TITLE

Late postoperative complications in laparoscopic vertical sleeve gastrectomy (LVSG) versus laparoscopic roux-en-y gastric bypass (LRYGB) procedures: A meta-analysis and Systematic Review

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INTRODUCTION

Obesity is now reported in epidemic proportions internationally, with many countries such as the United States, Mexico, Australia and New Zealand now reporting between a quarter and a third of their population as being obese[1]. As such, obesity and obesity-related chronic diseases are fast becoming the most significant health problems faced globally.

Obesity is responsible for a significant proportion of healthcare related costs. In Australia, AU$ 2 billion was attributed to obesity related health care costs in 2008, accounting for approximately 25% of the direct and indirect costs associated with obesity[2]. Similarly the annual costs associated with obesity in the United States and the United Kingdom respectively are estimated to exceed US$ 50 billion and GB£ 2 billion[3,4].

In this context, both effective population-based prevention strategies along with sustainable individual management approaches are being urgently sought to reduce the burden of disease and economic demands caused by widespread obesity. Bariatric surgical procedures, such as laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic vertical sleeve gastrectomy (LVSG), are increasingly being recommended as cost-effective and efficacious strategies to manage obesity related chronic disease and metabolic conditions in the moderately to severely obese individuals[1,5-7]. LRYGB is a two step procedure in which the gastric reservoir is significantly reduced and proximal intestine bypassed to induce a level of malabsorption to further facilitate weight loss[2,8]. Moreover changes in gastric hormone signaling (such as peptide YY and glucagon like factor -1) may further reduce appetite and modulate energy expenditure therefore maintaining weight loss over long period of time[9]. LVSG, on the other hand, is a purely restrictive procedure involving the permanent removal of 90% of the stomach volume while maintaining the integrity of the pyloric sphincter. However, as with all surgical procedures - particularly those in a high-risk bariatric population - these procedures are not without a degree of risk of complications that may lead to further burden on the health system and diminished postoperative quality of life. These complications may be related to surgical skills, surgical techniques, obesity, maladaptive physiological responses to the procedure, change in anatomy and malabsorption to name but a few[10,11]

This aim of this systematic review and meta-analysis is to study the peer review literature regarding *late postoperative complications* reported from randomised control trials (RCTs) comparing LVSG and LRYGB bariatric procedures.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria

RCTs comparing clinical outcomes of LVSG and LRYGB procedures were reviewed. Additional inclusion criteria included adult subjects (>18 years), elective surgical patients randomised to receive either LVSG or LRYGB, and clinically relevant outcomes reported pertaining to late complications (occurring >30-days postoperatively). These included mortality, major and minor complications, and interventions and/or hospital readmissions required for their management. Qualitative review was performed on all studies that met inclusion criteria, and meta-analyses were run on outcome variables where numbers and methods of reporting were sufficient to allow statistical analysis.

Search Strategies and Data Collection

Electronic databases (Medline, Pubmed, EMBASE, CINAHL, Cochrane Register of Systematic Reviews, Science Citation Index) were cross-searched for RCTs published between 2000 and November 2015 to capture the studies since Regan et al’s[12] description of the LVSG as a stand-alone procedure, using search terms optimised for each search engine in an attempt to identify all published papers meeting the inclusion criteria. Limits were set to RCTs and adult patients (>18yrs) to reflect the inclusion criteria. Search strategies utilized included combinations of "laparoscopy"[MeSH Terms] OR "laparoscopy"[All Fields] OR "laparoscopic"[All Fields]), "gastric sleeve"[All Fields] OR "sleeve gastrectomy"[All Fields] AND "roux en y"[All Fields] OR "*gastric bypass"[All Fields] AND "outcomes"[All Fields]. Reference lists of existing review articles were examined for additional citations. Authors of included papers were contacted by e-mail for clarification or additional information where required.

The Preferred Reporting of Systematic Reviews and Meta-Analyses (PRISMA) statement was adopted. Two authors (EO and MAM) independently appraised identified studies to confirm compliance with agreed inclusion criteria. One author (EO) undertook the data extraction. The authors were not blinded to the source of the document or authorship for the purpose of data extraction. The data were compared and consensus was achieved through discussion or contact with corresponding authors when required.

The methodological quality of identified studies was assessed using the Jadad scoring system[13]. This method produces a number between one and five based on the reporting of randomization, blinding and accounting for all subjects at the end of the follow up period, with higher scores representing a higher methodological quality[13].

Statistical Analysis

Meta-analyses were performed using odds ratios (ORs) for binary outcomes and weighted mean differences (WMDs) for continuous outcome measures. An amended estimator of OR was used to avoid the computation of reciprocal of zeros among observed values in the calculation of the original OR[14]. Random effects model (REM), developed by DerSimonian and Laird[15] using the inverse variance weighted method approach and the inverse variance heterogeneity (IVhet) model developed by Doi et al[16] were used to combine the data to estimate the common effect size of the outcome variables. Heterogeneity among the effect size measures was assessed using the Q statistic[17,18] and I^2 index[19,20]. Funnel plots were synthesized in order to assess for the presence of publication bias in the meta-analysis. Standard error was plotted against the treatment effects (Log OR for the dichotomous and WMD for continuous variables respectively)[21,22] to allow 95% confidence interval limits to be displayed. Estimates were obtained using computer programs written in R package for the random effects model, while the MetaXL program was used for computations under the inverse variance heterogeneity model referred to the paper[16,23]. All forest plots are for the estimates of the effect size obtained from the random effects model and were obtained using the 'rmetafor' package[24]. A significance level of 5% (α =0.05) was applied to tests of hypotheses.

RESULTS

Included Studies

Search outcomes revealed 478 citations identified through literature searches (k=473) and hand searches of bibliographical information (k=5). After removal of duplicates and screening of abstracts, 55 full text articles were retrieved and assessed against eligibility criteria. Of the 49 studies excluded, 39 were found not to be in conformity with RCT study design, 11 were reviews (including existing systematic reviews or meta-analyses), four studies reported different outcomes or follow up time frames of otherwise eligible studies, one did not report on clinical outcomes, one described outcomes of bariatric procedures in an adolescent population, one reported clinical outcomes of LVSG versus open LRYGB, while another reported LVSG versus mini gastric bypass. In addition, two protocols describing studies eligible for inclusion in this meta-analysis that currently in progress were also located[25,26]. Ultimately six studies[27-32] reported on a variety of late postoperative complication outcomes, and therefore were included for systematic review and meta-analysis as reported data allowed. See PRISMA diagram Figure 1.

Six RCTs involving a total of 695 patients (LVSG n=347, LRYGB n=348) reported late complications with sufficient information for analysis. LVSG was compared with LRYGB in six studies[27-32]. Included studies were of a moderate methodological quality, with an average Jadad score of 3 (range 2 to 5). All studies reported randomization and accounted for all patients throughout the follow up period, while blinding was reported to have occurred in only one study[27]. All included studies were published within the last five years reporting on studies conducted between 2005 and 2015. Follow-up periods reported ranged from three months to three years postoperatively, with 32% to 100% follow up completed at the completion of the follow up period. Late complications are defined those occurring after 30-days postoperatively. Table 1 outlines the characteristics of included studies.

Mortality

No study reported deaths occurring in the late postoperative period.

Late Major Complications

All six included RCTs representing 685 patients (LVSG n=345; LRYGS n=340) reported major complications occurring in the late postoperative period[27,28,31,32]: this was either implied within the paper or confirmed by correspondence with the authors. The categorization as to what constituted a major complication varied between studies: these included the Clavien-Dindo classification system for severity of complications[28], a specific set outcomes (death or reoperation, LOS beyond postoperative day seven, or the need for four or more blood transfusions) [31,32], bleeding[30], while two studies did not describe how complications were classified[27,29].

Major complications occurring in the late postoperative period are described in Table 2. Different patterns of complications were reported between LVSG and LRYGB, with fewer late complications being reported following the LVSG procedure than LRYGB (n=4 across k=3 versus n=8 across k=4 respectively).

A reduction in relative odds favoring the LVSG procedure was observed, however this did not reach statistical significance (OR 0.64; 95% CI 0.21, 1.97; p=0.4). No significant heterogeneity was observed in pooled results (Q=1.57, p=0.9; I^2 =0%, 0-47.2%). See Figure 2. REM and IVhet models provided equivocal results.

Late Minor Complications

Four RCTs representing 408 patients (LVSG n=208, LRYGB n=200) reported late minor complications, either expressed or implied in the text. Classification of minor complications varied from default classification if conditions for ‘major complication’ were not met[30-32], or no description provided[29].

Various late minor complications were reported, with a higher number reported in those having received LRYGB compared to LVSG (n=17 vs n=10 respectively).
Dumping and pneumonia were reported to occur in both procedures. See Table 3. Helmiö et al[31] reported proportionally higher incidents of late minor complications than the other studies reporting on this outcome.

A non-statically significant reduction in relative odds of 36% favoring the LVSG procedure was observed (OR=0.64; 95% CI 0.28, 1.47; p=0.3) when the REM was applied. No heterogeneity was observed in pooled results (Q=2.92 p=0.4; I^2 =0%, 0-95%) using the REM. See Figure 3. The IVhet model provided equivocal results to the REM.

Interventions and Readmissions Required for the Management of Late Complications

Reoperations and any other type of intervention required for the management of late complications and any hospital readmissions were extrapolated from the published papers, and where necessary, was confirmed with the corresponding authors. As such all six included papers (LVSG n=345; LRYGB n=340) contributed data for analysis.

Table 4 describes the required procedures by surgical type. Interventions for the management of late complications appeared to be required more frequently following LRYGB than LVSG (n=6 over k=4, compared to n=3 over k=4 respectively).

A 37% relative reduction in odds was observed in favor of the LVSG for the need for additional interventions to manage late postoperative complications, however this did not reach statistical significance (OR 0.63; 95% CI 0.19, 2.05; p=0.4). Figure 4. No heterogeneity in pooled data was detected (Q=1.7, p=0.9; I^2=0%, 0-49.3%). REM and IVhet models provided equivocal results.

No study specifically reported readmissions required for the management of late complication. One study reported all complications were able to managed with medication alone[29] and ambulatory management was confirmed with the authors of Peterli et al paper[28].

Publication Bias

Funnel plots do not suggest the presence of publication bias as evidenced by all points remaining within the 95% CI limits in plots of Log OR against standard error.

DISCUSSION

Complications after many complex bariatric surgical procedures vary widely across hospitals and surgeons. For a valuable quality assessment, relevant data on complications must be obtained in a standardized and reproducible manner to allow comparison for a particular procedure among different centers and amongst different surgeon within a center over time. The absence of consensus within the surgical community on the best way to report surgical complications has hampered proper evaluation of the surgeon’s work and possibly progress in the surgical field[10,11].This systematic review and meta-analysis was conducted to compare late complications for two different types of bariatric procedures, namely, LVSG and LRYGB. Our meta-analysis of six RCTs suggests that when considered in terms of the development of late complications, LVSG and LRYGB provide comparable outcomes. No statistically significant differences were observed in point estimates of the parameters that were included for meta-analysis, and outcomes appeared to be comparable between intervention groups within studies when compared qualitatively.

Although a number of reviews on this topic exist in the peer review literature, this is the first systematic review and meta-analysis to specifically review the development of late complications in LVSG versus LRYGB bariatric procedures. These are important considerations, given that both these procedures are irreversible and that many of the late complications reported (such as the development of strictures, bowel obstructions secondary to adhesions, and severe dumping syndrome) may pose significant malnutrition risks when patients remain symptomatic for extended periods. As such it is possible that though obesity and obesity-related comorbidities may be managed by bariatric procedures, late complications have the potential to give rise to a new set of malnutrition-related chronic health problems as a direct consequence of the bariatric procedure. However, the results of this review indicate that late complications reported between six months and three years postoperatively are equivocal between procedures. It should be noted that this time frame may not be sufficient to provide a clear indication of the prevalence or severity of complications arising in the later postoperative period. This is a concern as only two studies[29,32] reporting on 64 patients in each (18% of all participants represented in this review) were followed to three years postoperatively. Studies that specifically monitor the development of late complications beyond the initial years postoperatively are limited in the literature at the present time, while those specifically examining late complications that give rise to new chronic health problems are altogether lacking.

In addition to posing a more specific clinical question, the current review differs from those that already exist in the literature in a number of ways. Firstly, the present work has limited its inclusion to RCTs in an attempt to ensure the studies included are of sufficient methodological robustness and homogeneity to strengthen the conclusions drawn from combining them into a systematic review and meta-analysis. This is a significant point of difference from the recent systematic reviews and/or meta-analyses by Li et al, Yang et al and Zhang et al, who include a high number of uncontrolled studies included in their analyses[33-35]. By including only RCTs of laparoscopic LVSG and LRYGB procedures in the current work, we have strengthened the conclusions and applicability to practice by reducing potential bias and heterogeneity of the included studies. This has resulted in the additional benefit of describing a comparable number of patients receiving each procedure in the current work: This is uncommon in reviews of this topic, yet important for an impartial interpretation of outcomes. Furthermore the current work has been conducted using the PRISMA guidelines to ensure transparency in reporting. Importantly, it also includes several recently published RCTs that were not available for inclusion in previously reviews of this topic, several of which are well powered to demonstrate a clinical difference between procedures [28,31].

Finally, a further strength of this meta-analysis is that it has adopted the IVhet model recently described by Doi et al[16], in addition to the currently accepted REM. The IVhet model offers the advantage of being a distributional assumption free model of meta-analysis, thus overcoming the unjustified assumption of normally distributed random effects in the setting of meta-analysis[16]. Estimates obtained from the IVhet model offer a number of advantages over those obtained from the REM: (1) larger trials (with greater statistical power to demonstrate benefit/harm and less variance) are apportioned greater influence than smaller studies on the final point estimates, (2) produces more conservative point estimates and confidence intervals, which provide a measure of protection against spurious measures of statistical significance, and (3) reduces true variance independent of present heterogeneity[16]. These advantages take on increased significance when considered in light of the way the results of meta-analyses have the potential to alter clinical practice and to justify large research trials. Re-analysis of existing meta-analyses in the literature with models of meta-analysis that produce more conservative estimates than the REM have demonstrated the potential impact the use of different models may have on the results obtained and the subsequent conclusions drawn [36,37]. As these differences pose potential clinical and cost implications, an issue of considerable importance for the application of evidence-based practice. Clinical decision makers therefore have an obligation to ensure any changes to practice generated from the findings of meta-analyses are supported by the most robust statistical methods available to ensure safe and cost effective practice is maintained. The use of the IVhet model of meta-analysis therefore strengthens the conclusions drawn from it, and provides a further point of difference from other reviews on this topic.

LIMITATIONS

There are also a number of potential factors that may influence or confound the results of our systematic review and meta-analysis. First, we have focused complications occurring >30-days postoperatively following LRYGB and LVSG, however the methods of categorizing and describing complications vary between studies included. All studies reported major complications, however reporting of these ranged from an established classification system to no description at all. Minor complications were less routinely reported, and generally attributed to any complications that did not meet the conditions for being reported as a major complication. Late complications were generally less clearly defined than were early complications. Ultimately without consistent definitions being used to describe complications it is difficult to know if appropriate comparisons are being made between studies.

Second, in complicated bariatric procedures the technical skill of the operating surgeon is recognized to be an important factor contributing to both perioperative and postoperative complication rates. In a study investigating the relationship between surgical skill and complication rates after bariatric surgery, Birkmeyer et al[11] demonstrated that surgeons in the top quartile of skill ratings compared with those in the lowest quartile of skill rating had shorter operating times, fewer overall complications (5.2% vs 14.5%), lower rates of reoperation, 30-day readmission and emergency department presentations, and less postoperative mortality. Surgical skill was strongly correlated with procedure volume, however other factors such as years of bariatric surgical practice, completion of a fellowship in laparoscopic or bariatric surgery, or practice location did not appear to influence skill ratings[11]. In view of the apparent role of technical surgical skill in the development of postoperative outcomes, it is inappropriate to fully attribute the outcomes reported solely to the procedures themselves, as the experience of the surgeons involved remains unknown and unreported within the included studies. The role of surgical technique rather than skill is more important on the development of late complications such as anastomotic problems and bowel obstruction which occur over the surgical site. This could be complicated further by the choice of mechanical devices (i.e staplers) which may malfunction or fail. The link to surgical skill may be less obvious in the case of other complications that do not occur at the surgical site[11].

Third is the potential impact of the moderate methodological quality of the included studies. Of the six included studies, only one obtained a score of greater than three (of the possible five) according to the Jadad score[27], and this can be accounted for by the lack of blinding in the remaining studies. This is a recognized limitation of established scores to assess traditional measures of methodological quality, which are difficult to apply to surgical studies where blinding of interventions are often not possible or ethical. The usefulness of methodological assessments within meta-analysis remains a source of debate, and recommendations to individually assess studies against predetermined methodological qualities relevant to the given study context are gaining favor[38]. When considered in this light, the methodological quality of the included papers may perform better than their Jadad score implies.

Finally there remain a relatively small number of RCTs investigating this topic, which is a limitation to the statistical power of the analyses performed.

CONCLUSIONS

In conclusion, this systematic review and meta-analysis of RCTs suggests that the development of late complications is similar between LVSG and LRYGB procedures, six months to three years postoperatively. Due to the limited reporting after this time period conclusions about late complications developing beyond three years postoperative period cannot be made at this time. This highlights the need for longer-term surveillance of patients post bariatric procedures so as to more accurately describe the patterns of late complications that occur in this population, and to therefore inform surgical procedure selection appropriate to the best long-term outcomes.

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Table 1 – Characteristics of included studies

Authors / Year / Country	Study type / trials number	Number of participants by group (% follow up at final reporting point)		Dates study was run	Duration of follow up	Jadad score (R/B/W)	Inclusions			Exclusions	Primary outcome
		LVSG	LRYGB				BMI	Age (years)	Other		
Helmio et al (SLEEVEPASS preliminary) / 2012 / Finland[31]	Prospective RCT / assumed as per 2014 study	121 (100)	117 (98.3)	Mar 2008-Jun 2010	30 days	3 (2/0/1)	>= 40 or >= 35 with comorbidities	18 to 60	tried and failed diet and exercise	BMI >60, psych, ED, excess alcohol, GI issues	weight, resolution of comorbidities
Kehagias et al / 2011 / Greece[27]	Prospective double blind RCT / none stated	30 (93)	30 (96)	Jan 2005-Feb 2007	3 years	?4/5 (2/ 1or 2/ 1)	not stated	not stated	not stated	not stated	weight loss
Zhang et al / 2014 / China[32]	Prospective RCT / none stated	32 (81.2)	32 (87.3)	Jan 2007-July 2008	5 years	3 (2/0/1)	> 32 to <50	>16 to <60	acceptance of randomisation	chronic/psych illness, substance abuse, GI surgery	weight loss
Peterli et al (SM-BOSS) / 2013 / Switzerland[28]	Multicentre Prospective RCT / NCT00356213	107 (100)	110 (100)	Jan 2007-Nov 2011	3 years (1 year outcomes reported)	3 (2/0/1)	>40 with comorbidities	<60	2yrs unsuccessful conservative mx	major abdominal surgery, large HH, IBD	weight loss

Yang et al / 2015 / China[29]	Prospective double blind RCT / none stated	30 (100)	30 (100)	July 2009 – July 2014	3 years	3 (2/0/1)	>=28 to <=35 with diabetes	25 to 60	Poorly controlled DM after >6mths Rx, DM <10yrs	C-peptide <0.8, previous bariatric or complex abdominal surgery, poorly controlled comorbidities	glycaemic control at 36mths
de Barros et al / 2015 / Brazil[30]	Prospective RCT / none stated NCT02394353	26 (96.1)	25 (100)	Jan 2013- March 2015	90 days	2 (1/0/1)	>40	18 to 65	not stated	Chronic disease, heavy alcohol, medical contraindications for randomised intervention	glycaemic control at 90 days

R= Randomisation, B=blinding=withdrawals, ED= eating disorder, GI=Gastrointestinal, BMI=Body Mass Index; mth=month; yrs=years

Table 2 –Late major complications reported in included studies

Major complications	
LVSG	**LRYGB**
Abdominal abscess[27]	Anastomotic Ulcer[28]
Recurrent aspiration pneumonia[31]	Dehydration[31]
Severe GORD[28]	Gastrojejunal stenosis[32]
	Hernia[32]
	Incarcerated incisional hernia[31]
	Obstruction due to adhesions[27]
	Severe dumping syndrome[30]
	Stricture[28]

Table 3: Late minor complications reported in included studies

Minor complications	
LVSG	**LRYGB**
Infection (intra-abdominal or unknown source) [31] Pneumonia[31] Reflux oesophagitis[31, 32] Stricture at GEJ[31] Ketoacidosis[31] Persistent difficulties eating[31] Dumping[31]	Dumping[31, 32] Pneumonia[31] Ulcer at Gastro-jejunal anastomosis[31] Persisting trocar site pain[31] Diarrhoea[31] Dehydration[31] Hair loss[32] Anaemia[29]

Table 4: Reoperation or endoscopic procedures following complications

RCT	Procedures	Complications	Reoperation or Endoscopic procedures
Helmio et al 2012[31]	LRYGB	incarcerated incisional hernia	Relaparoscopy
Kehagias et al 2011[27]	LRYGB LVSG	leakage at cardio-oesophageal junction management of abdominal abscess	IV antibiotics and drainage CT guided percutaneous drainage and antibiotics
Zhang et al 2014[32]	LRYGB	incarcerated incisional hernia stricture/stenosis	Relaparoscopy Endoscopic dilatation
Peterli et al 2013[28]	LVSG LRYGB	severe GERD stricture/stenosis	Conversion to LRYGB Endoscopic dilatation