Chapter 20 SURGICAL TREATMENT OF OBESITY

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ABSTRACT

Obesity is one of the most prevalent pathogens in the developed world, causing numerous common and lethal diseases. Non-surgical treatments to date have failed to provide an effective, durable solution. Bariatric surgery includes the procedures of gastric bypass, sleeve gastrectomy, gastric banding and biliopancreatic bypass. These procedures have been shown to produce substantial and durable weight loss yet are provided annually to less than 0.2% of eligible obese people, making current bariatric surgery largely irrelevant to public health.

The principal mechanisms of effect vary between procedures and include control of hunger, change of appetite, restriction of intake, diversion of food from the proximal small intestine, malabsorption of macronutrients, increased energy expenditure, food aversion and possibly changes to the gut microflora and changes to serum bile acid levels.

Weight loss outcomes are typically 50-60% of excess weight loss (EWL) at 10 years for gastric bypass, 45-55% EWL for gastric banding, 70% EWL for biliopancreatic bypass. There are no long-term weight loss data for sleeve. In association with the weight loss there are significant and sustained improvements in the length of life, the quality of life and in many of the comorbidities of obesity. In particular, all procedures have been shown by randomised controlled trials (RCT) to induce remission of diabetes better than non-surgical therapies in the short-term. Medium and long term data from RCTs are not yet available.

The mortality risk reflects the type of surgery and varies between 0.1% for gastric banding to 1-2% for other procedures.

The criteria for consideration of bariatric surgery include the presence of obesity (BMI > 30), a history of multiple attempts at weight reduction by non-surgical means, an awareness of the potential risks and a commitment to attend the follow up program. The decision on which procedure should be used is based on patient or surgeon preference, availability of appropriate aftercare and the patient's tolerance of risk and permanent anatomical change. For complete coverage of this and related areas of endocrinology, plese see our on-line free web-book, www.endotext.org.

BACKGROUND

Obesity is one of the most significant pathogens in the developed world. It causes or exacerbates numerous common and lethal diseases. It can markedly reduce the quality of life and it competes with smoking as the commonest cause of premature death. The prevalence of obesity has increased markedly in the last thirty years. A systematic review of 199 countries in 2008 estimated 502 million people worldwide were obese[1]. According to the World Health Organization, obesity has more than doubled worldwide since 1980 and more than 600 million or 13% of the adult population were obese in 2014.

The epidemic is quite recent. In the United States, between 1960 and 1980, there was a relatively modest rise in the number of adults with obesity, from 12% to 14% only. This number has more than doubled since 1980[2]. Currently, approximately 80 million people in the USA, 34% of the adult population, are obese[3] and this number is estimated to increase to more than 140 million by 2030[4]. The direct health care costs were estimated to be $75 billion per year in 2003. These would rise to $140 billion per year and it would be an associated loss of productivity (indirect costs) of $580 billion[4] Based on the Health and Wellness Survey in 2008 there is estimated to be loss of 1.7 - 3.0 million productive person-years in the USA, representing a cost of $390 - $580 billion due to the current state of obesity[4] .

The morbidity caused by obesity makes it our greatest current health challenge because of its direct contribution to many chronic, debilitating and life-threatening diseases. These include type 2 diabetes, cardiovascular diseases such as ischemic heart disease, stroke, hypertension and dyslipidemia and several common cancers. The health care costs of obesity are now a major component of health budgets across the developed world. Currently there is no non-surgical method for predictably achieving major weight loss in the obese and maintaining that weight loss for an extended period. Current programs involving diet, behavioral modification, exercise and activity, with or without drug supplementation, are able to achieve a modest weight loss which is generally sustained only for the duration of the program.

In this chapter I will review the surgical options, their strengths and weaknesses, to provide a framework of evidence that enables a logical treatment approach to this major healthcare challenge. In doing so, I will seek an alignment of the views of health professionals and the general community so that they recognize obesity as a disease and not a sign of personal failing, they acknowledge the severity of this disease and they recognize the spread of invasiveness and risk and effectiveness associated with options for surgical treatments.

Surgical methods have been known to achieve substantial and durable weight loss for more than half a century and yet they have not achieved a significant impact on community health. Currently, less 1 in a 1000 world-wide and less than 1 in 250 in the USA and Australia of those who would benefit by treatment are having bariatric surgery. In terms of the public health, bariatric surgery is used so infrequently as to be largely irrelevant. In its early days the risks were high, undoubtedly discouraging many. But these risks have been reduced markedly[5]. The risk to benefit ratio has now become much more favorable and the cost to benefit ratio is also favorable. It is time for a change and the data are there to justify a change.

AN HISTORICAL PERSPECTIVE OF BARIATRIC SURGERY

Although the weight loss that accompanied surgery, particularly if it involved the stomach or small intestine, had been noted for as long as the procedures have existed, a direct use of surgery for the specific purpose of weight loss - bariatric surgery - really began in 1954 with the small bowel bypass procedure. It can be seen to pass through three phases so far. The small bowel bypass phase was replaced by the gastric stapling phase in the late 1960s and then, in the early 1990s, the introduction of laparoscopic surgery and gastric banding led to the third phase.

The Initial Phase (1950 – 1970) – Small Bowel Bypass.

Surgical management of obesity began with the introduction of the jejunoileal bypass (JIB) in the 1954[6]. In this procedure the proximal jejunum was diverted to distal part of the gut, leaving a long segment of excluded small intestine and a marked reduction in absorptive capacity. Many variations existed. In a typical procedure, the proximal 35 cm of proximal jejunum was joined end-to-side to the last 10 cm of ileum. The JIB procedures represented the best and the worst of bariatric surgery. Major and sustained weight loss was achieved and there were impressive health benefits, particularly in relation to lipid metabolism. However it was associated with serious side-effects including copious offensive diarrhea, electrolyte imbalances, oxalate calculi in the kidneys and progressive hepatic fibrosis with eventual liver failure[7-11]. For these reasons this group of procedures was generally abandoned by the 1970s in favor of stomach stapling procedures

The Middle Phase (1970 – 1990) – Stomach Stapling.

The Roux-en-Y gastric bypass (RYGB) operation was introduced by Edward Mason in 1960[12]. In this procedure the stomach was completely partitioned into a small upper gastric pouch, draining into a Roux–en-Y limb of proximal jejunum of variable length from 40 to 150 cm, and a distal excluded stomach. This procedure provided a hybrid between the malabsorptive approach of JIB and later, more purely restrictive, operations. It has undergone various modifications over the subsequent 40 years and still serves us well as an effective anti-obesity operation. However its drawbacks of perioperative death and significant perioperative and late morbidity, although markedly less threatening than those of JIB, have been nevertheless sufficient to cause most of the obese to stay away.

Dr Mason and his colleague, Dr Printen, then introduced a purely restrictive operation of gastroplasty in 1973[13]. The procedure involves partitioning the stomach into a small upper pouch draining through a narrow stoma into the remainder of the stomach. Numerous variations of this procedure have followed, the most significant variant being the vertical banded gastroplasty (VBG) which was first described by Dr Mason in 1982[14] . It was hoped that this group of operations would provide greater short and long term safety and yet retain the power of gastric bypass. Unfortunately both randomized controlled trials and observational studies have consistently shown that it has failed in both aspirations[15-18].

In the meantime there was a resurgence of malabsorptive surgery with Italian surgeon, Nicola Scopinaro, introducing the biliopancreatic diversion procedure (BPD) in 1976[19]. It too has undergone change with time and experience. The basic procedure involves distal gastrectomy leaving a proximal gastric pouch of 200 – 500 ml, a 200 cm length of terminal ileum anastomosed to the gastric pouch and the biliopancreatic limb entering at 50 cm from the ileocecal valve[20]**.** The most notable remodeling of the procedure has been the so-called duodenal switch variant (BPD-DS) proposed by Picard Marceau's group in 1993[21, 22] in which a longitudinal gastrectomy (sleeve gastrectomy) enabled retention of the gastric antrum for controlled gastric emptying, and the ileal limb was anastomosed to the proximal duodenum. The benefit of this variation remains controversial.

The Current Phase (1990 - Present) – Laparoscopic Procedures.

This phase is characterized by the advent of the laparoscopic approach to bariatric surgery particularly gastric bypass[23] and biliopancreatic diversion[24], introduction of the laparoscopic adjustable gastric band (LAGB) with the particular features of minimal anatomical disturbance, adjustability and potential reversibility[25, 26] and growth of the sleeve gastrectomy as a stand-alone procedure[27]. The reduced invasiveness and increased safety of these approaches has led to a major rise in the use of bariatric surgery for obesity across the world. In the United States the estimated total bariatric procedures in 1990 was 30,000. The total for 2008 was estimated to be 220,000 cases[28]

Adjustable gastric banding had first been proposed by two Austrian surgical researchers, Szinicz and Schnapka, in 1982[29]. The idea was brought into clinical practice as an open operation by Lubomyr Kusmak in 1986[30]. It did not attract major interest until the advent of the technology that enabled the performance of complex laparoscopic surgical procedures became widespread in the early 1990s. The BioEnterics® Lap-Band ® system (LAGB) was specifically designed for laparoscopic placement and was introduced into clinical practice by Mitiku Belachew from Huy, Belgium in September 1993. Because of the dual attractions of a controlled level of effect through adjustability and of laparoscopic placement without resection of gut or anastomoses, through the 1990s this procedure rapidly became the dominant bariatric procedure in all regions of the developed world except the USA, where its introduction was delayed until regulatory requirements were completed in June 2001. More recently, the challenges of maintaining good aftercare for the banded patient and the relative simplicity of the sleeve gastrectomy has seen this latter procedure take a dominant position.

In the meantime, laparoscopic approach to the RYGB was introduced by Wittgrove and Clark in 1994[31]. The technical challenge of completing the gastrojejunostomy laparoscopically has been variously managed by transoral passage of a circular stapler, end-to-end or side-to-side stapling transabdominally or a simple hand-sewn anastomosis. As the technical challenges of the laparoscopic approach were overcome, this procedure became the dominant approach in the USA until it was overtaken by gastric banding around 2008 and then by sleeve gastrectomy which, in 2015, is the most used procedure world-wide.

Laparoscopic BPD or its DS variant has remained clinically challenging. The mortality can be high[24] and few are now performed[28]. Most procedures are still performed by open technique and as they represents less than 2% of bariatric surgery worldwide, it is unlikely they will grow beyond that.

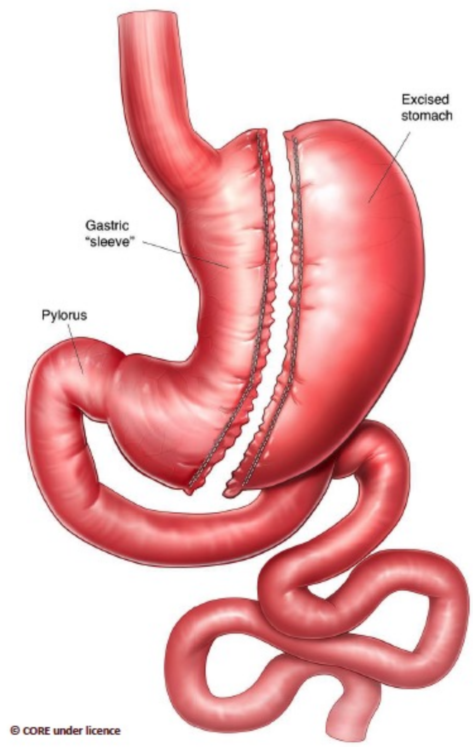
CURRENT METHODS IN BARIATRIC SURGERY

Sleeve Gastrectomy

The sleeve gastrectomy involves excision of approximately 80% of the stomach by using multiple firings of a linear stapler/cutter to separate a narrow tube or sleeve of the lesser curve of the stomach from the greater curve aspect. The antrum is preserved to maintain gastric emptying. A bougie is placed in the lesser curve segment during the resection to maintain adequate lumen yet achieve a standardised gastric remnant. The optimal size of this bougie is not yet agreed upon. A 36 French is the most common size but sizes from 30F to 50F are reported. The procedure is non-adjustable and non-reversible.

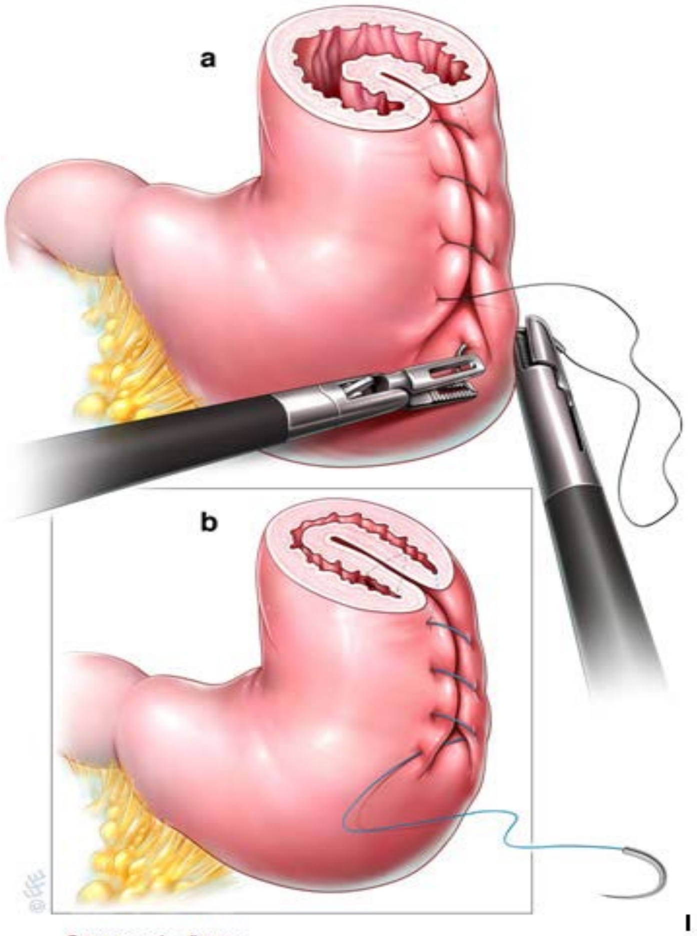
The procedure is a laparoscopic procedure, taking between 30 and 90 minutes. Some patients are treated on an outpatient basis but a one to two day stay is more common.

Figure 1. *Sleeve gastrectomy*



Gastric imbrication is a non-resectional variant of the sleeve gastrectomy. The greater curve vascular pedicles are ligated and then the gastric wall is imbricated using two rows of sutures to create a narrow lumen, similar in size to the sleeve gastrectomy. The costs are reduced by avoiding the use of multiple firings of stapling devices and the risks are expected to be lower by the absence of the stapled closure of divided stomach.

Figure 2. *Gastric imbrication. The upper panel shows the placement of the initial continuous suture after division of the greater curve vascular pedicles. The lower panel shows completion of the second row of sutures.*



Laparoscopic Adjustable Gastric Banding (LAGB).
The LAGB is the safest of the surgical options and therefore has tended to be considered ahead of other bariatric procedures on the hierarchy of risk because of its effectiveness in the setting of a better safety profile, minimal invasiveness and complete and easy reversibility. Its requirement for skilled follow up and adjustments has proved challenging for many.

The procedure was introduced into clinical practice by Dr Mitiku Belachew with the laparoscopic placement of a Lap-Band in a patient in Huy, Belgium on the 3rd September, 1993. Others quickly followed and soon it was being embraced as an important new procedure. However initially there were significant gaps in the knowledge of the process of care the LAGB required and skills in LAGB placement, optimal aftercare and management of late adverse events. It was not known how the band worked or even if it would work. There were no data on optimal placement and fixation. Protocols for the aftercare process, the adjustment protocols and the education of the patient into the specific requirements for eating and activity after the band were not present.

There has been important growth in knowledge since that time with more than 1,000 peer-reviewed papers defining the LAGB process and outcomes. It is now more studied than any bariatric procedure with better knowledge of its mechanisms and a higher quality evidence base than all the other bariatric options.

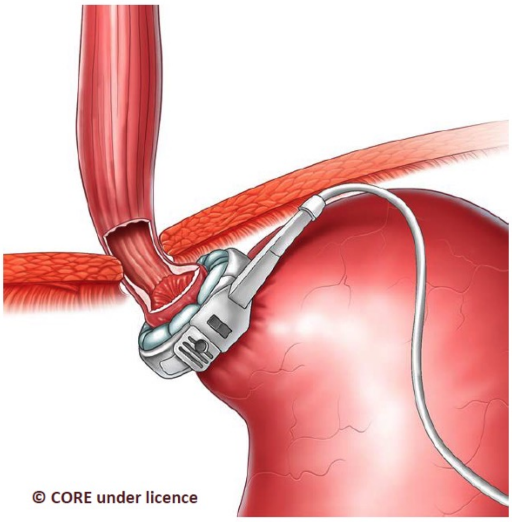
There are a number of adjustable gastric bands available. The principal two, which have approval of the US Food and Drugs Administration for use in the USA, are the Lap-Band ™ (Apollo Endosurgery, Austin, Tx) and the Realize Band™ (Ethicon Endosurgery, Cincinnati, OH). Others include the Mid-Band, the Heliogast band, the Minimizer band and the AMI band. These are in use principally in Europe. They lack adequate published data attesting to their effectiveness, they are not approved for use in the USA and so their uptake has been modest. The discussion below will focus primarily on the data from the Lap-Band.

The current version of the Lap-Band, known as the Lap-Band AP (for Advanced Platform), is shown in figure 3.

Figure 3. *The band consists of a ring of silicone with an inner balloon. The balloon is connected to an access port.*

The LAGB is placed laparoscopically. Commonly 3 x 5mm, 1 x 10mm and 1 x 15 mm ports are required. A path is developed from the top of the lesser curve of the stomach to the angle of His, the band is placed around this path, closed and then stabilized at this site with some sutures. The tubing passes to an access port, placed through a 3 cm incision over the left rectus abdominis muscle. The procedure takes 30 -50 minutes to complete and the patient is able to go home at a mean of 2 hours after completion of the procedure[32].

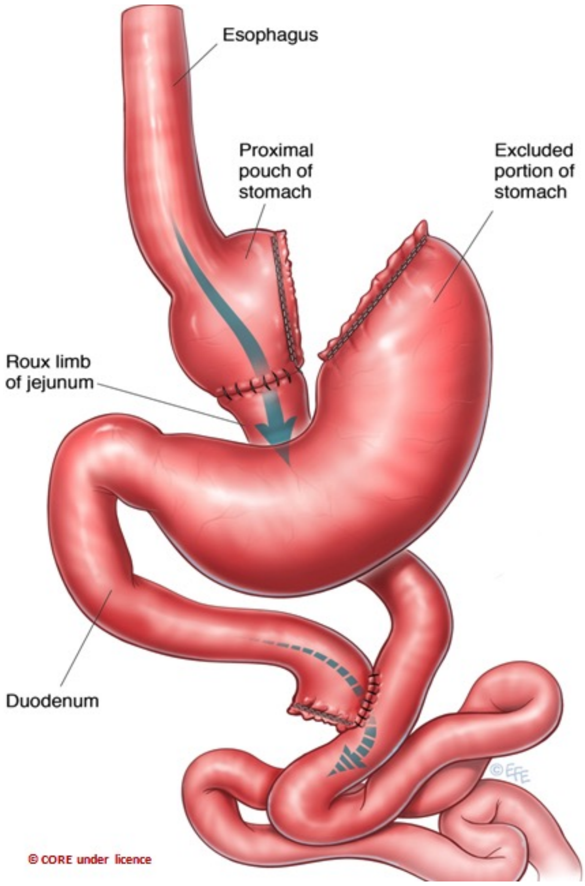
Figure 4*. The LAGB is placed over the cardia of the stomach within 1cm of the esophago-gastric junction.*



Roux en Y Gastric Bypass (RYGB)

Gastric bypass combines a marked reduction in the size of stomach available for food with a narrow stoma passing from the gastric pouch to a Roux-en-Y loop of jejunum diverting food from the duodenum and proximal jejunum. In a typical current laparoscopic version (figure 5), the stomach is divided completely by multiple firings of a device which places two rows of staples and cuts the gastric wall in between. This creates a small proximal gastric pouch of volume of 50ml or less and a large residual stomach, now excluded from the food. A Roux limb of jejunum is formed by dividing the proximal jejunum completely at about 50cm from the duodeno-jejunal flexure, taking the distal aspect of this point of division up to form a small anastomosis with the small gastric pouch and anastomosing the proximal aspect to the more distal jejunum at 50 cm below the gastro-jejunal anastomosis. The procedure takes 90 -150 minutes and the patient stays in hospital for 2 - 4 days.

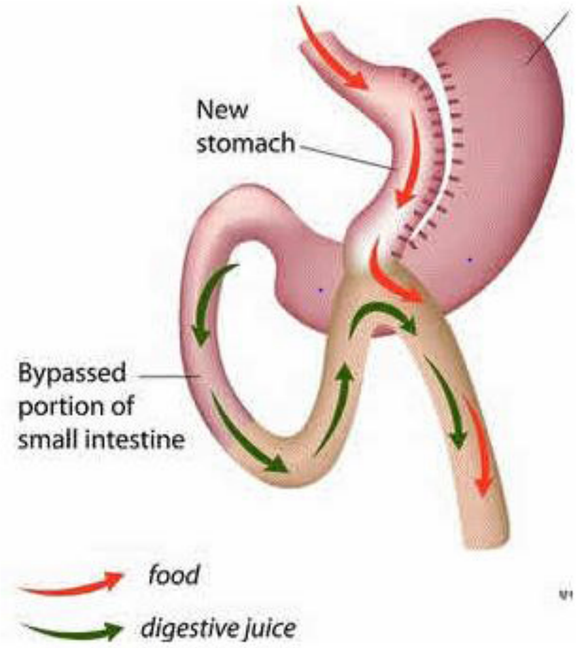
Figure 5. *RYGB showing a small gastric pouch, a narrow gastrojejunostomy and exclusion of foods from the duodenum and proximal jejunum.*



Single anastomosis Gastric Bypass (SAGB)

This form of gastric bypass is increasingly popular as an alternative to the RYGB. It is variously known as the SAGB, OAGB (one anastomosis gastric bypass), OLGB (Omega loop gastric bypass) or MGB (Mini gastric bypass). It differs from the RYGB by having a loop of small bowel rather than a Roux limb, a long and narrow lesser curve gastric pouch and a longer bypass of the duodenum and proximal jejunum (typically, 150 cm rather than 40 cm) (figure 6).

Figure 6. SAGB showing the gastric pouch as a sleeve of lesser curve of stomach and the loop gastrojejunostomy.



There are now extensive published data on outcomes which include large patient groups, long-term follow up and systematic literature reviews[33-36]. Early concerns regarding bile reflux leading to intractable gastritis and esophagitis have not proven to be valid.

In a prospective randomized controlled clinical trial performed on 80 patients with a two year follow up[37], the SAGB proved to be simpler and safer than RYGB, yet achieved similar outcomes for effects on the metabolic syndrome and quality of life and demonstrated no disadvantages over RYGB.

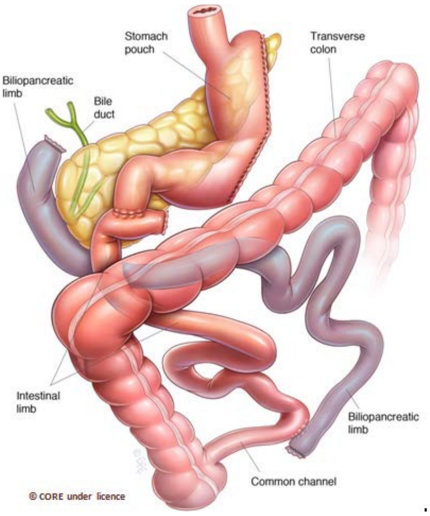
Biliopancreatic Diversion / Duodenal Switch (BPD/DS)

The BPD contains a "restrictive" component and a "malabsorptive" component. The restrictive component is a partial gastrectomy leaving a large proximal gastric segment of between 200 and 500ml. The actual size is only loosely defined. The originator of BPD, Dr Nicola Scopinaro, moved to the "ad hoc gastrectomy" with its wide variability of gastric pouch size after he had treated nearly 1000 patients. He recommended tailoring the gastrectomy to the patient's weight and some physical characteristics. He also recommended tailoring the intestinal lengths[38]. The validity and effect of these variations has not been reported.

The malabsorptive component consists of division of the small intestine, usually at 250cm proximal to the ileocecal valve, anastomosis of the distal side of this division to the gastric pouch and end-to-side anastomosis of the proximal side of the division to the terminal ileum, usually at 50cm proximal to the junction with the cecum.
In the duodenal switch variant of the BPD (figure 7) a sleeve gastrectomy is performed, preserving the pylorus and proximal duodenum. The distal end of the transected small bowel

is anastomosed to the duodenum. This structure is designed to avoid dumping syndrome but any particular benefit of one version over the other is unclear.

Figure 7. *The DS variant of BPD with a sleeve gastrectomy, retention of the gastric antrum, diversion of food into the mid small gut and diversion of pancreatic and biliary secretions to the distal small gut .Note both limbs are passing behind the transverse colon and a colour difference is added to help follow the respective pathways. The common channel is the normal ileum terminating at the ileo-caecal junction.*



It is the most metabolically severe of the current options and therefore hasn't proved to be popular with patients or surgeons in spite of favorable published outcomes. BPD has been available for 30 years[19] and yet remains a very minor part of bariatric surgery. Worldwide, it constitutes less than 2% of bariatric surgery[28]. However, it does generate good weight loss and should be considered on occasions as a second line bariatric surgical option.

MECHANISMS OF ACTION IN BARIATRIC SURGERY

Historically, bariatric surgical procedures were all subdivided into two groups. Some were classified as **restrictive,** with the creation of a small pouch that limited the size of a meal and a small opening from that pouch into the rest of the gut so that the transit of food was abnormally delayed. The best model of a restrictive procedure was the vertical banded gastroplasty used during the 1970s and 80s. Others were described as **malabsorptive**, in which the changed anatomy reduced normal macronutrient absorption. The best example of this was the original jejunoileal bypass. Some procedures are considered to be a hybrid containing both elements, the BPD being an example. Other possible mechanisms were not considered. This narrow dichotomous concept has happily faded as better research and more careful consideration has led to a much broader understanding of the mechanistic options[39]. Table 1 provides a list of current known mechanisms. It is undoubtedly incomplete but provides a more up-to-date view of how bariatric surgical procedures can achieve weight loss.

Table 1. *Possible mechanisms of bariatric surgical effect.*

Induce satiety, reduce appetite, control hunger
Change of taste preference - less sweet foods; lower fat content;
Restrict Intake
Diversion from upper GI tract
Malabsorption of macronutrients
Increased energy expenditure; Increased diet-induced thermogenesis
Aversion to food through side-effects
Inhibition of the metabolic adaptation to weight loss
Changes to the gut microflora
Changes to plasma bile acid levels
Changes in gut hormones: candidates include the incretins (GLP-1; GIP), ghrelin, CCK, Peptide YY,
Central mechanisms: Modify hedonics; central appetite control; altered liking and wanting;

Mechanisms in Sleeve Gastrectomy

Although primarily seen as a gastric **restrictive procedure,** it is likely that **satiety induction** is centrally important and occurs because of removal of most of the source for ghrelin. Further, with rapid gastric emptying the increase of nutrients into the small intestine may lead to change **in distal gut hormonal responses**. The sleeve gastrectomy is the first element of the duodenal switch variant of the BPD. It has lately become popular as a single procedure because of ease of surgery, early effectiveness and perceived lack of need for close follow up ("sleeve and leave").

Mechanisms of Gastric Bypass (RYGB and SAGB)

RYGB is a complex procedure both anatomically and physiologically. There are several mechanisms of action involved. First, there is **early satiation** after eating a small amount of food due to the small volume and slow emptying of the gastric pouch. The small stoma provides a **restrictive component** through delayed gastric emptying. The **diversion** of food away from the distal stomach, duodenum and proximal jejunum reduces the digestion and possibly the absorption of food by this area of the gut. However, as most of the small bowel remains in the absorptive pathway, it is unlikely the absorption of macronutrients is affected and so the standard RYGB should not be regarded as having a malabsorptive component. The long-limb version of RYGB where food is diverted from the digestive enzymes of the pancreas for 150cm or more[40] is more likely to contain a **malabsorptive component**. Micronutrients which are normally absorbed in the upper gut, such as calcium, are changed. Finally it can have an **aversion** effect with the symptoms of dumping syndrome occurring if there is ingestion of simple sugars or small osmotically-active molecules, leading to reduce sweet-eating. The diversion of food from the duodenum and proximal jejunum may mediate **gut hormonal effects** with increased release of GLP-1 and GIP from the distal gut. These hormones act as incretins, increasing release of insulin from pancreatic β cells.

Mechanisms in Laparoscopic adjustable gastric banding (LAGB)

The band lies at the very top of the stomach, around the cardia and within one cm of the esophago -gastric junction. The access port is place in the subcutaneous layer of the anterior abdominal wall and is accessed by a percutaneous injection. The primary mechanism of action of the gastric band is by the induction of a sense of satiety, a lack of appetite or hunger[41]. There are two components to this **- satiety and satiation**.

Satiety is the state of not being hungry. It is achieved for the LAGB patient by adding or removing of fluid from the system to change the degree of compression of the band on the gastric wall. When this compression is optimal, it induces a sense of satiety which is present throughout the day. Although some hunger may develop at times during the day, there is a general reduction of appetite, less interest in food and less concern about not eating. **Satiation** is the resolution of hunger with eating. For the LAGB patient, it is induced by each bite of food as it passes across the band. When the band is optimally adjusted each bite is squeezed across by esophageal peristalsis, generating increased pressure on that segment of the gastric wall. This reduces any appetite that may have been present and induces a feeling of not being hungry after eating a small amount. The combination of these effects allows the person to eat three or less small meals per day. The mean energy intake of the banded patient should be between 1,000 and 1,200 kcals per day[42].

Figure 8*. The Lap-Band AP with and without added fluid.*

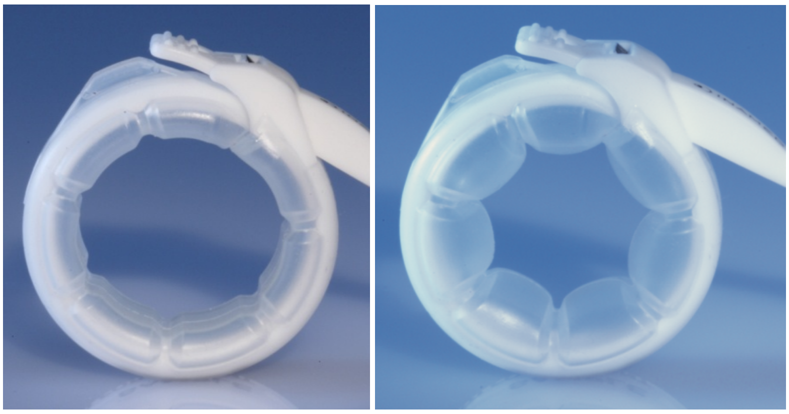
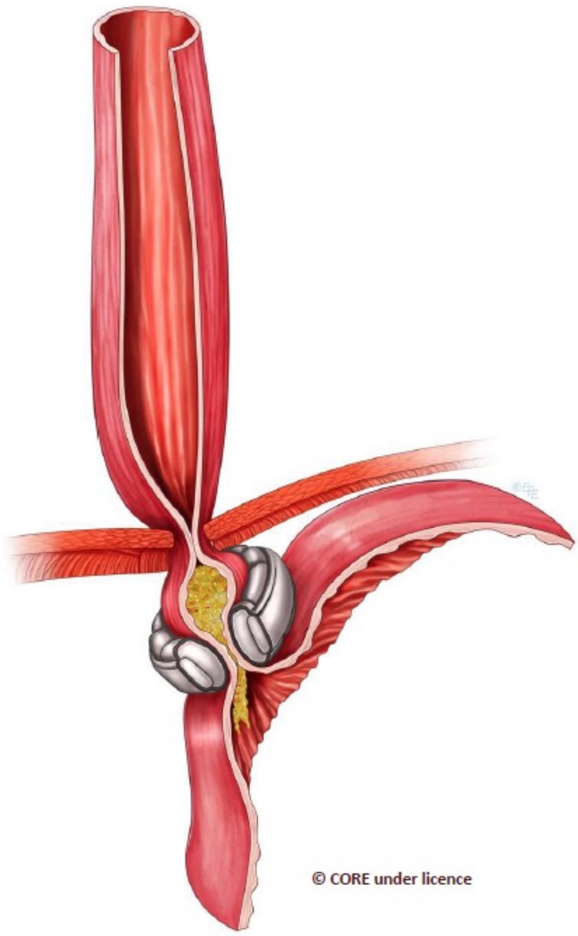


Figure 8 shows two views of the Lap-Band AP. On the left, it contains only the basal volume 3ml of saline and on the right it is well inflated band containing 7 ml of saline. The space within which is occupied by the cardia of the stomach. With 3ml added the internal space has an area of 357cm^2. This is reduced to an area of 139cm^2 with 7.0ml is present. These two areas represent the limits within which the LAGB is set for most patients. This ability to titrate the level of adjustment against the level of satiety is central to the effectiveness of the band.The optimally adjusted band modifies the normal transit of a food bolus into the stomach. With normal swallowing, a food bolus is swallowed and carried by oesophageal peristalsis down the esophagus. The lower esophageal sphincter (LES) relaxes and the bolus passes intact smoothly into the stomach. The LES facilitates the final transfer with an aftercontraction. With the band in its correct place with only 1-2 cm of cardia above the upper edge of the band and with the band optimally adjusted (exerting a pressure of between 25 and 35 mm Hg on the gastric lumen[43]), the esophagus must generate stronger peristalsis and the aftercontraction of the LES become more important. The bolus is squeezed through by these forces. It takes between two and six squeezes to achieve complete transit of a single small bite. This may take up to one minute.

Figure 9. *A small bite of food is being squeezed across the band, thereby compressing the vagal afferents and generating a feeling of satiety.*

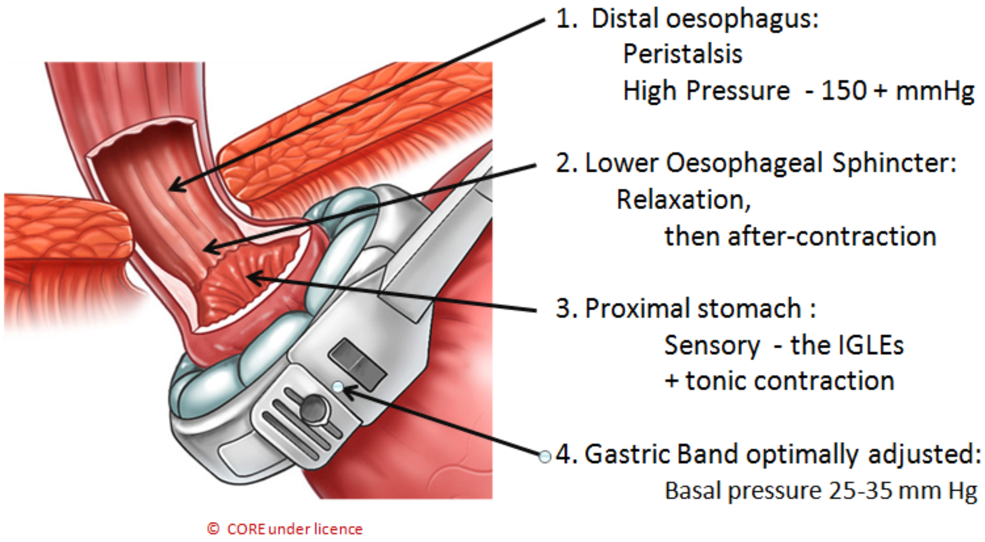


The aftercontraction of the LES is evident. Just part of each bite will transit on each peristaltic sequence. The remainder will reflux into the body of the distal esophagus, generate a secondary peristalsis wave and a further squeeze will occur. After several squeezes the bite will have passed. Importantly, each squeeze generates signals to the satiety centre of the hypothalamus. A second swallow should not commence until all of the previous bite has passed totally into the stomach below the band.

The signalling of both satiety and satiation to the arcuate nucleus of the hypothalamus does not appear to be mediated by any of the hormones known to arise from the cardia as none has been shown to be increased in a basal state after band placement and none increases post-prandially[44]. Vagal afferents are the more probable mediators and, among these, the intraganglionic laminar endings (IGLEs) demonstrate the characteristics needed to subserve this role[45, 46]

Figure 10 shows the components of the lower esophageal contractile segment (LECS), an entity described by Dr Paul Burton from extensive study of the "physiology" of the gastric band[47]. It brings together the key elements that together generate early onset of satiation after eating. The distal esophagus squeezes each bite of food to the stomach proximal to the band. The lower esophageal sphincter relaxes to allow passage and then contracts to maintain the forward pressure. The proximal segment of stomach maintains tonic contraction and detects the pressure increase. The band maintains an optimal compression to provide sufficient resistance to stimulate afferent signals but not sufficient to stop transit. There should be no restrictive component for normal functioning of the LAGB.

Figure 10. *The four components of the Lower Esophageal Contractile Segment (LECS)*



Mechanisms in Biliopancreatic bypass (BPD)

The initial element of the BPD is a partial gastrectomy either as a standard Bilroth II procedure for the standard BPD or as a sleeve gastrectomy in the DS variant of the BPD which generates a **restrictive element** and also through reduction of the ghrelin sources, and **sense of satiety** is induced. The gastric volume is reduced to 200 -500ml thus limiting food intake and this is considered to be the initial mechanism of effect[48]. Subsequently the separation of ingested food from the digestive enzymes until the last 50 cm of terminal ileum leads to **malabsorption of all macronutrients**. A number of positive and negative secondary effects occur. Through interruption of the enterohepatic circulation of bile and the bypassing of the proximal small intestine, there is a marked reduction of total cholesterol, triglycerides and LDL-cholesterol. Insulin sensitivity, as measured by HOMA, is improved[49]. Malabsorption of amino acids can lead to hypoproteinemia. Malabsorption of micronutrients and minerals can lead to osteoporosis and anaemia.

OUTCOME FROM BARIATRIC SURGERY

Mortality And Adverse Events

Perioperative mortality. There is a mortality risk with any surgery and this risk was strongly evident for bariatric surgery prior to the general use of laparoscopic approach. Pories et al[50] reported a perioperative mortality of 1.9% of the 605 patients treated by open gastric bypass. In a major series from Richmond, Virginia there were 31 perioperative deaths (1.5%) in 2011 patients having RYGB between 1992 and 2004. The mortality occurring at the level of community surgery is probably higher than from the major academic centers. Flum and Dellinger[51] used the Washington State Comprehensive Hospital Abstract Reporting System database and the Vital Statistics database to evaluated 30 day mortality of all people having a RYGB procedure in that state during the period 1987 to 2001. Of 3,328 procedures there were 64 deaths, a mortality rate of 1.9%. This period included both laparoscopic and open surgery and could be seen to reflect community practice.

The overall mortality has decreased in more recent years, particularly with the widespread use of a laparoscopic surgical approach as reported in the systematic reviews of the published data. Death after LAGB is rare and in most reports is 10-15 times less likely than after RYGB[52, 53]. At the Centre for Bariatric Surgery in Melbourne, we have performed more than 9000 primary LAGB procedures and have performed revisional LAGB surgery on more than 1500 of these or other patients without any 30-day mortality or any later death related to the LAGB procedure.

The most definitive evaluation of mortality currently available is derived from the Longitudinal Assessment of Bariatric Surgery (LABS) study report in 2009[5]. This NIH-sponsored study of bariatric surgery involved 10 sites, carefully selected for their expertise and experience. The 30-day rate of death was monitored closely. Of the 4776 patients studied, 3412 had RYGB, 1198 had LAGB and 166 had other procedures unspecified in the report. There were 15 deaths in the RYGB group (0.44%), 6 after a laparoscopic approach and 9 after an open approach. There were no deaths in the LAGB group of patients. The difference was highly significant.
Sleeve gastrectomy was not included in the LABS study. In a recent systematic review[54] there were 26 deaths in 8922 patients (0.3%) after sleeve gastrectomy, an outcome similar to RYGB in the LABS study.

Early adverse events. The LABS study serves also to inform on early adverse events for the two major bariatric procedures of RYGB and LAGB. Not surprisingly, the incidence of adverse events mirrored the perioperative mortality rates. Using a composite end-point of death, DVT or pulmonary embolism, reintervention or failure to be discharged by 30 days, they identified 189 who were positive to that end-point, 177 in the RYGB group (5.2%) and 12 in the LAGB group (1.0%), a difference that was highly significant. The complication rate for sleeve gastrectomy is at least comparable to RYGB. In the systematic review of all reports available on the sleeve gastrectomy reported by Brethauer in 2009[55], the quality of the data prevented careful analysis but those papers that included complications declared rates from 0% to 24%. Postoperative leaks from the staple line after sleeve gastrectomy are relatively frequent (2-3%) and appear to be independent of surgeon experience[56]. In contrast to leaks after RYGB, they tend to be slow to close thereby generating mortality, greater morbidity, long-term patient suffering and high hospital costs.

Late adverse events. There is, and always will be, a maintenance requirement with any bariatric procedure as we are treating a chronic disease. The procedure needs to remain effective over decades rather than years. It is inevitable that there will be the need to correct or repair. Whilst reversal of a bariatric procedure should be counted as failure, revision to correct or repair should not. It is a part of the process of care.
All bariatric procedures have been shown to have a maintenance requirement. The revisional surgery rate of the studies which report 10 or more years of follow-up, as shown in table 3, was a median value of 24% and it was not different between procedures. Sleeve gastrectomy is not included as there are no 10 year follow-up studies available to date.

The median rate for the six RYGB reports that provided data was 22% with a range of 8% - 38%. All of the LAGB sets provided data on revisional surgery. The median value was 26% with a range of 8% - 60%. As almost no details of the type of revisional procedures were provided and, as there were too few reports at ten years on other procedures, a more detailed analysis is not possible.

Weight Loss Outcomes

Weight loss can be described in different ways, each of which has its advantages and drawbacks. In bariatric surgery the percent of excess weight lost (%EWL) is the preferred method. The excess weight approximates the excess fat within the body. That is what we are trying to reduce and therefore a measure of that effect has more relevance in this clinical setting than measures of total weight change as are commonly used in the non-surgical weight loss literature. It could be argued that percent of excess BMI lost (%EBL) is the most relevant to health status. However as it has a fixed linear relationship to %EWL and it currently lacks broad usage, it has not yet been embraced. Most reports in the bariatric surgical literature provide %EWL, and thus allow comparison between studies.

As obesity is a chronic disease, for treatments to be effective they must also be effective in the long term. Short-term studies (1 - 3 years) are plentiful but simply suggest a potential effectiveness. Medium term studies (3 -10 years) are far fewer but are more assuring of real effectiveness. Long-term studies (greater than 10 years) are very few and yet are the only ones that truly enable rational decision making on effectiveness. There have been a number of systematic reviews bringing these data together. These provide perhaps the best understanding available of the reasonable weight loss expectations for bariatric surgery in general and for specific bariatric procedures. I will deal with these in order of the duration of follow up provided.

One year outcomes: The most quoted of all the systematic reviews is the report by Buchwald et al[57] published in JAMA in 2004. There was 47.5%EWL at one year after LAGB, 61.6%EWL for RYGB, 68.2%EWL for gastroplasty, principally vertical banded gastroplasty, and 70.1%EWL for biliopancreatic diversion. In dealing with the outcome data with one year follow up only, the study gave advantage to the stapling procedures as the weight loss generally peaks at this time for these procedures. However, for the LAGB procedures, weight loss continues for 2 -3 years and therefore assessment at one year was premature. Note that in this review gastroplasty, a procedure now largely discontinued, appeared to provide better weight loss than RYGB and was equivalent to BPD in this study.

Short-term (1 - 3 yr)outcomes: Chapman et al[52] performed a systematic review of the literature available up to mid-2001 and compared the published reports on LAGB, RYGB and VBG. They found that, although LAGB showed less weight loss at 1 and 2 years, all three groups of procedures produced comparable weight loss at 3-4 years, that being the longest follow up available on LAGB at that time. They noted the lower mortality associated with LAGB.

Maggard et al[53] reviewed the literature up to mid-2003 and identified 89 reports that provided weight loss data after bariatric surgery. Weight loss data were available at or beyond three years in 57 of these reports. Table 2 shows a summary of their weight loss findings for 3 or more years of follow up.

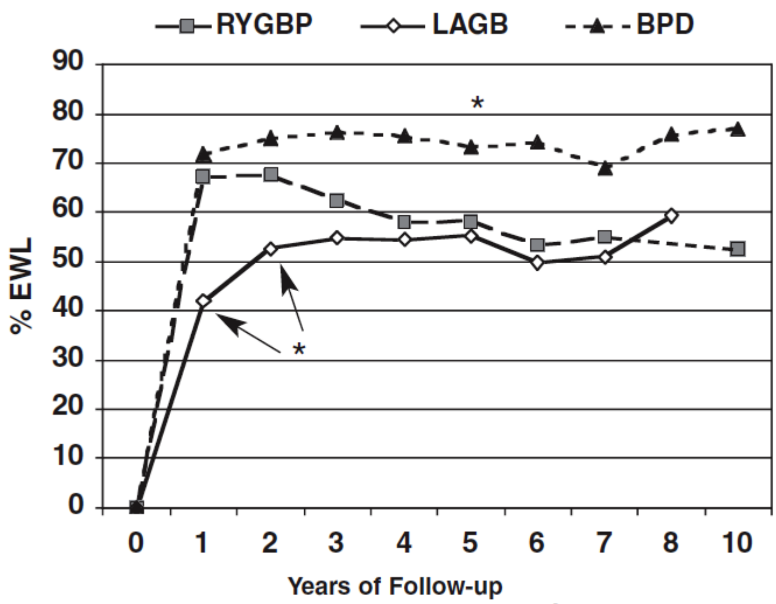
***Table 2**. Summary of published data providing three or more years of follow up (adapted from Maggard, 2005[53]). Note that they identified only one report for laparoscopic RYGB and for BPD at that time.*

Procedure	Weight Loss (kg)	95% CI	No. of Studies	No. of Patients
Open RYGB	41.6	37.4 - 45.8	20	1266
Laparoscopic RYGB	38.2	28.0 - 48.6	1	15
VBG	32.0	27.7 - 36.4	18	1877
LAGB	34.8	29.5 - 40.1	17	3076
BPD	53.1	47.4 - 58.8	1	50

Based on the confidence intervals, only BPD appears to offer better weight loss than the other procedures.

Medium-term (3 - 10 year)outcomes: A single systematic review has focused on the medium term-term outcomes and thus included only reports that provided at least three year data[58]. A total of 43 reports were included, 18 related to LAGB, 18 related to RYGB and 7 on BPD or its DS variant. Figure 11 shows the %EWL for these three procedures.

***Figure 11.** The pattern of weight loss over time after RYGB, LAGB and BPD (from* reference 58, with permission*).*



The most significant single finding was that each of these procedures was effective in achieving substantial weight loss over the medium term. RYGB was significantly more effective than LAGB at years 1 and 2 but not beyond that point. BPD appeared to be more effective than the other procedures but the difference was shown to be statistically significant at 5 years follow up alone.

Long-Term (>10 Year) Outcomes:

It is not hard to achieve substantial weight loss in the short term. Most lifestyle programs can do it. Showing weight loss after bariatric surgery in the short term cannot justify its costs or risks. The key weakness of the lifestyle programs is not their impotence but their lack of durability. For bariatric surgery to be worthwhile the effects must last. Yet most of the published studies deal with the short-term outcomes only.

Data published up to the end of 2011 on weight loss at 10 or more years after bariatric surgery have been subjected to systematic review[59]. At that time there were 9 reports of RYGB, 7 reports of LAGB, and 4 reports of BPD/DS with data beyond 10 years. No long-term outcome data for sleeve gastrectomy are yet available.

Table 3 summarizes the findings. Notably, all three procedures have generated substantial long-term weight loss. BPD/DS appears to be the most effective with 72% EWL. RYGB (54.0% EWL) and LAGB (54.2% EWL) are identical.

Table 3. Bariatric surgical procedures: systematic review of long-term outcomes (Adapted from ref 59).

Procedure	**RYGB**	**LAGB**	**BPD / DS**
No. of Reports	**9**	**7**	**4**
No. of patients – initial	**3194**	**6369**	**3408**
Perioperative mortality	**21/2102 (1.01%)**	**1/6369 (0.002%)**	**27/3066 (1%)**
% Follow up achieved	**64%**	**82%**	**83%**
% EWL at 10+ yr: Weighted mean % EWL (range)	**54.0 (28-68)**	**54.2 (33-64)**	**71.7 (69-75)**
Revisional procedures: Range as % of total followed up	**8-38**	**8-60**	**NR**

NR = not reported. As perioperative mortality was not reported in all studies, the denominator for mortality rates may be lower than the initial number of patients.

The results emphasize the laudable effectiveness of all of these procedures, each of which has been able to maintain more than 50% EWL beyond 10 years. Bariatric surgery does work and RYGB and LAGB appear to be equal in the long-term.

Sleeve Gastrectomy Outcomes.

Adequate weight loss reporting for sleeve gastrectomy remains a problem with no long term data, poor medium term data and major loss to follow up in all series providing this information. Brethauer et al provided a literature review of the 36 published reports involving 2570 patients that were available in 2009[55]. Only one report gave data beyond 3 years.

There was a mean weight loss for the full group of 55% EWL. The only study exceeding three years showed a weight regain of approximately 40% from 3 - 5 years[60].

In 2014, Diamantis et al[61] reported a systematic review of the literature which included 16 studies, involving a total of 492 patients, which reported more than 5 year follow-up. There was 62% EWL at 5 years, 54% at 6 years, 43% at 7 years and 54% at 8 years. Not included in this review were the data from Weiner from Frankfurt who has a large series with longer follow up[62]. He has reported the outcomes of 746 patients with up to 8 year follow up. The %EWL was 59% at 2 yr, 45% at 5 yr and 36% at 8 yr.

Gastric imbrication is too new to know much of the benefits or risks. Very few reports of weight loss outcomes are available. Brethauer et al report a 53%EWL in 6 patients at one year[63]. The anticipated freedom from perioperative complications needs to be shown. Just as with sleeve gastrectomy, there is a high likelihood of failure of initial weight loss or weight regain in the medium term. It remains an experimental procedure at this time.

Type 2 Diabetes and Bariatric Surgery

Type 2 diabetes mellitus is the paradigm of an obesity-related illness and improved control for diabetes and other metabolic disorders represents the greatest potential strength for bariatric surgery. The metabolic effects of weight loss following bariatric surgery have been well documented and provide clinicians with an obvious path for the prevention and treatment[64-66]. The effects of bariatric surgery on type 2 diabetes have been subject of 2 systematic reviews[64, 66]. Buchwald reported 86% of 1835 patients from multiple case studies showed remission or improved control[64]. Maggard et al[66] reviewed 21 case series and reported a range of 64% - 100% showing remission or improvement.

Sadly, few patients with diabetes have been offered this benefit to date. Arguments against the broad application of bariatric surgery have included: Safety concerns, lack of evidence from RCTs, insufficient understanding of mechanism, lack of proven durability of effect and lack of proven reduction of the complications of diabetes in association with long-term remission. All of these arguments are losing substance as new data continue to appear. However, not all have yet been answered fully. The question regarding long-term outcomes, in particular, needs to be better supported by data.

Safety.

The safety of bariatric surgery has improved greatly in recent years with almost no perioperative mortality risk associated with LAGB and, in expert centres, a mortality rate of 0.44% after RYGB[5]. Compared to the mortality risk of diabetes, bariatric surgery is a safe path.

Remission rates in RCTs.

Until recently, the lack of high levels of evidence has been the most valid criticism of reports of bariatric surgery and diabetes. The medical literature had been littered with numerous observational studies. These studies often carried major deficiencies including poor definition of both diabetes and its remission and extensive or unreported loss to follow up. Systematic reviews have sought to resolve these deficiencies through the pooling of data[64, 66].

We have now been provided with at least five high-quality randomised controlled trials[67-71].

Their findings should over-ride the past observational studies. All studies have compared one or more bariatric procedures with a group having non-surgical treatment (NST). However the studies are not directly comparable due to extensive heterogeneity, including different criteria for patient selection, various treatment durations and various definitions of remission of diabetes, particularly the cut-off values for HbA1c. Nevertheless, they serve to provide key comparisons with NST, the current offering to more than 99% of people with diabetes.

The key outcome of remission of diabetes from each of these studies is shown in figure 12. The first of the studies was performed by our group at the Centre for Obesity Research and Education (CORE) in Melbourne[67]. 60 patients were randomised to LAGB or non-surgical therapy (NST). They were required to have a BMI between 30 and 40 and to have been known to have type 2 diabetes for less than 2 years. Inter alia, remission was defined as a HbA1c of less than 6.2%. The results reported were after 2 yr of follow up.

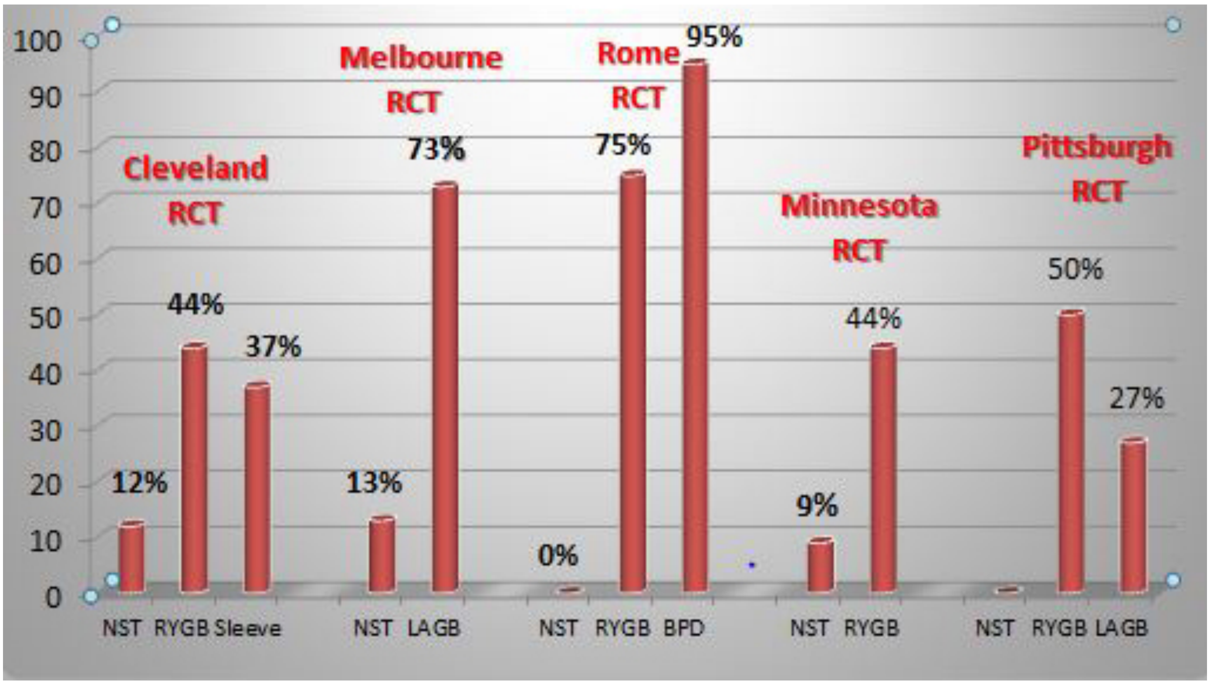
The study by Schauer et al[68] from the Cleveland Clinic randomised 150 patients and included NST, RYGB and sleeve gastrectomy. They defined remission, in part, as a HbA1c of less than 6.0%. They reported their results at one year and then at 3 years[72].

Mingrone et al[69] randomised 60 patients to three groups – NST, RYGB or BPD by open laparotomy and reported their outcomes after a two year follow up. They used a HbA1c cut-off of 6.5% to define remission. They have recently reported the five year follow up of these groups of patients[73].

Ikamuddin and coworkers[70], from Minnesota and other sites, performed a similar study to the Cleveland Clinic study except for restricting it to a comparison of NST with RYGB. It involved 120 patients and was multicentered, including a group from Taiwan. They defined remission as HbA1c of less than 6.0% and to date have reported the one[70] and two year[74] follow up data of a planned 5 year study.

Courcoulas et al from Pittsburgh randomised 69 patients into 3 groups – NST, RYGB and LAGB. They defined partial and complete remission, in part, as HbA1c values of less than 6.5% and 5.7% respectively. They have published the one year[71] and three year[75] outcomes to date. The data shown in figure 11 below are for partial remission.

Figure 12. Comparison of remission of type 2 diabetes in five RCTs of bariatric surgical procedures versus non-surgical treatment.



Three of the studies included a RYGB arm and report remissions rates of 44% at one year in 2 studies[68, 70] and 75% at two years in one study[69]. The remission rates for LAGB were 73% at two years[67], for biliopancreatic diversion (BPD) 95% at two years[69] and for VSG 37% at one year[68]. The studies contained sufficient heterogeneity to not permit head-to-head comparison between procedures but have established the significantly greater effectiveness of all bariatric surgical options over non-surgical treatment.

Mechanisms of effect.

This remains an area of contention and learning and is linked to the general study of mechanisms reviewed above. Optimal selection of the patients and the procedure requires more knowledge of what drives better outcomes. The two primary effects of bariatric procedures is an immediate and sustained reduction of nutritional intake and a reduction of insulin resistance associated with loss of weight. Additional factors include improvement on β cell function, changes in appetite and changes in the gut-associated incretins.

The relative effectiveness of different bariatric procedures has been subject to considerable debate. RYGB is associated with the incretin effects with increased release of GLP-1 and GIP from the distal gut, increasing β cell function, at least in the short term after the procedure[76]. However comparison with non-surgical patients taking a diet equivalent to the early post-operative RYGB patient suggests that an improvement in insulin resistance immediately after RYGB is primarily due to caloric restriction, and the enhanced incretin response after RYGB does not improve postprandial glucose homeostasis during this time[77].

The improvement in diabetes following weight loss is, in part, related to the dual effects of improvement in insulin sensitivity and pancreatic beta-cell function[78]. As beta-cell function deteriorates progressively over time in those with type 2 diabetes, early weight loss intervention should therefore be a central part of initial therapy in severely obese subjects who develop type 2 diabetes. For obese patients with type 2 diabetes, weight loss provides benefit not equalled by any other therapy, and may prove to be the only therapy that substantially changes the natural history of the disease[50, 79].

Durability of remission. Recent reports derived from several of the RCTs suggest a possible lack of durability of effect. For RYGB there has been reasonable stability for three of the four studies. In the Cleveland clinic study, at three years the remission rate for RYGB did not change significantly (43% to 38%). Partial remission for the RYGB patients in the Pittsburgh study changed from 50% at one year to 40% at three years. The multi-centered study based in Minnesota also showed stability of the RYGB effect between one and two years[74]. In contrast, for RYGB, the Rome study, found the remission rate fell from 75% at 2 years to 37% at 5 years, a relapse rate of 53%.
Sleeve gastrectomy was measured only in the Cleveland study and between one and three years it showed a marked fall from 37% to 24%, a 50% reduction[72]. The remission rate for the BPD group of the Rome study fell from 95% to 63% a 37% relapse rate[73] between the two and five year study points. LAGB partial remission rate in the Pittsburgh study was unchanged at three years (27% at year 1 and 29% at year 3).In the Pittsburgh study, comparing the relative effect of RYGB and LAGB, complete remission of diabetes had occurred in 17% of RYGB patients and 23% of LAGB patients at year 3.

Macrovascular and microvascular complication rates.

The durability of remission and the reduction of complications has been demonstrated at a fifteen year follow up in the Swedish Obese Subjects (SOS) study, a prospective matched cohort study[80]. They reported that the remission rate for the surgical group, predominantly gastroplasty, at two years was 72% and at 15 years was 31%. This remission rate, though reduced with time, was significantly better than their control group and indicates an important long-term benefit. Furthermore, and arguably more important than the remission rate, they found the macrovascular and microvascular complications of diabetes were fewer at 15 years in the surgical group than in the controls.

Earlier surgery improves outcome.

The duration of diabetes prior to bariatric surgery is a consistent and strong predictor of remission[72, 80]. A commitment to substantial weight loss must be a component of the early management of the obese person with diabetes. In a recent report from the SOS study, the patient who had bariatric surgery within the 1st year of diagnosis had more than twice the likelihood of remission of diabetes at two years and approximately six times the likelihood of remission at 15 years when compared to the patients who was diagnosed more than 4 years before surgery. If an obese patient with diabetes cannot achieve substantial weight loss by lifestyle change, early referral for consideration of bariatric surgery is an essential responsibility of the health care provider.

OTHER HEALTH OUTCOMES AFTER BARIATRIC SURGERY

Dyslipidemia Of Obesity

Increased fasting triglyceride and decreased high-density lipoprotein (HDL)-cholesterol concentrations characterize the dyslipidemia of obesity and insulin resistance[81]. This dyslipidemic pattern is highly atherogenic and the most common pattern associated with coronary artery disease [82]. Weight loss surgery produces substantial decreases in fasting triglyceride levels, an elevation of HDL-cholesterol levels to normal, and improved total cholesterol–to–HDL-cholesterol ratio [83-85]. Although elevation of total cholesterol is not obesity-driven, hypercholesterolemia can be controlled by malabsorptive procedures such as BPD[86] and, to a lesser extent, RYGB[87].

Hypertension

There is evidence of a reduction in both systolic and diastolic blood pressure (BP) following weight loss in association with a bariatric procedure[88]. We have studied the outcome of 147 consecutive hypertensive patients at 12 months after LAGB. Preoperatively, only 17 of these patients had BP within the normal range, all on therapy. Hypertension was present in 130 patients preoperatively; 101 of these were taking antihypertensive medications and the remaining 29 were not on therapy. Mean BP for these patients was 156/97 mm Hg prior to surgery. At 12 months after LAGB, 105 patients had normal BP, 42 remained hypertensive, and only 42 were taking any antihypertensive medication at that time. Mean BP was 127/76 mm Hg. From these data, we found that 80 patients (55%) had resolution of the problem (i.e., normal BP and taking no antihypertensive therapy), 45 patients (31%) were improved (less therapy and easier control), and 22 patients (15%) were unchanged[89]. We have demonstrated that the fall in blood pressure is sustained to at least 4-years after surgery but durability of blood pressure reduction over a longer period is uncertain[90].

Gastro Esophageal Reflux Disease (GERD)

GERD is much more common in the obese. The community adult prevalence is estimated to be 8-26% whereas 39 - 53% of an obese population have been shown to suffer the disease[91]. The reasons for this increase are still unclear but suggestions include reduced basal pressure at the lower esophageal sphincter, increased transient lower esophageal sphincter relaxations, hiatal hernia and abnormal motility patterns in the esophagus or stomach. Multiple observational studies of LAGB and RYGB have reported strong benefit with improvement in LES function, reduced acid reflux and a level of symptom relief comparable to standard anti-reflux surgery[91, 92]. However it appears that to date no RCTs have been performed directly comparing the two approaches in a well-constructed study. We studied 87 patients who had moderate or severe GERD and have been followed for at least 12 months after LAGB. 73 (89%) have had total resolution of the problem, as defined by the absence of symptoms without treatment for the previous month. Preoperative and postoperative pH study and manometry have been performed on 12 of these patients who had severe symptoms preoperatively. The mean DeMeester score was 38 +/- 15 preoperatively and 7.9 +/- 8 at follow-up ($p<0.001$). In all but one of these patients symptoms had resolved completely[93].

Asthma

There is a positive relationship between asthma and obesity with a possible dose-response effect in evidence[94, 95]. The Nurses' Health study identified a five-fold increase in the relative risk of asthma with a weight gain of 25kg from age 18 when compared to a weight stable group[96]. In the setting of obesity, asthma is more difficult to control[97, 98]. Weight loss by non-surgical means has shown to improve asthma. In an RCT from Finland[99] the weight loss group (14% of total body weight lost) showed improved lung function, symptoms, morbidity, and health status. However lack of durability of the weight loss programs limits the clinical application of the non-surgical approach.

Several observational studies have report major improvement in asthma after bariatric surgery. A study of 32 consecutive patient with asthma treated by LAGB reported improvement in all measured aspects of the disease, including symptoms, severity, need for asthma medications (including corticosteroids), and hospital admissions[100]. The asthma severity score fell from 44.5 before operation to 14.3 at 12 months after operation. Other studies have also reported benefit after LAGB[101] and community studies indicate an important reduction of asthma medications after bariatric surgery in the state of Michigan at a time when RYGB was the dominant procedure [102, 103]. No RCTs of bariatric surgery versus best medical care appear to have been performed to date.

Obstructive Sleep Apnea

A range of sleep disorders is associated with obesity. The most serious of these is obstructive sleep apnea (OSA). Severe obesity is the greatest risk factor for the development of sleep apnea, with a 10-fold increase in prevalence. Excessive daytime sleepiness, a disabling and potentially dangerous condition, is very common in the obese population and is not necessarily related to OSA[104]. There are major improvements in sleep quality, excessive daytime sleepiness, snoring, nocturnal choking, and observed OSA with weight loss following LAGB surgery[105].

Obstructive sleep apnea and other sleep disturbances has been studied in 313 patients prior to LAGB and repeated at one year after operation in 123 of the patients[105]. There was a high prevalence of significantly disturbed sleep in both men (59%) and women (45%). Observed sleep apnea was decreased from 33% to 2%, habitual snoring from 82% to 14%, abnormal daytime sleepiness from 39% to 4% and poor sleep quality from 39% to 2%.

Depression

Depression is common in the morbidly obese. Does the presence of obesity cause the person to be depressed or does depression cause the person to eat too much? We have investigated the effect of weight loss induced by LAGB on depression as measured by the Beck Depression Inventory (BDI)[106]. Preoperative BDI on 487 consecutive patients was a mean of 17.7+/- 9.5, a level within the range for moderate depression. Weight loss was associated with a significant and sustained fall in BDI scores with a mean score of 7.8 +/- 6.5 (N=373) at one year after surgery. By four years after surgery, the 134 patients studied had lost 54% of excess weight and had a BDI of 9.6 +/- 7.7. Although a small number remained in the major depressive illness category, the shift of the majority to normal values for BDI strongly indicates that most of the depression of obesity is reactive to the problem of obesity rather than a cause of obesity and is resolved by weight loss.

IMPROVEMENT IN QUALITY OF LIFE

Improvement in QOL is one of the most gratifying outcomes of bariatric surgery. A number of studies clearly demonstrate major QOL improvements following bariatric procedures [107-111]. A large prospective study of QOL after weight loss surgery employed the Medical Outcomes Trust Short Form-36 (SF-36). The SF-36 is a reliable, broadly used instrument that has been validated in obese people. In this study, 459 severely obese subjects had lower scores compared with community normal values for all 8 aspects of QOL measured, especially the physical health scores. Weight loss provided a dramatic and sustained improvement in all measures of the SF-36. Improvement was greater in those with more preoperative disability, and the extent of weight loss was not a good predictor of improved QOL. Mean scores returned to those of community normal values by 1 year after surgery, and remained in the normal range throughout the 4 years of the study. It is significant that patients who required revisional surgery during the follow-up period achieved the same improvement in measures of QOL. Similar improvements in QOL have been demonstrated in patients having LAGB for previously failed gastric stapling[112].

Studies of appearance orientation and appearance evaluation indicate that the severely obese usually have quite normal pride and investment in their appearance and presentation but they evaluate their appearance as being very poor[113]. Weight loss following LAGB has been shown to produce major improvements in self-evaluation of appearance, although it does not return to community normal levels. The extent of the improvement in appearance is related to the percent of excess weight loss. The discrepancy between one's pride and investment in appearance and presentation and one's self evaluation of appearance is lower with weight loss, reducing psychological stress[113].

IMPROVEMENT IN SURVIVAL

The ultimate test of effectiveness of a treatment is the reduction of mortality. A comparison of the long-term mortality of bariatric surgical patients with obese controls shows improved survival. A systematic review by Pontiroli and Morabito[114] identified 6 relevant trials, shown in table 4. They reported a reduction of risk of global mortality with an odds ratio of 0.55 (95% CI = 0.49 - 0.63) . The overall survival advantage was not different between LAGB (odds ratio 0.57) and RYGB (odds ratio 0.55).

Table 4. *The relative risk of mortality compared to controls after weight loss following bariatric surgery.*

Study	Operation	Relative Risk	Source of controls
Christou (2004)[115]	RYGB	0.11	Medical
Flum (2004)[51]	RYGB	0.67	Medical
SOS study (2007)[116]	Various	0.71	Medical
Busetto (2007)[117]	LAGB	0.38	Medical
Adams (2007)[118]	RYGB	0.40	Community
Peeters (2007)[119]	LAGB	0.28	Community

The source of the control patients should be known and considered in the interpretation of the trials as sourcing a control group from a medical setting can preselect those who already have an existing disease that will shorten their life expectancy. As an example, the study by Christou[115] used patients admitted to the Quebec provincial health insurance database with a diagnostic profile which included obesity as their control group. The reasons for admission were not known. This group had a mean age of 47 yr and had a mortality rate of 12.6 deaths per 1000 patient.years. By comparison, the Peeters' study (mean age of 55 yr) and Adams study (mean age of 39 yr) used true community controls and had mortality rates for the controls of 8.6 and 5.7 deaths per 1000 patient.years respectively. Adjusting for age, the mortality rate or the Christou patients was approximately twice those using community control, suggesting they included a number with late-stage illness

The study by Adams[118] had sufficient numbers and details to provide some sub-group analysis. They found that mortality was significantly reduced for deaths from diabetes, heart disease and cancer whereas the rates of death from accidents and suicide were higher in the surgical group.

In spite of some weaknesses in the data and the inability to do a matched controlled study, the consistent pattern of the various reports indicates that global mortality is reduced in association with weight loss after RYGB and LAGB

THE HIERARCHY OF OBESITY THERAPIES

Resolution of the disease of obesity requires substantial and durable weight loss. The therapeutic options available are listed in table 5 in order of their risk, side effects, invasiveness and costs. We should always begin with the simplest and safest and work down the list. Only when a simpler and safer option has failed should we seek a more complex or risky option.

Table 5. *Hierarchy of weight loss techniques in order of rating for invasiveness /risk / complexity /potential problems.*

Therapy	Rating
Lifestyle - Eat less and do more	1.0
Cognitive behavioural therapy Very low calorie diets Drug therapy	2.0
Endoscopic - gastric balloons et al	4.0
Laparoscopic adjustable gastric banding (LAGB)	5.0
Sleeve gastrectomy	6.0
Laparoscopic gastric bypass (RYGB and SAGB)	7.0
Open RYGB	8.0
Open Biliopancreatic diversion (BPD)	9.0
Laparoscopic BPD	10.0

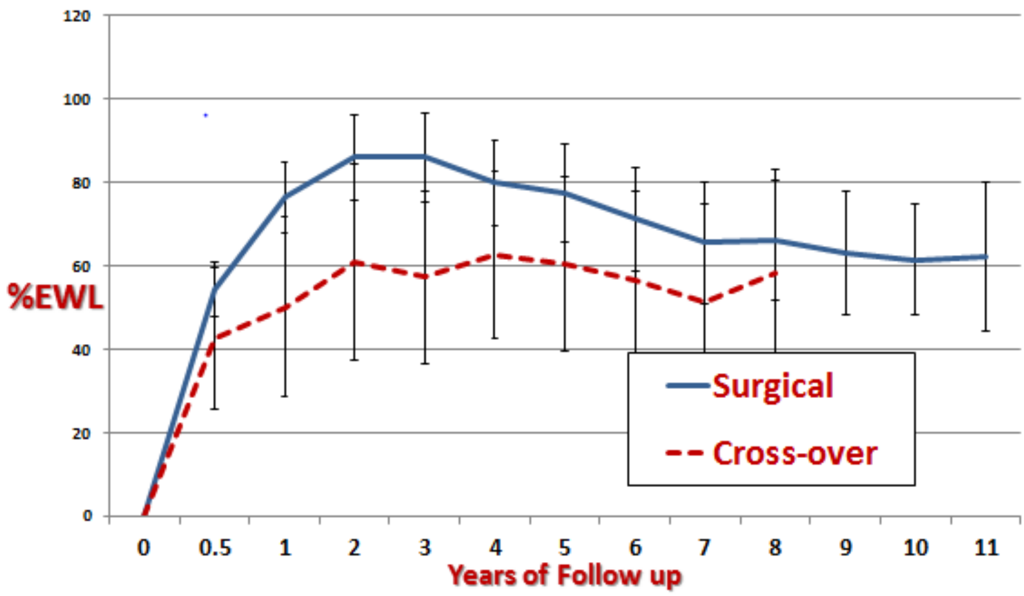
Lifestyle therapies (diet, exercise, behavioral change) should always be the first line of management. Multiple RCTs have shown that a modest weight loss of between 2 and 5 kg can be achieved at 12 months[120-123]. This level of weight loss is associated with a clinically valuable reduction of metabolic risk[124-126] but generally will not solve the problems of obesity. Lifestyle therapies should be applied optimally and sought to be maintained permanently. If however they fail to resolve the obese patient's problems, the next level of therapy should be considered. Current drug therapies add little further benefit[127]. Very low energy diets can be effective if taken correctly but are inevitably short term. The recent versions of the intragastric balloon have yet to show effectiveness by RCT and remain short term options. In spite of vigorous research effort, no additional endoscopic approaches are yet available which can provide even medium term benefit.

In general, this table provides a path along which the obese patient seeking treatment should travel. The procedure of gastric imbrication has not been placed on the list as its safety and effectiveness are not yet known.

Comparison of bariatric surgery with non-surgical therapies

We have performed three randomised controlled trials (RCT) in which we have compared gastric banding with optimal non-surgical programs. The initial RCT was of mild to moderately obese adults (BMI 30-35). We compared optimal non-surgical therapy, including lifestyle measures, drug therapy and very low energy diets with the gastric band and showed significantly better weight loss, health and quality of life for the banding group[128]. Adverse events were similar between groups. The gastric band patients had lost 86% of their excess weight (%EWL) compared to 21% EWL in the non-surgical group. The effects are durable as the substantial weight loss, health benefits and improved quality of life have remained at 10 yr follow up[129].

Figure 13. RCT outcomes at ten years (adapted from reference 129). Weight loss outcomes for the surgical group for the ten year period are shown by the continuous line. After completion of the two year randomised study, 17 of 40 patients in the non-surgical arm elected to cross-over to the LAGB. Their weight loss following cross-over is shown by the dotted line.



The second study was of obese adults (BMI 30 – 40) with type 2 diabetes. There was 73% remission rate of diabetes in the gastric band group and 13% in the lifestyle group[130]. Again, the metabolic syndrome was significantly improved in the banding group alone. The third RCT was of obese adolescents (BMI > 35; age 14 -18yr)[131]. The gastric band group lost 79% of their excess weight and showed a significant improvement on the metabolic syndrome which reduced from 36% to zero. There was also an improved quality of life.

Comparison between bariatric surgical procedures.

Table 6 lists a range of comparators and the position of each current option against these comparators.

Table 6. Comparison of attributes of the principal bariatric procedures

Attribute	LAGB	RYGB	Sleeve Gastrectomy	BPD +/- DS
Safe	+++	++	++	+
Weight loss:				
1. Short term	++	+++	+++	+++
2. Medium term	++	++	++	+++
3. Long term	++	++	Not known	?+++
Durable	++	++	?	++
Side effects	++	++	+	++
Reversible easily	Yes	No	No	No
Minimally invasive	+++	++	++	+
Controllable/adjustable	Yes	No	No	No
Low revision rate	+	++	?	++
Requires follow up	+++	++	++	++

The key outcome comparators between procedures are weight loss and safety. Short term data (<3 yr) are largely irrelevant as durability is essential. Systematic review of the medium term weight loss outcomes have shown no difference between RYGB and LAGB and suggest there is a better weight loss to be achieved with biliopancreatic diversion. Figure 10 shows the relative % EWL for the three principal procedures. Long term (> 10 years) weight loss as shown in table 3 also appears to be similar for RYGB and LAGB but several studies have a major potential for bias, particularly those with low numbers of patients.

WHO SHOULD BE CONSIDERED AND WHO SHOULD NOT?

BMI Criteria

There is level 1 evidence supporting a better outcome for using LAGB in the mild to moderately obese (BMI 30-35) when compared with lifestyle therapy[128, 130]. This approach is cost-effective[132, 133]. When the two treatment paths are modelled over time, the LAGB approach is dominant i.e. it provides increased number of quality-adjusted life years at a lower cost than the existing option of non-surgical therapies. Any person who is obese (BMI > 30), is suffering from the medical, physical or psychosocial consequences of the obesity and has diligently sought a solution through a range of lifestyle options over time, should be considered for LAGB.

Because the stapling group of surgical options lack level 1 data, are of greater risk, and are not controllable or reversible, maintenance of existing cut-off of BMI >40 or BMI > 35 with major comorbidities should remain for these procedures.

Age criteria.

We now have the results of a RCT showing the clear benefit for LAGB for the obese teenager[134] and we offer this option to severely obese teens from age 14 years. We do not consider offering an irreversible procedure to teens when a safe, effective and reversible option is available.

We are generally hesitant to offer bariatric surgery above the age of 65 but do at least consider people between age 65 - 70 who do not have chronic cardiovascular or pulmonary disease.

Contraindications.
Bariatric surgery is contraindicated in those with portal hypertension. Sleeve gastrectomy is considered by many to be contraindicated in those with severe gastro-esophageal reflux disease. LAGB is unsuitable for those who are mentally defective or otherwise unable to engage in the “partnership” needed for optimal outcome. Because of its particular aftercare needs, LAGB is also contraindicated in those who live remote from a follow-up center.

NEEDS AND CHALLENGES

Bariatric surgery is never a quick fix. It is a process of care that begins with a careful initial clinical evaluation and detailed patient education and it continues beyond the operative procedure through a permanent follow up. All procedures have the potential for perioperative complications and death. Revisional surgery is relatively common as maintenance of the correct anatomy is intrinsic to effectiveness. But bariatric surgery does provide a solution to the problem of obesity. It achieves substantial weight loss, improved health and quality of life and a longer life. We need to optimize these benefits and minimize the risks and the costs. The following are some of the areas for further research and development:

- A better understanding of the mechanisms of action of each procedure is required to enable optimum surgery and follow up.
- Accurate and comprehensive data management for all patients. Bariatric surgical procedures should be incorporated into national clinical registries to enable objective assessment of the risks and benefits across the community.
- More randomized controlled trials to define the benefits of weight loss on various comorbidities of obesity. More study is needed in particular for the patients with metabolic diseases – type 2 diabetes, metabolic syndrome, non-alcoholic steatohepatitis, the dyslipidaemias, polycystic ovary syndrome and obstructive sleep apnoea.
- Better definition of who is suitable and who is not suitable for bariatric surgery.
- Definition of safe and efficient pathways for assessment, surgery and aftercare.
- Cost-effectiveness evaluation of the bariatric surgical approach to disease management in comparison with existing options.

Bariatric surgery has the potential to be one of the most important and powerful treatment approaches in medicine. High quality of clinical care, good science and comprehensive data management will allow optimal application of this approach to be realized.

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