

Comparison of laparoscopic Roux-en-Y gastric bypass with laparoscopic sleeve gastrectomy for morbid obesity or type 2 diabetes mellitus: a meta-analysis of randomized controlled trials

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Background: Laparoscopic Roux-en-Y gastric bypass (LRYGB) is one of the most widely used bariatric procedures, and laparoscopic sleeve gastrectomy (LSG) as a single-stage procedure for treating morbid obesity is becoming more popular. We compared both techniques to evaluate their efficacy in treating morbid obesity or type 2 diabetes mellitus (T2DM).

Methods: We searched the Cochrane Controlled Trials Register databases, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database to identify randomized controlled trials (RCTs) of LRYGB and LSG for morbid obesity or T2DM published in any language. Statistical analyses were carried out using RevMan software.

Results: Five worldwide RCTs with 196 patients in the LRYGB group and 200 in the LSG group were included in our analysis. Compared with patients who had LSG, those who had LRYGB had a higher remission rate of T2DM, lost more weight and had lower low-density lipoprotein, triglycerides, homeostasis model assessment index and insulin levels. There was no difference in the reoperation rate between the groups. However, patients treated with LRYGB had a higher incidence of complication than those treated with LSG.

Conclusion: Our meta-analysis demonstrates that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. However, LSG is safer and has a reduced rate of complications. Further high-quality RCTs with long follow-up periods are needed to provide more reliable evidence.

Contexte : La dérivation gastrique laparoscopique Roux-en-Y (DGRY) est l'une des interventions bariatriques les plus utilisées, et la gastrectomie longitudinale laparoscopique (GLL) gagne en popularité comme intervention en une seule étape pour le traitement de l'obésité morbide. Nous avons comparé les 2 techniques pour évaluer l'efficacité dans le traitement de l'obésité morbide ou du diabète de type 2 (DT2).

Méthodes : Nous avons interrogé les bases de données du Registre des essais cliniques contrôlés de la Collaboration Cochrane, de même que les bases de données Medline, Embase, ISI et la base de données de la littérature biomédicale chinoise pour recenser les essais randomisés et contrôlés (ERC) publiés dans toutes les langues sur la DGRY et la GLL dans les cas d'obésité morbide ou de DT2. Les analyses statistiques ont été effectuées au moyen du logiciel RevMan.

Résultats : Cinq ERC ont été recensés dans le monde et ont été inclus dans notre analyse, totalisant 196 patients soumis à la DGRY et 200 soumis à la GLL. Comparativement aux patients soumis à la GLL, les patients soumis à la DGRY ont présenté des taux de rémission plus élevés de leur DT2, ils ont perdu plus de poids et ont présenté des taux plus faibles de lipoprotéines de faible densité et de triglycérides, une baisse de leur indice d'évaluation du modèle d'homéostasie) et de leur taux d'insuline. On n'a noté aucune différence entre les groupes pour ce qui est du taux de réintervention. Toutefois, l'incidence des complications a été plus élevée chez les patients traités par DGRY que chez ceux traités par GLL.

Conclusion : Notre méta-analyse démontre que la DGRY est plus efficace que la GLL pour le traitement chirurgical du DT2 et le contrôle du syndrome métabolique. Toutefois, la GLL est plus sécuritaire et s'accompagne d'un taux moindre de complications. Il faudra procéder à d'autres ERC de grande qualité comportant des suivis prolongés pour amasser des preuves plus fiables.

Obesity and type 2 diabetes mellitus (T2DM) are currently 2 of the most common chronic diseases in Western countries.^{1,2} The growing incidence of obesity and T2DM globally is widely recognized as one of the most challenging contemporary threats to public health.³ Uncontrolled diabetes can eventually lead to macrovascular and microvascular complications, including myocardial infarction, stroke, blindness, neuropathy and renal failure in many patients. Obesity and T2DM are closely related and difficult to control by current medical treatment, including diet, drug therapy and behavioural modification.⁴⁻⁶ Bariatric surgery is the most effective treatment of morbid obesity and, depending on the type of operation, is also very effective in the resolution of diabetes.⁷ This effect usually occurs even before the start of weight loss owing to changes in the gut hormones and the patient's diet.⁸

Laparoscopic Roux-en-Y gastric bypass (LRYGB), currently the preferred bariatric operation, involves 2 surgical alterations: restriction of the gastric volume and diversion of the ingested nutrients away from the proximal small intestine.⁹ In contrast, laparoscopic sleeve gastrectomy (LSG) preserves the integrity of the pylorus and does not include the intestinal bypass. Laparoscopic sleeve gastrectomy is the restrictive part of the biliopancreatic diversion and was initially applied as an isolated operation for super-obese patients with severe comorbidities as a staged concept.¹⁰ It is mainly a restrictive operation with no mal-absorptive effect. The long-term efficacy of the LSG procedure as a treatment of morbid obesity or T2DM has not been demonstrated; however, it is promising to observe weight loss in the first year after operation.^{11,12} At present, to our knowledge, there is no evidence to demonstrate whether LRYGB or LSG is superior for treating morbid obesity or T2DM.

Meta-analysis is a statistical tool that can be used to evaluate the literature qualitatively and quantitatively, accounting for variations in characteristics that can influence overall estimates of outcomes of interest. To our knowledge, meta-analysis of LRYGB versus LSG for morbid obesity or T2DM has not been performed previously. As deciding what kind of surgery to recommend to patients remains an important issue, we performed a meta-analysis of randomized controlled trials (RCTs) comparing LRYGB with LSG for the treatment of morbid obesity or T2DM.

METHODS

Study selection

We searched the Cochrane Central Register of Controlled Trials, Medline, Embase, ISI databases and the Chinese Biomedical Literature Database for RCTs published in any language between January 1966 and November 2012.

Our search terms were “gastric bypass,” “sleeve gastrectomy” and “bariatric surgery.” We manually searched the reference lists of pertinent articles to identify any additional studies relevant to our analysis. Two independent investigators (B.N. and K.-X.S.) reviewed all articles from the previous search based on the following selection criteria. Included studies must have been prospective RCTs comparing gastric bypass with sleeve gastrectomy for morbid obesity or T2DM. Quasirandomized trials, nonrandomized studies, nonhuman studies, nonsurgical interventions, case reports, letters and comments were excluded from our analysis. Finally, when the results of a single study were reported in more than 1 publication, only the most recent and complete data were included in our meta-analysis. Included trials were chosen by the 2 nonblinded authors (J.-F.L. and D.-D.L.). Disagreements were resolved by discussion.

Assessment of study quality

The quality of included reports was scored using the Jadad composite scale,¹³ which assesses descriptions of randomization, blinding and dropouts (withdrawals). The quality scale ranges from 0 to 5 points, with a low-quality report receiving a score of 2 points or less and a high-quality report receiving a score of at least 3 points.

Statistical analysis

All available trials with reporting data were summarized. Results for continuous outcomes are reported as weighted mean difference (WMD) or standard mean difference, and dichotomous outcomes are reported as odds ratios (ORs) with 95% confidence intervals (CIs). We performed all statistical analyses with RevMan version 5.0. We used the χ^2 statistic to assess heterogeneity among the trials and the I^2 statistic to assess the extent of inconsistency. If there was a significant heterogeneity, we used a random-effects model to confirm the case results. A fixed-effect model for calculations of summary estimates and their 95% CIs was also applied unless there was significant heterogeneity. We considered results to be significant at $p < 0.05$.

RESULTS

Included studies

Figure 1 shows the selection process from initial review to the inclusion in our meta-analysis. The initial search identified 581 publications, of which 576 were excluded, leaving 5 publications for analysis.¹⁴⁻¹⁸ One study,¹⁹ which was the subset of another study,¹⁴ was excluded; another study²⁰ was the republication of the trial by Woelnerhanssen and colleagues¹⁵ and was also

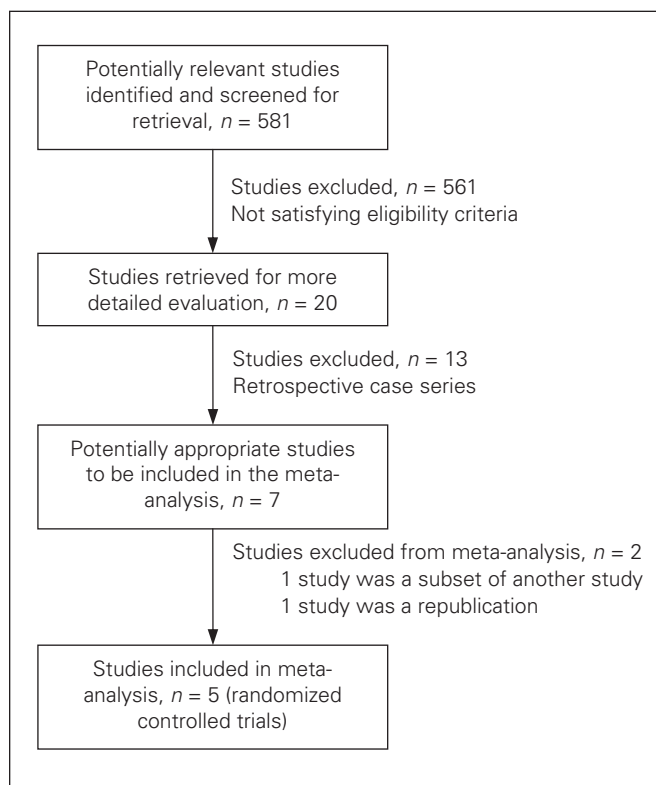


Fig. 1. Study selection.

excluded. The 5 trials of LRYGB and LSG for morbid obesity or T2DM with a total of 396 patients that we included in our analysis were retrieved from the electronic databases. The study by Lee and colleagues¹⁴ was the only trial to study surgical treatment of nonmorbidly obese patients (BMI < 35) with poorly controlled T2DM; the other 4 studies^{15–18} evaluated surgical treatment of morbidly obese patients (BMI > 35) with or without T2DM. There were 196 patients in the LRYGB group and 200 patients in the LSG group. Standard deviations were not reported in most studies; however, they were estimated either by means of ranges or *p* values. The characteristics and quality of each selected study are demonstrated in Table 1, and the outcome variables extracted from these trials are shown in Table 2. The studies were homogeneous in terms of clinical and methodological criteria.

Remission of T2DM

Remission of T2DM is defined as fasting plasma glucose levels less than 126 mg/dL in addition to HbA1c values less than 6.5% without the use of oral hypoglycemics or insulin. Three trials^{14,17,18} reported the remission of T2DM, which was much better in the LRYGB group than in the LSG group. The meta-analysis revealed a significant difference between the 2 groups (OR 9.08, 95% CI 2.39–34.41, *p* = 0.001; Fig. 2).

HOMA index

Insulin resistance was estimated by the HOMA index. Two trials^{14,15} that reported this outcome demonstrated the LRYGB group had a significantly lower HOMA index than the LSG group (WMD –0.42, 95% CI –0.63 to –0.22, *p* < 0.001; Fig. 3).

Insulin level

Two trials^{14,15} reported insulin level, which was significantly lower in the LRYGB group than in the LSG group (WMD –1.27, 95% CI –2.06 to –0.48, *p* = 0.002; Fig. 3).

Percent excess weight loss

Weight loss outcome was defined by percent excess weight loss (%EWL). For all studies, weight loss was reported as mean %EWL, defined as (weight loss ÷ excess weight) × 100. Meta-analyses were performed to examine mean %EWL outcomes separately for the LRYGB and LSG groups. Two studies^{14,15} reported weight loss. The LRYGB group experienced greater weight loss than the LSG group (WMD 6.76, 95% CI 4.61–8.91, *p* < 0.001; Fig. 4).

Reoperation

Two studies^{16,17} reported reoperation rates; there was no significant difference in reoperation between the groups (OR 1.24, 95% CI 0.37–4.16, *p* = 0.73; Fig. 2).

Complications

Three studies^{14,16,17} reported complications; the LRYGB group had a higher incidence of complications than the LSG group (OR 1.89, 95% CI 1.07–3.33, *p* = 0.030; Fig. 2).

Triglycerides

Bariatric surgery had a marked reduction in body weight and improvement of other associated metabolic disorders, including reduction of blood lipid levels. Two studies^{14,15} reported that the triglycerides level decreased after bariatric surgery, and the LRYGB group had a significantly lower triglycerides level than the LSG group after surgery (WMD –0.23, 95% CI –0.35 to –0.11, *p* < 0.001; Fig. 3).

Low-density lipoprotein

Two studies^{14,15} reported low-density lipoprotein (LDL) level. There was statistical heterogeneity among studies ($I^2 = 79%$, *p* = 0.030); random-effects models were used in the analysis. The LRYGB group had a significantly lower LDL level than the LSG group (WMD –0.73, 95% CI –1.25 to –0.22, *p* = 0.005; Fig. 5).

DISCUSSION

Despite the large volume of literature devoted to bariatric surgery and diabetes, only a small number of studies have been performed in a comparative way, with a level of evidence of 3 or higher. However, a meta-analysis is a design that allows merging results of small RCTs, increasing the possibility of detecting an intervention effect. To our knowledge, this is the first meta-analysis to date that evaluates data from multiple studies to assess RCTs on LRYGB and LSG for morbid obesity or T2DM.

Our results showed that LRYGB was associated with a higher remission rate of T2DM and that patients who underwent this procedure lost more weight than those who had LSG; gastric bypass may be a better choice for patients with metabolic syndrome or hyperlipidemia. However, the LSG procedure is safer than the more complex LRYGB

and avoids the long-term sequela of micronutrient deficiency after duodenum exclusion.

Our meta-analysis revealed that both LRYGB and LSG were effective in the treatment of patients with T2DM in whom current medical treatment had failed. However, the remission rate of T2DM in the LRYGB group was much higher than that in the LSG group. These results corroborate previous reports that gastric bypass may achieve an 80% T2DM remission and that purely restrictive procedures may achieve a rate of about 50%.^{21,22} Besides weight loss, the LRYGB group also achieved a lower blood lipid level. That is why the LRYGB group had a higher metabolic syndrome remission rate than the LSG group. Schauer and colleagues²³ found that obese patients with poorly controlled diabetes treated by either gastric bypass or sleeve gastrectomy combined with medical therapy were significantly more likely to achieve a glycated hemoglobin level of 6.0%

Table 1. Study characteristics and quality evaluation of each selected study

Characteristic	Lee et al. ¹⁴	Woelnerhanssen et al. ¹⁵	Helmiö et al. ¹⁶	Kehagias et al. ¹⁷	Ramón et al. ¹⁸
Jadad score	5	5	4	5	4
Double blind	2	2	1	2	1
Randomization	2	2	2	2	2
Lost to follow-up	1	1	1	1	1
Country	Taiwan, China	Switzerland	Finland	Greece	Spain
Clinical trial registration	NCT00540462	NCT00356213	NR	NR	NR
Study period	Sept. 1, 2007 to June 30, 2008	NR	March 2008 to June 2010	January 2005 to February 2007	April 2007 to March 2008
Publication year	2011	2011	2012	2011	2012
No. patients	60	23	238	60	15
LRYGB	30	12	117	30	7
LSG	30	11	121	30	8
Follow-up, mo	12	12	1	36	12
BMI	30.3 (25–34)	> 40, with comorbidity	44.6 (35–66)	< 50	> 40 or BMI > 35 with comorbidity
Condition	T2DM	Nondiabetic morbidly obese	Morbid obesity	Nonsuperobese	Nonsuperobese
Age, yr	45 (34–58)	< 60	49 (23–67)	NR	18–60
Deaths	0	0	0	0	NR

BMI = body mass index; LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NR = not reported; T2DM = type 2 diabetes mellitus.

Table 2. Outcome measures of included randomized trials

Trials	Treatment	Complication	Operation time, median (range) or mean (SD) min	Hospital stay, d	Reoperation
Lee et al. ¹⁴	LRYGB	4	117	2.2	0
	LSG	4	127	2.1	0
Woelnerhanssen et al. ¹⁵	LRYGB	NR	NR	NR	0
	LSG	NR	NR	NR	0
Helmiö et al. ¹⁶	LRYGB	31	94 (52–195)	4 (3–16)	4
	LSG	16	66 (40–188)	4 (1–22)	3
Kehagias et al. ¹⁷	LRYGB	3	186 (34.4)	NR	2
	LSG	3	126.5 (34.1)	NR	1
Ramón et al. ¹⁸	LRYGB	NR	NR	NR	NR
	LSG	NR	NR	NR	NR

LRYGB = laparoscopic Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy; NR = not reported; SD = standard deviation.

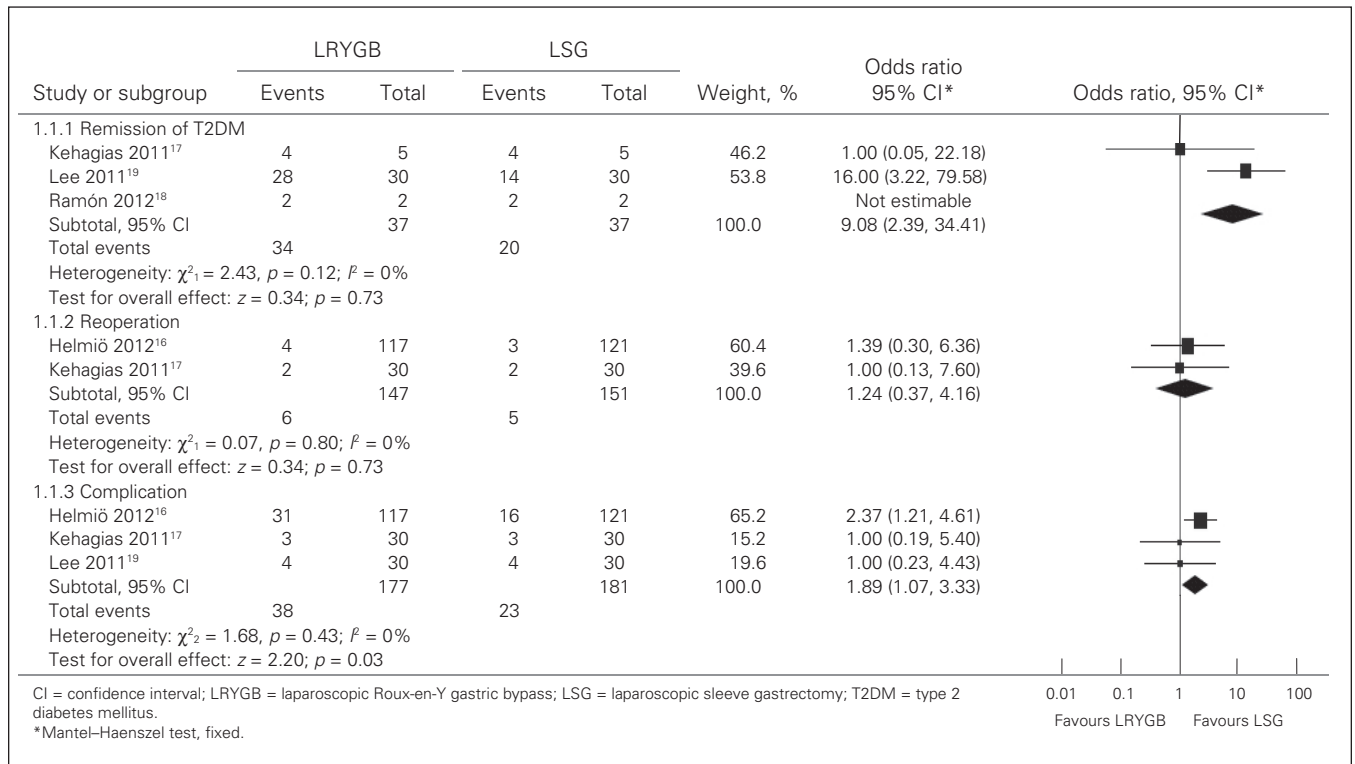


Fig. 2. Meta-analysis of studies comparing remission of type 2 diabetes mellitus (T2DM), reoperation and complication rates between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

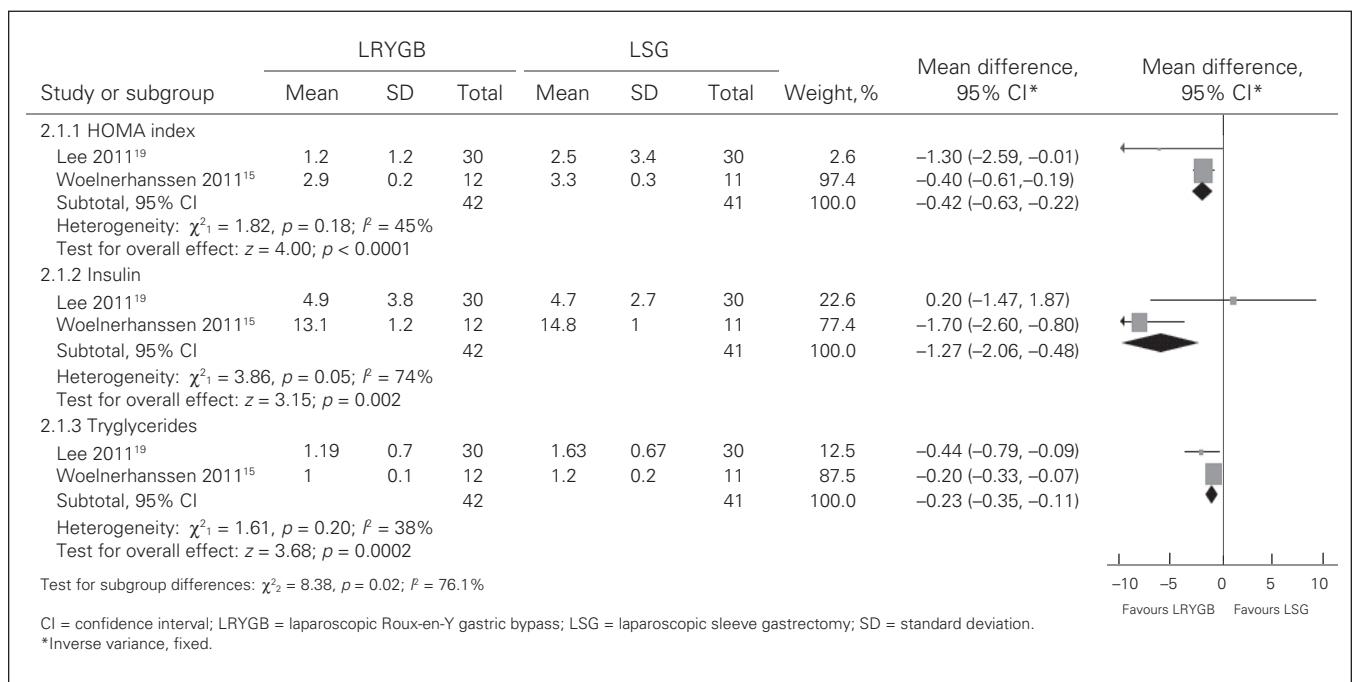


Fig. 3. Meta-analysis of studies comparing homeostatis model assessment (HOMA) index, insulin, and triglycerides between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

or less 1 year after randomization than those patients receiving medical therapy alone. Notably, many patients in the surgical group, particularly those in the gastric bypass group, achieved glycemic control without the use of diabetes medications. Although more clinical trials are needed, this meta-analysis and other studies have strongly recommended that LRYGB as a metabolic surgery should be included in the armament of T2DM treatments.

The underlying mechanism for T2DM remission after gastric bypass surgical procedures is intriguing. Four possible mechanisms have been proposed, including the starvation followed by weight loss hypothesis, the ghrelin hypothesis, the upper intestinal (foregut) hypothesis and the lower intestinal (hindgut) hypothesis.²⁴ None of these theories necessarily precludes the others, so any combination may be operational to some extent; therefore, it is difficult to design a study to elucidate the exact mechanism. The results of our meta-analysis strongly support the finding that the duodenum may play a role in T2DM resolution after bariatric surgery. The rapid postoperative remission of T2DM is primarily related to an improvement in insulin resistance rather than increasing insulin secretion.^{25,26} The difference in insulin resistance in the postoperative period between the 2 procedures found in this meta-analysis also supports the theory that duodenum exclusion is helpful for the reduction of insulin resistance. In recent studies, Korner and colleagues²⁷ found that reduction of insulin resistance correlated significantly with

weight loss only in patients who underwent gastric banding, not in those who had gastric bypass, and Bikman and colleagues²⁸ found that improved insulin sensitivity after gastric bypass was due to something other than weight loss. Because the duodenum was recently found to have a novel intestine–brain–liver neurocircuit to increase hepatic insulin sensitivity, it is possible that gastrointestinal surgery may help mediate antidiabetes effects, although this is currently unclear. More elaborate studies are needed to elucidate the underlying complex mechanism of T2DM resolution after gastric bypass surgery.

Limitations

The main limitation of this meta-analysis is the lack of RCTs with large sample sizes. Another limitation is the lack of long-term follow-up. Without long-term follow-up, we cannot confirm the durability of T2DM remission after surgery and the influence of possible weight change in the future. More elaborate clinical studies are indicated to elucidate this issue.

CONCLUSION

In summary, our meta-analysis has demonstrated that LRYGB is more effective than LSG for the surgical treatment of T2DM and control of metabolic syndrome. Patients treated with LRYGB lost more weight than those

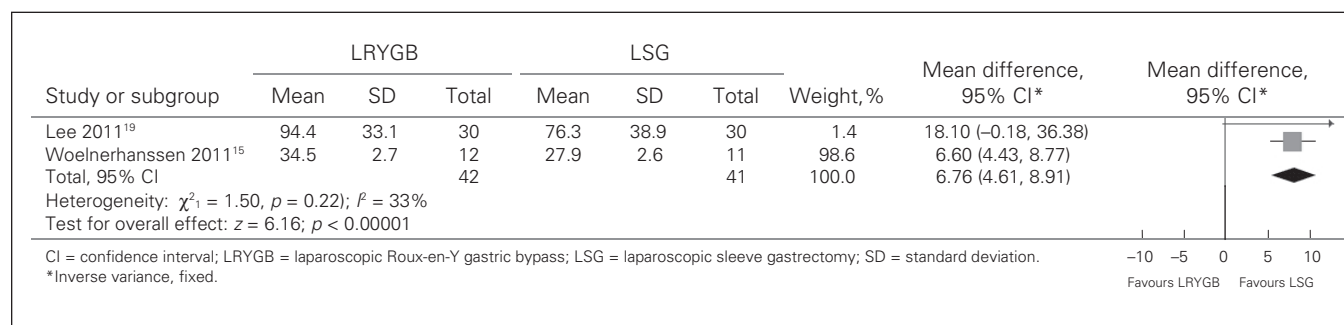


Fig. 4. Meta-analysis of studies comparing percent excess weight loss (%EWL) between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

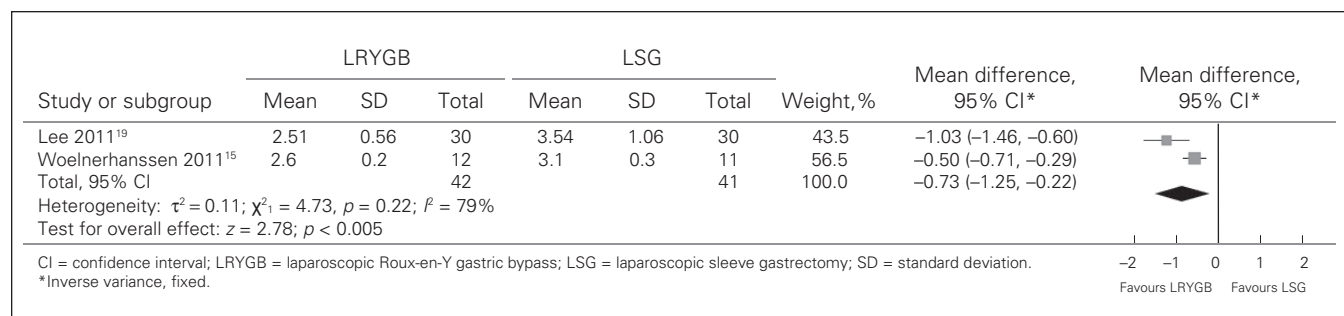


Fig. 5. Meta-analysis of studies comparing low-density lipoprotein between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) groups. CI = confidence interval.

treated with LSG. Further high-quality RCTs with large sample sizes and long follow-up periods are needed to provide more reliable evidence.

Competing interests: None declared.

Contributors: J.-F. Li and D.-D. Lai designed the study, acquired the data and wrote the article. B. Ni and K.-X. Sun analyzed the data. J.-F. Li, D.-D. Lai, B. Ni and K.-X. Sun reviewed the article. All authors approved its publication.

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