Title: Five Year Weight Loss Outcomes in Laparoscopic Vertical Sleeve Gastrectomy (LVSG) Versus Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) Procedures: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ABSTRACT

Background: Laparoscopic vertical sleeve gastrectomy (LVSG) has overtaken the laparoscopic Roux-en-Y gastric bypass (LRYGB) as the most frequently performed bariatric surgical procedure. To date little has been reported on the long-term outcomes of the LVSG procedure comparative to the traditionally favoured LRYGB. We undertook a systematic review and meta-analysis to review the five year outcomes of comparing LVSG and LRYGB. We undertook a systematic review and meta-analysis to compare five year weight loss outcomes of randomized controlled trials (RCTs) comparing LVSG to LRYGB.

Methods: Searches of electronic databases (Pubmed, EMBASE, CINAHL, Cochrane) were undertaken for RCTs describing weight loss outcomes in adults at five years postoperatively. Where sufficient data was available to undertake meta-analysis, the Hartung-Knapp-Sidik-Jonkman (HKSJ) estimation method for random effects model was utilised. The review was registered with PROSPERO and reported following in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Results: Five studies met the inclusion criteria totalling 1028 patients (LVSG=520, LRYGB=508). Moderate but comparable levels of bias were observed within studies. Statistically significant BMI loss ranged from -11.37kg/m^2 (range -6.3 to -15.7 kg/m^2) in the LVSG group and -12.6 kg/m^2 (range -9.5 to -15.4 kg/m^2) for LRYGB at five years ($p<0.001$). Systematic review suggested that LRYGB produced a greater weight loss expressed as percent excess weight and percent excess BMI loss than LVSG: this was not corroborated in the meta-analysis.

Conclusions: Five year weight loss outcomes suggest both LRYGB and LVSG are effective in achieving significant weight loss at five years postoperatively, however differences in reporting parameters limit the ability to reliably compare the outcomes using statistical methods. Furthermore, results may be impacted by large dropout rates and per protocol

analysis of the two largest included studies. Further long-term studies are required to contradict or validate the results of this meta-analysis.

Key words

Meta-analysis, Systematic review, sleeve gastrectomy, Roux-en-Y gastric bypass, five year outcomes, weight loss

INTRODUCTION

The prevalence of obesity has increased three-fold in the last four decades, with 37% of American adults now classified as obese [1]. Obesity poses health risks to the individual through contributing to the development of chronic diseases such as heart disease, diabetes, musculoskeletal conditions and some types of cancer. Furthermore, the annual economic impact of obesity has recently been estimated to approach $US150 billion on medical costs alone [2].

Bariatric surgery continues to be increasingly utilized to mitigate both individual health risks and healthcare costs associated with obesity [3]. While laparoscopic Roux-en-Y gastric bypass (LRYGB) has traditionally been used as the procedure of choice, in recent years the laparoscopic vertical sleeve gastrectomy (LVSG) has been increasingly favoured [3-6]. Until recently, however, long-term data regarding the safety, efficacy and clinical outcomes for the LVSG compared to the LRYGB procedure have not been available.

The aim of this systematic review and meta-analysis is to investigate five-year weight loss outcomes reported from randomized controlled trials (RCTs) that compare LRYGB with LVSG. The present work represents a continuation of our previous work [7], focusing exclusively the long-term weight outcomes with the intent of strengthening the evidence base used to inform bariatric procedure selection.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria and Search Strategies

The current work is an updated research synthesis of our previous meta-analysis [7] and therefore the inclusion and exclusion criteria previously described were maintained: These included RCTs comparing the weight loss outcomes of LRYGB with LVSG performed in patients over 18 years old. Any study with additional, potentially confounding interventions were excluded. Similarly, the previously utilized methodology for the searching of electronic databases remained unchanged, with the exception of date ranges altered to capture papers published since our original searches (2015 to 2019), and the addition of "five years" and "long term" to the search terms used. (See supplementary data).

Data collation

Two authors (EO and MAM) independently conducted searches and reviewed the identified papers for inclusion on confirmation of meeting the inclusion criteria. Data extraction was undertaken by one author (EO), which was cross-checked for consensus by a second author (MAM). Corresponding authors of included papers were contacted for additional information in situations where the reporting of the published data limited the ability to include, combine and analyse. Where there was not a unanimous interpretation of inclusion criteria/data for extraction, discussion was undertaken until consensus was reached. The Cochrane tool for assessing bias was used to assess included RCTs [8]. The review was registered prospectively with PROSPERO (registration number 112054) and reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [9].

Statistical Analysis

Qualitative assessment was undertaken for all studies meeting inclusion criteria. Computation of BMI change between baseline and five years data by procedure were obtained by paired sample t-tests. Meta-analysis was undertaken for outcome variables where number of studies and reported data were sufficient for this to be undertaken. Weighted mean differences (WMD) were computed using the Hartung-Knapp-Sidik-Jonkman (HKSJ) estimation method for random effects model [10]. Heterogeneity present in the effect size was determined using Cochrane's Q statistic and I^2 index. Point estimates of the population effect sizes and forest plots of 95% confidence intervals were produced using metafor package in R [11]. Funnel plots were generated to assess the presence of publication bias. Significance test of the population effect size was conducted using t statistic. A p-value of 0.05 was considered to be statistically significant.

RESULTS

Search outcomes yielded 167 records; 165 were identified from electronic database searches and two were identified from specific searches for further longitudinal data from the clinical trial numbers of the RCTs included in our previous work on this topic [7]. After removal of duplicates, 109 abstracts were screened, resulting in five studies remaining for full text review, all of which met criteria for inclusion [12-16] (LVSG=520, LRYGB=508). (Figure 1; Table 1).

Four of the five studies meeting the inclusion criteria in the present work represent the five-year follow-up data of included studies in our original meta-analysis [12-16]. Although Ruiz-Tovar et al [16] RCT included a third surgical arm, one anastomosis gastric bypass data was omitted for this review. The STAMPEDE study was excluded as the intensive medical intervention included concurrently with all surgical interventions posed a significant point of difference between it and the other included studies [17]. Four of the five studies have reported five-year outcomes within the last two years [13-16], while one had reported five year follow-up data at the time of our initial analysis [12].

Weight loss was the primary outcome for all studies. Weight loss was described in terms of percent excess weight loss [%EWL] (k=2) and percent excess BMI loss [%EBMIL] (k=3). BMI data was available for all studies.

A moderate degree of bias was present in all studies (Figure 2). As the bias levels appeared largely comparable between the included studies, no further sensitivity analyses were undertaken.

Missing data and loss to follow-up

Follow-up at five years across the included studies ranged from 73 to 92% (median 84%; IQR 11%). Two studies applied intention to treat (ITT) statistical analysis [12,13] while per protocol (PP) analysis was utilised by Ruiz-Tovar et al [16], Salminen et al [15], and Peterli et al [14], the latter two studies in accordance with their adoption of equivalence study design. Missing data represented 0.46%, 25.8%, 3.2%, 31.8% and 5.5% of data points at one to five year respectively in the SM-BOSS study [14], while Salminen et al report missing data was present in at least one time point in 25% of their patients [15]. Both studies managed missing data in the same way: Missing values were imputed by a multiple imputation technique based on a Markov Chain Monte Carlo simulation, and sensitivity analyses were conducted using 10 sets of generated data [14,15].

BMI from baseline to five years

Following correspondence with the authors of the SM-BOSS and SLEEVEPASS studies [14,15], BMI data was available for all studies at three and five years follow-up.

Systematic review

The average BMI at baseline in the European studies were ~45kg/m^2, while that of Zhang et al's [12] Chinese study was lower at ~39kg/m^2, reflecting the difference in BMI thresholds for obesity-related disease and indications for bariatric surgery between differing ethnic groups. All studies demonstrated a rapid BMI reduction in the first 12 months and a gradual but progressive regain over the five year follow-up period in both the LRYGB and LVSG groups [12-16]. Based on data collated from the included studies, there was a significant BMI loss maintained from baseline to five years follow-up (p<0.001), with an average BMI loss of -11.37kg/m^2 (range -6.3 to -15.7 kg/m^2 in the LVSG group and -12.6 kg/m^2 (range -9.5 to -15.4 kg/m^2) for LRYGB. BMIs at five years were similar between studies and procedures (30-35kg/m^2). (Figure 3a and b).

When considering the results of individual studies, statistically significantly lower BMIs were reported in the LRYGB vs LVSG group consistently from the second to fifth year of postoperative follow-up by Zhang et al [12] and Ruiz-Tovar et al [16]; conversely Ignat et al [13] demonstrated significantly lower BMIs in the LVSG vs LRYGB groups from the third to fifth postoperative years. Though not described as being statistically significant, trends favouring lower BMIs in the LRYGB relative to LVSG were reported by both Peterli et al [14] and Salminen et al [15].

Meta-analysis

Meta-analysis was performed for BMI data available annually to five years postoperatively. With the exception of a statistically significant difference favouring LRYGB at two years (WMD 0.87, 95% CI 0.27-1.46, p=0.02; Q=2.87, p=NS, I^2 =0%) that was lost in subsequent years' analysis, statistically significant differences were not found in BMIs attained between the two procedures in the pooled estimates. A non statistically significant trend favouring lower BMI at five years was noted with LRYGB over LVSG (WMD 0.72, 95% CI -1.48-2.92, p=NS; Q=14.7, p=0.01, I^2 =81.62%). (Figure 4a and b).

Funnel plots vary in distribution over the time points, however no data points fall outside of the expected range to suggest the presence of publication bias. This is difficult to interpret in the context of less than 10 studies for the generation of a funnel plot [14].

Percent Excess BMI Loss (%EBMIL) from baseline to five years

Peterli et al [14], Zhang et al [12] and Ruiz-Tovar et al [16] reported their weight loss outcomes meeting the %EBMIL definition.

Systematic review

Zhang et al [12] reported statistically significant greater %EBMIL in the LRYGB group from the second through to the fifth year of postoperative follow-up comparative to LVSG ($p<0.05$ at these time points). Peterli et al [14] also reported significant differences between the %EBMIL achieved between procedures when adjustments for multiple comparisons were not applied (p=0.03). These differences were lost, however, when adjusted for multiple comparisons [14]. In view of this, the predefined minimal clinical difference of ±10% EBMIL was not detected (i.e. LVSG and LRYGB yielded comparable %EBMIL outcomes at five years) [14]. Ruiz-Tovar et al [16], on the other hand, did not report differences between procedures in %EBMIL were found at one, two or five years follow-up.

Generally, the greatest %EBMIL was seen in the first year following surgery, and %EBMIL reduced marginally with each year of postoperative follow-up. However, there was a small degree of further %EBMIL observed in the LRYGB group between the first and second postoperative year described by Peterli et al [14] (76.7% to 77.4%) before falling into the reported pattern. At five years follow-up, LRYGB maintained a greater average ~10% more %EBMIL than LVSG based on individual study data. (Figures 5a and b).

Meta-analysis

Meta-analysis was not undertaken for %EBMIL owing to insufficient data being available for analysis.

Percent Excess Weight loss (%EWL) from baseline to five years

Ignat et al [13] and Salminen et al [15] reported their weight loss outcomes meeting the definition of %EWL. Data points were not available for two and four years for Salminen et al [15], and four years for Ignat et al [13].

Systematic review

Ignat et al [13] demonstrated a statistically significant difference in %EWL favouring LRYGB in the third and fifth years of postoperative follow-up ($p<0.05$). Salminen et al [15], though reporting their data in terms of an equivalence methodology, did not demonstrate equivalence between procedures based on their predefined equivalence margins of ±9% EWL: LRYGB was shown to produce greater weight loss compared to the LVSG at all timepoints, however the difference was not considered to be clinically significant.

With the exception of the three year LRYGB data by Ignat et al [11], %EWL reduced with each year of postoperative follow-up, with LRYGB maintaining on average ~8% more %EWL than LVSG at five years follow-up. (Figures 6a and b).

Meta-analysis

No statistically significant differences in %EWL were found at one, three or five years postoperatively between LVSG and LRYGB, however by the fifth year of postoperative follow-up there was a non-significant trend favouring LRYGB (LVSG n=153, LRYGB n=140 from k=2; WMD -7.86 [-23.67, 7.95], p=NS; Q=0.23, p=NS, I^2 =0%). The significant heterogeneity observed between the included studies at three years had resolved at the five year data points. (Figure 7).

Funnel plots do not suggest the presence of publication bias, however with such a low number of eligible studies no valid conclusion can be made [18].

DISCUSSION

This systematic review and meta-analysis of RCTs has examined the five year weight loss outcomes obtained in RCTs comparing LVSG and LRYGB. When results are considered holistically, it appears that both procedures are effective in facilitating and maintaining long-term weight loss. Despite differences in the measures used to report on weight loss outcomes, all included RCTs suggest a trend towards greater weight loss and maintenance at five years with LRYGB over LVSG, however this does not appear to be clinically different based on the conclusions from the equivalence methodology utilised by two of the largest studies [14,15].

The current review builds on our previous work by focusing on weight loss outcomes at a five year follow-up period. In our earlier meta-analysis, which similarly suggested equivalence in weight loss outcomes between the two procedures, only one of the nine included studies reported data to five years [12], with the majority only reporting weight loss data to 12 months [7]. Achieving long-term, sustainable weight loss is a primary goal of bariatric surgery, and as such, the ability of the offered procedure to deliver this outcome is of key importance to patients, clinicians and third party payers. It is therefore essential that the strongest possible evidence base underpinning our understanding of long-term weight loss outcomes of the commonly utilised bariatric procedures be strengthened by follow-up synthetic reviews as further data becomes available so as to inform clinical decisions.

Unfortunately, the ability to make stronger conclusions regarding the weight loss outcomes in the present work were limited by the lack of consistent reporting measures used between included studies. While the American Society for Metabolic and Bariatric Surgery have proposed reporting standards for bariatric surgery research that include the use of initial BMI, change to BMI, % total body weight loss and %EBMIL [19], there are no universally accepted metrics for reporting weight loss outcomes in bariatric surgery studies.

This issue of using different metrics to describe weight loss outcomes affects the ability to synthesise data across studies and may also confound the interpretation of actual outcomes achieved. A retrospective review of the weight loss outcomes from the Bariatric Outcomes Longitudinal Database (BOLD) computed and compared the coefficient variation (CV) between percentage total weight loss (%TWL), %IBMIL, %EWL, and percent of initial body weight lost (%IWL) (equivalent of %TWL) [20]. They concluded that given %IWL / %TWL represent the most accurate expression of weight loss in the post bariatric surgery population owing to them demonstrating the lowest CV and therefore recommend their use for reporting [20]. Furthermore, modelling from retrospective clinical data has suggested the degree of obesity may affect the comparability of these metrics: While %EWL yields comparable results in both the obese and super obese, %TWL will appear greater in the super obese, while %EBMIL has been shown to be higher in less obese patients in the first two years postoperatively [21]. It appears that a greater understanding of the implications of the choice of weight loss metric is required, and that this should inform standardized reporting of weight loss outcomes in bariatric surgical research in the future.

BMI was the only weight-related metric common to all studies in this systematic review and meta-analysis. While BMI as a standalone outcome lacks the specificity to describe the magnitude of postoperative weight loss seen, it nevertheless allows for qualitative review of weight change and weight maintenance in the post-operative period and describes the weight trajectory to five years after surgery. From qualitative review of the data we see that BMIs reduced in all procedures, and from quantitative review we see that there is no significant difference in BMI at any time points between procedures. Given the nature of the measures, the relative measures of weight loss reported in the included studies (%EWL and %EBMIL) were observed to inversely follow the trend of BMI over the follow-up period.

Notwithstanding the data points at two and three years that suggest further small weight loss continuing in the LRYGB groups in the Peterli et al [14] and Ignat et al [13] studies respectively, a clear trend for modest weight regain over the five year follow-up is evident across the measures of weight and weight loss for both LRYGB and LVSG. This appears to be relatively equivalent between procedures, representing ~2-2.5kg/m^2 between the lowest BMI reported at the first postoperative year and that reported at the fifth. This pattern of weight recidivism is consistent with studies of across a range of methodologies that report weight outcomes annually to five years in LRYGB and/or LVSG to five years [22-26].

The factors contributing to weight recidivism are complex, and a number appear to be attributable to aspects specific to the procedures utilized. Dilatation of the gastric pouch and gastric outlet in LRYGB, and sleeve in LVSG, may negate the desired volume restriction and have been observed to be associated with postoperative weight regain [27,28]. Where this is the primary identified reason for weight regain, revisional procedures have been used with success to reverse the undesired weight trends observed in individuals [29].

Similarly, a range of physiological adaptations may occur over time to reduce weight loss efficacy, and may vary with the procedure utilized. Alterations to the secretion of gastrointestinal hormones such as of GLP-1, PPY, GIP, and ghrelin have been postulated to play in a role in the weight regain patterns as gastrointestinal hormone profile differences have been observed in patients with and without weight regain following RYGB [30,31]. Less information about the hormonal impact on the differences in weight outcomes post LVSG is currently available given the relatively recent uptake of this procedure [31].

Additionally, it seems plausible that bypassed small bowel, as in the case of LRYGB, may experience similar luminal adaptation as described in short bowel syndrome (SBS): The timeframes associated with bowel adaptation for resumption of optimised adaptation following SBS mirror the patterns seen in weight recidivism following bariatric surgery [32].

In addition to the considerations specific to the two procedures investigated, modifiable physiological, lifestyle and psychological factors also exert an impact on postoperative weight recidivism. Changes in metabolic rate following bariatric surgery have been hypothesized to contribute to weight regain. Lowered resting metabolic rates (RMR) have been found in post-bariatric surgery patients who regained weight compared to those with sustained weight loss [33-35]. These changes may in part be explained by postoperative reduction in fat free mass (FFM). FFM has been shown to be influenced by dietary choices (reduced with high fat/carbohydrate and low protein consumption) [36] [28,36-38] and to increase with physical activity in post-bariatric surgery patients [39-41]. Therefore, focusing on anthropometric and metabolic optimisation through postoperative lifestyle interventions may represent an effective avenue by which bariatric surgical weight outcomes may be sustained.

Finally, depression, anxiety [28], lack of self-efficacy and inappropriate psychological dependence on food (such as comfort eating), if not identified and treated, are likely to continue to exert a negative impact on postoperative weight status. Similarly, given the high incidence of (often undiagnosed) binge eating disorders and food addiction in bariatric surgery candidates, ongoing manifestation of these issues may also contribute to weight regain following surgery [37,42-44].

The prevention and management of post-surgical weight regain, therefore, is complex and is likely to benefit from multidisciplinary management. Of the included studies, only two make brief reference to any form of multidisciplinary postoperative follow-up provided to patients undergoing surgery – Ruiz-Tovar et al report dietary and exercise counselling at time of discharge [16], and Peterli et al report nutritional counselling and participation in physiotherapy group [14]. Greater focus on supporting patients holistically after surgery with ongoing dietetic, psychological, physiotherapy or exercise physiology involvement, as well as specialist medical and/or surgical follow-up, has a role in maintaining the efficacy of weight loss outcomes in view of the modifiable reasons for postoperative weight regain. Bariatric surgery may therefore be better conceptualised as tool to support long-term lifestyle and behaviour changes, rather than 'a magic bullet' approach to managing obesity.

At five years there is a high rate of loss to follow-up and/or missing data points was reported in the included studies – this has implications for the interpretation of long-term clinical outcomes. Reviews of bariatric surgery trials highlight the challenges of maintaining adequate post-surgical follow-up in this patient group: Compared to the 6% average loss to follow-up reported by Akl et al in trials involving general medical patients [45], average loss to follow-up in the bariatric surgery literature is described at 30% at the stated study end point [46]. Notably loss to follow-up further increased with study duration [46]. By contrast, the collective loss to follow-up described in the studies included in this systematic review and meta-analysis was 16%. This lower than previously described rate likely reflects the more rigorous procedures incorporated into a clinical trial compared to those that are possible in standard clinical practice. However, this degree of loss to follow-up represents a significant vulnerability for the conclusions that can be drawn from the studies individually as well as collectively. The means by which missing data is handled in clinical trials has been shown to lead to over- and underestimates of treatment effects [45]. Two of the largest studies included in this meta-analysis utilised PP analysis in keeping with their adoption of equivalence methodology [47]. In these analysis methodologies, PP analysis is favoured with a view to minimising the dilution of treatment effects, and thus reduce the risk of inadvertently predisposing results in the direction of the alternative hypothesis of the non-inferiority test (i.e. that there is no difference between interventions) [47,48]. However, PP analysis risks introducing bias [47,48] and modifications to traditional ITT analyses have been suggested to be more appropriate for use with equivalence and non-inferiority trial methodologies [47]. Given that the PP data from the SM-BOSS [14] and SLEEVEPASS [15] studies represent nearly half of the data (45%) in this systematic review and meta-analysis, the strength of conclusions that can be drawn from the present work must be viewed in light of this limitation.

The primary limitation of the current systematic review and meta-analysis is that the statistical power to draw strong conclusions is limited in view of the few studies that meet our inclusion criteria at five years, and further due to the differences in metrics used to report weight outcome data. We have nevertheless proceeded with both a qualitative and quantitative analysis of the available five year data while acknowledging the subsequent limitations, as we recognise the clinical importance of the data involved in view of the rapid uptake of the LVSG procedure and the limitations of comparative long-term data currently available. In time we hope results of this work can be verified or updated as data from long-term RCTs comparing the two procedures become available.

Notwithstanding these limitations, the present work has several strengths that are unique to the reviews on this topic [49-54]. First, the strictest possible inclusion criteria have been adopted to minimise the influence of confounding factors. This is important as methodological diversity has been shown to exaggerate treatment effects [55,56], and poor handling of avoidable clinical diversity risk undermining the assumptions that underpin the statistical models of meta-analysis [57].

Second, the statistical expertise drawn from within the multi-disciplinary author group has allowed the early adoption of more sophisticated methods for the application of random effects models of meta-analysis (HKSJ) [10]. Compared to the DerSimonian and Laird (DL) method, HKSJ method has been shown to have less inflated error rates when combined studies are of unequal sizes, number of studies is small and demonstrate between-study heterogeneity [10]. Given that this description well describes the included studies, HKSJ method was considered a more appropriate method to be applied under these circumstances. Indeed, the HKSJ provides a more conservative summary data compared to that obtained through DL method, which demonstrated statistical significance in %EWL outcomes favoring LRYGB (data not shown). Given the greater weighting placed on meta-analysis data within contemporary health care decision making, the judicious selection of method used for analysis is essential to support appropriate clinical decision making and represents the responsible handling of the data in question.

CONCLUSION

This systematic review and meta-analysis of five year weight outcomes described in RCTs comparing LVSG and LRYGB have suggested both procedures are effective in achieving and maintaining statistically significant weight loss at five years postoperatively. While all studies display a trend toward greater weight loss being achieved with LRYGB, these are not supported by results of meta-analysis. These conclusions, though based on the strictest application of meta-analysis methodology, should be viewed with caution due to the small numbers of RCTs with five year data currently available, the differences in the weight loss metrics used to report outcomes and the degree of loss to follow-up within some of the included studies. This review has highlighted that long-term studies providing comparative outcomes of LVSG and LRYGB continue to be required, and that there is a critical need for the adoption of standardized reporting to facilitate synthesis of data with a view to allowing valid and meaningful qualitative and quantitative reviews to occur in the future.

Conflict of Interest Statement

The authors declare that they have no conflict of interest.

Ethical approval Statement

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

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