Internal hernia following laparoscopic gastric bypass

By

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Dedicated to my wife and sons for their love and support.

Declaration of Originality

The work presented herein is my own work. References to other researchers work have been appropriately cited.

Copyright Declaration

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Abstract

Obesity is increasingly recognised as a major health threat in the developed world, with more than 120 million people worldwide classified as clinically obese. Increased weight causes increased morbidity and mortality due to its association with cardiovascular disease, diabetes and certain cancers. Bariatric surgery is currently the most efficacious treatment for morbid obesity and has the best long-term outcomes. Bariatric surgery is not without risks. Some of the early risks include postoperative bleeding, anastomotic leaks, and venous thromboembolism. Late complications include marginal ulcer formation, nutritional deficiencies and small bowel obstruction. The latter may be caused by internal hernia formation.

In this thesis, an analysis of the causes of small bowel obstruction after laparoscopic Roux-en-Y gastric bypass (LRYGB) is presented, looking specifically at internal hernia formation. A detailed account of the presentation and radiological findings of internal hernia following laparoscopic gastric bypass is provided. The impact of altering surgical technique on the occurrence of internal hernia is analysed: an Observational Clinical Human Reliability Assessment (OCHRA) tool was used for root cause analysis of internal hernia following gastric bypass and in the final study, the employment of a new technique demonstrated significant reduction in the incidence of internal hernia.

Papers originated from the thesis

1. **Ahmed AR**, O'Malley W
   Internal hernia with roux loop obstruction during pregnancy after gastric bypass surgery. *Obesity Surgery 2006; 16: 1246-1248*

2. Husain S, **Ahmed AR**, Johnson J, Boss T, O'Malley W
   Small bowel obstruction after laparoscopic roux-en-y gastric bypass: etiology, diagnosis and management.
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3. **Ahmed AR**, Rickards G, Husain S, Johnson J, Boss T, O'Malley W
   Trends in internal hernia incidence after laparoscopic roux-en-y gastric bypass.
   Obesity Surgery 2007 Dec;17(12):1563-6

4. **Ahmed AR**, Rickards G, Husain S, Johnson J, O'Malley W, Boss T
   Bioabsorbable glycolide copolymer staple-line reinforcement decreases internal hernia rate after laparoscopic roux-en-y gastric bypass.
   Obesity Surgery 2008 Jul; 18 (7): 797-802

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   Roux limb obstruction secondary to constriction at transverse mesocolon rent after laparoscopic roux-en-y gastric bypass. *SOARD* 2009 Mar; 5(2):194

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   Root cause analysis of internal hernia and Roux limb compression following laparoscopic Roux-Y Gastric Bypass using Observational Clinical Human Reliability Analysis (OCHRA). *SOARD 2012 8:158-163*

Presentations to learned societies

1. Trends in internal hernia incidence after laparoscopic roux-en-y gastric bypass. *SAGES, Las Vegas 18-22/04/07*

2. Roux limb obstruction secondary to constriction at transverse mesocolon rent after laparoscopic roux-en-y gastric bypass. *SAGES*, *Las Vegas 18-22/04/07*

3. The effect of Seamguard^{TM} on internal hernia incidence after laparoscopic roux-en-y gastric bypass. *SAGES, Las Vegas 18-22/04/07*

4. Radiological findings in symptomatic internal hernias after laparoscopic Roux- en-Y gastric bypass. *IFSO, Porto, 5-8/09/2007*

5. Laparoscopic management of internal hernias after RYGB. *IFSO, Porto, 5-8/09/2007*

6. Internal hernia with roux loop obstruction during pregnancy after gastric bypass. *EAES, Stockholm, 11-14/06/2008*

7. Bioabsorbable glycolide copolymer staple-line reinforcement decreases internal hernia rate after laparoscopic roux-en-y gastric bypass. *IFSO, Buenos Aires, 25-27/09/2008*

8. An appraisal of abdominal procedures after gastric bypass. *IFSO, Buenos Aires, 25-27/09/2008*

9. Surgical morbidity associated with laparoscopic bariatric surgery in diabetic patients. *IFSO, Long Beach 3-7/09/2010*

10. Surgical morbidity following laparoscopic bariatric surgery. *IFSO, Long Beach 3-7/09/2010*

List of Abbreviations

BMI – Body Mass Index

BPD – Bilio-Pancreatic Diversion

CB – Cannabinoid

CBD – Common Bile Duct

CT – Computed Tomography

DS – Duodenal Switch

EMA – European Medicines Agency

IH – Internal Hernia

JI – JejunoIleal

(L)RYGB – (Laparoscopic) Roux-en-Y Gastric Bypass

LC – Laparoscopic Cholecystectomy

SBO – Small Bowel Obstruction

SLR – Staple Line Reinforcement

UGI - Upper Gastrointestinal Series

OCHRA - Observation clinical human reliability assessment

NICE - National Institute for Clinical Excellence

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1. LITERATURE REVIEW

1.1 Impact of obesity

Obesity is a worldwide problem, taking on pandemic proportions – it has been estimated that in the United States of America 30.5% of people are obese and 64.5% are overweight (1). Body mass index (BMI) is the preferred method by the WHO to define obesity and it is calculated using weight in kilograms divided by height in meters^2, expressed as kg/m^2 (2). A BMI above 25kg/m^2 defines overweight and above 30kg/m^2 obese. Morbid obesity begins at 40 kg/m^2, and super obesity at a BMI of 50 kg/m^2. The picture in the UK in 2001 was equally alarming as 21% of men and 20% of women were found to be obese in the Health survey for England and Wales (3). Collectively, data from both the US and UK suggest an exponential rise in obesity. Data from the Department of Health predicted UK obesity rates to rise drastically such that in 2010, 6 million women and just under 7 million men would be classified as obese (BMI > 30kg/m^2) (4). According to the latest Lifestyle Statistics published by the Information Centre for the NHS in 2009, 24% of adults (aged 16 or older) in England were classified as obese and the current population of morbidly obese (BMI > 40kg/m^2) in England has been estimated to be approximately 1.2 million i.e. 2% of the total population (5).

In the mid-1950s, data obtained from the insurance industry in the US indicated that intentional weight loss may have some health benefit. People applying for life insurance had to supply their height and weight, and overweight subjects were asked to pay higher insurance premiums if they decided not to lose some of their excess weight. Both the group that underwent intentional weight loss and the group that decided not to lose weight (but instead paid the higher insurance premiums) were followed until their death.

The intentional weight loss group showed a significant health benefit. A recent observational case control study supplied the strongest evidence to date that intentional weight loss leads to health benefits as in a cohort of 6391 people questioned, those who reported intentional weight loss had the lowest mortality (6). This observation, in fact, formed the basis for the Swedish Obese Subjects study, which is described later (7).

Although BMI as a measurement is the preferred choice of the World Health Organisation for epidemiological quantification of obesity, as alternative options are costly and not universally available (2). However, it is not without its problems. This definition has been criticised as it reflects the health outcome of a Caucasian population (8). If BMI is used to compare health outcomes of obese Caucasians and South Asians it becomes clear that the latter is subject to complications of obesity at BMIs of approximately $28kg/m^2$, while the BMI definition of obesity for a Chinese population should probably be as low as $26kg/m^2$(8). Thus, recording waist circumference has been gaining popularity, as this may be a better surrogate marker, at least with regards to obesity associated cardiovascular morbidity (9). As such, in males a waist circumference of >40 inches and in females >32 inches is classified as high risk.

It is widely acknowledged that those who are classified as overweight or obese have an increased risk of diseases. The risk of developing Type 2 Diabetes is 20 times greater for people with severe obesity (BMI > $35kg/m^2$) than for those with a BMI between 18-25 kg/m^2 (10,11). Ten percent of all cancer deaths amongst non-smokers are attributed to obesity (12). The risk of coronary heart disease increases 3.6 times for each unit increase in BMI (13). Also, 85% of all hypertension cases are amongst individuals with BMI > $25kg/m^2$ (11). Although these co-morbidities contribute greatly to the mortality associated with obesity, other conditions such as osteoarthritis, gallbladder disease, obstructive sleep apnoea and subfertility further exacerbate the morbidity burden (14). These together with the personal and professional discrimination affecting obese individuals, challenge the belief that anyone would choose to become obese or that obesity is the result of greediness or lack of self-control (15).

It has also been stated that morbidly obese individuals (i.e. BMI > $40kg/m^2$) are likely to die on average 11 years earlier than a healthy weight individual (16). This is comparable to, and in some cases worse than, life reduction as a result of smoking (16). Given the wide range of diseases and conditions, which are directly attributable to obesity, it is not surprising that obesity places a significant financial burden on the NHS. It has been estimated that direct costs are approximately £4.2 billion per annum and forecasts suggest that this will double by 2050 (17). This does not take into account the even greater indirect costs due to the loss of productivity, sickness benefits etc. Obese patients consume a significantly higher proportion of health care - an adult obese patient will generate 27% more ambulatory care spending than a non-obese patient of the same age (18). The highest cost drivers are those relating to the management of co-morbidities associated with obesity; t is estimated that obesity accounts for 85% of the total cost of treating type II diabetes, and 45% of the costs of treating hypertension (16).

1.2 Treatment options for obesity

The goal when treating severe obesity should be to improve the patient's health by helping them achieve and maintain a weight loss routine that prevents and reduces the risk of life-threatening factors and improves performance of activities of daily living. Treatment options include those targeted through diet, pharmacology and surgery and will be discussed in further detail.

1.2.1 Weight loss through dieting

The loss and subsequent regain of weight have been examined in studies such as the Minnesota Men's Study (19). This study was set up following the Second World War to investigate the best way to regain weight following severe starvation. The study was commissioned by the US government and utilised conscientious objectors who volunteered to be placed in a converted football stadium where they were subjected to very low calorie diets over a prolonged period. Following the period of starvation different methods were used to regain weight. During the weight loss phase the subjects lost fat and lean mass and showed a decrease in resting metabolic rate as well as unconscious movement, while during the weight regain phase they replaced their fat stores before replacing their muscle mass (19). This is a pattern, which repeats itself and can also be observed in the so-called "yo-yo" dieting (20).

Results of intentional weight loss and weight maintenance following lifestyle changes have been disappointing (3). Many studies have explored the combined benefit of low calorie diet, with either exercise or behavioural therapy. Most of these studies report only short-term effects with a degree of weight loss. However, studies reporting long term follow up data demonstrate that the excess weight invariably returned to similar, or even higher levels (7). It can be argued that this is simply consistent with evolutional change amongst early humans who lived in hunter-gatherer societies. These humans experienced continuous cycles of feast and famine and this may have resulted in an evolutionary advantage for those that could in times of famine still function during hunger, while also being able during times of feast to replace all the weight loss and even increase their weight above previous levels to serve as a buffer against possible future famine (21, 22).

This may also contribute to the yo-yo dieting pattern so commonly observed. Nowadays, humans are no longer exposed to feast or famine cycles as for most in the developed world there is a continuous and abundant supply of food. However with the self-imposed restrictions of low calorie diets the same hunger signals that our ancestors experienced are invoked, thus, leading to a similar response of weight regain when the diet is discontinued (20).

1.2.2 Weight loss utilising pharmacotherapy

The role of pharmacotherapy in weight loss remains controversial. Obesity is viewed by many as a result of poor will power and should, on these grounds, not be considered for pharmacotherapy. However, the same argument was levelled at hypercholesterolaemia and it was only after effective agents became available to treat this co-risk factor for cardiovascular disease that pharmacotherapy was more widely accepted. Large pharmaceutical companies are heavily investing in drugs to target obesity. To date, no one has been able to elucidate which components of the complex system controlling energy homeostasis and weight maintenance should be targeted. Thus a remarkable redundancy exists in the processes regulating energy homeostasis and weight maintenance. This, together with the possible detrimental influence of drugs on health, has prevented many agents making it to market so far.

Currently only two agents are available. The first, orlistat, a lipase inhibitor, prevents up to 30% of the absorption of fat by the gastrointestinal system (23). The mechanism of weight loss however, is not directly linked to the pharmacodynamics, but more to the effects of when fatty food is ingested while orlistat is being used. The resulting diarrhoea or oily leak is unpleasant enough to discourage the continuation of a high fat diet. The patient, if well informed, will usually revert to a lower fat, less energy dense diet with a resulting decrease in weight. Yet weight loss on orlistat therapy is not a universal phenomenon as many perpetual dieters taking the medication consume low fat foods, thus avoiding the side effects, but because of the volume of these meals, still have an energy surplus. Orlistat has recently been made available as over the counter medication in the UK (24).

Sibutramine was available until recently but the European Medicines Agency (EMA) has suspended its license due to an increased risk of adverse cardiovascular effects. This noradrenaline and serotonin reuptake inhibitor was originally designed to be an antidepressant (23). The initial phase I and II trials, however, showed that the antidepressant effect was weak, but that a significant appetite reduction occurred. Yet the side effect profile has caused some concern, as a number of patients are not able to tolerate the medication due to its noradrenalergic effects causing insomnia and gastrointestinal disturbances (25). Physicians were also obliged to check blood pressure on a regular basis and to withdraw patients from treatment when systolic or diastolic blood pressure increased by 10mmHg (25).

Another drug, Rimonabant, also had its license suspended by the EMA due to an increased risk of serious psychiatric disorders. This drug, like sibutramine, is a centrally acting drug. It is a cannabinoid one (CB1) receptor blocker and acts on the CB1 receptors. The CB1 receptors are found in the hypothalamus and are involved in controlling our intake of highly palatable, sweet or fatty foods. Over-activation of the CB1 receptors is associated with increased appetite, cravings for food and fat build-up. Rimonabant blocks CB1 receptors, thus, reducing cravings for these types of foods and helps control hunger and decrease appetite. This again helps decrease the overall calorie intake and results in weight loss. Furthermore, Rimonabant seems to have other beneficial effects including improving diabetes control and lowering cholesterol. It has also been shown to help people give up smoking. The drug, however, comes with psychiatric adverse effects including depression, anxiety, agitation and sleep disorders. It is contraindicated in people with active psychiatric illnesses and it may increase risk of suicide (25). It is for these reasons that its license was suspended by the EMA.

The second class of drugs that may be used to obtain weight loss specifically in type 2 diabetics are the glucagon-like peptide (GLP-1) agonists Exenatide and Liraglutide which have to be injected subcutaneously. Both function as incretin mimetics by stimulating glucose-dependent insulin secretion, inhibiting glucagon secretion and suppressing appetite. The expected weight loss is about 5Kgs with one year of treatment.

It is predicted that pharmacotherapy will continue to show rapid growth as most lifestyle interventions have been shown to be ineffective if not applied in conjunction with pharmacotherapy. Several new drugs and classes of drugs are in the pipeline for future use against the epidemic of obesity and the situation currently may be analogous to the early 1960s when patients with hypertension had to be treated with crude diuretics or centrally acting agents. The side effect profiles of these medications were significant, but with further development of the drugs a substantial useable health benefit may be achievable.

1.2.3 Weight loss utilising surgical interventions

Surgical interventions for weight loss – also referred to as bariatric surgery – have proven to be the most effective methods for intentional weight loss and post weight loss maintenance (26-29). Weight loss surgery is not a cosmetic procedure and does not involve the removal of adipose tissue. Instead, the rationale for the original interventions was based predominantly on either restricting the progression of food through the gastrointestinal system, or by causing some form of malabsorption, or a combination of the two. However, interestingly, it has been shown that animals undergoing such procedures have a marked reduction in appetite (30-33), a result which has also been observed in humans (27,28,33). The three possible mechanisms causing the reduction in appetite include neural, psychological and humoral factors. It is most likely that all three factors play a role in this appetite suppression, and this concept for the cause of such significant weight loss is gaining popularity.

Before patients can be considered for surgery it is vital that they have been treated with traditional methods such as diet, exercise and in some cases with pharmacological methods. For a small proportion of the severely obese population these methods may result in weight loss that is sustained and is beneficial to their health, but for the majority weight loss is not maintained. One report documents that non-surgical methods alone only work for 1 out of 20 severely obese individuals: fewer than 5% show any significant weight loss which they are able to maintain in the long run (34). In a study carried out over a period of nearly four years, which utilised a two-drug regime, behaviour modification, diet and exercise, the initial positive results were not sustained. There was a dropout rate of one third and for those individuals who followed the study throughout the four years, the average final weight loss was only 3lbs or 1.4 kg (35).

For the right group of patients, surgery leads to significantly greater, and sustained, weight loss than that achieved with non-surgical treatments. This leads to the resolution of, or significant improvement of, many weight related diseases and conditions which in turn leads to increasing a patients' life expectancy and significantly improving their quality of life. Bariatric surgery is complex and highly specialised, and it is performed in an extremely high-risk group of patients. The specific operative complications will be discussed in detail (See Chapter 2). Given the life-altering post-operative sequelae, in terms of both the potential complications and the impact surgery can have on patients' lives, the decision to operate should not be taken lightly. There has to be complete "buy-in" from the patient and their family – they must commit to the post-operative regime to try and prevent potentially life-threatening complications such as pulmonary embolism, which given their high BMI they are at increased risk of (36, 37, 38). The recovery period is long, they are not able to eat solids for weeks after their surgery, and even once they have healed they will never be able to eat in a normal way again. There are also the psychological factors that take place as the patient's body habitus alters as the weight is lost, and some patients' personal relationships improve, but also they can break down (39). That said, for some patients, this surgery provides them with a new lease of life (39).

1.2.4 History of weight loss surgery

There are currently three common bariatric operative procedures, the gastric banding, sleeve gastrectomy and Roux-en-Y gastric bypass. It is important to consider the more dated techniques, in order to fully understand the rationale behind their conception. Jaw wiring was first used in the mid-1970s and it was used to restrict the opening of the patient's mouth, thus making the consumption of a usual meal impossible. These patients could only consume liquid meals by using a straw. This highly regimented protocol ensured dramatic weight loss as the liquid diet contained far fewer calories (40). This form of surgical intervention was accompanied by a behaviour modification programme, which tried to teach the patients to follow a low calorie diet after the removal of the jaw wires. However, the end results were very disappointing; although all the patients lost significant amounts of weight while their jaw movement was restricted, they invariably regained all the weight after the wires were removed (40).

Henrikson in 1950 was the first to describe an abdominal surgical procedure for obesity consisting of a massive small bowel resection, leaving a short bowel (41). This led others to perform bypasses of the small intestine. The Jejuno-Ileal (JI) bypass, in various forms became a popular operation in the 1970s for severe obesity (42-44). However, the JI bypass was associated with serious complications such as blind loop syndrome due to bacterial overgrowth, abdominal bloating, migratory arthralgias, urinary stones, and, unless adequate protein was consumed, liver problems (45).

In order to perform an operation without the side-effects of the JI bypass, in the mid-1960s, Mason developed the gastric bypass, using a horizontal divided gastric pouch, joined to a loop of jejunum (46). Since the resultant gastrojejunostomy anastomosis was often under tension, Griffen developed the Roux-en-Y gastric bypass (RYGB) to help prevent this (47). Torres made a further modification to this - a vertical pouch on the lesser curvature of the stomach (48). The RYGB has undergone many modifications since and it is the most common operation in the USA for effective weight loss (49). The laparoscopic technique applies itself effectively to RYGB and its popularity continues to increase primarily since when compared to the traditional open approach it has fewer perioperative complications, a shorter hospital stay, and a more rapid recovery time than open surgery (50-52).

Around the same time as the bypass was being developed, Scopinaro in Italy developed the Bilio-Pancreatic Diversion (BPD), with the intent to avoid the problems associated with the blind loop formed after JI bypass. This primarily malabsorptive operation only allows for the absorption of carbohydrates and fats in the distal 50-70cm of the ileum. BPD has been reported to provide the highest long-term weight loss of any bariatric operation, however patients need close long-term post-operative follow-up for protein, vitamin and mineral deficiency as this remains as a significant complication following this surgery (53). The BPD was modified by Marceau and Hess to the duodenal switch (DS). In this procedure a vertical gastric tube, or sleeve, remains along the lesser curve of the stomach. The 1st part of the duodenum is divided 3cm distal to the pylorus; the proximal duodenum is then anastomosed to the ileum, which has been divided 250cm proximal to the ileocaecal valve. The proximal end of the biliopancreatic limb is blind-ending, and the distal end of the biliopancreatic limb is anastomosed to the side of the ileum 75-100cm proximal to the ileocaecal valve, which becomes the common channel. The intact pylorus reduces the risk of dumping syndrome.

The DS in the super-super obese patients who were very high-risk used to be performed as a staged procedure. Stage one would involve creation of the gastric tube or sleeve. The patient would then experience some weight loss from this process alone, and then would return to the operating room for stage two, which would involve the more complex intestinal reorganisation. In fact, the weight loss seen from stage one was so impressive that this stomach reduction, or sleeve gastrectomy, has gained popularity in its own right as a primary weight loss surgery (laparoscopic sleeve gastrectomy). It is now being performed increasingly as a stand-alone procedure with the surgeon having the option to add the DS portion or RYGB as a second operation if there is any future weight gain (54). A recent consensus meeting on the sleeve gastrectomy reports impressive results with this operation as weight loss and health benefits are in line with those seen after LRYGB (55).

In the 1980s, in the search for a simpler technique, gastric restrictive procedures to limit intake were developed by Carey and Gomez (56, 57). These involved stapling across the stomach below the GOJ leaving a reduced size gastric food reservoir, and only a central gap in the staple line to allow food intake to pass through. However, the small horizontal pouch enlarged as did the outlet. Mason in 1982 reported the vertical banded gastroplasty (VBG) in which a stapled but non-divided vertical pouch along the lesser curve of the stomach is formed. The outlet from this pouch into the gastric remnant is restricted by a non-dilatable band or mesh. This technique continues to be performed with various modifications, yet its popularity has decreased due to frequent regain of weight in the long term usually a consequence of failure of the pouch staple line.

In the early 1980s, Molina in the USA developed gastric banding as a restrictive procedure with a band placed high around the stomach, producing a tiny pouch (58). Subsequently, others developed an inflatable gastric band attached by tubing to a subcutaneous reservoir through which saline could be instilled or withdrawn via a tiny needle to control band size in order to adjust its tightness around the body of the stomach (59,60) (Figure 1.1). The normal course of events is for the stomach pouch to dilate and for the band to loosen as the fat around the stomach decreases. The result is a looser fitting band, which allows the patient to become hungrier and to consume more food, followed by weight regain. In such circumstances, the band is filled and the restriction around the stomach restored (61). With the band operation, patient selection is very important as disorders such as bulimia nervosa or "binge eating disorder" may have a higher complication rate and less overall excess weight loss (62). It is usual for patients to experience some post procedure vomiting as the stomach perceivable volume is suddenly so much smaller than what the patient is used to and they are not accustomed to the significantly reduced amount of food that can be tolerated safely.

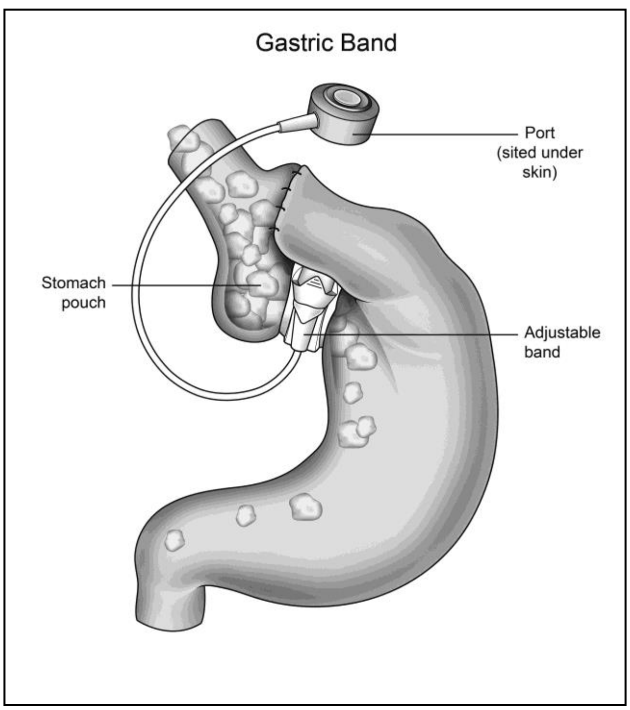


Figure 1.1 Gastric Band

Another procedure that aims to restrict the food consumed is the placement of an intragastric balloon (63). This is inflated within the stomach and thus reducing the potential space for food. The complication rate is significant with balloons bursting or causing obstruction. The presence of the balloon can also cause severe vomiting if too much food is consumed. Weight loss is not maintained as unlike in other procedure, appetite is not normally affected and therefore the patient remains hungry while the balloon is in place and can consume large amounts of food when the balloon is removed. This procedure is used in some units as a method to prepare extremely obese patients for other forms of more definitive weight reducing surgery.

More recently, gastric pacing is being researched following the work of Cigaina (64). Two electrodes are positioned in the muscle of the anterior gastric wall at the lesser curvature, and are connected to leads attached to a subcutaneous electrical generator. This ‘pacemaker’ stimulates its own rhythmic gastric waves, and produces satiety, and reduces the plasma levels of Ghrelin. The initial results available from using this technique have demonstrated some weight loss, although long term maintenance results are awaited (65).

More recently, GI Dynamics’ EndoBarrier Gastrointestinal Liner System is an endoscopically-delivered device that offers an alternative approach (66). The device shields the duodenum and upper jejunum from contact with chyme, thereby mimicking the foregut bypass effect of a gastric bypass procedure without altering the patient’s anatomy. Pancreatic and biliary secretions pass along the outside of the devices and then mix with chyme in the upper jejunum. Based on animal experiments and clinical observations, the EndoBarrier Gastrointestinal Liner may provide a useful non-surgical intervention for treating type 2 diabetes with an added benefit of providing weight loss, however there is not yet sufficient volume of evidence to demonstrate this conclusively in humans (66).

1.2.5 Common types of weight loss surgery

Currently, the three most common bariatric procedures performed worldwide are the Gastric band, the gastric bypass and the sleeve gastrectomy (49).

1.2.5.1 Gastric Band

This procedure has already been discussed above (1.2.3.1). As a restrictive procedure, by creating a small upper-stomach pouch it limits food intake by decreasing hunger and increasing the feeling of fullness after meals. The precise mechanisms underlying weight loss are still unclear but it has been hypothesized that due to presumed pressure on the vagus nerve from the band, hunger is reduced (67). The best results are seen when the band is sequentially adjusted at regular intervals to provide optimal reduction in hunger and increased fullness, which is inextricably linked with good patient compliance with the post-operative program. This then will lead consistently lower caloric intake and reliable weight loss will follow. Gastric banding were originally an operation of choice in patients without significant comorbidities, and who were just simply obese. The idea of a solution that is removable and does not require any irreversible anatomical alteration also appealed to some patients. It is, overall, losing popularity, however, since it is expensive, not without complication and easily abused by patients who then do not get sustained weight loss thus defeating the purpose of the surgery (49).

1.2.5.2 Gastric Bypass

The gastric bypass is the most common bariatric procedure performed worldwide. It is increasingly performed laparoscopically. The gastric bypass operation commences with formation of the vertical gastric pouch some 15-20 mls in size. Dissection starts along the lesser curve, and the retrogastric adhesions and angle of His are freed. Sequential firings of a stapler create a vertical gastric pouch. There has been much research into the size of the pouch. A retrospective study has suggested that smaller pouches may be associated with greater weight loss, although accurate measurement of pouch volume is difficult and prospective data are lacking (68). Most surgeons choose the transection point by measuring from the oesophago-gastric junction as accurately as simply "eye-balling" the anatomy, or by counting vascular arcades. If too large, it can cause an increase in the rate of marginal ulceration and reduced weight loss.

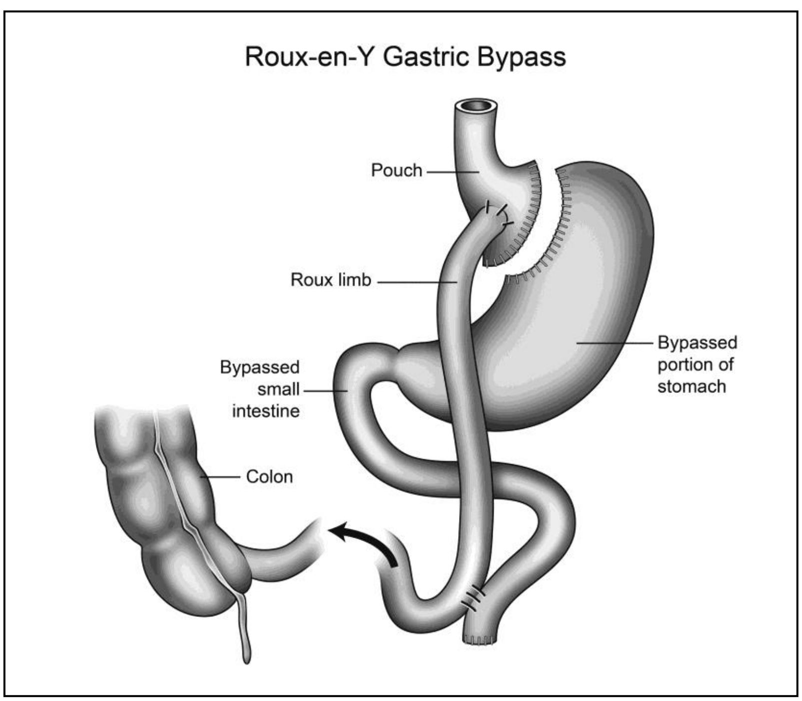


Figure 1.2 Roux-en-Y gastric bypass

Having created the pouch, the next step is to alter the configuration of the small bowel. In order to create the Roux-en-Y bypass, first the jejunum is divided at a point typically 30-40 cm distal to the ligament of Treitz. The distal segment is then moved cephalad to form the alimentary or Roux limb, and is surgically connected to the gastric pouch. This segment can either be brought ante or retro-colic, (in front of or behind the colon), and ante or retro-gastric (in front of or behind the stomach) and there are different techniques in use for the formation of the gastrojejunostomy. These include a handsewn or stapled approach, with the latter using either a straight (linear) or circular stapler. Each of the different techniques have been assessed in the literature and care should be taken when choosing the approach as there is a varying associated risk of stenosis and leak (69). Benefits of the ante-gastric route include the relative increased ease of accessing the anastomosis and re-examining it if necessary at subsequent surgery, particularly in revision or re-look surgery since it is not hidden underneath the stomach. However, if the patient has a short mesentery, this can mean that there is extra tension put on the anastomosis thus increasing the risk of leak. In these circumstances, a retro- approach is usually better. The proximal bowel segment, also called the biliopancreatic limb, is usually connected to the alimentary limb 75-150cm distal to the gastrojejunostomy, thus creating the common channel (Figure 1.2.).

Several authors have addressed the issue of alimentary limb length during RYGB. For patients with a BMI of 50 kg/m2 or less, there is no proven benefit for alimentary limbs longer than 150cm (70). Other studies examining the use of alimentary limbs longer than

250cm for patients with a BMI greater than 50kg/m2 have found improved weight loss over standard RYGB, but if greater than 300cm there is increased nutritional deficiencies and need for reoperation (70).

One of the consequences of performing a RYGB is the creation of mesenteric defects in the transverse mesocolon if it is a retrocolic Roux limb, the small bowel mesentery for the formation of the jejunojejunostomy or through Petersen's defect. The latter defect is between the mesentery of the Roux limb and the transverse mesocolon. Loops of small intestine may become trapped in such defects thus forming "internal hernias", and give rise to small bowel obstruction. Internal hernias are more commonly observed in the laparoscopic approach rather than the open RYGB. This has been postulated to be a result of the fewer adhesions found in the laparoscopic technique (71). The closure of these defects at the primary operation is not performed universally by all surgeons, but traditionally has been recommended by most surgeons (72,73). The RYGB is the most commonly performed operation due to its impact on obesity-related co-morbidities and also weight loss itself. Yet it is also a complex procedure with significant associated complications. The pros and cons of the operation will be discussed in detail later in this chapter.

1.2.5.3 Sleeve Gastrectomy

This operation involves converting the stomach into a long, thin tube by stapling it along its length and removing the excess stomach (Figure 1.3). As mentioned earlier it was initially the first stage of a DS operation but the patient's resultant weight loss and comorbidity reduction has resulted in it becoming a recognised stand alone operation. Unlike a gastric bypass where food enters a small pouch and then passes straight into the small bowel, the route the food follows after a sleeve gastrectomy is the same as the one followed prior to the surgery. As the stomach is smaller, it is able to hold less and stretches more quickly to give a feeling of fullness and satisfaction. Equally excision of the stomach fundus means that the ghrelin producing cells which drive hunger are removed.

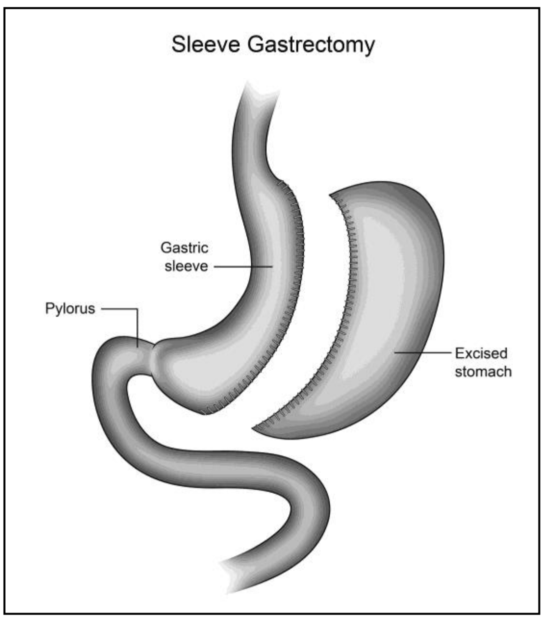


Figure 1.3 Sleeve gastrectomy

1.2.6 Eligibility for weight loss surgery

In accordance with the National Institute for Clinical Excellence NICE criteria bariatric surgery is considered for those people who have (74):

1. BMI ≥ 35 kg/m^2 with obesity related comorbidities (such as diabetes, sleep apnoea or joint problems)

2. BMI ≥40 kg/m^2

3. Have tried all other methods of losing weight (diets, exercise, medication) including 6 months medically supervised programme but have not been able to sustain weight loss

4. Have no specific medical or psychological reasons why they should not have this type of surgery

5. Are fit enough to undergo an anaesthetic and surgery

6. Understand the need for long-term follow-up

In an update document, NICE now recommend all individuals with BMI ≥50 to be directly considered for surgery without the need for a prior 6-month medically supervised weight loss (75).

1.2.7 Pros and cons of weight loss surgery

Long term clinical benefits –the pros of bariatric surgery

1.2.7.1 Weight Loss

Weight loss per se is likely to be the *least* important measure of bariatric surgical outcomes, although it is highly correlated with recognized risk factors and with patient satisfaction. Weight loss is conventionally expressed as percentage of excess weight loss (%EWL). "Excess" refers to the weight that exceeds actuarial standards of weight adjusted for height ('desirable' or 'ideal' weight) corresponding to minimal mortality. In a recent meta-analysis, mean EWL (and 95% CI) after biliopancreatic diversion was 70.1% (66.3-75.9%), gastric bypass 61.6% (56.7-66.5%), vertical banded gastroplasty 68.2%

(61.5-74.8%) and adjustable gastric banding 47.5% (40.7-54.2%) (76). There are few longitudinal (> 10 year) studies of laparoscopic adjustable gastric banding and none for laparoscopic sleeve gastrectomy. Weight loss after adjustable gastric banding has generally been greater in Europe and Australia than in the United States, with fewer operative complications (77-79), although some recent studies from the US have shown improved results (80).

1.2.7.2 Survival Advantage

Reducing mortality is the most important goal of bariatric surgery. In 2006, the Swedish Obese Subjects study, the first prospective controlled study designed specifically to assess mortality, reported significantly lower mortality over 13 years in patients who had undergone surgery than in those treated conventionally with the best medical therapy (81). Another study matched 7,925 surgical patients with the same number of severely obese non-surgical patients. The results were that long-term mortality decreased by 40% for the surgical group (82). Numerous other studies have also been published and using different types of data sources like death registries, case-control series and meta-analyses, also demonstrate reduced mortality risk after bariatric surgery (83-87). However there is, like in many fields of surgery, a correlation between better outcomes in high volume centres as well as with the obese patients' own baseline status. Sicker patients get poorer outcomes.

1.2.7.3 Co-morbidity Reduction

Surgery results in long-term weight loss and significantly improves or resolves many obesity related co-morbidities. Purely gastric-restrictive procedures do not appear to have the durability of co-morbidity reduction seen after diversionary operations (88-90). As an example, dyslipidemia is best corrected after biliopancreatic diversion (BPD), followed in effectiveness by gastric bypass and adjustable gastric banding. The same applies to Type 2 diabetes resolution, which happens fastest and to the greatest extent after BPD, then RYGB, and then banding. With regards to Type 2 Diabetes a recent study compared patients who had received bariatric surgery with those who were receiving traditional treatment (diet, exercise, drugs) (91). The study showed that, after 2 years, 73% of those who had surgery no longer had diabetes compared to only 13% in the non-surgical group (91). Furthermore, it has been known that diabetic patients' insulin requirements, with or without the addition of oral hypoglycaemic agents, rapidly drop within days of surgery and certainly before any significant weight loss with certain types of bariatric procedures. The speed of resolution of diabetes after RYGB or BPD has been associated with changes in the levels of various gut peptides such as glucagon like peptide 1 (GLP-1) (92).

For specific obesity related co-morbidities, a recent systematic review of 136 studies, which included over 22,000 patients, demonstrated (76): 77% resolution of type 2 diabetes; 62% resolution of hypertension; 86% resolution of sleep apnoea; and 71% resolution of high cholesterol. Furthermore, patients who have undergone weight loss surgery have a 40% reduced risk of developing cancer (81), improved mobility, improved fertility (93), and many other benefits (94). Several studies show that following weight loss surgery, both maternal and foetal outcomes are improved (95). Interestingly, a recent study of 113 babies born after maternal bariatric surgery who were followed for 2-18 years revealed a reduction of obesity to local population standards (96).

1.2.7.4 Economic benefits of weight loss surgery

Weight loss surgery is effective in the treatment or improvement of a number of obesity related co-morbidities. In the future, therefore, there will be a reduction in the medical treatment of these co-morbidities for example reduction in prescribing costs, reduction in hospital visits, primary care interventions etc. A 2004 Canadian study demonstrated the economic benefit of weight loss surgery within 3.5 years as a result of reductions in direct healthcare costs. After five years, the total hospitalisation costs for those who did not have surgery was 29 % higher than for those who did (87).

An independent cost effectiveness model demonstrates that the surgical treatment of obesity leads to a greater improvement in Quality of Life than traditional treatment, and that weight loss surgery represents good value for money (97). The model based on French costs shows that Adjustable Gastric Banding is cost saving in private clinics and cost effective in public hospitals compared to traditional treatment. Cost benefits are evident both from the first year of treatment, and after 5 years of follow-up. In 2006, NICE recommended that for weight loss surgery the "evidence suggests that surgery in general is a cost-effective intervention relative to a limited non-surgical management option in a typical severely obese group" (75).

With regards to type 2 diabetes, it has been claimed that bariatric surgery is one of the major breakthroughs in diabetes care to have emerged since the discovery of insulin! As such, the cost-effectiveness of bariatric surgery for diabetes has been evaluated in prior studies (98,100), but these studies have been limited by simplistic diabetes models with parameter inputs derived from individual trials. Only one previous study of LRYGB has accounted for the future complications of diabetes (101).

In contrast, the authors of one recent study found that bariatric surgery, based on currently available data, is cost-effective over the lifetimes of severely obese patients with diabetes (99). Bypass surgery had incremental cost-effectiveness ratios (ICERs) of $7,000/QALY and $12,000/QALY for severely obese patients with newly diagnosed and established diabetes; banding surgery had slightly higher ICERs of $11,000/QALY and $13,000/QALY for the two respective diabetic groups. The ICERs for both surgeries are very favourable since values below the $200,000/QALY threshold in the U.S. are now considered cost-effective. Other diabetes treatments, such as intensive glycemic and lipid control in comparison to conventional risk factor control, have previously been found to have ICERs of $41,384/QALY and $51,889/QALY.

While these results are extremely promising for bariatric surgery, the validity of this analysis and others like it depends on the quality of the research in bariatric surgery. Unfortunately, bariatric surgery studies are plagued by inadequate patient retention and short durations of follow-up. The accepted standard for patient retention in both published studies and clinical practice is 50%, which is far below the norm for clinical studies in other areas of medicine. These low retention rates are highly problematic because they have the potential to introduce strong selection bias. Patient attrition after bariatric surgery is very likely related to satisfaction with the surgery and its effects.

Thus, reported results from bariatric surgery likely overestimate rates of diabetes remission and improvement and underestimate costs.

In conjunction with the practice of allowing low retention rates, follow-up time for the majority of bariatric surgery studies is less than 2 years. This short duration of follow-up is thought to be appropriate for most surgical research since complications usually occur within a few years of surgery. However, bariatric surgery can also cause lifelong side-effects such as nutritional deficiencies, dumping syndrome, cholelithiasis (as described above), and long-term operative complications (to be described in the following chapters), which may be underrepresented in short-term studies The need for studies of the long-term effects of bariatric surgery is well-known, and efforts are being made to address it.

1.2.7.5 Quality of Life

Patients who have severe weight problems also have to live with the social stigma attached to this condition. This often leads to issues such as depression and difficulties in social interactions as well as lack of confidence and low self-esteem. Weight loss surgery will have a significant and superior impact on the quality of life of severely obese patients compared with traditional treatment (97).

The lifestyle benefits of weight loss surgery include: Improved mobility and stamina; better mood and greater self-esteem; better relationships; enhanced quality of life (102); patients become less self-conscious; they develop a greater ability to explore social and vocational activities formerly inaccessible; they benefit from increased marital satisfaction (102). It is important to note, however that some patients fail to achieve the quality of life that they think that the surgery will provide them (39). This is sometimes due to complications of the weight loss itself such as loose and baggy skin, with some patients wishing that they had never had the surgery (103,104). These issues are discussed further below. The importance of careful psychological assessment and pre-operative screening cannot be understated.

The Cons of bariatric surgery

1.2.7.6 Complications and Side-effects

1.2.7.6.1 Perioperative Mortality

Severe complications have decreased over time; deaths generally occur in less than 1% of patients. The Swedish Obese Subjects study reported 5 deaths in 2,000 patients, corresponding to a mortality rate of 0.2% (105); however, single series and population studies have reported significantly higher mortality rates approaching 2% (106-108) with the highest figures pertaining to complex revision procedures.

Low perioperative mortality rates affect the interpretation of the role of weight reduction per se on mortality, now demonstrated to be reduced after bariatric surgery (84-87). Operative mortality is strongly related to surgical volume (109) and has decreased dramatically with the wide adoption of laparoscopic procedures during the last 6 years. A comprehensive systematic review comparing short-term mortality among 5,780 patients with laparoscopic adjustable gastric banding (0.05%), 2,858 with vertical banded gastroplasty (0.31%) and 9,258 patients with gastric bypass (0.50%) demonstrated significantly lower mortality rates with laparoscopic adjustable gastric banding. The most common causes of death are pulmonary embolism, unrecognized intra-abdominal leaks and myocardial infarction, although the incidence of fatal myocardial infarction is lower after surgical than medical treatment of obesity (106).

A recent NIH funded study is arguably one of the most significant studies ever conducted on the safety of bariatric surgery (110). This was the first large-scale study conducted by LABS (Longitudinal Assessment of Bariatric Surgery), which followed 4,776 first-time bariatric surgery patients for 30 days at 10 U.S. hospitals between 2005 and 2007 (3.412 gastric bypass patients and 1,198 gastric band patients, 166 patients had other procedures that were not included in the final analysis). Some of the key findings were at 30 days post-surgery, researchers found the mortality rate among patients who underwent a Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding to be 0.3%, and a total of 4.3% of patients had at least one major adverse outcome. Complication rates were greater in people with a history of clot problems, sleep apnoea and certain other medical issues. The study found that the risks of bariatric surgery have dropped dramatically and, currently, the risks are no greater than gallbladder or hip replacement surgery. The risks of surgery are lower than the longer-term risk of dying from heart disease, diabetes and other consequences of carrying more weight than a person's organs can tolerate. The findings of this research strongly reaffirm the safety of bariatric surgery and should help to inspire greater confidence from the general public and policymakers.

1.2.7.6.2 Surgical Complications

Overall the mortality rate associated with bariatric surgery is low (0.08%-0.31%) (111). A recent systematic review has shown that most post-operative complications tend to occur after bypass surgery but the reoperation rate is highest in those undergoing gastric banding (111). Some complications are procedure-specific: for example adjustable gastric banding does not entail entering the gastrointestinal tract and does not affect bowel function. However, band erosion can cause pain and obstruction. Pouch enlargement and band slippage can result in acid reflux, and slippage can also contribute to vomiting and can lead to gastric ischaemia if the prolapsed stomach twists forming a volvulus. Patients who undergo biliopancreatic diversion may suffer from significant reflux and also metabolic complications due to malabsorption (112). The former is rarely seen after gastric bypass because most of the stomach acid-producing cells are excluded and the latter does not occur either with bypass as only a short segment of small intestine is bypassed in relative terms to the whole length of the small intestine.

Marginal ulcers may develop at any stage after gastric bypass surgery on the intestinal side of the anastamosis and may occur in up to 10% of patients. The aetiology is multifactorial and may be related to one or more of the following: gastric acid; tobacco; non-steroidal anti-inflammatory drugs; Helicobacter pylori; gastro-gastro fistula; anastomotic tension with or without ischemia, foreign body (suture), and large pouch size (113). In operations involving stapling of the GI tract, added risks (1%) from bleeding and leak exist and rise if the surgery is of a revisional nature.

Similarly, surgical approach (open versus laparoscopic) affects the types of complications. A recent review of gastric bypass (114) found statistically significant differences in numerous complications, particularly wound problems in 6.6% of open procedures compared with 3% in laparoscopic cases. Incisional hernias are more common after open surgery, whereas other complications are more common after laparoscopic surgery, such as small-bowel obstruction (3.1% versus 2.1%), anastomotic stenosis (4.7% versus 0.7%) and gastrointestinal bleeding (1.9% versus 0.6%). There were no differences in the number of leaks (1.2%), pulmonary emboli (< 1%) or pneumonia (0.1-0.3%). Specific complications related to the laparoscopic gastric bypass will be discussed in the next Chapter.

1.2.7.6.3 Cholelithiasis

Obesity itself is a major risk factor for cholelithiasis. However, accelerated weight loss, which occurs after gastric bypass surgery, may result in cholelithiasis (115). One study reports 36% of 105 gastric bypass patients develop gallstones within 6 months (116).

1.2.7.6.4 Nutritional deficiencies

Long-term adverse effects of bariatric surgery include deficiencies of vitamins and minerals, especially after diversionary malabsorptive operations. Gastric-restrictive operations have mostly caused iron deficiency in menstruating women, due to reduced meat consumption; rarely excessive vomiting can cause thiamine deficiency sometimes leading to neuropathy (117). Gastric bypass and biliopancreatic diversion are associated with deficiencies of vitamin B12 (118), folate, calcium and vitamin D (119-120). Patients are urged to have blood nutrient levels monitored yearly. Although not proven, it is our understanding that daily oral vitamin and mineral supplementation is sufficient to prevent the aforementioned deficiencies from occurring in bypass and band patients. The varying efficacy of oral vitamin B12 supplementation is partly related to patient adherence, although some studies have demonstrated decreased uptake after surgery (118). Bone loss tends to occur during the first year after gastric bypass surgery and then stabilizes with unchanged vitamin D levels (120).

1.2.7.6.5 Weight-loss Failure

The most challenging long-term complication of bariatric surgery is poor or inadequate weight loss. This is defined as %EBWL < 50% for gastric bypass surgery patients but a more accurate definition should encompass return of comorbidities. The incidence of this complication remains unknown, perhaps because most centres do not wish to publish what may be considered to be failures of surgery. One study from Canada reports weight regain in as many as 20% of patients 10 years after surgery (121). Regardless, reoperations are more difficult than primary procedures and have higher perioperative complication rates (122). By and large, failed gastric-restrictive procedures are, nevertheless, best handled by conversion to a diversionary operation. Long-term failure of diversionary operations requires the careful adjustment of intestinal limb lengths to create more malabsorption, with the risk of creating frank malnutrition. This will be discussed more in the next chapter.

1.2.7.6.6 Skin complications

Although weight loss is one of the desired effects of bariatric surgery, unfortunately as this occurs post-operatively, some patients begin to suffer from progressively increasing loose and baggy skin (123). The consequences of this loose skin affects some patients so much that retrospectively they would rather not have undergone a bypass operation (104,103). The most common complication of this skin is in the abdominal region where patients develop a panniculus. They can develop sub-panicular itching, skin rashes, dermatitis and then more functionally, difficulty with exercise, sex and finding clothes that fit (103,104,123). The further drawback for these patients is that although body-contouring surgery exists to try and correct the skin issues, this is not available for everyone (123). Even if funding is secured, they may be faced with multiple further surgeries from which they will have to recover, increased risk of wound infection and poor healing, and even once it has healed then there will be significant additional scarring (103,104,123).

Chapter 2

2. COMPLICATIONS AFTER LAPAROSCOPIC GASTRIC BYPASS

2.1 Introduction and literature review

Laparoscopic gastric bypass is complex surgery that can result in significant complications. These can occur early (within the first 24 hours of surgery), intermediate (within the first 48 hours) or late (more than 48 hours after surgery). Such complications include, but are not limited to, gastro-intestinal (GI) bleeding, anastomotic leak, anastomotic ulceration or fistulation, GI obstruction, deep vein thrombosis and pulmonary embolism, skin complications, nutritional, metabolic and neurological complications, cholelithiasis and rarer complications. The post operative bariatric patient adds an additional challenge to the physician caring for them since they often mask more usual symptoms and signs of the particular complications they are suffering from, and due to their body habitus, clinical and radiological examination can be difficult. It is therefore essential that a high index of suspicion is maintained at all times to save patients from coming to any undue harm. The more common complications post LRYGB are discussed below.

In the early phase following gastric bypass surgery bleeding (1-2%) and leaks (1-2%) at any of the staple lines or anastamoses may occur and require urgent reoperation. Delay in the treatment of a leak may result in severe sepsis and death. The presentation of a leak in the bariatric patient may be subtle with few symptoms other than just feeling ‘unwell’ and a mild tachycardia. Hence the bariatric surgeon must have high vigilence and a low threshold for re-exploration.

Gastric remnant distention can occur acutely or chronically and may present in the early postoperative period or years after surgery from obstruction of the biliopancreatic limb or common channel. Patients are usually in distress and have epigastric pain, nausea, and tachycardia. In addition to leukocytosis, patients with an obstruction distal to the second portion of the duodenum may have elevated liver function test results and pancreatic enzymes from high duodenal pressure.

Marginal ulcers may develop at any stage after surgery and may occur in up to 10% of patients. The aetiology is multifactorial and may be related to one or more of the following: gastric acid; tobacco; non-steroidal anti-inflammatory drugs; Helicobacter pylori; gastro-gastro fistula; anastomotic tension and/or ischemia, foreign body (suture), and large pouch size. Patients with ulcer perforation typically experience acute, severe epigastric pain and present with tachycardia, fever, leukocytosis, and free air on plain radiographs or CT studies.

Yet another specific complication related to the laparoscopic gastric bypass includes gastrointestinal tract obstruction. Due to the very nature of how the gastric bypass is constructed, it can result in blockages from scarring at the various anastomoses or by loops of small intestine becoming kinked secondary to getting stuck in spaces within the peritoneal cavity that did not exist before the surgery. Therefore, a blockage can occur at the gastrojejunostomy from a postoperative stricture (1%) or food bolus obstruction. More distally, small bowel obstruction (SBO) may be related to internal hernia formation (1-2%) where small bowel becomes trapped within iatrogenic gaps in the mesentery of the small bowel or transverse colon (in the case of retrocolic LRYGB). A further complication of the retrocolic LRYGB is Roux limb obstruction caused by narrowing within the transverse mesocolic defect. This tends to present earlier than internal herniation and is usually caused by cicatrix formation and extrinsic circumferential compression of the Roux limb. Chapter 5 looks at this problem in more detail. Other possible causes of small bowel obstruction in this population include intussusception; adhesions; port site hernias; and obstruction at the jejunojejunostomy from kinking, stricture, or blood clot.

Interestingly, the laparoscopic approach results in a higher incidence of post-operative bowel obstruction. In a review including 3464 patients, Podnos et al. (114) reported a higher frequency of both early and late obstructions in laparoscopic bypasses when compared to open cases. Similar findings were noted by two prospective trials comparing laparoscopic to open gastric bypasses (124,125). However some reports suggest a similar incidence in laparoscopic and open cases (126,127). Nelson et al (128) compared the incidence of small bowel obstruction between 326 laparoscopic and 458 open gastric bypasses and found that the difference was not statistically significant. One reason attributed to the higher incidence of obstruction with the laparoscopic approach is because very few adhesions are formed allowing small bowel loops freedom to move and become 'stuck' in spaces that did not exist before the surgical 're-organisation' that occurs with the gastric bypass.

Internal hernias after gastric bypass are an important cause of bowel obstruction and a previous review article estimates mean time to presentation at nine months postoperatively but this is likely to be an underestimation because of the limited duration of follow-up (51). The observed weight loss in the time period between initial operation and internal hernia development certainly as weight to the hypothesis of reduced intra-peritoneal fat leading to larger mesenteric defects (129) and thus greater herniation risk. Paroz et al (130) have also noted a mean loss of 14.5 BMI units between primary operation and internal hernia presentation.

The reported literature documents significant variation between studies in regards to hernia location. Garza et al (131) reported transverse colon hernias as the most common in their series. Interestingly, they did not encounter any entero-enterostomy hernias which comprise the second largest group in our series. Comeau et al (132) and Carmody et al (133) reported Petersen's hernias as the most common site, which comprised only 7% in our population. Paroz et al (130) and Eckhauser et al (134) reported entero-enterostomy as the most common location. In a review article, Ianelli et al (51) found transverse mesocolon as the most common site of herniation. Similarly, Higa et al (135), in their review of 2000 consecutive gastric bypass patients, found transverse mesocolon as the most common location. This is in agreement with previous reports though some studies put the incidence of Peterson's hernias above enteroenterostomy hernias (136). The reasons underlying the observed differences are not well known as an antecolic Roux limb by definition obviates the need to create a window in the transverse mesocolon and this in turn eliminates this site as a potential area for herniation. This has been noted previously (126, 137, 138, 132) and is also the reason why some surgeons have switched from the retrocolic to the antecolic route. However, others favour the reduced tension on the gastrojejunostomy with retrocolic Roux positioning.

Despite what is known, there remain many unanswered questions – who gets internal hernias, when do they occur, what causes some to be symptomatic, some deadly and some remain subclinical, and of course what can the surgeon do to minimise complications related to internal hernias? What is perhaps most interesting to note is that internal hernias can potentially also occur in other branches of gastrointestinal surgery where there is division of the mesentery. This includes colorectal surgery, hepatic and oesophagogastric resectional surgery necessitating a roux-en y type reconstruction (139). Perhaps the reason why internal hernias have become more commonly seen in gastric bypass for weight loss is because firstly, nearly all such surgery is now performed using the laparoscopic approach (resulting in far fewer adhesions that would normally 'fix' bowel loops) and secondly, the weight loss subsequent to surgery leads to mesentery thinning (loss of fat from the mesentery) making intraperitoneal gaps and spaces appear where previously there were none.

2.2 Conclusions of literature search

Obesity has reached epidemic proportions in the developed world. RYGB offers an efficacious and reliable method of weight loss. Over the last decade, the number of bariatric procedures performed each year has grown exponentially. It is inevitable that general surgeons will encounter post-operative complications with higher frequency due to increased numbers of index surgeries performed. In depth knowledge of post-bypass anatomy and careful interpretation of imaging studies is essential to prompt diagnosis and treatment of this group of patients.

Since the time of open gastric bypass surgery, surgeons have been noting the incidence of complications and these have been focussed mainly on wound problems and immediately life threatening complications of bleeding and anastomotic leaks. The laparoscopic era has shifted the focus away from wound problems towards intestinal obstruction which is firstly, more common than bleeds or leaks and, secondly, seemingly occurs more frequently using the laparoscopic approach. In particular, internal hernias, though described in the surgical literature previously, have hitherto been an uncommon finding for the average gastrointestinal surgeon. There is a dearth of evidence documenting this complication with very few large patient series with long follow-up. Moreover the causes of intestinal obstruction after LRYGB, their incidence, detection and potential technique for to reduce their occurrence remains unanswered.

2.3 Outline of the thesis

The work presented in this thesis attempts to improve our understanding of the causes of SBO after LRYGB. It focuses on the two commonest causes of SBO complication – internal hernias and roux limb obstruction after LRYGB. I then look at intra-operative ways of minimising the incidence of internal hernias in particular.

In the next chapter, I will present a detailed analysis of the causes of SBO following LRYGB. The chapter will discuss the experience at a high volume center with the management of post-LRYGBP intestinal obstruction, with special focus toward clinical presentation, aetiology, and the diagnostic clues used. In chapter 4, a detailed analysis is made of how best to image symptomatic IH after LRYGB. Chapter 5 looks at another cause of SBO after LRYGB, namely Roux limb constriction at the transverse mesocolic rent. The aim of that study is to examine the incidence of Roux limb compression with particular attention to the timing of presentation and associated weight loss. A Kaplan-Meier time to event analysis is performed to compare Roux limb obstruction with internal hernia. Chapter 6 focuses on different surgical techniques that may be used by the surgeon to try and reduce the incidence of internal hernias. Chapter 7 utilises root cause analysis techniques for the first time in the field of bariatric surgery to analyze the operative videos of 3 groups: an IH group, a Roux compression group, and a control group. All errors were categorized and an assessment made to see if any particular intraoperative errors can be identified that predispose to IH or roux limb compression. Chapter 8 looks at a different surgical technique of performing gastric bypass (antecolic, non mesenteric division and non closure of IH spaces) and analyses its effects on IH incidence.

2.4 Aims of the thesis

(i) To assess the aetiology and incidence of small bowel obstruction after laparoscopic Roux-en-Y gastric bypass

(ii) To understand the common radiological findings in symptomatic internal hernias

(iii) To analyse the condition of Roux limb obstruction secondary to constriction at the transverse mesocolon window

(iv) To assess the impact of surgical technique on the incidence of internal hernia in particular:

(a) the method of closing mesenteric defects and antecolic Roux limb placement,

(b) the use of bioabsorbable glycolide copolymer staple-line reinforcement and internal hernia incidence

(v) To perform a root cause analysis of bowel obstruction after LRYGB using Observational Clinical Human Reliability Assessment (OCHRA)

(vi) To investigate an alternative surgical technique, namely antecolic antegastric, LRYGB without mesenteric division, in an attempt to reduce IH incidence.

2.5 Thesis Methodology

Chapters 3, 4 and 5 provide descriptive statistics of prospectively collected but retrospectively analysed surgical data. This surgical data was obtained through physically reviewing the medical records of all patients undergoing surgery to relieve intestinal obstruction after LRYGBP between May 24, 2001, and December 1, 2006 at the Strong Health Bariatric Center, Highland Hospital. This set of patients was identified through interrogating the hospital's internal bariatric surgery electronic database over the specified time period using the specific procedure codes used for gastric bypass and reoperation after gastric bypass. This yielded over 2300 entries. The medical records (including operating room records) of these were scrutinised to assess those patients that had a reoperation for bowel obstruction specifically (other causes for reoperation included body contouring surgery, reoperating for bleeding, leaks, and abdominal wall hernia repairs). Patients with gastrojejunal strictures were treated endoscopically and were not included in this series. Also, intestinal obstructions occurring after open bypasses were excluded. This yielded a subset of 111 patients whose notes were painstakingly reviewed and factual data extracted to feed a purpose built spreadsheet (see Appendix 1). A standardized protocol was used for data extraction. Records were reviewed to note patients' demographic data, operation date and type of LRYGB, time to representation with SBO, presenting symptoms, imaging studies used, causes identified at exploration, and type of procedure performed (laparoscopic vs open). Operative notes were analyzed in detail to assess the technique used to perform gastric bypass including Roux limb orientation, the use of adjuncts such as staple line reinforcement and the type of sutures and their placement in the closure of IH defects. For data capturing in Chapter 7, individual videos of operations were reviewed by two assessors.

As particular chapters focus on individual causes of small bowel obstruction, and in some cases its management, the study sample cohort size changes appropriately. This, and the statistical analysis for each individual study is described in the chapter's methodology section.

Chapter 3

3. AETIOLOGY OF SMALL BOWEL OBSTRUCTION AFTER LAPAROSCOPIC GASTRIC BYPASS

3.1 Introduction

The proven efficacy of laparoscopic gastric bypass has resulted in increased popularity of this procedure and is currently the most common bariatric procedure performed worldwide (140). Compared to its open counterpart, the laparoscopic approach results in a lower rate of wound complications, incisional hernias and a shorter hospital stay. However, LRYGB has been reported to have a higher incidence of small bowel obstruction (114,124-125). In this chapter, a detailed study of the causes of SBO after LRYGB is presented.

3.2 Aim

To examine the clinical presentation and causes of intestinal obstruction after LRYGB

3.3 Methods

3.3.1 Patients

All patients undergoing surgeries to relieve intestinal obstruction after LRYGB were included between Jun 01 and Sep 06. Intestinal obstructions occurring after open bypasses were excluded.

3.3.2 Setting

Strong Health Bariatric Center, Highland Hospital

3.3.3 Procedure

During the study period, 2325 LRYGB were performed using a standardised technique. Procedures were performed using five 12 mm trocars. Access to peritoneal cavity was gained using trocar with visualization at the left upper quadrant or umbilical region. The remainder of the trocars were placed over the right upper quadrant, subxiphoid and left flank regions under direct laparoscopic visualization. Jejunum was divided about 30 cm from the ligament of Treitz using a linear stapler. A side to side enteroenterostomy was accomplished using linear stapler 150 cm distal to the point of Jejunal division. The resultant enterotomies were closed using 3-0 Vicryl sutures. “Anti-obstruction sutures” as described by Brolin (141) were placed to prevent angulation at enteroenterostomy. A 20-30 ml stomach pouch was created by sequential firing of linear stapler. If a retrocolic technique was used, the Roux limb was passed through a window in transverse mesocolon into the lesser sac and mesenteric defects at enteroenterostomy, mesocolon and Petersen’s sites were closed using non-absorbable sutures. In cases where antecolic technique was used, the Roux limb was passed through a small opening created in the omentum. Mesenteric closures were not undertaken in antecolic cases. Side-to-side gastrojejunostomy was performed using a linear stapler in all cases and a double-layered, hand sown closure was used for resultant enterotomies.

3.3.4 Assessment

A retrospective review was performed between Jun 01 and Sep 06. Patients medical notes were reviewed to record presenting symptoms, aetiologies identified at exploration and type of procedure performed (laparoscopic versus open).

3.3.5 Statistical analysis

The clinical presentation and causes are tabulated. Chi-square test was used. Significance level was set at p value of <0.05.

3.4 Results

3.4.1 Patients characteristic

Over the study period, 111 procedures were carried out with a pre-operative diagnosis of intestinal obstruction out of a total of 2325 laparoscopic gastric bypasses performed. No evidence of intestinal obstruction was found in 9 cases and these procedures were labelled as negative explorations. In the remaining 102 cases, intestinal obstruction was confirmed intra-operatively, yielding an overall incidence of 4.38%. The 102 cases presenting with SBO were mainly women (94 women and 8 men) which mirrors the population of patients undergoing LRYGB. Mean age was 44, pre-LRYGB BMI was 50 kg/m^2 and mean BMI at the time of reoperation was 34 kg/m^2.

3.4.2 Clinical picture

Most of the patients in our series presented with abdominal pain, which was documented in 91 (82%) patients. Other common presenting symptoms included nausea in 54 patients (48.6%), vomiting in 52 patients (46.8%), bloating in 3 patients (2.7%) and dysphagia in one patient (0.9%). Thirty one (27.9%) patients were noted to present with all three of the above motioned symptoms.

3.4.3 Onset of presentation

The interval between LRYGB and intervention for bowel obstruction varied greatly ranging from 3 to 1215 days with a mean of 313 days. Figure 2.1 presents the distribution of surgical explorations over time. We witnessed a steady decline in the number of explorations performed for intestinal obstruction with increasing interval after LRYGB.

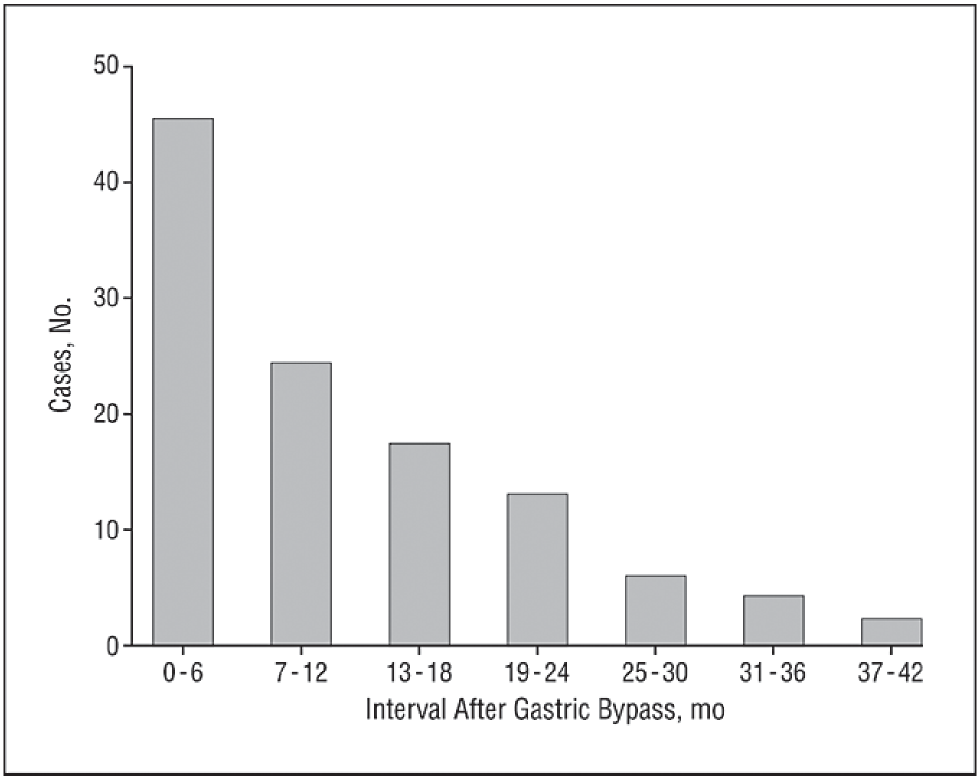


Figure 2.1 Distribution of small-bowel obstruction after gastric bypass

3.4.4 Causes of bowel obstruction

Out of a 102 cases of bowel obstruction confirmed upon exploration, the most common cause in our group was internal hernias seen in 55 patients (53.9%). The second most common cause of intestinal obstruction was scar-induced stricture of the Roux limb as it passed through the mesocolic window encountered in 21 patients (20.5%). Adhesion induced obstructions were encountered in 14 patients (13.7%). Remaining causes of small bowel obstructions were angulation at enteroenterostomy observed in 7 patients (6.8%), 2 patients (1.9%) at port site and at enteroenterostomy level and one patient (1%) of abscess induced obstruction.

Out of a total of 111 explorations, laparoscopic technique was used in 92 patients (83%) and conversion to open procedures was required in only 19 patients (17%). Pathology necessitating bowel resection was encountered in 2 cases. There were no deaths in this series.

3.4.5 Discussion

This is one of the largest series of bowel obstructions post LRYGB that has been studied. Over the study period, 111 procedures were done with a pre-operative diagnosis of intestinal obstruction out of a total of 2325 laparoscopic gastric bypasses performed. Nine explorations were considered negative as no evidence of intestinal obstruction was found intra-operatively. In the remaining 102 cases, intestinal obstruction was confirmed intra-operatively; an overall incidence of 4.38%. The reported incidence of small bowel obstruction after LRYGB ranges from 1.5 to 5% (126,142,136,143,137).

Most of the patients in our series presented with abdominal pain, which was documented in 82% of patients. We encountered both acute abdominal discomfort and chronic, intermittent presentations. Other common presenting symptoms included nausea and vomiting. Nausea and vomiting, the dominant symptoms of small bowel obstruction (144), were seen in less than half of our patients (48.6% and 46.8% respectively). Due to the small size of gastric pouch, voluminous vomiting is rarely encountered in this patient population and most of our patients reported small amounts of clear emesis or dry heaving. Bilious vomiting in a gastric bypass patient indicates obstruction at or beyond the level of enteroenterostomy until proven otherwise and warrants an expeditious workup and intervention. One notable exception is Gastro-gastric fistula, which may manifest as abdominal pain and bilious vomiting; however, this is a rare complication with a completely isolated gastric pouch (145).

The most common cause of obstruction in our group was internal hernias seen in 53.9 % cases. Interestingly, internal hernias are reported to be a rare complication after open gastric bypasses (135). The second most common cause of intestinal obstruction was scar induced stricture of the Roux limb as it passed through the mesocolic window, encountered in 20.5% cases and further analysis of this is presented in Chapter 4. Surprisingly, adhesion induced obstructions which usually comprise the leading cause of post-op bowel obstruction in open surgeries comprised only a small fraction of patients (13.7%).

Reported literature about laparoscopic management of post LRYGB intestinal obstructions indicates a high rate of conversion to open when intestinal obstructions were managed laparoscopically. Champion et al (126) reported a conversion rate in cases of bowel obstruction of 2/13 while Nguyen et al (142) reported a rate of 2/8. Papasavas et al (138) were able to manage 14 out 15 obstructions laparoscopically. We were able to successfully relieve obstruction laparoscopically in the majority of the cases and conversion to open procedures was required in only 19 cases.

Small bowel obstruction in bypass population is frequently complicated by bowel ischemia and often involves bowel resection. Hwang et al (136) required bowel resection in 30/55 cases and Capella et al. reported resection in 3/68 (146). Frezza et al (147) described resection in 14% cases. In our series, only two patients required bowel resection. We follow a policy of maintaining a high index of suspicion and a low threshold for laparoscopic exploration which, perhaps, resulted in the lower resection rate. The drawback of this policy is potential for negative explorations which were encountered in 9/111 cases in our series. However, the risks associated with delayed intervention outweigh the risk of a negative exploration.

Chapter 4

4. RADIOLOGICAL FINDINGS IN SYMPTOMATIC INTERNAL HERNIAS

4.1 Introduction

Clinically, internal hernias can be asymptomatic or cause significant discomfort ranging from constant vague epigastric pain to intermittent colicky periumbilical pain. Patients with symptomatic internal hernias often present acutely to the emergency department with clinical features suggestive of bowel obstruction – intolerance of oral intake, nausea, vomiting and abdominal pain. Symptom severity relates to the duration and reducibility of the hernia and the presence or absence of incarceration and strangulation. The differential diagnosis includes anastomotic stricture, Roux limb constriction (in cases of retrocolic Roux limb placement), adhesions, cholelithiasis, and marginal ulceration.

In order to narrow the diagnosis, diagnostic imaging techniques need to be used. These include plain abdominal X-ray, ultrasound, Upper Gastro-Intestinal UGI series and Computed Tomography CT scan. Because of the propensity of these hernias to spontaneously reduce, patients are best imaged when they are symptomatic. However delayed treatment can have catastrophic consequences and patients with worrisome findings on presentation should be considered for immediate surgical exploration without radiological work-up.

4.2 Aims

The objective of this study was to determine (i) the most accurate imaging modality to diagnose internal hernias post LRYGB and (ii) radiological signs suggestive of internal herniation.

4.3 Methods

4.3.1 Patients

We performed a retrospective review of the notes of all patients (2578) undergoing LRYGB and identified those who developed symptomatic internal hernia requiring operative intervention between Jan 1, 2000 and September 15, 2006. During the postoperative observation period, 58 patients presented with abdominal pain, nausea, vomiting, or a combination of these symptoms and were found at relaparoscopy to have an IH; thus, the overall IH rate in the series was 2.2%.

4.3.2 Setting

Strong Health Bariatric Center, Highland Hospital

4.3.3 Details of radiological procedures

Imaging modalities were (i) plain X-ray; (ii) upper GI series with orally administered water-soluble contrast medium (diatrizoate meglumine and sodium [Gastroview]; Mallinckrodt Medical, St Louis, Mo); (iii) Helical CT scanner (Philips Brilliance 16P, Philips, Cleveland, Ohio) with section thickness of 5mm whereas the scans were obtained with intravenous 100 mL of 64% iodinated non-ionic contrast medium (ioversol [Optiray 300]; Mallinckrodt Medical) administered at a rate of 2–3 mL/sec with a power injector (OptiVantage DH, Liebel-Flarsheim,Mallinckrodt Medical). Oral contrast medium was also used routinely.

4.3.4 Assessment

A retrospective review of the medical records of the 58 patients with an IH was conducted and the following information noted: the types of radiological tests performed on presentation and their results were recorded; all radiology reports were accessed using an electronic radiology results database (Stentor) and the final verified radiologist report used for this study. A second analysis was performed to see if any clear radiological patterns emerged suggesting (i) presence of internal herniation and (ii) location of internal herniation.

4.4 Results

Fifty eight symptomatic internal hernias were recorded, of which 56/58 (97%) underwent radiological investigation; 2/58 went directly to surgery. Figure 3.1 demonstrates the types of imaging tests performed in the cohort. A number of patients underwent more than 1 imaging tests. Table 3.1 summarizes the results of the imaging tests performed. For the purposes of our analysis, a positive finding of an internal hernia is defined as any abnormal radiological finding suggestive of intestinal obstruction since direct identification of an internal hernia defect itself is difficult.

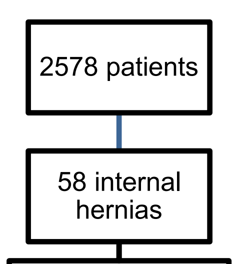


Figure 3.1 Diagnostic imaging tests performed in 58 symptomatic internal hernias.

Table 3.1 Type of diagnostic imaging modality performed and results.

Radiological test performed	***N***	***Positive finding suggestive of internal hernia (%)***
Abdominal x-ray	41	19 (46%)
CT	37	34 (92%)
Upper GI contrast	26	17 (65%)
CT + Upper GI contrast	10	10 (100%)
Ultrasound abdomen	8	0 (0%)

None of the 8 abdominal ultrasound scans diagnosed internal hernias. The main indication for ordering abdominal sonogram was to exclude acute gallbladder pathology. Thirty four out of 37 (92%) CT scans (with oral contrast) performed were reported positive for internal hernia. The CT scan reports were further analysed and their findings summarized. Four recurring findings suggestive of internal hernia were identified: (i) dilated small bowel, (ii) distended gastric remnant, (iii) excess small bowel loops in the lesser sac, and (iv) thickened fluid filled small bowel. Of the 3 internal hernias (2 transverse mesocolic and 1 entero-enterostomy) that were negative on CT, two underwent upper GI series which had positive findings suggestive of internal hernia; the third patient underwent laparoscopy as the CT scan although negative for internal hernia demonstrated a thickened appendix suggestive of appendicitis. At laparoscopy, an entero-enterostomy internal hernia was found. Seventeen out of 26 (65%) of upper GI contrast series were reported positive for internal hernia. The upper GI radiology reports identified 4 recurring findings suggestive of internal hernia: (i) dilated fluid filled small bowel loops, (ii) redundant Roux limb in lesser sac, (iii) preponderance of bowel loops in the left upper quadrant, and (iv) slow emptying of contrast with prolonged transit times, especially on delayed films. Of the 9 upper GI series that were reported negative, CT scans were performed in 4 of these and were reported positive for internal hernia. The results of this study also demonstrate that the 10 patients who underwent both CT and Upper GI series had correctly diagnosed internal hernia in all cases. In our secondary analysis, we could not find any evidence to suggest an association between particular radiographic findings and location of internal hernia.

4.5 Discussion

Internal hernias are a known complication after LRYGB with an incidence of around 2% in the present series which is in keeping with a recent review of 26 studies (51). It is important to identify them so that timely treatment may be instituted. Patients often present with non-specific symptoms with a diverse differential diagnosis. Hence it is useful to know which diagnostic imaging test offers the most likelihood of correctly identifying IH. The results of this study indicate that CT scanning with intravenous and oral contrast correctly identified IH in 92% of cases. In equivocal cases, the addition of UGI study increases the diagnostic rate to 100%. Regardless of these findings, it is important not to delay surgical exploration in sick patients, even in the absence of a positive finding on imaging, in the hope that some less threatening diagnosis is responsible for the patient's condition. This practice may lead to potentially devastating bowel strangulation and sepsis.

Previous reports have been published regarding the range of radiological findings seen after LRYGB (50, 148-160). Performing diagnostic imaging in the morbidly obese is associated with certain limitations. There are two main modalities used to aid diagnosis in post-LRYGB patients: Computed tomography (CT) and UGI series. CT in postoperative morbidly obese patients may be difficult or impossible because of excessive weight and girth. UGI studies have the advantage that they can be performed with the patient standing and thus there is no weight restriction. Technical problems do occur and include difficulty in positioning of patients for optimal radiographs, inability to place the image intensifier over the patient, extreme difficulty during fluoroscopy in depicting intraabdominal structures, and suboptimal radiographs caused by markedly scattered radiation (154). On the other hand, spiral CT scanning technology has resulted in shorter scanning time and improved image quality resulting in a detailed view of the anatomy after LRYGB, with all important structures clearly depicted (161). These factors have contributed to the increased use of this modality for the detection of complications after gastric bypass surgery that might not be readily identified with a conventional UGI series. CT also offers the added advantage of providing guidance for interventional procedures such as aspiration and drainage of fluid collections. CT scanning is, however, more expensive and exposes the patient to greater radiation than UGI series.

With regards to IH diagnosis post LRYGB, our UGI diagnostic rate of 65% is similar to that reported previously by Blachar et al who noted 6 of 9 internal hernias correctly diagnosed on UGI in their series of 15 patients presenting with small bowel obstruction

(162). They were able to ascertain from the radiographs that the herniated bowel was usually the Roux limb or the biliopancreatic limb. Our series demonstrates a high diagnostic rate (92%) for IH using CT scan. Both Blachar et al (162) and Yu et al (160) found CT to only correctly diagnose 66% of IH, but their numbers of IH patients that underwent CT were very low, 3 in each study. Interestingly it was noted that the two positive CTs for IH were in the absence of clinical features of bowel obstruction (160). Others have demonstrated that CT scanning allows an accurate diagnosis of IH after liver transplantation which also necessitates a Roux-en-Y reconstruction (163-165).

Although it is difficult to distinguish small-bowel obstruction caused by adhesions from that caused by internal hernia on the basis of findings from CT, UGI series, or both; there are certain repeated radiological findings in the series of 56 IH that underwent preoperative diagnostic imaging. In particular the finding of clustered small bowel loops in the left upper quadrant seems to be a fairly specific finding for IH in the study as well as that of Blachar et al who noted this specific finding was present in 89% of patients with IH (162).

Whilst we were unable to document any association between a particular radiological sign and type of IH (transverse mesocolic vs. enteroenterostomy vs. Peterson's), others have found that the appearance of internal hernias, particularly on CT, depends on their location. Clustering of dilated small-bowel loops and crowding and congestion of the mesenteric vessels are generic features seen in all IH cases (149). But in cases of herniation through the transverse mesocolon, the herniated cluster of bowel is located posterior relative to the stomach (in the lesser sac) and may exert mass effect on its posterior wall. In herniations through the small-bowel mesentery, the clustered bowel is pressed against the abdominal wall with no overlying omental fat, causing central displacement of the colon (149). The same investigators also noted that the Peterson type hernia is difficult to diagnose because it has neither a confining sac nor a characteristic location, and the only clues to its presence may be engorgement and crowding of the mesenteric vessels and evidence of small bowel obstruction.

In this study, 41/56 IH patients had a plain abdominal X-ray and 8/56 patients underwent abdominal sonogram. Emergency department physicians requested the plain X-rays. Just under half of these were reported as having signs consistent with IH. In fact there is no radiological sign for IH on plain abdominal radiograph, but the radiologists reports took into account the context in which the X-rays were taken, namely, in post LRYGB patients with clinical features of subacute bowel obstruction and this, in turn, provided an important clue to the underlying diagnosis. Unsurprisingly, none of the sonograms were positive for IH, the reason being they were requested to rule out gallbladder pathology (acute cholecystitis) post LRYGB.

This study has some important limitations. The primary limitation of the study is that it is retrospective, and results therefore are compromised by the factors that limit all retrospective studies. In addition, the results are affected by a population bias in that only patients with suspected IH underwent diagnostic imaging. Currently, we do not have imaging data on post-LRYGB patients who are asymptomatic or only mildly symptomatic and yet have IH. Hence, I am unable to calculate sensitivity, specificity, positive and negative predictive values for CT and UGI as diagnostic tests for IH. Another limitation is that regarding the standardization of administration time of oral contrast agents prior to imaging. Unfortunately, these data were not noted and it may influence the diagnostic rate for IH, particularly in the context of CT scanning. However, tolerance of per oral intake in this group if acutely presenting with IH patients will always be limited.

Upper gastrointestinal radiography and CT are useful in depicting the normal anatomy after gastric bypass surgery and are complementary in detecting complications after surgery, thus allowing early diagnosis and treatment. Internal hernias present a diagnostic challenge. Preoperative CT scanning indicated the presence of IH in 92% of cases in the current study, the diagnostic rate rising to 100% when CT is combined with UGI examination. Regardless, patients with worrisome findings on presentation should be considered for immediate surgical exploration without radiological work-up.

Chapter 5

5. ROUX LIMB OBSTRUCTION SECONDARY TO CONSTRICTION AT TRANSVERSE MESOCOLON WINDOW

5.1 Introduction

Small bowel obstruction is a recognised complication of laparoscopic Roux-en-Y gastric bypass (LRYGB) occurring in up to 4.3% of patients undergoing surgery (Chapter 2). Causes include internal herniation, postoperative adhesive bands, anastomotic strictures and incarcerated incisional hernias. In retrocolic LRYGB, partial small bowel obstruction can also occur as a result of circumferential extrinsic compression of the retrocolic Roux limb as it traverses the transverse mesocolon rent from thickened cicatrix formation in this area. Patients can present with acute symptoms of vomiting and, occasionally, with less acute symptoms of upper abdominal discomfort and intolerance of any oral intake other than liquids. Upper GI contrast study and CT scan can confirm the diagnosis, however, in some cases the diagnosis is only clear at laparoscopy. In most cases the Roux limb can be mobilised laparoscopically to resolve the compression caused by cicatrisation and thus relieve the obstruction. Previous studies have noted the incidence of retrocolic Roux limb compression to be 0.4-1.2% (126,142,136,138, 166, 167) although no definite evidence has been forthcoming regarding the timing of this complication post weight loss surgery.

5.2 Aim

The aim of this study is to examine trends in Roux limb constriction at the transverse mesocolic window after retrocolic LRYGB.

5.3 Methods

5.3.1 Patients

Between Jan 1, 2000 and September 15, 2006, 2215 patients underwent retrocolic LRYGB. During the observation period, 20 patients presented postoperatively with abdominal pain, nausea, vomiting, or a combination of these symptoms. They were all investigated with an upper GI contrast study and were found at re-laparoscopy to have Roux limb compression at the transverse mesocolic defect.

5.3.2 Setting

Strong Health Bariatric Center, Highland Hospital

5.3.3 Surgical technique

The operative technique used for the retrocolic LRYGB begins with CO2 insufflation. The small bowel is divided approximately 30 cm from the ligament of Treitz with an ETS-45 stapler (Ethicon Endo-Surgery Inc, Cincinnati, OH). Distal bowel is measured 150 cm and this will be the length of the Roux limb. A side-to-side functional end-to-side enteroenterostomy is performed between the afferent limb to the 150 cm mark on the Roux limb. A transverse application of the ETS-45 stapler with the 3.5 mm cartridge is followed by multiple vertical applications of the same type of stapler to create a completely isolated proximal gastric pouch approximately 15 to 30 cc in volume. The harmonic scalpel is used to create a longitudinal window in an avascular area in the transverse mesocolon just lateral of the middle colic vessels. The stapled end of the Roux limb is passed across the aforementioned rent retrocolic retrogastric and a side-to-side functional end-to-end gastrojejunostomy is performed. We used a continuous 3/0 silk suture to secure the Roux limb to the transverse mesocolon to prevent Roux limb slippage and transverse mesocolic hernias. In September 2003, we switched from using a continuous suture to using 4 x 3/0 interrupted silk stitches to secure the Roux limb to the transverse mesocolon in an attempt to reduce our Roux obstruction rate, hoping that interrupted sutures will be less of a stimulus for cicatrix formation.

Our operative technique for treating Roux limb compression at the transverse mesocolon rent comprises establishing pneumoperitoneum. By elevating the transverse colon cephalad and toward the anterior abdominal wall, the transverse mesocolon defect is exposed. Previously placed stitches anchoring the Roux limb circumferentially to mesocolon are cut and the transverse mesocolic space is gently stretched to break free cicatrix, occasionally the harmonic scalpel is required to maintain haemostasis. At this stage it is quite common to find the Roux limb circumferentially indented where it was being externally compressed by cicatrix. A further 3 to 4 stitches are then reinserted between Roux limb and mesocolon to prevent occurrence of transverse mesocolic internal hernia.

5.3.4 Assessment

A retrospective review of the medical records of the 20 patients with Roux limb obstruction was performed and the following information recorded: the patient's age, sex, and preoperative BMI; the mesocolic window closure technique (interrupted vs continuous suture); the upper GI contrast study result; the amount of postoperative weight loss (percentage of excess body weight lost [%EBWL]); and the postoperative time to presentation with Roux limb obstruction.

5.3.5 Statistical analysis

The information obtained on patients with Roux limb obstruction in whom the mesocolic window was closed with continuous suturing (657 of the 2215) was compared with data on patients with interrupted closure of the same (1558 of the 2215). Chi square test was used to test the hypothesis that a difference in suturing technique affects Roux limb obstruction incidence. A second follow-up analysis was used to compare the Roux obstruction group of patients with a second series of patients from the same population of 2215 LRYGB patients who developed internal hernias to evaluate time to event difference in the two groups. The Kaplan-Meier method was used for this follow-up analysis and the groups were compared with the log-rank test. A p value less than or equal to 0.05 was considered to represent a significant difference.

5.4 Results

The overall incidence of Roux limb obstruction in our series was 0.9%. The mean follow-up time in the entire series of 2215 patients who underwent LRYGB was 36 months. The mean time until postoperative presentation with abdominal symptoms in the 20 patients found to have Roux limb compression was about 48 days after LRYGB. These patients presented acutely to the Emergency Department or through an urgent outpatient consultation with symptoms of abdominal pain, intolerance of oral intake, nausea and vomiting. All patients were managed laparoscopically by releasing the constricted Roux limb by the technique described above; none of the cases required any bowel resection.

Table 4.1 shows demographic, operative, and follow-up data on the 20 patients in whom Roux limb obstruction occurred after LRYGB. In 18 of the 20 patients, upper GI contrast study confirmed the diagnosis by demonstrating dilated small bowel in the lesser sac and/or a stenosis at the transverse mesocolic defect (Figure 4.1).

Table 4.1 Demographic, operative, and follow-up data in patients with postoperative Roux limb obstruction, according to mesocolic window closure using continuous suture or interrupted suture

	Patients with Roux limb obstruction (n = 20)		
	Continuous suture closure (n = 11)	**Interrupted suture closure (n=11)**	***p* value**
Mean age, years (range)	42 (25-55)	42 (25-60)	
Sex: M/F	1/10	1/8	
Mean preoperative BMI	47	48	
Mean no. of postoperative days to presentation with Roux obstruction (range)	53 (27-105)	42 (24-114)	0.17
Average % excess body weight loss (%EBWL) at presentation with Roux obstruction	29	28	0.22
Incidence (%)	11/657 1.7%	9/1558 0.6%	***0.02***
Upper GI contrast study diagnostic	Yes (10/11),	Yes (9/9)	

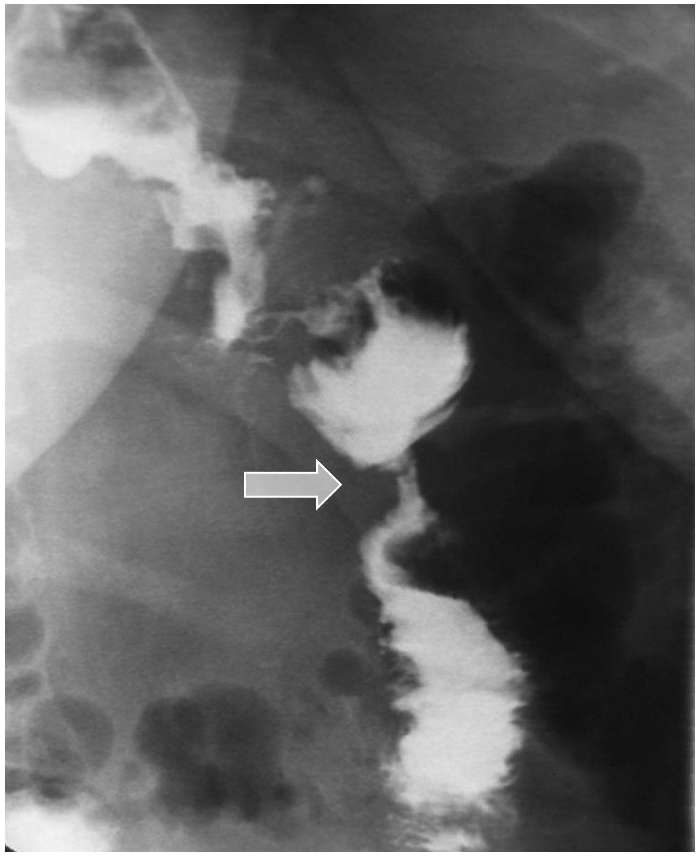
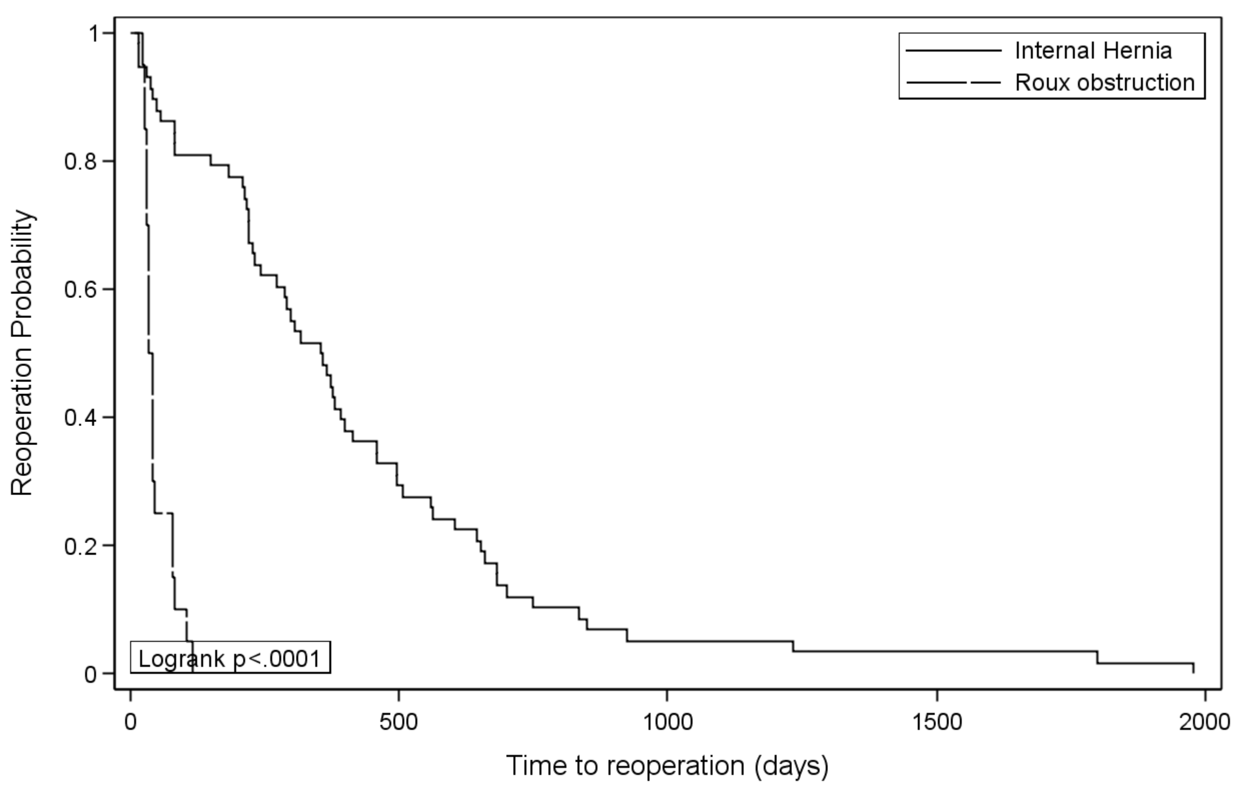


Figure 4.1 Upper GI contrast study x-ray demonstrating compression of Roux limb as it goes across the transverse mesocolic rent

In the other two cases, the radiologist's report was equivocal but the surgeon felt Roux limb compression was present in one case; previous contrast from a CT scan made the upper GI series images in the other case difficult to interpret. The Roux limb obstruction rate among 657 patients who had a continuous closure of the mesocolic defect was 1.7%, whereas that among the 1558 patients who had interrupted closure was 0.6%; this difference was significant (p = 0.02). Among the 20 patients in whom Roux obstruction occurred, the baseline patient demographics, amount of weight loss, and time to presentation were similar in the continuous suture-closure and the interrupted suture-closure groups. There was, however, a difference in mean follow-up time in the 2 groups (48 months for continuous closure vs. 24 months in the interrupted group).

Figure 4.2 shows time to reoperation when comparing 20 patients in whom bowel obstruction occurred from Roux obstruction compared with a series of 58 internal hernia patients from the same population of 2215 LRYGB patients. Roux limb obstruction patients present for surgery significantly earlier than those patients who have internal hernias ($p < 0.0001$ for difference in time to presentation).



	No. of Subjects	Event	Censored	Median Survival (95% CL)
Internal Hernia	58	100% (58)	0% (0)	355.0 (241.0 414.0)
Roux obstruction	20	100% (20)	0% (0)	37.5 (32.0 44.0)

Figure 4.2 Time to reoperation for Roux limb obstruction or internal hernia: Kaplan-Meier estimates of survival function

5.5 Discussion

Narrowing at the transverse mesocolon rent is an uncommon complication after laparoscopic (retrocolic) Roux-en-Y gastric bypass. Our 0.9% incidence in 2215 patients is consistent with Higa and Boone's rate of 1% in their series of 1040 patients (126). Our data report the incidence of this complication in one of the largest documented series of retrocolic LRYGBs, which benefits from an extensive mean follow-up period (3 years).

This study demonstrates that upper GI contrast study is useful in making the diagnosis. 95% of cases were successfully diagnosed pre-operatively. Based on our findings, we advocate the use of upper GI series when Roux limb compression is suspected. In a series of 11 asymptomatic postoperative patients, Smith and White noted on upper GI series five (45%) exhibited a circumferential irregular narrowing with intact mucosal appearance, corresponding to the point at which the Roux limb passed through and was sutured to the transverse mesocolon (168). There exists, therefore, a possibility of having an abnormal radiographic appearance in the absence of symptoms.

Our time-to-event analysis demonstrates that unlike internal hernias, which tend to occur later in the clinical course, Roux limb obstruction occurs much earlier after LRYGB. Several researchers have suggested that the commonly observed long time to presentation with internal hernias may be associated with a decrease in mesenteric fat with weight loss over time that results in a pulling through of sutures in the mesentery tissue (51, 137, 146). The observed time gap of 48 days to Roux limb obstruction development would be consistent with scar tissue development at the mesocolic rent compressing the Roux limb.

Using interrupted stitches in place of a continuous stitch to close the mesocolic window appears to reduce the incidence of Roux limb compression. This is not unexpected as a single stitch is likely to have a purse-stringing effect when tightened, thus, narrowing and compressing the mesocolic window circumferentially around the Roux limb. Another possibility may have been to leave the mesocolic space completely open but this would increase the risk of internal hernia. Using other types of suture material in place of silk to close this space may also have an impact in reducing cicatrix formation. The risk of Roux limb compression together with the increased incidence of mesocolic internal hernias may persuade some surgeons to choose an antecolic Roux limb placement to avoid these complications altogether.

The primary limitation of this study is that it is retrospective, and it is therefore liable to all the potential factors that limit retrospective studies. In addition, the true incidence of Roux obstruction may have been underestimated in this study, as only symptomatic cases will have been reported. Furthermore, some cases may have been missed if they presented to other hospitals, although we urge our patients to return to our centre for any postoperative problem. All retrocolic LRYGBs will have been performed by one surgeon although various surgical trainees may have performed different parts of the operation including closure of the mesocolic defect. The impact of this is difficult to assess but all operations were wholly supervised and assisted by the senior surgeon and thus there is no reason to suspect this will have had a significant effect on the results of this study.

It may be argued that the 20 cases of Roux limb obstruction identified in this study were managed sub-optimally by release of cicatrix and circumferentially re-suturing Roux limb to mesocolic rent, a situation that may lead to a repeat of the event. An alternative would have been laparoscopic conversion to an antecolic alimentary limb. This is a considerable undertaking and it was judged as unjustifiable. None of the 20 patients presented in this series had any recurrence of Roux obstruction and none have presented to date with internal hernia.

Chapter 6

6. IMPACT OF SURGICAL TECHNIQUES ON THE INCIDENCE OF INTERNAL HERNIA

This chapter entails two studies to investigate the influence of different surgical techniques on the incidence of internal hernias.

6.1 Effect of the method of closing mesenteric defects and antecolic Roux limb placement

6.1.1 Introduction

It has been suggested that the laparoscopic approach results in fewer postoperative adhesions and thus reduced fixation of small intestine loops to the abdominal wall (126). The subsequent increased mobility of bowel loops leads to an increased risk of entrapment in hernia defects created as a result of the operation. Furthermore, it has been observed that the vast majority of internal hernias present months and not days after surgery (162). It has been postulated that the weight loss seen in these patients, typically occurring some months after surgery, results in reduced intraperitoneal fat which in turn leads to larger mesenteric defects. Potential internal hernia locations include: transverse mesocolon defect, enteroenterostomy mesenteric defect and Petersen's space (the area in between the posterior aspect of the mesentery of the Roux limb and the transverse mesocolon). Complications (if left untreated) of internal hernia may include closed loop obstruction leading to bowel strangulation and/or anastomotic dehiscence as well as gastric remnant dilatation. Consequently, the patient may suffer bowel perforation (9.1%) and death (1.6%) (135).

Previous studies have suggested that certain intraoperative factors may influence the incidence of internal hernia. Some of these include: closure of all potential defects with running suture, using nonabsorbable suture, and antecolic Roux limb placement rather than retrocolic.

To further investigate the effects of surgical technique, one of the surgeons in the study switched to using a continuous running closure of all mesenteric defects versus interrupted which was being done previously; the other surgeon switched to using only antecolic Roux limb placement.

6.1.2 Aim

This study aims to examine (i) when do internal hernias occur and what degree of weight loss has occurred by this stage, (ii) whether switching to running closure of mesenteric defects has an impact on incidence of internal hernia, and (iii) whether using an antecolic Roux limb placement affects the incidence of internal hernia.

6.1.3 Methods

6.1.3.1 Patients

All patients undergoing LRYGB and developed symptomatic internal hernia requiring operative intervention between Jan 1, 2000 and September 15, 2006 was performed. For each case, age, gender, weight, body mass index (BMI) and time gap from initial surgery to secondary presentation with internal hernia were recorded.

6.1.3.2 Setting

Strong Health Bariatric Center, Highland Hospital

6.1.3.3 Review of cases

This is a retrospective review of the notes and operative records to assess the method used (interrupted nonabsorbable versus continuous nonabsorbable) for closure of the mesenteric defects and whether an antecolic or retrocolic Roux limb placement was used.

6.1.3.4 Statistical analysis

GraphPad Instat version 3 (GraphPad Software Inc., USA) was used to perform statistical analysis. The data are expressed as mean +/- standard error of mean (SEM). Odds ratios were calculated following Chi-square statistical analysis. A p value <0.05 was accepted as significant.

6.1.4 Results

A total of 2572 patients underwent LRYGB in the study period.

Table 5.1 Incidence of internal hernia

Total Internal hernia incidence	54/2572 (2.1%)
Mean (±SEM) time to intervention	413 ±46 days; (Range: 14-1978)
Average % excess body weight loss (%EBWL±SEM) at intervention	59 ±3.3; (Range 9-108)

Fifty four patients (50 women and 4 men) had to undergo further surgery to treat the complication of internal hernia. Mean age was 42, pre-LRYGB BMI was 50 kg/m^2 and mean BMI at the time of reoperation was 34 kg/m^2. Out of the 54 patients presenting with internal hernias, 34 (63%) had undergone abdominal operations (mainly tubal ligations followed by Caesarian section, appendectomy and cholecystectomy) prior to their gastric bypass surgery. There was no significant difference in age and gender distribution in internal hernia patients compared to those patients with no internal hernia. Overall, the site of internal hernia varied with transverse mesocolon hernias being the most common, followed by enteroenterostomy and then Peterson's space hernias (Figure 5.1). In the antecolic LRYGB group, internal hernias were equally distributed between Peterson's defect and the enteroenterostomy defect.

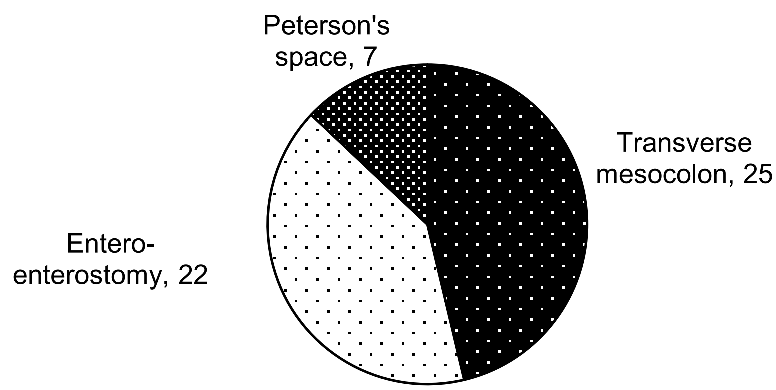


Figure 5.1 Nature of 54 internal hernias

Table 5.2 demonstrates the impact of operative technique on internal hernia incidence. Subgroup analysis demonstrates the internal hernia incidence to be 2/357 (0.6%) in antecolic Roux versus 52/2215 (2.4%) in retrocolic Roux limb (Odds ratio= 4, P=0.03). Furthermore, of the 7 patients presenting with a Peterson's type internal hernia, 3 had undergone interrupted closure and 4 had undergone continuous closure of this defect. Of the 22 enteroenterostomy internal hernias, 13 underwent interrupted closure of the defect and 9 continuous closure. The impact of the suturing technique used on internal hernia incidence was not statistically significant, *P* = 0.79. All the patients presenting with transverse mesocolic window internal hernias had interrupted closure of this space and not continuous suturing due to the increased theoretical risk of causing Roux limb compression with the latter.

Table 5.2 Impact of operative technique on internal hernia incidence.

Operative technique		***Internal hernia incidence***	***p* value**
Roux limb	Antecolic	2/357 (0.6%)	Odds ratio= 4
	Retrocolic	52/2215 (2.4%)	*P* = 0.03
Suturing of mesenteric defects	Continuous	9/22* 4/7**	*P* = 0.79
	Interrupted	13/22* 3/7**	

* Enteroenterostomy defect; **Peterson's defect

6.1.5 Discussion

This work documents one of the largest reported series of internal hernias accrued over a six-year period. It demonstrates that internal hernias, on average, present some 14 months after the initial surgery. By this stage, the average weight loss has been around 44 kg with the majority of patients experiencing 52-66%EBWL (mean 59%). Most (88%) of the patients with internal hernias were noted within the first two years after surgery. Only 12% of patients were diagnosed afterwards. A previous review article estimates mean time to presentation at 9 months postoperatively but this is likely to be an underestimation because of the limited duration of follow-up (51). The observed weight loss in the time period between initial operation and internal hernia development certainly adds weight to the hypothesis of reduced intraperitoneal fat leading to larger mesenteric defects (129) and thus greater herniation risk. Paroz et al (130) have also noted a mean loss of 14.5 BMI units between primary operation and internal hernia presentation. Whatever the mechanism, the incidence of internal hernia in this study was around 2% and this makes it one of the most common long-term complications after LRYGB and, therefore, emphasizes the need for early exploration in patients presenting with symptoms and signs of bowel obstruction after LRYGB. Failure to do so may result in serious consequences of bowel ischemia and perforation.

The location of internal hernias has been documented with transverse mesocolon hernias commonest followed by enteroenterostomy and then Peterson’s space hernias. The reported literature documents significant variation between studies in regards to hernia location. Garza et al (131) reported transverse colon hernias as the most common in their series. Interestingly, they did not encounter any enteroenterostomy hernias which comprise the second largest group in our series. Comeau et al (132) and Carmody et al (133) reported Petersen’s hernias as the most common site, which comprised only 7% in our population. Paroz et al (130) and Eckhauser et al (134) reported enteroenterostomy as the most common location. In a review article, Ianelli et al (51) found transverse mesocolon as the most common site of herniation which is in agreement with our findings. Similarly, Higa et al (135), in their review of 2000 consecutive gastric bypass patients, found transverse mesocolon as the most common location. This is in agreement with previous reports though some studies put the incidence of Peterson's hernias above enteroenterostomy hernias (136). The reasons underlying the observed differences are not well known. We showed that Roux limb configuration plays a significant role as transverse colon hernias seem to be the most common amongst retrocolic Roux placement whereas enteroenterostomy hernias appear to be the most common in antecolic Roux placement.

An attempt has been made to analyse what operative factors affect the risk of developing internal hernias. As such, an antecolic Roux limb by definition obviates the need to create a window in the transverse mesocolon and this in turn eliminates this site as a potential area for herniation. Our study demonstrates a fourfold increased risk of internal hernias when a retrocolic Roux limb is used. This has been noted previously (126, 137, 138, 132) and is also the reason why some surgeons have switched from the retrocolic to the antecolic route. However, others favour the reduced tension on the gastrojejunostomy with retrocolic Roux positioning.

One of the surgeons evaluated in this study switched from interrupted closure of the enteroenterostomy mesenteric defect and Peterson's space to running closure on the 1st of October 2003 whilst maintaining all other aspects of the operation unchanged. The hypothesis was that a running closure would ensure a complete closure of the mesenteric defect. The rate of internal hernias before and after this change did not reveal any differences. This may be the result of low power of the study, particularly as the effect is likely to be small. Other surgeons who have modified their operative techniques, changing from absorbable to non-absorbable sutures and from interrupted to running sutures have noted a reduction in the incidence of internal hernias (51,135, 130, 169, 170).

Although not directly part of the analysis of this study, it is interesting to note that all the internal hernias in the study were managed via laparoscopic reduction and suturing of the mesenteric defect, no bowel resections were needed.

This is a retrospective study and, therefore, is subject to all the potential flaws associated with this form of analysis. However, the majority of the data was captured from patients' operative notes which are transcribed according to a standardized template thus reducing the chance of missing data. The internal hernia incidence was dependent on our postoperative patients presenting with symptoms and signs warranting investigation. It is possible that the actual incidence of internal hernia may be higher if one includes cases that have not become symptomatic enough. Internal hernias may not necessarily present as an all or none effect with bowel obstruction. Small bowel may episodically become trapped and untrapped at the site of an internal hernia and these episodes may present quite subtly without typical bowel obstruction features. Therefore, clinician alertness is a factor in the correct diagnosis of internal hernias. Accurate calculation of the incidence of internal hernias also depends on patients returning to this institution and not presenting to other hospitals' emergency departments. The centre where the study was performed emphasises continued clinical follow-up after bypass with an overall follow-up of 80%. Lastly, errors may be introduced into the analysis from combining the outcomes of two different surgeons. Both surgeons in our group followed a standardised operative technique mirroring each other except for Roux limb positioning.

Internal hernias are an important complication of LRYGB, presenting usually a year after surgery. Not surprisingly, the use of an antecolic Roux limb eliminates the occurrence of the transverse mesocolic hernia thereby reducing the total incidence of internal hernia. It remains to be seen whether switching to a running closure of the mesenteric defects instead of interrupted sutures will significantly alter the incidence of internal hernia.

6.2 Bioabsorbable glycolide copolymer staple-line reinforcement and internal hernia incidence

6.2.1 Introduction

Randomized controlled trials have shown that application of bioabsorbable glycolide copolymer staple-line reinforcement (SLR; GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement, WL Gore & Associates, Inc, Flagstaff, AZ) to the mesenteric defects created by the LRYGB procedure (Figure 5.2), or to the gastric pouch, decreases the rate of intraoperative staple-line bleeding and may reduce the incidence of postoperative gastrointestinal haemorrhage (171, 172).

6.2.2 Hypothesis and Aim

In our unit, SLR was initially used in 2003 to mitigate staple-line bleeding in LRYGB procedures. We later observed adhesion formation at the cut edges of the mesentery (where the SLR had been placed) in patients undergoing a second abdominal operation (Figure 5.3). We hypothesised that such adhesiogenesis creates a strong tissue-fusion–based bond that may prevent or decrease development of IHs after LRYGB. In January 2003, one surgeon evaluated in this study switched from suturing closed all mesenteric defects created at surgery to applying bioabsorbable polymer SLR to all cut mesenteric ends and not formally suturing the defects. This is a retrospective study to examine whether use of SLR was associated with a decreased rate of IH formation after LRYGB.

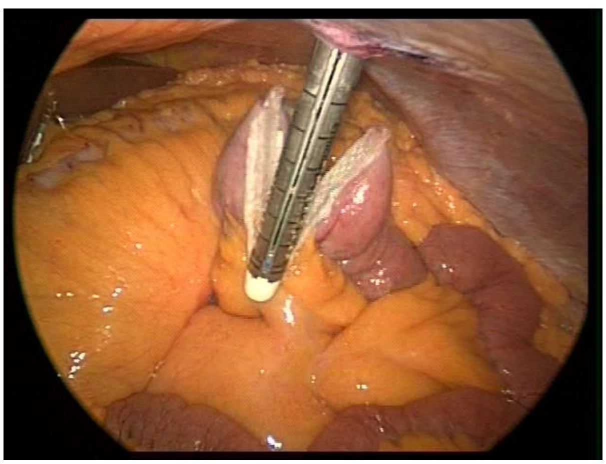


Figure 5.2 Intraoperative photograph showing stapling and concurrent application of bioabsorbable glycolide copolymer staple-line reinforcement to bowel and mesentery during a laparoscopic Roux-en-Y gastric bypass.

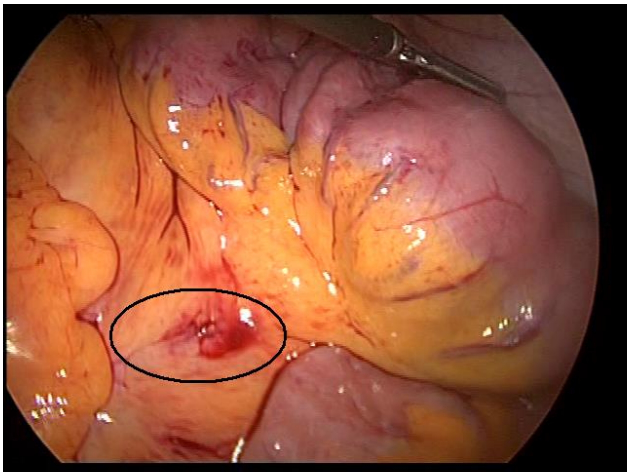


Figure 5.3 Photograph obtained at diagnostic laparoscopy performed 12 months after the patient underwent laparoscopic Roux-en-Y gastric bypass. The bioabsorbable glycolide copolymer staple-line reinforcement has created a bond (within circle) at the junction between the two mesenteric defects.

6.2.3 Methods

6.2.3.1 Patients

Between January 2003 and September 2005, 1704 patients underwent LRYGB in our study. In 1350 cases (79%), all mesenteric defects were closed by suturing (3-0 silk). In the other 354 cases (21%), bioabsorbable polymer SLR was applied during stapling and the mesenteric defects created at surgery were left alone.

6.2.3.2 Surgical technique

6.2.3.2.1 Suture-closure group

Pneumoperitoneum was established, and the omentum and transverse colon were reflected, exposing the ligament of Treitz. The small bowel was divided approximately 30 cm from the ligament of Treitz with use of an ETS-45 stapler (Ethicon Endo-Surgery

Inc, Cincinnati, OH), and a second firing was made through the mesentery with a 2.5-mm cartridge. About 150 cm of the distal bowel was measured out to establish the length of the Roux limb. A side-to-side functional end-to-side enteroenterostomy was performed to create the anastomosis between the biliopancreatic and Roux limbs. The mesenteric defect was closed with running 3-0 silk sutures to mitigate the risk of an IH at the enteroenterostomy.

A trial movement of the Roux limb in the antecolic antegastric position was performed to check for possible tension on its mesentery. If potential tension was observed, the stapled end of the Roux limb was passed retrocolic through an avascular rent in the transverse mesocolon into the lesser sac space and then retrogastric to the gastric pouch. The gastric pouch was fashioned by using a transverse application of an ETS-45 stapler (3.5-mm cartridge), followed by multiple vertical applications of the stapler to create a completely isolated proximal pouch with a volume of approximately 15 to 30 ml. The stapled end of the Roux limb was then positioned beside the gastric pouch and a side-to-side functional end-to-end gastrojejunostomy performed. The defect in the transverse mesocolon was closed circumferentially around the Roux limb with five interrupted 3-0 silk stitches to decrease the risk of a development of a mesocolic IH. To reduce the likelihood of IH formation at Peterson's space, the Roux limb was tacked to the peritoneal undersurface of the transverse mesocolon with running seromuscular 3-0 silk sutures. The pneumoperitoneum was then released and the trocars were withdrawn.

6.2.3.2.2 SLR group

The surgical technique used in the SLR group was the same as that in the suture-closure group except that the three mesenteric defects were not closed. Instead, the SLR sleeves were loaded on an ETS-45 stapler when the first small-bowel division was made approximately 30 cm from the ligament of Treitz. A second firing was made through the mesentery in the same way. After creation of the enteroenterostomy anastomosis, one 2-0 silk suture was placed on the antimesenteric border of the two bowel limbs just joined to prevent kinking at the anastomosis and to serve as a “crotch” stitch to prevent splaying at the staple line. SLR was not applied at the mesocolic rent in cases in which a retrocolic Roux position was used. Instead, the defect in the transverse mesocolon was closed circumferentially around the Roux limb with five interrupted 3-0 silk stitches to decrease the risk of mesocolic IH.

6.2.3.3 Data collection

During the postoperative observation period, 43 patients presented with abdominal pain, nausea, vomiting, or a combination of these symptoms and were found at re-laparoscopy to have an IH; thus, the overall IH rate in the series was 3%. A retrospective review of the medical records of the 43 patients with an IH was conducted and the following information recorded: the patient’s age, sex, and preoperative BMI; the LRYGB technique used (antecolic or retrocolic); whether the mesenteric defects were closed (suture-closure group) or not (SLR group); the amount of postoperative weight loss (percentage of excess body weight lost [%EBWL]); the total amount of time since the LRYGB operation, the postoperative time to presentation with IH symptoms; and the location of the IH.

The information obtained on patients with IHs in whom SLR was used was compared to the information obtained on patients with IHs who had a suture closure. A second analysis also compared the suture and SLR groups but excluded patients with IHs in the transverse mesocolon so that the LRYGB technique employed would not affect the results (because transverse mesocolic IHs do not occur after antecolic procedures).

6.2.4 Statistical analysis

Fisher's exact test was used in both analyses to compare the IH rate in the suture-closure group with that in the SLR group. A p value less than or equal to 0.05 was considered to represent a significant difference.

6.2.5 Results

The mean follow-up time in the entire series of 1704 patients who underwent LRYGB was 22 months. The mean time until postoperative presentation with abdominal symptoms in the 43 patients found to have an IH was about a year. These patients presented in the hospital's emergency department or an outpatient setting with an acute illness characterized by abdominal pain, intolerance of oral intake, nausea, and vomiting. All IHs were managed laparoscopically by reduction of herniated small bowel and suturing of the mesenteric defect; no bowel resections were required.

Table 5.3 shows demographic, operative, and follow-up data on the patients in whom an IH occurred after LRYGB. The IH rate among the 1350 patients who had a suture closure after LRYGB was 2.9%, whereas that among the 354 patients in whom SLR was used was 0.8%; the difference between the rates was significant ($p = 0.01$). Among the 43 patients in whom IHs occurred, the baseline patient demographics, overall follow-up time, amount of postoperative weight loss, and time to presentation with an IH were similar in the suture-closure and SLR groups.

Because both antecolic and retrocolic Roux limb placements were performed in our series and a difference in IH rates between the two techniques has been described in our analysis. Therefore a separate analysis was conducted to determine the rate of IHs at the enteroenterostomy and Peterson's space alone. Thus, the herniation rates in the suture-only and SLR groups were calculated with exclusion of transverse mesocolic IHs. Data on patients in whom an IH other than a transverse mesocolic lesion occurred are shown in Table 5.3. Twenty of the twenty one patients with an IH in the enteroenterostomy or Peterson's space had a suture closure at LRYGB; only one had application of SLR (p = 0.05 for difference in IH rates).

Table 5.3 Demographic, operative, and follow-up data in patients with a postoperative IH, according to whether LRYGB-created mesentery defects were closed with suture or SLR was applied

	Patients with any IH (n = 43)		**Patients with any IH except transverse mesocolon (n = 21)**	
	Suture closure (n = 40)	**SLR applied (n = 3)**	**Suture closure (n = 20)**	**SLR applied (n = 1)**
Mean age, years (range)	42 (23-58)	48 (51-54)	43 (25-56)	41
Sex: M/F	3/37	½	2/18	1/0
Mean preoperative BMI	50	57	48	44
LRYGB technique: A/R	0/40	2/1	0/20	1/0
Mean no. of days since LRYGB (range)	868 (222-1306)	833 (726-947)	900 (222-1306)	827
Mean postoperative %EBWL	57%	60%	62%	69%
Mean no. of postoperative days to presentation with IH (range)	332 (14-849)	412 (357-506)	336 (14-849)	506
Location of IH				
Transverse mesocolon	20	2	—	—
Enteroenterostomy	16	1	16	1
Peterson’s space	4	0	4	0

Notes. IH denotes internal hernia; LRYGB, laparoscopic Roux-en-Y gastric bypass; SLR, staple-line reinforcement; BMI, body mass index; A/R, antecolic/retrocolic; and %EBWL, percentage of excess body weight lost.

6.2.6 Discussion

A review of the records of the 43 patients with postoperative IH development in our series of 1704 who underwent LRYGB between January 2003 and September 2005 found that the IH rate in patients in whom bioabsorbable polymer SLR was applied when dividing the bowel and mesentery, without closure of the mesenteric defects thereby created, was significantly lower than that in patients who had suture closure of the mesenteric defects.

This study is apparently the first to assess whether use of bioabsorbable polymer SLR in LRYGB would decrease the postoperative IH rate. We think that the presence of SLR on the cut edges of the mesentery evokes local adhesion formation and tissue fusion that creates a bond stronger than that provided by sutures, which may cut through the mesenteric tissue when the amount of fat decreases with weight loss. We hypothesize that this bond sealed the defects created at surgery and decreased the rate of post-LRYGB IH formation. In our opinion, SLR can therefore be used in LRYGB procedures not only with the objective of decreasing gastrointestinal bleeding (171) but also with the aim of reducing the postoperative IH rate. Although we did not directly analyse the operative times in those cases where SLR was applied versus those cases where IH space was sutured close, it was evident that SLR usage had the added advantage of shortening operating time by avoiding the time-consuming process of suture closing the mesenteric defects.

Our study had the usual limitations associated with a retrospective design. It is possible that not all the cases of post-LRYGB IH that occurred in our overall series were identified by our record review. However, our mean follow-up time was long (22 months), and because of the location of study, all our patients who had not moved away would have either presented in the unit's Emergency department when their IH symptoms developed or been referred back to us for treatment if they presented elsewhere. Another possible limitation is that both antecolic and retrocolic LRYGBs were included in our series and the different positioning of the Roux limb could have represented a confounding factor. However, this limitation was addressed by excluding transverse mesocolic IHs from our second analysis.

It may be argued that the use of SLR is not cost effective, particularly because of the low IH rates in some recent studies [0.4% (126), 0.2% (173), and 0% (174)]. SLR application adds cost to each surgery (around GBP 90 per firing of 1 stapler cartridge). Our opinion is that in the light of the costs of hospital or outpatient visits for unexplained episodic abdominal pain, tests ordered to investigate the pain, and, eventually, reoperation, prophylactic use of SLR may save money. Additional studies are required to compare both the costs and outcomes of LRYGB procedures that use SLR with those of other LRYGB techniques.

In conclusion therefore, the results from this study suggest that application of bioabsorbable glycolide copolymer SLR at stapling of the bowel and mesentery may be one useful option in reducing IH . Clearly further investigation of this technique is needed combined with a cost to benefit analysis.

Chapter 7

7. ROOT CAUSE ANALYSIS OF BOWEL OBSTRUCTION AFTER LRYGB USING OBSERVATIONAL CLINICAL HUMAN RELIABILITY ASSESSMENT (OCHRA)

7.1 Introduction

Advanced laparoscopic surgical procedures are characterised by multiple steps. Not only does each step have to be performed meticulously and precisely but also in the correct sequence to ensure desired outcomes are achieved consistently. Failure to so may lead to adverse events and surgical complications. Observational Clinical Human Reliability Assessment (OCHRA) is a technique that allows analysis of the mechanisms underlying technical errors and human factors that shape the performance of surgeons (175).

The study of human error in industry typically uses simulation exercises to predict the occurrence of errors in real circumstances (176). However, these predictions need to be validated by observing and collecting data from real life situations. This led to the development of human reliability analysis, a method of systematically evaluating task performance and the potential consequences of errors. The technique of human reliability analysis has been used for years in high-risk industries (such as nuclear power plants) to study and enhance human performance of complex dynamic interactive tasks (177-180). The aim of this method is to identify what causes errors and what corrective action can be taken to reduce the likelihood of the error recurring.

Surgery requires a high level of manual dexterity. Typically operations can easily be broken down into a series of tasks consisting of steps. Deviation from standard execution of a step or from the sequence order of steps can lead to errors. Laparoscopic operations ideally lend themselves to the human reliability assessment approach as they are performed on visual display monitors with the facility to routinely record the procedures and thus create a source of observational data that can be used for error analysis at a later time.

The application of the OCHRA technique in laparoscopic surgery has been performed in the setting of laparoscopic cholecystectomy (175,181), laparoscopic gastrojejunostomy and cholecystojejunostomy (182), laparoscopic pyloromyotomy (183) and cataract surgery (184).

In the study by Tang et al (175), 200 videos of laparoscopic cholecystectomy performed by 26 different surgeons were analysed for errors. A total of 38062 steps were noted and 2242 errors identified. On average, each operation was found to have 11 errors of which 4 were consequential (had a negative impact). Dissection of Calot's triangle was noted to have the highest concentration of errors and all conversions and postoperative complications resulted from errors committed during this task.

Talbpour et al (182) reviewed 20 videos of laparoscopic bypass operations for advanced gastric and pancreatic cancer (gastrojejunostomy and cholecystojejunostomy). The majority of errors occurred during the task of intracorporeal suturing and consisted of concentration lapses (n=1321), misjudgements (n=209) and impaired coordination (n=108) amongst others. In the same study errors were also used as a measure for the proficiency gain curve during the training phase of this operation.

Tang et al (183) analysed 50 videotapes of laparoscopic pyloromyotomy performed in a Dutch hospital. They found an average of 6 errors per operation. Most of the errors were of the execution type and concentrated in task 3 (“splitting the incision previously made over the pylorus”). Furthermore, in addition to human errors such as use of excessive force during dissection, the study also identified that poor design and functionality of the laparoscopic instruments also played a role in the occurrence of errors.

OCHRA has also been used in the setting of surgical training. Tang et al (185) applied the technique to a training model of laparoscopic cholecystectomy performed by 60 junior surgical residents in an ex-vivo pig model. They identified 1067 errors (331 consequential and 736 non-consequential). Not surprisingly in this cohort, the majority of consequential errors were related to the use of excessive force (execution error). The study also documented a wide variation in the number of errors between trainee surgeons. On the basis of their findings, the authors’ conclusions were that laparoscopic training should be structured, menu-driven and individualised.

These studies demonstrate that any given surgical procedure can be divided into a series of tasks and that each task is subject to errors. These errors can be classified in relation to the underlying causative mechanism either into procedural and execution errors. Procedural errors correspond to the ability of the surgeon to execute a number of steps in the correct order. Execution errors are those resulting from a failure of the surgeon to execute a specific component step of the operation in the correct manner. The end result of an error may be neutral (inconsequential error) or negative (consequential errors).

7.2 Applying OCHRA to LRYGB complications – IH and Roux compression

A number of studies have looked at the technique of OCHRA retrospectively to analyse the nature of technical errors that can occur during a particular operation. This yields useful information on what are the critical parts of an operation, and what mechanisms can be placed to minimise errors in these segments, so called 'error-reduction' mechanisms. Such surgical error reduction systems may include better cognitive training to reduce procedural errors, and practical training in laparoscopic box trainers or virtual reality simulators, which may help reduce execution errors.

However, to the best of our knowledge, no one has used OCHRA to analyse a particular task within a surgical procedure (known to have a postoperative complication) to see if there is any association with errors observed during the performance of that task and that particular postoperative complication.

In the previous chapters, I described the incidence and trends of two causes of bowel obstruction observed after LRYGB – internal hernias (IH) and Roux limb compression. The current knowledge on the operative factors that may lead to internal hernia formation and Roux limb compression were described. Retrocolic Roux limb placement causes significantly more internal hernia formation than antecolic placement. Also, the use of interrupted sutures results in less Roux limb compression than running sutures but does not cause a statistically significant difference when it comes to IH at the TM.

To date, there has been very little investigation of the surgical errors at the index operation that could favour an internal hernia or Roux limb compression. It is possible that errors occurring during the suturing of the mesenteric defects may lead to, or contribute to, the development of post-operative complications. Laparoscopic surgery requires a high skill level and thus a significantly higher error rate is likely.

In order to answer the aforementioned question, in this chapter, we describe the use of OCHRA on operative videos of (i) LRYGB complicated by IH, (ii) LRYGB complicated by Roux compression and (iii) LRYGB without complications to see if there is any association between any observed errors at the index surgery and incidence of IH or Roux compression postoperatively.

On completion of the data collection, the errors identified can be correlated with their resultant complications, to identify the errors that play a role in the occurrence of internal hernias as oppose to Roux limb compression. If analysis shows that most errors are procedural, this will highlight the need to reinforce operative rules and may indicate that training needs to focus more on menu-driven execution. If on the other hand, errors are mainly due to poor suturing technique, this emphasises the need for more practice of this specific skill. In this way, the study may help to identify the corrective action needed to reduce the incidence of internal hernia and Roux limb compression.

7.3 Aim

The aim of this study is to analyse intraoperative performance and identify technical causes underlying the occurrence of internal hernia and roux compression.

7.4 Methods

7.4.1 Study cohort selection

The study cohort was retrieved from a comprehensive database of 2215 consecutive retrocolic LRYGB procedures at the University of Rochester Medical Centre (URMC) between 2000 and 2005. Forty-seven patients developed either an internal hernia at the transverse mesocolon or Roux limb compression postoperatively. Of those, 25 full-length videos could be retrieved. Twenty-one operative videos of patients without any complication (median follow up of 7 years) were randomly selected. The videos/DVDs were coded, with the observer blinded to the outcome of the operation. For each video/DVD, the patient ID number, gender, preoperative BMI and weight loss was recorded.

7.4.2 OCHRA

As described earlier, OCHRA is a method to analyse technical errors occurring during surgical performance. These methods were derived from similar techniques used in other high-risk industries (186,187). The procedure consists of a formal task and error analysis, followed by observations of the operation. Finally, observations with a negative outcome were analysed in order to identify common anomalies from the normal process.

7.4.2.1 Task and subtask analysis

Our technique of LRYGB has already been described in the previous chapter. The operation is lengthy and consists of numerous complex steps. A task analysis has been performed and divided the procedure into 27 steps (Table 6.1). For the purposes of this study, we have selected those videos of LRYGB for analysis where the outcome has been either (i) IH at TM or (ii) Roux compression. We have also included a control arm where the patients, to date, have not suffered from neither of the two complications. As the study is only interested in the postoperative complications of IH at TM and Roux compression, the task analysis is focused on steps of the operation when the Roux limb is secured in the transverse mesocolon rent in order to close this potential internal hernia defect.

Table 6.1 Task analysis for retrocolic LRYGB

No.	***Task***
1.	Patient is placed on the operating table in the supine position with foot board and leg straps.
2.	General anaesthesia is administered.
3.	The patient's abdomen is prepped and draped in sterile fashion including use of Opsite.
4.	The abdominal cavity is entered through a small, transverse, Left Upper Quadrant incision with the bladeless 12-mm trocar loaded with the 10-mm O-degree laparoscope under laparoscopic observation.
5.	A pneumoperitoneum is established to 15-mmHg pressure carbon dioxide.
6.	A total of 4 bladeless 12-mm trocars are passed obliquely through the abdominal wall, including left upper quadrant, left flank and umbilical midline.
7.	At this stage the omentum and the transverse colon are then reflected cephalad to expose the ligament of Treitz.
8.	The small bowel is the divided approximately 30-cm from the ligament of Treitz with the ETS-45 stapler and this is followed by a second firing made through the mesentery with the 2.5-mm cartridge.
9.	Distal bowel is measured to 150-cm and this would be the length of the Roux limb.

10. A side-to-side functional end-to-side enteroenterostomy is then performed by tacking the afferent limb to the 150-cm mark on the Roux limb making parallel antimesenteric enterotomies and firing the ETS-45 stapler into the lumen of each.
11. The resulting enterotomy is closed with interrupted 3-0 Vicryl and the mesenteric defect is closed with running 3-0 silk sutures.
12. The stapled end of the Roux limb is passed into the lesser sac space through an avascular rent made with the harmonic in the transverse mesocolon .
13. The gastrocolic ligament is divided and the Roux limb is seen within the lesser sac space below.
14. A small incision is then made below the xiphoid process and a 10-mm blunt probe is passed into the abdominal cavity under laparoscopic observation to retract the left lateral segment of the liver medially exposing the GE junction.
15. The phrenogastric membrane on the left side of the GE junction is sharply then bluntly dissected to free the angle of His.
16. Next a window is made in the lesser omentum along the lesser curvature of the stomach approximately 3-cm inferior to the right side of the GE junction.
17. Again the retrogastric space is entered.
18. A transverse application of the ETS-45 stapler with the 3.5-mm cartridge is followed by multiple vertical applications of the same type of stapler creating a completely isolated proximal gastric pouch approximately 15 to 30 cc in volume.
19. Next the stapled end of the Roux limb is passed into the retrogastric space to lie next to the proximal gastric pouch and a side-to-side functional end-to-end gastrojejunostomy is performed by first making an anterior inferior gastrotomy in the proximal gastric pouch and a matching antimesenteric enterotomy near the stapled end of the Roux limb, applying the ETS-35 stapler to two-thirds of its depth into the lumen of each and firing.
20. The resulting enterotomy is closed with a layer of running 3-0 Vicryl and a second outer layer of interrupted seromuscular 3-0 Vicryl.
21. The 34 French Ewald orogastric tube is introduced, making sure an easy passage across the anastomosis is achieved and is then backed into the distal oesophagus.
22. This is followed by the leak test; With the Roux limb occluded, the anastomosis is submerged under saline and distended with oxygen via the Ewald tube . Multiple distentions while submerged to confirm there is no evidence of leak.
23. The defect in the transverse mesocolon is circumferentially closed around the Roux limb with 5 interrupted 3-0 silk stitches.
24. The Roux limb is tacked to the peritoneal undersurface of the transverse mesocolon with running seromuscular 3-0 silk sutures.
25. The pneumoperitoneum is allowed to escape.

26. The trocars are withdrawn under laparoscopic vision ensuring there is no bleeding from the port site.
27. The wound is irrigated with normal saline and infiltrated with 0.25% Marcaine and closed with staples.

Task step 23, the closure of the mesenteric window was further broken down into 8 subtasks. Table 6.2 demonstrates this task analysis for this particular part of the LRYGB operation. The defect in the transverse mesocolon is circumferentially closed around the Roux limb with 5 interrupted 3-0 silk stitches. The Roux limb is then tacked to the peritoneal under surface of the transverse mesocolon with running seromuscular 3-0 silk sutures. The stitches are placed at specific points as described below. The steps are illustrated in Figure 6.1.

Table 6.2 Task analysis for closure of mesenteric window (step 23)

Step	*Sub-Task*	**Description**
1	Stitch 1	Stitch between transverse mesocolon and Roux limb mesentery left side. The stitch is then secured and the knot ends are cut
2	Stitch 2	Stitch 2: Stitch between transverse mesocolon and mesenteric side of Roux limb left side (2 o'clock). The stitch is secured and the knot ends are cut
3	Stitch 3	Stitch between mesocolon to antimesenteric Roux limb (12 o'clock). The stitch is secured and the knot ends are cut
4	Stitch 4	Stitch between mesocolon to Roux limb, right side (9 o'clock). The stitch is then secured but the ends are left uncut
5	Stitch 5	Stitch between transverse mesocolon and Roux limb mesentery right side. The stitch is secured but the ends are left uncut

6	Running from bottom	Running suture from stitch 5 towards stitch 4
7	Running from top	Running suture from stitch 4 towards stitch 5
8	Securing final knot	Securing of sutures by tying together ends of stitch 5 and stitch 4.

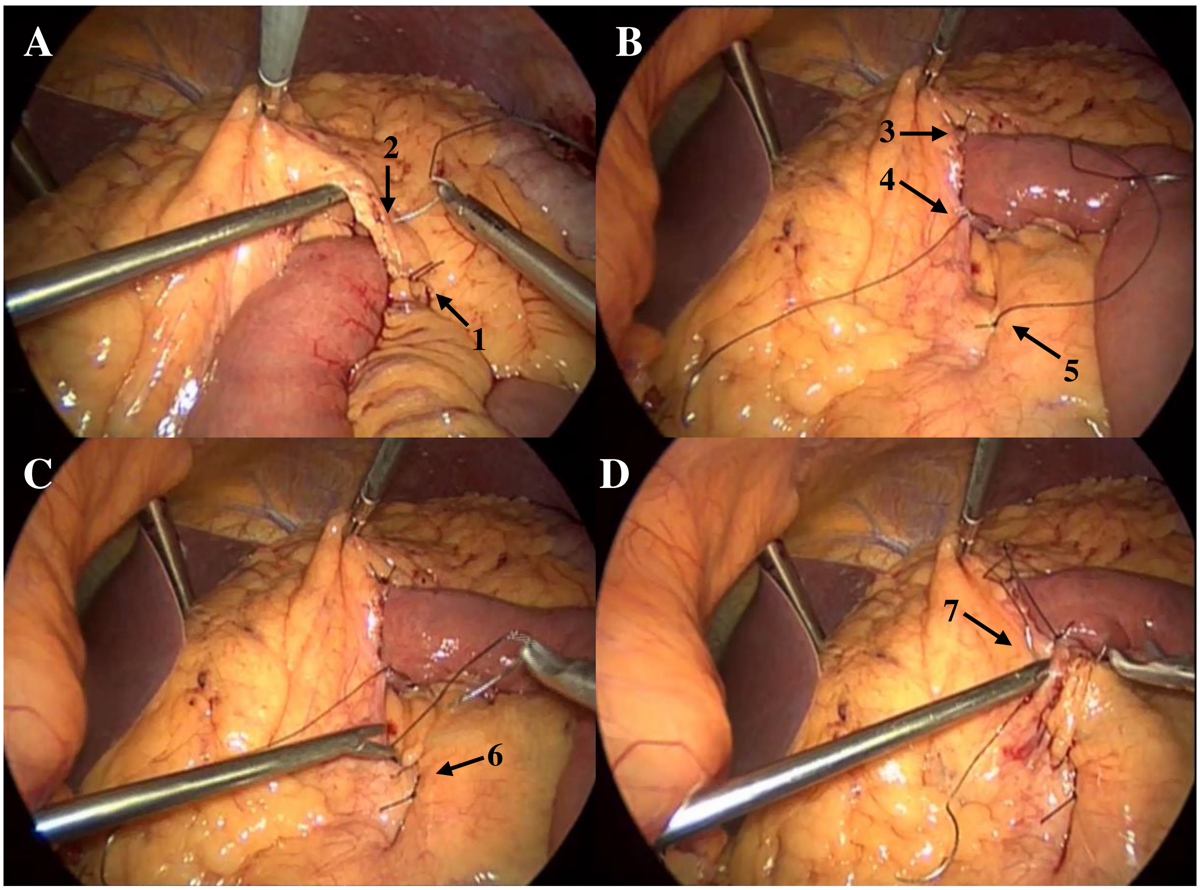


Figure 6.1 a) Stitch 1 between transverse mesocolon and Roux limb mesentery left side. Stitch 2 between transverse mesocolon and mesenteric side of Roux limb left side (2 o'clock). b) Stitch 3 between mesocolon to antimesenteric Roux limb (12 o'clock). Stitch 4 between mesocolon and Roux limb, right side (9 o'clock). Stitch 5 between transverse mesocolon and Roux limb mesentery right side. c) Running suture from bottom, from stitch 5 up to stitch 4. d) Running suture from top, from 4 towards suture 5. The ends of stitch 4 and 5 are then tied together.

6.4.2.2 Categorisation of errors

An error was defined as “something that was not desired according to a set of rules” or “something that led to a consequence outside the acceptable limits” (175). In accordance with this definition, consequential and non-consequential (“near misses”) errors were recorded. The categorisation of errors was based on External Error Modes (EEM), a categorisation system originally developed for human reliability assessment for work processes in nuclear power plants (186). The system was previously adopted and validated for laparoscopic surgery (181). There are 6 modes describing procedure errors and 4 modes describing execution errors. Some errors can potentially be followed by an immediate consequence (e.g. bleeding). If such a direct consequence was present, this was also recorded (Table 6.3).

Table 6.3 Error categorisation using External Error Modes and descriptions of consequential errors

	*EEM**	*Examples*	*Direct consequence (examples)*
Procedural errors	Step not done	Stitch 1 not done	Lose knot Bleed (oozing) Pulsating bleeding Cutting through tissue Haematoma Perforation of bowel Tissue avulsion
	Step partially completed	Number of throws too little	
	Step repeated	Two stitches in position 3	
	Step done in addition	Additional stitch between 1 and 2	
	Second step done instead of first	Stitch 2 before stitch 1	
	Step done out of sequence	Begin with stitch 3	
Execution errors	Too little	- Grasped too much tissue - Stitch is too clockwise	
	Too much	- Grasped too little tissue - Stitch is too anticlockwise	
	Wrong	Wrong knot tying technique	
	Wrong object	Wrong instrument used	

In order to document errors, a scientific event logging software for observational data collection was used (Observer XT, Version 8, Noldus Information Technology Inc., Leesburg (VA), USA). Observer XT is a professional, manual event recorder for the collection, management, analysis and presentation of observational data. It allows the study of behavioural processes at a level of detail that cannot be obtained without an automated system. The observer watches a video, and simultaneously enters their observations (in this study errors committed) in the form of codes according to what he/she has specified in an earlier phase. Each step in the closure of the rent was observed to record the errors committed, as well as any resulting consequences or corrective actions taken. The screenshot for the above is displayed in Figure 6.2.

A second assessor rated all videos after being trained on how to use the software and on the error categorisation system.

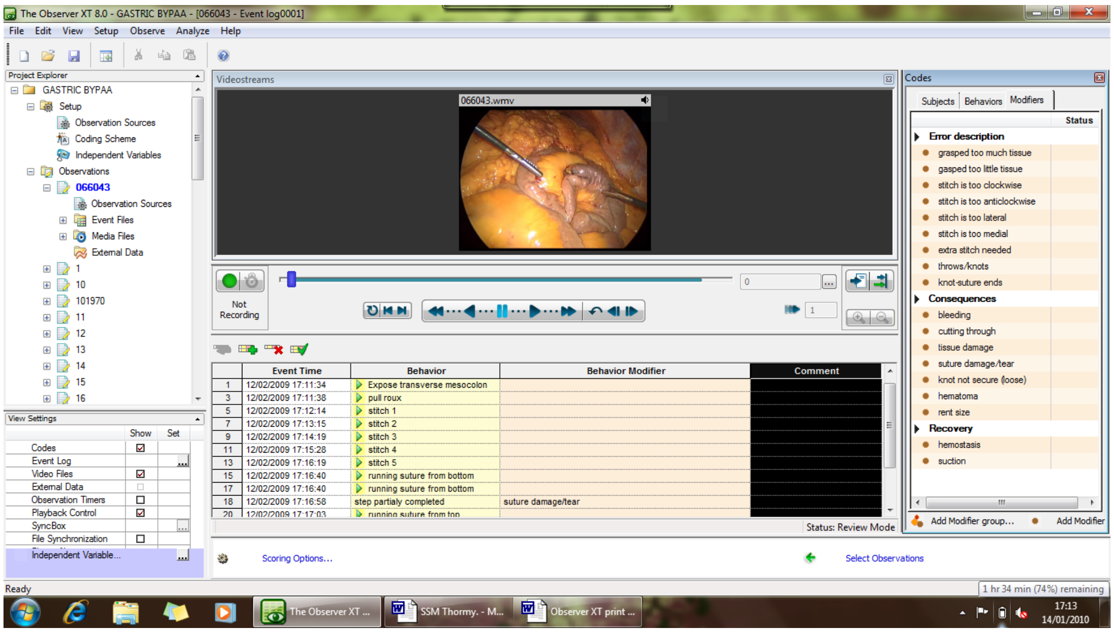


Figure 6.2: Observer XT screenshot

7.4.3 Rent size

In addition to errors, the size of the incision at the transverse mesocolon was estimated. During playback of the operative videos, image capture techniques were used to take stills of the mesenteric rent at the time of creation and prior to step 1. It was ensured that the image captured also included surgical instruments (needle driver, grasper) or needle in the same plane as the rent. The known length of the tip of the instrument in reality and the according distance on the image was used to generate a scale. The scale was then used to estimate the approximate size of the rent (Figure 6.3).

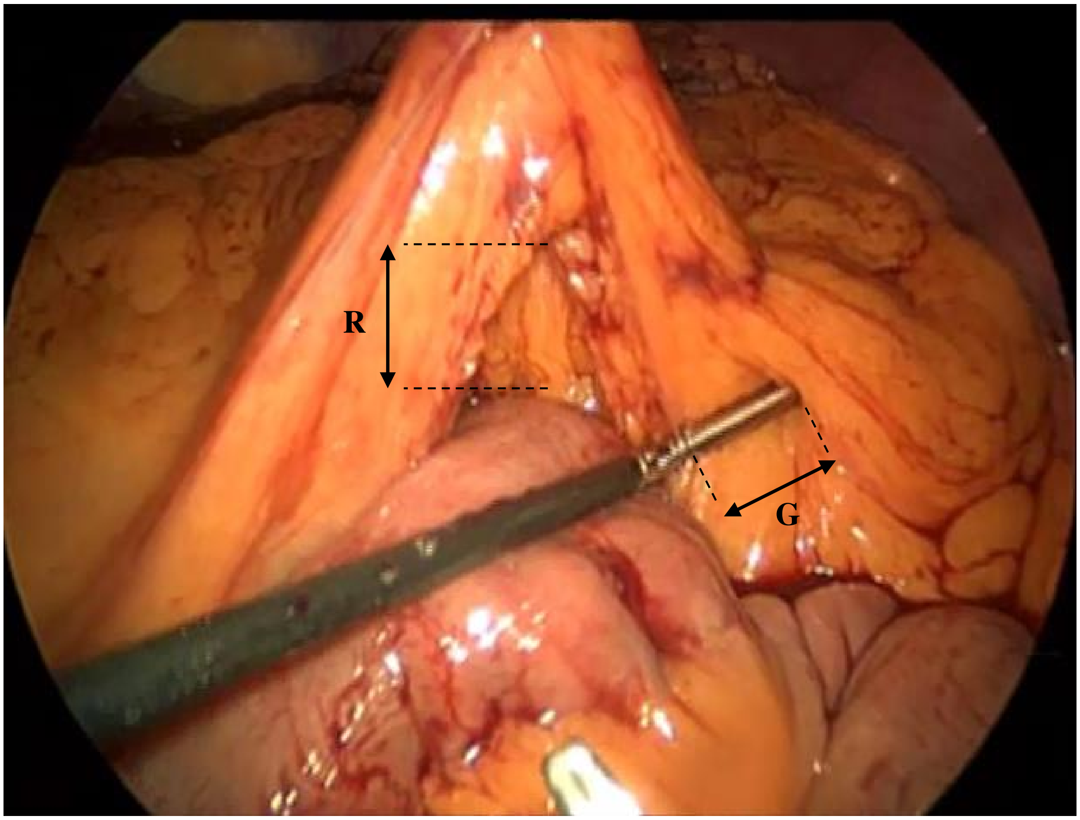


Figure 6.3 Estimation of rent size at the transverse mesocolon. The known length of the tip of the instrument (e.g. grasper = 2.5cm) and the according distance on the image (G) was used to generate a scale. The distance of the rent on the image (R) was measured and the scale used to approximate the size of the rent in reality.

7.4.4 Statistical analysis

The Statistical Package for the Social Sciences software [Version 18.0.2, SPSS Chicago (IL), USA] was used. Inter-observer reliability was assessed using Cohen's kappa using a binary datasheet (same error detected by both observers). Non-parametric tests were used, as data were not normally distributed (as shown by detrended QQ plots). For categorical data the chi-square test was used. A linear regression model was applied to analyse the predictive implication of individual error types.

7.5 Results

The analysis was performed on 46 cases, 12 in the internal hernia group ("IH"), 13 in the Roux limb compression group ("RC") and 21 in the control group ("control"). There was no difference for age, gender, preoperative BMI or average weight loss after 1 year for the three groups (Table 6.4).

Table 6.4 Patient demographics

	IH group N=13	***RC group N=13***	***Control group N=21***	***p-value****
Age	40 (23-58)	39 (25-55)	44 (26-59)	0.534
Female	n=10	n=11	n=20	0.473
BMI pre	53 (40-69)	47 (39-54)	50 (40-87)	0.110
BMI 1 year post	33 (28-49)	32 (23-37)	32 (25-68)	0.470
BMI drop 1 year	19 (12-40)	16 (15-19)	15 (10-25)	0.069*

All values median (range), p-values calculated by Kruskal Wallis for continuous data, ANOVA for categorical data
* after removing outlier (BMI loss of 40), the intergroup difference is clearly not significant (p=0.187)

Inter-observer reliability for error detection was high with a Cohen's κ=0.849. A total of 141 errors were detected for all cases.

Table 6.5 Overall number of errors

Group	Number of errors (mean)	95%CI	SD
1	0.67	0.29-1.05	0.76
2	2.85	1.83-3.86	1.67
3	3.82	2.48-5.16	1.99

Analysis was performed for each complication group (1=control, 2= roux compression, 3= internal hernia): There is a highly significant overall effect between the groups: **p=0.00002**; chi2=21.7; df 2 (Kruskal Wallis)

There was a significant difference in the number of errors between the three groups, indicating that on average in the IH group 5.7 times and in the RC group 4.5 times more errors were detected than in the control group (average errors: IH=3.82, RC=2..85, control=0.67, p<0.001). This effect was also present between the two complication groups, with significantly more errors in the IH group compared to the RC group (p=0.025). The strongest effect was found for the EEM "step not done" for the IH group (Table 6.6). Analysing which steps were not done, it was shown that steps 1, 6 and 7 were missed significantly more often in the IH group (Table 6.7). These steps are exclusively stitches between the mesentery of the Roux limb and colonic mesentery medially and laterally. Summary statistics are presented below, the frequency and nature of the errors observed in the study are given in Appendix 2..

Table 6.6 Kruskal Wallis results for External Error Modes (EEM) compared between the complication groups and the control group

EEM	*Internal*	*Roux limb compression*
Step not done	**0.026**	0.266
Step partially completed	**0.046**	0.248
Step repeated	0.527	1.000
Step done in addition	-	-
Second step done instead of	-	-
Step done out of sequence	-	-
Too little	0.705	1.00
Too much	1.00	0.114
Wrong	0.273	0.273
Wrong object	-	-

Table 6.7 ANOVA results for subtask analysis of errors for IH group

Task	*Description*	*p-value*
1	Stitch 1	**<0.001**
2	Stitch 2	0.209
3	Stitch 3	0.209
4	Stitch 4	0.440
5	Stitch 5	0.315
6	Running suture from bottom	**0.003**
7	Running suture from top	**0.000**
8	Securing final knot	0.155

Consequential errors and size of mesenteric window

There was no relationship between observed intraoperative bleeding/haematoma and Roux compression (p = 0.793). As shown in Table 6.8 the size of the mesenteric window did not predict the occurrence of either complication (median rent size IH=1.80cm, RC=2.05cm, Control=1.44cm, p=0.321).

Table 6.8 Rent size measurements- Groups 1-3

ID number	*Rent size (cm)*	*ID number*	*Rent size (cm)*	*ID number*	*Rent size (cm)*
066043	3.750	568588	1.125	2	1.296
101970	0.990	569778	2.813	3	0.800
308997	1.368	573338	2.420	4	2.400
374290	6.480	573479	2.127	5	1.800
390382	1.571	573866	0.833	6	2.979
426501	0.415	574032	2.500	7	2.092
437325	3.750	575008	0.000	8	1.917
480946	1.000	576490	0.167	9	4.200
535528	3.273	576715	0.933	10	3.017
536900	0.692	577478	1.143	11	2.618
543584	1.389	578114	1.440	12	2.500
543584a	1.458	580202	3.750	13	2.782
554965	1.733	580873	0.938	14	2.541
559198	4.000	582746	1.260	15	1.875
563960	1.800	585057	1.705	16	4.375
565963	3.150	1	0.563	17	1.011

Logistic regression

Logistic regression including missing stitches for all different positions (tasks) reveals that missing the first stitch between mesentery of the Roux limb and the transverse mesocolon was the only stitch significantly predicting an internal hernia (B=1.727, p=0.025). All other stitches did not predict a complication. Hence, missing the first intermesenteric stitch on the left side of the Roux limb independently leads to a higher risk for internal hernias.

7.6 Discussion

A detailed study of the errors that occur during the closure of the mesenteric defect at the transverse mesocolon, and their resultant complications has been presented so that corrective action to reduce the likelihood of internal hernia or Roux limb compression may be undertaken. The analysis performed suggests that the main technical reasons for the occurrence of internal hernias at the TM after LRYGB are missing stitches between colonic and ileal mesentery on the medial and/or lateral side. This is plausible as anchoring the Roux limb along the edges of the mesocolic rent would prevent herniation of the former through the latter. It is interesting to note that the analysis demonstrates that a missed stitch at positions 1, 6 and 7 (the stitches approximating Roux limb mesentery and colon mesentery) are the most likely associated with postoperative occurrence of internal hernia. My own work has already demonstrated that internal hernias present on average 14 months after the index operation, a time interval during which patients have lost significant amounts of weight (median weight loss 44 kg). The loss of mesenteric fat leads to a widening of the intermesenteric space and the likelihood of internal hernias rises. It was hypothesised previously that the internal hernias might occur due to pulling through of sutures. Our results, however, suggest that a technical error may also be a preventable cause of this complication. A failure of standardised approximation of the mesenteries of small bowel and colon was shown to significantly increase the rate of postoperative internal hernias and a substantial number of complications can potentially be prevented using the correct technique

One would expect that Roux compression would most likely be associated with too many stitches or bleeding at the site where stitches were placed creating excessive cicatrix formation. However, our analysis did not reveal any such association. For the Roux limb compression group the overall number of errors was also significantly higher, although it was not possible to establish a relationship to a single error type. This may be due to a small sample size but it is also possible that other factors, such as local inflammatory response contributing to the occurrence of this complication.

The size of the avascular mesocolic rent created also does not appear to influence the incidence of either internal hernia formation or Roux compression. One would expect that the larger the rent created, the greater the risk for internal herniation and, conversely, the smaller the rent, the higher the chance of Roux compression. However, the study findings do not demonstrate any association between mesocolic rent size and complications of internal hernia and Roux compression.

The LRYGB procedure has numerous steps and our study has demonstrated that a subsection of this operation can be successfully analysed using OCHRA. By analysing the videos of operations which are known to result in postoperative complications, the OCHRA system provides a novel and interesting approach in identifying those key intraoperative steps that may have either been missed or might have led to errors. The objective of such analysis would be to draw surgeons' focus to these key steps in an attempt to reduce their incidence and, thus, reduce the postoperative complication rate.

This study has utilised a scientifically approach to demonstrate that a standardised closure technique of the mesenteric gap is likely to prevent the occurrence of internal hernias.

To my knowledge, this is the first application of OCHRA within the field of bariatric surgery. The use of the OCHRA system to assess the quality of surgical operative performance has many advantages over retrospective population-based research. In the first instance, the system provides objective and comprehensive tracking of errors related to the performance of a specific operation. Secondly, it identifies hazard zones of an operation where technical errors occur most commonly and are likely to jeopardise clinical outcome. The objective is to reduce surgical complications by placing steps to reduce errors in the particular hazard zones of an operation.

Although auditing of clinical data is important for day-to-day service quality assessment, it usually does not allow for the analyses of root causes of undesirable outcomes. It is worrying that unless complications accumulate, a problem may not be identified at all. Introducing human reliability methods into regular quality assessment of a surgical service could have an immediate and unambiguous impact on clinical practice, as demonstrated in this study. OCHRA enables the clinician to identify hazard zones and technical errors that are likely to jeopardise clinical outcome. The results of this study have direct applications and should be used to adapt operative practice in order to reduce complications. In addition, regular structured reviewing and critical self-appraisal of videotaped operations may be useful for surgeons to continuously improve their technique (188). Recent advances in video recording technology and increased availability of storage capacities using hard-drives and other digital media favour this approach. Modern laparoscopic stacks often provide software for the setup of video libraries to easily access full-length operating videos.

However, there are also limitations to this study. Above all, it takes a significant amount of time to assess full-length videotapes. Although assessment time can be reduced with increasing experience and by selective reviewing, as demonstrated in the present study, time remains an insurmountable obstacle for surgeons with a busy practice. Further technological developments, such as pattern recognition software to facilitate task analysis and error identification may be required before these methods can be implemented into daily clinical practice.

Secondly, the focus of the study is on retrocolic, retrogastric bypass only, and specifically on the steps involved in the closure of the transverse mesocolic rent. Furthermore the operations reviewed were performed in a standardised way by one surgeon and other surgeons may perform the same retrocolic LRYGB but with their own nuances. Thus the question remains whether the results of this study can be extrapolated more widely to all cases of LRYGB.

Laparoscopic procedures are routinely recorded and thus observational material is readily available to carry out a retrospective analysis of surgical performance using a HRA technique. Future work should look at analysing videos of the index operations of cases, which resulted in a complication so that we can learn from the errors committed at the index surgeries. Furthermore, the knowledge gained can be used to focus training in those parts of the operation where most errors occur, and by knowing the nature of errors more specific skills training can be applied depending on whether errors are executional or procedural. More than any other surgery, laparoscopic surgery lends itself to OCHRA.

Chapter 8

8. PRELIMINARY EXPERIENCE USING ANTECOLIC ANTEGASTRIC LRYGB WITHOUT MESENTERIC DIVISION

8.1 Introduction

Internal hernias after LRYGB will occur despite the surgeon's best efforts. Previous chapters have described in detail the incidence, presentation, and diagnosis of IH as well as techniques to reduce their incidence both in terms of surgical technique as well as through using alternative methods such as staple line reinforcement. My own work is in agreement with other authors demonstrating the antecolic antegastric technique (AA-LRYGB) reduces the risk of IH in comparison to the retrocolic technique, most likely due to the absence of the transverse mesocolic defect (189-192). Table 7.1 summarizes the findings of all papers published to date on the incidence of internal hernias in AA-LRYGB. The mean incidence appears to be around 3% but with a wide range from range from 0 to 14.4%. This wide range reflects the variations in technique used by different surgeons.

Traditionally, during AA-LRYGB small bowel mesentery is usually divided to release potential tension from the gastrojejunal anastomosis. The division of the mesentery creates mesenteric defects. Steele et al (193) performed AA-LRYGB with division of the mesentery and closure of all mesenteric defects. They found the incidence of IH to be zero. Other surgeons have reported their findings with AA-LRYGB with division of the mesentery but without closure of IH spaces. These surgeons have suggested that as the antecolic technique creates fewer defects than the retrocolic technique, routine closure of mesenteric defects is not necessary. Finnell et al found this to be the case, operating on 300 patients with a mean follow-up of 18 months, with no patients developing an internal hernia (174). However, another report describes an IH incidence of 6.9%, with 6.2% arising at Petersen's space (134).

Table 7.1 Incidence of IH in AA-LRYGB

Author	Year	Patients	IH incidence (%)	IH at JJ (%)	IH at Petersen's space (%)	Division of mesentery	Closure of mesenteric defects/ spaces?	Mean/median follow-up
Steele et al (163)	2008	205	0	0	0	Yes	Yes	nr
Ahmed (158)	2007	357	0.6	0.3	0.3	Yes	Petersen only [SLR at JJ]	34 months
De La Cruz-Munoz et al (166)	2010	1727	0.05	0	0.05	Yes	JJ only	53 months
Muller et al (160)	2007	33	6.1	6.1	0	Yes	JJ only	35 months
Rodriguez et al (162)	2010	187	14.4	9	5.4	Yes	Yes	36 months
Nelson et al (103)	2006	326	0.3	0.3	0	Yes	Yes	16months
Escalona et al (161)	2007	454	0.6	0.4	0.2	Yes	Yes	16 months
De La Cruz-Munoz et al (166)	2010	352	11.7	10	1.7	Yes	No	101 months
Finnell et al (123)	2007	300	0	0	0	Yes	No	18 months
Bauman and Pirrello (117)	2009	1,047	6.9	0.7	6.2	Yes	No	nr
Comeau et al (115)	2005	731	3.3	1.3	2	Yes	No	nr
Gandhi et al (165)	2009	702	2.1	2.1	0	Yes	No[a]	nr
Rogula et al (159)	2007	2,343	0.3	nr	nr	Yes	Nr	nr
Rodriguez et al (162)	2010	172	1.1	1.1	0	No	Yes	26 months
Iannelli et al (164)	2007	625	1.6	1.6	0	No	Yes[b]	nr
Cho et al (120)	2006	1400	0.2	0	0.2	No	No	11 months
Abasbassi et al (116)	2011	652	6.9	6.3	0.6	No	No	45 months
SUMMARY		**11613 (total)**	**3.26**	**2.45***	**0.99***			

nr = not reported; * Rogula et al excluded
[a] Closure of JJ mesenteric defect in the last 18 months
[b] Only in the last 155 cases

Some authors have performed AA-LRYGB successfully without division of small bowel mesentery in an attempt to reduce the IH incidence by removing a potential IH space. Rodriguez et al. (194) performed AA-LRYGB without division of the mesentery but with closure of all mesenteric folds / spaces. His incidence was 1.1% .

Yet another variation of the AA-LRYGB technique has been reported by Cho et al (173) who performed AA-LRYGB without division and without closure of the mesenteric defects. They report an impressively low incidence of internal hernias (0.2%) at 11 months mean follow-up, though 2 of the 3 internal hernias they report occurred over 12 months after surgery and it may be that later hernias were missed due to a short follow-up period. In contrast, using a similar technique, Abasbassi et al (133) report a higher IH rate of 6.9%, with most occurring at the jejunojejunostomy defect. The higher rate of IH found in this study may have been due to their longer mean follow-up period (45 months) and differences in the surgical technique used. Abasbassi et al used a modified cut omega loop technique leaving a longer distance of remaining small bowel between the two anastomoses (GJ and JJ). Subsequently their JJ lies lower than average and in turn this may give rise to a larger mesenteric defect.

There have been very few studies comparing the incidence of IH between AA-LRYGB with and without mesentery division. One such study (194) divided patients into 2 groups; group 1 in which the mesentery of the jejunum was widely opened, the mesenteric defect was closed and the Petersen space was not sutured. In group 2 the mesentery was not divided and both, the mesenteric folds and the Petersen space were closed. In group 1 14.4% developed IH and in group 2 only 1.1% developed IH. The authors concluded that leaving the mesentery unopened and closing all defects significantly decreased the incidence of small bowel obstruction.

In this Chapter, I will describe my own experience with using an antecolic antegastric Roux limb without division of mesentery and without closure of IH defects and its effect on the incidence of IH.

8.2 Rationale for this technique

We have established that IH occurs through spaces or mesenteric defects that can occur in 3 locations with the retrocolic/retrogastric technique and in 2 locations with the antegastric/antecolic technique. For this reason the majority of bariatric surgeons have traditionally closed mesenteric defects at the time of the primary surgery.

8.2.1 Variations in IH defects

Clinically, internal hernias can be asymptomatic or cause significant discomfort ranging from constant vague epigastric pain to intermittent colicky periumbilical pain to frank small bowel obstruction and in extreme cases leading to peritonitis from bowel gangrene. Similar to abdominal hernias, symptom severity relates to the duration and reducibility of the hernia and the presence or absence of incarceration and strangulation.

We have previously demonstrated that there is an association between IH occurrence and time after LRYGB which may be a surrogate marker for weight loss; fat loss within the mesentery may potentially allow previously suture closed spaces to partially open up. A loop of small bowel may then become trapped in a small mesenteric defect and lead to symptoms.

It would be fair to assume that the smaller the mesenteric defect, the more likely it is for a loop of small bowel to become trapped. Whilst in larger defects, small bowel loops may intermittently slip in and out without even the patient having any symptoms.

Thus small internal hernia defects are more likely to become symptomatic whereas large defects may pass unnoticed. This is also the reason why most bariatric surgeons do not close the Petersen internal hernia space in the antecolic antegastric technique (but will close this space in retrocolic retrogastric technique) as it is a large space (but smaller in the retro technique).

The aforementioned observation poses the question – do large internal hernia spaces need to be closed especially as they are unlikely to cause symptoms. Champion et al were the first to question whether closure of all potential IH is necessary (126, 195).

8.2.2 What is a defect and what is a redundant space?

A mesenteric defect is created by the surgeon when small / large bowel mesentery is divided. In contrast, a redundant space may be created when bowel loops are re-arranged in position within the peritoneal cavity. Typically 'spaces' are much larger gaps than defects. A classical example is the Petersen' s space created during LRYGB. My own work has already demonstrated that is the most rare site of symptomatic internal herniation.

It is therefore reasonable to ask the question if LRYGB is performed using a technique that does away with mesentery division, would this not reduce the rate of symptomatic IH? Moreover the need to close a IH space would no longer exist as there would be no IH defect as such, only a large redundant space through which small bowel loops could freely move in and out of. This is not a novel suggestion as some surgeons (133,173) have described LRYGB without division of mesentery and without closure of intermesenteric spaces. Advantages of such a technique are (i) a shorter operating time by avoiding the time-consuming process of suturing closed all the mesenteric defects and (ii) reduced risk of trauma to mesenteric blood vessels during IH closure.

8.3 Methods

8.3.1 Patients

Between 1 January 2008 and 1 June 2012, 444 patients underwent primary LRYGB by a single surgeon using a standard antecolic antegastric technique without division of mesentery and without closure of redundant spaces (IH defects are non-existent in this technique).

8.3.2 Setting

Imperial Weight Centre at Charing Cross Hospital

8.3.3 Surgical technique

This is not a novel technique but it is based on a modification of Lonroth's technique (196). Pneumoperitoneum was established, and the omentum and transverse colon were reflected, exposing the ligament of Treitz. The small bowel was divided approximately 30 cm from the ligament of Treitz with use of an ETS-45 stapler (Ethicon Endo-Surgery Inc, Cincinnati, OH). About 100 cm of the distal bowel was measured out to establish the length of the Roux limb. A side-to-side functional end-to-side enteroenterostomy was performed to create the anastomosis between the biliopancreatic and Roux limbs. The gastric pouch was fashioned by using a transverse application of an ETS-45 stapler (3.5-mm cartridge), followed by multiple vertical applications of the stapler to create a completely isolated proximal pouch with a volume of approximately 15 to 30 ml. A vertical split in greater omentum was made. The stapled end of the Roux limb was then positioned antecolic antegastric beside the gastric pouch and a side-to-side functional end-to-side gastrojejunostomy performed. The pneumoperitoneum was then released and the trocars were withdrawn.

8.3.4 Data collection

A retrospective review of the medical records of the 444 patients was conducted and the following information recorded: the patient's age, sex, and preoperative BMI, the amount of postoperative weight loss (percentage of excess body weight lost [%EBWL]); the incidence of symptomatic IH and the postoperative time to presentation with IH symptoms; and the location of the IH. The information obtained on patients with IHs was compared with that on patients without IHs.

A second analysis also compared the incidence of IH in this series with a historical group of 2215 retrocolic retrogastric LRYGB (with mesentery division and IH defects closure) performed at Strong Health Bariatric Center, Highland Hospital who developed symptomatic internal hernia requiring operative intervention between Jan 1, 2000 and September 15, 2006. For each case, age, gender, weight, body mass index (BMI) and time gap from initial surgery to secondary presentation with internal hernia were recorded.

8.3.5 Statistical analysis

GraphPad Instat version 3 (GraphPad Software Inc., USA) was used to perform statistical analysis. The data are expressed as mean +/- standard deviation (SD). Unpaired t test was used to compare the different means in the IH group versus non IH group. Chi-square test was used in the final analysis to compare the IH rate in the AA-LRYGB versus retrocolic retrogastric LRYGB groups. Odds ratios were calculated following Chi-square statistical analysis. A p value less than or equal to 0.05 was considered to represent a significant difference.

8.4 Results

During the postoperative observation period, 2 patients (DCA, MO) presented with abdominal pain, vomiting, or a combination of these symptoms and were found at relaparoscopy to have an IH; thus, the overall IH rate in the series was 0.45%. Another patient SW underwent reoperation for a marginal ulcer where an incidental internal hernia was noted at this surgery, but as this was non-symptomatic, and not the reason for presentation, its occurrence will not be included for the purpose of this study’s results.

The mean follow-up time in the entire series of 444 patients who underwent LRYGB was 43 months, range 16-70 months. 365 out of the 444 participants were contacted by telephone at the time of analysis to ensure they had not presented to any other unit with IH, this represents a follow-up rate of 82%. The remaining 79 patients were non-contactable.

Table 7.2 shows demographic and follow-up data on the patients presented in this series: (i) No internal hernia and (ii) internal hernia. Comparing the 442 patients in whom symptomatic IHs did not occur with the 2 in which IH did occur, there was no statistically significant difference in baseline patient demographics (except age), mean follow-up time, amount of postoperative weight loss in both groups. Interestingly, the % EBWL in the IH group at the time of reoperation for IH is 78%. The average time interval between initial surgery and reoperation for IH is 355 days. In the non-IH group, the %EBWL at 364 days is 57% ±17 (mean ±SD). Although this difference does not quite reach statistical difference ($p=0.08$) due to the uneven group sizes, one can see there may be an association between those patients having the most weight loss and symptomatic internal hernia occurrence.

Table 7.2. Baseline patient characteristics

Characteristic	***No internal hernia (n=442)***	***Internal hernia (n =2)***	***p value***
Age (yr)			
Mean ± SD	44 ±10	28 ±6	*0.013*
Range	18-70	24-33	
Gender (n)			
Women	327	1	-
Men	114	1	
Weight (kg)			
Mean ± SD	132 ±24	177 ±8	*0.004*
Range	80-230	172-183	
Excess body weight (kg)			
Mean ± SD	71 ±21	106 ±10	*0.010*
Range	23-164	98-113	
BMI (kg/m^2)			
Mean ± SD	47 ±7	55 ±3	*0.11*
Range	33-77	53-57	
Weight at year 1 postop			
Mean ± SD	90 ±18	108 ±3	*0.16*
Range	44-166	106-110	
%EBWL at 1 year postop			
Mean ± SD	57 ±17	65 ±3	*0.51*
Range	17-116	63-68	
BMI (kg/m^2) at 1 year postop			
Mean ± SD	33±7	34 ±2	*0.64*
Range	18-55	33-35	

BMI = body mass index.; %EBWL = % excess body weight loss

Table 7.3 gives further details on the patients who presented with IH. The mean time until postoperative presentation with abdominal symptoms was 22 months for patient MO. MO was noted at relaparoscopy to have an obstructed loop of small bowel (Roux limb) stuck in the space between the mesentery of the biliopancreatic limb and the mesentery of the common channel. Due to difficulty in obtaining good laparoscopic views (bowel very dilated), a small laparotomy was made and the trapped bowel released. The space between the mesenteries was closed with interrupted sutures. MO made an excellent recovery and was discharged home after 3 days. Patient DCA presented at 19.5 months postoperatively with symptoms but at relaparoscopy, no abnormality was noted. DCA then represented 6 months later (a total of 25.5 months from the index surgery) with symptoms and at relaparoscopy a obstructed small bowel loop (Roux limb) was seen stuck in the Petersen space. This was successfully reduced laparoscopically and the space closed with interrupted sutures. DCA was discharged home the next day after surgery.

Table 7.3 Internal hernia patient characteristics

Characteristic	***Patient CDA***	***Patient MO***
Preoperative weight	183	172
Weight at reoperation (Kg)	94	95
BMI at reoperation	28	29
%EBWL at reoperation	78	78
Time period between 1st operation and reoperation for IH (days)	407	303

Next a comparison was made in IH rates in the antecolic antegastric LRYGB non-mesenteric division, non IH closure group with a historical sample of retrocolic retrogastric LRYGB with mesenteric division, with IH closure.

The IH rate among the 2215 patients who had a suture closure after mesentery divided retrocolic retrogastric LRYGB was 2.4%, whereas that among the 444 AA-LRYGB patients in whom no IH spaces were closed and no mesentery divided was 0.45%; but the difference between the rates was not statistically significant. Among the 54 patients in whom IHs occurred, the baseline patient demographics (except pre-operative weight), overall follow-up time, amount of postoperative weight loss, and time to presentation with an IH were similar in both groups (Table 7.4).

Table 7.4 Internal hernia patients' characteristics: Group 1 antecolic antegastric (non-mesenteric division non IH closure,) vs. Group 2 retrocolic retrogastric (with mesenteric division and IH closure)

Characteristic	*Group 1*	*Group 2*	*p value*
Number of patient in series	444	2215	
Number of patients with IH	2	52	
Internal hernia incidence (%)	0.45	2.4	0.01*
Preoperative weight (Kg)	177 ±8	138 ±25	0.03
Weight at reoperation	94.5 ±0.7	94.1 ±24	0.98
BMI at reoperation	28.5 ±0.7	34.1 ±8	0.33
%EBWL at reoperation	78 ±0.4	59 ±25	0.29
Time period between 1st operation and reoperation for IH (days)	355 ±73	411 ±348	0.82

* Chi-square test;

8.5 Discussion

Closure of internal hernia defects during LRYGB remains a controversial issue amongst bariatric surgeons. Many surgeons favour routine closure whereas others have found no difference in internal hernia rates by leaving these spaces open. The current study goes some way in answering the question do internal hernia defects created at the time of LRYGB need to be closed?

The results of this work demonstrate that by using an antecolic antegastric approach without division of small bowel mesentery, the incidence of internal hernia is lower than the incidence observed when the surgeon routinely closes all internal hernia defects in the retrocolic retrogastric LRYGB. One potential explanation for this rather paradoxical finding is that in the non-mesentery division technique, large redundant spaces are created through which loops of small bowel may displace in and out without becoming stuck. In cases where IH defects are routinely closed, gaps in the mesentery may develop as a result of weight loss, thus, trapping small bowel loops.

In the sample population presented and using the technique described of antecolic antegastric non-mesentery division LRYGB, only 0.45% developed symptomatic internal hernia requiring surgery. This is with a mean two-year follow-up with 82% follow-up rate. This is less than the 2.4% internal herniation rate seen in a previous comparable historical control of retrocolic retrogastric LRYGB patients. The 0.45% IH rate in our AA-LRYGB cohort compares favourably with two other AA-LRYGB studies using non-mesentery division non-mesentery closure technique (6.9%[116] , 0.2%[120]). Although our sample size was not as large as some of the other studies, the mean follow-up time of three and a half years with 82% follow-up rate is sufficient, in our opinion, for all potential cases of IH to be manifest. Some previous reports do not benefit from the same length of follow-up.

Furthermore, we have identified a possible association between the amount of weight loss after LRYGB and symptomatic internal hernia occurrence. This is similar to the study of Schneider et al (197), who reported that a significant number (46.5%) of their patients who developed IH experienced a period of rapid postoperative weight loss. Abasbassi et al (133) also noted in their series of AA-LRYGB a tendency for development of IH in patients who have a high excess weight loss during the first 3 months after surgery.

Due to the retrospective nature of the study, various limitations are expected. One such limitation is the follow-up period, which may still be too short and potential future internal hernias might have been missed in this cohort. This, in my opinion, is unlikely as previous authors have documented that the vast majority of internal hernias occur around 14 months after LRYGB. The mean follow-up period in this study was 42 months with a range of 16 to 70 months. Unfortunately there was a loss in follow-up of 18% of the study population. However I do not think this would have had a major impact on the IH incidence as the Imperial Weight Centre is the largest bariatric unit in the South East of Engkand and 99% of complications seen after bariatric surgery tend to present back at this hospital or get transferred in. Indeed most bariatric surgeons are very good at notifying colleagues of any complications seen after surgery. Thus even if a patient from this sample population presented to a different unit, in all likelihood, I would have been informed about at the very least or accepted the patient back as a transfer at best.

A further limitation of this study is that certain patients from our study cohort could have had asymptomatic internal hernias. In fact one patient in the cohort was indeed found to have an IH during surgery for another problem. One would argue that if they are not symptomatic then it does not make any difference if IHs are picked up or not. Lastly, bariatric surgeons who routinely close internal hernia defects would argue that spending another 10 to 20 minutes to close these defects adds little time to surgery but saves patients from requiring re-surgery in the future. This study provides evidence in support of the opposite argument – in that seemingly closure of IH is associated with a higher symptomatic IH incidence from the postulated reopening of mesenteric defects seen after weight loss. Furthermore, one must not forget that the surgical technique employed in closure of the defects may also be associated with adverse events. These include mesenteric bleeding and haematoma, kinking and obstruction at the entero-entero anastomosis.

CHAPTER 9

9. DISCUSSION AND CONCLUSIONS

Whereas the first half of this thesis concentrates on providing descriptive statistics and trends based on one of the largest series of LRYGB. The second half of the thesis focuses on the effect of altering surgical technique in order to minimise the commonest complication after LRYGB, namely SBO. Initially I have looked at altering individual steps involved in the surgery which would theoretically reduce the incidence of IH or roux constriction. Following on from this, I have used a more analytical approach (root cause analysis) in order to try and establish what are the 'errors' that may occur intra-operatively that may lead to the complications of IH and roux compression. If bariatric surgeons are aware of these errors then focussed attempts can be made to try and minimise these. In the final chapter, by using an antecolic roux limb without cutting any mesentery and closing any defects, I have altered my own surgical technique substantially to try and completely eliminate IH and roux compression. I have shown a substantial reduction in IH using this modified technique.

The next few paragraphs will summarise some of the key findings from the research presented in the thesis.

I have established that following LRYGB, SBO occurs with an overall incidence of 4.38%. In order to come to this conclusion, a population of over 2000 LRYGB cases was searched for reoperations and amongst these those for SBO. This is the first time such a large study population has been used to establish the incidence of SBO after LRYGB. This makes SBO one of the commonest complications after this surgery. I was also able to scrutinise the medical records in order to some other facts, such as, most of the patients in our series presented with abdominal pain, which was documented in 82% of patients. Other common presenting symptoms included nausea and vomiting.

By detailed review of all the cases of SBO found in the study population, I established that the most common cause of obstruction in our series was internal hernias seen in 53.9 % of SBO cases. The second most common cause of intestinal obstruction was scar induced stricture of the Roux limb as it passed through the mesocolic window, encountered in 20.5%. Surprisingly, adhesion induced obstructions which usually comprise the leading cause of post-op bowel obstruction in open surgeries comprised only a small fraction of patients (13.7%). This is indeed a very important finding as most surgical textbooks traditionally, and even now, still mention adhesions as being the main cause of bowel obstruction after abdominal surgery. This work challenges this commonly held view and draws attention to the fact that in the laparoscopic era, adhesional bowel obstruction has been replaced with bowel obstruction from other causes (IH and roux limb obstruction as characterised in this thesis). Surgeons who are not practising bariatric surgery need to be acutely aware of this in case they are faced with a post gastric bypass patient with abdominal pain.

Internal hernias are a known complication after LRYGB with an incidence of around 2% in the present series which is in keeping with other studies (51). This work's strength is that it documents one of the largest reported series of internal hernias accrued over a six-year period. The location of internal hernias has been documented with transverse mesocolon hernias (46%) commonest followed by enteroenterostomy (40%) and then

Peterson's space hernias (14%). The strength of this analysis comes from the large number of cases reported in our series as well as the long follow-up we have, hitherto not seen in the published literature.

We demonstrate that internal hernias, on average, present some 14 months after the initial surgery. By this stage, the average weight loss has been around 44 kg with the majority of patients experiencing 52-66%EBWL (mean 59%). The importance of this is twofold. Firstly it re-emphasizes the point that LRYGB patients need longterm follow-up as IH typically occurs a year after the index surgery. Typically in surgical patients, the vast majority of postoperative complications take place within the first 30 days. Our data has shown that the most common complication after LRYGB surgery actually occurs more than a year after surgery. Secondly the timing of IH occurrence coincides with the time of maximum weight loss seen which in turn lends substantial weight to the hypothesis that IH occurs subsequent to loss of tissue (fat) from the mesentery allowing previously closed spaces to open up, allowing gaps for small bowel loops to become trapped in. A finding in chapter 8 that adds strength to this hypothesis is the observation that in the antecolic antegatsric non mesentery division non closure of IH space cohort of patients, the two patients that developed IH were the ones in fact the greatest weight loss seen in the cohort by the time of reoperation.

Patients often present with non-specific symptoms with a diverse differential diagnosis. Hence it is useful to know which diagnostic imaging test offers the most likelihood of correctly identifying IH. The results of this work indicate that CT scanning with intravenous and oral contrast correctly identified IH in 92% of cases. In equivocal cases, the addition of UGI study increases the diagnostic rate to 100%. Once again this study finding is of great significance as it allows clinicians to choose the most appropriate imaging modality when faced with LRYGB patients presenting with abdominal pain.

Our results demonstrate that narrowing at the transverse mesocolon rent is the second commonest cause of SBO in retrocolic LRYGB. We report an incidence of 0.9% incidence in 2215 patients, one of the largest documented series of retrocolic LRYGBs, which benefits from an extensive mean follow-up period (3 years).

We demonstrate that upper GI contrast study is the most appropriate imaging modality for making the diagnosis. 95% of cases in our series were successfully diagnosed pre-operatively using this modality. Based on our findings, we advocate the use of upper GI series when Roux limb compression is suspected.

Our time-to-event analysis demonstrates that unlike internal hernias, which tend to occur later in the clinical course (a year after surgery), Roux limb obstruction occurs much earlier after LRYGB. Once again this finding adds strength to the hypothesis of reduced intraperitoneal fat leading to larger mesenteric defects and thus greater herniation risk. On the other hand the observed time gap of 48 days to Roux limb obstruction development would be consistent with scar tissue development at the mesocolic rent compressing the Roux limb. The difference in time to presentation for these two causes of SBO after LRYGB is a very important finding as it aids the clinician to make the correct diagnosis.

Having established the incidence, timing, clinical features and imaging characteristics of IH and roux compression, an attempt has been made to see if variations in LRYGB surgical technique can reduce IH and roux compression incidence. As such, we ascertained that using interrupted stitches in place of a continuous stitch to close the mesocolic window appears to reduce the incidence of Roux limb compression. Another finding has been that an antecolic Roux limb by definition obviates the need to create a window in the transverse mesocolon and this in turn eliminates this site as a potential area for herniation. Although the aforementioned should not come as a surprise, what my research has shown is that the magnitude of this effect. My work demonstrates a fourfold increased risk of internal hernias when a retrocolic Roux limb is used. We also evaluated the effect of switching from interrupted closure to running closure of the enteroenterostomy mesenteric defect and Peterson's space. This did not appear to have any effect on IH incidence, but may have been due to small sample size for this part of our analysis.

On the other hand, when bioabsorbable polymer SLR was applied when dividing the bowel and mesentery, without closure of the mesenteric defects thereby created, there was a significantly lower IH incidence than in patients who had suture closure of the mesenteric defects (0.8% vs 2.9%). This study is the first to observe usage of SLR in LRYGB associated with a decreased IH rate. It is my hypothesis that the presence of

SLR on the cut edges of the mesentery evokes local adhesion formation and tissue fusion that creates a bond stronger than that provided by sutures, which may cut through the mesenteric tissue when the amount of fat decreases with weight loss. This bond seals the defects created at surgery and thereby decreases the rate of post-LRYGB IH formation. This is a new found effect of SLR and the manufacturers have already been contacted informing them of this. Therefore , SLR can therefore be used in LRYGB procedures not only with the objective of decreasing gastrointestinal bleeding but also with the aim of reducing the postoperative IH rate.

Whereas chapter 6 was concerned with alterations in various steps in LRYGB surgery and the impact on IH incidence, chapter 7 shifts the focus onto analysis of intraoperative errors. Currently, there is little knowledge on the surgical errors that may lead to internal hernia formation and Roux limb compression. Admittedly, even if surgical performance is flawless, weight loss after surgery may lead to pulling on the sutures placed in the mesenteric defects. Similarly, Roux limb compression may still occur due to cicatrix formation. However, surgical performance and the errors made during surgery may be a contributing factor in the incidence of complications. This study has demonstrated that by submitting operative videos to OCHRA, errors can be identified and can be correlated with their resultant complications; in our specific study, a missed stitch securing the Roux limb mesentery to the transverse mesocolon appears to play a role in the occurrence of internal hernias and Roux limb compression. This constitutes a procedural error and thus highlights the need to reinforce operative rules and indicates that surgical training of this procedure may benefit more by ensuring proper sequential conduct of the operation (menu-driven execution).

The studies conducted thus far clearly demonstrate how changes in intraoperative technique can affect the incidence of IH and roux compression. It was evident to me that the antecolic roux limb routing would be by far preferential by eliminating completely the risk of roux compression. In addition the antecolic routing removes the possibility of IH at the transverse mesocolic rent reducing the overall IH incidence. In order to reduce the incidence of IH further, I decided to alter my technique and perform LRYGB without dividing any mesentery. The final part of this thesis examines this further.. Furthermore not closing any potential herniation sites would keep any redundant intermesenteric spaces wide enough to allow loops of bowel to slip in and out with little risk of entrapment causing SBO. Chapter 8 demonstrates that by using an antecolic antegastric approach without division of small bowel mesentery and non-closure of the mesenteric spaces, the incidence of internal hernia can be substantially reduced.. In fact what is perhaps most interesting is that the incidence of IH using this modified LRYGB technique is substantially lower than in the standard LRYGB technique where most surgeons are, through tradition, indoctrinated into closing IH spaces. The findings from this research challenge surgical dogma. In fact by closing IH spaces, surgeons may be doing a disservice to patients and paradoxically increasing IH incidence. I realise this is counter intuitive but the observations from my research which are scientifically valid would certainly warrant a re-examination of the common practice of closure of IH. In the field of surgery, many traditions have been followed from one generation to the next.

Examples are routine use of nasogastric tubes; mechanical bowel preparation; irrigation of the abdomen; bowel obstruction: never let the sun set on it. All of these, through scientific research, have been shown to make no difference to surgical outcomes. Similarly it is my position from the research presented that routine closure of IH spaces can actually lead to a higher incidence of IH and that using the modified LRYB technique described can actually minimise IH rates.

Study Limitations

The primary limitation of this work is that it is a retrospective analysis (apart from chapters 7 and 8), and it is therefore liable to all the potential factors that limit retrospective studies

The majority of the data was captured from patients' medical records and in particular operative notes from two hospitals where I worked – Strong Health Bariatric Centre in Rochester, New York and the Imperial Weight Centre, London. In both units, data from the notes was extracted according to a standardized template thus reducing the chance of missing data.

The internal hernia and Roux constriction incidences were dependent on postoperative patients presenting with symptoms and signs warranting treatment. It is possible that the actual incidence of internal hernia may be higher if one includes cases that have not become symptomatic enough to trigger a hospital visit.

Accurate calculation of the incidence of internal hernias also depends on patients returning to the host institution and not presenting to other hospitals' emergency departments. At Strong Health Bariatric Center, where part of this study was performed, the follow-up rate after bypass is 80%. The follow-up rate from the Imperial Weight Centre study was 94%. The mean follow-up period for the data presented was 36 months (Strong Health Bariatric Center) and 25 months (Imperial Weight Centre).

Lastly, errors may be introduced into the analysis from combining the outcomes of different surgeons. All the surgeons whose results were used in this study follow a standardised operative technique with no deviation from one case to the next and differ amongst each other only in those steps of surgical technique that were the subject of assessment.

Conclusions

The work presented in this thesis comprises one of the largest series of bowel obstructions post LRYGB that has been studied. Through a rigorous retrospective analysis of prospectively collected data, I have successfully obtained important facts concerning this not uncommon complication following gastric bypass surgery. Significantly, using OCHRA for the first time in bariatric surgery, I have established objective evidence of where the occurrence of a surgical technical error is significantly associated with an adverse outcome – IH. This work goes a long way in challenging what has been a surgical dogma that all IH defects need closure. The work presented in fact strongly suggests that by using an antecolic antegastric technique without mesenteric division and mesenteric space closure, the incidence of IH is actually lower than in those cases where the latter has been performed.

Future Directions

Now that it has been established that non-division of the mesentery and non-closure of intermesenteric spaces is associated with reduced IH rates, this creates the opportunity for further work in this area. In particular a randomised controlled trial examining AA-LRYGB with mesentery division/closure compared to AA-LRYGB without mesentery division/closure would certainly be possible and lead to level 1 evidence further supporting the results of this thesis. Furthermore by recording all the laparoscopic operations performed in both arms, all those cases with an adverse outcome could be subjected to OCHRA analysis. This would yield objective evidence of where in the surgery are the key steps that require meticulous performance in order to keep complication rates at a minimum.

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APPENDIX 1: data input form with sample data extract

MR	Name	Year	Surgeon (WO/TB)	Age	Sex	Date first surgery	Date reop	Time period between 1st op and reop (days)	Height	BMI at 1st op	Kg at 1st op	BMI at reop	Kg at reop	Weight loss (kgs)	BMI drop	IBW	EBWL preop - IBW	% EBWL wt lost/EBW	Continuous suture used (Y/N)	Seamguard (Y/N)	Antecolic Roux (Y/N)	Findings at reop
				31	F	19/12/2003	22/08/2005	603	5'7"	46.1	134	26.5	77	57	19.6	63.5	70.5	80.9	Y	N	N	transverse mesocolon internal hernia
				31	F	11/07/2002	04/06/2004	683	5'8"	49.6	148	33.5	100	48	16.1	64.9	83.1	57.8	N	N	N	transverse mesocolon internal hernia
				31	F	16/09/2003	08/08/2005	682	5'7"	53.2	154	24.8	72	82	28.4	63.5	90.5	90.6	N	N	N	transverse mesocolon internal hernia
				46	M	07/05/2002	28/07/2002	81	6'5"	48.6	186	36.5	140	46	12.1	83.2	102.8	44.7	N	N	N	transverse mesocolon internal hernia
				29	F	20/12/2002	21/01/2003	31	5'7"	53.5	155	48.6	141	14	4.9	63.5	91.5	15.3	N	N	N	transverse mesocolon internal hernia
				40	F	29/07/2003	30/05/2005	661	5'9"	40.1	123	26	80	43	14.1	66.2	56.8	75.7	N	N	N	transverse mesocolon internal hernia
				23	M	09/07/2003	09/05/2004	300	6'2"	69.3	245	30.8	109	136	38.5	77.6	167.4	81.2	N	N	N	transverse mesocolon internal hernia
				58	F	10/12/2003	26/04/2005	496	5'2"	56.3	140	27.4	68	72	28.9	56.7	83.3	86.4	Y	N	N	transverse mesocolon internal hernia
				40	F	04/02/2004	18/06/2005	494	5'2"	53	132	28.2	70	62	24.8	56.7	75.3	82.3	Y	N	N	transverse mesocolon internal hernia
				56	F	08/10/2004	17/01/2006	459	5'5"	52.9	144	32.6	89	55	20.3	60.8	83.2	66.1	Y	N	N	transverse mesocolon internal hernia
				53	F	02/04/2004	15/04/2005	373	5'8"	61.5	184	47.9	143	41	13.6	64.9	119.1	34.4	Y	N	N	transverse mesocolon internal hernia
				55	F	27/10/2004	17/12/2004	50	5'5"	56.1	153	51.2	140	13	4.9	60.8	92.2	14.1	Y	N	N	transverse mesocolon internal hernia

APPENDIX 2: Frequency and nature of the errors observed in the OCHRA study [raw data]

Patient ID	Gender	Error Frequency	Nature of error
	F	2	needle broke off thread while running bottom- therefore more running top. Final suture ends too short.
	F	1	S2 small bleed - no action taken
	F	1	bleeding - suction
	F	1	one running suture from brottom grasped too little
	F	3	S1 missed. Rent too big. Extra stitch done at very end to reduce rent size.
	M	2	S1 missed. Rent too big - no corrective step.
	F	3	S1 missed. S3 too clockwise so extra stitch added before S4.
	F	0	
	F	0	
	F	1	S3 ends cut too short
	F	0	UNSURE - rent size?
	F	0	
	F	1	small bleed - no action taken
	F	0	
	F	0	
	F	3	S1 missed. S4 incomplete done as simple. Therefore no running top
	F	7	S1 missed. S2 too little grasped. S4 too little grasped and incomplete. No S5, running bot or top
	F	5	S1 missed. S4 incomplete done as simple. No S5 Therefore no running bottom or top
	F	5	S1 missed. S4 and S5 incomplete done as simple. Therefore no running bottom or top
	F	5	S1 missed. S4 and S5 incomplete done as simple. Therefore no running bottom or top
	F	7	S1 missed. S3 too anti and thus rent too big. S4 and S5 incomp thus no run bot or top
	M	7	S1 missed. S3 too anti and thus rent too big. S4 and S5 incomp thus no run bot or top
	F	7	S1 missed. S3 too anti and thus rent too big. S4 and S5 incomp thus no run bot or top
	M	8	S1 missed. S3 too anti. S4 and S5 incomp thus no run bot or top. Extra stitch bet S4/S5 lead to bleeding.
	F	7	S1 missed. S3 too little grasped. S4 and S5 incomp.Extra stitch bet S4/S5. no run bot or top
	F	8	S1 missed. S3 too anti and lead to bleeding. Rent too big. S4 and S5 incomp thus no run bot or top. Extra stitch bet S4/S5
	F	4	S1 missed. S2 minor bleed. S3 too anti and thus rent too big.
	F	3	S1 missed. Extra stitch bet S2/S3 cause bleed. Too little grasped on bottom running
	F	1	S1 missed
	M	6	S1 missed. S3 too little grasped. S4 and S5 incomplete done as simple. Therefore no running bottom or top
	F	5	S1 missed, S4 and S5 incomplete done as simple. Therefore no running bottom or top
	F	5	S1 missed, S4 and S5 incomplete done as simple. Therefore no running bottom or top