

Systematic review and meta-analysis of outcomes after revisional bariatric surgery following a failed adjustable gastric band

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Title: Systematic review and meta-analysis of outcomes after revisional bariatric surgery following a failed adjustable gastric band.

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Conflict of interest statement:

The authors (Mr A Sharples, Mr V Charalampakis, Mr M Daskalakis, Dr A Tahrani and Mr R Singhal) all confirm that they have no conflict of interests to declare.

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Abstract

Introduction: Laparoscopic adjustable gastric band (LAGB) related complications have been reported in significant numbers of patients often leading to band removal. Increasingly revisional bariatric surgery (RBS) is offered, most commonly either band to roux-en-y gastric bypass (B-RYGB) or band to sleeve gastrectomy (B-SG).

Objectives: We conducted a systematic review and meta-analysis of studies to evaluate the efficacy of RBS following failed LAGB.

Methods Medline, Embase, The Cochrane Library and NHS Evidence were searched for English language studies assessing patients who had undergone LAGB and who subsequently underwent RBS (either B-RYGB or B-SG).

Results: Thirty-six studies met the inclusion criteria. In total there were 2617 patients. B-RYGB was performed in 60.5% (n=1583). There was only one death within 30 days reported (0.0004%). The overall pooled morbidity rate was 13.2%. There was no difference between the B-RYGB and B-SG groups in overall morbidity, leak rate or return to theatre. Percentage excess weight loss (%EWL) following the revisional procedure for all patients combined at 6, 12 and 24 months was 44.5%, 55.7% and 59.7% respectively. There was no statistical difference in %EWL between B-RYGB and B-SG at any time point. The rates of remission of diabetes, hypertension and obstructive sleep apnoea were 46.5%, 35.9% and 80.8% respectively.

Conclusions: Randomised controlled trials (RCTs) do not exist on this issue but the available observational evidence does suggest that RBS is associated with generally good outcomes similar to those experienced after primary surgery. Further, high quality research, particularly RCTs, is required to assess long-term weight loss, comorbidity and quality of life outcomes.

Introduction

The prevalence of obesity worldwide continues to grow and is a significant burden on individuals and healthcare systems. Bariatric surgery is the most effective treatment option that results in significant long term sustainable weight loss.{{593 Colquitt,J.L. 2014; 595 Courcoulas,A.P. 2014; 594 Gloy,V.L. 2013}} The laparoscopic adjustable gastric band (LAGB) was the first bariatric procedure to gain widespread acceptance due to its good weight loss results in the short term, its relative simplicity and low early complication rates.{{599 Chapman,A.E. 2004}} However, randomised and non-randomised studies have shown that roux-en-y gastric bypass (RYGB) and sleeve gastrectomy (SG) are superior to LAGB in terms of weight loss and impact on obesity related comorbidities.{{601 Boza,C. 2011; 605 Hutter,M.M. 2011; 600 Tice,J.A. 2008}} As a result there has been a significant fall worldwide in the number of LAGBs performed in favour of RYGB and SG.{{597 Buchwald,H. 2013; 596 Buchwald,H. 2009; 598 Angrisani,L. 2015}}

The rate of LAGB related complications such as band erosion, band slippage, oesophageal dilatation and dysmotility and tube or port dysfunction can be as high as 15-58% often leading to band removal.{{602 Gustavsson,S. 2002; 607 Lanthaler,M. 2010; 603 Suter,M. 2006; 604 Spivak,H. 2012; 584 Weber,M. 2003}} In addition, a substantial proportion of patients fail to lose sufficient weight with LAGB alone;{{606 Biertho,L. 2005; 607 Lanthaler,M. 2010}} in one study insufficient weight loss (defined as percentage excess weight loss (%EWL) of <25%) was reported in 10.5% of patients at 5 years.{{603 Suter,M. 2006}}

Increasingly therefore, revisional bariatric surgery (RBS) is being performed to remove the gastric band and convert to another bariatric procedure, most commonly RYGB or SG.

Previous systematic reviews have demonstrated both the safety and efficacy of RBS.{{609

Mahawar,K.K. 2015; 610 Cheung,D. 2014; 608 Elnahas,A. 2013}} Despite this, the efficacy of RBS in terms of weight loss might be inferior to primary bariatric surgery (PBS) and the complication rates higher.{{ 611 Zhang,L. 2015; 609 Mahawar,K.K. 2015; 612 Mor,A. 2013}} However, the choice that patients and clinicians face is not between RBS and PBS but between RBS and medical management in patients who have already undergone LAGB. Patients requiring RBS are different to those undergoing PBS; they have by definition failed a primary bariatric surgical intervention for a variety of reasons which might put them at higher risk for a further revisional procedure. Therefore direct comparison of RBS with PBS is not necessarily of great relevance.

In addition, while the impact of PBS on obesity-related comorbidities is well established, the impact of RBS on these comorbidities is far less certain{{ 499 Aftab,H. 2014; 500 Kanoupakis,E. 2001; 501 Sarkhosh,K. 2013; 498 Sovik,T.T. 2011; 497 Sjostrom,L. 2004}}

Obesity has a negative impact upon quality of life (QOL){{ 627 Kushner,R.F. 2000}} and there is increasing evidence that QOL can be improved significantly following bariatric surgery.{{ 623 Driscoll,S. 2016; 624 Major,P. 2015; 625 Andersen,J.R. 2015; 626 Hachem,A. 2016}} It is tempting to extrapolate the positive impact that PBS has been shown to have on QOL and hypothesise that RBS, if achieving similar levels of weight loss and comorbidity improvement should result in similar QOL improvements. However, patients undergoing RBS are likely to have different characteristics to patients receiving bariatric surgery for the first time. It is possible that some of those physical, psychological or social factors have contributed to the failure of their initial LAGB and therefore may be more resistant to treatment. Indeed, there is much evidence to suggest that psychological and social factors, both preoperative and postoperatively, are predictive of poorer outcomes following bariatric surgery.{{ 556 Gordon,P.C. 2014; 561 Kalarchian,M.A. 2008; 552 Livhits,M. 2012; 553 van Hout,G.C. 2005; 554 Wedin,S. 2014; 555 Wimmelmann,C.L. 2014}}

Hence, we aimed to conduct a systematic review and meta-analysis of observational and interventional studies to evaluate the efficacy and safety of revisional bariatric surgery (RYGB and SG) following a failed LAGB in regards to complication rates, weight loss, resolution of obesity-related comorbidities and QOL.

Methods

A systematic review and meta-analysis was performed. This was performed using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) recommendations.{{239 Moher,D. 2010}}

Eligibility Criteria

English language, prospective and retrospective, observational and interventional studies were included. Studies were included if they: 1. Included patients who had undergone PBS in the form of a gastric band and who subsequently underwent RBS: either a gastric band converted to RYGB (B-RYGB) or a gastric band converted to SG (B-SG); 2. Presented data on one or more of the following postoperatively: weight change at a minimum of six months; obesity-related comorbidities at any time point; or quality of life data at any time point; 3. Included more than 10 patients. Studies including patients undergoing other types of revisional procedure (eg. revisions of vertical banded gastroplasty, revisions of sleeve gastrectomy or gastric band revisions not in the form of either B-RYGB or B-SG) were excluded unless the data regarding B-RYGB and B-SG was clearly separable from other data. Other exclusions included studies reporting on data from less than 10 patients and studies reporting data from open revisional procedures.

Information sources and search strategy

A literature search was performed using Medline, Embase, The Cochrane Library and NHS Evidence up to November 2015. The search was performed using combinations of keywords: laparoscopic adjustable gastric banding; laparoscopic sleeve gastrectomy; laparoscopic roux-en-y gastric bypass; revision; revisional; reoperation; salvage; rescue; repeat; weight loss;

postoperative complication; surgical complication; morbidity; mortality; quality of life; comorbidities. The exact search strategy can be seen in Appendix 1. In addition to the above databases, the reference lists of included studies were also searched manually for additional studies.

Study selection

Studies identified by the search strategy above were screened for inclusion using a two-step process. Firstly, the titles and abstracts of each study were assessed (AS and VC), if these were felt to be relevant then the full text or the paper was accessed. Secondly, the full text was assessed for the inclusion and exclusion criteria listed above (AS and VC). Differences between the assessors were resolved by discussion and mutual agreement.

Data collection

Data collected included: study design; the inclusion and exclusion criteria of each study; sample size; demographic data; pre and postoperative body mass index (BMI) and/or weight; length of hospital stay (LOS); operative time; postoperative morbidity and mortality; length of follow-up; %EWL; comorbidity resolution or improvement; QOL data.

Where %EWL was not explicitly stated, this was, where possible, calculated using the formula: $\text{postoperative weight loss} / (\text{preoperative weight} - \text{ideal body weight})$. The weight at which a BMI of 25 would be obtained was used as the ideal body weight. {{652 Deitel,M. 2007}}

Summary measures and synthesis of results

Stats Direct version 3.0.141 (StatsDirect Ltd., Altrincham, UK) was used to analyse data. Mean values for follow-up, operation time and LOS were combined and expressed using weighted means. Meta-analysis of effect size, Forest plots, relative risk and pooled

prevalence data were calculated using the Dersimonian-Laird random effects model.{{240
DerSimonian,R. 1986}} A p-value of less than 0.05 was considered statistically significant.
Heterogeneity was expressed using I^2 , where values of 25%, 50%, and 75% correspond to cut
off points for low, moderate, and high degrees of heterogeneity.{{633 Higgins,J.P. 2003}}

Results

Study selection

The literature search produced 358 results. Figure 1 shows the PRISMA flow diagram detailing the process of study selection. Ultimately the process produced 36 studies which were included in the final analysis. {{416 Aarts,E. 2014; 587 Abu-Gazala,S. 2012; 463 Acholonu,E. 2009; 438 Alqahtani,A.R. 2013}} {{420 Carandina,S. 2014; 417 Carr,W.R. 2015; 430 Delko,T. 2014; 419 Emous,M. 2015}} {{464 Frezza,E.E. 2009; 447 Goitein,D. 2011; 418 Gonzalez-Heredia,R. 2015; 443 Hii,M.W. 2012}} {{451 Jacobs,M. 2011; 437 Jennings,N.A. 2013; 440 Kafri,N. 2013; 436 Khoursheed,M. 2013}} {{537 Langer,F.B. 2008; 433 Liu,K.H. 2013; 427 Marin-Perez,P. 2014; 585 Mognol,P. 2004; 435 Moon,R.C. 2013}} {{586 Moore,R. 2009; 474 Muller,M.K. 2008; 421 Noel,P. 2014; 434 Perathoner,A. 2013}} {{588 Rebibo,L. 2012; 446 Robert,M. 2011}} {{428 Silecchia,G. 2014; 441 Slegtenhorst,B.R. 2013; 475 Spivak,H. 2007}} {{465 Topart,P. 2009; 472 Topart,P. 2007; 432 Tran,T.T. 2013; 584 Weber,M. 2003}} {{439 Yazbek,T. 2013; 411 Yeung,L. 2015}}

Study characteristics

Table 1 describes the study designs and population characteristics of the included studies.

Out of 36 studies, eight studies{{587 Abu-Gazala,S. 2012; 417 Carr,W.R. 2015; 435 Moon,R.C. 2013; 427 Marin-Perez,P. 2014; 420 Carandina,S. 2014; 411 Yeung,L. 2015; 436 Khoursheed,M. 2013; 418 Gonzalez-Heredia,R. 2015}} reported patients undergoing B-RYGB and B-SG separately. In total therefore there were 44 data sets. The 36 studies included a total sample of 2617 patients (2144 female, 415 male, two studies did not state{{418 Gonzalez-Heredia,R. 2015; 474 Muller,M.K. 2008}}). The smallest study included 10 patients (as per the inclusion criteria){{464 Frezza,E.E. 2009}} whilst the largest

included 300 patients.{{421 Noel,P. 2014}} Twenty-six studies were retrospective and 10 were prospective studies. No controlled or randomised studies were identified. The earliest study was published in 2003,{{584 Weber,M. 2003}} while 61.0% (22 out of 36) were published in the last five years.

Most revisional procedures were B-RYGB (n=1583, 60.5%) while the remaining were B-SG (n=1034, 39.5%). Women made up 83.8% (2144 of 2559) of the overall study population and the weighted mean age was 42.7. Further demographic data can be seen in Table 2.

A one-stage procedure involves removal of the gastric band concomitantly with performance of RBS whereas with a two-stage procedure the band is removed and RBS performed at a subsequent date. In ten studies all patients underwent a one-stage conversion and in three studies all patients underwent a two-stage conversion. Nineteen studies included patients undergoing a mixture of one and two-stage procedures. Four studies did not specify whether the procedures were one or two-stage. In the 32 studies where this data was available 79.7% (1117 of 1402) of RYGBs and 47.2% (412 of 873) of SGs were performed as one-stage procedures ($p<0.0001$).

Twenty-eight ~~28~~ studies (2300 patients) reported their indications for revision (Table 3). The most common indication for revision was insufficient weight loss. Most studies defined this as %EWL less than 25%, however a number of studies did not provide a definition.

Twenty-four studies reported their mean length of follow-up. Weighted mean follow-up was 27.1 +/-10.0 months.

Synthesis of results

Mortality and Morbidity

Thirty-four studies reported on mortality and only one death within 30 days was reported (0.0004%). Morbidity and postoperative complications were reported by 33 studies. The overall pooled incidence of complications was 13.2% (95% CI: 9.5-17.3%, $I^2=87.1\%$, 32 studies). Seventeen studies broke complications down into early (less than 30 days) and late (greater than 30 days). The pooled early incidence of complications was 8.9% (95% CI: 6.5-11.7%, $I^2=56.6\%$) and the pooled late incidence of complications was 8.1% (95% CI: 4.4-12.8%, $I^2=85.5\%$). Anastomotic or staple line leak was reported in 2.0% (95% CI: 1.5-2.7%, $I^2=13.2\%$, 33 studies) and return to theatre in 5.4% (95% CI: 3.4-7.8%, $I^2=73.7\%$, 24 studies). The conversion rate to an open procedure was 1.2% (95% CI: 0.7-1.9%, $I^2=31.1\%$).

Results for separate pooled analysis of studies reporting RYGB and SG can be found in table 6.

A number of studies compared morbidity between groups undergoing B-RYGB and B-SG. Meta-analysis of these studies demonstrates that there was no difference between the groups in overall morbidity (RR 1.69, 95%CI: 0.95-3.01, $p=0.07$, 6 studies{{436 Khoursheed,M. 2013; 427 Marin-Perez,P. 2014; 411 Yeung,L. 2015; 587 Abu-Gazala,S. 2012; 420 Carandina,S. 2014; 418 Gonzalez-Heredia,R. 2015}}), leak rate (RR 1.43, 95% CI: 0.46-4.46, $p=0.54$, 7 studies{{418 Gonzalez-Heredia,R. 2015; 436 Khoursheed,M. 2013; 587 Abu-Gazala,S. 2012; 420 Carandina,S. 2014; 417 Carr,W.R. 2015; 411 Yeung,L. 2015; 427 Marin-Perez,P. 2014}}) or return to theatre (RR 2.79, 95% CI: 0.80-9.80, $p=0.11$, 4 studies{{587 Abu-Gazala,S. 2012; 417 Carr,W.R. 2015; 436 Khoursheed,M. 2013; 411 Yeung,L. 2015}}).

None of the studies directly compared morbidity rates between one and two-stage RBS.

Pooling of the morbidity from the studies that did not mix one and two-stage procedures suggests overall morbidity for RYGB was 10.0% (95% CI: 5.7-15.2%, $I^2=26.8\%$, 4 studies)

and 16.2% (1 studies) in the one and two-stage groups respectively. For SG the overall morbidity was 7.3% (95% CI: 3.2-12.9%, $I^2=60.3\%$, 6 studies) and 6.6% (95% CI: 0.5-19.1%, $I^2=89.9\%$, 3 studies) in the one and two-stage groups respectively.

Operation Time

Twenty-six studies reported mean operative time. The weighted mean operative time was higher for B-RYGB than B-SG (152.8 +/-41.0 minutes vs 125.0 +/-16.1 minutes, $p<0.01$).

Length of stay

Twenty studies reported mean LOS. The weighted mean LOS was longer for B-RYGB patients than B-SG (5.2 +/-1.9 days vs 4.1 +/-1.5 days, $p<0.01$).

Weight loss

Weight loss outcomes for all studies can be found in Table 7. Different studies used different weight loss outcome measures. The majority of studies (30 of 36) reported %EWL with various lengths of follow-up. %EWL for all patients combined at 6, 12 and 24 months was 44.5% (95% CI: 41.0-48.0%), 55.7% (95% CI: 52.7-58.7%) and 59.7% (95% CI: 55.6-63.8%) respectively (Table 8). Tables 9 and 10 show the %EWL following B-RYGB and B-SG. A number of studies directly compared %EWL between patients undergoing B-RYGB and those undergoing B-SG. There was no statistical difference in %EWL between these two groups of patients at 6 months (3 studies { {420 Carandina,S. 2014; 418 Gonzalez-Heredia,R. 2015; 436 Khoursheed,M. 2013} } : $d=-0.17$, $p=0.67$), 12 months (7 studies { {436 Khoursheed,M. 2013; 427 Marin-Perez,P. 2014; 435 Moon,R.C. 2013; 587 Abu-Gazala,S. 2012; 420 Carandina,S. 2014; 417 Carr,W.R. 2015; 418 Gonzalez-Heredia,R. 2015} } : $d=0.11$, $p=0.63$) and 24 months (4 studies { {420 Carandina,S. 2014; 417 Carr,W.R. 2015; 427 Marin-Perez,P. 2014; 435 Moon,R.C. 2013} } : $d=0.37$, $p=0.24$) (Figure 2).

A number of studies analysed the mean reduction in BMI. Weighted mean BMI decrease at 6, 12 and 24 months was 10.9 \pm 2.5 (five studies { {584 Weber,M. 2003; 475 Spivak,H. 2007; 585 Mognol,P. 2004; 437 Jennings,N.A. 2013; 463 Acholonu,E. 2009} }, 11.2 \pm 3.1 (five studies { {437 Jennings,N.A. 2013; 585 Mognol,P. 2004; 584 Weber,M. 2003; 441 Slegtenhorst,B.R. 2013; 430 Delko,T. 2014} }) and 11.5 \pm 5.3 (three studies { {430 Delko,T. 2014; 437 Jennings,N.A. 2013; 446 Robert,M. 2011} }) respectively.

Eleven studies compared BMI before LAGB as well as before and after RBS. The mean BMI prior to LAGB in these studies was 46.4 (95% CI: 45.5-47.4), prior to RBS was 43.7 (95% CI: 42.4-44.9) and a mean of 17.2 (95% CI: 12.6-21.8) months after RBS was 33.5 (95% CI: 32.5-34.5). Therefore RBS contributed 78.8% (95% CI: 70.5-87.1%) of their total weight loss.

Comorbidity Outcomes

Definitions of what exactly constituted remission or improvement of a comorbidity varied between studies. For diabetes and hypertension, all studies defined remission as the cessation of medications and improvement as the reduction in dose or number of medications. However, whereas Moon et al { {435 Moon,R.C. 2013} } required patients to achieve a fasting glucose level of <125mg/dl or a blood pressure of <140/90mmHg for diabetes and hypertension respectively, other studies did not specify this. Robert et al { {446 Robert,M. 2011} } simply required a normal HbA1C or blood pressure to be reached with no definition of what values they consider normal. The other studies { {441 Slegtenhorst,B.R. 2013; 439 Yazbek,T. 2013; 411 Yeung,L. 2015} } classified patients purely on the basis of their medications. Robert et al { {446 Robert,M. 2011} } considered obstructive sleep apnea (OSA) to be in remission if patients achieved an apnea-hypopnea index (AHI) of <15. They

considered improvement to be an AHI <30. Yazbek et al{{439 Yazbek,T. 2013}} classified remission as a cessation of the use of continuous positive airway pressure (CPAP).

Comorbidity outcomes for individual studies can be seen in Table 11. Five studies reported remission rates in patients with diabetes prior to their revisional procedure.{{411 Yeung,L. 2015; 441 Slegtenhorst,B.R. 2013; 446 Robert,M. 2011; 435 Moon,R.C. 2013; 439 Yazbek,T. 2013}} The pooled remission rate was 46.5% (95% CI: 21.2-72.9%, $I^2=83.5$) among the 79 (pooled incidence of diabetes in these five studies was 19.9%, 95% CI: 14.9-25.6%) patients with diabetes studied. Three studies reported that 84.0% (95% CI: 51.5-99.7%, $I^2=84.7$) of 52 (pooled incidence of diabetes = 21.4%, 95% CI: 13.0-31.1%) patients achieved either remission or improvement.{{411 Yeung,L. 2015; 435 Moon,R.C. 2013; 446 Robert,M. 2011}}

Of five studies, looking at 150 (pooled incidence of hypertension = 37.2%, 95% CI: 30.9-43.9%) patients with hypertension, four reported on remission{{439 Yazbek,T. 2013; 411 Yeung,L. 2015; 441 Slegtenhorst,B.R. 2013; 435 Moon,R.C. 2013}}. Of these, 35.9% (95% CI: 23.1-49.8%, $I^2=57.8$) were considered to be in remission following revisional surgery. Three studies reported on remission or improvement and reported 71.6% (95% CI: 54.5-86.0%, $I^2=67.6$) of patients achieved either remission or an improvement in their hypertension.{{435 Moon,R.C. 2013; 446 Robert,M. 2011; 411 Yeung,L. 2015}}

Only two studies reported improvement of OSA, demonstrating that 80.8% (95% CI: 65.0-92.6%, $I^2=0.0$) of patients improved or were cured.{{439 Yazbek,T. 2013; 446 Robert,M. 2011}}

Quality of life

Only two studies looked at QOL outcomes.{{446 Robert,M. 2011; 440 Kafri,N. 2013}} Kafri et al{{440 Kafri,N. 2013}} reported the extent to which patients agreed with four statements. They did not use a validated QOL measure. The study demonstrated that 73% of patients reported being happier, 63% reported feeling more attractive and 70% reported being satisfied with their appearance after their revisional surgery. However, only 22% were satisfied with the extent of their weight loss. Robert et al{{446 Robert,M. 2011}} used the BAROS questionnaire{{566 Oria,H.E. 1998}} to assess QOL. They reported a mean 1.5 point gain in QOL following revisional surgery.

Discussion

Revisional bariatric surgery is on the rise due to the rapid increase in patients undergoing bariatric surgery. Unfortunately, there is a relative lack of evidence to support the practice. Unlike PBS, for which there are now well conducted longitudinal and randomised controlled trials (RCTs), our systematic review shows that the evidence for RBS is limited with no RCTs and many retrospective studies.{{616 Buchwald,H. 2004; 619 Christou,N.V. 2004; 593 Colquitt,J.L. 2014; 617 Picot,J. 2009; 620 Sjostrom,L. 2007}}

The results of this systematic review suggest that both B-RYGB and B-SG are viable options for patients after failed LAGB. The pooled morbidity and mortality rates described in this systematic review are comparable to those reported for PBS and do not suggest that RBS is associated with a significant increase in morbidity rates.{{609 Mahawar,K.K. 2015}}

Anastomotic or staple line leaks are the most feared complication following RBS. However the pooled leak rate of 2.2% after B-SG is similar to that described by Aurora et al in their systematic review of leak rates after primary SG.{{643 Aurora,A.R. 2012}} Similarly, a leak rate of 1.8% after B-RYGB is similar to that reported for primary RYGB.{{609 Mahawar,K.K. 2015; 644 Morales,M.P. 2011}} Some authors have suggested that complication rates, particularly leak rates, may be higher after B-SG than after B-RYGB.{{463 Acholonu,E. 2009; 629 Coblijn,U.K. 2013}} However, this has not been seen in our results.

Our data suggests that surgeons are more hesitant about performing one-stage B-SG than B-RYGB. B-RYGB was significantly more likely to be performed in a single stage than B-SG in our analysis. This is potentially influenced by the fear of increased leak rates in B-SG as discussed above. The limited data we are able to present would suggest that one-stage procedures are not associated with higher morbidity.

Overall, these findings suggest that patients should expect a %EWL of 44.5%, 55.7% and 59.7% at 6, 12 and 24 months respectively. A number of systematic reviews analysing weight loss after PBS have reported %EWL of 61-70%.{{616 Buchwald,H. 2004; 621 Chang,S.H. 2014; 622 Garb,J. 2009}} However, such direct comparisons lack relevance due to the differences in the study populations. Nonetheless, the %EWL observed in this systematic review is clinically relevant and would have a significant impact on obesity related comorbidities.{{637 Magkos,F. 2016; 638 Wing,R.R. 2011}} It should be emphasised again that the choice facing patients and clinicians is not between PBS and RBS but between RBS and medical management. There does not appear to be a difference in %EWL outcomes between B-RYGB and B-SG but the number of studies is small and further research to assess which procedure is most effective is needed.

This systematic review shows that there is a paucity of evidence regarding the impact of RBS on obesity related comorbidities. A small number of studies showed that a significant proportion of patients will notice an improvement in their diabetes, hypertension and OSA (84.0%, 71.6% and 80.8% respectively), which is similar to that reported following PBS.{{616 Buchwald,H. 2004; 621 Chang,S.H. 2014}} Although these results are promising, further studies are needed to assess and quantify the benefits that patients are able to achieve in their medical comorbidities following RBS.

Our study identified only two studies which looked at QOL outcomes following RBS. Of these only one{{446 Robert,M. 2011}} used a validated QOL assessment tool (the BAROS questionnaire). Their results did suggest an improvement in QOL after revisional surgery. It is important that QOL is assessed more rigorously in future studies.

Although the number of LAGB procedures performed is falling, large numbers of patients are living with a gastric band and more are being inserted each year.{{598 Angrisani,L. 2015;

597 Buchwald,H. 2013; 596 Buchwald,H. 2009}} Estimates suggest that 15-40% of patients will require revisional surgery after LAGB.{{ 601 Boza,C. 2011; 620 Sjostrom,L. 2007; 640 Van Nieuwenhove,Y. 2011; 641 Himpens,J. 2011; 642 O'Brien,P.E. 2013}} Therefore it is likely that the number of patients with gastric bands presenting for consideration of RBS is likely to rise further over the next decade. It is critical therefore that high quality evidence to guide practice is available and although interest in this area is growing (as evidenced by the increased number of recent studies in this review), good quality evidence is still lacking. RBS is undoubtedly more technically challenging than PBS and therefore should be performed with caution, ideally in high volume tertiary centres.{{ 630 Stefanidis,D. 2013}} Although our results suggest that RBS can be associated with good outcomes, selection of patients for RBS after LAGB should still be carefully considered and take into account individual patient factors, preferences and reasons for failure of LAGB.

This is not the first systematic review to focus on revisional surgery after LAGB. In 2013, Coblijn et al{{ 629 Coblijn,U.K. 2013}} systematically reviewed the data for B-RYGB or B-SG after primary LAGB. They concentrated on postoperative morbidity rather than longer term weight loss and concluded that although revisional surgery was safe it did carry a higher complication rate than primary procedures. Elnahas et al{{ 608 Elnahas,A. 2013}} in 2012 reviewed the weight loss data for patients having RBS after primary LAGB. This study predates the majority of studies included in our review and the number of patients included was much smaller. The mean %EWL they describe is similar to our findings for B-RYGB, however they describe a %EWL of only 22% for B-SG. In contrast, our findings do not suggest a difference, at least in the short term, in %EWL between B-RYGB and B-SG. Most recently, Mahawar et al{{ 609 Mahawar,K.K. 2015}} performed a systematic review comparing revisional RYGB and SG to their respective primary procedures. Whilst they did not restrict themselves purely to revisions following LAGB, the majority of patients had

undergone LAGB as their primary procedure. They concluded that RBS carried a higher complication rate than PBS. Although they did not perform meta-analysis on the weight loss data, they found that the majority of included studies reported inferior weight loss for RBS than PBS. Our study, is more recent and therefore includes significantly more patients. In addition, none of the previous systematic reviews include data on comorbidity resolution and QOL in the analysis.

Our study has several limitations. The quality of any systematic review is limited by the quality of the included studies. None of the included studies were RCTs, all were observational studies of variable size, design and quality. Length of follow-up, outcome measures, surgical techniques and inclusion criteria all varied widely between studies. Although the overall number of patients was relatively large (2617), the wide variety of outcome measures analysed by the different studies means that for each outcome the number of patients available for analysis was often small. The relatively recent enthusiasm for RBS naturally limits the availability of long-term follow up and most of the studies include only relatively short term results.

Conclusions

This study shows that the evidence for RBS, though limited and lacking in RCTs, suggests that RBS results in significant weight loss, obesity-related comorbidity resolution and has a positive impact on QOL, with an acceptable safety profile. Further, high quality studies, particularly RCTs are required to assess long-term efficacy and safety of RBS.

Tables

Table 1 – Design and population characteristics of included studies

	Year	Country	Setting	Design	Revisional procedure	Number	Exclusions	% Female	Age	Preoperative BMI	Follow up (months)
Weber{{584 Weber,M. 2003}}	2003	Switzerland	Single-centre	Prospective	RYGB	32		71.9	46.0	42.0	10.5
Mognol{{585 Mognol,P. 2004}}	2004	France	Single-centre	Retrospective	RYGB	70		72.5	41.0	44.9	7.3
Muller{{474 Muller,M.K. 2008}}	2007	Switzerland	Single-centre	Prospective	RYGB	30				41.9	
Spivak{{475 Spivak,H. 2007}}	2007	USA	Single-centre	Prospective	RYGB	33		90.9	43.8	42.8	15.7
Topart{{472 Topart,P. 2007}}	2007	France	Single-centre	Retrospective	RYGB	32		90.6	40.9	43.1	
Langer{{537 Langer,F.B. 2008}}	2008	Austria	Single-centre	Retrospective	RYGB	25	Band complications	96.0	38.0	47.6	
Acholonu{{463 Acholonu,E. 2009}}	2009	USA	Single-centre	Retrospective	SG	15		80.0	46.6	38.7	6.0
Frezza{{464 Frezza,E.E. 2009}}	2009	USA	Single-centre	Retrospective	SG	10		60.0	50*		19.0
Moore{{586 Moore,R. 2009}}	2009	USA	Single-centre	Retrospective	RYGB	26		88.5	46.0	40.0	18.0
Topart{{465 Topart,P. 2009}}	2009	France	Single-centre	Retrospective	RYGB	58		91.4	42.5	43.2	
Goitein{{447 Goitein,D. 2011}}	2011	Israel	Single-centre	Retrospective	SG	46		73.9	40	43.1	17.0
Abu-Gazala{{587 Abu-Gazala,S. 2012}}	2012	Israel	Single-centre	Retrospective	RYGB	18		55.6	43.7	41.6	14.6
					SG	18		77.8	38.6	40	14.0
Jacobs{{451 Jacobs,M. 2011}}	2011	USA	Single-centre	Retrospective	SG	32		78.1	45.4	42.7	26.0
Robert{{446 Robert,M. 2011}}	2011	France	Multi-centre	Retrospective	RYGB	85		84.7	39.3	42.9	22.0
Hii{{443 Hii,M.W. 2012}}	2012	Australia	Single-centre	Prospective	RYGB	82		85.4	49*	43.0	
Kafri{{440 Kafri,N. 2013}}	2013	Israel	Single-centre	Prospective	SG	12		100	48.8	37.9	17.0
Rebibo{{588 Rebibo,L. 2012}}	2012	France	Single-centre	Retrospective	SG	46		93.5	42.0	44.0	

Alqahtani{{438 Alqahtani,A.R. 2013}}	2013	Saudi Arabia	Single- centre	Retrospective	SG	56		71.4	33.5	44.4	24.0
Jennings{{437 Jennings,N.A. 2013}}	2013	UK	Single- centre	Prospective	RYGB	55		81.8	46.3	49.7	24.0
Khourshead{{436 Khoursheed,M. 2013}}	2013	Kuwait	Single- centre	Retrospective	SG	42		85.7	35.6	38.5*	9.8
					RYGB	53		86.8	39.0	43.2*	29.3
Liu{{433 Liu,K.H. 2013}}	2013	France	Single- centre	Retrospective	RYGB/SG	88		84.1	42.8	44.7	35.6
Moon{{435 Moon,R.C. 2013}}	2013	USA	Single- centre	Retrospective	RYGB	41		90.2	43.7	41.8	
					SG	13		92.3	40.8	39.0	
Perathoner{{434 Perathoner,A. 2013}}	2013	Australia	Single- centre	Retrospective	RYGB	108		85.2	46*	37.9*	40.8
Slegtenhorst{{441 Slegtenhorst,B.R. 2013}}	2013	Netherlands	Single- centre	Retrospective	RYGB	66		87.9	42.0	46.2	12.0
Tran{{432 Tran,T.T. 2013}}	2013	USA	Single- centre	Retrospective	RYGB/SG	61		91.8	43.7	42.9	12.4
Yazbek{{439 Yazbek,T. 2013}}	2013	Canada	Single- centre	Retrospective	SG	90		85.6	41.0	42.0	24.0
Aarts{{416 Aarts,E. 2014}}	2014	Netherlands	Single- centre	Retrospective	RYGB	195	Band complications Band in place less than 1 year	82.1	43.0	41.0	40.0
Carandina{{420 Carandina,S. 2014}}	2014	France	Single- centre	Retrospective	RYGB	74		93.2	42.1	45.6	29.1
					SG	34		91.2	42.4	47.5	24.2
Delko{{430 Delko,T. 2014}}	2014	Switzerland	Single- centre	Prospective	RYGB	48		75.0	43.5	41.9	
Gonzalez- Heredia{{418 Gonzalez- Heredia,R. 2015}}	2015	USA	Single- centre	Retrospective	SG	26			38.6	48.6	
					RYGB	12			33.9	44.6	
Marin- Perez{{427 Marin-Perez,P. 2014}}	2014	USA	Single- centre	Prospective	RYGB	39		84.6	49.0	42.0	22.0

					SG	20		75.0	44.0	39.0	33.0
Noel{{421 Noel,P. 2014}}	2014	France	Single-centre	Retrospective	SG	300		87.0	43.3	43.0	35.0
Silecchia{{428 Silecchia,G. 2014}}	2014	Italy	Multi-centre	Retrospective	SG	76		78.9	45.5*	43.9*	
Carr{{417 Carr,W.R. 2015}}	2015	UK	Single-centre	Prospective	RYGB	64		79.7	47.7	49.5	
					SG	25		68.0	49.8	52.7	
Emous{{419 Emous,M. 2015}}	2015	Netherlands	Single-centre	Prospective	RYGB	257		82.9	43*		29.0
Yeung{{411 Yeung,L. 2015}}	2015	USA	Single-centre	Retrospective	RYGB	32		81.3	51.0	41.4	
					SG	72		84.7	45.0	39.6	

Where cells are empty data was not available

Table 2 – Basic population demographics of patients included in the systematic review

	Data sets	Patients	Number of patients (%)
Male	41	2559	415 (16.2)
Female	41	2559	2144 (83.8)
RYGB	44	2617	1583 (60.5)
SG	44	2617	1034 (39.5)
Age	38	2054	42.7 (41.6-43.7)
Time to revision (months)	28	1457	49.7 (42.4-57.1)
BMI (before LAGB)	19	982	46.5 (45.7-47.4)
BMI (before revision)	38	2071	43.4 (42.5-44.3)
One stage	29	2034	1223 (60.1)
Two stage	29	2034	811 (39.9)
Diabetes	14	742	142 (19.1)
Hypertension	13	694	210 (30.3)
Obstructive sleep apnoea	8	479	80 (16.7)
Dyslipaemia	6	371	77 (20.8)

Table 3 – Indications for revisional procedure

Indication	Number (%)
Weight regain	251 (10.9)
Insufficient weight loss	1079 (46.9)
Slippage	265 (11.5)
Erosion	36 (1.6)
Pouch/oesophageal dilatation	255 (11.1)
Band intolerance/dysphagia/reflux	329 (14.3)
Infection	18 (0.8)
Tubing complications	42 (1.8)
Other	25 (1.1)

Table 4 – Operative times, length of stay and postoperative morbidity described in included studies

	Number	Revisional procedure	One stage	Two stage	Mean Op time (mins)	LOS days Mean	LOS median	Mortality	Morbidity	Leak	Return to theatre
Weber{{584 Weber,M. 2003}}	32	RYGB			215	8.9		0	4 Early 2 Late	1	2 Early 2 Late
Mognol{{58 5 Mognol,P. 2004}}	70	RYGB	47	23		7.2		0	10 Early 6 Late	0	4 Early 0 Late
Muller{{474 Muller,M.K . 2008}}	30	RYGB						0	Early not described 2 Late	0	Early not described 6 Late
Spivak{{475 Spivak,H. 2007}}	33	RYGB	33	0	105	2.8		0	1 Early 1 Late	0	1 Early 1 Late
Topart{{47	32	RYGB	31	1	135			0	4	0	3

2 Topart,P. 2007}}											
Langer{{53 7 Langer,F.B. 2008}}	25	RYGB			219	5		0	1 Early 3 Late	0	
Acholonu{{ 463 Acholonu,E. 2009}}	15	SG	13	2	120	5.5		0	2 Early Late not described	1	1
Frezza{{464 Frezza,E.E. 2009}}	10	SG			87			0	0	0	0
Moore{{586 Moore,R. 2009}}	26	RYGB	24	2	160	3		0	2	1	1
Topart{{46 5 Topart,P. 2009}}	58	RYGB	50	8	128	7.7		0	5	0	3
Goitein{{44 7 Goitein,D. 2011}}	46	SG	26	20	117	3		0	3 Early Late not described	2	2 Early Late not described
Abu- Gazala{{58 7 Abu- Gazala,S. 2012}}	18	RYGB			195	3.9		0	1	0	0
	18	SG			111	4.3		0	2	1	1
Jacobs{{451 Jacobs,M. 2011}}	32	SG	32	0				0	0	0	0
Robert{{44 6 Robert,M. 2011}}	85	RYGB	71	14	166	5.2	4	0	6 Early 4 Late	0	2 Early 1 Late
Hii{{443 Hii,M.W. 2012}}	82	RYGB	64	18	132		4.5	0	38	1	10
Kafri{{440 Kafri,N. 2013}}	12	SG	12	0				0			
Rebibo{{58 8 Rebibo,L. 2012}}	46	SG			138	5.8		0	4	2	3
Alqahtani{{ 438 Alqahtani,A .R. 2013}}	56	SG			129	2.6		0	2 Early O Late	0	0

Jennings{{437 Jennings,N. A. 2013}}	55	RYGB	43	12			3				
Khourshead {{436 Khoursheed ,M. 2013}}	42	SG			108		2	0	3	0	0
	53	RYGB			161		3	0	11	1	2
Liu{{433 Liu,K.H. 2013}}	88	RYGB/SG	29	59				0	1 Early 10 Late	1	
Moon{{435 Moon,R.C. 2013}}	41	RYGB	41	0	72	1.2					
	13	SG	10	3	90	1.5					
Perathoner{{434 Perathoner, A. 2013}}	108	RYGB	56	52	197		7	0	11 Early 38 Late	3	9 Early 18 Late
Slegtenhors t{{441 Slegtenhors t,B.R. 2013}}	66	RYGB	40	26		4.9		0	10	0	
Tran{{432 Tran,T.T. 2013}}	61	RYGB/SG	46	15	159	2		1	11 Early 12 Late	4	3 Early 6 Late
Yazbek{{439 Yazbek,T. 2013}}	90	SG			112	4.2		0	13	5	
Aarts{{416 Aarts,E. 2014}}	195	RYGB	195	0	112	4.5		0	14	2	8
Carandina{{420 Carandina, S. 2014}}	74	RYGB	0	74	172	7.1		0	10 Early 2 Late	4	
	34	SG	0	34	91	6.7		0	1 Early	1	
Delko{{430 Delko,T. 2014}}	48	RYGB	47	1	201			0	9 Early 11 Late	2	
Gonzalez- Heredia{{418 Gonzalez- Heredia,R. 2015}}	26	SG	21	5	130	3		0	0	0	
	12	RYGB	11	1		2.6		0	0	0	

Marin-Perez{{427 Marin-Perez,P. 2014}}	39	RYGB			142	5		0	1 Early 8 Late	0	
	20	SG			121	4		0	3 Early 1 Late	1	
Noel{{421 Noel,P. 2014}}	300	SG	0	300	130			0	6	3	4
Silecchia{{428 Silecchia,G. 2014}}	76	SG	0	76				0	13	0	0
Carr{{417 Carr,W.R. 2015}}	64	RYGB	51	13				0		1	1
	25	SG	10	15				0		0	0
Emous{{419 Emous,M. 2015}}	257	RYGB	220	37				0	12 Early 9 Late	7	
Yeung{{411 Yeung,L. 2015}}	32	RYGB			224			0	5 Early 0 Late	2	4 Early 0 Late
	72	SG			156			0	4 Early 4 Late	1	2 Early 0 Late

Table 6 – Pooled analysis of morbidity rates for RYGB and SG

	RYGB (%)	SG (%)
Overall morbidity	16.5 (11.2-22.6) $I^2 = 87.7$	7.7 (4.4-11.6) $I^2 = 70.9$
Leak rate	1.8 (1.2-2.6) $I^2 = 4.6$	2.2 (1.2-3.5) $I^2 = 18.7$
Return to theatre	7.8 (4.9-11.3) $I^2 = 69.2$	2.0 (1.0-3.4) $I^2 = 19.6$

Table 7 – Post operative weight loss described in included studies

			%EWL				BMI Reduction				Pre Band		%EWL at 29 months	
	Number	Revisional procedure	6 mths	12 mths	18 mths	24 mths	6 mths	12 mths	24 mths	36 mths	6 mths	12 mths	One Step	Two Step
Weber{{584 Weber,M. 2003}}	32	RYGB					7.7	7.9						
Mognol{{585 Mognol,P. 2004}}	70	RYGB	50.0	59.0	70.2		10.4	11.0						
Muller{{474 Muller,M.K. 2008}}	30	RYGB								6.1				
Spivak{{475 Spivak,H. 2007}}	33	RYGB					8.9							
Topart{{472 Topart,P. 2007}}	32	RYGB		58.8										
Langer{{537 Langer,F.B. 2008}}	25	RYGB	40.5	50.8							48.5	56.9		
Acholonu{{463 Acholonu,E. 2009}}	15	SG	64.2				14.3							
Frezza{{464 Frezza,E.E. 2009}}	10	SG			20.0									
Moore{{586 Moore,R. 2009}}	26	RYGB									51.0	56.0		
Topart{{465 Topart,P. 2009}}	58	RYGB		66.1										
Goitein{{447 Goitein,D. 2011}}	46	SG	37.0	53.0		51.0								
Abu-Gazala{{587 Abu-Gazala,S. 2012}}	18	RYGB		52.0										
	18	SG		69.7										
Jacobs{{451 Jacobs,M. 2011}}	32	SG				60.0								
Robert{{446 Robert,M. 2011}}	85	RYGB							8.1					
Hii{{443 Hii,M.W. 2012}}	82	RYGB	43.0	50.0	54.0	55.0								
Kafri{{440 Kafri,N. 2013}}	12	SG			44.3									
Rebibo{{588 Rebibo,L. 2012}}	46	SG	28.8	47.4		53.1								
Alqahtani{{438 Alqahtani,A.R.}}	56	SG	48.4	66.4		80.1								

2013}}														
Jennings{{437 Jennings,N.A. 2013}}	55	RYGB	51.6	59.5		59.4	13.6	16.3	18.1					
Khourshead{{436 Khoursheed,M. 2013}}	42	SG	45.6	47.4										
	53	RYGB	42.0	45.6										
Liu{{433 Liu,K.H. 2013}}	88	RYGB/SG	40.9	52.4		51.7								
Moon{{435 Moon,R.C. 2013}}	41	RYGB		57.4		62.4								
	13	SG		47.7		65.6								
Perathoner{{434 Perathoner,A. 2013}}	108	RYGB		43.9										
Slegtenhorst{{441 Slegtenhorst,B.R. 2013}}	66	RYGB		48.4				10.2						
Tran{{432 Tran,T.T. 2013}}	61	RYGB/SG	52.2	60.2		66.8								
Yazbek{{439 Yazbek,T. 2013}}	90	SG	51.8	61.3	61.6	53.0								
Aarts{{416 Aarts,E. 2014}}	195	RYGB		60.0		65.0								
Carandina{{420 Carandina,S. 2014}}	74	RYGB	45.2	59.9		70.2								
	34	SG	37.4	52.2		59.9								
Delko{{430 Delko,T. 2014}}	48	RYGB		41.8		45.1		9.2	10.1					
Gonzalez- Heredia{{418 Gonzalez- Heredia,R. 2015}}	26	SG	53.0	64.4										
	12	RYGB	36.2	46.0										
Marin- Perez{{427 Marin-Perez,P. 2014}}	39	RYGB		59.0		55.0								
	20	SG		35.0		28.0								
Noel{{421 Noel,P.	300	SG		64.0		64.0								

2014}}														
Silecchia{{428 Silecchia,G. 2014}}	76	SG	46.5	66.4		78.5								
Carr{{417 Carr,W.R. 2015}}	64	RYGB		52.1		47.9								
	25	SG		44.1		42.0								
Emous{{419 Emous,M. 2015}}	257	RYGB										53.0	67.0	
Yeung{{411 Yeung,L. 2015}}	32	RYGB	50.2	51.2										
	72	SG	30.6	34.9										

Table 8 – Pooled %EWL for RYGB and SG

	Studies	Patients	%EWL (95% CI)
3 months	6	407	31.0 (28.0-34.0)
6 months	16	1055	44.5 (41.0-48.0)
12 months	26	2085	55.7 (52.7-58.7)
18 months	5	264	59.1 (44.5-73.8)
24 months	17	1485	60.5 (56.0-65.0)
36 months	7	690	58.1 (48.5-67.7)
48 months	3	393	59.9 (52.1-67.7)
60 months	3	603	60.6 (31.8-89.4)

Table 9 - Pooled %EWL for RYGB

	Studies	Patients	EWL
3 months	3	160	28.5 (23.3-33.7)
6 months	8	403	45.9 (42.2-49.6)
12 months	18	1072	54.2 (50.7-57.7)

18 months	2	152	61.5 (-41.1-164.1)
24 months	8	598	59.5 (52.6-66.4)
36 months	4	459	60.7 (39.5-81.9)
48 months	2	269	62.0 (20.6-103.4)
60 months	2	303	51.3 (22.7-79.9)

Table 10 - Pooled %EWL for SG

	Studies	Patients	EWL
3 months	2	98	31.3 (20.0-42.6)
6 months	10	503	43.1 (36.2-50.0)
12 months	14	864	57.6 (51.4-63.7)
18 months	2	102	59.6 (-11.3-130.4)
24 months	11	738	61.8 (54.0-69.6)
36 months	3	170	55.4 (37.3-73.4)
48 months	2	124	55.4 (28.2-82.6)

Table 11 – Comorbidity response rates described in included studies

					Diabetes			Hypertension			OSA	
Study	Numb er	Procedur e	Patien ts	Follow up (mths)	Inciden ce	Remissio n	Improvem ent or remission	Inciden ce	Remissio n	Improvem ent or remission	Inciden ce	Improvem ent or remission
Robert{{44 6 Robert,M. 2011}}	85	RYGB	85	22	26	22	26	29		17	12	10
Moon{{435 Moon,R.C. 2013}}	54	RYGB/SG	54		9	2	5	20	8	6		
Slegtenhors t{{441 Slegtenhors t,B.R. 2013}}	66	RYGB	66	12	13	3		19	4			

Yazbek{{43 9 Yazbek,T. 2013}}	90	SG	90	24	14	9		32	17		17	14
Yeung{{411 Yeung,L. 2015}}	104	RYGB/SG	104		17	5	14	50	14	28		

Figures

Figure 1: PRISMA flow diagram.{{239 Moher,D. 2010}}

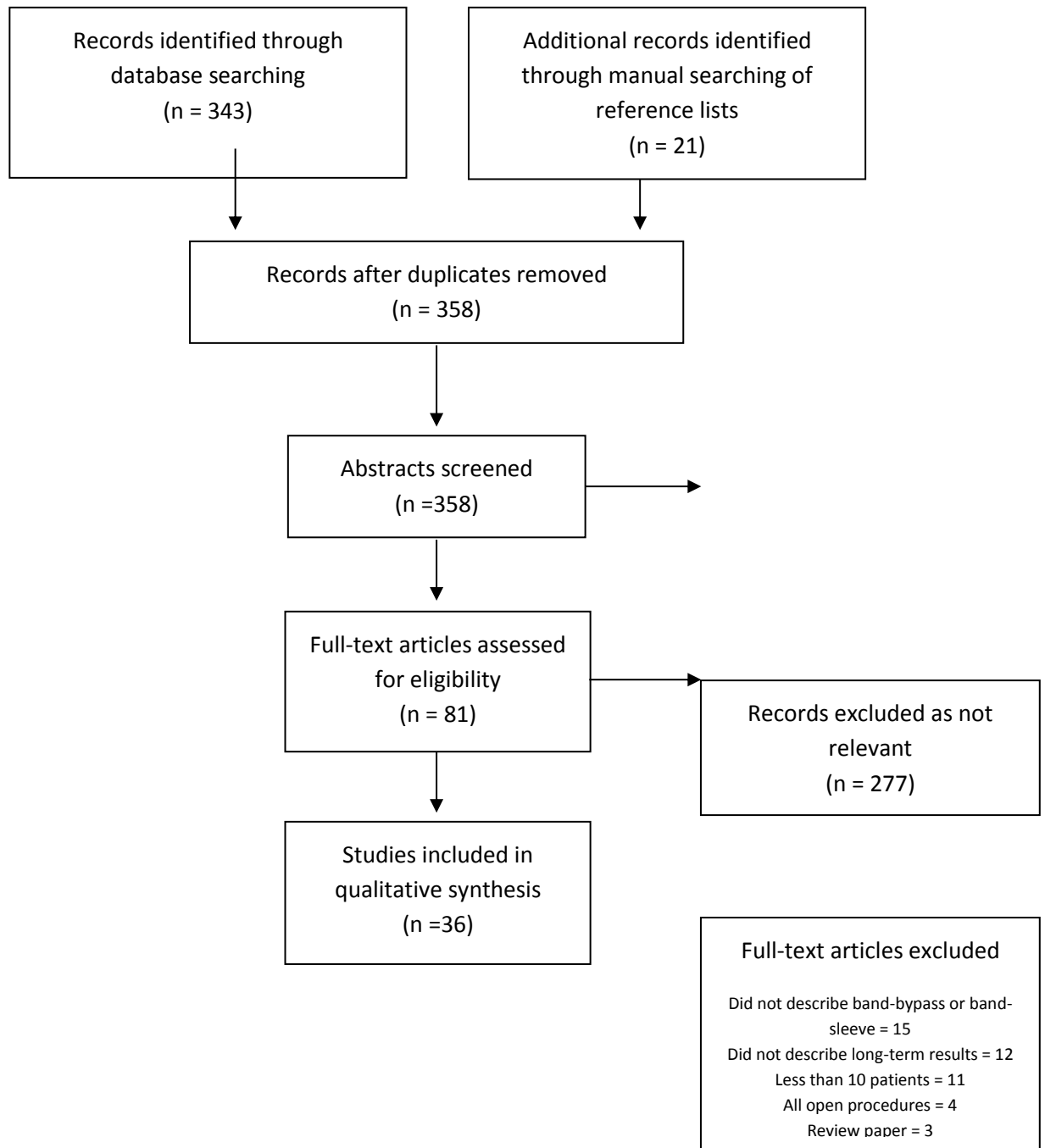
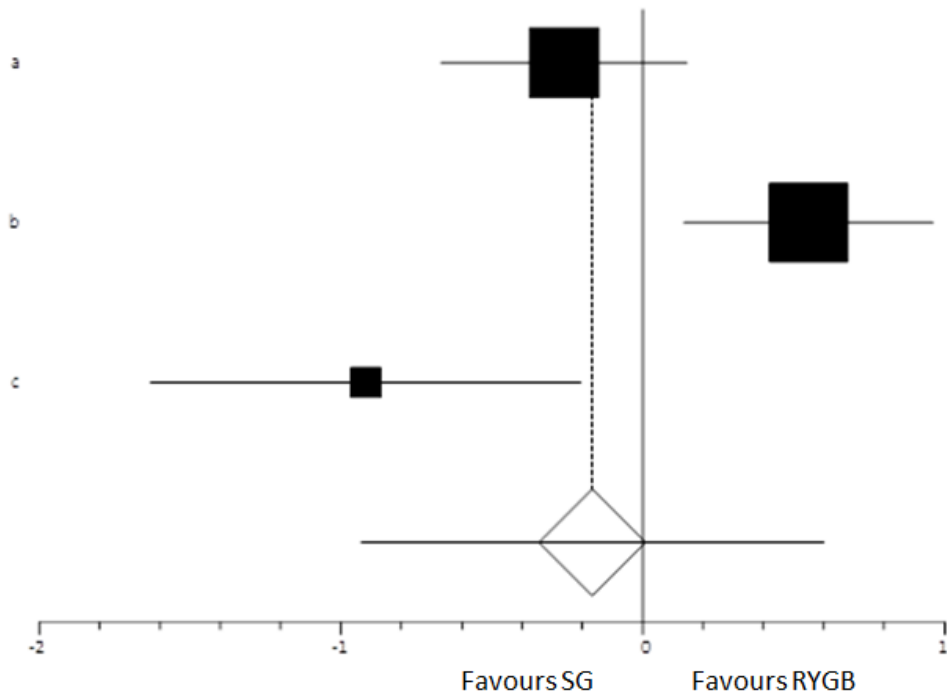
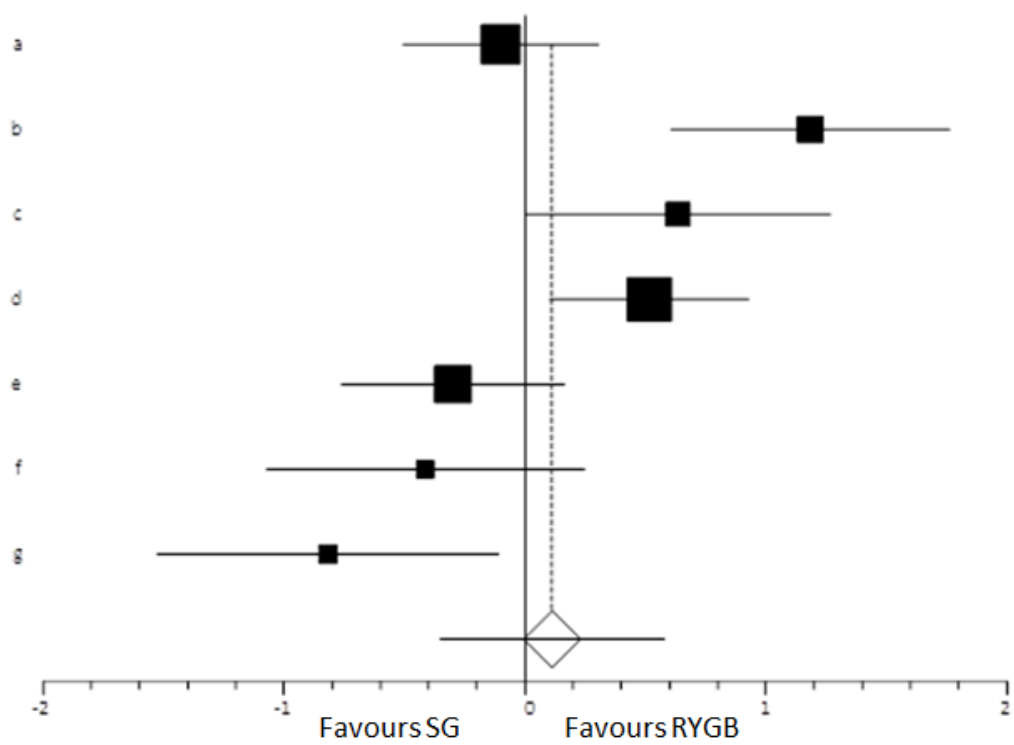


Figure 2: Meta-analysis of studies comparing %EWL between B-RYGB and B-SG at 6, 12 and 24 months.

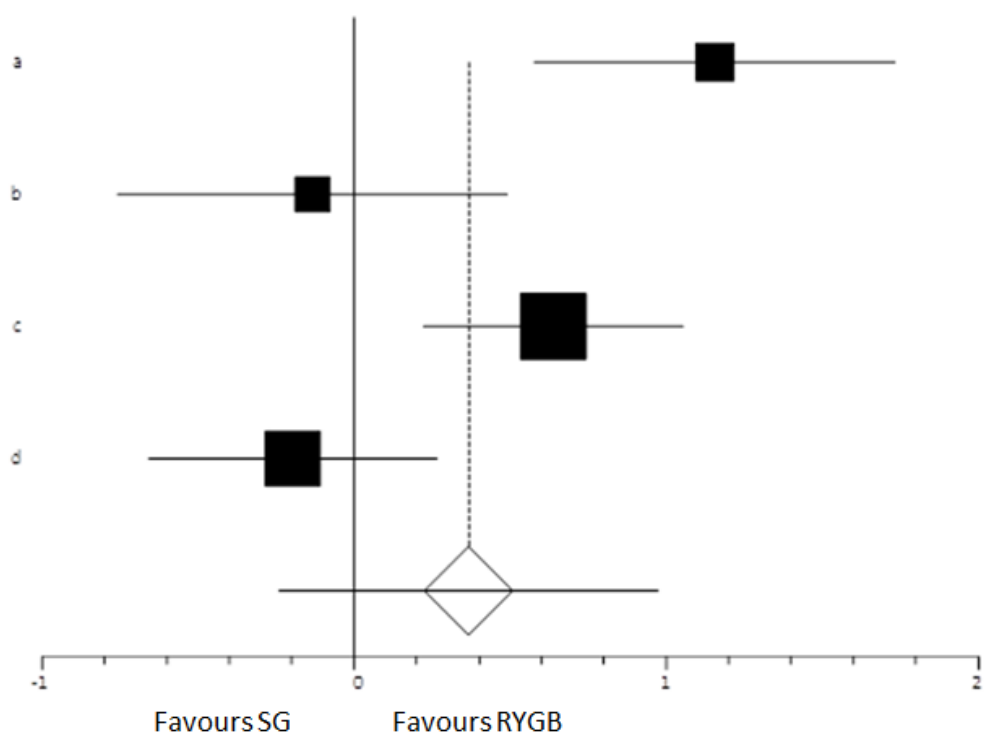
a) 6 months



b) 12 months



c) 24 months



Appendix 1: Electronic Search Strategy

A comprehensive literature search was run Medline, Embase, The Cochrane Library and NHS Evidence up to November 2015. The following search strategy was used:

‘Laparoscopic Adjustable Gastric Banding OR Laparoscopic Sleeve Gastrectomy OR Laparoscopic Roux-en-Y Gastric Bypass’, ‘Revision OR Revisional OR Reoperation OR Salvage OR Rescue OR Repeat’, ‘Weight loss OR Postoperative Complication OR Surgical Complication OR Morbidity OR Mortality OR Quality of Life OR Comorbidities’.