (38.9), general health (40.4), MH (40). Follow-up: physical functioning (54.7), general health (56.7), MH (50). Calculated change: physical functioning: +15.8, general health: +16.3, MH: +10. Weight loss: Baseline: µ119.8+22.2kg. Calculated change: -24kg. EWL%: 46%, p= <0.05. Adverse events: Epigastric pain: n=11/11, esophagitis: n=2/11, throat pain: n=3/11, nausea: n=2/11, mild dysphagia: n=3/11. Comorbidities: Baseline: T2DM: n=4/11, HTN: n=6/11, hyperlipidaemia: 4/11.	
Mui et al 2010 (22) Prospective study-; 2005-2006. China IGB: n=119, 86F (72.3%), µ37.8+10y, BMI: µ38.4+8.0 kg/m2, (range: 26.5 - 69.1kg/m2).	BioEnterics IGB Duration of Tx: 6m Method: inserted & removed by surgical team, µ542.7+28.2mL. Follow-up: weekly with dietitian for 1m, then monthly.	Quality of life (6m follow-up) SF-36: (Chinese Version): Physical functioning baseline: µ28.8+19, follow-up: µ39.8+15.2, calculated change: -11, (p>0.0005). General health baseline: µ 40.3+10.5, follow-up: 49.4+11.3, calculated change: µ-9.1. MH: baseline: µ43.8+12.4, follow-up: µ47.7+13.3, calculated change: µ3.9, (p>0.014). Weight loss(kg): Baseline: µ103.7+24.1kg, (range: 63.8-183.6kg). Follow-up: µ 91.3±23kg. Calculated change: -µ12.4+6.9kg, p<0.0005. EWL%: µ45.1±35.3%. Adverse events: Intolerance (early removal): n=4/119, anaemia: n=1/119, hypokalaemia: n=1/119. Comorbidities: MS Baseline; µ 42.9%, follow-up: µ15.1%, FBG (mmol/l) baseline: µ6.1+2.0 follow-up µ5.3+1.7, HBA1c (%) baseline: µ7.4+1.6, follow-up: µ5.8+0.7,(p<0.0005), TC (mmol/l) baseline; µ5.1+0.9,follow-up; µ4.7+0.9 (p<0.0005), TG (mmol/l) baseline; µ1.7+1.0 follow-up µ1.3+0.7, (p<0.0005), SBP (mmHg) baseline; µ145.4+19.7 follow-up; 133.2+20.9 (p<0.005), DBP baseline; µ84.3+12.6, follow-up; µ78.8+15.4 (p<0.005), CRP (mg/l) baseline; µ6.9±6, follow-up; µ6.1+6.5 (p<0.024).	

Norén, E.; Forssell, H, 2016 (58) Prospective observational study-; 2012-2013. Sweden Exclusion: MI <3m, known malignancy, chronic liver or kidney disease major upper GI surgery, psychiatric disease including substance abuse, ED, mental retardation or other intellectual disability. Aspiration Therapy: n=25, follow-up n=20; 23F (92%), µ48y, (range: 33-65y), BMI µ39.8+4.3 kg/m2.	Aspire Assist System. Duration of Tx: 12m (participants had option to continue therapy for an additional 12m). Method: custom gastrostomy tube (A-tube, Aspire Bariatrics) percutaneously inserted during gastroscopy under sedation. Drainage & irrigation of the stomach performed 3x/day (76% patients aspirated 3x/day), 20mins post-meal for 1-2y. Diet + exercise counselling during Tx. Follow-up: 4 in 3m, then every 3m. Cognitive behavioural therapy, 8 sessions.	Quality of life (12m follow-up): EQ-5D baseline: µ0.7+0.3, follow-up: µ0.9+0.1 (p<0.01), VAS baseline: µ63+15, follow-up: µ83+14, (p<0.01). Weight loss (kg): Baseline: µ107.4+18.7kg, follow-up: µ88.4+16.9kg, calculated change: -µ19kg (p<0.01). EWL%: µ44.5+28.8%. Adverse events: moderate pain: n=13/25, severe pain: n=3/25, hospital admission (suspected leakage): n=2/25, intra-abdominal leakage at gastrostomy site: n=1/25, stoma site related problems: n=3/25. Comorbidities: (n=20) Baseline: T2DM: n=7/20, HTN: n=8/20, high cholesterol n=2/20, mood disorder n=6/20, GERD n=2/20. Follow-up: T2DM n=5/20, HTN n=7/20, high cholesterol n=2/20, mood disorder n=6/20, GERD n=3/20. HbA1c (mmol/mol) Baseline; µ47 median (IQR 43-66), follow-up; 42, (36-64), (p<0.03),	Funding support by Scientific Committee of Blekinge County Council. Initial exploratory safety study.
Ponce et al., 2012 (49) RCT-; 2010- 2011. Exclusion: peptic ulcer, erosive esophagitis, hiatus hernia >2cm, etc. USA IGB: n=21, follow-up n=20, 17F (81%), µ38.9+9.1y, BMI µ34.7+2.6kg/m2.	ReShape Duo IGB System. Duration of Tx: 6m Method: 900mL saline. Follow-up: monthly-6m, bi-weekly-48weeks. Diet and exercise counselling.	Quality of Life (6m follow-up): SF-36 domain scores: baseline physical functioning (83.6), general health (73.9), MH (87.3). Follow-up: physical functioning (96.9), general health (80.7), MH (86.1). Calculated change: physical: +13.3, general health +6.8, MH -1.2. Weight loss: Baseline: µ100.8+11.6kg. EWL%: 31.8%. Adverse events: Hypoxia: n=1/21, nausea: n=4/21.	Funding by and written with assistance from ReShape Medical Inc. Contacted author for numerical data, unable to provide.
Reimao, 2018 (48) Prospective observational study-; 2014-2016. Exclusion: any contradictions to IGB or impossibility of follow-up. Brazil IGB: n=36 analysed (40 included); follow-up n=38, 28F (77.7%), µ45.3+7.6y (range: 25-57y), BMI µ32.9+2.0 kg/m2.	Orberra IGB. Duration of Tx: 6m Method: inserted under general anaesthesia, 600mL saline and methylene blue dye. Follow-up: monthly (nutritionist). Hypocaloric diet (1000kcal/day), 120 min/week physical activity suggested. Caloric intake estimated by five 24-h dietary recall on non-consecutive days for 1m.	Quality of life (6m follow-up): SF-36 (validated Portuguese version) Physical Aspects (%) baseline: µ70, follow-up: 92, calculated change: +22. General Health (%) baseline: µ43, follow-up: µ68, calculated change: +25. MH (%) baseline: µ62, follow-up: µ79, calculated change: +17. Data reported graphically. Weight loss: Baseline; µ89.8+12.1kg, Follow-up: µ77.5+14.6kg, calculated change: -µ12.3kg, (p<0.001). TBWL%: 13.7%. Adverse events:	Author contacted about numerical values of bar graph (QOL).

		Fungal colonisation of IGB: 2/40.	
Raftopoulos et al., 2017. (47) Prospective observational, nonrandomised study. Exclusion: HF, COPD, previous bariatric therapy, pregnancy, etc. Greece. IGB: n=12, 58%F, µ41y (range: 18-59y), BMI µ36.1+3.2kg/m2.	Elipse Balloon. Duration of Tx: 4m. Method: insertion via swallow with water, 550mL water containing citric acid/potassium sorbate preservative. Follow-up: fortnightly. Diet and exercise program.	Quality of Life (12m follow-up): IWQOL-Lite score: Baseline 65. Follow-up: 58. Calculated change: -7. Weight loss: Baseline: µ103.5+15.8kg. Calculated change: -6.5kg. EWL%: 17.6%. Adverse events: Nausea: n=4/12, vomiting: n=1/12, abdominal cramping: n=1/12, GERD: n=2/12, constipation: n=2/12.	Raftopoulos received consulting fees for Allurion Technologies.
Guedes et al 2017(2),Guedes et al 2016 (46) Prospective observational study-; 2011-2012. Exclusion: T1/T2DM, pregnancy, previous gastric surgery, hiatal hernia >5cm, clotting disorders, potentially bleeding gastrointestinal lesions, alcoholism or use of drugs, previous hx of psychiatric disorders, current use of anti-depressants or other psychiatric drug, and weight loss treatment within the previous 6m. Brazil IGB: n=50, follow-up n=39, 40F (80%), µ34.6+7.1y, BMI µ40+6.3 kg/m2.	Silmed Silicone IGB. Duration of Tx: 6m Method: inserted under sedation, 650mL saline solution (0.9%) and 20mL methylene blue solution. Follow-up: weeks 0, 8,16 & 24.	Quality of life (6m follow-up): WHOQOL-BREF Physical domain baseline; µ54.3+17.9 (14.2-92.8), follow-up; µ67.0+16.2, (25.0-100.0), p<0.01, Psychological domain baseline; µ55.9+17.2 (12.5-91.6), follow-up; µ64.5+19.9 (16.6-95.8), p 0.03. Calculated change: physical: +12.7, psychological: +8.6. Weight loss: Calculated change: µ11.7+9.6, (p<0.0001) BMI: µ -4.4+3.5kg/m2 (p<0.0001). Adverse events: Gastric intolerance: n=4/50, balloon rupture: n=5/50, uterus cancer: n=1/50.	Funding by Silmed Silicone Instrumental Medico Ciurgico Hospital Ltda, Rio de Janeiro, RJ, Brazil. The funding body had no role in study design, collection, analysis, interpretation of data or writing the manuscript.
		Depression/Anxiety (6m follow-up): *BDI: Baseline: µ16 (median), (range: 1-32), follow-up; µ6, (range: 0-45), change: µ4.57±10.6, (p=0.0019). HADS-D baseline: µ7 (range: 1-14), follow-up: 4 (0-18), change: 1.82+5.16, (p=0.0345).	
Tayyem, Atkinson & Martin, 2014 (45) Single centre, prospective study-; 2010-2010. Exclusion: no written consent, ESL. Scotland. IGB: n=12, 62%F, µ40y, BMI µ55.9kg/m2.	BioEnterics IGB (BIB) System Duration of Tx: 6m Method: inserted under sedation, 600mL saline containing methylene blue.	Quality of Life: SF-36 domain scores: Baseline physical functioning: 36.5, general health: 29. Follow-up: physical functioning: 57.5, general health: 63. Calculated change: physical functioning: +21, general health: +34. Weight loss: Baseline: µ156+21kg. Calculated change: -15+12kg. EWL%: 25.4%. Comorbidities:	Authors contacted about IGB data; data provided.

		Baseline depression: n=10/12.	
Tayyem, Obondo Ali, 2011 (44) Prospective longitudinal study-; 2008-2010. Exclusion: previous bariatric surgery/abdominal surgery, hiatus hernia, peptic ulcers, unfit for surgery/anaesthesia. Scotland. IGB: n=17, 65%F, µ40.9y, BMI µ61.4+8.3 kg/m2.	BioEnterics IGB (BIB) System Duration of Tx: 6m Method: inserted under sedation, 600mL saline containing methylene blue. Follow-up: quarterly.	Quality of Life (9m follow-up): SF-36 domain scores: Baseline physical functioning: 35, general health: 28. Follow-up: physical functioning: 72, general health: 70. Calculated change: physical functioning: +37, p<0.041, general health: +42, p<0.021. Data reported graphically. Weight loss: Baseline: µ172+19.5kg. Calculated change: -µ25.6+14.4kg, p<0.001. EWL%: 26.2+14%. Adverse events: Nausea: n=4/17, vomiting: n=4/17. Comorbidities: Baseline: DM: n=3/17, HTN: n=6/17, hyperlipidaemia: n=3/17, IHD: n=4/17, OSA: n=2/17. Follow-up: DM 1/17, HTN 1/17, hyperlipidaemia 1/17, IHD 2/17, OSA 1/17.	Author contacted for numerical values of graphs. Orlistat 120mg prescribed 3/d for weight loss, access to helpline and referrals to gym/slimming activities provided pre-procedure.
Thompson et al, 2017 (57) RCT-; 2012-2015. Exclusion: hx of gastrointestinal disease or previous abdominal surgery increasing the risk of A-tube placement, previous bariatric surgery, chronic abdominal pain, serious CVD, medication significantly impacting on weight loss or weight gain and hx of major depressive, psychiatric or eating disorders. USA Aspiration therapy: n=82 (n=26 withdrew pre-enrolment, n=29 dropped out), 68F (82.9%), µ43.5+10.2y, BMI µ42.4+5.0 kg/m2.	Aspire Assist System Duration of Tx: 52w Method: Endoscopically placed percutaneous gastrostomy tube (15cm fenestrated intragastric portion) with an external device to facilitate drainage of 30% of calories consumed 20mins post-meal. Follow-up: week 0, 2,6,10,14,20,24,28,32,36,40,44,48 & 52. Diet and lifestyle counselling program.	Quality of life (12m follow-up): IWQOL Total Score change: µ6.2+13.4, Physical Function score change: 7.1+15.5. Weight loss: Baseline: 116.9±21.2, Change: µ14.2+11.3kg. EBWL%: µ37.2+27.5%. Adverse Events: Abdominal pain within 4 weeks: n=42/111, peristomal granulation tissue: n=45/111, peristomal irritation: n=19/111, nausea/vomiting: n=19/111, intermittent abdominal discomfort: n=18/111, peristomal bacterial infection: n=15/111, dyspepsia: n=7/111, peristomal inflammation: n=6/111. Serious adverse events: n=4/111, severe abdominal pain: n=1/111, peritonitis: n=1/111, pre-pyloric ulcer: n=1/111, a-tube replacement (skin port malfunction): n=1/111. Comorbidities: HbA1c baseline; µ5.7+0.5, change: 0.36% (p<0.0001), TG baseline: µ140.8+81.7, change: 9.9% (p=0.02), SBP baseline: µ12.2+13.3, change: 1.2% (p=0.38), DBP baseline; µ78.8+8.9, change: 2.6%(p=0.06), LDL; baseline µ115.4+32.8, change: 4.2% (p=0.06%)	Funded by Aspire Bariatrics - performed statistical analysis & assisted preparing the manuscript. Participants were permitted to continue in the study for an additional 48m if they lost and maintained at least 10% of their body weight from baseline.

Footnote:

BDI: Beck Depression Inventory; BDI-II: Beck Depression Inventory II; BFM: Body fat mass; BMI: body mass index; BW: Body weight; CRP: C-reactive Protein; DBP: Diastolic blood pressure; DLD: dyslipidaemia; DM: diabetes mellitus; ED: Eating disorder; EQ-5D: European Quality of life measurement questionnaire; ESL: English as a second language; EW: Excess weight; EWL: excess weight loss; FBGL: Fasting blood glucose; GIQLI: Gastrointestinal Quality of Life Index; Hx: history; HDAS-A: Hospital Anxiety and Depression Scale (Anxiety score); HDAS-D: Hospital Anxiety and Depression Scale (Depression Score); HTN: hypertension; IBD: inflammatory bowel disease; IGB: intragastric balloon; IQR: interquartile range; IWQOL-Lite: Impact of Weight on QOL-Lite; LDL: low density lipoprotein; MH: mental health; MI: myocardial infarction; MS: Metabolic Syndrome; NR: not reported; QOL: quality of life; SBP: Systolic blood pressure; SD: standard deviation; SF-12: Quality Metric's Short Form; SF-36: 36-Item Short-Form Health Survey; TBWL: Total body weight loss; TC: Total Cholesterol; TG: Triglycerides; TOGA: transoral gastroplasty; VAS: Visual Analogue Scale; WC: Waist circumference; WL: Weight loss.

QOL/Mental health assessment tools (indication of improvement):

BDI: score decreases [58]

BDI-II: score decreases [59]

EQ-5D: score increases[60] GIQLI: score increases. 4 is the most desirable option, 0 is the least desirable option [61]

HDAS: score decreases[62]

IWQOL-BREF- A higher score indicates an improved quality of life [63]

IWQOL-Lite: score increases. Scores range from 0 to 100, with 100 representing the best quality of life [64]

IWQOL- higher scores indicated lower levels of functioning and QOL [65]

SF-12: score decreases [66]

SF-36: A higher score indicates a better health status [67]

Table S3: Risk of bias assessments and justifications using Academy of Nutrition and Dietetics Quality Criteria Checklist.

Study ID	1. Was the research question clearly stated?	2. Was the selection of study subjects free from bias?	3. Were study groups comparable ?	4. Was method of handling withdrawals described ?	5. Was blinding used to prevent introduction of bias?	6. Were the intervention/therapeutic regimens/exposure factor or procedure and any comparisons described in detail? Were intervening factors described?	7. Were outcomes clearly defined and the measurements valid and reliable?	8. Was the statistical analysis appropriate for the study design and type of outcome indicators?	9. Are conclusions supported by results with biases and limitations taken into consideration?	10. Is bias due to study's funding or sponsorship unlikely?	Overall study quality (positive/negative/neutral)
Ahmed et al., 2019	Yes	No	N/A	No	N/A	Unclear	Unclear	No	Unclear	Unclear	Neutral
	"To evaluate the effect of weight loss and aspects of quality of life after BIB insertion." p.42. 1.3 Participants not specified.	2.3 No comorbidity data only age, weight & gender. 2.4 Included only single females 20-40y. Selection method not stated.	N/A	4.2 Withdrawal/ lost to follow-up not reported. 4.3 Enrolled subjects not accounted for.	N/A	6.4 No drop out or adverse events reported. Compliance unclear. 6.5 Dietary control not described for IGB group.	7.1 QoL tool type not reported. 7.4 Aspects of domains reported as outcomes rather than outcomes of domains.	8.1 Changes reported in categorical variables. 8.2 No discussion of non-parametric results. Only means, no SD. 8.4 Nil intention to treat. 8.5 No multivariate analysis or analysis for confounders.	9.1 Discussed findings. 9.2 Limitations briefly discussed; no bias discussed.	10.1 "No any sources of funding for the research." 10.2 No conflicts of interest to declare. Author is "Manager of Hospital for Endoscopic and Bariatric Surgery" p.42.	
De Castro et al., 2010	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Positive
	"To evaluate the efficacy,	2.4 "40 subjects referred to	3.3 Unclear-not stated. 3.4 No	4.4 Unclear.			7.4 Not all measureme	8.2 Non-parametric test		10.2 No conflict declaration	

	safety, and tolerance of this new device compared to the saline-filled BIB® balloon" 1.3 Population not specified.	place a gastric balloon" - sampling unclear.	adjustments in statistical analysis.				nt methods described.	discussed, mean, SD reported. 8.3 p-values reported only in text. 8.5 No adjustment for confounders.		present. 10.1 FISS grant.	
Familiari et al., 2011	Yes	Yes	Unclear	Yes	N/A	Yes	Yes	No	Yes	No	Positive
	"To evaluate the safety and efficacy of TOGA at 12-month follow-up." 1.3 Population not specified.	2.4 Offered the treatment at bariatric clinic 'consecutive sampling".	3.4 Unclear-no comparison between groups. Differed in health status. Statistical analysis adjustments not stated.	4.2 21% of patients lost to follow-up. 4.4 Unlcear.	5.3 Unclear if measurement of outcomes & risk factors blinded.		7.2 IWQOL and SF-36 used for QoL, scores not reported. 7.4 Not all data collection methods/ measures described.	8.1 Inadequate description - statistical program & level of significance not reported. 8.2 Statistical tests not described-mean + SD reported-no discussion of non-parametric variables. 8.3 p-values reported but level of significance not		10.1 Funded by Satiety Inc. 10.2 Sponsor collaborated with investigators in data collection & analysis.	

								discussed. 8.4 Nil intent to treat. 8.5 No adjustment for confounders. 8.6 Clinical significance not reported.			
Fuller et al., 2013	Yes	Yes	N/A	Unclear	N/A	Yes	Yes	Unclear	Yes	No	Positive
	"Evaluated the efficacy and safety of an IGB in obese individuals with metabolic syndrome (MS)". - p1562. Population, intervention, outcomes stated (1.1-1.3).	2.4 Selection method not stated.	N/A	4.3 Tables do not describe number of participants analysed.			7.6 No confounding variables considered.	8.1 Results expressed only as mean and CI, no discussion about non-parametric values. 8.4 Unclear. 8.5 No multivariate analysis. 8.6 clinically significance is referred to with the QoL & weight changes.		10.1 Funding received. 10.2 Conflicts of interests: 1 author employee of Allergan institute.	
Alfredo et al., 2014	Yes	Yes	N/A	Yes	N/A	No	Yes	No	Unclear	No	Neutral
	"To investigate the efficacy of	2.4 Convenience	One study group.	4.2 Dropouts described		6.4 No comparison of patients that		8.1 Data tables do not include		10.1 Funding not reported. 10.2 No	

	multiple balloon treatment in the long term (6 years) in terms of weight loss, influence of comorbidities and QOL in patients refusing surgery". - p.307. Population, outcomes & intervention stated (1.1-1.3).	sampling p.308 - Recruited from prospective database.		. Final follow-up analysis on 74%. 4.3 Tables & figures do not state number of participants included in analysis.		underwent >2 IGBs to those that had 2.		participant numbers. 8.2 Reported mean and SE. 8.4 Nil intention to treat. 8.5 No adjustments for confounders.		conflicts of interest reported.	
Guedes et al., 2019	Yes	Yes	N/A	No	N/A	Unclear	Yes	Unclear	Yes	Unclear	Neutral
	"To evaluate the changes in body weight, total and central body adiposity, dietary intake, habitual physical activity and quality of life, of patients with obesity submitted to IGB treatment for 6 months." - p.843. Outcomes, participants & intervention stated (1.1-1.3).	"Potential participants were recruited among patients who had already scheduled the placement of nonadjustable IGB" - p.844 convenient sample.	One group in study.	4.2 Withdrawal reasons not specified.	No control group, blinding not possible.	6.4 Compliance not reported.		8.1 Shapiro Wilk test for normality. 8.2 Mean & SEM for parametric data (inaccurate reporting of data). 8.3 P= <0.05. 8.5 Confounders adjustments not stated -p846.		10.1 Funding not stated. 10.2 Declared no conflicts.	

Guedes et al., 2016	Yes	Yes	N/A	Yes	N/A	Yes	Yes	No	Yes	Yes	Positive
	"Investigate the effects of a 6-month treatment with IGB on body composition and depressive/anxiety symptoms in obese individuals with MS". 1.3 Setting not stated.	2.4 "consecutive sample of 50 patients who sought treatment for obesity and MS".	One group in study.	4.2 21% lost to follow up, all withdrawals described.		6.5 Ancillary treatments not discussed.	7.6 Other factors not accounted for.	8.2 Only means reported, no discussion of non-parametric data. 8.4 Nil intention to treat. 8.5 No multivariate regression	9.1 Discussion included. 9.2 Limitations discussed.	10.1 Funding not stated. 10.2 No conflicts declaration stated.	
Guedes et al., 2017	Yes	Yes	N/A	Yes	N/A	Yes	Yes	Yes	Yes	Unclear	Positive
	"To investigate the effect of 6 months of treatment with an intragastric balloon (IGB) on health-related quality of life (HRQOL) and its relation to changes in body fat in obese individuals with metabolic syndrome (MS)."	2.4 Consecutive sampling.	One group in study	4.2 22% patients withdrew from study.	One group in study.	6.5 Co-interventions not reported.	7.6 Other factors not accounted for.	8.4 Nil intention to treat.		10.1 Funding "not applicable". 10.2 No conflicts of interest reported.	
Machytka et al., 2017	Yes	Yes	N/A	Yes	N/A	Yes	Unclear	No	Yes	Yes	Neutral
	"To assess the safety of Elipse and to	2.3 No demographics.	One group in study.		One group in study.	6.3 4-months.	7.3 4-months -	8.1 Insufficient	9.1 Discussed findings.	10.1 Funding not stated. 10.2 Two	

	measure its effects on weight loss, metabolic parameters and quality of life" 1.3 Population not stated.	2.4 Sample from 2 hospitals - consecutive sample. Unclear if representative sample.					insufficient. 7.4 Validated measures - accuracy questioned. 7.6 Other factors not accounted.	information. 8.4 Nil intention to treat. 8.5 No adjustment for confounders.	9.2 Limitations discussed.	authors received consulting fees, 1 is a consultant and 2 are shareholders in Allurion Technologies.	
Marinos et al., 2014	Unclear	Yes	Unclear	Yes	N/A	Yes	Yes	No	Unclear	No	Neutral
	To evaluate the safety and efficacy of the clinical procedure and device. - p.929. Intervention & population not stated (1.1, 1.3).	2.4 Sampling method not reported.	3.2 Unclear.	4.2 10% of patients withdrew, reasons stated.	No control group, blinding not possible.		7.3 3-month data not sufficient. 7.6 Other factors not accounted for.	8.1 Inadequately described. 8.2 No discussion on non-parametric variables. 8.4 Nil intention to treat. 8.5 Nil adjustments for confounders.	9.2 Limitations not discussed.	10.1 Sponsored by Baronova. 10.2 2 authors were consultants.	
Moreno et al., 2008	No	Yes	N/A	Yes	N/A	Yes	Yes	No	No	No	Neutral
	"6-month results of second phase of the pilot trial with the TOGA system" Outcomes & population (1.2, 1.3).	2.4 Patients recruited into the bariatric practice - sampling unclear.	Single arm study	4.1 Follow-up described. 4.2 90% follow-up rate, withdrawal stated.			7.6 Other factors not accounted for.	8.1 Insufficient information & unclear reporting of QoL Score. 8.2 Results reported as	9.2 Limitations not discussed.	10.1 Funded by Satiety inc. 10.2 Conflicts declared.	

								mean + SEM. 8.4 Nil intention to treat. 8.5 No adjustment for confounders. 8.7 Negative findings in IWQOL-Lite reported but not identified.			
Mui et al., 2010	Yes	Yes	N/A	Yes	N/A	Yes	Yes	Unclear	Unclear	unclear	Positive
	"To evaluate the outcome of IGB on weight loss and the impact of it on obesity-related illnesses and quality of life in obese Chinese." - p.1128.	2.4 Consecutive sampling	One group in study.	4.2 Withdrawals stated n=8. 4.3 n=119 in analysis, 93% withdrew n=119/127 (p.1129)		6.3 6 & 12m. 6.4 lost to follow-up/drop-out excluded from analysis.	7.6 Other factors present but not accounted for.	8.1 Student's t test for parametric data & McNemar test where appropriate. 8.2 Only mean & SD reported.	9.2 Unclear, limitations on IGB not the study.	10.1 Source of funding not reported. 10.2 Conflicts of interests not discussed.	
Norén, et al., 2016	Yes	Yes	N/A	Yes	N/A	Yes	Yes	Yes	Yes	Yes	Positive
	"To evaluate weight loss, safety and quality of life with AspireAssist treatment for 1 to 2 years in	2.4 Consecutive sample.	One group in study.	4.2 Withdrawals described & number stated, 80%		Number of aspirations measured but not reported.	7.6 Other factors not accounted for	8.5 No adjustments for confounders.		10.1 Authors received research support for study from the Scientific committee of Blekinge	

	obese subjects". -p2.			follow-up.						County Council, SCBCC Sweden. 10.2 Declared no conflicts.	
Ponce et al., 2012.	Yes	Yes	Unclear	Yes	No	Yes	Unclear	No	Yes	No	Neutral
	"Evaluated the safety and efficacy of an intragastric dual balloon as an adjunct to diet and exercise in obese patients compared with diet and exercise alone."	2.4 Sampling unclear.	3.3 Concurrent control 3.4 Confounders not accounted for.	4.3 Unclear, tables not labelled with participant number.	5.1 No blinding - unable to blind with adverse events post insertion unmasking treatment group - p.292.	6.4 Compliance measured (food journal).	7.4 Not reported. 7.6 Other factors not accounted for.	8.1 Insufficient reporting. 8.2 Inappropriate statistical methods. 8.4 Nil intention to treat. 8.5 No adjustment for confounders.	9.1 Discussion included. 9.2 Limitations discussed.	10.1 Funded by Reshape medical. 10.2 1 author is a consultant for the funder.	
Reimao et al., 2018	Yes	Yes	N/A	Yes	N/A	Yes	Yes	Unclear	Yes	Unclear	Positive
	"To evaluate the effects of IGB in overweight or class 1 obese patients, by analysing body composition and quality of life". -p1806.	2.4 Consecutive sample.	One group in study.	4.2 10% attrition - withdrawals described.		6.4 Compliance not reported.		8.3 QoL data reporting method unclear. 8.4 Nil intention to treat. 8.5 No adjustments made.		10.1 funding not reported. 10.2 Declared no conflict.	
Raftopoulos et al., 2017.	Unclear	Yes	N/A	Yes	N/A	Yes	Unclear	Unclear	Yes	No	Neutral
	"This study aims to report on 12-month safety and	2.4 "Unselected sample" Recruitmen	One group in study.	4.2 No patient drop-outs or		6.3 3-4 months (time differed). 6.4 Exposure measured.	7.2 IWQOL-Lite used. 7.3 1-y.	8.2 IWQOL score decrease		10.1 Funding not reported. 10.2 One author	

	efficacy outcomes." Intervention & population not reported (1.1, 1.3).	t method not described.		missing data, 1 patient excluded-91% follow-up rate.		6.5 Co-interventions described.	7.4 Not all measurements described.	referred to significant improvement. 8.5 Pearson correlation used to assess linear relationship. 8.7 No power calculation completed		received consulting fees from Allurion techonologies.	
Tayyem, Atkinson & Martin, 2014.	Unclear	Unclear	N/A	No	N/A	No	No	Unclear	Unclear	Unclear	Neutral
	"Develop and validate a new bariatric specific 81-item self-report HRQOL instrument called the Bariatric and Obesity-Specific Survey (BOSS)." 1.3 Population not reported	2.4 Sampling method unclear.	One endoscopic group in study.	4.2 follow-up rate 49%, reasons described. 4.3 Unclear.		6.1 Protocol not described. 6.3 Not stated. 6.4 Therapy exposure not measured. 6.5 Other treatments not described.	7.1 Outcomes not stated. 7.4 2weeks not sufficient.	8.1 Reported appropriately. 8.2 Appropriate tests. 8.3 $p<0.05$. 8.4 Nil intention to treat. 8.5 No adjustment for confounders.	9.2 Limitations not discussed.	10.1 funding not reported. 10.2 No conflicts declared.	
Deliopoulo et al., 2013	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Neutral
	"To examine the 6-month outcome of depression status - assessed by a well-recognised psychological	2.1 Exclusion criteria not stated. 2.3 BD-II, BMI, sex. 2.4 "consecutively	3.2 Non depressed versus depressed (grouped into severity). 3.4 Chi-square	4.2 Withdrawals not reported. 4.3 Tables do not state number of	5.1"The Beck Depression Inventory score was used at time 0 to blindly	6.1 Insufficient information. 6.3 6month. 6.4 Patient drop out not discussed. 6.6 Co-interventions described.	7.1 Outcomes stated. 7.3 6month. 7.4 Standard/ valid measures.	8.1 Reported appropriately. 8.3 $p<0.05$. 8.4 Nil intent to treat.	9.1 Discussed findings. 9.2 Limitations discussed.	10.1 Funding not reported, author contacted and stated reported no funding sourced. 10.2	

	measure, namely the Beck Depression Inventory in all patients treated by intragastric balloon.... between depressed and non-depressed individuals" - p.669.	present obese female patients" 100% female not representative.	analyses used to account for differences in confounders.	participants in analysis.	discriminate the 100 obese women into those with an absence of depression [score from 0 to 9, n=35 patients] and those having depressive symptoms of varying severity [score from 10 to 63, n=65]." - p.670.		7.6 Chi Square analysis for depressed group only no analysis of confounders for non-depressed group. 7.7 Non-depressed group no measure for QoL change.	8.5 multivariate analysis used.		Declared no conflicts.	
Tayyem, Obondo Ali, 2011.	Yes	Yes	N/A	Yes	N/A	Yes	Yes	Unclear	Yes	Unclear	Positive
	"Describe short-term outcome and quality of life (QoL) of endoscopically placed gastric balloon (EPGB) and laparoscopic adjustable gastric band (LAGB)." 1.3	2.1 Inclusion & exclusion reported. 2.3 Age, weight & comorbidities described. 2.4 Convenience sample.	One endoscopic group in study.	4.1 Follow-up described time point unclear. 4.2 No withdrawals or dropouts reported.	Blinding N/A	6.4 Compliance not stated.	7.4 Not all measurement instruments described. 7.6 Complications measured. Confounder stated - orlistat 120mg	8.2 No discussion of non-parametric variables. 8.4 Nil intent to treat. 8.5 No adjustment for confounders - univariate		10.1 Funding not reported. 10.2 No conflicts declared.	

	Population not stated.						taken 3x/day prescribed in pre-therapy to aid weight loss -p.3.	analysis (Orlistat not accounted for).			
Thompson et al, 2017	Yes	Yes	Unclear	Yes	N/A	Yes	Yes	Yes	Yes	No	Positive
	"To evaluate the efficacy and safety of AspireAssist for weight management in persons who have obesity." - p.448.	2.4 Sampling unclear conducted at 10 sites.	3.3Historical controls. 3.4 Changes made to treat cardiometabolic conditions by the participants primary care physicians (p.454) but not accounted for in analysis.	4.2 Withdrawals described <74%.	5.1 Participants not blinded due to the nature of study. 5.2 Unclear if data collectors blinded.		7.5 Measurement of effect not described. 7.6 Other factors not measured.	8.1 No discussion of non-parametric variables & what data is presented in the statistical analysis. Mean, SD reported in tables & labelled. 8.4 Modified intention to treat in statistical analysis & tables. 8.5 No multivariate analysis. 8.7 power calculation used.		10.1 Funded by Aspire Bariatrics. 10.2 2 authors are employees of Aspire Bariatrics.	
Fiorillo et al., 2020	Yes	No	N/A	No	N/A	Yes	Yes	Unclear	Yes	Unclear	Neutral

	"To compare QoL after ESG and LSG using a propensity score analysis". 1.3 Population not specified.	2.1 No exclusion. 2.2 Age, sex, comorbidities. 2.3 Consecutive sample but then sample exclusion through propensity score matching (PSM). Not representative.	Only ESG data reviewed.	4.2 Reason for withdrawal not reported. 51.5% of patients followed up & only 27% included in study after PSM. 4.3 Yes.		6.5 No description of co-interventions.	7.1 Outcomes described.	8.1 Inadequately described. 8.2 Unclear-Logistic regression not appropriate. 8.3 p-value reported. 8.4 Nil intent to treat. 8.5 Logistic regression.		10.1 Funding source not reported. 10.2 Authors declare that they have no conflict of interest.	

Table S4: GRADE assessment of the confidence in the body of evidence

Question: What is the effect of endoscopic bariatric procedures on post-procedure QoL and mental health of adult patients? (in comparison to pre-procedural QoL and mental health).

Certainty assessment							№ of patients		Effect	Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pre-procedure	Post-procedure	Absolute (95% CI)	
Quality of Life (QOL) (follow up: range 4 months to 76 months; assessed with: SF-36, EQ-5D, GIQLI, IWQOL-BREF, IWQOL-Lite, SF-12; Scale from: 0 to 100)										
19	Observational studies	Seriousa	not serious	not serious	not serious	Strong association	768	654	SMD 0.83 SD higher (0.67 higher to 0.99 higher)	⨁⨁◯◯ LOW
Mental Health (follow up: mean 6 months; assessed with: BDI, SF-36 Anxiety, HDAS-A, HDAS-D; Scale from: 7.9 to 84)										
8	Observational studies	Very seriousb	Very seriousc	not serious	Seriousa,c	Strong association	409	363	SMD 0.41 SD higher (0.23 higher to 0.6 higher)	⨁◯◯◯ Very LOW

CI: Confidence interval; SMD: Standardised mean difference; SD: Standard deviation

Explanations

a. Primary research outcome and patient centred outcome.

b. Confounding variables not accounted for.

c. Heterogeneity was 92% indicating serious imprecision and may have been the result of the type of tool used to assess mental health and/or the amount of multidisciplinary support provided to patients.

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