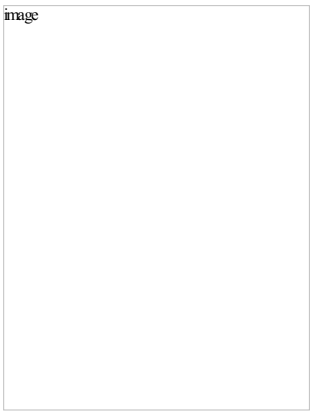

Antral resection versus antral preservation during laparoscopic sleeve gastrectomy for severe obesity: Systematic review and meta-analysis

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www.elsevier.com/locate/bios

PII: S1550-7289(18)30113-8
DOI: https://doi.org/10.1016/j.soard.2018.02.021
Reference: SOARD3303

To appear in: *Surgery for Obesity and Related Diseases*

Cite this article as: E.R. McGlone, A.K. Gupta, K.M. Reddy and O.A. Khan, Antral resection versus antral preservation during laparoscopic sleeve gastrectomy for severe obesity: Systematic review and meta-analysis, *Surgery for Obesity and Related Diseases,* doi:10.1016/j.soard.2018.02.021

Title page:

Title:

Antral resection versus antral preservation during laparoscopic sleeve gastrectomy for severe obesity: systematic review and meta-analysis

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Category of manuscript:

Systematic review and meta-analysis

Running title:

Antral resection in sleeve gastrectomy

Acknowledgements:

The study was pre-registered with the Prospective Register of Systematic Reviews, PROSPERO identification code CRD42016048657.

During the conduct of this study ER McGlone had her salary supported by a One-year Surgical Research Fellowship from the Royal College of Surgeons of England and by a Clinical Research Training Fellowship from the Medical Research Council.

Abstract:

Introduction: Although laparoscopic sleeve gastrectomy is an established operation for severe obesity, there is controversy regarding the extent to which the antrum is excised. ~~Some surgeons spare the gastric antrum whilst others commence resection close to the pylorus.~~ The objective of this systematic review was to investigate the effect on peri-operative complications and medium-term outcomes of antral resecting versus antral preserving sleeve gastrectomy.

Methods: Medline, EMBASE and Cochrane databases from 1946 to April 2017 were searched. Eligible studies compared antral resection (staple line commencing 2-3cm from pylorus) with antral preservation (>5cm from pylorus) in patients undergoing primary sleeve gastrectomy for obesity. Meta-analyses were performed with a random effects model and risk of bias within and across studies was assessed using validated scoring systems.

Results: Eight studies (619 participants) were included: six randomized controlled trials and two cohort studies. Overall follow up was 94% for the specified outcomes of each study. Mean percentage excess weight loss at 12 months was 62% (seven studies; 574 patients) and at 24 months was 67% (four studies; 412 patients). Antral resection was associated with significant improvement in percentage excess weight loss at 24 month follow-up: mean 70% vs 61% (standardized mean difference 0.95; CI 0.35-1.58, p <0.005), an effect that remained significant when cohort studies were excluded. There was no difference in incidence of peri-operative bleeding, leak or de novo gastro-esophageal reflux disease.

Discussion: According to the available evidence, antral resection is associated with better medium-term weight loss compared to antral preservation, without increased risk of surgical complications. Further randomized clinical trials are indicated to confirm this finding.

Key words:

Laparoscopic sleeve gastrectomy; Obesity; Antral sparing; Antral excising; Surgical technique

Registration:

PROSPERO: CRD42016048657

Abbreviations:

LSG laparoscopic sleeve gastrectomy; RYGB Roux-en-Y gastric bypass; AP antral preserving; AR antral resecting; %EWL percentage excess weight loss; GERD gastro-esophageal reflux disease; BMI body mass index; RCTs randomized controlled trials; SLR staple-line reinforcement; USPSTF US Preventive services Task Force; GRADE Grading of Recommendations Assessment, Development and Evaluation; SMD standardized mean difference; RR relative risk

Main text:

Introduction:

Laparoscopic sleeve gastrectomy (LSG) is an effective operation for severe obesity, with comparable short-term outcomes to Roux-en-Y gastric bypass (RYGB) for weight loss and diabetes resolution [1-4]. In recent years the number of LSG performed has significantly increased [5], however despite its popularity, the performance of this operation is far from standardized [6].

One aspect of controversy is the extent to which the antrum is excised. When fashioning the sleeve the staple line may be commenced close to the pylorus or at some distance away, resulting in more or less antral excision. Practice between surgeons is highly variable [7]. Proponents of a radical antral resection argue that more restriction leads to better weight loss [8]. They point out that since LSG alone is primarily a restrictive bariatric operation, the restriction must be profound to maximize weight loss [9]. Opponents of radical antral resection stress the importance of preserving the physiological emptying mechanism of the stomach, in order to avoid increased intraluminal pressure, arguing that consequences of raised intraluminal pressure could potentially include staple-line leak in the short-term and gastro-esophageal reflux in the longer term [10] [11].

The objective of this systematic review and meta-analysis was to compare complication rates and weight loss outcomes between antral-sparing (AP) and antral-resecting (AR) LSG for obesity.

Methods:

Literature search:

This study was performed following the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) guidelines [12]. The study was registered with the Prospective Register of Systematic Reviews, PROSPERO identification code CRD42016048657, prior to conducting the research. Study titles were searched using MEDLINE (1946 to April 2017) and Embase (1947 to April 2017) databases using Ovid Online (Ovid Technologies Inc, 2016) in May 2017. Key term combinations were as follows: 'antr* preserv* OR antr* exc* OR antr* resect* OR antr* spar* OR antrectomy' AND 'gastr* adj5 sleeve' AND 'obes*'. No language restrictions were applied. Cochrane database and reference lists of original articles were additionally searched (to April 2017). Published conference abstracts were included where there was sufficient information provided for eligibility to be assessed.

Eligibility criteria:

Studies of participants undergoing primary laparoscopic sleeve gastrectomy for obesity were included. Studies designed to compare the difference in outcome between a radical antral resection (defined as commencing the staple-line 2-3cm from the pylorus: AR) and an antral-sparing resection (defined as commencing the staple-line >5cm from the pylorus: AP) were included. Retrospective analyses of cohorts in which extent of antral resection was one of several technical and clinical variables were not included. Studies were also excluded if there was no extractable data on any one of the pre-specified outcomes (see below).

Outcomes assessed:

Outcomes studied were divided into two groups:

- Weight loss outcomes: percentage excess weight loss (%EWL) at 12 months post-LSG, %EWL at 24 months post-LSG.
- Complications: post-operative staple-line bleed, staple-line leak, 30-day mortality, and incidence of de novo gastro-esophageal reflux disease (GERD).

Studies which did not report any of these outcomes were excluded.

Study selection:

Two authors screened all titles and abstracts for relevance. Only clearly irrelevant material was excluded at this stage. Two authors independently screened the full texts, assessing eligibility for inclusion. Any differences were resolved by discussion and consensus. Where necessary, study data was confirmed with the corresponding author.

The following data were retrieved where reported on a piloted spreadsheet: date of publication, study design, randomization method, number of randomized patients, definition of AR/AP used by study authors, demographics including pre-operative body mass index (BMI) of patients, staple-line leaks, staple-line bleeds, 30-day post-operative mortalities, de-novo GERD, %EWL at 12 months, %EWL at 24 months and other outcomes.

Quality assessment of studies:

Risk of bias was assessed on the study level for all included studies, using the Jadad scoring system for randomized controlled trials (RCTs) [13] and the US Preventive services Task Force (USPSTF) Quality Rating Criteria for cohort studies [14]. The Jadad score is a validated tool to assign a score between 0 (weakest) and 5 (strongest) based on the quality of study design and the USPSTF Quality Rating Criteria is a similar tool for case-control studies where studies are graded 'good', 'fair' or 'poor' depending on fulfilment of internal validity criteria.

Risk of bias across studies was evaluated using guidance from the Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) [15,16]. Based on overall quality of evidence, confidence in each outcome measure can be classified into one of four levels – high, moderate, low and very low.

Subgroup analysis was planned to investigate causes of heterogeneity, where found to be significant in initial analysis. This was planned for measures of trial quality: RCT or not, and Jadad score. It was also planned for other technical variables that have been associated with differences in likelihood of adverse outcome: bougie size and presence of staple-line reinforcement (SLR) [7].

Statistical analysis:

Stata 14 (StataCorp. 2015. *Stata Statistical Software*: Release 14. College Station, TX: StataCorp LP) was used for estimating summary statistics for these meta-analyses. For each outcome summary measures with 95% confidence intervals: standardized mean differences (SMD) and pooled relative risk (RR) (for continuous and dichotomous variables, respectively)

were estimated. As AR is considered the intervention, and AP the comparator, RRs are reported as AR/AP ratios.

The I^2-statistic was used to assess the impact of heterogeneity on the analysis. Heterogeneity was considered significant when I^2 was greater than 50%. A random effects model was used to calculate the overall effect. Meta-regression to explore for the cause of heterogeneity, where significant, was planned.

Results:

Study selection:

The search yielded 197 articles. After de-duplication and exclusions (Figure 1), a total of eight studies remained which provided data for a total of 619 patients [8,11,17-22]. Table 1 summarizes the participants and interventions for the included studies. Each study examined fewer than 200 patients. Two retrospective cohort studies were included: these described full operative procedure and reported no differences in surgical technique between the cohorts except for antral length. Bougie size and presence of staple line reinforcement varied between, but not within, studies (see Table 1).

The outcomes for each study population considered as a whole are also indicated in Table 1. Mean percentage excess weight loss (%EWL) at 12 months was 62.2% (seven studies; 574 patients) and at 24 months was 66.8% (four studies; 412 patients). The overall incidence of complications was low. Overall follow up of patients was 94% for the specified outcomes of each study. Given the small number of included studies, tests for funnel plot asymmetry were not performed.

Risk of bias within studies:

Risk of bias according to the Jadad score is summarized in Table 2 for the six randomized controlled trials (RCTs). All RCTs scored 3 or less: this can be attributed to a lack of double-blinding in any of the trials, and to two of the trials consisting of abstracts only, with a consequent lack of methodological detail [18,19].

Two cohort studies were selected for inclusion [17,22]. Obeidat et al analyzed two consecutive single-center, single-surgeon cohorts, in which there was an isolated change in practice from 6cm antral resection (AP) to 2cm antral resection (AR). The two groups were comparable pre-operatively. Yormaz et al analyzed two groups of patients for which operative technique was consistent apart from antral length, and who were pre-operatively demographically similar. In this study no information was given regarding how patients were allocated to the two groups, but loss to follow-up reasons were given and there was no evidence of systemic bias. Both studies were rated as 'good' according to the USPSTF Quality Rating Criteria.

Outcomes: Weight loss

Weight loss at 12 months post-surgery (12 month %EWL):

Seven studies reported on this outcome, five of which were RCTs [8,11,18,20,21], (Figure 2). Only one RCT found a statistically significant difference in 12 month %EWL and this was in favor of AR [11]. Both cohort studies [17,22] found a statistically significant difference in favor of AR for this outcome.

Meta-analysis for weight loss at 12 months post-surgery demonstrated non-significantly better weight loss for AR both with RCTs only (SMD 0.32, CI -0.02 to 0.67), and also with inclusion of the cohort studies (SMD 0.67; CI -0.05 to 1.38). For the RCT data alone there was moderate heterogeneity (I^2 = 51.4%), and with all studies combined heterogeneity was high (I^2 = 93.4%). The latter was mainly due to the very large effect size of one cohort study (SMD 2.64; CI 2.20 to 3.08) [22], as removal of this study from analysis substantially reduced heterogeneity (SMD 0.40, CI 0.12 to 0.69, I^2 =48.2%). The residual heterogeneity can mainly be explained by small study size, with some contribution from study type and age of patients.

Weight loss at 24 months post-surgery (24 month %EWL):

Four studies reported on this outcome, two of which were RCTs [11,19] (Figure 3). Both RCTs found that AR was associated with increased 24 month %EWL than AP although this was only statistically significant in one [11]. The two cohort studies [17,22] also both reported significantly greater 24 month %EWL with AR when compared to AP.

Meta-analysis for weight loss at 24 months post-surgery demonstrated increased 24 month %EWL with AR (SMD 0.95; 95% CI 0.32 to 1.58). This was also the case when RCTs alone were included (SMD 0.67, CI 0.09 to 1.26). There was significant heterogeneity for the overall analysis (I^2 = 88.5%), which again is largely attributable to a large effect size of one of the cohort studies [22]. The exclusion of this study resulted in a greatly reduced homogeneity (I^2 = 30.8% with maintained effect in favor of AR (SMD 0.68, CI 0.38 – 0.99).

Outcomes: Complications

Incidence of staple-line leak:

Four studies reported incidence of staple-line leak [11,17,20,22]. Three showed a trend towards higher risk of leak in patients undergoing AR when compared to AP, however the number of leaks reported was low (seven in total), confidence intervals were high and none reached statistical significance.

Meta-analysis for this outcome showed no significant increased risk for leak with AR compared to AP (RR 1.87; 95% CI 0.46 to 7.61), with no significant heterogeneity (I^2 = 0.0%, p=0.910).

Incidence of staple-line bleed:

Five studies reported on staple-line bleed [8,11,17,20,22]. No difference was seen between the two surgical approaches in incidence of bleed in any individual study or on meta-analysis (RR 1.27; CI 0.4 to 4.01; I^2 = 0.0%). Total reported number of cases of bleed was twelve.

Incidence of post-operative de novo gastro-esophageal reflux disease (GERD):

Three studies reported on incidence of GERD [8,11,17]: There was no statistically significant difference between the two surgical techniques in terms of GERD incidence demonstrated in any individual study or on meta-analysis (RR 0.69; CI 0.26 to 1.82; I^2 = 3.6%).

Sub-group analysis and risk of bias across studies:

Sub-group analysis was performed for the factor 'RCT or not' for the outcomes of %EWL (see above). Jadad score was 3 or below for all studies, and so subgroup analysis for this factor was omitted. The other factors initially planned for sub-group analysis (bougie size and SLR) showed too much variability/ insufficient group sizes for this to be useful, given the small overall number of eligible studies.

Risk of bias across studies for each outcome measure is illustrated in table 3.

Discussion:

Although LSG is generally associated with good weight loss, some patients experience poor primary weight loss and a significant proportion of patients demonstrate weight regain (which tends to occur following a plateau of maximal weight-loss at about 12-18 months post-surgery [23,24]). Both of these adverse events are clearly clinically important, and there is much interest in operative approaches to prevent them[25]. This meta-analysis demonstrates that weight loss at 24 months is better following AR than AP, a feature which was not seen at 12 months (although there was a trend at this time point in favor of AR). These findings suggest that the advantage of AR over AP for weight loss increases over time. This could potentially reflect the cumulative effect of improved weight loss becoming significant at 24 months, or a differential reduction in weight regain conferred by AR when compared to AP.

Mechanistically, one of the main differences between AR and AP that could theoretically influence weight loss and weight regain is sleeve volume: in AR procedures the fashioned sleeve would be expected to have a smaller volume – a finding which has been confirmed

on volumetric CT scanning [26]. Few studies have examined the impact of sleeve volume on weight loss, but evidence suggests that while initial sleeve volume is not correlated with early weight loss [27,28], beyond two years the formation of a narrower sleeve intraoperatively may be associated with significantly improved weight loss [29]. It should be noted however that the volume of sleeves, and also the relative differences in volume between AR and AP sleeves, does change with time from surgery [26]. Longer-term follow up in trials of patients undergoing AP and AR sleeve gastrectomy is indicated to determine whether the weight loss advantage with AR continues to increase with time and what correlation, if any, this has with sleeve volume. Additionally, other technical factors such as bougie size also influence overall sleeve volume and shape, and the interaction of these variables with extent of antral resection are yet to be explored. Future research could determine whether antral resection has a specific effect on weight loss, independent of any difference conferred by a smaller sleeve volume.

Bleeding is a serious early complication of LSG with an incidence of up to 5% [30,31]. Intuitively, one might expect that AR would lead to a higher incidence of staple-line bleed than AP for two reasons: firstly, the technique involves a longer staple-line; and secondly, the staple-line passes through the antrum, which has a thicker wall than other parts of the stomach, and thus is likely to be more susceptible to stapler failure. This study, however, shows no difference between AR and AP in incidence of bleed. Potentially this failure to see a difference between the two techniques could simply reflect the small numbers of patients included in the meta-analysis. Alternatively, the findings of this study may indicate that good surgical technique in conjunction with advances in stapling technology (e.g. staple gun

cartridge design and staple-line buttressing [32]) can compensate for any theoretically increased risk of bleeding in AR over AP.

With regard to long-term outcomes, reflux is a common and troublesome complication after LSG [33]. From a theoretical perspective one might expect reflux to be more common following AR than AP due to a lower volume (and therefore presumably higher pressure) of the sleeved stomach. However, an increased incidence of *de novo* GERD following AR was not observed in our meta-analysis. The explanation for this is unclear. One possibility could relate to the observation that gastric emptying is accelerated after sleeve gastrectomy [8,34]. A recent randomized controlled trial comparing AR and AP reported that gastric emptying as measured by scintigraphy was increased at six months follow up in both groups, and that by 12 months it was faster in the AR group than in the AP group [26]. It may therefore be the case that increased gastric emptying compensates for the potentially reflux genic effect of reduced volume of the AR stomach. It should also be noted that gastric emptying is highly complex, and it has been suggested be that disruption of the antrum in itself may actually be protective against reflux in the context of fundal resection [35].

The main limitations of this review are those of the primary studies. The small numbers of patients enrolled in each of the studies make it difficult to draw conclusions about rare but serious complications- for example although this study found no difference in leak rate between the two groups, the total number of leaks was very low. There was a risk of bias in the included RCTs with method of randomization not described in several and poor detail regarding dropouts and withdrawals. Another important limitation was the short length of follow up of most studies, with only four reporting %EWL at 24 months. In terms of study

selection, the inclusion of good quality retrospective studies can be defended on the basis of paucity of available data. Meta-analyses were performed for RCTs only as well as for all studies, and both direction and magnitude of effect were similar.

There was also a lack of standardization between studies with respect to outcome reporting and surgical technique between studies, although within chosen studies operative technique was consistent between study groups with antral length the only variable. As with other surgical RCTs, confounding factors related to the complexity and variability of surgical interventions are difficult to circumvent [36]. For example the use of AR or AP is one variable which is likely to interact with other demographic and technical variables to give overall risk of outcome. Although planned, it was not possible to perform subgroup analyses to address some of these potential confounders because of the small numbers of studies and cases eligible for inclusion. It should also be noted that this study only included primary sleeve operations. LSG is however now increasingly being used as a revision bariatric procedure following failed gastric banding [37], and it is not clear if any of differences between AP and AR seen here in primary surgery would be replicated in the setting of revisional surgery.

Despite these provisos, this is the first meta-analysis to examine the differences in outcomes following AP and AR sleeve gastrectomy. Based on the available evidence, it appears that AR is associated with improved short-medium term %EWL when compared with AP, without any difference in complication rates. These results may indicate that AR is preferable to AP in primary laparoscopic sleeve gastrectomy for morbid obesity. Further large scale and high quality RCTs on this topic are warranted.

Disclosure statement

None of the authors have a conflict of interest relating to the topic of this article.

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Titles and legends of tables and figures

Table 1: characteristics of included studies

Legend:

AR: antral resecting; AP: antral preserving; SD: standard deviation; GORD: gastro-oesophageal reflux disease

* No leak or bleed assumed from statement in abstract 'no serious postoperative complications in both groups'. Author uncontactable to clarify.

$ Values are means across the study population as a whole, with standard deviation where available.

Table 2: risk of bias in included randomized controlled trials (Jadad score)

Table 3: Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) evidence profile

Legend:

* For most studies there was an inadequate method of randomisation (if at all) and no blinding in any study

$ For dichotomous outcomes the number of events was very low so results are imprecise

Figure 1: PRISMA flow diagram to illustrate study selection

Figure 2: weight loss at 12 months post-surgery

Legend:

Forest plot comparing percentage excess weight loss (%EWL) at 12 months following antral-excising (AR) and antral-preserving (AP) sleeve gastrectomy for obesity, stratified for study type. AR is the comparator: positive SMDs favour AR.

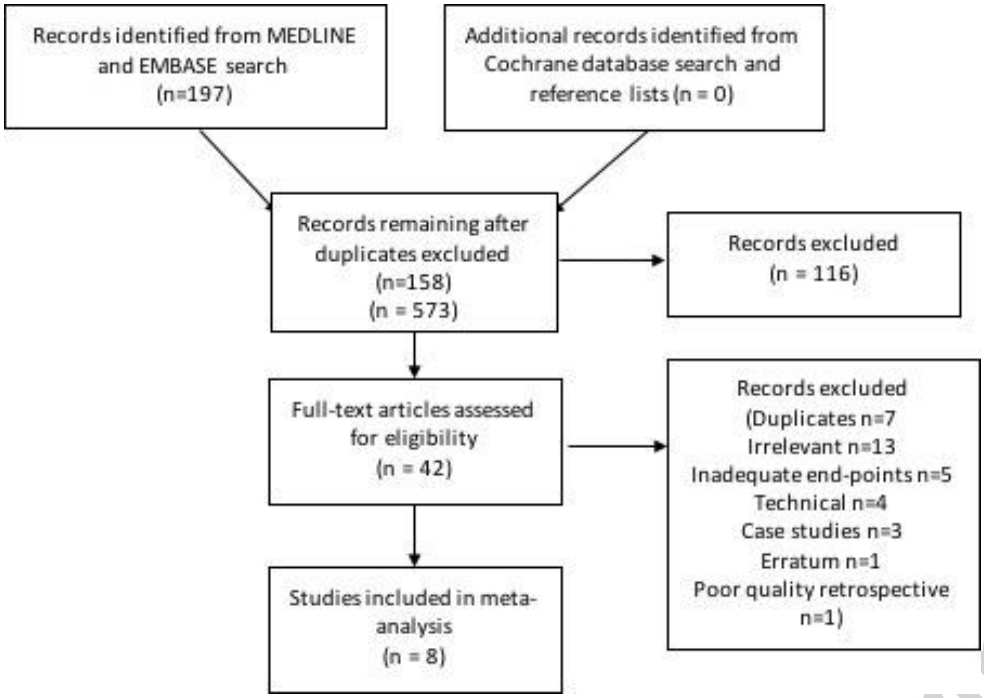
RCT: randomised controlled trial; SMD: standardised mean differences; CI: confidence interval

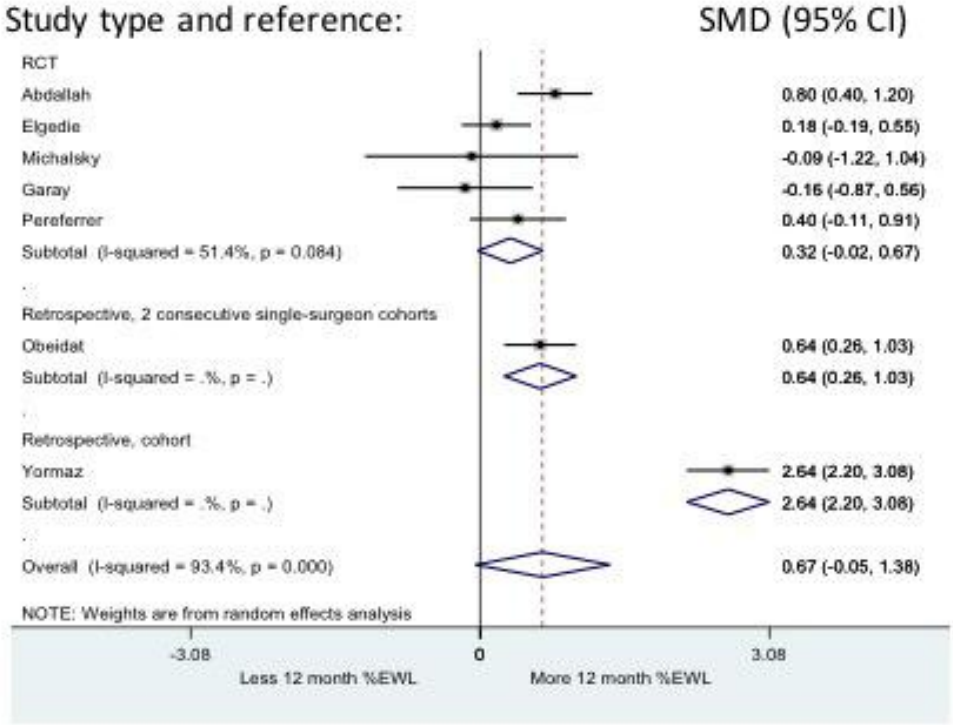
Figure 3: weight loss at 24 months post-surgery

Legend:

Forest plot comparing percentage excess weight loss (%EWL) at 24 months following antral-excising (AR) and antral-preserving (AP) sleeve gastrectomy for obesity, stratified for study type. AR is the comparator: positive SMDs favour AR.

RCT: randomised controlled trial; SMD: standardised mean differences; CI: confidence interval





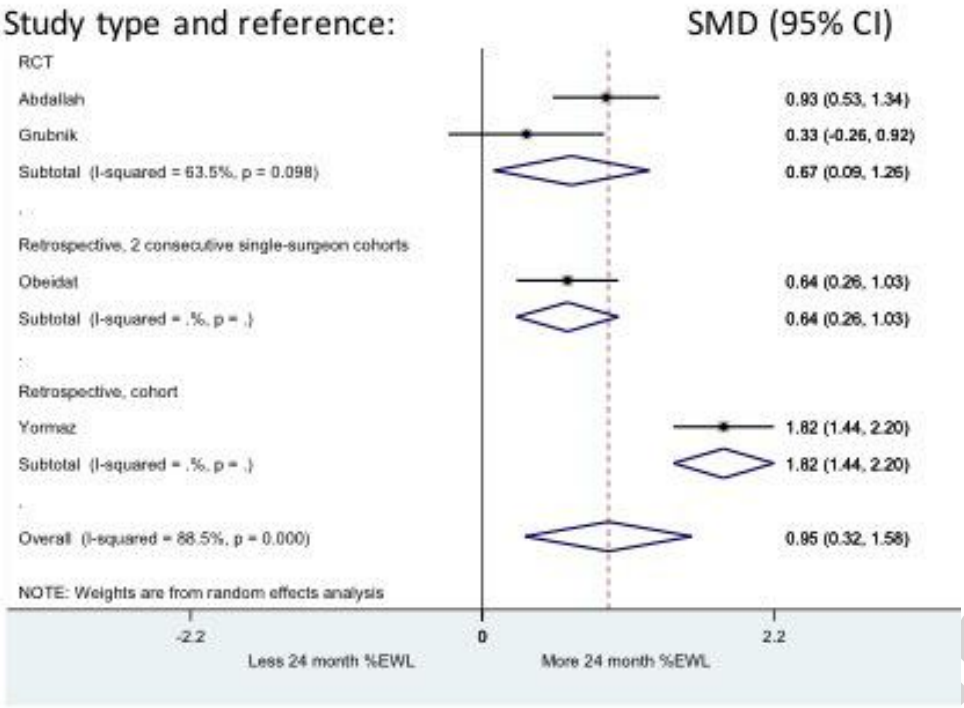


Table 1: characteristics of included studies

First author and year of publication (full-length paper unless otherwise indicated)	Number treated	Number completing study (number in intervention group – AR)	Definition of intervention (AR) and comparator (AP) in cm from pylorus	Pre-operative BMI in kg/m2 mean (SD)[$]	Staple line reinforcement	Bougie size in French	Mean %Excess weight loss (SD) at 12 months post-surgery[$]	Mean %Excess weight loss (SD) at 24 months post-surgery [$]	Total early mortality (% of cases)	Total Leak (% of cases)	Total Bleed (% of cases)	Total de novo GORD (% of cases)	Jadad score
Abdallah[10] 2014	105	105 (52)	2 vs 6	51.7 (7.5)	Not routine	38	57.8 (16)	66.5 (12.7)	1 (1.0)	3 (2.9)	1 (1.0)	5 (4)	3
Elgeidie[20] 2014	114	106 (55)	2 vs 6	44.8	Not routine	38	66.1	Not given	1	1 (0.9)	3 (2.7)	Not given	2
Garay (abstract)[18] 2016	30	30 (14)	2 vs 5	Not given	Not given	Not given	57.7	Not given	Not given	Not given	Not given	Not given	1
Grubnik *(abstract)[19] 2015	45	45 (22)	2 vs 6	49.6 (6.8)	Not given	Not given	Not given	56.4	0 (0)	0 (0)	0 (0)	Not given	1
Michalsky[7] 2013	12	12 (6)	2.5 vs 6	41.4	Not routine	36	61.8	Not given	0 (0)	0 (0)	2 (16.7)	3 (25)	2
Obeidat[17] 2015	125	110 (56)	2 vs 6	46.1 (7.9)	Oversewn	38	72.9 (23.5)	73.2 (27.3)	0 (0)	1 (1.0)	3 (2.7)	10 (9)	NA (cohort study)
Pereferrer[21] 2017	60	59 (30)	3 vs 8	51.1	Seamguard	38	60.5[&]	Not given	0 (0)	Not given	Not given	Not given	3
Yormaz[22] 2017	168	152 (84)	2 vs 6	48.8 +/-5.3	V-loc™ wound closure device	36	56.3	65.5	0 (0)	2	3	Not given	NA (cohort study)

AR: antral resecting; AP: antral preserving; SD: standard deviation; GORD: gastro-oesophageal reflux disease

* No leak or bleed assumed from statement in abstract 'no serious postoperative complications in both groups'. Author uncontactable to clarify.

[$] Values are means across the study population as a whole, with standard deviation where available.

Table 2: risk of bias in included randomised controlled trials (Jadad score)

Reference	Described as randomised?	Adequate method of randomisation? (One point deducted if inappropriate)	Described as double-blind?	Adequate method of double-blinding? (One point deducted if inappropriate)	Description of dropouts/ withdrawals?	Jadad score
Abdallah[10]	Yes	Yes	No	No	No dropouts	3
Elgeidie[20]	Yes	Yes	No	No	Yes	3
Garay[18]	Yes	Not described	No	No	No statement	1
Grubnik[19]	Yes	Not described	No	No	No statement	1
Michalsky[7]	Yes	Not described	No	No	No withdrawals	2
Pereferrer[21]	Yes	Yes	No	No	Yes	3

Table 3: Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) evidence profile

Outcome	Risk of bias*	Inconsistency	Indirectness	Imprecision[$]	Publication bias	Classification
12 month %EWL	Serious limitations	Serious limitations (inconsistent Forrest plot estimates)	No serious limitations	No serious limitations	Undetected	Low
24 month %EWL	Serious limitations	Serious limitations (heterogeneity)	No serious limitations	No serious limitations	Undetected	Moderate
Staple-line leak	Serious limitations	No serious limitations	No serious limitations	Very serious limitations	Undetected	Very low
Staple-line bleed	Serious limitations	No serious limitations	No serious limitations	Very serious limitations	Undetected	Very low
GORD	Serious limitations	No serious limitations	No serious limitations	Very serious limitations	Undetected	Very low

* For most studies there was an inadequate method of randomisation (if at all) and no blinding in any study

[$] For dichotomous outcomes the number of events was very low so results are imprecise