LRYGB: Outcomes

24

William R.J. Carr and Kamal K. Mahawar

Abstract

Roux-en-Y Gastric Bypass (RYGB) is the most commonly performed bariatric procedure worldwide. This chapter discusses the outcomes from RYGB for weight loss and co-morbidity resolution and compares them to those from other procedures. The early and late morbidity and mortality associated with RYGB is compared to other procedures and the argument is made as to why many believe RYGB to be the "gold standard" bariatric procedure.

Keywords

Roux-en-Y gastric bypass • Weight loss • Diabetes • Mortality • Morbidity • Marginal ulcers

24.1 Introduction

Roux-en-Y Gastric Bypass (RYGB) has become the gold standard bariatric operation performed worldwide, accounting for nearly half of all procedures (Table 24.1) [1]. This popularity is because RYGB has consistently achieved effective weight loss and comorbidity resolution with acceptable complications and mortality rates. The first report of the National Bariatric Surgery Registry (NBSR) demonstrated this popularity reporting that 3817 from a total of 7045 (54.7 %) procedures were RYGB [2]. The journey from Mason's open loop bypass to the many different techniques of laparoscopic RYGB in use today has been associated with gradual improvement in safety and efficacy of this procedure. This evolution is continuing as variations such as the "banded bypass" and "mini bypass" have become more widely performed.

Defining success after a bariatric operation is not straightforward. An ideal bariatric procedure must achieve durable weight loss and co-morbidity resolution with low rates of complications and mortality. Although excess weight loss is the widely used measure to compare outcomes between different procedures, it is not ideal. Success or failure after bariatric surgery requires consideration of a number of variables including weight loss, effect on co-morbidities and impact on quality of life and complication rates. The following discussion will demonstrate the benefits of RYGB and why many believe it to be the ideal bariatric procedure.

24.2 Adverse Outcomes

24.2.1 Early (<30 Day) Mortality and Morbidity

An early mortality rate of 0.2 % is widely accepted for Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) [3, 4]. Flum presented a comparison of adverse outcomes comparing Laparoscopic adjustable gastric banding (LAGB) to LRYGB and open RYGB [4]. Death rates of 0.2 % were noted for LRYGB compared to 0 % with LAGB and 2.1 % with open RYGB. Thromboembolic events were noted in 0.4 % for LRYGB, 0.3 % for LAGB and 1.1 % for open RYGB. Likewise reoperation was required within 30 days for 3.2 % LRYGB, 0.8 % for LAGB and 3.4 % for open RYGB. This was also reflected in the failure to be discharged by 30 days postoperatively which was 0.4 % for LRGB, 0 %

W.R.J. Carr, FRCS • K.K. Mahawar, MS, MSc, FRCSEd (✉)
Department of Surgery, Sunderland Royal Hospital, Sunderland, UK
e-mail: kamal_mahawar@hotmail.com

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Table 24.1 Percentage distribution of metabolic bariatric procedures worldwide

Procedure	Number	Percentage
Roux-en-Y gastric bypass	158,729	46.6
Sleeve gastrectomy	94,689	27.8
Adjustable gastric band	60,677	17.8
Biliopancreatic diversion/ duodenal switch	7,595	2.2
Mini gastric bypass	5,250	1.5
Vertical banded gastroplasty	2,297	0.7
Electric pacers	34	0.01
Others and revisions	11,497	3.4
Total procedures	340,768	

Buchwald and Oien [1]

for LAGB and 0.9 % for open RYGB. Whilst LAGB may appear to have a better safety profile this is offset by less weight loss, co-morbidity resolution and band related complications and failure. High volume centers have shown that complication rates from RYGB can be reduced further through standardized operative approaches and prompt management of complications. In a series of 2606 RYGB, Dillemans reported 5.8 % early complication rate, including gastrointestinal hemorrhage in 3.4 % patients, intestinal obstruction in 0.35 %, and anastomotic leak in 0.19 % [5]. There was one death from pneumonia. High body mass index (BMI) and age, male sex, hypertension, and factors predisposing to DVT/PE are recognized as risk factors for adverse events [6].

Postoperative hemorrhage is a common early complication with varying incidence in the literature. Staple lines, surgical anastomoses, retrogastric/short gastric vessels and port sites are all possible sources. Anastomotic leak has been reported to occur between 0.1 and 5.3 % and is dependent on surgical expertise and on the technique chosen for the anastomosis [7].

24.2.2 Late (>30 Day) Mortality and Morbidity

RYGB is associated with a number of late complications, which, if not managed appropriately, can result in significant morbidity and even mortality. With increasing follow up data now available readmission rates of 0.6–6.6 % have been reported [8]. Three main areas of concern persist resulting in the need for further intervention and occasionally emergency surgery, namely marginal ulceration, stomal stenosis and internal herniation. Gallstones and nutritional deficiencies are also longer-term issues that require consideration. Further details on the management of these complications are covered elsewhere in this book.

24.3 Therapeutic Outcomes

24.3.1 Weight Loss

The most compelling data supporting RYGB came from Buchwald's meta-analysis published in 2004 in which RYGB was the most commonly performed procedure and resulted in 62 % excess weight loss and a 30-day mortality rate of 0.5 % [3]. This compared favorably to other procedures, providing marginally less weight loss than the duodenal switch but at less than half the mortality rate (1.1 %). Alternative procedures suffer with adverse safety record (example, duodenal switch, biliopancreatic diversion), lack of long-term data (example, gastric band, sleeve gastrectomy and mini-bypass), poorer weight loss and co-morbidity resolution (example, gastric band, sleeve gastrectomy) or "controversy" amongst surgeons regarding bile reflux and potential risk of malignancy (mini-bypass).

24.3.1.1 Comparison with Other Procedures

It is worth noting that although many authors have reported sustained weight loss with LAGB, long-term complication rates with LAGB are high, requiring conversion to RYGB [9, 10]. The longest running randomized controlled trial comparing RYGB and LAGB presented 10 year follow up data recently showing superior excess weight loss with RYGB compared to LAGB (76.2 % vs. 46.2 %) [11].

Since 2004 laparoscopic sleeve gastrectomy (LSG) has become increasingly popular and the subject of several recent trials which have reached conflicting results [12, 13]. The largest comparison of these procedures showed that weight loss at 1, 2 and 3 years were not significantly different although a trend towards superior weight loss with RYGB was suggested (Fig. 24.1) [14]. Quality adjusted life year (QALY) scores between the procedures were not significantly different nor was the rate of nutritional deficiencies. Troublesome de novo reflux symptoms often occur following sleeve gastrectomy necessitating conversion to RYGB and many authors regard pre-existing reflux disease to be a contra-indication to sleeve gastrectomy or an indication for RYGB [14–16]. Long-term data from randomized trials comparing RYGB and laparoscopic sleeve gastrectomy (LSG) is not available.

Mini gastric bypass (MGB) is an increasingly popular procedure involving a single anastomosis loop jejunostomy instead of the Roux-en-Y reconstruction. The only randomized clinical trial comparing MGB and RYGB showed slightly superior weight loss results with MGB but no difference in comorbidity resolution [17]. However, experience with MGB is limited and more long-term experience is needed before it can challenge the current status of RYGB. A recent systematic review of MGB showed it to be

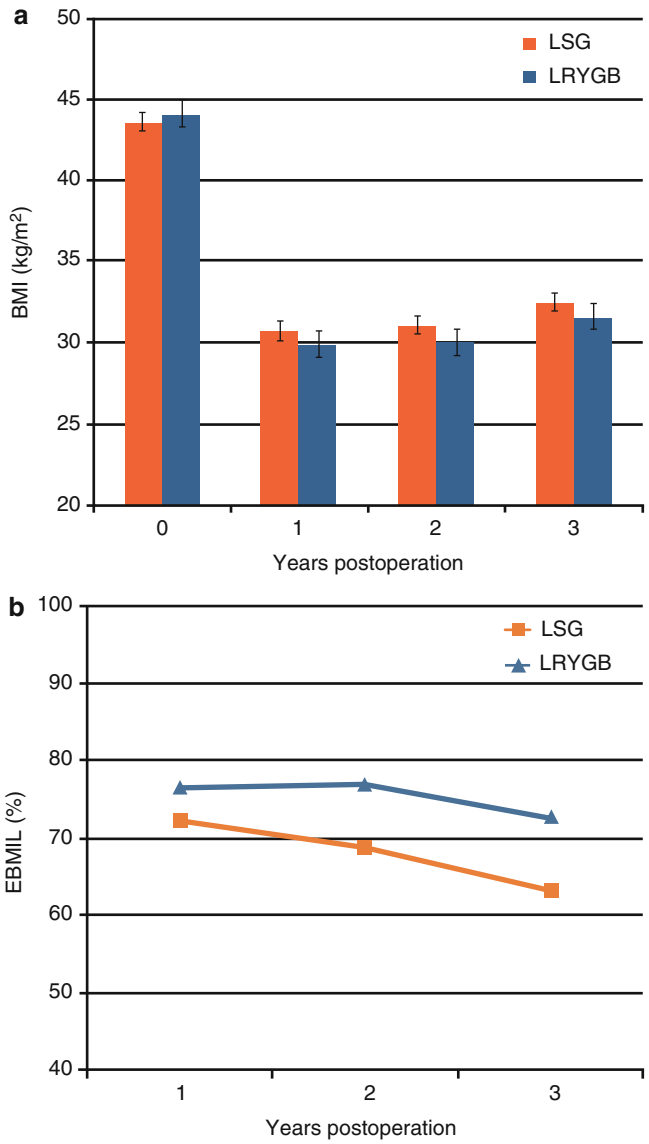

Fig. 24.1 Results of RCT comparing LRYGB and LSG. (**a**) Change in BMI. (**b**) Excess BMI loss [14]

an equally safe alternative with comparable short term results [18].

The first report of NBSR suggests that for patients with co-morbidities, RYGB is the procedure of choice within the UK [2]. Although the registry is unable to determine why the authors hypothesize that this is reflection of the belief that RYGB will produce quicker and more effective improvements in co-morbidities.

24.3.1.2 Weight Loss Outcomes with RYGB

RYGB results in significant early weight loss, which is maintained in the longer term. Most patients can expect to lose more than 50 % of their excess weight and an average excess weight loss of more than 70 % can be expected in the first 12 months after surgery. The Swedish Obese Subjects (SOS) Study [19]. provides the longest matched prospective follow up data comparing surgical intervention against non surgical management and shows open RYGB to be superior to vertical banded gastroplasty surgery (VBG) and LAGB throughout the study period in terms of weight loss (Fig. 24.2). Weight loss with RYGB was maximal at 2 years at 32 % before decreasing slightly to 25 % at 10 years and maintaining this up to 20 years post op [19]. This modest weight regain is not unique to RYGB.

These results have been replicated in the UK. The first report of the NBSR reported excess weight loss of 67.8 % for RYGB compared to 43.2 % for gastric banding and 54 % for sleeve gastrectomy.

The addition of banding the bypass has been shown to improve early weight loss compared to the traditional bypass. However longer-term studies looking at the safety and effectiveness on banding the bypass are awaited and there appears to be a risk of band related complications [20, 21]. Trials comparing different lengths of gastric bypass have not shown significant differences in weight loss outcomes [22].

Despite excellent weight loss figures reported in Buchwald's meta-analysis, there are still a percentage of patients who fail to lose 50 % excess weight loss or reach a BMI of less than 35 kg/m^2. This figure for failed bypass is between 5 and 40 % [23–25]. For the super obese acceptable weight loss may be achieved with a final BMI remaining in excess of 35 kg/m^2.

24.3.2 Effect on Comorbidity

Improvements in obesity-related co-morbidities tend to be in proportion to weight loss. For example in Buchwald's review resolution of hypertension was 43.2 % after LAGB, 69.0 % after VBG, 67.5 % after RYGB and 83.4 % after BPD and DS. The postoperative decrease in hyperlipidemia and sleep apnea syndrome follows a similar trend.

Furthermore a recently published systematic review comparing LSG and RYGB has shown that RYGB is significantly better at resolving type 2 diabetes, hypertension, hypercholesterolemia, and arthritis [26]. The NBSR 1st report provides an insight into the resolution of co-morbidities over a 12 month period following RYGB. In summary, sleep apnea rates fell by 63 %, dyslipidemia rates by 61 %, the proportion of patients able to climb three flights of stairs increased from 26.9 to 70.4 % whilst type 2 diabetes and gastro esophageal reflux disease (GERD) fell by 56 %.

24.3.2.1 Sleep Apnea/ Respiratory Problems

Sleep apnea remains a recognized risk factor for complications following bariatric surgery. A recent randomized trial

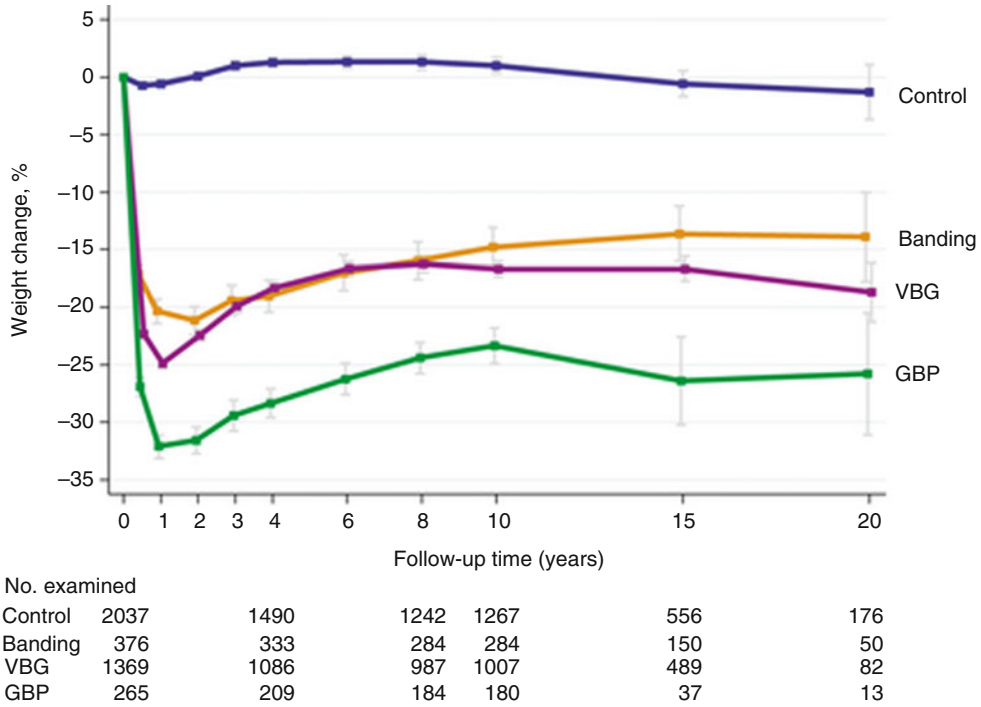

Fig. 24.2 Long term weight loss from the Swedish Obesity Study [19]

has demonstrated the effect RYGB has on obstructive sleep apnea [27]. Compared against intensive lifestyle intervention, RYGB patients had a 66 % remission rate while the control group had 40 % remission rate. On further analysis, these benefits were directly attributable to weight loss alone. A further systematic review has, however, suggested that despite significant improvements in the apnea hypopnea index induced with surgery, there will still be a need for many patients to continue treatment to minimize its long term complications [28].

24.3.2.2 Type 2 Diabetes Mellitus

Within Buchwald's meta-analysis, diabetes remission occurred in 80 % of RYGB patients compared to 57 % after banding, but was less than for duodenal switch (DS) (95 %). (LSG was not included in the analysis) [3]. Given that the meta-analysis clearly shows that the benefits of RYGB in terms of weight loss and diabetes remission are greater than all other procedures except DS it is worth considering why DS is not so widely accepted

In 2012, Mingrove presented the results of a randomized controlled trial (RCT) comparing the effects of bariatric surgery on 60 diabetic patients [29]. At 2 years, diabetes remission had occurred in no patient in the medical group, 75 % in the RYGB group and 95 % in bilio-pancreatic diversion group. A similar effect was seen for improvements in lipid profile and hypertension with BPD showing better results than RYGB. Weight loss from the two groups was however not significantly different. Even in this small group of patients the intestinal malabsorption after bilio-pancreatic was noted in 10 % of patients compared to none in the RYGB group. These findings were confirmed in another RCT comparing bypass against DS in which 60 patients with a BMI >50 were randomized to RYGB or DS. Whilst QALY and cardiovascular risk improved equally with both procedures the rate of adverse events was nearly double for DS (62 %). Adverse nutritional events only occurred after duodenal switch.

Diabetes is perhaps the most important comorbidity associated with obesity and Buchwald's meta-analysis showed RYGB to be the most effective procedure after DS. However given that early weight loss is comparable between RYGB and LSG, it is important to note that RYGB is more effective in inducing diabetes remission than LSG and other purely restrictive procedures, an effect thought to be related to duodenal exclusion. Lee et al. conducted a randomized controlled trial comparing diabetes resolution in diabetic patients with BMI of 25–35 kg/m^2, showing that RYGB was associated with significantly better diabetes remission at 12 months after the surgery when compared to LSG (93 % vs. 43 %) [30]. This effect was also noted in obese patients with BMI >35 kg/m^2 [31]. More recently, the Stampede Trial reported 3 year results comparing RYGB to LSG and medical treatment for poorly controlled type 2 diabetes [32]. They found that an HBA_{1c} level of less than 6.0 % was achieved in 5 % of medical patients, compared with 37 % of RYGB and 24.5 % LSG, with less use of glucose lowering medication in the surgical patients.

RYGB appears therefore to have an additional effect on diabetes remission that is superior to restrictive procedures alone and given this success, it has now been incorporated into management guidelines for patients with class 1 obesity

if their type 2 diabetes mellitus is proving difficult to manage.

24.3.2.3 Cardiovascular Risk Factors

The Diabetes Surgery Randomized Control Trial demonstrated the added effects of RYGB over lifestyle and medical management in patients with a BMI 30–39.9. With surgery, 49 % of patients achieved the composite endpoint of HBA_{1c} less than 7 %, low density lipoprotein cholesterol less than 100 mg/dL and systolic blood pressure less than 130 mmHg compared to 19 % in the control arm [33] This was achieved with three fewer medications.

The 6-year follow up data of Adams comparison of outcomes from RYGB and non surgical management paper showed sustained improvements following RYGB in major cardiovascular and metabolic risk factors including diabetes remission, reduced incidence of dyslipidemia and hypertension while there was worsening of these parameters in the control (nonsurgical) group [34]. This study showed a diabetes remission rate of 62 % at 6 years showing the effects noted by many at 2 years persist. Sustained increases in HDL-C (and hence reduction of cardiovascular risk) were also noted. In a previous publication, Adams had already noted that RYGB leads to a 40 % reduction in all cause mortality compared with non-surgical management, a result replicated elsewhere [34–37]. Improvements in cardiovascular risk profile and type 2 diabetes, and increased physical mobility are likely to account for most of the beneficial effects seen.

24.3.2.4 Polycystic Ovarian Syndrome

Polycystic ovarian syndrome (PCOS) is relatively common (5.5 %) in obese females. Nevertheless, RYGB has been shown to achieve excellent amelioration of PCOS manifestations and improvement in fertility rates in up to 100 % of patients desiring pregnancy after surgery [38].

24.3.2.5 Non-alcoholic Fatty Liver Disease (NAFLD)

Chronic liver disease caused by obesity is becoming increasingly common. For NAFLD patients, RYGB has been shown to reduce the grade of steatosis, hepatic inflammation, and fibrosis in majority of patients [39]. With up to 74 % of obese patients suffering with NAFLD, this is an important disease process in which the exact role of bariatric surgery is not fully elucidated. NAFLD alone is not currently an indication for RYGB.

24.3.3 RYGB and Reduced Mortality

Despite significant improvements in obesity associated comorbidities that have shown to persist over longer-term follow-up, this has not been shown to reduce mortality rates until over 10 years postoperatively. In Swedish Obese Subjects trial the mortality benefits of weight loss surgery with different procedures did not become apparent till 13 years after the surgery [19]. This was also noted in the high risk patient study in the Veterans Affairs study [40]. Conclusive data showing long-term mortality benefits between procedures are not available and is unlikely to be significant until many years after the surgery. At the same time, it is worth noting that mortality due to accidents and addictions may increase. There is also long-term mortality related to RYGB specific surgical complications such as internal hernia, marginal ulcer and gastro-gastric fistula.

24.3.4 Quality of Life

The Swedish Obese Subjects trial provides long term evidence of improvements in Health Related Quality of Life (HRQoL) [19]. At baseline, the patients in the surgery group had generally worse HRQoL than those in the non-surgical treatment group. At 2 years follow up, surgical patients had significant improvements in all HRQoL measures compared to patients receiving non-surgical treatment. These changes were significantly related to the magnitude of the weight lost which was greatest with RYGB. The improvements peaked one year after surgery followed by a gradual decline till the sixth year after surgery, remaining stable till 10 years after surgery. All HRQoL measures were improved at 10 years compared with baseline for the surgery group, but in the non-surgical group some had improved while others had worsened. Other studies have shown that over longer term follow up, general health perceptions and vitality are the most likely to be improved after RYGB [41].

24.3.5 Effect on Cancer Risk

Whilst cardiovascular risk reduction is an important outcome from bariatric surgery, SOS study noted that that more patients died from cancer than myocardial infarction (76 versus 38) during the study period [42]. This trial also demonstrated that weight loss reduced the risk of cancer, particularly female cancers (Fig. 24.3). This risk reduction is not exclusive to RYGB although this procedure resulted in the most sustained weight loss.

24.4 Cost-Effectiveness

Cost-effectiveness of any intervention is a significant factor in any healthcare system and few operations can truly be regarded as cost saving. There are significant upfront costs with RYGB but it is widely acknowledged that this cost is recovered after surgery through reduced expenditure on

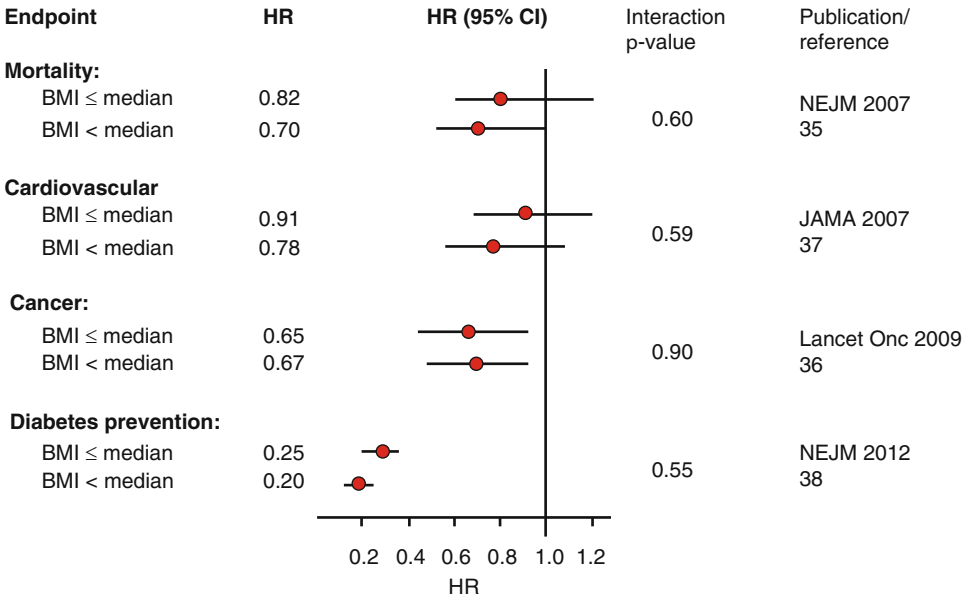

Fig. 24.3 Surgical treatment effects (Hazard ratio) on indicated endpoints in subgroups below and above the median BMI at baseline as well as BMI–treatment (surgery vs. control) interactions (interaction P-value) for each endpoint. The treatment effect was not significantly related to BMI (interaction P-value nonsignificant) for any of the analyzed endpoints [19]

healthcare and gains in economic productivity of individuals. The time taken to achieve this is perhaps longer than initially predicted [43, 44] With gradual improvements in availability and safety profile of surgery, cost effectiveness is likely to further improve. Cost benefits are also probably highest in those with most severe forms of obesity and this has led many funding bodies to prioritize bariatric surgery for these individuals.

24.5 Revision and Reversal

Not all patients will achieve satisfactory weight loss with any bariatric procedure and some may gain weight in the long term. Moreover, some patients need complete reversal of their procedure for one reason or the other. RYGB is no exception in this regard. Revision of RYGB to add a longer bypass limb to promote weight loss has been described and associated with increased risk of nutritional deficiencies [45] Surgeons have also tried to add an adjustable band to a failed RYGB with variable success [46]. How to manage poor weight loss following RYGB remains a controversial issue which lacks a commonly accepted solution; which is perhaps testament to the accepted reliability of good outcomes following RYGB as first line treatment.

24.6 Summary

RYGB has been the subject of multiple studies from which long-term outcome data is now becoming available. With the exception of malabsorptive procedures, which are less commonly performed due to high rates of nutritional deficiencies, RYGB provides superior weight loss to gastric banding and similar weight loss to LSG. However RYGB is the preferred procedure for patients with GERD and diabetes as both of these improve the most with RYGB. Modifications to RYGB by banding the bypass may further improve weight loss at the expense of band related complications, whilst the mini bypass may eliminate internal herniation and shorten operative time but at the expense of bile reflux with uncertain long-term implications. Long-term studies of LRYGB have identified that marginal ulceration and internal herniation affect a small minority of patients in the long term although these remain the Achilles heel of RYGB. Nevertheless, the low complication rate, excellent weight loss and co-morbidity resolution mean RYGB remains the gold standard bariatric procedure for most patients. For the super morbidly obese undergoing RYGB 60 % excess weight loss may still leave the patient with a BMI of over 35. Long-term trial data comparing RYGB with a staged LSG+/–DS in these patients has not been performed.

Key Learning Points

- RYGB remains the most commonly performed bariatric procedure worldwide.
- RYGB is the procedure of choice for patients with pre-existing reflux disease.
- Weight loss, comorbidity resolution and improvements in mortality have now been published in long term follow up studies after RYGB.
- Modifications of RYGB with banding or the mini bypass are becoming increasingly popular.
- Revision of the RYGB for poor weight loss remains a challenging area with no consensus regarding the optimal approach.

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