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ORIGINAL CONTRIBUTIONS

Postoperative Early Major and Minor 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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Abstract
Background Laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic vertical sleeve gastrectomy (LVSG) have been proposed as cost-effective strategies to manage obesity-related chronic disease. The aim of this meta-analysis and systematic review was to compare the "early postoperative complication rate i.e. within 30-days" reported from randomized control trials (RCTs) comparing these two procedures.
Methods RCTs comparing the early complication rates following LVSG and LRYGB between 2000 and 2015 were selected from PubMed, Medline, Embase, Science Citation Index, Current Contents, and the Cochrane database. The outcome variables analyzed included 30-day mortality, major and minor complications and interventions required for their management, length of hospital stay, readmission rates, operating time, and conversions from laparoscopic to open procedures.
Results Six RCTs involving a total of 695 patients (LVSG $n=347$, LRYGB $n=348$) reported on early major complications. A statistically significant reduction in relative odds of early major complications favoring the LVSG procedure was noted ($p=0.05$). Five RCTs representing 633 patients (LVSG $n=317$, LRYGB $n=316$) reported early minor complications. A non-statically significant reduction in relative odds of 29 % favoring the LVSG procedure was observed for early minor complications ($p=0.4$). However, other outcomes directly related to complications which included reoperation rates, readmission rate, and 30-day mortality rate showed comparable effect size for both surgical procedures.
Conclusions This meta-analysis and systematic review of RCTs suggests that fewer early major and minor complications are associated with LVSG compared with LRYGB procedure. However, this does not translate into higher readmission rate, reoperation rate, or 30-day mortality for either procedure.

Keywords Bariatric surgery · Laparoscopic · Sleeve gastrectomy · Roux-en-Y gastric bypass · Meta-analysis · Systematic review

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Introduction

Obesity is now considered to be a global endemic with its prevalence having doubled internationally in the last three decades [1]. Overweight and obesity now contribute to an estimated 2.8 million deaths per year globally as well as accounting for 35.8 million disability-adjusted life years (DALYs) [2]. In Australia, 28 % of adults are now considered to be obese [3] and similar rates of obesity have recently been reported in the USA (33 %), UK (25 %), and New Zealand (29 %) [4].

Obesity has been linked to the development of chronic disease conditions that pose significant health and quality of life burden including cardiovascular disease, diabetes, musculoskeletal disorders, and cancers such as colon, breast, and endometrial [1]. Concomitant with this, annual costs associated with overweight and obesity pose a significant financial burden to the Australian healthcare system; 10 years ago, this was as high as AU$ 56.6 billion [5], and in 2008 this figure rose to AU$ 58.2 billion [5].

As obesity prevalence increases, so does the chronic disease burden and healthcare costs. Projections that in Australia Type 2 diabetes will become the leading cause of disease burden in males and the second leading cause in females by 2023 [1, 6] may be directly linked to the increasing prevalence of obesity in both adults and children. The associated costs with this increase in diabetes are projected to contribute an additional AU$ 8 billion to healthcare spending in Australia [6]. Similarly, in the USA and UK, an estimated 6 to 8.5 million new cases of diabetes, 5.7 to 7.3 million cases of heart disease and stroke, and 492,000 to 669,000 additional presentations of cancers expected by 2030 [3, 7] are related to the projected increase of obesity (65 and 11 million in the USA and UK, respectively). The subsequent burden on the healthcare systems posed by these increases in obesity related disease has been estimated to be in excess of US$ 50 billion and 2 billion pound sterling annually in the US and UK, respectively [4, 7]. In addition to the economic costs, this burden of disease is anticipated to result in 25 to 65 million quality-adjusted life years forgone in these nations [1, 7].

Utilization of bariatric surgical procedures, such as laparoscopic roux-en-y gastric bypass (LRYGB) and laparoscopic vertical sleeve gastrectomy (LVSG), have been proposed as cost-effective and efficacious strategies to manage obesity-related chronic disease and metabolic conditions in the moderately to severely obese individuals [8–10]. It was initially believed that the LRYGB worked through inducing malabsorption by shortening the transit through the small intestine, in combination with food restriction caused by a smaller stomach and a narrow passage through the gastrojejunal anastomosis [11]. However, recent studies reveal that there might be other reasons underlying the effective weight loss and amelioration of comorbidities associated with this technique [11]. Some studies have indicated that the LRYGB reduces weight effectively through changes in gastric hormone signaling (e.g., peptide YY and glucagon-like factor-1). These gut hormones are elevated within days after surgery and remain elevated for at least a decade after LRYGB. It is therefore possible that the gastric bypass technique works through changing hunger and satiety signaling and through affecting the energy expenditure [11].

LVSG, on the other hand, is a purely restrictive procedure involving the permanent removal of 90 % of the anatomical stomach while maintaining the integrity of the pyloric sphincter. However, as with all surgical procedures, especially those in a high-risk bariatric population, these procedures are not undertaken without a degree of risk of complications that may lead to further burden on the healthcare system and diminished postoperative quality of life.

The aim of this meta-analysis and systematic review was to appraise the peer review literature and compare the "early postoperative complications" reported from randomized 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. For inclusion, studies must also have been conducted in adult patients (≥16 years), in an elective setting, and have reported on clinically relevant outcomes pertaining to early complications, i.e., within 30 days experienced in the postoperative period. These included 30-day mortality, major and minor complications and interventions required for their management, length of hospital stay (LOS), readmission rates, operating time, and conversions from laparoscopic to open procedures. Qualitative review was performed on all studies that met inclusion criteria, and meta-analyses were run on outcome variables where numbers 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 January 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 optimized for each search engine in an attempt to identify all published papers meeting 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 review was prepared in accordance with the Preferred Reporting of Systematic Reviews and Meta-Analyses (PRISMA) statement. Two authors (EO and MAM) independently appraised identified studies to ensure 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 independently compiled data were analyzed by two authors and consensus was achieved through discussion when required.

The methodological quality of identified studies was assessed using the Jadad scoring system [13] which 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, in which a higher score represents 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 to estimate the common effect sizes. 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 estimate the common effect size of the outcome variables and provide confidence intervals. Heterogeneity among the effect size was assessed using the Q statistic [17–19] and I^2 index [20, 21]. Funnel plots were created in order to assess 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) [17, 22, 23]. Forest plots were produced to display 95 % confidence interval limits for the common effect size. Estimates were obtained using computer programs written in R code for the random effects model, while the MetaXL program was used for computations under the inverse variance heterogeneity model [16, 24]. All forest plots for the estimates of the effect size are obtained from the random effects model using the "metafor" package [25]. A significance level of 5 % (=0.05) was applied to all statistical tests of hypotheses.

Results

Included Studies

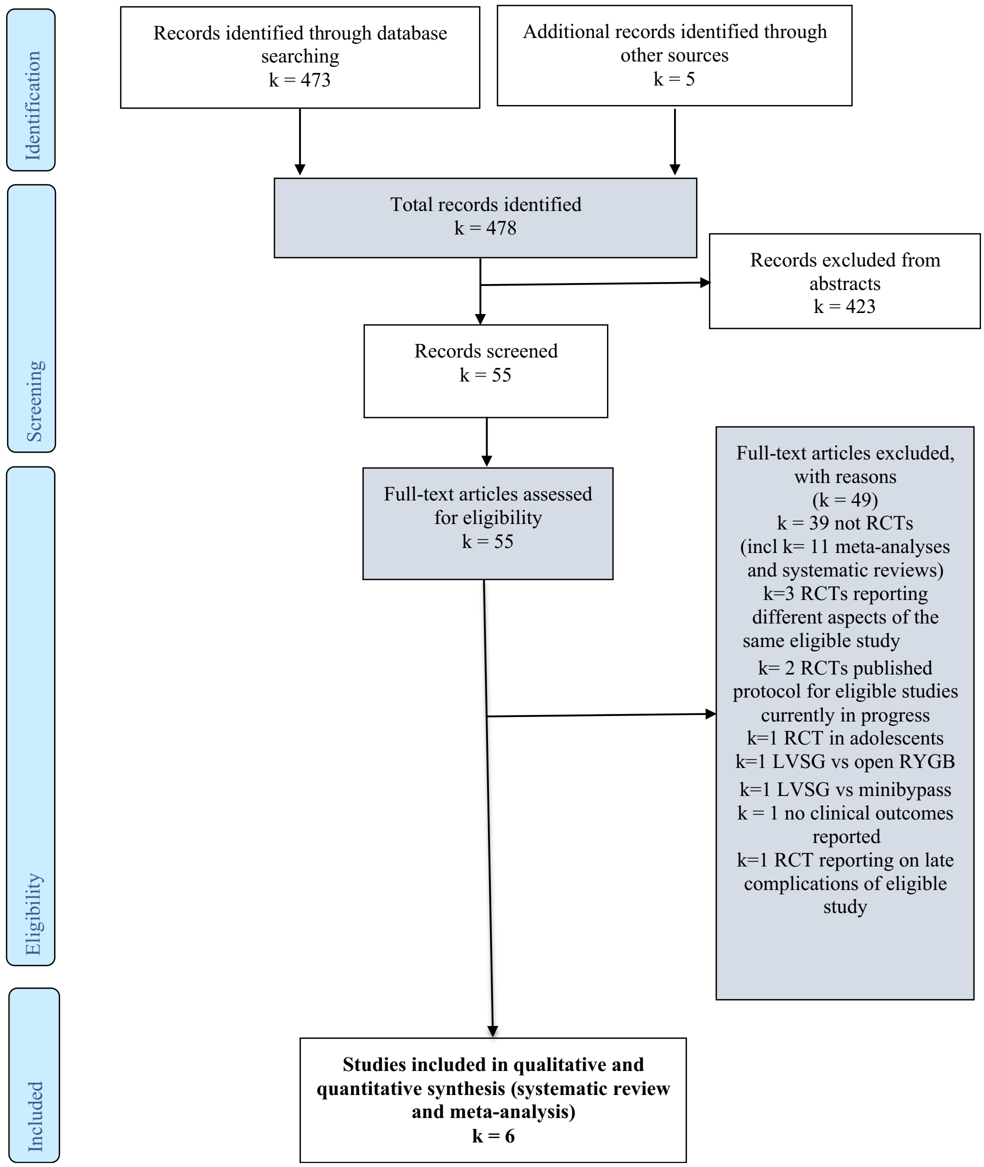
Search outcomes revealed 478 citations identified through literature searches ($k=473$) and hand searches of bibliographical information ($k=5$). After removal of duplicates and screening of abstracts, 55 full-text articles were retrieved and assessed against eligibility criteria. Of the 49 studies excluded, 39 were found not to be in conformity with RCT study design which included 11 reviews (such as existing systematic reviews or meta-analyses), three 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 are currently in progress were also located [26, 27]. Ultimately, six studies [28–33] reported on a variety of early postoperative complication outcomes and therefore were included for systematic review and meta-analysis as reported data allowed (PRISMA Fig. 1).

Six RCTs involving a total of 695 patients (LVSG $n=347$, LRYGB $n=348$) reported early complications with sufficient information for analysis. LVSG was compared with LRYGB in six studies [28–33]. 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 [28]. All included studies were published within the last 5 years reporting on studies conducted between 2005 and 2015. Follow-up periods reported ranged from 3 months to 5 years postoperatively, with 32 to 100 % follow-up completed at the completion of the follow-up period. Early complications are defined those occurring within 30 days. Table 1 outlines the characteristics of included studies.

Early Major Complications

All six included RCTs reported on major complications occurring in the early postoperative period [28–33]. This was either implicit from the paper or confirmed by correspondence with the authors. The most common method used to describe what constituted a "major complication" was that which resulted in death or reoperation, LOS beyond postoperative day (POD) 7, or the need for blood transfusion [29, 33]. Other classifications utilized include the Clavien-Dindo classification system for severity of complications [30] and bleeding [32]. Two studies did not describe how complications were classified [28, 31].

Fig. 1 PRISMA flow diagram



Reported early major complications are described in Table 2. With the exception of de Barros et al. [32] and Yang et al. [31], all other studies reported major complications occurring within their study population in the early postoperative period. While bleeding, obstructions, infections, and leaks were reported postoperatively in both procedures, pneumonia was reported more frequently following LVSG, and the development of enterocutanous fistulae, ileus and/or adhesions, and incarcerated incisional hernias were only reported in those having received LRYGB.

A statistically significant reduction in relative odds of major complications within 30 days favoring the LVSG procedure was noted (OR 0.49; 95 % CI 0.24, 1.0; $p=0.05$). No significant heterogeneity was observed in pooled results ($Q=2.67$, $p=0.7$; $I^2=0$ %, 0–63.9 %) (Fig. 2). REM and IVhet models provided equivocal results.

Early Minor Complications

Five RCTs representing 633 patients (LVSG $n=317$, LRYGB $n=316$) reported minor complications occurring in the postoperative period [29–33]. Methods used to classify minor complications included a structured classification system [30], default classification of "minor complication" if conditions for "major complication" were not met [28, 29, 33], or no description provided [31, 32].

A variety of minor complications were reported between studies during the follow-up period, and appear comparable between procedures. Bleeding and infections were the most commonly reported minor complications postoperatively and occurred in both procedures (Table 3).

A non-statistically significant reduction in relative odds of 29 % favoring the LVSG procedure was observed for minor

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 [29]	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 [28]	Prospective double-blind RCT/none stated	30 (93)	30 (96)	Jan 2005–Feb 2007	3 years	5 (2/2/1)	Not stated	Not stated	Not stated	Not stated	Weight loss
Zhang et al./2014/China [33]	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 randomization	Chronic/psych illness, substance abuse, GI surgery	Weight loss
Peterli et al. (SM-BOSS)/2013/Switzerland [30]	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	2 years unsuccessful conservative mx	Major abdominal surgery, large HH, IBD	Weight loss
Yang et al./2015/China [33]	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 >6 months Rx, DM <10 years	C-peptide <0.8, previous bariatric or complex abdominal surgery, poorly controlled comorbidities	Glycemic control at 36 months
de Barros et al./2015/Brazil [32]	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 randomized intervention	Glycemic control at 90 days

R randomization, *B* blinding = withdrawals, *ED* eating disorder, *GI* gastrointestinal, *BMI* body mass index

Table 2 Early major complications reported in included studies

Major complications	
LVSG	LRYGB
Bleeding [30]	Bleeding [30, 31]
Bowel perforation [30]	Enterocutaneous fistula [29]
Gastric inlet obstruction [29]	Infection [31]
Infection [31]	Intestinal obstruction [29, 31]
Intra-abdominal infection [30]	Intra-abdominal infection [30]
Leak at cardio-esophageal junction [29]	Leak [31]
Obstruction [31]	Torsion of enteroanastomosis [30]
Outlet obstruction [30]	
Pneumonia [30]	

complications within 30 days (OR = 0.71; 95 % CI 0.31, 1.67; $p = 0.4$) when the REM was applied. No heterogeneity was observed in pooled results ($Q = 4.4$, $p = 0.3$; $I^2 = 23$ %, 0–92.1 %) using the REM (Fig. 3). The IVhet model similarly provided a non-statistically significant reduction in relative odds favoring the LVSG procedure in the absence of heterogeneity (OR 0.62; 95 % CI 0.30, 1.28; $Q = 4.4$, $p = 0.3$; $I^2 = 10.5$ %).

Interventions Required for the Management of Early Complications

Reoperations and any other type of intervention required for the management of early complications were extrapolated from the published papers and, where necessary, clarified with the corresponding authors. Table 4 outlines the surgical or endoscopic procedures required by surgical type.

Data was obtained for all six included studies. Based on the description provided, one study did not report any early complications occurring [31]. In most other studies, early complications and procedures required for the management appeared to be comparable, with the exception of one study [30] in which a notably higher number of early complications were reported in the LRYGB group. This, however, did not translate into a high number of reoperations or other interventions required for the management of early complications [30]. The number of required interventions appears equivocal between studies and procedures.

A non-statically significant reduction in relative odds of 42 % favoring LVSG for additional interventions to manage early postoperative complications within 30 days was noted; however, this did not reach statistical significance (OR 0.58; 95 % CI 0.23, 1.51; $p = 0.3$) (Fig. 4). No heterogeneity in pooled data was detected ($Q = 1.57$, $p = 0.9$; $I^2 = 0$ %, 0–43.6 %). REM and IVhet models provided equivocal results.

Operating Times

Five studies ($n = 629$) reported on the operating times; however, only four described this in sufficient detail to allow for meta-analysis ($n = 565$; LVSG $n = 283$, LRYGB $n = 282$) [29–31, 33]. A statistically significant shorter operating time was reported for LVSG compared to LRYGB with both models; however, significant heterogeneity was reported (REM—WMD −32.1 min; 95 % CI −49.4, −14.6 min, $p < 0.01$, $Q = 17.2$, $p < 0.01$, $I^2 = 86.3$ %; IVhet −28.8 min, 95 % CI −44.6–12.9 min, $Q = 17.2$, $p < 0.01$, $I^2 = 85.5$ %).

When considered qualitatively, there appears to be a trend toward shorter operation duration for LVSG compared with LRYGB; however, there are inconsistencies between studies. Those reporting means ranged from 58 to 126 min for those receiving LVSG and 98 to 186 min in those with LRYGB [28, 30–32], while the study that reported medians described the LVSG as taking 66 min (range 40 to 188 min) and 94 min (range 50 to 195 min) for LRYGB [29].

Fig. 2 Early major complications

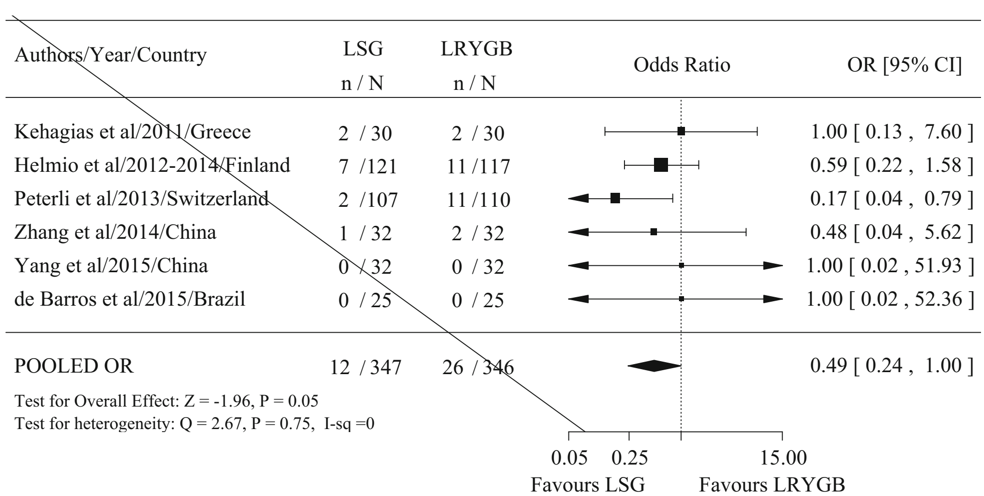


Table 3 Early minor complications reported in included studies

Minor complications	
LVSG	LRYGB
Bleeding [30]	Bleeding [30]
Dysphagia [31]	Dehydration [30]
Heartburn [29]	Dysphagia [31]
Intra-abdominal infection [30]	Intra-abdominal infection [30]
Non-surgical [31]	Non-surgical [31]
Pneumonia [30]	Pneumonia [30]
Reflux [30]	Superficial wound infection [30]
Superficial wound infection [30]	Surgical [31]
Surgical [31]	
Trocal site pain [30]	
Vomiting [29]	

Conversion of Laparoscopic to Open Procedure

All six RCTs reported conversion from laparoscopic approach to open procedure as an adverse perioperative outcome. This outcome was only reported in one study [30], with equal incidence in each group ($n = 1$ LVSG, $n = 1$ LRYGB).

Length of Hospital Stay (LOS)

Only two studies reported LOS (total $n = 304$, [LVSG $n = 153$, LRYGB $n = 151$]) [29, 31], and as such, this parameter was not suitable for meta-analysis.

A qualitative review is difficult due to differences in reporting due to the different measures of central tendency used. Helmio et al. [29] reported a 4-day LOS for each group, but with variation in range (LVSG 1–22 days, LRYGB 3–16 days). Yang et al. [31], on the other hand, suggest a slightly shorter LOS with LVSG (LVSG 5.2 days vs. LRYGB 6.6 days) reporting in means.

Readmission Rates

Two RCTs [29, 30] reporting on 300 patients (LVSG $n = 151$, LRYGB $n = 149$) described the number of patients requiring readmission to manage complications postoperatively. The number of readmissions varied between studies when reviewed qualitatively. In the study by Kehagias et al. [28], 6.6 % readmission rate ($n = 2$) was reported in each study arm. By contrast, Helmiö et al.'s [29] data appears to suggest a slightly higher readmission rate within the LVSG group when adjusted for patients lost to follow-up at the end of the 6-month follow-up period (4.2 %, $n = 9$ vs. 2.7 %, $n = 11$ in LRYGS); however, it is unclear if this is clinically significant.

Postoperative Mortality

All six studies reported on postoperative mortality, with only one death reported in the LRYGB group [30]. There was no difference in mortality outcomes between procedures (OR 0.78; 95 % CI 0.17, 3.65; $p = 0.7$), and heterogeneity was not observed in the pooled results ($Q = 0.3$, $p = 0.99$; $I^2 = 0$ %, n/a%). No difference was observed with the results obtained from the REM and IVhet models.

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

This meta-analysis and systematic review of RCTs suggests that LVSG may be associated with the development of fewer major early postoperative complications than LRYGB. However, it also appears that while this may be the case, other

Fig. 3 Early minor complications

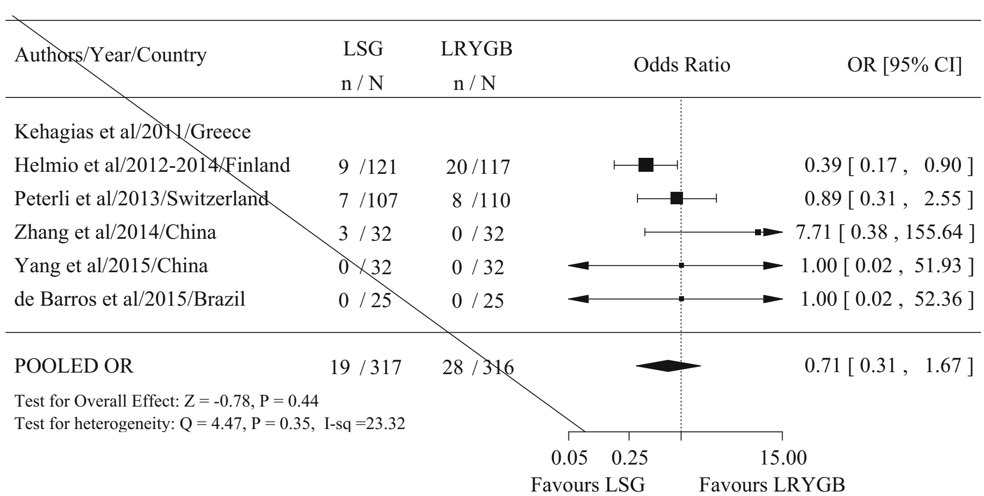


Table 4 Reoperation or endoscopic procedures following complications

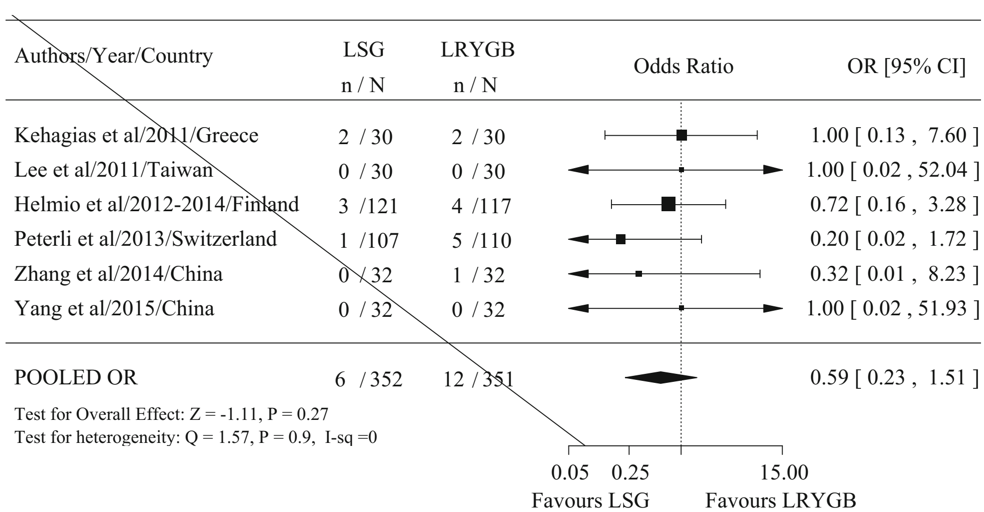
RCT	Procedures	Complications	Reoperation or endoscopic procedures
Helmio et al. [29]	LRYGB	• Postoperative bleeding ×2 • Torsion of the enteroanastomosis resulting in an imminent blow-out rupture of the gastric remnant • Postoperative severe bleeding due to pseudo-aneurysm of left gastric artery	Relaparoscopy Laparotomy Relaparoscopy, laparotomy and angiography, and coiling of aneurysm
	LVSG	• Postoperative bleeding ×2 • Postoperative bleeding followed by Intestinal perforation ×1	Relaparoscopy ×1 Laparotomy ×1 Relaparoscopy and laparotomy ×1
Kehagias et al. [28]	LRYGB	• Intestinal obstruction due to an organized intraluminal hematoma, just below the jejunojejunal anastomosis • Ventral hernia treated with mesh placement along with the main bariatric procedure	Anastomosis revised and reconstructed by laparotomy Enterocutaneous fistula at the site of the mesh placement necessitating open enterectomy and removal of the infected mesh
	LVSG	• A large residual gastric fundus was revealed after radiologic evaluation, which was acting as a valve thus obstructing the gastric inlet	Further gastric resection - unclear if open or laparoscopic method
Zhang et al. [33]	LRYGB	• Internal herniation • Gastrojejunal stenosis ×2	Relaparoscopy Endoscopic dilatation
Peterli et al. [30]	LRYGB	• Gastrojejunal stricture	Endoscopic dilatation

surgical outcomes such as postoperative mortality and the requirement for readmission or further interventions for the management of early complications do not differ between procedures.

The findings of this meta-analysis appear to support a recently published analysis of the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) database which reviewed the clinical data of over 24,000 patients undergoing laparoscopic LVSG and LRYGB between 2010 and 2011 [34]. Similar to the present work, Young et al.'s analysis appears to favor LVSG over LRYGB to produce statistically significant lower postoperative complications—specifically transfusion requirement due to bleeding/blood loss, fewer deep wound infections, and lower serious morbidity [34]. As with the present study, 30-day mortality was similarly low between groups in the NSQIP data; however, a significant difference in 30-day reoperations was noted in favor of LVSG not seen in the current work [34]. Despite the differences in methodologies between this meta-analysis and systematic review and analysis of the American College of Surgeons' NSQIP database, it appears that encouragingly similar results support the use of LVSG over LRYGB.

Although a number of reviews on this topic exist in the peer review literature, the conclusions that can be drawn are limited by a number of factors. Firstly, the combination of studies with varying research methodologies weakens the capabilities of meta-analysis to detect differences between groups through the introduction of heterogeneity that the process of

Fig. 4 Interventions for early complications



meta-analysis was never designed to adjust for, irrespective of which model is utilized [35]. Strong conclusions that can be justifiably incorporated into clinical practice can only be reliably drawn from meta-analyses conducted on well-designed RCTs. For this reason, the conclusions of recent studies by Yang et al. [36], Li et al. [37], and Zhang et al. [38], though similar to the current work in that their results favor LVSG over LRYGB for reduced postoperative complications, need to be considered in view of the high number of uncontrolled studies included in their analyses. The finding by Li et al. [37] that reoperation rates were higher (though this did not reach statistical significance) in LRYGB may in part be explained to this methodological flaw.

Other reviews, while including studies of non-randomized methodologies, have attempted to strengthen the conclusions able to be drawn from their work by analyzing the outcomes of differing study methodologies separately. Chang et al. [39] reviewed the effectiveness and risk of a number of bariatric procedures performed as either laparoscopic or open procedures (including gastric bypass (GB) ± duodenal switch, vertical banded gastroplasty, vertical sleeve gastrectomy (VSG), and adjustable gastric bands). Though presenting their results as mean percentages with 95 % CIs rather than summary statistics, their results clearly illustrate the variability in reported outcomes obtained with different study methodologies with significantly different percentages and 95 % CIs reported between RCT and observational studies. The postoperative complications of GB and VSG reported in the RCTs differ significantly from the current work in that it would appear that postoperative mortality is lower in GB compared to VSG (0.08 % [0.01–0.3], 0.39 % [0.01–0.86] and 0.5 % [0.01–3.38], 6 % [0–11] for <30-day and >30-day mortality, respectively), as are reoperation rates (2.56 % [0.61–5.61] vs. 9.05 % [0.77–34.56]) [39]. Conversely, overall complication rates are reported to be higher in GB than VSG (21 % [12–33 %] vs. 13 % [0.7–13]) [39]. This may in part be due to the inclusion of both laparoscopic and open procedures in the analysis, the higher number of patients represented in GB than VSG groups, and that direct comparisons between GB and VSG cannot be made due to the differences in meta-analysis methodology utilized (i.e., simple averaging method proposed by Bhaumik et al. versus Bayesian meta-analysis [40]).

Other meta-analyses [39, 41] investigating this topic available in the literature—particularly on those drawing on older papers—draw conclusions based on considerably higher numbers of patients undergoing LRYGB than those undergoing LVSG. For example, Zellmer et al. [41] reviewed and compared risks—specifically anastomotic leak and mortality—associated with LRYGB and LVSG and found outcomes to be equivocal between procedures [41]. However, this conclusion was drawn from papers which collectively reported on more than twice as many patient outcomes in LRYGB than LVSG despite reporting on similar numbers of studies ($n = 10{,}906$ vs. $n = 4816$ and $k = 28$ vs. $k = 33$, respectively) [41], thereby making the reported results difficult to interpret. Similar discrepancies in numbers are found in Chang et al. [39], where postoperative outcomes were reported on a significantly higher number of patients undergoing GB than VSG (e.g., postoperative mortality GB $n = 954$ vs. VSG $n = 40$).

There are several recent meta-analyses that have focused specifically on the outcomes of obese patients with Type 2 diabetes undergoing LRYGB or LVSG. These reviews have focused primarily on metabolic outcomes such as changes in blood sugar control, requirement for hypoglycemic medications, and anthropometric measurement postoperatively, and therefore describe postoperative complications in less detail. Wang et al. [42], a meta-analysis of RCTs, do not provide summary statistics for postoperative complications but describe no difference between groups in the three of their four included studies that reported on postoperative outcomes (hospitalization, reoperation, postoperative mortality). Rao et al. [43], a meta-analysis of both prospective and retrospective studies, only qualitatively report on complications within their included studies.

One meta-analysis was identified that closely resembled the aims of the current work. Li et al. [44] conducted a meta-analysis of RCTs comparing a variety of postoperative outcomes post-LRYGB with LVSG in patients indicated for the procedures either for morbid obesity or Type 2 diabetes in 2013. While a similar methodology to that employed in the present study and similar outcomes were demonstrated (complications favoring LVSG and no differences in reoperation rates [44]), the present study was warranted in view of the publication of number of well-powered RCTs studies investigating this subject since the late 2012 literature end point of the literature review underpinning Li et al.'s meta-analysis [44].

There are also a number of potential confounding or limiting factors that may be impacting the results of our meta-analysis. First, we have focused this review on early postoperative complications following LRYGB and LVSG; however, the methods of describing and reporting complications vary between included studies. While all included studies report on major complications, only two used the same definition of what constituted a major complication [29, 33] and only one used a recognized system of categorization of complications [30]. Furthermore, other complications such as the development of minor early complications were not reported in all studies, thus reducing the statistical power to observe differences between groups. Other methods of describing adverse postoperative outcomes such as total complications [29, 30] and the requirement for additional but non-urgent postoperative procedures [30] were adopted by too few studies to allow for meta-analysis or meaningful systematic review. Ultimately, without consistent definitions being used to describe complications, it is difficult to know if like is being compared with like between studies.

Second, the technical skill of the operating surgeon is recognized to be an important contributing factor to both perioperative and postoperative complication rates, particularly in complicated procedures such as LRYGB [45]. A recent study investigating the relationship between surgical skill and complication rates following bariatric surgery has 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 [45]. Interesting surgical skill was strongly correlated with procedure volume, while other factors such as years of bariatric surgical practice, completion of a fellowship in laparoscopic or bariatric surgery, or practice location did not impact skill ratings [45]. Given the role of technical surgical ability in the development of postoperative outcomes, it is difficult to fully attribute the outcomes reported in any study of this kind solely to the procedures themselves, as the skill and experience of the surgeons involved remain unknown and unreported. This is true of the current studies and indeed all other systematic reviews and meta-analysis comparing surgical outcomes.

Third is the potential impact of methodological quality of the included studies. While all studies accounted for all patients throughout the follow-up period, and all but one reported methods of randomization to achieve in adequate detail to receive the highest score possible for this element, only two reported using a blinded or double blinded methodology. Lack of blinding is therefore the reason for the average methodological quality of the included studies, as measured by the Jadad score. This is not an uncommon situation in surgical studies, where blinding of intervention is often not possible.

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

The current study has a number of strengths that set it apart from the existing reviews on this topic in the literature at the current time. Including only RCTs of laparoscopic procedures, we have minimized the potential bias and heterogeneity introduced, thereby strengthening the conclusions and implication for clinical practice. Limiting inclusion to RCTs has also allowed equivocal number of patients receiving LRYGB and LVSG to be represented in the current work, which is relatively rare in reviews of this topic but important for an objective interpretation of outcomes. Similarly, the current work has been conducted in accordance with the stringent requirements of the PRISMA process to ensure transparency in reporting. Finally and importantly, recently published well-powered RCTs investigating this topic have been able to be included in the current work [29, 30].

Furthermore, as well as utilizing the accepted REM of meta-analysis, we have also conducted our meta-analyses using the IVhet model recently proposed by Doi et al. [16]. This has been proposed as a distributional assumption free model of meta-analysis to overcome the unjustified assumption of normally distributed random effects in the setting of meta-analysis, where the underlying effects do not represent a random sample from the population [16]. Estimates obtained from the IVhet model have the advantages over the REM in that it (1) affords larger trials (with greater statistical power to demonstrate benefit/harm and less variance) greater influence than smaller studies on the final point estimates, (2) provides more conservative point estimates and confidence interval (to ensure that spurious measures of statistical significance are minimized), and (3) reduces true variance independent of present heterogeneity [16]. These factors translate into important advantages over the currently accepted models of meta-analysis in the age of evidence-based practice, where the outcomes of meta-analyses are often used as the justification for changes to established clinical practice or to support larger scale research trials. Spurious results obtained from meta-analysis may result in significant organizational and economic implications for the healthcare system, as well as in terms of outcomes for the recipients of the clinical interventions. A recent example of this is the REDOXS study [46]. Based on several meta-analyses suggesting that supplementation with glutamine and antioxidants during critical illness may confer a survival benefit, this large multi-centered randomized controlled trial was undertaken; however, instead of finding mortality benefit, it demonstrated increased mortality in those receiving glutamine, particularly in the setting of multi-organ failure [46]. Similarly, re-analysis of existing meta-analyses in the literature utilizing the IVhet model or similar models that produce more conservative estimates than the REM demonstrates the potential impact the different models may have on the results obtained, of which the clinical implications are significant [47, 48]. Clinicians have an ethical obligation to ensure any changes to practice resulting from research based on secondary data are underpinned by the most robust methods available to ensure safe practice is maintained: the IVhet model appears to present a more responsible method for application to the meta-analysis of clinical trials.

Conclusions

In conclusion, this meta-analysis and systematic review of RCTs suggests that fewer early major and minor complications are associated with LVSG compared with LRYGB procedure; however, no differences were found with regards to reoperation, readmission, or mortality rates between these two procedures despite this finding. This review suggests the effectiveness and risk of LVSG and LRYGB are equivocal provided the surgery is performed by a skilled and experienced surgeon in a high-volume bariatric center.

Authors' contributions 1. MAM was responsible for the concept and design of this meta-analysis. Furthermore, he takes full responsibility for the integrity of the work as a whole, from inception to published article.

2. EO and MAM were responsible for acquisition and interpretation of the data.

3. RMY, SK, and TA were responsible for analyzing and interpretation of the data in depth from the statistical point of view. They were responsible for producing all the statistical diagrams (Forest and Funnel plots).

4. All authors were involved in drafting the manuscript and revising it critically for important intellectual content and have given final approval of the version to be published. Furthermore, all authors have participated sufficiently in the work to take public responsibility for its content.

Compliance with Ethical Standards

Conflicts of Interest The authors declare that they have no competing interests.

Ethical Approval For this type of study, i.e., meta-analysis, formal consent is not required.

Informed Consent Does not apply

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