The United Kingdom National Bariatric Surgery Registry

Second Registry Report

2014

Prepared by

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Dendrite Clinical Systems

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Foreword

Obesity and bariatric surgery are rapidly rising up the NHS agenda as a consequence of social and lifestyle choices. As in all branches of medicine, prevention is better than cure, but this report clearly demonstrates that when required, bariatric surgery is effective and safe. This is based on detailed data on over 18,000 patients. The survival rate of over 99.9% and the decreasing length of time spent in hospital is all the more impressive given the increasing illness of patients being sent for surgery.

Perhaps most importantly this second report demonstrates the commitment of British surgeons to share their data in the interests of understanding and improving the quality of care they offer. It describes the state of the art in 2014. The pooling of so much data will help define the place of surgery for people debilitated by obesity and will, in time, help to refine surgical strategies and even unravel the mystery of why this surgery has such an instantaneous, profound and beneficial effect on diabetes, another scourge of our society.

In short, this report is a tribute to the professionalism of the British Obesity & Metabolic Surgery Society.

Prof. Sir Bruce Keogh

Medical Director of the National Health Service in England

Reflections from Down Under

This second report of the National Bariatric Surgery Registry (NBSR) analyses the cohort of bariatric surgery patients having procedures during the financial years 2011-2013 inclusive, and examines 16,956 primary and 1,327 revisions or planned second stage procedures. The report provides very detailed insights into changing patterns among those having bariatric operations and the procedures that they are undergoing, and the overall early outcomes achieved. This commentary will focus on the changing characteristics of those choosing to seek a surgical procedure, which of course is influenced by selection criteria that may vary regionally and with public *versus* private payment.

An important trend since the inception of the United Kingdom registry in 2009 has been the increasing proportion of men seeking surgery. In 2006, 16% of those having primary procedures were men, while in 2013 the proportion had risen to almost 26%. It is important to recognise that while men in the United Kingdom are more likely to be overweight or obese, and the rates of obesity (BMI >30 kg m^{-2}) for men and women are similar; women dominate the class III obese category by around 2:1 (1.5% for men and 3.0% for women) [1]. Men who have surgery tend to be a little older and have, on average, a higher BMI than women, and they make up just 10% and 24% of those having surgery in the class I and Class II ranges respectively. Therefore, the increase in the proportion of patients who are men, from 16% to 26%, represents a major step towards gender equity in those electing to have surgery, especially for men with Class III obesity.

Comorbidities

The average number of reported obesity-related comorbidities increases with age and also for those with a greater BMI before surgery. There are clear gender differences in obesity-related comorbidity reported prior to surgery. Women are more likely than men to report depression, asthma and gastro-oesophageal reflux; while men report higher rates of hypertension, obstructive sleep apnoea, type-2 diabetes, dyslipidaemia, atherosclerosis, and liver disease. Men and women report similar rates of poor functional status and arthritis. There has been a steady increase in the average numbers of obesity-related comorbidities reported between 2006 and 2013 for both men (2.6 to 3.7) and women (2.3 to 3.4). These increases have been reported across the whole BMI range, especially in those with a BMI below 40.

The relationship between reported comorbidity rates and BMI is of interest, as for some conditions there is a clear positive linear relationship, while for others there is not. Poor functional status, arthritis, asthma, sleep apnoea, and depression in women all have a clear pattern of increased prevalence in reporting with increased BMI, but gastro-oesophageal reflux, hypertension, dyslipidaemia, type-2 diabetes and atherosclerosis do not demonstrate such clear relationships. These non-linear associations are important and have been noted previously. Increased BMI imparts major restrictions on quality-of-life and function, but not necessarily on classical cardio-metabolic risk factors.

The Edmonton Obesity Staging System (EOSS) has been used to better assess and stage obesity-related comorbidity. In brief, it assesses mechanical, metabolic and psychological aspects of obesity, and separates patients into five risk groups: no clear risks (stage 0), pre-clinical (stage 1), established risks or disease (stage 2), end-organ damage (stage 3), and end-stage disease (stage 4). The majority of all patients operated were classified as stage 2 before surgery. However, the proportion of patients classified in stages 3 or 4 has increased substantially between 2006 and 2013; the proportion of women who fell in to stages 3 or 4 patients has risen from 7% to 26%, and for stage 4 alone from 1% to greater than 16%; the proportion of men classified as either stage 3 or stage 4 rose from 10% to 37% over the same period, and men in the stage 4 category alone rose from 5% to more than 20%. These changes reflect a clear trend to treating those patients with greater risk of mortality associated with their obesity [2,3]. At the same time as operating on patient populations with ever-increasing rates of comorbidity and more severe disease, average hospital stay has reduced: an extraordinary achievement.

Type 2 diabetes

During the triennium 4,121 primary procedures were performed on patients with type 2 diabetes and 742 with impaired fasting glucose or glucose tolerance. Type 2 diabetes was reported in 25% of women and 45% of men before surgery. Remission of diabetes, which was based on report rather than strict biochemical criteria, was noted more frequently as the first 3 years following surgery progressed: at 3 years 80% in total were classified as being in clinical remission. Reported remission was strongly related to weight loss at every time point. BMI as a predictor of remission was not evident, supporting the important observation that it is not attained BMI that is important, but the weight loss (excess weight loss) state itself that drives much of the improvement. The registry data support the observations that a longer duration of diabetes and type 2 diabetes requiring insulin therapy,

two factors that are clearly related, reduce the likelihood of glycaemic improvement. Clearly bariatric-metabolic surgery has become an acceptable option for the management of type 2 diabetes in those with clinically severe obesity and the results in terms weight loss and glycaemic control are impressive.

Clinically severe obesity

The management of clinically severe obesity involves chronic disease management. Joining up clinical pathways throughout the tiers of health care delivery is therefore logical for obesity just as it is for other chronic disease [4]. For bariatric surgery patients, a continuum of care and integration from primary care through to the specialised provision of bariatric surgery is an essential element in the chronic disease management process. Surgery provides a brief, but important, interval of attention within the context of long-term care, in a similar way that cardiac, vascular, endocrine, oncology, gastrointestinal and orthopaedic surgery must integrate at many levels in delivering optimum health outcomes for chronic disease management. Recognition that joining up obesity clinical pathways and delivery of Tier 3 obesity assessment and management services has been a fundamental step in providing better care for those with clinically severe obesity [4,5].

Finally, how do we prioritise surgical therapy to those most in need and most likely to benefit? The answer is not clear and requires a broad health care provider perspective. There is an important distinction between being eligible for surgery or prioritised for surgery. Prioritisation implies that, given the patient's current health status, bariatric-metabolic surgery should be recommended, by a caring physician, as best care. This concept is an accepted responsibility of health care providers, but for those with clinically severe obesity barriers dominate rights. How can the registries locally and globally assist in addressing this important health delivery gap?

Summary

1. The increased proportion of men, higher rates of obesity related comorbidity, and higher EOSS scores reported in the last triennium indicate a change in the selection of patients. This may be due to a maturation in our understanding of the surgical risks to benefits and an acceptance of the health benefits of substantial, sustained weight loss.
2. The high proportion of patients with diabetes among those seeking surgery indicates that the message regarding bariatric-metabolic surgery and type 2 diabetes is being heard.
3. The more formal streamlining of clinical pathways and expansion of Tier 3 obesity assessment and management services will add an important layer to improving patient care and outcomes. This provides an opportunity and a challenge for the registry to incorporate outcome measures relevant to the continuum of care.
4. How do we prioritise surgical therapy to those most in need and most likely to benefit?

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A patient's perspective

It was a rare and welcome honour to be approached by the Committee responsible for this excellent report to contribute to its introduction. Weight Loss Surgery Information and Support (WLSinfo) is a large, patient-led charity established in 2003, of which I am proud to be the Chair. I have been both blessed and fortunate to see an increase in the number of Bariatric Surgery operations nationally, and steady improvements in its quality over the years. Our inclusion as stakeholders here reflects for me the importance that BOMSS places on the partnership with patients. The first NBSR report gave a comprehensive set of baseline data, which has been added to and improved in this second edition. As a patient, I am reassured by the findings regarding mortality, complications and length-of-stay.

Patients are often inquisitive as to a surgeon's experience in a particular procedure, and this report goes a long way towards reassuring patients about their chosen surgeon.

The surgeons who have contributed to the NBSR have measured their collective activity and this will be expanded in coming years to allow a continuous quality improvement process, and will surely contribute favourably to the debate around the clinical-effectiveness and cost-effectiveness of bariatric surgery.

The NHS faces opportunities and challenges in areas including Commissioning NHS services and proposed changes to NICE guidelines. This makes the need for good-quality, robust data even more important.

I congratulate the Database Committee, the Society and all who have contributed to this excellent report.

I recommend all patients considering surgery to look at the information it contains regarding their surgeon and to discuss it with them.

Ken Clare

Chair of Trustees Weight Loss Surgery Information and Support (WLSinfo)

Executive summary

This is the second comprehensive, nationwide analysis of outcomes from bariatric (obesity) and metabolic surgery in the United Kingdom & Ireland:

In overview:

- 161 surgeons from 137 hospitals recorded 32,073 operations; 18,283 in the three financial years ending 2011, 2012 and 2013.
- In 2011-2013 76.2% operations were funded by the National Health Service; 22.6% were independently funded and a tiny proportion were paid for by private insurers.
- The majority of the analyses include data on operations carried out in the financial years 2011-2013, and include information on 9,526 gastric bypass procedures, 4,705 gastric band operations and 3,797 sleeve gastrectomy operations.
- 95.4% of all primary operations were performed laparoscopically over the last three financial years 2011, 2012 and 2013.
- The observed in-hospital mortality rate after primary surgery was 0.07% overall (and just 0.07% for gastric bypass), much lower than that for many other planned operations.
- The recorded surgical complication rate overall for primary operations was 2.9%.
- These figures compare to the best internationally available outcome benchmarks. Thus, surgery in the United Kingdom & Ireland, in the hands of the contributors, is safe.
- The average post-operative stay was 2.7 days, indicating efficient use of resources.

At the time of primary surgery:

- The average BMI was 48.8 kg m^{-2}, which means that patients were almost twice their ideal weight.
- 53.9% of men and 41.4% of women had a high level of co-existing disease (4 or more obesity-related diseases).
- 44.6% of men and 25.9% of women had type 2 diabetes.
- 39.9% of men and 15.8% of women were on treatment for sleep apnoea.
- 73.2% of men and 71.5% of women had some functional impairment, *i.e.,* they could not manage to climb 3 flights of stairs without resting.
- Comparing the financial years 2009-2010 to 2011-2013, the average BMI has increased from 48.5 kg m^{-2} to 48.8 kg m^{-2}; the average number of comorbidities has increased from 3.2 to 3.4; the average Obesity Surgery Mortality Risk Score (OSMRS) has increased from 1.6 to 1.8; and average post-operative stay has fallen from 3.1 days to 2.7 days, even more remarkable given that the proportion of operations that were gastric banding (typically a 24-hour stay operation) has decreased and the proportion of operations that were sleeve gastrectomy procedures (where patients stay 2-3 days typically) has increased.

Follow-up data derived from some 30,933 follow-up entries for the 2011-2012 patients show:

one year after primary surgery:

- On average, patients lost 58.4% of their excess weight (36.6% for gastric banding, 68.7% for gastric bypass & 58.9% for sleeve gastrectomy).
- Over half of patients (64.0%) with pre-operative functional impairment returned to a state of no impairment one year after surgery, meaning they could climb 3 flights of stairs without resting.
- 61.0% of patients with sleep apnoea were able to come off treatment.

two years after primary surgery:

- 65.1% of patients with type 2 diabetes returned to a state of no indication of diabetes, meaning, in practice, that they were able to stop their diabetic medications.

three years after primary surgery for the 2006-2011 cohort:

- On average, patients lost 59.6% of their excess weight (52.9% for gastric banding, n=453; 65.4% for gastric bypass, n=536; & 59.0% for sleeve gastrectomy, n=40).

Comment on mortality data:

- Two external sources have assessed mortality using independently-collected Hospital Episodes Statistics (HES) data:
  - In an analysis conducted by the Quality Outcomes Research Unit in Birmingham presented on page 42 as part of the Surgeon-Level Outcomes Publication (2013) the estimated mortality for primary bariatric surgery for the 4 years April 2009 to February 2013 was 0.11% (25 / 23,760).
  - In an earlier HES analysis of patients having bariatric surgery between 2000 and 2008, the 30-day mortality rate was 0.27% (19 / 6,953). When laparoscopic cases alone were considered, the mortality was much lower at 0.16% (7 / 4,436) [1].
- Taking the evidence together, the NBSR Committee believes our results in the Second Report to be an accurate representation of the outcomes of those surgeons who submitted their data. We do not have 100% data submission yet, but this will come.

Healthcare implications:

- Severe & Complex Obesity is a serious, life-long condition associated with many major medical conditions, the cost of which threatens to bankrupt the NHS. For severely obese people, medical therapy, lifestyle changes and attempts at dieting rarely succeed in maintaining long-term, clinically beneficial weight loss due to the hormonal effects of the obese state, dieting, and energy balance and metabolic rate.
- For all comparisons, the data show that there is great benefit from bariatric surgery for all the diseases studied, in particular the effect on diabetes has important implications for the NHS.
- By implication, bariatric surgery greatly and cost-effectively improves the health of obese patients, much more so than other treatments.

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From the Chairman of the Database Committee and President of BOMSS

It is an honour and a privilege to present this Second Report of the National Bariatric Surgery Registry. Since the inaugural report in 2011 on data from over 8,000 operations, bariatric surgery in the United Kingdom has become more formalised, with NHS England publishing the Clinical Commissioning Policy for Complex and Specialised Obesity Surgery in April 2013. The Royal College of Physicians has also issued a call to action to ramp up medical obesity services and awareness of treating overweight and obese patients. Despite all this, the rate of surgery in the United Kingdom has fallen significantly, and this poses many challenges for clinicians trying to offer clinically- and cost-effective care for their patients. It is therefore timely to present data on a further 18,000 patients operated upon in the United Kingdom between 2010 and 2013, demonstrating some remarkable improvements in obesity-related disease after surgery, with up to 3 years of follow up data recorded.

When bariatric surgery for severe and complex obesity was first undertaken over 50 years ago, all surgery was undertaken using open surgical techniques. The scene has now changed dramatically, with nearly all surgery performed by laparoscopic (keyhole) techniques, which, together with protocols for enhanced recovery, mean that pain is much reduced for the patient and hospital stay is much shorter than before. The data presented in this report cover 3 main operations: gastric bypass, gastric banding and sleeve gastrectomy. We do not know which is the *best* bariatric surgery operation [1]. Surgical techniques and trends change over time and with experience, but collecting a large amount of data on many thousands of patients means that important observations can be made that, in turn, lead onto and form the basis for research questions.

We urge those new to the field to look at the sections on diabetes control: the NHS is saving money because patients are coming off their diabetes medication (pages143-147 and 152-155) as a direct result of their bariatric surgery. Patients are also seeing vast improvement in their functional status, where even wheelchair users or housebound patients recover the ability to climb stairs (pages 143-151). These findings clearly show the efficacy of bariatric surgery for patients.

It is important to note that the NBSR was formed as a collaboration between three specialist surgical societies: the Association of Laparoscopic Surgeons, the Association of Upper Gastrointestinal Surgeons and the British Obesity and Metabolic Surgery Society (BOMSS), and their data management partner Dendrite Clinical Systems, and in large part to date has received no public funding. Bariatric surgery was one of the 10 specialties to participate in the publication of Surgeon-Level Consultant Outcomes in 2013 and anticipates receiving funding from the Healthcare Quality Improvement Partnership for the next round in October 2014. Aside from this, there has been no offer of public funding for the Registry whose day-to-day administration was taken over by BOMSS in January 2014. Publication of this report involved no public funding and the committee does not receive remuneration.

On a hospital level in the United Kingdom there is a distinct lack of administrative support to assist surgeons in assuring data quality; in particular there is no infrastructure to address the 3 problems of data quality, namely: missing records, incomplete records and erroneous data. There is also poorly-developed infrastructure, especially in capturing follow up beyond 2 years, in stark contrast to the processes deeply embedded within the NHS to collect data on, for example, cancer treatment and survival. This is a big challenge: how to improve the follow up of patients and record 5-year outcome data within the NHS. Even so, the complications and mortality data presented are comparable with the international literature, and there are many new findings that have not been observed before on the scale of a national registry on the outcomes following surgery for obesity-related disease.

This unique database provides clear evidence that bariatric surgery radically improves health for patients with severe and complex obesity. It demonstrates that the health benefits of bariatric surgery reported in the international literature apply equally to our patients in the United Kingdom.

The challenges of raising awareness of the effects of bariatric surgery and increasing service provision are considerable. Many factors including deeply held societal prejudice and reorganisations within the NHS appear to be limiting the provision of surgery, which is much less than in other equivalent countries. For our part, those surgeons who submitted their data to the Registry in England have been open and transparent with their operative results, and to facilitate the pathway of patients from their GP to surgery BOMSS has developed multi-collegiate commissioning guidance. The texts of both the 2013 Consultant Outcomes Publication and the 2014 Tier 3 Commissioning Guidance are reproduced in subsequent pages.

The NBSR Database Committee is grateful to all those surgeons who have voluntarily contributed their NHS and private patient data to the Registry in the time leading up to April 2013, when data submission became mandatory for units providing NHS surgery. There has been a substantial increase in the number of surgeons contributing since the first report from 84 to 150, and the number of contributing hospitals has increased from 86 to 129.

We are also immensely grateful to Dr Peter Walton and Dr Robin Kinsman of Dendrite who have enthusiastically, patiently and expertly put in many, many hours of time to project plan, analyse the data and help us deliver the report over the last 6 months.

We are also indebted to Professors John Dixon, Paul O'Brien, Alberic Fiennes and Michel Gagner for contributing invited commentaries for the sections on gastric banding, gastric bypass and sleeve gastrectomy respectively. The NBSR Database Committee and bariatric surgeons are immensely grateful to Jenny Treglohan, who took on the considerable burden of being NBSR Administrator for the Surgeon-Level Outcomes Publication in 2013, and Sarvit Wünsch and Nichola Coates who took over as NBSR administrators this year.

Richard Welbourn

President of the BOMSS and Chair of the NBSR Database Committee

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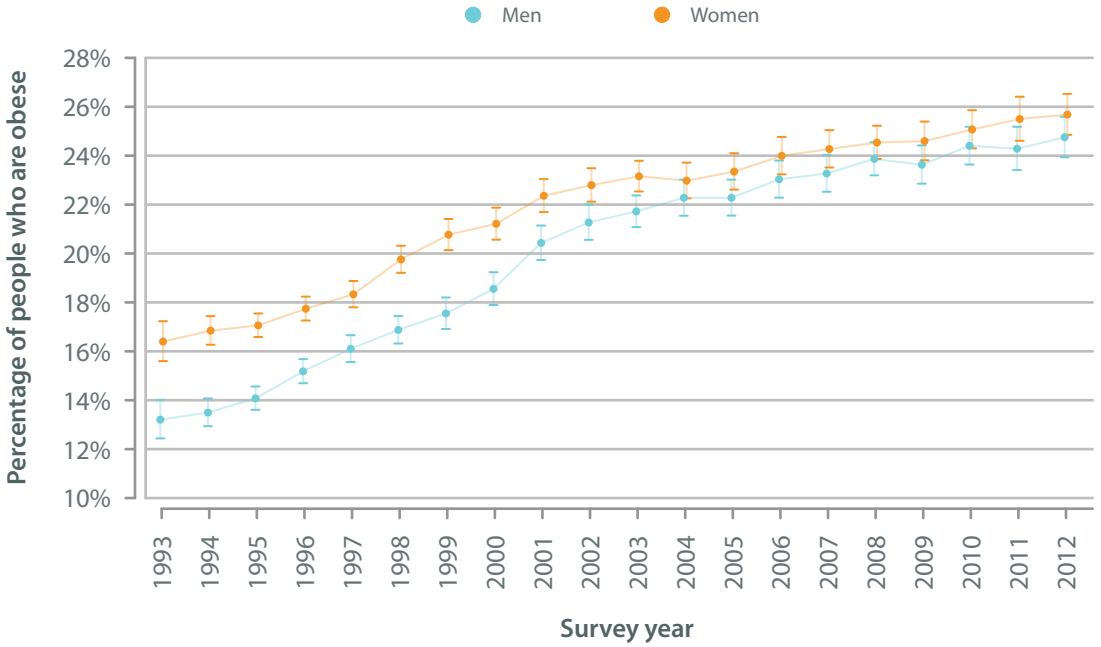
Introduction

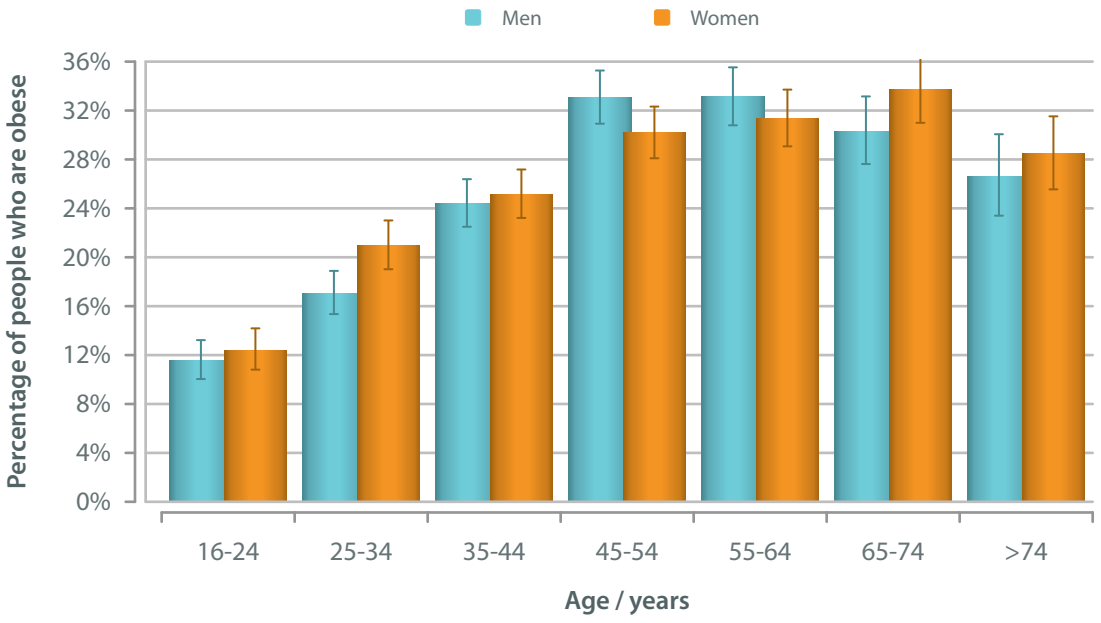
The United Kingdom in the context of the worldwide obesity epidemic

The worldwide epidemic of obesity and obesity-related disease such as type 2 diabetes continues to worsen [1]. Compared to data from 1980, the overall prevalence in the world of people being overweight (body mass index, BMI, of 25 kg m^{-2} or more) or obese (BMI 30 kg m^{-2} or more) has risen from 28.8% to 36.9% in men and from 29.8% to 38.0% in women. Internationally, every country is failing in its attempts to combat obesity. In developed countries, the prevalence has also increased substantially in children and adolescents, with 23·8% of boys and 22·6% of girls overweight or obese in 2013.

Health Survey for England [i]: Trends in obesity (BMI ≥30 kg m^{-2}) in England

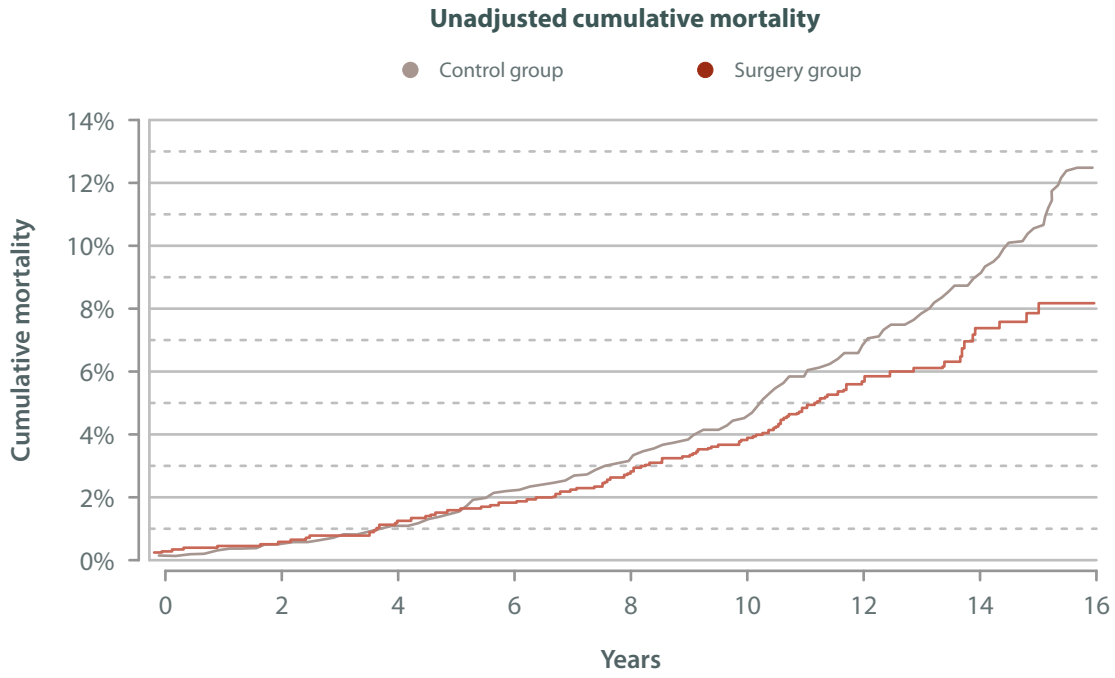


Health Survey for England [i]: Obesity (BMI ≥30 kg m^{-2}), age and gender in England; survey years 2010-2012



For the United Kingdom, the data indicate that we are the 3rd most obese country in western Europe after Iceland and Malta. In 2013, as many as 67% of men aged 20 and over were overweight or obese compared to 57% for females. Overall, the figure was 62% for the United Kingdom population in this age group, an increase of 13% over 1980 levels. In the Health Survey for England 2008-2010, 3.5% of men and 1.5% of women had a body mass index of 40 kg m^{-2} or more [2]. This proportion alone represents some 1.5 million people.

There is substantial evidence that the obese state shortens life expectancy [3]. For example, the years of life lost for Caucasians aged 20-30 years with a BMI greater than 45 kg m^{-2} is 13 for men and 8 for women. For men, this represents a 22% reduction in expected remaining lifespan. Data from a recent large systematic review and meta-analysis suggested that in 61,000 people followed for 10 years *there is no healthy pattern of increased weight* even in those who did not appear to have metabolic disease [4]. There is currently no effective treatment for obesity other than general lifestyle advice to continue dieting. However, it is now accepted that the effects of dieting are modest: the 2014 NICE Public Health Guidance (PH53) indicates that *people attending a lifestyle weight management programme lose around 3% of their body weight* only, and accepts that weight loss of more than 5% is needed to gain substantial benefit, and this weight loss needs to be maintained life-long to keep the benefit [5]. Given that worldwide efforts to prevent or treat obesity have consistently failed, invasive techniques (surgery) need to be taken seriously.



This graph from the long running Swedish Obese Subjects (SOS) trial [10] shows the cumulative mortality for 2,010 patients who chose to have bariatric surgery compared to 2,037 matched controls who did not have surgery. The difference in survival between the two groups was statistically significant (p=0.04). The patient groups were not randomised since in 1987, when the time the study began, only open surgery was available and it was not considered ethical to do a randomised study in bariatric surgery.

i. Health Survey for England 2012. Publication date 18 December 2013. Data downloaded on 05/06/2014. Source data Excel file *Health Survey for England - 2012, Trend tables: Adult trend tables* located at: www.hscic.gov.uk/searchcatalogue?productid=13888

The potential role of bariatric surgery

Bariatric surgery is now established worldwide as an effective treatment for severe and complex obesity. It is estimated that more than 340,000 procedures were carried out by more than 6,700 surgeons worldwide in 2011 [6]. A systematic review of survival benefit, as well as 2 important studies in the New England Journal of Medicine, demonstrates that bariatric surgery provides survival benefit compared to no surgery [7, 8, 9].

In addition, scientific evidence is accumulating that bariatric surgery is far more effective than medical therapy and constant cycles of dieting at helping patients keep weight off in the long term, and effectively treats obesity-related disease such as type 2 diabetes. In long-term studies surgery patients maintain 25–30% weight loss at 10 years or more compared to 4.7 % at 8 years for Intensive Lifestyle Intervention [10, 11].

In practice, most patients having surgery will have spent a lifetime trying to diet with inevitable *yo-yoing*, recidivism and rebound weight regain up to a higher level, according to the hormonal effects of the obese state, dieting and consequent changes in energy balance and metabolic rate [12]. In one study, patients had dieted for an average of 22 years and had a net gain of 55 kg at the time of surgery, despite also losing 61 kg in multiple weight loss attempts in the intervening years [13].

Effect of bariatric surgery on the treatment of diabetes and other obesity-related disease

The fact that type 2 diabetes can be effectively treated by an operation is still neither understood nor appreciated by most clinicians or commissioners. There is level 1 evidence (meaning randomised controlled trials, systematic reviews and meta-analyses) that surgery is superior to medical therapy in improving diabetes control and the metabolic syndrome [14]. Surgery reduces the number of hypoglycaemic medications required, including getting patients off insulin. Simply considering the reduced costs of diabetes treatment, bariatric surgery pays for itself within 2-3 years. So, it is very important that priority is given to bariatric surgery as a treatment option purely from the economic perspective of the tax payer.

Surgery can also put many patients into remission (normal HbA1c, normal fasting glucose, off all medication, relative risk 22.1) and markedly reduce incident diabetes compared to matched patients not having surgery [10, 14]. The gastric bypass has been called the equivalent of a *free injection of GLP-1 for life*. The International Diabetes Federation even recommends bariatric surgery as:

> *an appropriate treatment for type 2 diabetes and [patients with] BMI ≥35 not achieving recommended treatment targets with medical therapy, especially where there is other obesity-related comorbidity* [15]

It is also accepted that the BMI threshold for bariatric surgery may be reduced by 2.5 kg m^{-2} for Asian patients due to their greater susceptibility to diabetes and metabolic syndrome.

Bariatric surgery is also very effective at reducing the number of anti-hypertensive medications required by patients, probably for several years, but the indications are that over time, as patients get older, they will eventually go back on treatment. All the other comorbidities associated with obesity show improvement, with patients stopping treatments [16].

Fertility is known to improve in those female patients with polycystic ovary syndrome.

Surgery also reduces the risk of cardiovascular events and the risk of gynaecological cancers [9]. It also restores functional capacity: in the first United Kingdom Registry report on data from 8,000 patients with an average BMI of 47 kg m^{-2}, 70% were unable to climb 3 flights of stairs before surgery; one year later, half of these patients were no longer functionally impaired. Surgery in the United Kingdom is safe, with a mortality rate of around 1 in 1,000, according to external validation (Hospital Episodes Statistics data), which is less than many more common gastrointestinal procedures [17].

It is the remarkable effect of bariatric surgery on improving the *metabolic syndrome* (type 2 diabetes, hypertension, dyslipidaemia and polycystic ovary syndrome) that spurred a change in emphasis away from the old-fashioned term *weight reduction surgery*, which carries social stigma and prejudice, to the current term *metabolic surgery*, (hence BOMSS, the British Obesity & Metabolic Surgery Society), indicating it is an intervention that happens to be an operation, and that treats and cures disease.

Different types of bariatric procedures

The 3 most commonly performed bariatric procedures in the United Kingdom are: gastric bypass, vertical sleeve gastrectomy and gastric banding. Worldwide these are also the most frequently performed procedures. Roux en Y gastric bypass (the commonest variety of this operation) comprises 46.6% of bariatric surgery in the United Kingdom, sleeve gastrectomy makes up 27.8% of operations, and gastric banding at 17.8%. The bilio-pancreatic diversion with duodenal switch, an operation that works primarily through inducing malabsorption, comprises 2.2% of all bariatric surgery. Sleeve gastrectomy has increased in popularity from 5.3% in 2008 to 27.9% in 2011, and the rate of gastric banding has decreased from 42.3% to 17.8% in the same time period. The reasons for these trends are not known; however, the choice of operation appears to be largely determined by surgeon- and patient-preference, and the local expertise of each bariatric unit.

An illustration of each kind of surgery is shown below.

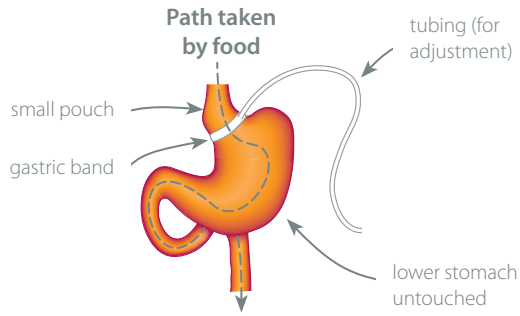


Fig. 1. Diagrammatic representation of a gastric band in place

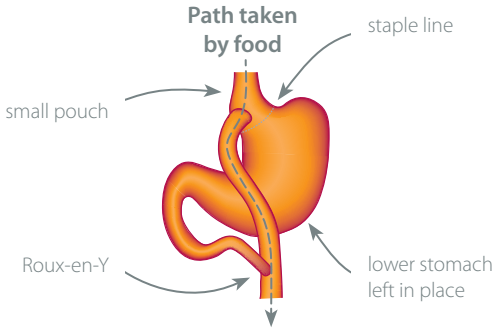


Fig. 2. Diagrammatic representation of a Roux-en-Y gastric bypass procedure

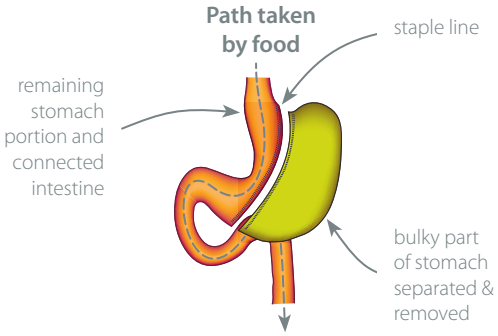


Fig. 3. The basics of a sleeve gastrectomy procedure

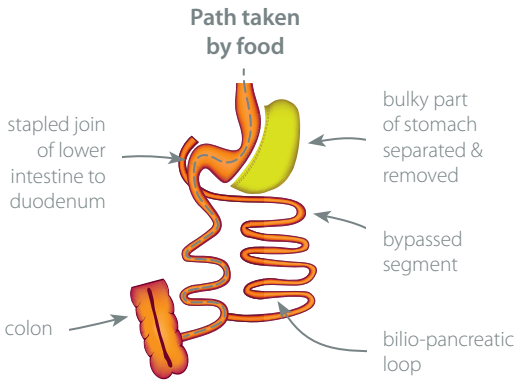


Fig. 4. Duodenal switch

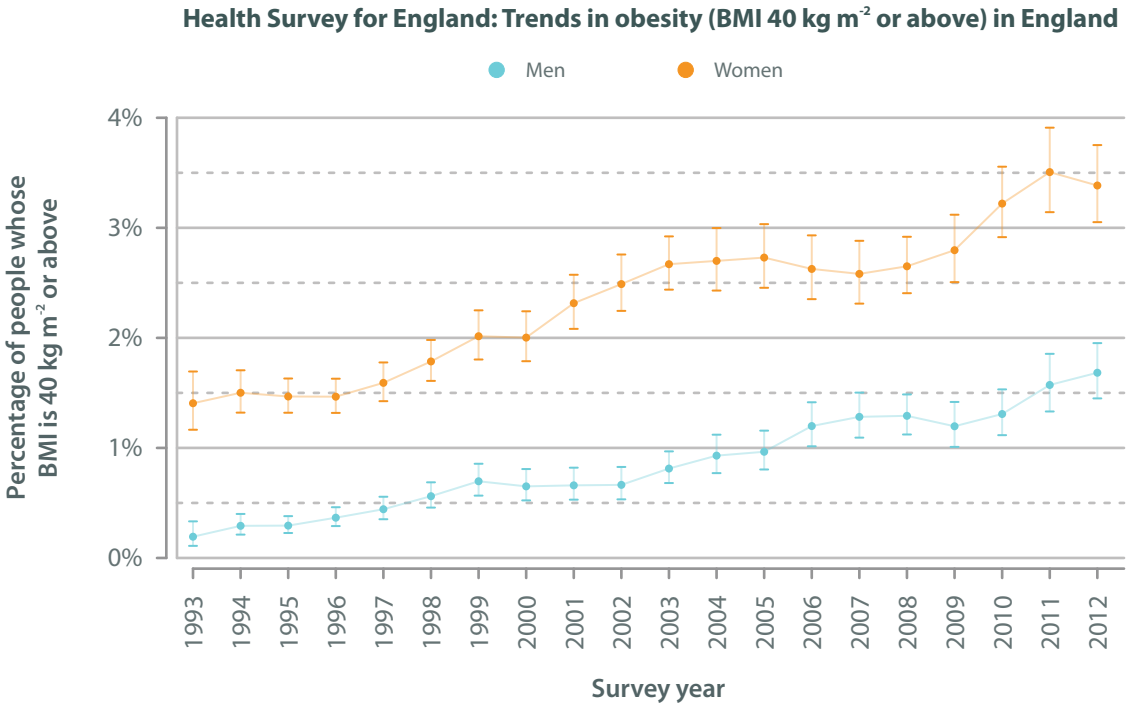
Mechanism of action of the 3 commonest operations

All of the operations appear to work by inducing physiological change. Gastric bypass and sleeve gastrectomy enhance the flow of nutrients through the stomach into the small bowel, and elevations in hormones such as Protein YY (PYY) and Glucagon-like Peptide-1 (GLP-1) occur soon after eating. These, and probably many other gut hormones, are associated with changes in appetite and satiety [18]. There is no significant protein-calorie malnutrition after gastric bypass nor after sleeve gastrectomy.

Typically, patients feel that a *switch has been turned* in their heads, as often for the first time in their lives they feel that their appetite has been switched off, and they feel full quickly. Gastric banding's effect seems to be mediated through stimulation of the vagus nerve *via* nerve endings in the lining of the stomach wall of the pouch, which is created when the band is placed around the upper part of the stomach [19]. The aim is to find the optimal *sweet spot* of restriction *via* injections of saline into a subcutaneous access port.

Commissioning of bariatric surgery in the United Kingdom

Despite the clear message from the **First Registry Report to March 2010** on data from the NBSR, where excellent patient-safety was reported and powerful improvements in health outcomes at time-points one and two years after surgery were demonstrated for a cohort of over 8,000 patients, the commissioning of bariatric surgery in the United Kingdom has decreased [16]. At least 1.5 million people in the United Kingdom have a body mass index (BMI) of 40 kg m^{-2} or more (2.5% of a national population of around 60 million [2]), and the number of people with a BMI of 35 kg m^{-2} or more with at least one obesity-related disease that could be improved by weight loss surgery is estimated at several million.



The current rate of service provision is much less than 1% of those with a BMI of 40 kg m^{-2} or more. In the latest year for which we have data, the Health and Social Services Information Centre indicated that there was a 10% fall in the number of NHS bariatric surgery procedures, as shown in the following table [19,20]:

Hospital Episode Statistics (HES): admitted patient care; finished consultant episodes (FECs); 2012-2013

	Period					
	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013
Bariatric surgery for obesity	2,617	4,138	7,290	8,187	8,829	**7,984**

The operation numbers would have to rise by more than 5,000 *per annum* to achieve even 1% of the estimated need. By comparison, the rate of surgery in a comparable European country, Sweden, was 78 procedures *per* 100,000 population in 2013, for a population of 9.87 million (data from Scandinavian Obesity Surgery Register [21]).

The equivalent rate of surgery in the United Kingdom would be 49,000 procedures *per annum* for a population of 63 million, more than 6 times the current rate of service provision of around 13 procedures *per* 100,000. There is no medical, nor any surgical reason for this difference; the comparison becomes even more striking when the fact that the prevalence of obesity in the general population of the United Kingdom is higher than that in Sweden. So, there is a huge under-provision of bariatric surgery in the United Kingdom.

Health commissioners in Sweden have identified the cost-effectiveness of surgery as a key driver for increased service provision. In the most recent cost-effectiveness analysis by the Health Technology Assessment programme in the United Kingdom, the Incremental Cost Effectiveness Ratio *per* Quality Adjusted Life Year (which is used as a standard measure) was between £2,000-4,000 for a patient with a BMI 40 kg m^{-2} or above. Generally, NICE views an ICER / QALY ratio of <£20,000 as cost-effective, and the calculated figure for a patient with a BMI 40 kg m^{-2} or over indicates that it is one of **the** most cost-effective interventions in existence [23].

Current data from the United States of America suggest that the break-even time for recouping the cost of surgery for a patient with type 2 diabetes is about 2-3 years after the operation, simply considering the cost savings alone of reduced insulin usage, and not taking into account any of the other benefits of surgery that are provided as a *free add-on* [24].

There is no medical, nor surgical reason why so few should be offered surgery; so why is such an effective treatment not made available to many more patients in the United Kingdom? The state of the economy and difficulty in funding an up-front cost could be an underlying factor in commissioning decisions. There are also pervasive, inherent, societal beliefs (prejudice) that treatment should not be offered to obese people (*… if only they tried they could keep the weight off themselves*) [25]. Perhaps, also, healthcare workers hesitate to engage with patients on the sensitive issue of weight, and fail to recommend surgery due to lack of knowledge of its benefits and safety. Ill-judged reporting in the popular media may also contribute to views that the obese are lazy or bad, and that surgery therefore must be inappropriate. Policy-makers need to balance the challenges of prevention with the cost of not treating those whose obesity-related disease is increasingly expensive to the NHS. If the perception were changed to this being an intervention for diabetes (that also brings many other benefits) then it would make financial sense, according to the available data, for the health service to embrace it without hesitation.

The wider effects of bariatric surgery (outcomes not considered in cost effectiveness analyses) include returning to the same rates of paid employment as the population norm and a decreased reliance on state benefit claims [26]. An independent report estimated that if 140,000 eligible patients had surgery, the boost to the economy at 3 years by patients returning to work would be £1.3bn, with a further £150m being returned to the economy by reducing benefits costs.

The effects of NHS England policy

The exact reasons for the decline in bariatric surgery provision already evident in 2012 / 2013 are not known. However, in April 2014 NHS England published its policy on severe and complex obesity [27]. In this policy it was stated that patients referred for surgery must first have been through a medical obesity assessment (so-called *Tier 3*) clinic. In many regions in the United Kingdom, medical weight and assessment management clinics were either non-existent or rudimentary, and this shortfall has led to established bariatric units experiencing a further decline in the number of referrals to their service, as the patient's route direct from the GP to the bariatric surgery centre was no longer available. There has been healthy debate about the value of adding bariatric physicians to the care pathway, but it is clear that there is a greater need than surgeons could ever treat, even in the most well-funded health economy, and patients need their obesity-related chronic disease ameliorating and optimising by specialists in addition to surgeons.

In the NHS England policy it was also stipulated that the duration of the time spent in the local specialist obesity service weight loss programme *will have been for [the] duration of 12-24 months*. For patients with a BMI more than 50 kg m^{-2} *the minimum acceptable period is six months*. The time to be spent in the medical clinic (*Tier 3*) has caused even more delays in patients being allowed access to surgery. There is no evidence whatsoever that it takes 12-24 months for a patient to be prepared for a bariatric procedure. The effect on weight alone of management in the clinic is not likely to be large since it is known that *on average, people attending a lifestyle weight management programme lose around 3% of their body weight* [5].

To compound the problem, it also became NHS England policy that weight assessment and management clinics should be commissioned and paid for by Local Authorities, and not by the NHS [28]. This has potentially made it even more difficult for patients to access appropriate care as local services were not being commissioned [29]. There is ongoing debate about whether or not this situation can be reversed, with medical clinics being commissioned and funded by Clinical Commissioning Groups (CCGs). In December 2013 the BOMSS conducted a survey of its members on the subjects of access to care and provision of services, and one responder stated that:

> *… we have no Tier 3 service at all locally and so we are in a position where it is very difficult to comply with NHSE guidance. Moreover, we are powerless in respect of our influence over the CCGs to establish one. It forms a constructive way to prevent the further development of bariatric surgery.*

Accredited commissioning guidance for weight assessment and management clinics

In an effort to improve the care pathway for potential bariatric surgery patients, the British Obesity and Metabolic Surgery Society (BOMSS) worked with the Royal College of Surgeons of England and the Royal College of Physicians to produce Commissioning Guidance for Weight Assessment and Management Clinics, using a methodology accredited by the National Institute of Health and Clinical Excellence (NICE).

The Guidance describes the pathway into the clinics, what should happen in the clinics, and who should be referred for a bariatric surgery assessment, and is intended to be a major step towards streamlining the patient-pathway to bariatric surgery. The Guidance Development Group (GDG) consisted of representatives from 5 Royal Colleges and 10 specialty colleges / associations in all.

The sponsoring Royal Colleges, Specialty Associations and official bodies were:

- The Royal College of Surgeons of England
- The Royal College of Physicians
- The Royal College of Pathologists
- The Royal College of Psychiatrists
- The Royal College of General Practitioners
- The Faculty of Public Health
- The British Obesity & Metabolic Surgery Society
- The British Dietetic Association
- The British Psychological Society
- The National Obesity Forum

The GDG followed a prescribed process of data search, development group meetings and e-mail discussions to provide the best synthesis of the available evidence, including best-practice guidelines, existing commissioning policies and published guidance from BOMSS. Two face-to-face meetings were held, in June and August 2013, and multiple revisions were circulated within the group *via* e-mail. There was also a period of public consultation from September-December 2013, where more than 20 individuals and groups contributed more than 130 responses. The final document was published in March 2014, and contained research recommendations that highlighted the lack of knowledge base in bariatric surgery and pre- and post-surgery follow up care [30]. The Guidance was published on the RCS and BOMSS websites in March 2014 and we reproduce parts of it here.

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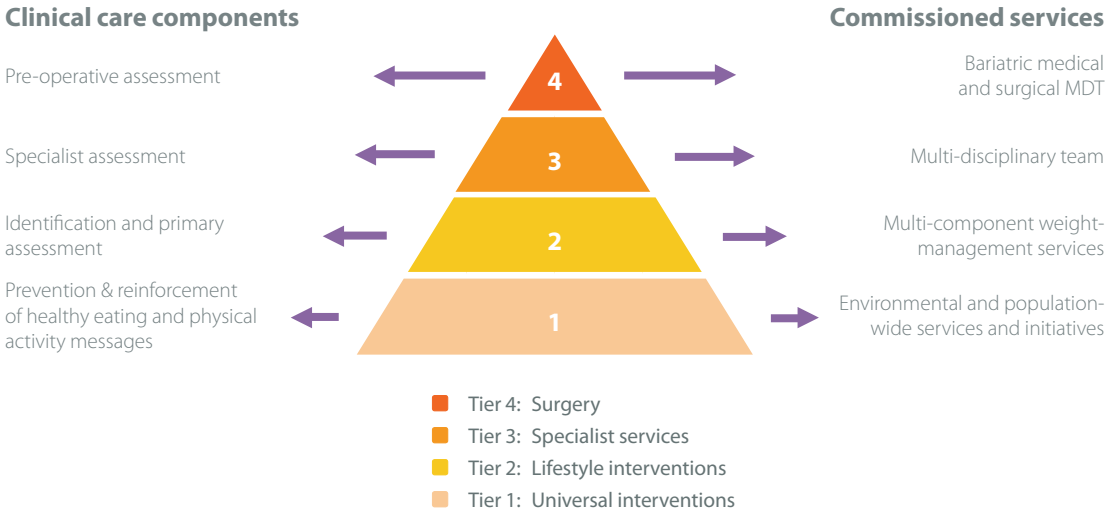
Commissioning guide 2014

Weight assessment and management clinics

This guidance and recommendations are to be read in conjunction with the Commissioning Policy A05 Complex and Specialised Obesity Surgery Services of the NHS Commissioning Board April 2013 [1]. The A05 policy describes the pathway of patients within the multi-disciplinary bariatric surgical service and states that patients referred for bariatric surgery will come from a primary or secondary care specialist obesity service. Post-operative follow up within the bariatric surgical service is commissioned for 2 years, and dovetails with the ongoing care provided peri- and post-operatively by the specialist obesity service.

The process of care overall is intended to fit within a chronic disease model overseen by specialist weight management clinics, according to the plans described in *Action on Obesity: comprehensive care for all*, a report of the Royal College of Physicians (January 2013) and *Measuring up. The medical profession's prescription for the nation's obesity crisis*, a report of the Academy of Medical Royal Colleges (February 2013) [2, 3]. Currently there is not universal geographical coverage of Tier 3 weight management services in the NHS. Therefore this Guidance is intended for Tier 3 Specialist Services that provide the link between Tier 1 / 2 Environmental and population-wide services / Lifestyle interventions, and Tier 4 Multi-disciplinary Specialist Bariatric Surgical Services, which is covered by NICE Guidance and BOMSS standards for clinical services and guidance on commissioning [4-6]. The tiers are defined below according to the terminology from the 2013 Department of Health (DH) Tier 2 guidance [7].



It is recognised that the label *Tier 3* in this context could apply to a clinic (*Weight Assessment & Management Clinic*) based either in primary or secondary care, but if in primary care it would be distinct from Tier 2 services [i]. Also, the Guideline Development Group recognises the changing nature of the definitions and that Tier 4 services (*bariatric surgery*) may also include specialist non-surgical bariatric services, including medical, dietetic and psychological support. For NHS England Tier 3 services will be commissioned by Clinical Commissioning Groups and will liaise closely with Tier 4 services, which are commissioned centrally [2].

This Tier 3 guidance describes the role of the referring GP, what should be achieved in the clinics and who should be referred for bariatric surgery. Given the lack of consistency in the provision of medical obesity services, this guidance should provide an organised structure and evidence-base for treatment, guidance for referral into and out of the Tier 3 service: either back to primary care (Tier 2) or on to specialist or surgical assessment (Tier 4). The advice on type 2 diabetes is also intended to guide GPs in the management of severely obese patients in whom prevention strategies have failed [8].

i. Tier 2 refers to lifestyle weight management services plus prescribing in appropriate clinical circumstances.

The potential uptake to the clinics is unknown, although the population in the United Kingdom with a body mass index (BMI) of ≥40 kg m^{-2} alone is around 1.3 million, and there is an annual incidence of this level of obesity of about 60,000. The scale of the problem underlines the need for guidance on how patients with severe and complex obesity should be assessed and managed. Although it is not known how many would wish to be referred to the clinics, or how many would subsequently opt for bariatric surgery, there need to be enough bariatric physicians and allied health professionals in these teams to provide this care.

A literature search was carried out to identify research articles that evaluated the effectiveness and cost-effectiveness of Tier 3 weight management services. Although much high-grade evidence exists with respect to the clinical management of patients with obesity there was little evidence at a system level on how services should be organized to achieve the best patient outcomes in the most cost-effective manner. The search also did not identify the peer-reviewed publications of existing community-based weight management programmes relevant to the management of obesity in the United Kingdom [9, 10]. Therefore, the recommendations in this guidance specify the scope of care that patients should receive in a Tier 3 weight management service, but how this care is organized will be a locally-based decision. Wherever possible meta-analyses, systematic reviews or Randomised Controlled Trial evidence is presented. Observational trial data have also been included where the panel felt that the findings from several studies were consistent and effect sizes large [11,12].

It must be considered that many patients eligible for bariatric surgery may choose not to have it, but still require and want assessment to treat issues beyond simply weight, and talk about treatment options so as to provide feedback to the GP about a long-term plan; this would require a review at a specialised clinic [13]. It is assumed that patients will only be referred on by GPs to Tier 3 if they have tried and failed a supervised lifestyle weight management programme or self-directed dieting. Patients need not spend a prolonged time in Tier 3 in preparation for referral to a Tier 4 bariatric surgery clinic, but the Tier 3 clinic should not only be for assessing patients to refer on for surgery. A large proportion of patients who the GPs have struggled with (hence the referral to Tier 3) would be referred back after assessment with a management plan.

Although there is no evidence base for how long a patient being assessed for surgery should be in the Weight Assessment and Management clinic, typically the process of evaluation and assessment may take a period of months for complex patients. During this time clinically meaningful benefit may be achieved without the need or wish for referral for surgery. Equally, it is important to avoid undue delays in referral for surgery such as repeating failed prior interventions inappropriately due to the high likelihood of recidivism with weight regain and yo-yo dieting. This is particularly relevant to patients with BMI >50 kg m^{-2} for whom surgery is considered the next option instead of repeating failed lifestyle interventions [4, ii]. Patients fulfilling the BMI thresholds for surgery *should be eligible* (evidence level 1, grade A recommendation) for a procedure and part of the clinic's role should be to facilitate this appropriately [14].

Thus, overall the pathway is for primary care services that include community based interventions referring into a specialist multi-disciplinary bariatric service, which includes a bariatric physician (the Weight Assessment and Management Service). A proportion of patients would then be considered for bariatric surgery, with the whole team also being involved in the peri-operative care, usually as part of the same team if the surgery service is located in the same hospital. After discharge from the surgical service patients would be managed in a chronic disease model of care. As the available literature did not distinguish between assessment clinics that contained surgeons (in addition to the rest of the multidisciplinary team) and clinics that did not contain surgeons, the guidance describes overall best practice and does not subdivide what should be done in each clinic if the services are run separately.

The guidance also provides the tools for measuring equity of access into the clinics and referral onwards for surgery, and it is expected that set-up costs of Tier 3 clinics would be offset by potential savings from reduced medication costs, consultation costs and hospital visits in those having bariatric surgery. There would also be considerable overlap and sharing of staff between diabetes clinics (with diabetologists / endocrinologists usually the predominant group of bariatric physicians), sleep medicine, dietetics / nutrition, psychology, psychiatry, and physical therapy for instance which would mitigate against new set-up costs.

ii. Other groups of patients needing expeditious decision-making include severely obese patients needing renal transplants or presenting to gynaecologists with pelvic cancer.

High Value Care Pathway for weight assessment and management clinics [iii]

Guidance for General Practitioners

- Use every opportunity to identify overweight and obese patients including opportunistic case finding and routine health checks [15].
- Discuss with an overweight or obese patient his / her understanding of the likely resulting health problems, assess the individual health risks and engage with the patient in a partnership to modify the risks as part of a holistic approach that includes his / her emotional wellbeing [15].
- Encourage training for doctors and practice nurses so that they can provide support for overweight and obese patients such as motivational interviewing [16].
- Provide a set of scales capable of weighing up to 200 kg in every surgery, and offer to refer a patient over this weight to a service capable of weighing and monitoring him / her.
- Record the patient's current weight and height to calculate body mass index (BMI) and measure waist circumference if BMI <35 kg m^{-2}.
- Discuss with the patient his / her previous attempts at weight loss and encourage those who have never successfully dieted to participate in a community or commercial Tier 2 weight management plan.
- Assess carefully how engaged a patient is with the process before any decision is made about referral to the weight assessment and management clinic [17].
- Recognise the patient with a long history of cyclical weight loss and regain (yo-yo dieting) and consider direct referral to a weight assessment and management clinic without making him / her participate in a further Tier 2 programme as a qualifying threshold [17].
- Discuss the benefits of weight maintenance if the patient is not yet ready to engage with a programme, and encourage him / her to return at any point if they decide they need help.

In discussing with a patient whether to refer him / her to the Weight Assessment and Management Clinic GPs should [iii, iv] :

- Consider that it is an accepted option to refer a patient with BMI of ≥35 kg m^{-2} and type 2 diabetes [42].
  - This recommendation may be reduced by 2.5 kg m^{-2} of BMI in Asians [5, 18].
  - In exceptional circumstances a patient with BMI <35 kg m^{-2} may be referred to the Tier 3 clinic [18].
- Consider referring adults with a BMI of 40 kg m^{-2} or ≥35 kg m^{-2} + obesity-related comorbidity *e.g.,* metabolic syndrome, hypertension, obstructive sleep apnoea (OSA), functional disability, infertility and depression if specialist advice is needed regarding overall patient management.
  - Occasionally a patient may be referred whose BMI is below these thresholds, if he / she has exceeded the thresholds in the past; this may include a patient who has already had bariatric surgery presenting with a problem such as weight regain or nutritional deficiency or where revisional surgery might be considered.
- Consider referring children and adolescents with obesity to age-appropriate specialist services especially if their weight interferes with secondary school education [46].

iii. The current BMI thresholds for surgery were chosen arbitrarily as the criteria for referral into the clinic since the quoted literature predominantly refers to patients in these groups.

iv. If a patient is already being treated in secondary care it should be accepted practice to refer to the Weight Assessment and Management Clinic directly if the patient fulfils the criteria.

In the Weight Assessment and Management Clinic:

- The multi-disciplinary team (MDT) should contain at least a bariatric physician, a dietitian, a specialist nurse, a clinical psychologist and a liaison psychiatry professional; there should be access to a physical therapist [20-23, v].
- The patient should have his / her weight and height measured and the trend in BMI assessed
- A dietary history should be taken to ascertain the patient's feelings and expectations about potential outcomes and willingness to consider treatment options, and information and education should be provided so that he / she has appropriate understanding of the relationship between eating habits and weight, aiming to [20-22, 24]:
  - Help him / her understand the necessary changes in eating habits to improve health, and identify risk factors and vulnerabilities so that interventions can be planned to address and improve them.
- Encouragement should be provided for weight loss or maintenance, and structured eating plans, meal replacements and Very Low Energy Diets may be considered.
- The bariatric physician should consider screening for rare hormonal or genetic causes for weight gain if there is clinical suspicion.
- The bariatric physician should investigate for obesity-related comorbidities that may be previously undiagnosed, in particular type 2 diabetes, hypertension, OSA, heart failure, atrial fibrillation, chronic kidney disease, non-alcoholic fatty liver disease and depression, to optimise and modify all identified risks, and so that those referred for surgery are as fit as possible; cardiologists and respiratory physicians could also be involved by separate referral if patients need super-specialist care [14, 22].
- The Edmonton Obesity Staging System or similar should be considered as a means of assessing the risk from obesity-related disease in individual patients [25].
- Lifestyle advice should include access to a physical activity programme so as to promote health gains and general fitness individually tailored for each patient [22, 26].
- Given the high prevalence of psychiatric comorbidity the patient should be screened for psychological and lifestyle issues which may interfere with engagement, including anxiety and depression, self-harm and suicidal behaviours, eating disorders such as binge eating and bulimia nervosa, borderline personality disorders, alcohol / substance misuse, childhood adversity and blocks for voluntary weight which are not clearly understood, so as to identify the patient who may need additional long term support or who may be at risk of self-harm after surgery; examples of screening tools are the IWQOL-Lite, SF-12 V2, EQ5D, GIQLI, HADS, EDE-Q and EHQ [17, 27-34].
- When screening for bariatric surgery the clinical psychologist and liaison psychiatry professional should [17, 27, 35]:
  - Identify the patient for whom surgery may be inappropriate (severe learning disability, active uncontrolled psychosis, severe personality disorder).

v. No literature was identified that distinguished between care provided by the bariatric physician or by the bariatric surgeon, or regarding the order in which they were seen by the different specialists. The panel recognised that the physician would often or usually be shared between the Weight Assessment and Management Clinic and the bariatric surgery team, which in practice would together provide the care and would in effect be the same clinic if located in the same hospital. The panel considered the guidance presented as best practice according to the identified literature and recognised that existing services may have examples of good practice that might not fit into different interpretations of the tier structure. Also the panel recognised there is no literature to identify which professionals are best placed to provide mental health interventions in weight management, and further research is required (section 7.1, page 16). For the purpose of the guidance *liaison psychiatry professional* may include a psychiatrist and a mental health-trained nurse with specialist expertise in weight management. The panel recommends that the ideal service has both a clinical psychologist and a liaison psychiatry professional; however it recognises that this is aspirational and there needs to be local flexibility in commissioning as services develop. Liaison psychiatry refers to a sub-specialty multidisciplinary team that provides an interface between physical and mental health for patients in secondary care. The panel recognised that close working relationships need to be established between the groups described and community mental health teams where available.

  - Identify individuals not presently suitable for surgery (*e.g.,* untreated or unstable mental health presentation, active alcohol or substance misuse, active eating disorder, self-harm in past 12 months, dementia, current non-adherence to treatment and recent significant life event *e.g.,* bereavement or relationship breakdown) and provide an intervention or access to treatment before reassessing for surgery.
  - Identify and manage weight gain associated with psychotropic medications.
  - Identify the patient who may need specific attention and support following surgery.
- After a mental health assessment a traffic light system may be useful to identify a patient who is not currently suitable for surgery or who may be suitable although deemed at higher risk and requires psychological treatment before being considered for surgery [36].
- Recognising that most will have multiple previous episodes of cyclical weight loss / regain, and that absolute weight loss *per* cycle may be modest, patients should not be made to achieve a set weight loss target before referral to the bariatric surgery service as a means of *qualifying* for surgery; instead they should expect to lose weight during a short, supervised diet in order to make surgery technically feasible, and demonstrate engagement with the process [9, 18, 37-430].
- For a patient with type 2 diabetes [18, 44]:
  - The team should strive for satisfactory glycaemic control before surgery (HbA1c <68 mmol mol^{-1}) but inability to achieve this within a reasonable period of time should not be a bar to or delay referral for bariatric surgery.
  - Macro- and micro-vascular risk should be assessed and the information made available before a referral for surgery.
- Smoking cessation advice should be given and appropriate referral made for a long-term solution [14, 22, 44].
- Vitamin and micronutrient status should be assessed and deficiencies corrected, to include recognition of diets deficient in protein, in those being referred for bariatric surgery [14, 22].
- The patients should be encouraged to attend education sessions usually arranged by the bariatric surgery team if referral for surgery is being considered [24].
- The team, led by the bariatric physician, should meet physically or audiovisually, to discuss all patients at least once before deciding on referral back to the GP or for bariatric surgery.
- Patient information leaflets written in plain English and other languages as appropriate should be provided for all proposed interventions.

The patient should be referred for bariatric surgery if the Weight Assessment and Management Clinic is satisfied that [iv]:

- The patient is adequately engaged with the team, fully understands the surgery, is well-informed and motivated to have surgery and has realistic expectations [17, 20, 21].
- All management options have been put to the patient including the characteristics of the various surgical procedures available and the risks and side effects.
- He / she is medically optimised.
- There is no medical, surgical, nutritional, psychological, psychiatric or social contraindication.
- He / she understands the importance of complying with nutritional requirements before and after surgery and recognises the need for life-long follow up [14].

iv. The clinic should also be able to refer patients to the bariatric surgery team for ongoing treatment if they have had previous bariatric surgery elsewhere, or where a surgical complication or revisional surgery is being considered; those patients already known to the bariatric team should also be able to be referred back to the medical clinic in a two-way process

The patient should be referred back to the GP when:

- He / she does not engage with the team, for instance if resistant to recommended health and lifestyle changes.
- Obesity-related diseases have been addressed and the team agrees with the patient that ongoing treatment and management plans can now appropriately be provided by the GP and,
- The patient does not want to be considered or does not appear to be appropriate for referral for bariatric surgery assessment or does not appear to be suitable for the Weight Assessment and Management clinic.

The patient may remain within the Weight Assessment and Management Clinic if:

- He / she has complex weight-related comorbidity and the MDT agrees to keep him / her under review on a shared care arrangement with the GP, for instance for early supervision of a Very Low Energy Diet or specific more intensive programme

Peri-operatively and in the period of surgical aftercare bariatric physicians and surgeons should liaise closely with GPs to [v]:

- Ensure that diabetes management remains optimized [14].
- Ensure that medications for other obesity-related and non-obesity-related conditions are assessed regularly and adjusted *e.g.,* blood pressure and epilepsy; GPs may be best placed to supervise these with the support of the medical and surgical MDTs [41].
- Supervise long term assessment of nutritional and trace mineral status and dietary replacement according to published recommendations, with the help of the dietitian [14].
- Identify issues that may require referral back to the surgical team and establish local protocols / *red flags* for urgent re-referral if a patient has a suspected surgical or nutritional complication.
- Support the patient's mental health and psychosocial needs and ensure that he / she has continued, adequate access to a clinical psychologist and a liaison psychiatry professional when appropriate, especially for those who may be made more vulnerable after surgery by developing depressive illness, risk of self-harm, significant eating disturbance, post-operative alcohol / substance misuse, and significant body image disturbance.

After discharge from the bariatric surgery service bariatric physicians and GPs [vi] should:

- Put in place a shared care model of chronic disease management led by the physician that clarifies what is expected of each role and what should be achieved at each review [46, 47]
- Provide the patient with clear written information on the importance of and reasons for long term follow up, to include advice about what to do if a patient becomes pregnant; contact details should be provided for the Tier 3 clinic.
- Arrange for each patient to be reviewed at least annually, indefinitely.
- Liaise closely together so that diabetes control is optimized in the medium and long term by at least an Annual Review.
- Consider continuing medications indefinitely for those previously at high cardiovascular risk due to diabetes, dyslipidaemia and hypertension [14, 48].
- Ensure that a patient on treatment for OSA is reviewed appropriately by a sleep clinic.
- Continue to supervise long term assessment of nutritional and trace mineral status and dietary replacement with the help of the dietitian [14].

v. Note - the surgical aftercare period in the Commissioning Policy A05 is 2 years.

vi In the context of the tier terminology *bariatric physicians and GPs* implies Tier 3 and primary care services. The panel also recognised that there are existing examples of best practice where in the absence of a bariatric physician or Weight Assessment and Management Clinic surgical teams and GPs have already developed what is in effect a shared model of care.

- Refer patients back to the surgeons if red flags are identified, as above.
- Ensure that the patient continues to have adequate access to a clinical psychologist and a liaison psychiatry professional.
- Establish local protocols for appropriate investigation of post-bariatric surgery abnormalities such as anaemia or symptoms such as pain or vomiting, or for weight regain.
- Arrange to undertake, or refer back for, band adjustments as required in conjunction with the surgical team.
- Arrange and supervise physical activity individually tailored to each patient [26, 49].
- Consider referring patients for removal of excess tissue that interferes with function if clinically appropriate [50].
- Arrange for ongoing annual submission of data to the National Bariatric Surgery Registry according to the current dataset requirements.

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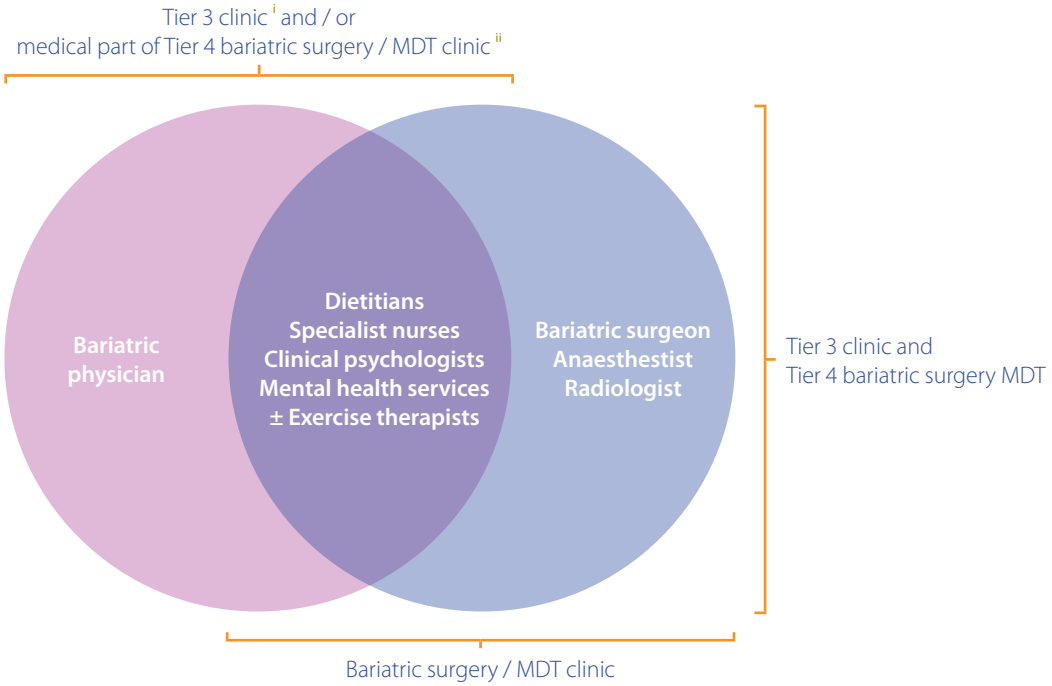
Patient pathway

A schema for how the new Tier 3 Weight Assessment and Management Clinics could interact with bariatric surgery services is shown in this Venn diagram.



It appears that the most efficient way for a Tier 3 medical Weight Management and Assessment Clinic to work is alongside a Bariatric Surgery Unit, where all the MDT members are already provided. The addition of a *bariatric physician* means that this is in effect a combined Tiers 3 and 4 clinic. There are already examples in the United Kingdom of GP- or secondary care physician-led medical clinics. To some extent the examples in Europe and Australia are that GPs already fulfil the role of the physician as part of a shared care chronic disease model.

The professional view of BOMSS is that there does not need to be a time limit to be spent in medical assessment and work up before a referral to a bariatric surgical team, contrary to the A05 NHS England Commissioning Policy (2013). The whole process of assessment, optimisation of obesity-related disease and preparedness for bariatric surgery, if that is what the patient wants, can be managed through the essential team members that are likely to be shared between medical and surgical aspects of the MDT, *i.e.,* they are the same individuals all working together in the same clinic.

There is no published literature that describes the order in which the team members should see the patient, and BOMSS envisages that this could be decided at the MDT meetings after initial assessment by one or more of the team members, which could be a dietitian or specialist nurse. As stated in the Commissioning Guidance, many established teams will already have ways of working that are entirely in the spirit of the Guidance, but which do not mandate that each patient spends up to 2 years trying to lose weight or maintain weight loss. If most patients could do this by themselves then there would be no need for referral for surgery. However, it is clear from clinical practice and the published literature that failing to achieve or maintain significant weight loss is precisely the reason why surgery is such a valuable option for so many of these patients.

There is little evidence that prolonged medical weight assessment is of long-term benefit, and there are currently no data from the United Kingdom on what is achieved in medical weight assessment and management clinics. BOMSS is, however, extremely supportive of the initiative by the Royal College of Physicians to establish these clinics nationally [iii].

The real benefit of medical input is that obesity-related disease can be managed by appropriate specialists who see large volumes of patients, rather than expecting GPs to undertake all the care when they may have no experience of patients having bariatric surgery. It is going to take a period of settling in for a shared care model of chronic disease management to evolve in the United Kingdom; and, as there are far more patients with severe obesity than could ever be operated on, physicians need to be involved with the care of those not suitable for, who do not want, or who do not gain public funding for bariatric surgery.

i If located in community has its own staff and refers in for surgery MDT = Tier 3 clinic

ii. If located in secondary care staff likely shared with surgery service = Tier 3 or 4 clinic

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Publication of surgeon-level data

In December 2012 the Department of Health announced that 10 specialties (9 surgical and one medical) would publish mortality data at the level of individual surgeons by the summer of 2014 [1]. Bariatric surgery (a sub-specialty of the specialty of *general surgery*) was one of the 10. After a wide-ranging discussion with consultant contributors to the NBSR regarding the ownership of data that were contributed to a registry funded by surgical specialty associations and not the NHS (notwithstanding the fact that it was data on NHS patients that was being requested), there was near universal agreement and explicit consent to publish the data. The NBSR Committee was pleased to publish the data on behalf of the contributors, as asked, and on time.

It seems entirely appropriate and in the interest of openness and transparency to reproduce here the text of the document so that patients and commissioners are aware that bariatric surgeons are entirely open to sharing their operative results, as well as demonstrating in the rest of this report the remarkable effects of bariatric surgery on patients with severe and complex obesity.

Comment on mortality of bariatric surgery in the United Kingdom

There have been several negative reports in the popular press about possible under-reporting of mortality in the United Kingdom. Therefore, it is important to comment on this further as it is highly relevant to the Surgeon-Level Outcomes Publication below and the overall results presented from the NBSR in this Second Report. Two external sources of data have assessed mortality: the HES analysis conducted by the Quality Outcomes Research Unit in Birmingham presented on this page, and a further HES report in the British Medical Journal in 2010 [1]. In the BMJ analysis of 6,953 patients having bariatric surgery between 2000 and 2008, the number of deaths within 30 days of the operation was 19 (0.27%). When laparoscopic cases were considered in isolation, the mortality was much lower at 0.16% (7 / 4,436).

A further publication has commented on bariatric mortality in the United Kingdom. In the National Confidential Enquiry into Patient Outcome and Death study published in 2012, pathologists were asked to submit data on *post-mortem* examinations carried out in the last 3 years subsequent to bariatric surgery [2]. Twenty-nine deaths were recorded, 14 of which were within 30 days of surgery and 15 were 31 days or more after the patient's operation. The median time to death was 8 weeks and the maximum time was 16 years. As it was estimated that one-third of the deaths was unrelated to the surgery and there was no knowledge of the denominator (*i.e.,* in what number of patients this death rate occurred), it is difficult to analyse the data further or draw any definite conclusions from it.

Summary

The NBSR Committee on behalf of the British Obesity and Metabolic Surgery Society presents the operative outcomes data for NHS patients having primary bariatric surgery for the financial year 2012 / 2013. The main results are:

- 106 consultant surgeons contributed to the NBSR and the total number of primary operations recorded was 4,389.
- 101 surgeons consented to their data being released (95%).
- The average body mass index (BMI) for the patients was 50.6 kg m^{-2} and the average weight was 141 kg, indicating that the patients were twice the ideal weight for their height, and 72.8% were female.
- The average number of obesity-related diseases for each patient (for example type 2 diabetes, hypertension and sleep apnoea) was 3.6.
- There were 3 recorded deaths for an in-hospital mortality rate of 0.07%, equivalent to a survival rate of 99.93%.
- The average length of hospital stay for all operations was 2.5 days.
- There were no potential statistical outliers for mortality nor length-of-stay.

Using Hospital Episode Statistics (HES) codes we estimated that there were 138 NHS surgeons doing bariatric surgery in the 11 months April 2012 to February 2013, and 5,656 operations were recorded. Therefore, most bariatric surgeons (77%) were entering data and the great majority of NHS patients (up to 78%) were being recorded into the Registry.

According to HES, we estimate that the overall in-hospital mortality rate for bariatric surgery was 0.11% for the 4 financial years ending 2010, 2011, 2012 and 2013, equivalent to a survival rate of 99.89%, validating the very low mortality from bariatric surgery recorded by the consultant surgeons contributing to the NBSR.

In this report we have not been able to include bariatric surgery done as a revision procedure (to revise a previous bariatric surgical operation); also, submission of data to the NBSR has been voluntary for surgeons up until April 2013. Although, for these two reasons, and probably others, our case ascertainment (the proportion of NHS operations recorded out of the total performed) is not 100%, it still seems that the survival rates in the NBSR are an accurate reflection of overall practice.

In-hospital survival rates after bariatric surgery are at least as good, if not better than, many other common laparoscopic gastrointestinal procedures.

Richard Welbourn, Simon Dexter, David Hewin, Marcus Reddy, Peter Sedman, Peter Small, Shaw Somers, Peter Walton, Robin Kinsman

NBSR Database Committee, July 2013

1. Burns EM, Naseem H, Bottle A, Lazzarino AI, Aylin P, Darzi A, Moorthy K, Faiz O. Introduction of laparoscopic bariatric surgery in England: observational population cohort study. *BMJ*. 2010; **341**: c4296.

2. Too Lean a Service? A review of the care of patients who underwent bariatric surgery. National Confidential Enquiry into Patient Outcome and Death (2012).

Background

In December 2012 the Commissioning Board for NHS England announced that it would require publication of surgeon-level outcomes data in 10 specialties, including bariatric surgery, by the summer 2013 [1]. The mandate to publish individual surgeon results has largely come from the legacies of the Kennedy Report (2001) [2] that dealt with the adverse cardiac surgery outcomes in Bristol and more recently the Mid Staffordshire enquiry that culminated in the Francis Report (2013) [3].

The institutional failings found in both reports highlighted a need for more clarity about individual-surgeon outcomes. We note that the Executive summary of the Francis report used the phrase *openness, transparency and candour* 9 times and each of these words separately on numerous other occasions: part of the inevitable momentum towards specialist societies being aware of the outcomes results of their members in a process of encouraging continuous quality improvement.

National Bariatric Surgery Registry

The NBSR Committee and bariatric surgeons (BOMSS) entirely accept the culture of being open and transparent about outcomes data. In fact, as far back as 2009 three specialist societies, the Association of Laparoscopic Surgeons, the Association of Upper Gastrointestinal Surgeons, and the BOMSS, set up the NBSR specifically for this purpose. Since then more than 30,000 patient records have been entered, and we have already published a first report of the overall outcomes, with very low mortality, in over 8,000 patients (April 2011) [4].

Bariatric surgery is an area of healthcare that is very much in the public eye and this is likely to continue to be the case. However, the NBSR does not currently receive public funding and this has added to the challenges of producing this report within a very short timescale.

Unit data versus individual surgeon reporting

The Commissioning Board, NHS England, called for publication of individual surgeon-level outcomes. Our preference was to present outcomes data from units, since it is units that are commissioned to deliver services to patients, not individual surgeons.

We want to take the opportunity to highlight the fact that bariatric surgery is just one aspect of a multi-disciplinary team (MDT) process of care that involves a wide range of healthcare professionals dedicated to the care of patients with severe and complex obesity. These include dietitians, specialist nurses, psychologists, bariatric physicians, anaesthetists, theatre teams and recovery staff, ward nurses including high-dependency and intensive care nurses, out patient staff, radiographers, radiologists and exercise therapists.

The close working and performance of the whole MDT is integral to the overall outcome. The NCEPOD report in October 2012 highlighted the importance of team working [5]. Pragmatically it is difficult to measure, and even more difficult to record in a format such as a registry.

Administrative support for data entry and validation

Currently, most NHS bariatric units do not have sufficient administrative support to ensure completeness of data entry and internal validation. As the NBSR became mandatory for NHS providers from 1st April of this year, we now look to commissioners and hospitals to address this issue. The United Kingdom community of Bariatric Surgeons are broadly committed to ensuring the collection of accurate and complete data in the NBSR.

Recognising that lack of support could have led to missing records, incomplete records or inaccurate data entry and thus possible under-reporting of complications such as 30-day return to theatre rates, we had to take a view on the outcomes to analyse and present. It has limited the outcomes to those we are confident to publish, due to shortage of time and resources for external validation of submitted data.

Potential difficulties with publishing individual surgeon-level data

There are many potential problems and pitfalls with publishing individual surgeon data, including incorrectly identifying the performance of a particular surgeon as below par due to inaccurate or missing data entry, or failing to capture all aspects of the patient's care in the Registry dataset. Individual surgeon volume must also be interpreted with caution since units may only start surgery part way through an analysis period or a surgeon may stop operating if they retire or a service is moved elsewhere as part of NHS service changes. Surgeons may also operate on NHS patients in 2 or more hospitals so that one unit's activity may not reflect the overall workload of an individual.

There is also the possibility of a competent surgeon apparently being seen to be an outlier in one particular time-period when over a longer time-period he / she would be seen to have completely satisfactory results. A recent debate at the Association of Surgeons meeting outlined these principles and highlighted the issues [6].

Hospital Episode Statistics coding

At least 51 different OPCS4 codes are used to define the range of bariatric surgical procedures, but not a single one accurately describes Roux-en-Y gastric bypass, the operation that accounts for two-thirds of NHS procedures. We would like to influence coding practice and standardise the HES codes used for bariatric surgery. However, HES recording has previously shown that the mortality within 30 days of surgery in the United Kingdom for the financial years 2000-2008 was 0.27% (19 / 6,953 patients) [7], so it seemed reasonable to compare and validate our NBSR mortality data, the most important surgical outcome, with current data from HES.

Further limitations of HES data include the inability to risk-adjust confidently, since two of the variables needed to assess risk, body mass index (BMI) and hypertension, are either not recorded or the recording is unreliable. Also, HES does not reliably distinguish between primary surgery and elective revisional surgery. All these are necessary for risk adjustment. Furthermore, the named consultant listing the patient for the operation may not be the same as the one operating. In contrast, the NBSR dataset captures all these variables and is accepted by bariatric surgeons as the best way to produce meaningful data.

Methodology for the June 2013 reporting

The NBSR Committee asked for explicit consent for publication from each contributing consultant, recognising the inherent conflict with the Data Protection Act 1998 regarding the ownership of voluntarily submitted data and the current mandate to present individual surgeon-level outcomes.

We have also published a policy on how to manage potentially outlying data, available on the BOMSS website (www.bomss.org.uk / audit.htm).

Although the NBSR dataset captures much more information, we decided, due to the limitations of data validity, to limit the hard outcomes published to surgeon volume, in-hospital mortality and length-of-stay. Eight outcomes in all are presented for the year 1st April 2012 to 31st March 2013:

- Consultant workload for primary operations (total number of operations).
- Operation split by consultant.
- BMI on entry into the weight loss programme.
- Comorbidity count *per* type of operation (number of comorbidities recorded *per* patient).
- Obesity Surgery Mortality Risk Score (OSMRS) and class *per* operations and overall *per* consultant.
- Initial BMI overall *per* consultant (box and whisker plots).
- Length-of-stay for primary procedures compared to the rest *per* consultant.
- In-hospital mortality, described as survival.

The comorbidity count was taken from the NBSR dataset of comorbidities:

- Type 2 diabetes.
- Hypertension on treatment.
- Dyslipidaemia.
- Atherosclerosis (includes angina, MI, CABG, stroke, claudication).
- Sleep apnoea.
- Asthma.
- Poor functional status (unable to climb 3 flights of stairs without resting).
- Back or leg pain from arthritis.
- GORD.
- Liver disease (suspected NAFLD or worse).
- Polycystic ovary syndrome (female patients only).
- Depression (clinically significant depression as a reason for bariatric surgery).

The Obesity Surgery Mortality Risk Score is the only validated measure of operative risk for patients undergoing

bariatric surgery [8]. A point is added for each of the following risk factors that are present, up to a maximum of 5 points: age at surgery ≥45 years, BMI ≥50 kg m^{-2}, male gender, recorded hypertension, one or more known risk factors for deep vein thrombosis (DVT) / pulmonary embolism (PE). Using the resultant score, complication and mortality rates can be risk-adjusted; the higher the score / group, the greater the risk of surgery. Patients can be stratified for risk according to how many of these risk factors are present. It is normal practice to refer to the calculated scores in three groups:

- Group A (0-1 points).
- Group B (2-3 points).
- Group C (4-5 points).

The data were harvested for this analysis at 11:00 am on 14 May 2013 by Dendrite Clinical Systems Ltd, the NBSR software provider. The data were assessed for obvious validation errors and erroneous data entry such as duplicate errors. Any data that looked as if they might be duplicate entries were reported to the individual units and consultants for validation and review. Where no response was obtained from the responsible unit or consultant, duplicate patient records were omitted from analysis on a *least data entered record* basis. Each consultant was invited to review the individual data online before the publication date.

We worked with the Quality Outcomes Research Unit in Birmingham University (QUORU) to analyse the available HES data, and using a refined set of OPCS4 codes were able to estimate the mortality for primary bariatric surgery for the 4 years April 2009 to February 2013 (D McNulty, D Pagano; unpublished). Due to time limitations we were not able to analyse HES data for any other potential outcome.

Presentation of results

To minimise the possibility of error, and because we are reporting only primary surgery, we do not attempt to present individual unit data on case ascertainment (proportion of patients entered on the NBSR), but present, instead, overall numbers. We recognise that the data presented for surgeons doing 10 or fewer operations in the analysis period are not likely to be representative of their overall practice.

Data for each variable is presented either as line charts, bar charts or box-and-whiskers charts. Comments are included to help interpret the results.

We make no attempt to comment on operating volumes for hospitals or individual surgeons in this report. This was beyond our scope as we are aware that several units have undergone personnel and location changes during the period, with new consultants being appointed or moving hospitals. These are additional reasons why individual surgeon data may not be representative of each surgeon's practice as a whole. Commissioners should refer to the April 2013 Commissioning Board for guidance on the minimum number of recommended volumes [10].

Results

The results can be found on the website www.bomss.org.uk / audit.htm and nbsr.e-dendrite.com.

Main data

- The total number of operations recorded by 106 consultant surgeons contributing to the NBSR was 4,389.
- 101 surgeons consented to their data being released (95%).
- There were 3 recorded deaths for an in-hospital mortality rate of 0.07%, equivalent to a survival rate of 99.93%.
- The average body mass index (BMI) for the patients was 50.6 kg m^{-2}, median 49.9 kg m^{-2} (inter-quartile range 45.2-54.9 kg m^{-2}), the average weight was 141 kg, indicating that the patients were twice the ideal weight for their height; 72.8% were female.
- The average number of obesity-related diseases for each patient (for example, type 2 diabetes, hypertension and sleep apnoea) was 3.6.
- The average length of hospital stay for all operations was 2.5 days.
- There were no potential statistical outliers for mortality or length-of-stay.

From HES analysis

- Using a refined set of codes, we estimated from HES data that there were 138 NHS surgeons doing bariatric surgery in the 11 months April 2012 to February 2013, and 5,656 operations were recorded, indicating that 77% of bariatric surgeons entered data and up to 78% of NHS patients were recorded.
- According to HES the total number of operations for the financial years ending 2010, 2011, 2012 and 2013 was estimated at 23,760 and we estimated there were 25 deaths for an overall in-hospital mortality rate of 0.11%, equivalent to a survival rate of 99.89%.
- Both sets of data are entirely equivalent to a US benchmark, the American College of Surgeons Bariatric Surgery Center Network, where the published mortality rate was 0.12% (35 out of 28,616) for patients operated from 2007-2010 [10].

Additional notes

We know that there is a high likelihood that the numbers for each surgeon presented here underestimate the overall volume of their surgery as we have not been able to include re-do surgery (done as a revision of a previous bariatric operation) due to the sheer complexity of analysis required. Many very experienced surgeons specialise in revision surgery and have particular expertise in this area and several have contacted us to make this clear.

We know that the reasons for those surgeons not consenting to their data being published were that their recorded data were incomplete and therefore underestimated the total volume of surgery. Given the very tight timescale for producing this report there was also not enough time to correct potentially erroneous data entry. There were concerns that their practice would be misrepresented as a result. Supporting documentation may be available on their websites, and as far as we know the details of their practices we are fully supportive of the quality of their work. None of these surgeons was a statistical outlier. We are also fully supportive of the practices, as far as we know the details, of the three surgeons who reported mortality in the analysis period, none of whom was a statistical outlier.

Several hospitals with their own established, pre-existing registries / databases attempted to submit their relevant data for merging and analysis alongside the data entered directly to the NBSR, but have been unable to for reasons beyond their control. The reasons include file formats being incompatible; lack of funding to transmit data or have it analysed at the receiving end; deadlines too tight logistically with timescales unworkable for the actual merging of data; and probably other reasons as well. These units / hospitals were:

- Chelsea and Westminster Hospital
- North Bristol / Southmead Hospital
- University Hospitals Leicester
- Western Sussex Hospitals
- Phoenix Health / Aintree University Hospital / Countess of Chester Hospital

Several or all of these units intend to comply with the submission to NBSR in addition to publishing their data on their own local websites. We also had contact with:

- Imperial Weight Centre, which maintains its own database but was not able to provide the NBSR dataset requested in the timescale required due to administrative challenges with moving hospital site during the year 2012 / 2013.
- Barking, Havering and Romford Hospitals, who alerted us to the fact that the local Specialist Commissioners had stopped bariatric surgery in Queen's Hospital in Romford in April 2012, hence they were only able to report very few patients in the analysis period.
- Princess Royal University Hospital, Orpington, part of South London Healthcare Trust; the Trust is due for reconfiguration and has so far not been able to submit data due to administrative reasons, however this is now being rectified.
- North Tees University Hospital, Stockton-on-Tees, which started contributing patients to the NBSR after the analysis period.
- Spire Regency Hospital, Macclesfield, Spire Fylde Coast, Blackpool and BMI Alexandra Hospital, Manchester, which did not have administrative support to enter complete data and perform internal validation of submitted data.

- Derby Hospitals, which has a large proportion of revision surgery, therefore the data are not representative of their overall volume.
- Several other units, including Oxford Bariatric Unit and Royal Berkshire Hospital, Reading, were concerned that their data were not fully representative of their NHS practice as lack of administrative support and technical reasons meant they had missing data.

Interpretation of results

The data presented are a snapshot only of the overall process of bariatric surgery.

This report is part of an *iterative process*, that is, we expect the overall results to be updated continuously as more units are able to submit their data, and as the dataset evolves over time as part of an overall bariatric surgery quality improvement process. Surgeons who join mid-way through the audit process are continuing to back-populate the Registry and we are grateful to them for showing their commitment to this initiative.

We expect that patients will be able to use the data presented in the surgeon graphs to facilitate their consultations with the local bariatric team and help them make informed decisions about surgery.

Patients should be reassured that in-hospital mortality is extremely low after bariatric surgery: survival from bariatric surgery is at least as good if not better than many common laparoscopic gastrointestinal procedures.

A note on the conventions used throughout this report

There are several conventions used in the report in an attempt to ensure that the data are presented in a simple and consistent way. These conventions relate largely to the tables and the graphs, and some of these conventions are outlined below.

The specifics of the data used in any particular analysis are made clear in the accompanying text, table or chart. For example, the majority of analyses sub-divide the data on the basis of the kind of operation that the patient undergoes, and the titles for both tables and charts will reflect this fact.

Conventions used in tables

On the whole, unless otherwise stated, the tables and charts in this report record the number of procedures (see the example below, which is a modified version of the table presented on page 72).

Primary operations: age and gender distributions; financial years 2011-2013

		Gender			
		Male	Female	Unspecified	**All**
Age at operation / years	<25	108	462	0	**570**
	25-29	157	852	0	**1,009**
	30-34	271	1,125	0	**1,396**
	35-39	429	1,609	0	**2,038**
	40-44	661	2,243	0	**2,904**
	45-49	789	2,177	0	**2,966**
	50-54	679	1,919	0	**2,598**
	55-59	529	1,308	0	**1,837**
	60-64	318	796	0	**1,114**
	>64	140	344	0	**484**
	Unspecified	6	34	0	**40**
	All	**4,087**	**12,869**	**0**	**16,956**

Each table has a short title that is intended to provide information on the subset from which the data have been drawn, such as the patient's gender or particular operation sub-grouping under examination.

The numbers in each table are colour-coded so that entries with complete data for all of the components under consideration (in this example both age at operation and gender) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as unspecified in green text. The totals for both rows and columns are highlighted as emboldened text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value.

Rows and columns within tables have been ordered so that they are either in ascending order (age at procedure: <20, 20-24, 25-29,30-34, 35-39 years, *etc.*; post-procedure stay 0, 1, 2, 3, >3 days; *etc.*) or with negative response options first (No; None) followed by positive response options (Yes; One, Two, *etc.*).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

- insufficient space on the page to accommodate both the table and graph.
- there would be more rows and / or columns of data than could reasonably be accommodated on the page (for example, Kaplan-Meier curves).
- the tabular data had already been presented elsewhere in the report.

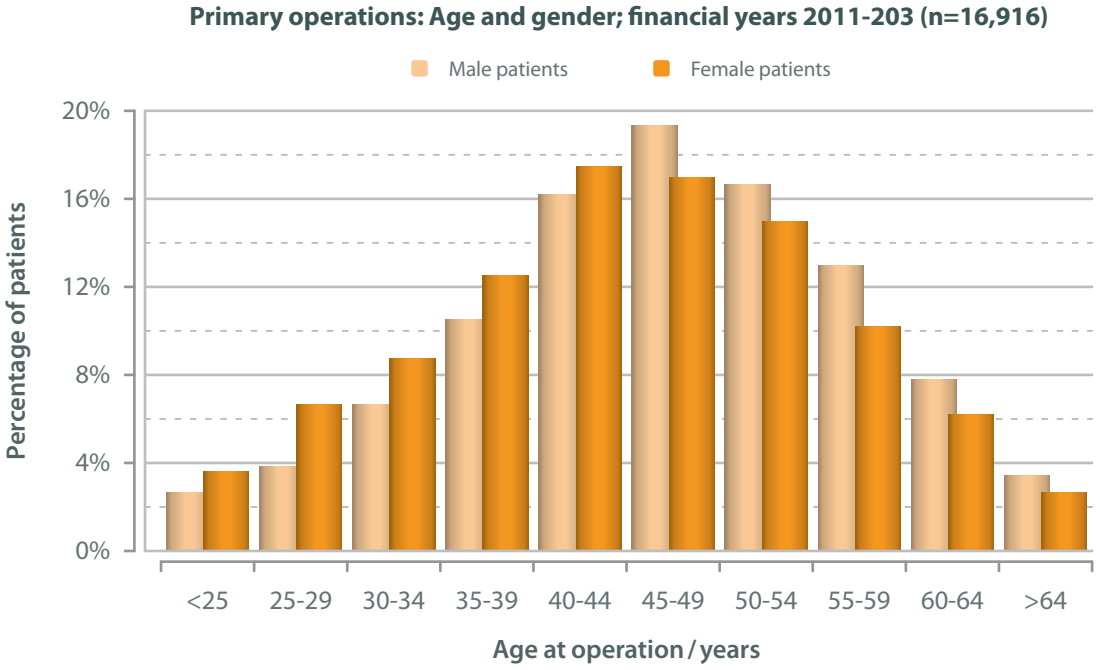
Conventions used in graphs

The basic principles applied when preparing graphs for this Second Registry Report were based, as far as possible, upon William S Cleveland's book *The elements of graphing data* [1]. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: The counts (shown in parentheses at the end of each graph's title as n=) associated with each graph can be affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in this report are graphic representations of results for a particular group (or subset) extracted from the database, such as patients undergoing gastric banding or Roux-en-Y gastric bypass procedures. This clearly restricts the total number of database-entries available for any such analysis.

In addition to this, some entries within the group under consideration have data missing in one or more of the database questions under examination (reported as unspecified in the tables); all entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph below, only the database entries where the patient is having primary surgery and both the patient's age and gender are known are included in the analysis; this comes to 16,916 patient-entries (the sum of the numbers in regular black text in the table; the 40 entries with unspecified data are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals [2]. The width of the confidence interval provides some idea of how certain we can be about the calculated rate of an event or occurrence. If the intervals around two rates do not overlap, then we can say, with the specified level of confidence, that these rates are different; however, if the bars do overlap, we cannot make such an assertion.

Bars around averaged values (such as patients' age, post-operative length-of-stay, *etc.*) are classical standard error bars or 95% confidence intervals; they give some idea of the spread of the data around the calculated average. In some analyses that employ these error bars there may be insufficient data to legitimately calculate the standard error around the average for each sub-group under analysis; rather than entirely exclude these low-volume sub-groups from the chart their arithmetic average would be plotted without error bars. Such averages without error bars are valid in the sense that they truly represent the data submitted; however, they should not to be taken as definitive and therefore it is recommended that such values are viewed with extra caution.

1. Cleveland WS. *The elements of graphing data*. 1985, 1994. Hobart Press, Summit, New Jersey, USA.

2. Wilson EB. Probable inference, the law of succession, and statistical inference. *Journal of American Statistical Association*. 1927; **22**: 209-212.

Database structure

Glossary

Body mass index Shortened to the abbreviation BMI, this measure of a person's size is calculated as:

$$\frac{\text{body mass (kg)}}{\text{height}^2\ (\text{m}^2)}$$

Twenty-five (kg m^{-2}) is taken as a convenient upper limit for a normal BMI, according to the convention currently used in the bariatric literature.

In the NBSR, surgeons have the opportunity to record the patient's weight when first seen and the most recent weight at the time of surgery, which will often be on the day of admission for the operation. This provides an opportunity to assess patients' weight loss in preparation for surgery (see page 88 for more details and explanation).

Excess weight loss Excess weight loss is defined as:

$$\frac{\text{initial mass (kg) - current mass (kg)}}{\text{initial mass (kg) - [25 (kg m}^{-2}\text{)} \times \text{height}^2\ (\text{m}^2)\ ]} \times 100\%$$

By convention, surgeons use the term *percentage excess weight loss* (%EWL) to describe weight loss after bariatric surgery. Again, the figure of 25 kg m^{-2} is often used as the upper limit for a normal BMI. Absolute weight loss in kilogrammes and percentage body weight loss are alternative measures; however, %EWL is used most often in the surgical literature. Percentage EWL data must be interpreted with the understanding that a patient with a very high BMI may lose many kilogrammes, but their %EWL will be less than a lighter patient who loses the same number of kilogrammes.

For example, a person who was initially 100 kg overweight and who then loses 50 kg will, by definition, have lost 50% of their excess weight (50% EWL); however, a patient who is 50 kg overweight and then loses all this will have 100% EWL. Thus percentage EWL must always be interpreted with reference to the patient's initial weight.

Primary surgery The first bariatric operation that a patient undergoes.

Revision surgery as a primary in your hands A subsequent bariatric operation where the previous operation was performed in another hospital. The time-line for weight-loss starts at the revision operation. Having this classification system allows us to avoid problems associated with merging data from patients undergoing primary surgery (where the patient's initial weight is known and documented) with that of patients undergoing a revision of an operation performed elsewhere (in which case, only the patient's weight at the time of the revision is known with any certainty). In addition, all revision surgery carries higher risk due to scarring of the tissues which occurs after the first operation, and therefore it is important to be able to characterize this risk separately from that for primary procedures.

Revision surgery A subsequent bariatric operation where the first operation was done in the same unit; for example the first procedure failed, *e.g.,* a vertical banded gastroplasty (an operation that is now largely obsolete) and this is *revised* to another bariatric operation such as a band or bypass. The time-line for weight-loss starts at the primary operation so that weight loss can be followed over time on an intention-to-treat basis.

Planned 2nd stage Subsequent bariatric operations where all procedures were carried out in a single hospital as part of a planned course of treatment; for example, a sleeve gastrectomy followed by a gastric bypass operation a year later. Over a patient's lifetime it may be necessary to perform two or even three bariatric procedures; therefore, a planned 2nd stage operation might also be viewed as a specific kind of revisional surgery. For the purposes of the NBSR we made the arbitrary decision that the defining difference would be whether or not the subsequent operation was planned. Time, and the data, will tell whether or not this distinction is useful. Again, the time-line for weight-loss starts at the primary operation so that weight loss can be followed over time on an intention to treat basis.

Revisional gastric banding

There is a separate section for patients who have redo operations for their previously implanted gastric bands. It is known that these bands can sometimes develop long-term complications, of which four constitute the vast majority: bands may slip in their position around the stomach; they may become infected (*e.g.*, port site infection); the port or tubing may become disconnected or punctured by needlestick injury during adjustment in the clinic; or the band may erode into the stomach. The last is the most serious complication, and requires careful surgery in a high-risk situation as there is a local perforation of the stomach wall [1].

Many authors have published data on the rate of re-operation for band complications, but on a population or national registry scale the rate of redo surgery on an intention-to-treat basis is unknown. We hope that the NBSR data will enable us to develop a comprehensive picture of the longevity of gastric bands on a population basis.

Required fields

There are 22 fields in the database that are absolutely required for meaningful data collection:

Section	Question
Add a new patient	Date of birth
	Date of operation
	Patient's gender
Initial information	Patient's height
	Patient's weight
	Funding category
Baseline comorbidity	ASA grade
	Type 2 diabetes & Duration of diabetes
	Hypertension on treatment
	Cardiovascular
	Sleep apnoea
	Asthma
	Functional status
	Known risk factor for pulmonary embolus
Operation record	Operating surgeon
	Type of operation
	Operative approach
	Operation
Post-operative course & discharge	Cardiovascular complications
	Other complications
	Discharge date
	Discharge destination

1. Suter M, Calmes JM, Paroz A, Giusti V. A 10-year Experience with Laparoscopic Gastric Banding for Morbid Obesity: High Long-Term Complication and Failure Rates. *Obesity Surgery*. 2006; **16**: 829-835.

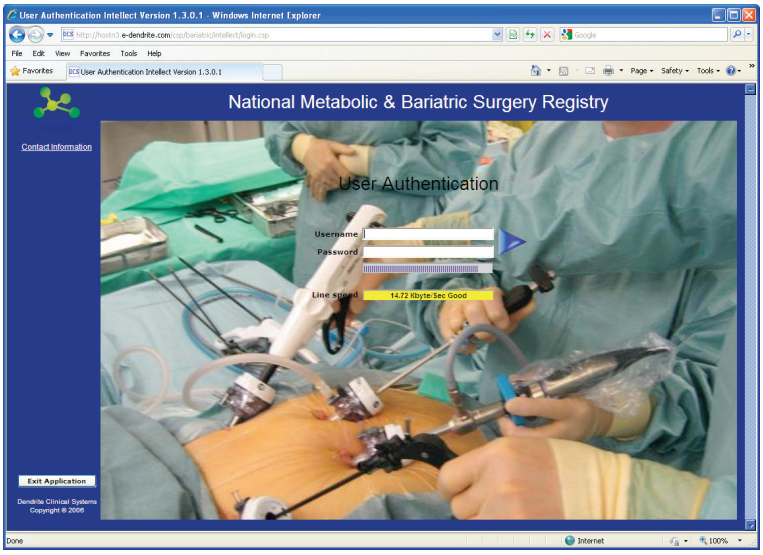
How the NBSR registry works

Access to the NBSR

The NBSR software is a bespoke web registry application built by Dendrite Clinical Systems using their *Intellect Web* proprietary software, and it is hosted on a secure Dendrite server within the NHSNet *N3* network. The *N3* server offers a fast, reliable link from any NHS computer that offers NHS Intranet access. The Dendrite server also incorporates an additional network card, which provides secure, dedicated access from outside the NHSnet, so that surgeons and delegates can enter data from any private hospital, provided they have appropriate security access.

Welcome screen

To gain access to view, add new or edit existing data, each user must have their own ID and password (with C2-level strong authentication). These are issued only to registered bariatric surgeons and their designated, named delegates. Each user can only see their own data, and not data belonging to any other surgeon. Access to the database as a whole is restricted solely to the system administrator. Oversight of the database design is controlled by the NBSR Database Committee.



User authentication screen

Typically, it takes less than eight minutes or so to complete the on-line database record and even for a relatively complex case. To aid data collection, the system also offers downloadable PDF forms for each section of the database and for each operation type; these are shown in the appendices (see pages 276-295). These forms can be attached to the patient notes and completed in stages as the patient moves through their hospital care, to be returned to a computer workstation for entry into the database at the time the patient is discharged.

While access to the live database is tightly restricted to only bariatric surgeons and / or their appointed delegates, Dendrite offer free access to a parallel demonstration system; please contact info@e-dendrite.com to request a login.

Database entry

After logging on to the Dendrite database software, users are presented with a demographic screen as a main menu option. The demographic database listing shows users all their entries in the database, so that they can keep track of cases, edit data whenever needed and add follow-up data or complication / revision operation information as required.

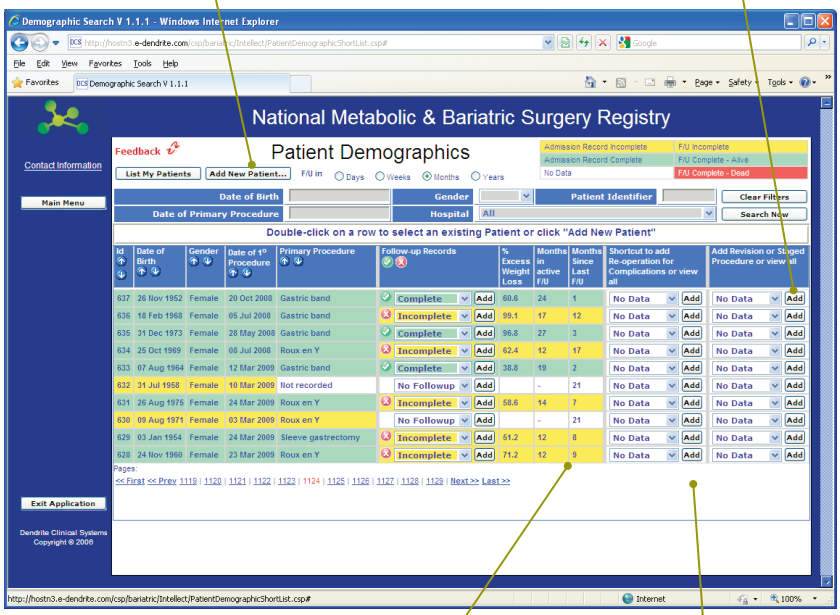
The patient data are anonymised to comply with United Kingdom Data Protection laws, such that the only information required to create a new record or to identify an existing patient-entry are the *date-of-birth*, *gender* and *date-of-operation*. Each line in the demographic screen listing represents a single patient, and a colour-coding system allows instant identification of records that are *complete* or *incomplete*, as shown in the screen-shot:

Add a new patient

Click here to to enter data for a new patient.

Revisions / staged procedures

Access pages for recording revisions / staged procedures



Patient demographic listing screen

Tracking data

% excess weight loss
Follow-up period
Months since last follow-up

Complications

Access pages for recording surgical complications, if applicable.

The main data entry screens offer a series of inter-linked pages with a number of integrated features:

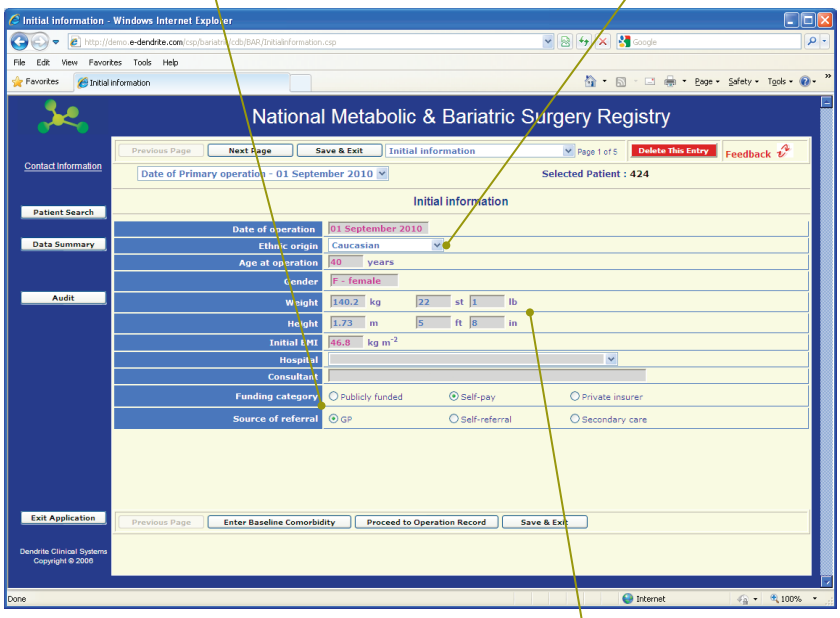
- use of simple radio buttons, multi-choice tick boxes and drop down lists, presenting only validated choice options.
- free-text boxes are limited as much as possible (to aid future data analysis).
- widespread use of hover-tip prompts to provide extra information to guide users on the most suitable response-options to select.
- automated cross calculations between imperial and metric measurements.
- on-screen auto-calculations for Body Mass Index.
- on-screen data validation checks (to prevent future dates being entered inappropriately).
- on-screen data validation involving cross checking between questions to prevent entry of illogical / incompatible data.
- *soft mandatory* fields, so that the user is warned of incomplete key fields when moving from one screen to another.
- easy forwards / backwards navigation.
- automated production of operation notes and clinic letters.
- auto-save features so that data are automatically saved when exiting a screen.

Single-choice fields

Radio buttons indicate mutually-exclusive response-options.

Dropdown box

Click anywhere on the box to reveal the list of available options.

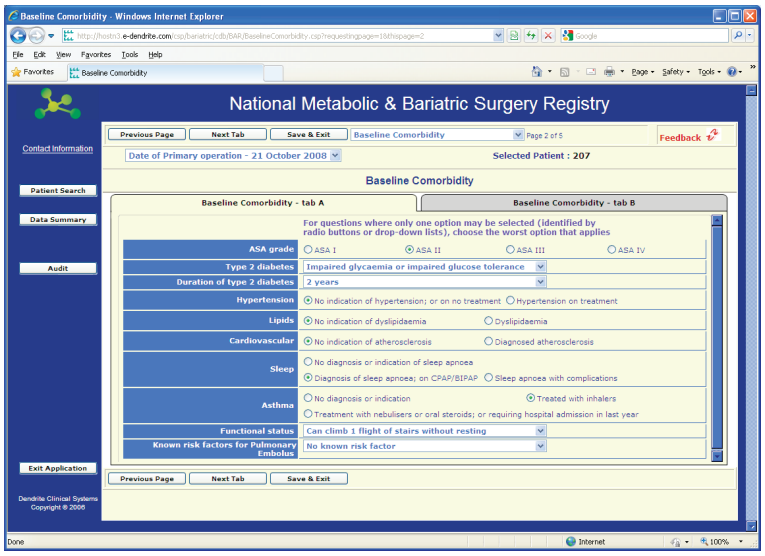


Initial information screen

Numeric fields

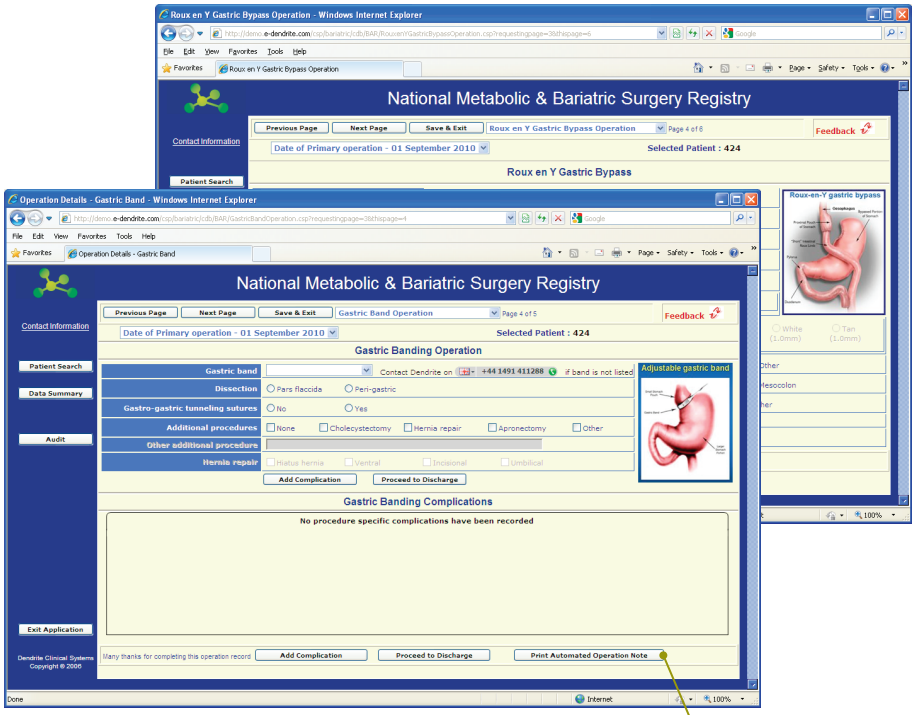
Height & weight data may be entered in either metric or imperial boxes; if entered as metric the imperial boxes auto-populate, and *vice versa*. Both have validation to ensure nonsense values are not accepted.

There are two screens dedicated to recording comorbidity data in some detail. These pages are of critical importance and contain numerous *soft mandatory* questions to encourage data entry to be as complete as possible.



User authentication screen

Visual cues are sometime presented so that users know exactly which section of the database they are in when moving quickly from screen-to-screen, *e.g.,* the gastric band screen, or the Roux-en Y bypass section as shown below:



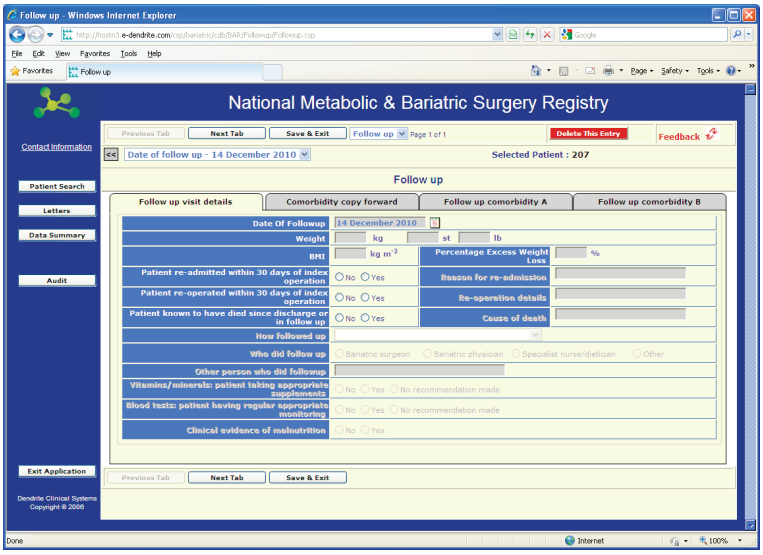
Operation data screens

Automated operation note

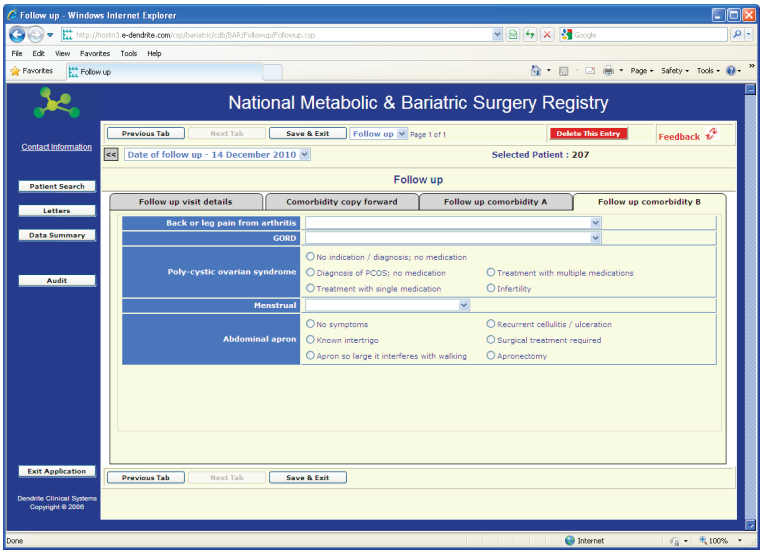
Click here to generate an html operation note.

The follow-up section allows for data capture of an unlimited amount of longitudinal data and, importantly, tracks not just weight (and weight loss) over time, but also the status of each comorbidity status in detail so that the long-term benefits of weight-loss surgery can be assessed.

The importance of collecting complete follow data on bariatric surgery patients cannot be over-emphasised. The International Federation for Surgery in Obesity (IFSO) recommend that patients should be seen annually and follow-up should be life-long.



First follow up screen



Final follow up screen

During follow-up consultations, some surgeons and specialist bariatric nurses enter the follow-up data in real time during the clinic visit. The software can then generate an automated follow-up letter, which details the procedure that was performed, the weight and excess weight-loss over time, depicted as a line graph, and lists the most current comorbidity status for each key comorbid condition. The letter can be either sent to the GP or given to the patient themselves.

St Elsewhere's Hospital NHS
NHS Trust

ATTACH
PATIENT
STICKY
HERE

Bariatric operation: Gastric band (on 09/04/2008)
Clinic date: 08/07/2009
Date of birth: 23/07/1967

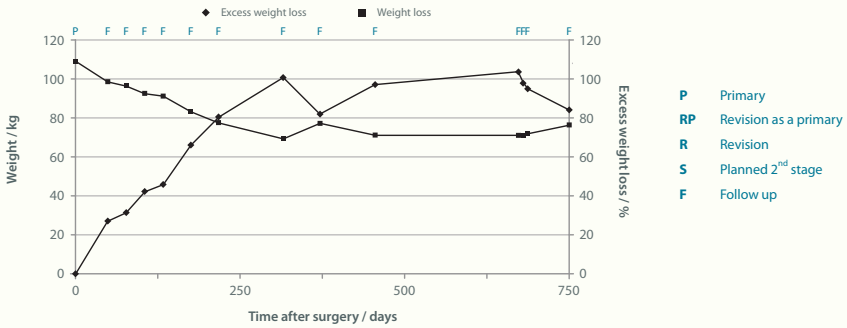
Pre-op weight: 109 kg
Pre-op BMI: 38.9 kg m^{-2}

Current weight: 76.4 kg
Current BMI: 27.2 kg m^{-2}

Total weight loss: 32.6 kg
Excess weight loss: 83.9 %

Vitamins / mineral supplements: Yes
Regular monitoring (blood test): Yes
Clinical evidence of malnutrition: No

Weight loss and excess weight loss



P Primary
RP Revision as a primary
R Revision
S Planned 2nd stage
F Follow up

Current comorbidity status

Type 2 diabetes: Impaired glycaemia or impaired glucose tolerance
Hypertension: No indication of hypertension
Sleep: No diagnosis or indication of sleep apnoea
Asthma: No diagnosis or indication of asthma
Functional: Can climb 3 flights of stairs without resting
Back / leg pain from OA: Intermittent symptoms; no medication
GORD: Intermittent medication
PCOS: No indication / diagnosis; no medication
Menstrual: Regular menstrual cycle
Apron: No symptoms

Any other information for the notes / GP

Current progress: Satisfactory, as expected Unsatisfactory (specify)

Next appointment: _____ months

Example auto-generated follow-up letter

Database overview

Database overview

The growth of the database

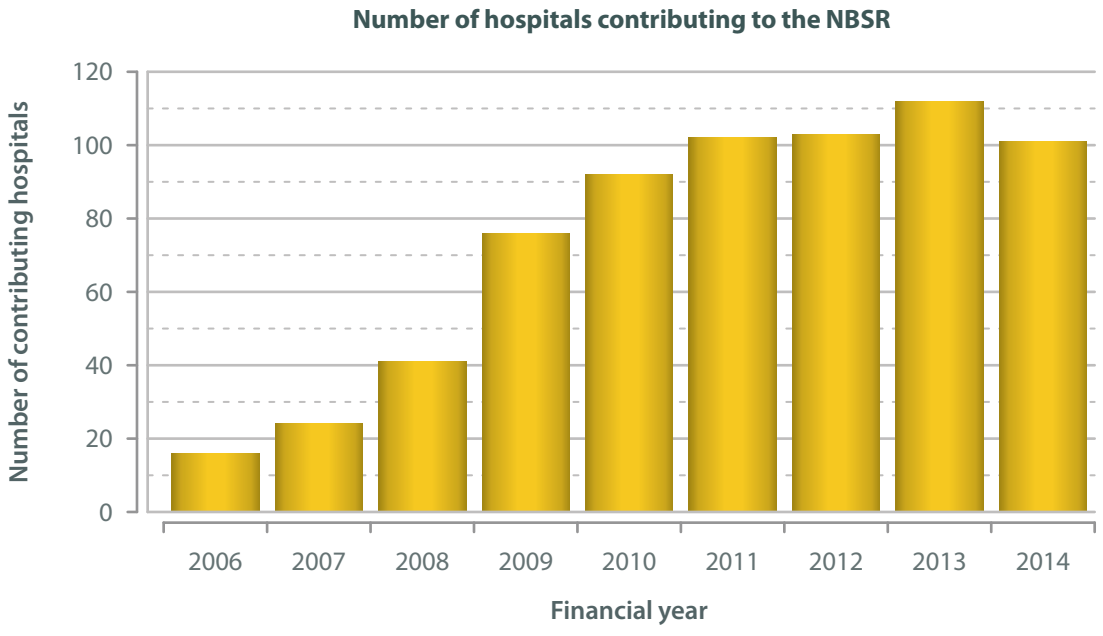
The first report from the NBSR of operations entered up to 1 March 2010, and with follow up entered up until 1 November 2010, demonstrated near exponential growth in the number of entries. This was a testament to the rapid and enthusiastic adoption of the database by United Kingdom bariatric surgeons together with possible expansion in the provision of bariatric surgery in the United Kingdom.

This second report details slower but continued growth in the number of entries year on year. This is to be expected, and represents both the consistent entry of patient-data into a maturing database, but also reflects a continued yet slow growth in the provision of such surgery in the United Kingdom.

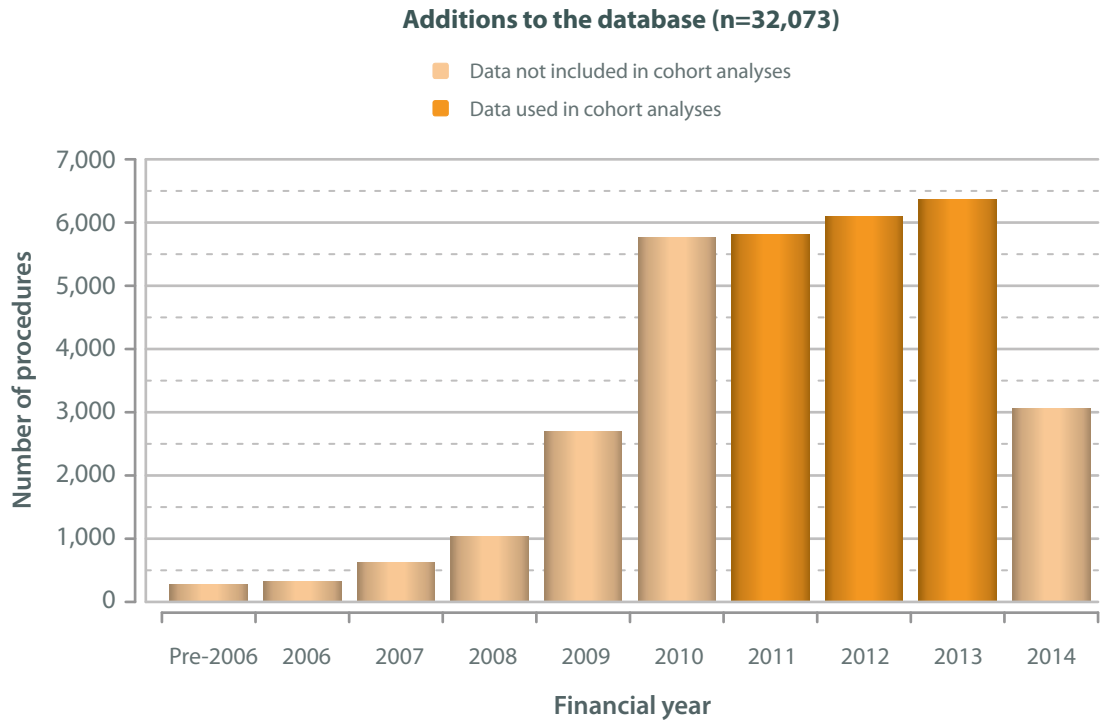
Number of entries in the database

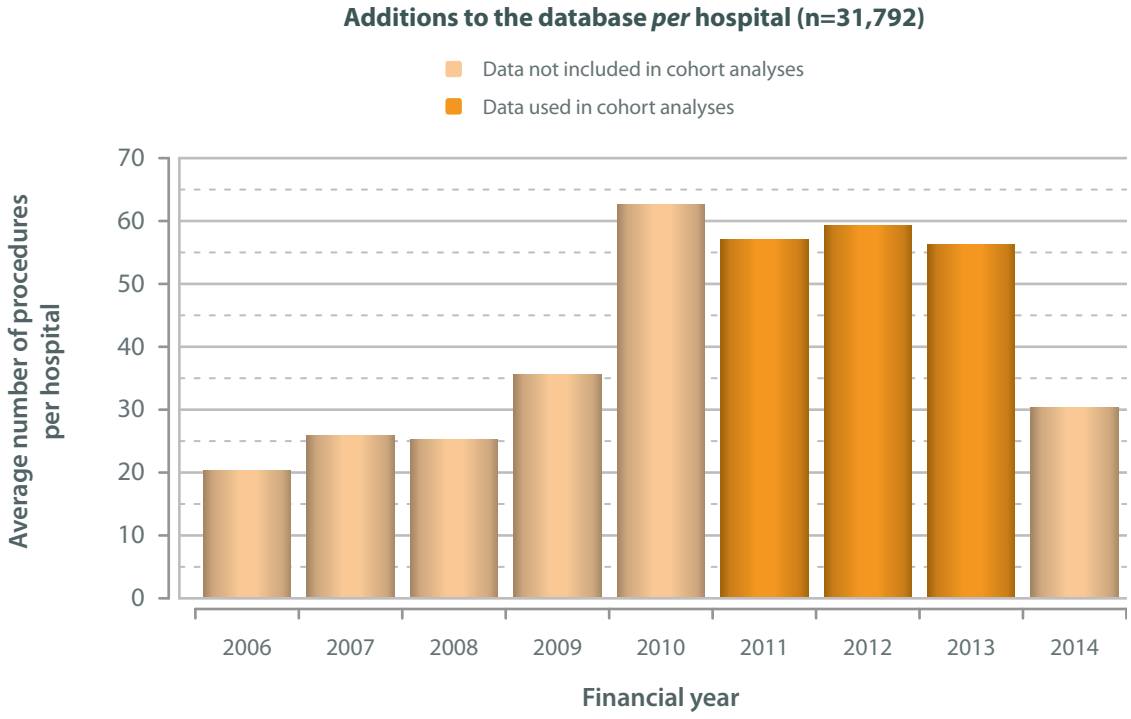
		Data	
		Count	Percentage
Financial year ending	Pre-2006	281	0.9%
	2006	326	1.0%
	2007	622	1.9%
	2008	1,038	3.2%
	2009	2,702	8.4%
	2010	5,758	18.0%
	2011	5,817	18.1%
	2012	6,102	19.0%
	2013	6,364	19.8%
	2014	3,063	9.6%
	All	**32,073**	

The year 2014 represents only part of the financial year as the data were harvested in October 2013.



Submission of data to the NBSR has recently become a condition for NHS commissioning of bariatric surgery [1], so in future the NBSR should contain data on all NHS-funded bariatric surgery patients. Whilst submission of data for privately funded patients is not yet mandatory, it is anticipated that data for most of these patients will also be included. The data from the financial year ending 2014 were only around 50% complete as data were harvested in October 2013. The 2014 data have therefore been excluded from subsequent cohort analyses as they do not represent a full year of activity.





1. Clinical Commissioning Policy: Complex and Specialised Obesity surgery. NHS Commissioning Board April 2013.

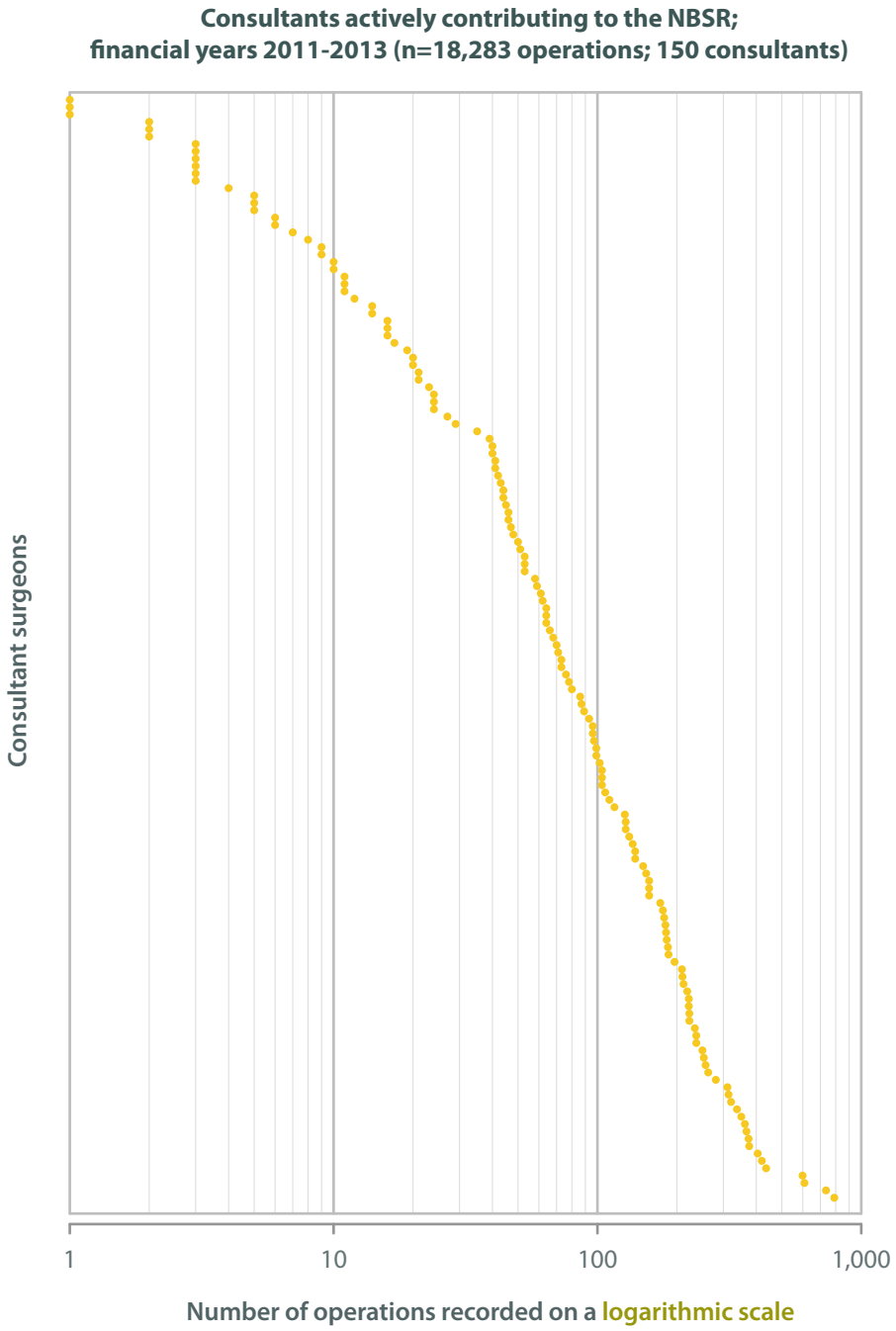
Number of entries submitted

Number of entries for each consultant

Since 2010 there has been a 74% increase in the number of Consultants contributing to the NBSR (from 86 to 150). This may reflect an increase in the number performing bariatric surgery, or an increase in the proportion of established bariatric surgeons contributing data to the NBSR, or, most likely, a combination of both.

UK guidelines [1] recommend that bariatric surgeons should perform more than 40 operations annually.

The annual number of NBSR entries *per* surgeon is not necessarily a wholly accurate reflection of the actual number of operations performed by each contributor, as the number of operations recorded depend, in part, on the time at which surgeon started to contribute to the NBSR, and also depends on their enthusiasm for entering data.



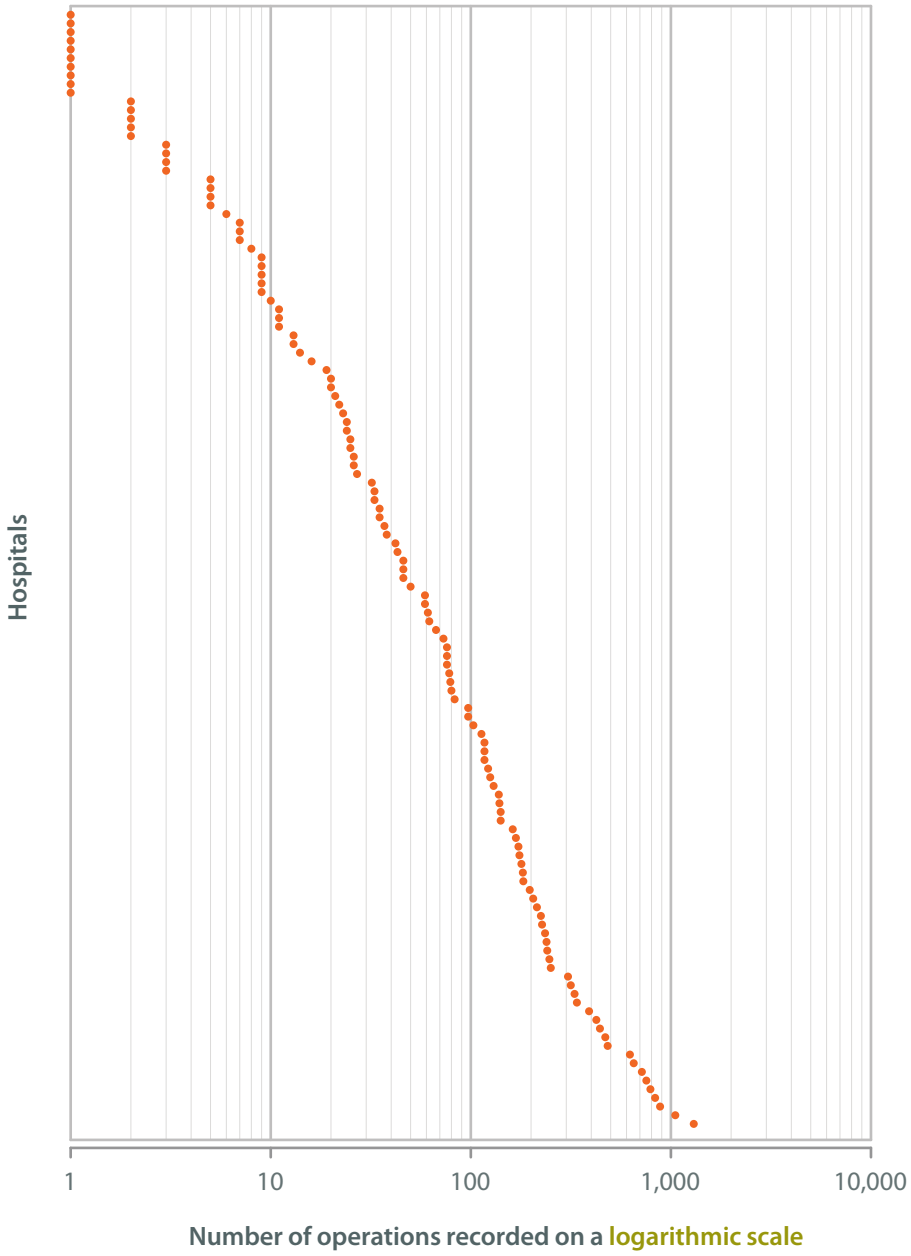
1. BOMSS Standards for Clinical Services & Guidance on Commissioning: http://www.bomss.org.uk/pdf/clinical_services_standards/Service_std-2012.pdf

Number of entries for each hospital

At the time of the last report consultants from 84 hospitals had submitted data; now there are 129 hospitals participating, which represents a 54% increase in the number of hospitals represented; both NHS and private hospitals have contributed data.

In the current merged database, the median number of cases recorded *per* hospital, across both the NHS and the private sector, has increased from 23 in the financial year 2010 to 33 operations in 2013.

**Hospital units actively contributing to the NBSR;
financial years 2011-2013 (n=18,283 operations; 129 hospitals)**



Type of procedures performed

Operation and type of surgery

Over 95% of all operations recorded in the NBSR were either Roux-en-Y gastric bypass (RYGB), gastric banding or sleeve gastrectomy operations.

RYGB remained the most commonly performed bariatric / metabolic surgery procedure recorded in the NBSR, comprising 52.3 % of all operations in the financial years 2011-2013. This is similar to the corresponding figure of 54.7% of operations performed over the period 2009-2010, as described in the previous NBSR report.

In contrast, there has been a marked change in the relative numbers of gastric band and sleeve gastrectomy operations performed over time: the percentage of gastric band operations has decreased year-on-year since 2006, reaching a low of 22.4% in 2011-2013, as compared to 30.7% of all operations performed during 2009-2010. In contrast, sleeve gastrectomy operations have become more common each year since 2008, reaching a rate of 20.9% of operations performed over the period 2011-2013; over the period 2009-2010 this procedure accounted for only 8.3% of bariatric surgery.

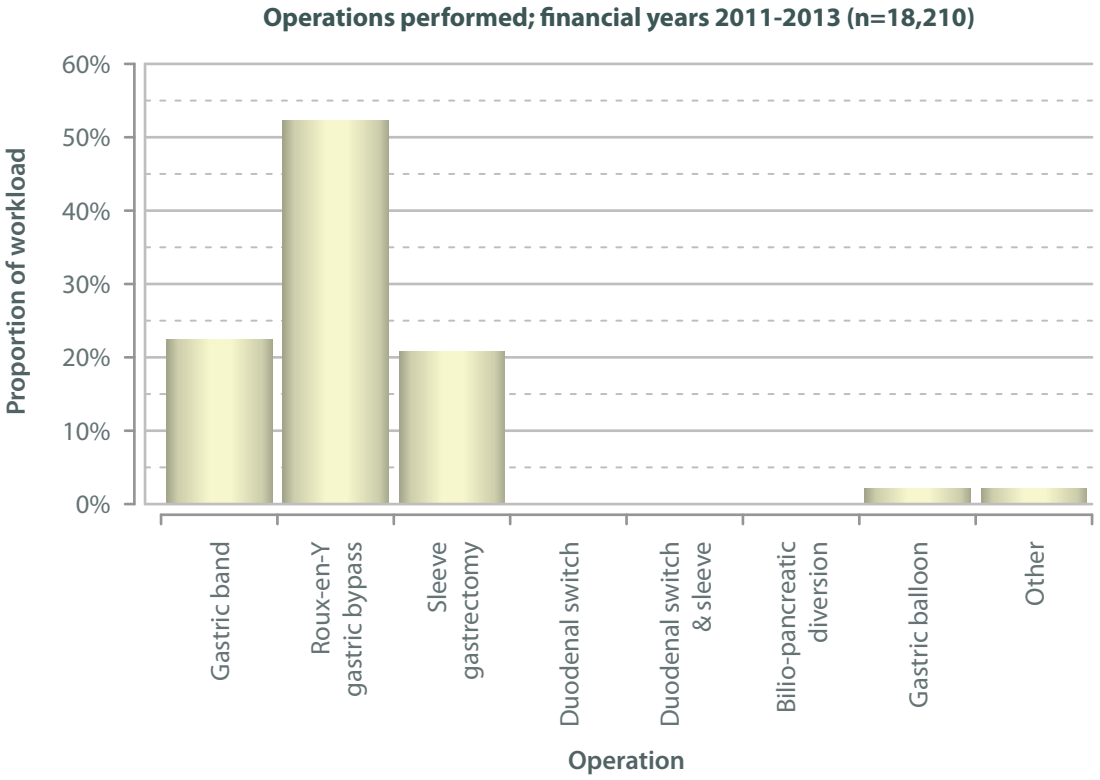
Similar trends in the relative numbers of each kind of operation have been described worldwide [1]; in particular, the patterns of change evident in the NBSR data are very similar to those reported across the rest of Europe.

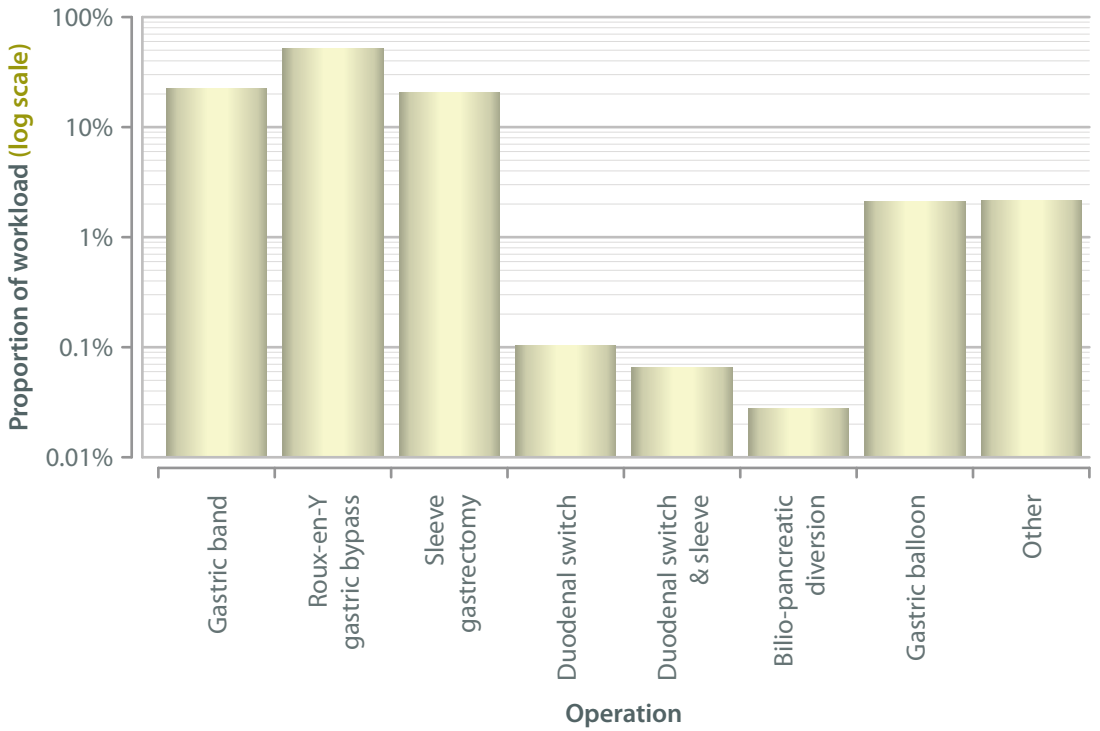
The endoscopic insertion of a gastric balloon for weight loss is an established technique. The absolute number of these procedures recorded *per* year in the NBSR has increased (130 *per* year over the last three full financial years compared to 100 *per* year in 2009-2010 according to the current merged database), even though the proportion that this operation represents has fallen over time (falling from 3.1% of the total in 2009 to 2.1% on 2013); it is unclear as to whether this truly reflects a fall in its popularity, or is simply some kind of artefact resulting from changes in the consultants / hospitals entering data onto the NBSR. This is one of many changes that it will be interesting to monitor over time.

Type of operation performed; financial years 2011-2013

		Type of surgery					
		Primary	Revision as a primary	Revision	Planned 2nd stage	Unspecified	All
Operation	Gastric band	3,633	295	142	5	0	**4,075**
	Roux-en-Y gastric bypass	9,133	267	86	40	0	**9,526**
	Sleeve gastrectomy	3,631	80	32	54	0	**3,797**
	Duodenal switch	0	7	1	11	0	**19**
	Duodenal switch & sleeve	11	0	0	1	0	**12**
	Bilio-pancreatic diversion	0	5	0	0	0	**5**
	Gastric balloon	294	0	3	89	0	**386**
	Other	181	106	79	24	0	**390**
	Unspecified	73	0	0	0	0	**73**
	All	**16,956**	**760**	**343**	**224**	**0**	**18,283**

1. Buchwald H *et al.* Metabolic / bariatric surgery worldwide 2011. *Obesity Surgery*. 2013; **23**: 427 - 436

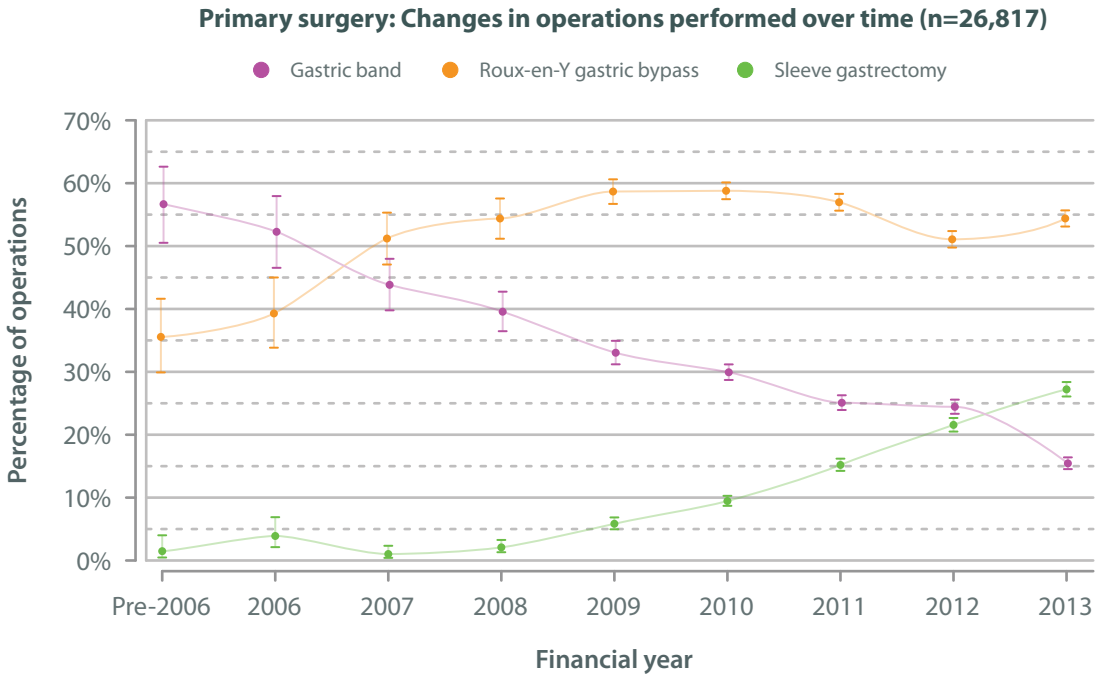

Operations performed; financial years 2011-2013 (n=18,210)
Proportion of workload
60%
50%
40%
30%
20%
10%
0%
Gastric band
Roux-en-Y gastric bypass
Sleeve gastrectomy
Duodenal switch
Duodenal switch & sleeve
Bilio-pancreatic diversion
Gastric balloon
Other
Operation


Proportion of workload (log scale)
100%
10%
1%
0.1%
0.01%
Gastric band
Roux-en-Y gastric bypass
Sleeve gastrectomy
Duodenal switch
Duodenal switch & sleeve
Bilio-pancreatic diversion
Gastric balloon
Other
Operation

Changes in the type of surgery over time

The following chart makes it very clear that there has been a significant and sustained move away from gastric banding towards other kinds of bariatric surgery. Over the early period covered by the NBSR (financial years 2006-2009), there was a rise in the proportion of operations that were Roux-en-Y gastric bypass, which then reached a plateau at around 55-60% of the total workload.

Until 2008 sleeve gastrectomy represented only a very small proportion of bariatric surgery, after which time there has been a near linear increase in the proportion of this kind of primary surgery. By 2013, over 25% of all primary bariatric surgery was sleeve gastrectomy.



Subsequent bariatric surgery

Only a very low proportion of patients require revisional surgery after a primary gastric band, Roux-en-Y gastric bypass or sleeve gastrectomy operation. This is very reassuring: the rates reported here are lower than those recorded in the published scientific literature. It is also possible that there is under-reporting of re-operations and revisions, or that these are done in different hospitals, and therefore the data are not linked to the original record. Also, the period covered by these data is relatively short and the revision rates could be expected to rise as time from the primary operation increases. In due course we plan to de-anonymise the Registry by adding NHS numbers, and this should enable us to track subsequent re-operations and revisions over time in the same patient, provided that the contributors record these data.

When gastric band operations required revisional surgery, repositioning or replacement of the gastric band was the most common procedure employed. This contrasts with the data for primary RYGB or sleeve gastrectomy patients who more commonly underwent an entirely different procedure when they required revisional surgery.

Gastric balloons are often used to prepare patients for more definitive surgery. Some bariatric surgery units in the United Kingdom use gastric balloon insertion as a way to help high-risk patients lose weight prior to more definitive bariatric surgery. This is likely to have been the case for a significant proportion of the 14.6% of patients who went on to have either a sleeve gastrectomy or RYGB operation. The balloons also have a limited life-span; it is recommended that gastric balloons should be removed after six months, but subsequent reinsertion is possible, as recorded for 28% of the patients reported here. These two facts in tandem explain why a much greater proportion of patients who had an endoscopic gastric balloon insertion went on to have a subsequent procedure recorded in the NBSR.

Primary operations: subsequent bariatric surgery recorded in the NBSR; financial years 2011-2013

Primary operation			Count	Percentage
	Gastric band	None	3,569	98.2%
		Gastric band	39	1.1%
		Roux-en-Y gastric bypass	5	0.1%
		Sleeve gastrectomy	6	0.2%
		Other	14	0.4%
	Roux-en-Y gastric bypass	None	9,099	99.6%
		Roux-en-Y gastric bypass	2	0.0%
		Other	32	0.4%
	Sleeve gastrectomy	None	3,611	99.4%
		Roux-en-Y gastric bypass	15	0.4%
		Sleeve gastrectomy	2	0.1%
		Other	3	0.1%
	Gastric balloon	None	167	56.8%
		Gastric balloon	83	28.2%
		Roux-en-Y gastric bypass	6	2.0%
		Sleeve gastrectomy	37	12.6%
		Other	1	0.3%

Operation and approach

Over 90% of all types of bariatric operations were performed using a laparoscopic (*keyhole surgery*) approach. Laparoscopic operations are performed *via* small incisions (between 5 mm and 15 mm in size), which minimises post-operative pain and facilitates much faster recovery from operations. The laparoscopic approach is therefore seen as the *gold standard* approach for such surgery.

Laparoscopic rates for primary and planned second stage operations during 2011-2013 were similar to those in the previous NBSR report, at 95.4 and 96.8% respectively. However, more detailed year-on-year analysis of the laparoscopic rates for RYGB and sleeve gastrectomy operations from 2007 onwards revealed steadily increasing laparoscopic rates. Such improvements seem likely to have resulted from the bariatric surgeons' increasing experience and skills.

Operation performed, type of surgery and operative approach; financial years 2011-2013

		Type of surgery and approach								
		Primary			All revisions			Planned 2nd stage		
		Laparoscopic or endoscopic	Open	Unspecified	Laparoscopic or endoscopic	Open	Unspecified	Laparoscopic or endoscopic	Open	Unspecified
Operation	Gastric band	3,622	8	3	414	19	4	5	0	0
	Roux-en-Y gastric bypass	8,373	748	12	294	35	24	37	3	0
	Sleeve gastrectomy	3,605	18	8	101	2	9	54	0	0
	Duodenal switch	0	0	0	8	0	0	11	0	0
	Duodenal switch & sleeve	11	0	0	0	0	0	1	0	0
	Bilio-pancreatic diversion	0	0	0	3	2	0	0	0	0
	Gastric balloon	291	0	3	3	0	0	87	0	2
	Other	173	4	4	143	37	5	19	4	1
	Unspecified	4	0	69	0	0	0	0	0	0
	All	**16,079**	**778**	**99**	**966**	**95**	**42**	**214**	**7**	**3**

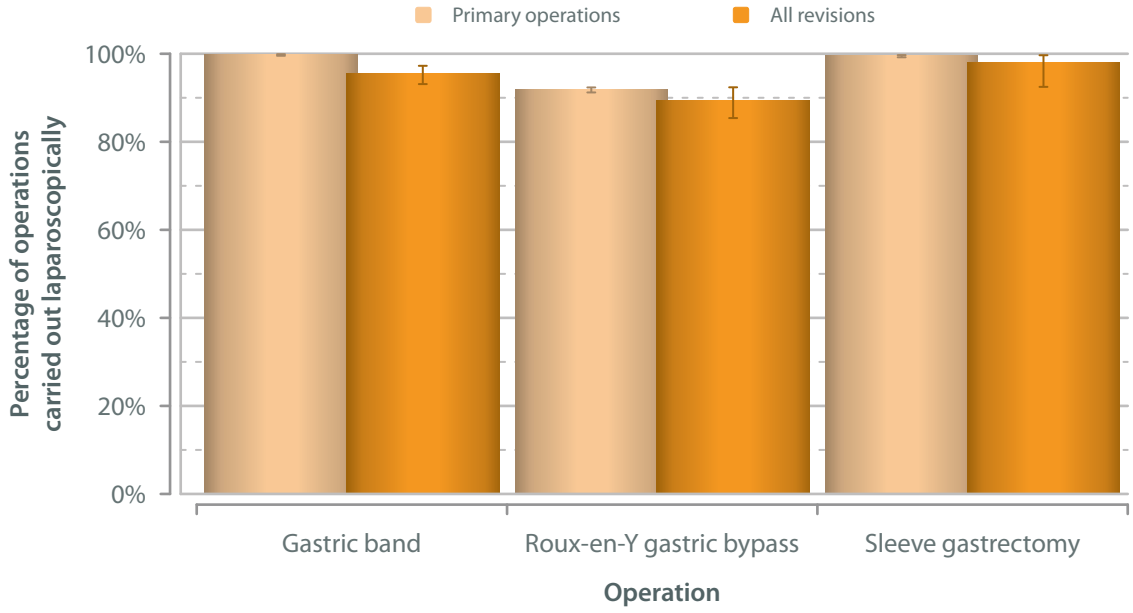
Percentage of operations performed laparoscopically / endoscopically for each kind of operation and type of surgery; financial years 2011-2013

		Type of surgery and approach		
		Primary	All revisions	Planned 2nd stage
Operation	Gastric band	99.8% (99.5-99.9%)	95.6% (93.1-97.3%)	100.0% (54.9-100.0%)
	Roux-en-Y gastric bypass	91.8% (91.2-92.4%)	89.4% (85.4-92.4%)	92.5% (78.5-98.0%)
	Sleeve gastrectomy	99.5% (99.2-99.7%)	98.1% (92.5-99.7%)	100.0% (94.6-100.0%)
	Duodenal switch	NA	100.0% (68.8-100.0%)	100.0% (76.2-100.0%)
	Duodenal switch & sleeve	100.0% (76.2-100.0%)	NA	100.0% (5.0-100.0%)
	Bilio-pancreatic diversion	NA	60.0% (17.0-92.7%)	NA
	Gastric balloon	100.0% (99.0-100.0%)	100.0% (36.8-100.0%)	100.0% (96.6-100.0%)
	Other	97.7% (93.9-99.3%)	79.4% (72.7-84.9%)	82.6% (60.5-94.3%)
	Unspecified	100.0% (47.3-100.0%)	NA	NA
	All	**95.4%** (95.1-95.7%)	**91.0%** (89.1-92.7%)	**96.8%** (93.3-98.6%)

A more-recent, marked improvement in laparoscopic rates for revisional surgery has also been demonstrated: increasing from a rate of 81.6% recorded in the last report, to 91.0% over the financial years 2011-2013. Revisional surgery is more technically challenging than primary surgery and has been adopted later by most surgeons in the United Kingdom. The increase in laparoscopic revisional surgery may also be, in part, due to a higher proportion of primary operations having been performed laparoscopically.

Over 99% of both primary gastric band and sleeve gastrectomy operations were performed laparoscopically. The proportion of primary Roux-en-Y gastric bypass (RYGB) operations performed laparoscopically was lower at 91.8%, but this is not surprising as RYGB is technically more demanding. Note the logarithmic scale on the lower chart.

Operative approach for the most frequently-performed operations; financial years 2011-2013 (n=18,239)



Primary surgery: Changes in operative approach over time (n=19,054)

Age and gender

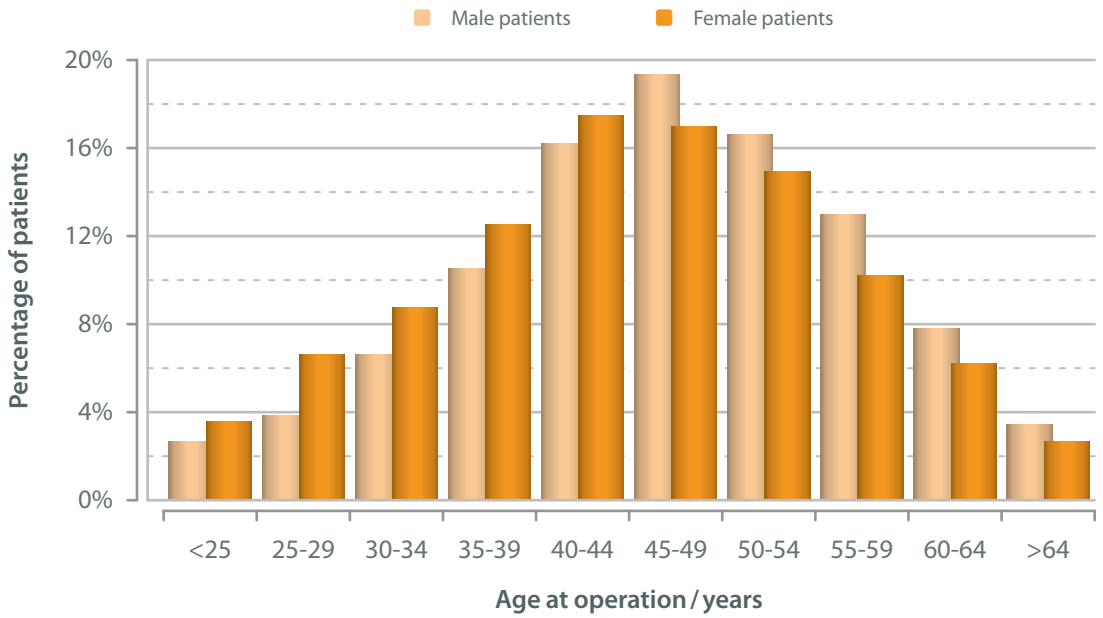
Most patients undergoing bariatric surgery were female. The reasons for this gender bias are unclear, but the data do not reflect gender-specific obesity rates in the United Kingdom [1] (see page 22); this predominance of women in bariatric surgical patient-populations is reported worldwide.

For patients over the age of 24 years, there was a statistically significant decrease in the proportion of patients who are female with increasing age: from 84.4% of 25-29 year-olds to 71.1% of those over the age of 64 years ($p<0.001$; χ^2-test for trend). A similar association between age and gender was evident in the last NBSR report. These data suggest that women seek or are referred for surgery at an earlier age compared to men. Again the reasons for this are unclear, but it may be a reflection of gender-specific cultural attitudes to weight, or other pressures that pertain especially to women.

Primary operations: age and gender distributions; financial years 2011-2013

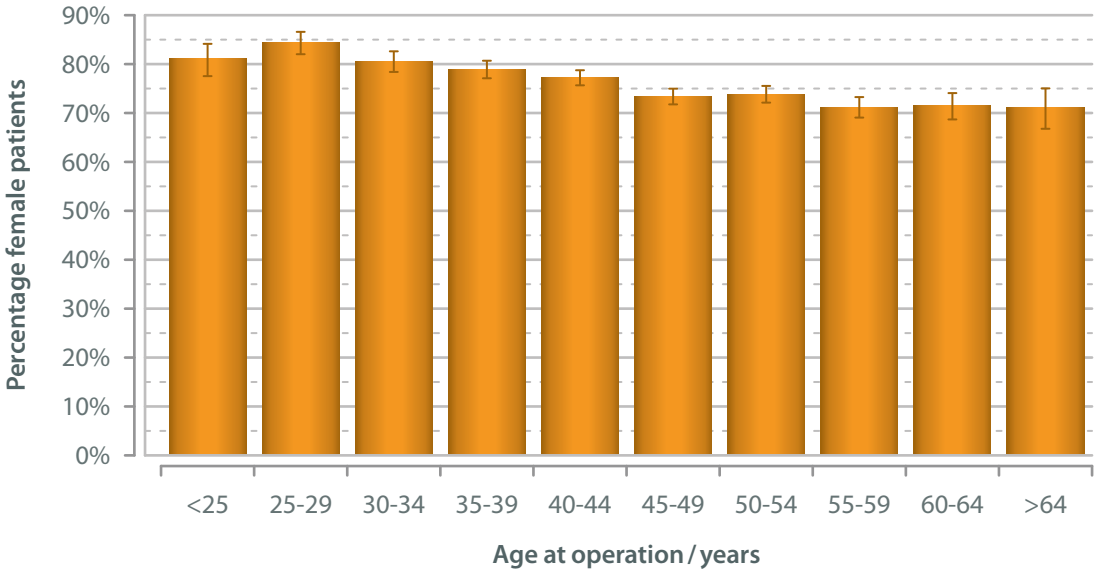
		Gender			
		Male	Female	Unspecified	**All**
Age at operation / years	<25	108	462	0	**570**
	25-29	157	852	0	**1,009**
	30-34	271	1,125	0	**1,396**
	35-39	429	1,609	0	**2,038**
	40-44	661	2,243	0	**2,904**
	45-49	789	2,177	0	**2,966**
	50-54	679	1,919	0	**2,598**
	55-59	529	1,308	0	**1,837**
	60-64	318	796	0	**1,114**
	>64	140	344	0	**484**
	Unspecified	6	34	0	**40**
	All	**4,087**	**12,869**	**0**	**16,956**

Primary operations: Age and gender; financial years 2011-2013 (n=16,916)

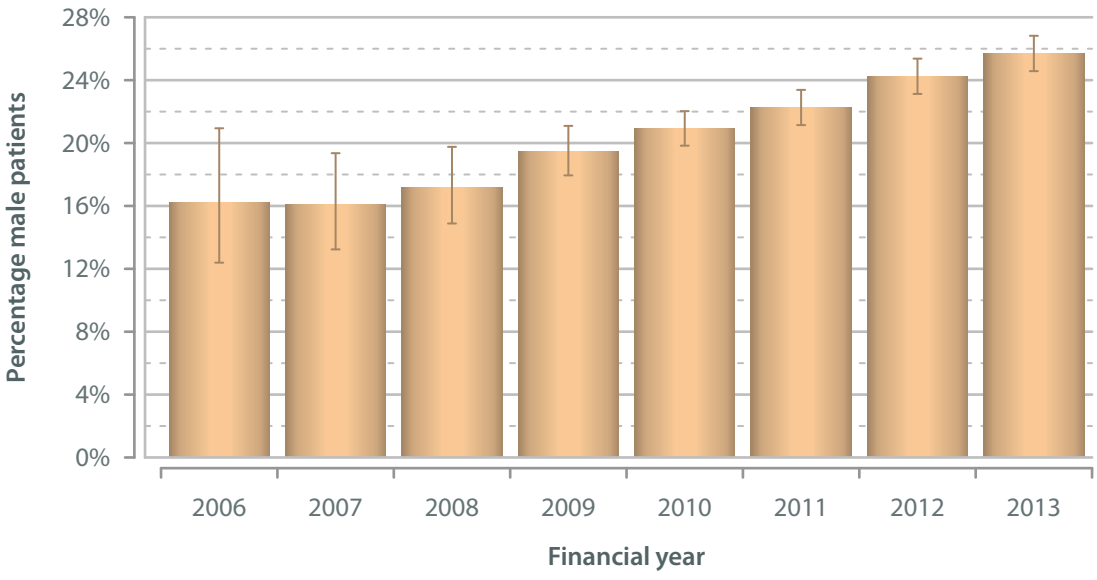


It is very interesting to note that there has been a statistically significant increase in the proportion of men undergoing bariatric surgery during 2011-2013 (24.1%; 26.2% of publicly-funded surgery, and 17.2% of privately-funded operations) compared to the period of 2008-2010 (24.1% *versus* 20.5%; $p<0.001$, χ^2 2×2 contingency table). The proportion of patients who are male has been increasing year on year since 2007. This may be due to an increasing awareness and / or acceptance of bariatric surgery amongst male patients.

Primary operations: Female gender according to age category; financial years 2011-2013 (n=16,916)



Primary operations: Changes in the proportion of male patients over time (n=26,661)



1. http://www.noo.org.uk/NOO_about_obesity/inequalities.

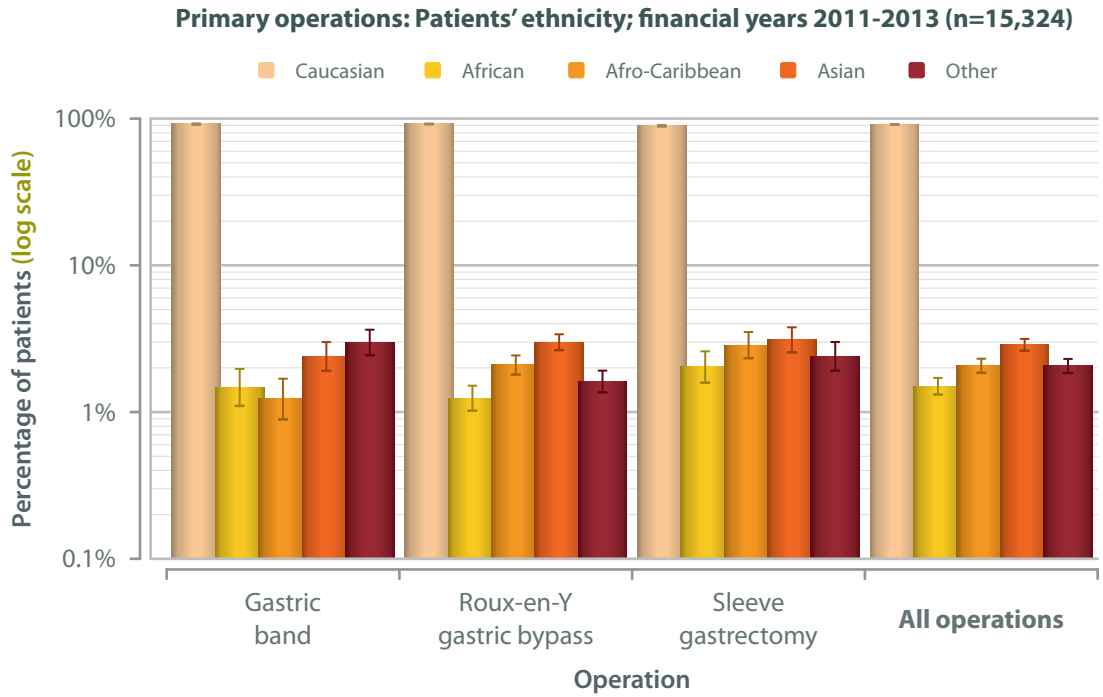
Ethnicity

Little contemporaneous data exist describing the prevalence of obesity in adults from minority ethnic groups in the United Kingdom, with the most comprehensive information originating from the 2004 Health Survey for England [1]. It is therefore difficult to draw any conclusions regarding the frequency of surgery for minority ethnic groups, but it does appear quite likely that there could be inequality of access for these patients.

As the NBSR data matures it will be important to look at this area in more detail as the prevalence of obesity related conditions such as type 2 diabetes and hypertension varies by ethnic group. Consequently, differing body mass index thresholds for surgery have been suggested for differing ethnic groups [2].

Primary operations: patients' ethnicity; financial years 2011-2013

		Ethnic origin						
		Caucasian	African	Afro-Carribean	Asian	Other	Unspecified	All
Operation	Gastric band	2,989	48	40	78	97	381	**3,633**
	Roux-en-Y gastric bypass	7,688	104	175	250	135	781	**9,133**
	Sleeve gastrectomy	2,910	66	93	101	78	383	**3,631**
	Duodenal switch & sleeve	10	0	0	0	1	0	**11**
	Gastric balloon	252	5	4	4	3	26	**294**
	Other	146	7	4	6	1	17	**181**
	Unspecified	26	0	1	1	1	44	**73**
	All	**14,021**	**230**	**317**	**440**	**316**	**1,632**	**16,956**



1. http://www.noo.org.uk/NOO_about_obesity/inequalities#d6892).
2. NICE public health guidance 46: guidance.nice.org.uk/ph46).

Funding

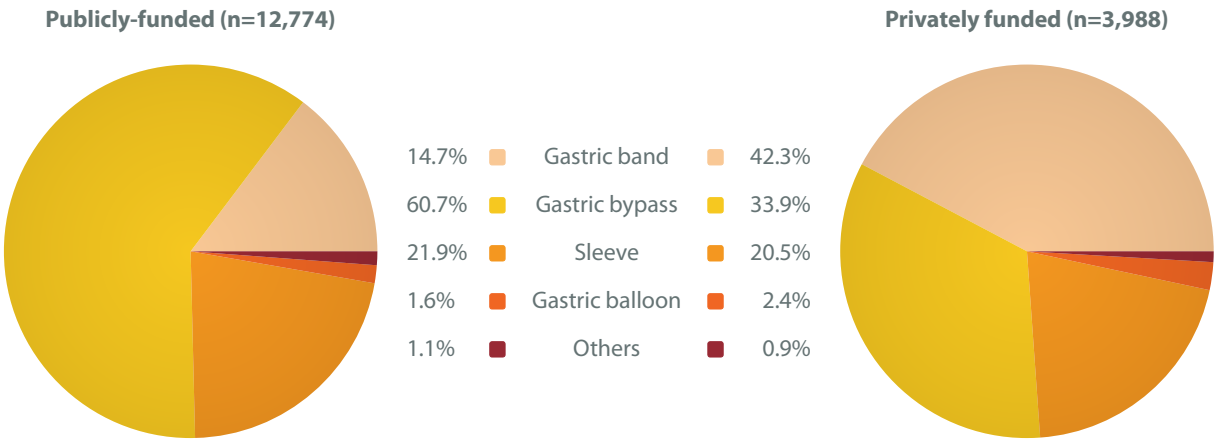
The current data from the NBSR show that the proportion of bariatric operations that were publicly funded was 72.1% in 2009-2010, rising significantly to 76.2% by 2011-2013 ($p<0.001$; χ^2 2×2 contingency table). This may be due to an increasing provision of surgery funded by the National Health Service, but may also be a reflection of the worsening economic climate over the latter period, with fewer patients being able to afford bariatric surgery privately. However, there have also been significantly fewer publicly funded operations. The reasons for this are not known but may reflect reluctance to fund an area of surgery that is well known to suffer from prejudice.

Whilst the proportions of both Roux-en-Y gastric bypass and gastric band operations that were publicly funded significantly increased over the two time-periods (2009-2010 *versus* 2011-2013), the proportion of sleeve gastrectomy operations that were publicly funded decreased significantly ($p=0.039$); however, the numbers here are small, and future NBSR reports will reveal whether this is a real and continuing trend.

Primary operations: type of operation and source of funding; financial years 2011-2013

		Funding				
		Publicly	Self-pay [i]	Private [i]	Unspecified	**All**
Operation	Gastric band	1,879	1,666	20	68	**3,633**
	Roux-en-Y gastric bypass	7,750	1,228	122	33	**9,133**
	Sleeve gastrectomy	2,795	758	61	17	**3,631**
	Duodenal switch & sleeve	6	5	0	0	**11**
	Gastric balloon	198	95	1	0	**294**
	Other	146	31	1	3	**181**
	Unspecified	46	14	0	13	**73**
	All	**12,820**	**3,797**	**205**	**134**	**16,956**

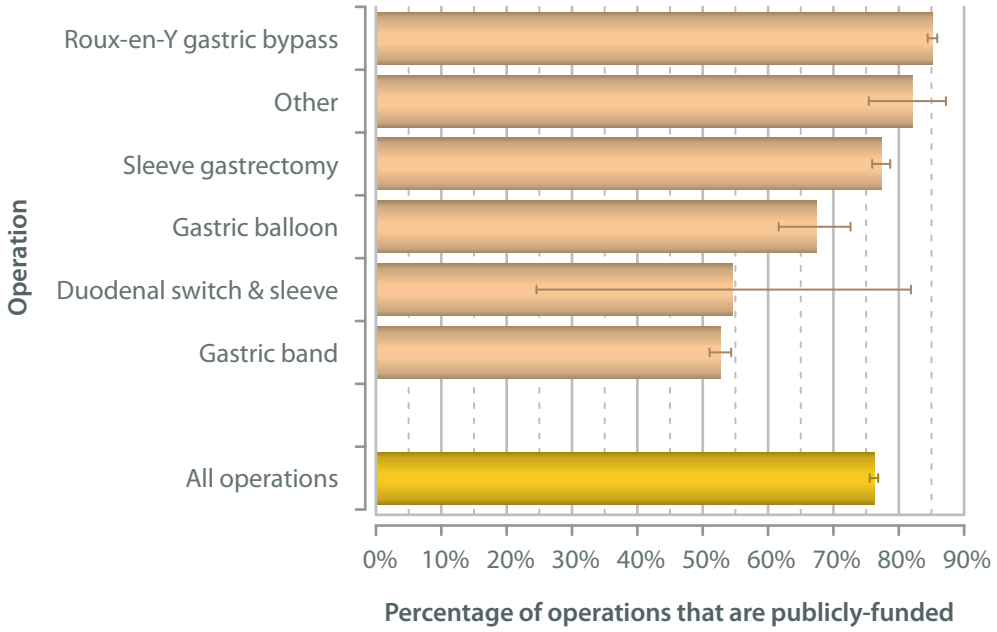
Primary operations: Funding and operation; financial years 2011-2013



i. Privately funded comprises those patients who have paid for their own operation (*Self-pay*) and a small cohort of patients with private medical insurance (*Private*).

1. Teachman BA, Brownell KD. Implicit anti-fat bias among health professionals: is anyone immune? *International Journal of Obesity Related Metabolic Disorders*. 2001; **25**: 1525-1561.

Primary operations: Funding and operation; financial years 2011-2013 (n=16,822)



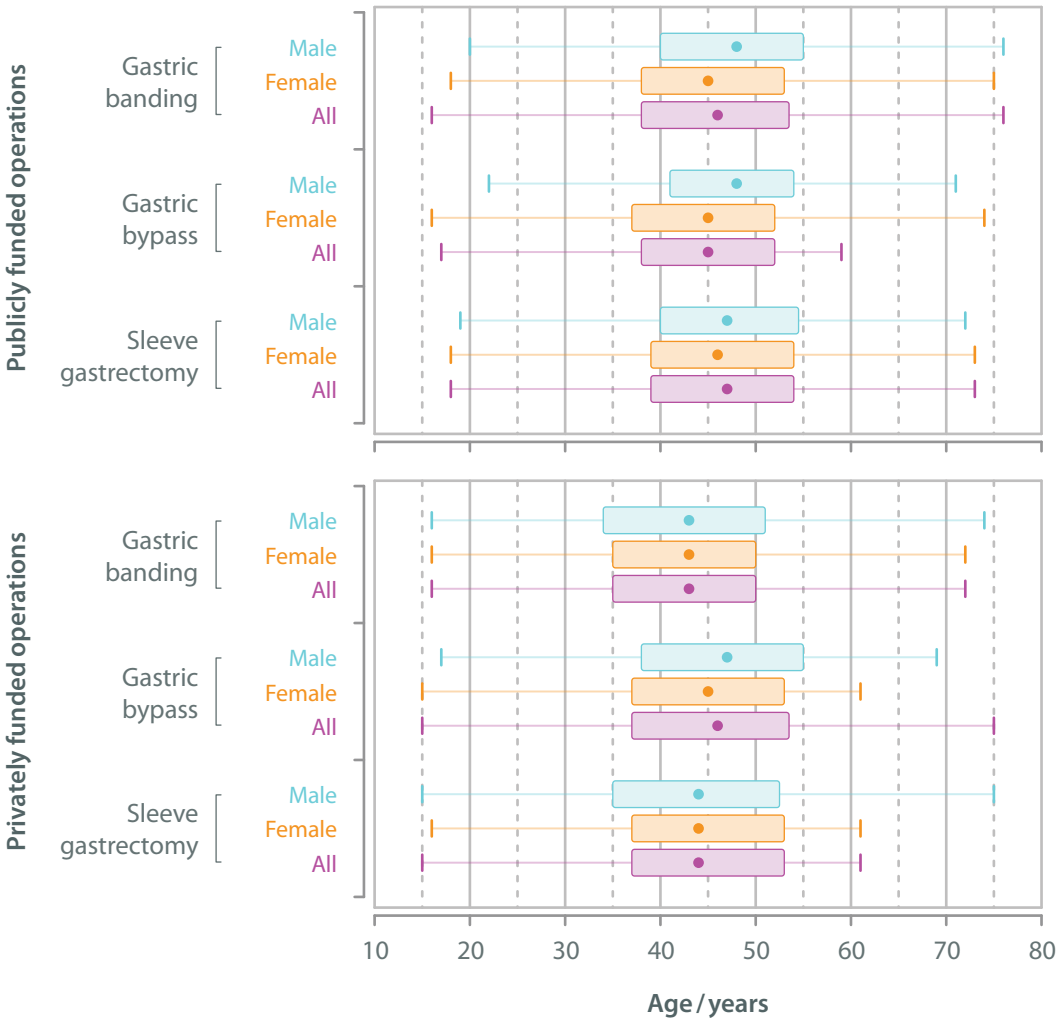
Age, operation and funding

This table shows the patients' average age for publicly funded operations *versus* those privately funded for each of gastric banding, gastric bypass and sleeve gastrectomy. As noted in the First NBSR Report, patients having self-funded gastric banding were, on average, more than 3 years younger than those having publicly funded surgery. For gastric bypass, the patients' average age was very similar across the two funding groups; for those undergoing sleeve gastrectomy, the patients funding their surgery privately were younger than those having the same kind of operation publicly funded.

Primary operations: basic statistics on age according to type of operation, funding and gender; financial years 2011-2013

Operation, funding and gender				Count	Average	Median	IQR (lower-upper)	Range (min-max)
Gastric band	Publicly funded		Male	424	47.5	48	40-55	16-76
			Female	1,450	45.2	45	38-53	18-75
			All	1,874	45.7	46	38-54	16-76
	Privately funded		Male	205	43.3	43	34-51	16-74
			Female	1,481	42.5	43	35-50	16-79
			All	1,686	42.6	43	35-50	16-79
Roux-en-Y gastric bypass	Publicly funded		Male	1,948	47.0	48	41-54	14-80
			Female	5,783	44.4	45	37-52	16-99
			All	7,731	45.0	45	38-52	14-99
	Privately funded		Male	264	45.9	47	38-55	17-69
			Female	1,084	44.7	45	37-53	15-99
			All	1,348	45.0	46	37-54	15-99
Sleeve gastrectomy	Publicly funded		Male	841	47.1	47	40-55	13-77
			Female	1,945	46.0	46	39-54	18-84
			All	2,786	46.3	47	39-54	13-84
	Privately funded		Male	197	44.1	44	35-53	15-75
			Female	618	44.5	44	37-53	16-76
			All	815	44.4	44	37-53	15-76

Primary operations: Age distributions according to operation, gender and funding; financial years 2011-2013



Height, weight and body mass index

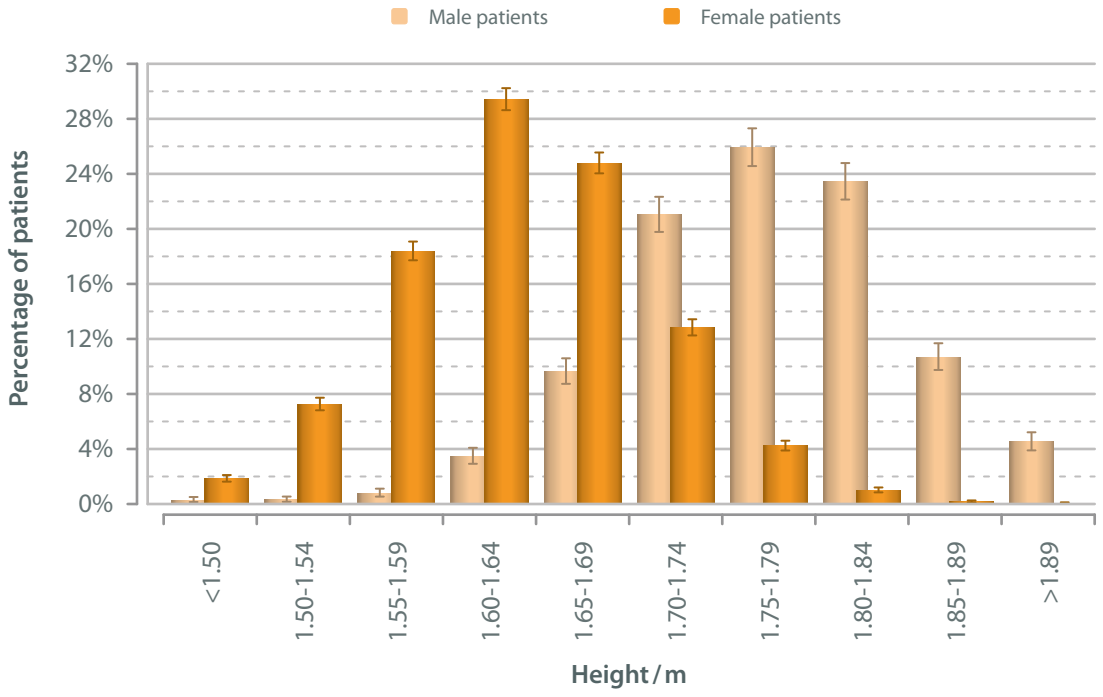
Height and gender

As one might expect, male patients were generally taller than females. The height distribution of both sexes conforms to that of the general population of England as measured for the 2012 Health Survey for England [1], which reported average heights of 175.3 cm and 161.9 cm for men and women respectively. The distribution of heights has not changed when compared to those described in the first NBSR report.

Primary operations: height and gender distributions; financial years 2011-2013

		Gender			
		Male	Female	Unspecified	All
Height / m	<1.50	11	233	0	**244**
	1.50-1.54	12	914	0	**926**
	1.55-1.59	31	2,316	0	**2,347**
	1.60-1.64	138	3,706	0	**3,844**
	1.65-1.69	384	3,122	0	**3,506**
	1.70-1.74	839	1,616	0	**2,455**
	1.75-1.79	1,034	533	0	**1,567**
	1.80-1.84	935	127	0	**1,062**
	1.85-1.89	426	21	0	**447**
	>1.89	180	7	0	**187**
	Unspecified	97	274	0	**371**
	All	**4,087**	**12,869**	**0**	**16,956**

Primary operations: Height and gender; financial years 2011-2013 (n=16,585)



1. http://www.hscic.gov.uk/catalogue/PUB13218.

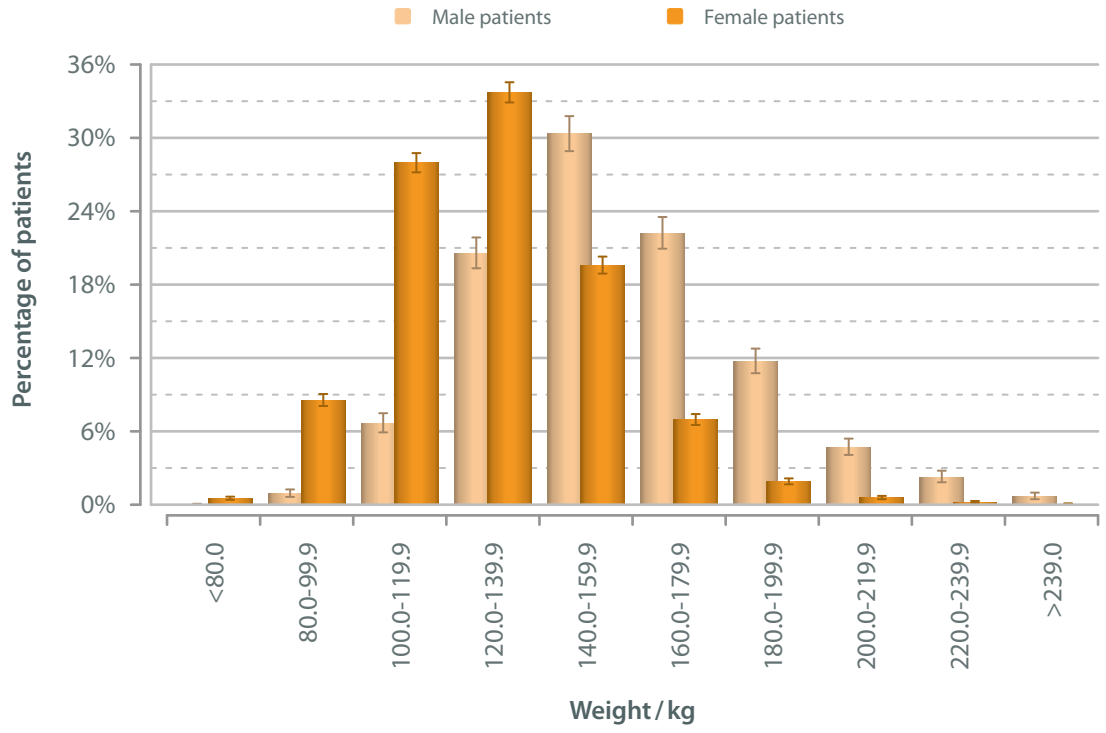
Weight and gender

In marked contrast to height data, the distribution of initial pre-operative weights for patients in the NBSR was very different to that of the general population as recorded in the 2012 Health Survey for England [1], which reported average weights of 84.0 kg for men and 70.7 kg for women. It is clear that male patients tended to weigh more than female patients. However, in order to assess whether or not this is simply a reflection of the fact that men are generally taller, it is necessary to assess the patients' body mass index (BMI) data, as shown on the following pages.

Primary operations: weight and gender; financial years 2011-2013

		Gender			
		Male	Female	Unspecified	All
Weight / kg	<80	0	65	0	**65**
	80-99	36	1,083	0	**1,119**
	100-119	268	3,542	0	**3,810**
	120-139	828	4,271	0	**5,099**
	140-159	1,221	2,481	0	**3,702**
	160-179	894	881	0	**1,775**
	180-199	472	240	0	**712**
	200-219	189	72	0	**261**
	220-239	91	26	0	**117**
	>239	27	6	0	**33**
	Unspecified	61	202	0	**263**
	All	**4,087**	**12,869**	**0**	**16,956**

Primary operations: Weight and gender; financial years 2011-2013 (n=16,693)



Body mass index

Body mass index and gender

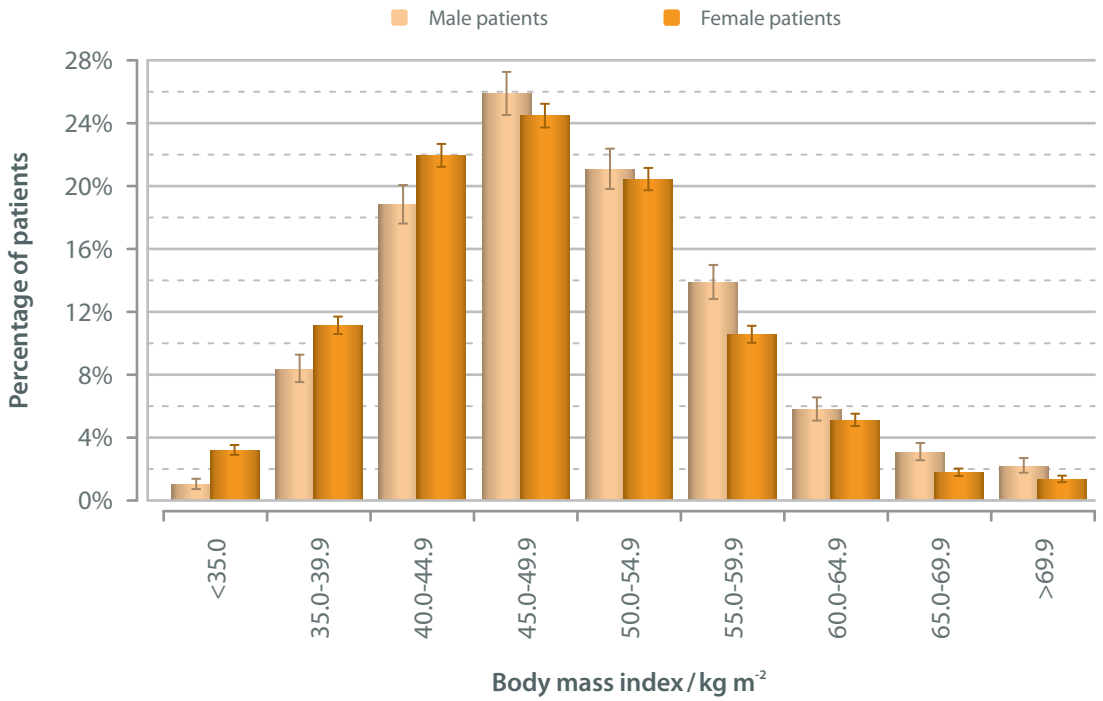
The BMI is calculated using the formula previously described on page 52, and gives a measure of how overweight an individual can be considered to be for their height. The BMI data below demonstrate that there was a greater proportion of men in the higher BMI groups compared to women ($p<0.001$; χ^2 test).

A simple categorical analysis suggests that the women treated in 2011-2013 tended to have a higher BMI compared to women who had their operations in 2009-2010 ($p<0.001$; χ^2 test; data from the current NBSR merge). The BMI data for men also showed some differences across the two time-periods, but the overall effect was less distinct, and hard to describe in simplistic terms.

Primary operations: body mass index and gender; financial years 2011-2013

		Gender			
		Male	Female	Unspecified	**All**
Body mass index / kg m^{-2}	<35.0	40	403	0	**443**
	35.0-39.9	333	1,401	0	**1,734**
	40.0-44.9	749	2,762	0	**3,511**
	45.0-49.9	1,030	3,080	0	**4,110**
	50.0-54.9	839	2,572	0	**3,411**
	55.0-59.9	552	1,329	0	**1,881**
	60.0-64.9	230	644	0	**874**
	65.0-69.9	122	224	0	**346**
	>69.9	87	171	0	**258**
	Unspecified	105	283	0	**388**
	All	**4,087**	**12,869**	**0**	**16,956**

Primary operations: BMI and gender; financial years 2011-2013 (n=16,568)

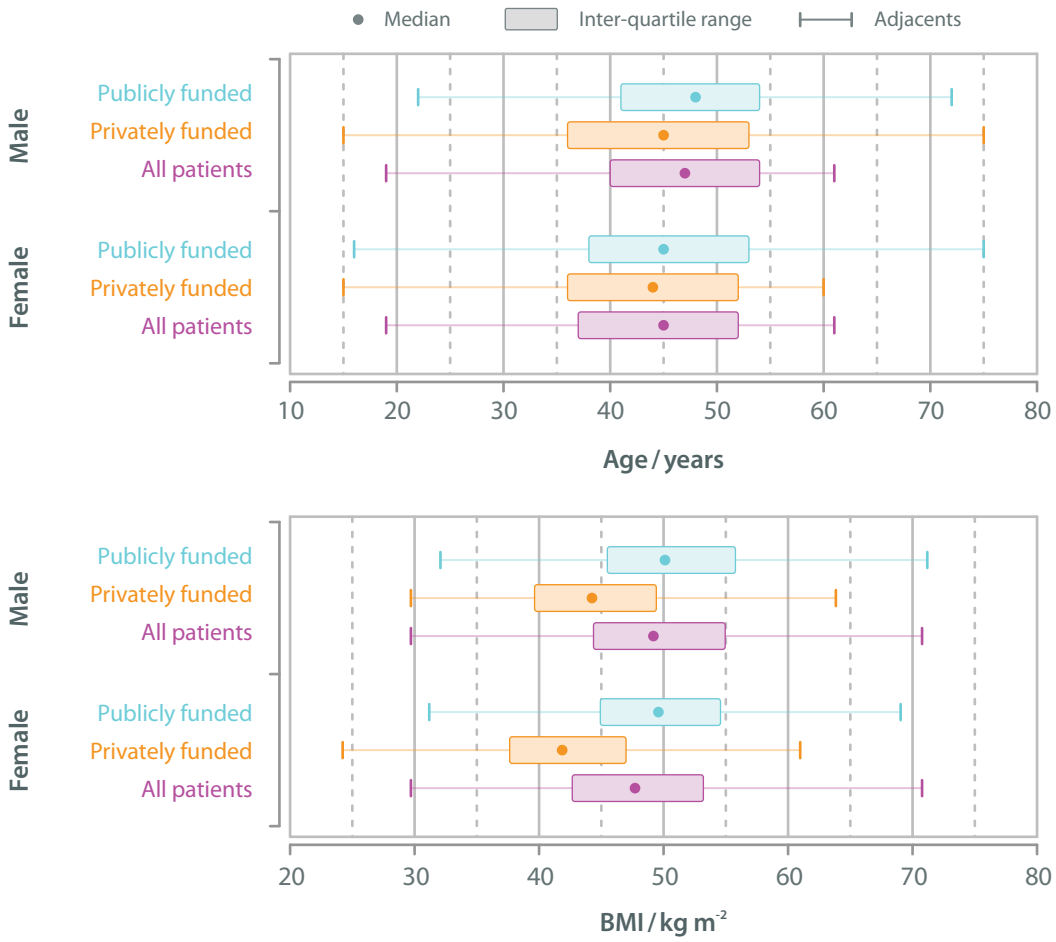


The average age for male patients was 46.7 years old and they had an average BMI of 50.1 kg m^{-2} (47.1 years and 51.1 kg m^{-2} for publicly funded surgery *versus* 44.5 years and 45.2 kg m^{-2} for privately funded operations). The average age for female patients was 44.5 years and their average BMI was 48.4 kg m^{-2} (44.9 years and 50.3 kg m^{-2} for those funded by the NHS *versus* 43.6 years and 42.9 kg m^{-2} treated in the private sector).

Primary operations: basic statistics on age, height, weight and BMI; financial years 2011-2013

		Count	Average	Median	IQR (lower-upper)	Range (min-max)
Age at surgery (years)	Male	4,081	46.7	47	40-54	12-80
	Female	12,835	44.5	45	37-52	15-99
Height (m)	Male	3,990	1.77	1.77	1.72-1.82	1.19-2.06
	Female	12,595	1.63	1.63	1.59-1.68	1.17-2.57
Weight (kg)	Male	4,023	156.9	154.2	137.0-173.0	84.5-298.3
	Female	12,667	128.9	127.0	112.6-142.8	64.0-261.0
BMI (kg m^{-2})	Male	3,982	50.1	49.2	44.4-55.0	29.7-103.8
	Female	12,586	48.4	47.7	42.7-53.2	17.7-118.0

Primary operations: Basic statistics on age and BMI by gender; financial years 2011-2013



Body mass index, operation and gender

The following table and chart present data with the body mass index of patients segmented into 10 kg m^{-2} groups from <40kg m^{-2} up to >69.9 kg m^{-2}.

The chart presents these data for the three most-commonly recorded operations in the registry (accounting for >95% of bariatric surgery in the United Kingdom). It shows that for each operation there were a greater proportion of female patients in the smaller BMI groups. This suggests that regardless of which procedure they undergo, women come to surgery at a lower BMI *i.e.,* sooner in the disease process than men.

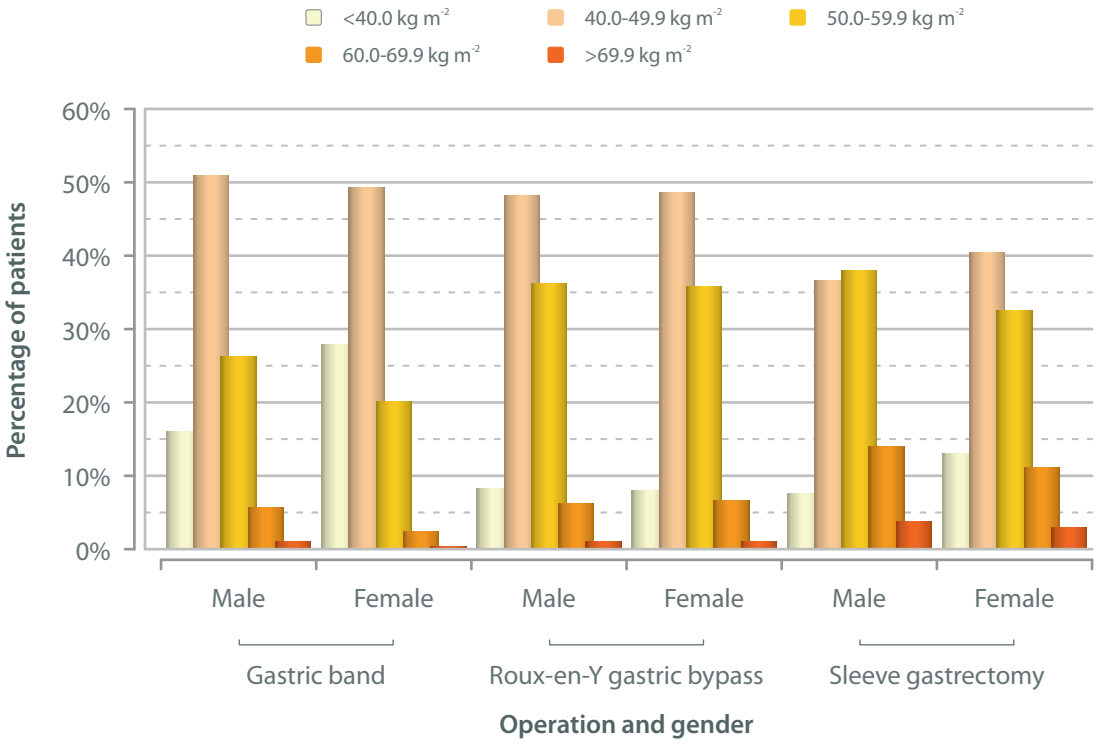
Irrespective of gender, patients having a Roux -en-Y gastric bypass operation tended to have a higher BMI than those undergoing gastric banding, and that, in turn, sleeve gastrectomy patients tended to have a still higher BMI. This implies that gastric banding is deemed more suitable for patients with lower BMIs, whereas for patients with a higher BMI a more definitive and perhaps more long-term procedure (RYGB or sleeve gastrectomy) is indicated.

Interestingly, for the patients who had a sleeve gastrectomy operation, the BMI distribution curves for both men and women have shifted to the left since the publication of the last NBSR report. This means that sleeve gastrectomy is now more often deemed suitable for patients with relatively low BMIs. Taken together with the data presented on page 68, this reflects a worldwide change in surgeons' and patients' attitudes towards this procedure: sleeve gastrectomy was originally developed as the first part of a two-operation strategy for patients with very high BMIs (>60 kg m^{-2}), with patients having a duodenal switch operation after their sleeve gastrectomy, once they had lost significant weight. With time it became clear that a significant number of these patients did not require the second operation to achieve their weight loss goals. Subsequently sleeve gastrectomy alone has become increasingly seen as a valid option for all bariatric surgery patients rather than being restricted to treatment for those with a very high BMI.

Primary operations: body mass index, age and gender; financial years 2011-2013

Gender and operation			Body mass index / kg m^{-2}					
			<40.0	40.0-49.9	50.0-59.9	60.0-69.9	>69.9	Unspecified
	Male	Gastric band	102	323	167	36	7	9
		Roux-en-Y gastric bypass	178	1,042	783	135	24	62
		Sleeve gastrectomy	77	375	389	143	39	26
		Duodenal switch & sleeve	0	1	1	0	0	0
		Gastric balloon	10	9	28	30	14	4
		Other	5	23	16	8	2	2
		Unspecified	1	6	7	0	1	2
	Female	Gastric band	818	1,444	591	69	10	57
		Roux-en-Y gastric bypass	536	3,281	2,417	452	68	155
		Sleeve gastrectomy	330	1,023	824	283	74	48
		Duodenal switch & sleeve	1	6	0	2	0	0
		Gastric balloon	71	19	30	52	18	9
		Other	33	54	27	6	1	4
		Unspecified	15	15	12	4	0	10

Primary operations: Initial BMI, operation and gender; financial years 2011-2013 (n=16,040)



Body mass index, operation and funding

The following tables and charts show that for each of the three most common operations and for all operations taken together, publicly funded patients had significantly higher BMIs than privately funded patients. In the first registry report this difference was significant only for female patients; in contrast, in the current sample of data, the difference was significant for both men and women.

The reasons for such differences are not clear; however, it would seem likely that higher BMI thresholds for access to surgery imposed upon some publicly funded patients will be at least partially responsible [1]. A new policy for patients operated in the NHS in England from April 2014 theoretically removed any ability for local commissioners to impose higher BMI and / or disease thresholds for surgery [2].

Primary operations: body mass index, operation and source of funding; financial years 2011-2013

			Body mass index / kg m^{-2}					
			<40.0	40.0-49.9	50.0-59.9	60.0-69.9	>69.9	Unspecified
Funding and operation	Publicly funded	Gastric band	157	989	589	88	16	40
		Roux-en-Y gastric bypass	407	3,596	2,940	533	87	187
		Sleeve gastrectomy	121	1,057	1,076	386	107	48
		Duodenal switch & sleeve	0	3	1	2	0	0
		Gastric balloon	4	19	55	82	32	6
		Other	20	62	43	13	3	5
		Unspecified	6	17	17	4	1	1
	Privately funded	Gastric band	758	751	153	13	0	11
		Roux-en-Y gastric bypass	303	721	257	54	5	10
		Sleeve gastrectomy	283	340	136	36	6	18
		Duodenal switch & sleeve	1	4	0	0	0	0
		Gastric balloon	77	9	3	0	0	7
		Other	17	13	0	1	0	1
		Unspecified	7	2	1	0	0	4

Primary operations: average BMI (count; ±95% CI) for selected operations according to the source of funding

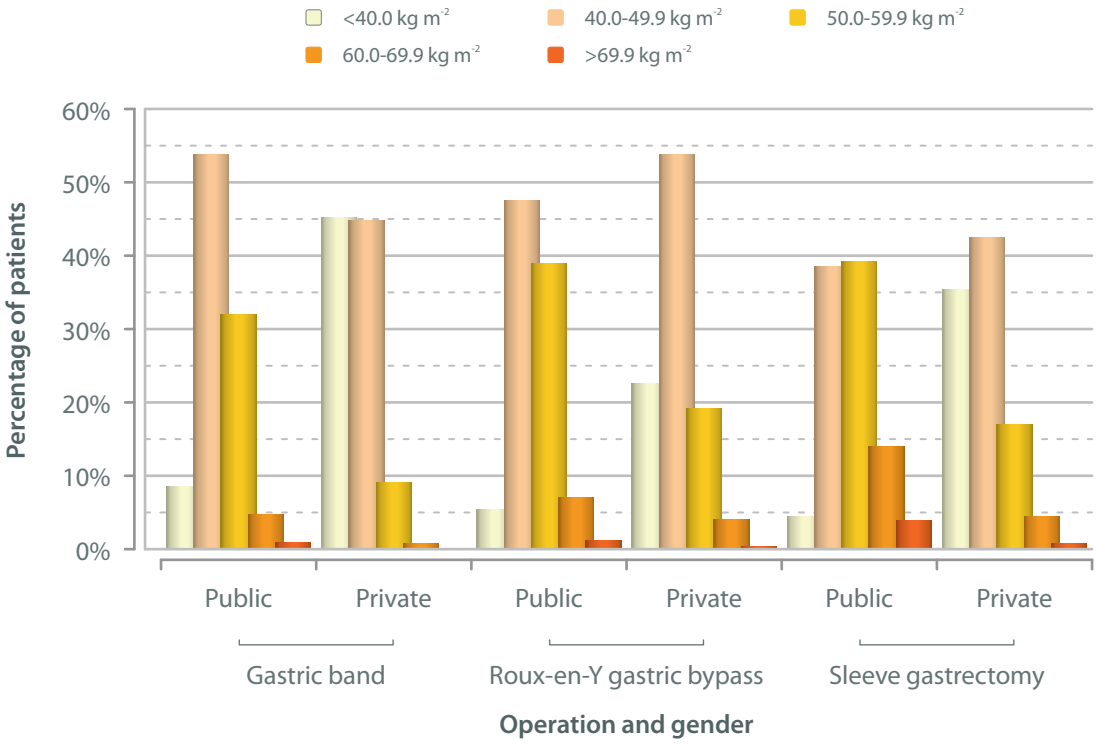
		Funding		
		Publicly funded	Privately funded	p [i]
Operation	Gastric band	48.4 (1,839; 0.32)	41.4 (1,675; 0.30)	<0.001
	Roux-en-Y gastric bypass	50.1 (7,563; 0.16)	45.7 (1,340; 0.38)	<0.001
	Sleeve gastrectomy	52.4 (2,747; 0.33)	44.3 (801; 0.57)	<0.001
	All	50.5 (12,533; 0.14)	43.3 (3,951; 0.23)	**<0.001**

i. independent samples t-test

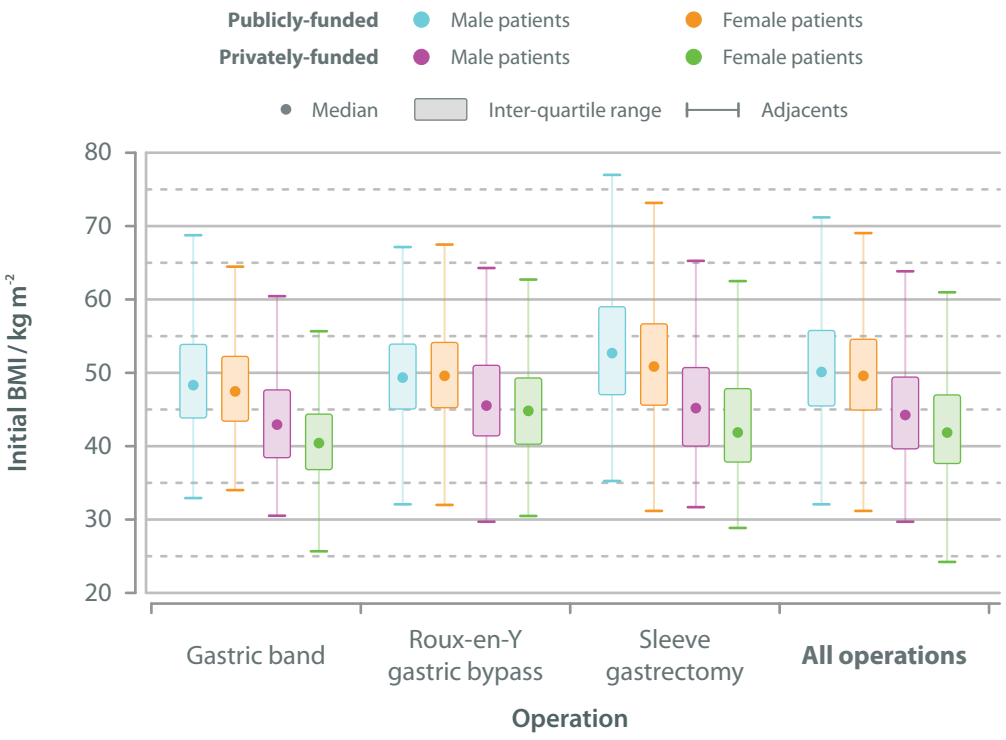
1. O'Neill P. Shedding the Pounds: Obesity Management, NICE Guidance and Bariatric Surgery in England. Washington, DC: OHE; 2010. http://www.ohe.org/publications/article/shedding-the-pounds-obesity-management-in-england-16.cfm.

2. NHS Commissioning Board. Clinical commissioning policy: complex and specialised obesity surgery. 2013. www.england.nhs.uk/wp-content/uploads/2013/04/a05-p-a.pdf

Primary operations: Initial BMI, operation and funding; financial years 2011-2013 (n=15,965)



Primary operations: Median BMI (with inter-quartile range & adjacents), funding and operation; financial years 2011-2013



Weight-loss prior to surgery

Weight loss prior to surgery is calculated by comparing the weight measured at first surgical consultation with that measured immediately before surgery (an optional data field). The data presented show that the majority of patients (64.9%) lost some weight prior to surgery. One-quarter (24.4%) of patients remained the same weight whilst a minority (10.8%) gained weight prior to surgery. Similar proportions of patients undergoing gastric bypass (68.2%) and sleeve gastrectomy (67.5%) procedures lost weight pre-operatively. A smaller proportion of gastric band patients (54.6%) lost weight prior to surgery.

Weight loss prior to surgery can be attributed to three factors: firstly, most bariatric surgery units in the United Kingdom, and worldwide, require patients to adhere to a low calorie *liver reducing* diet for between one to four weeks prior to surgery. This technique is used as it has been demonstrated to make operations technically less challenging to perform, and inevitably results in weight loss for most patients immediately prior to surgery. Secondly, a number of units require all patients to lose a defined target amount of weight using more conventional dietary and lifestyle alterations over a number of months prior to being listed for surgery. The proportion of units employing this approach is uncertain. Some units may require a selection of their patients who have higher BMIs or other high risks factors, to lose a target amount of weight (typically around 10 kg) before they are listed for surgery, the aim being to reduce the individual patient's operative risk.

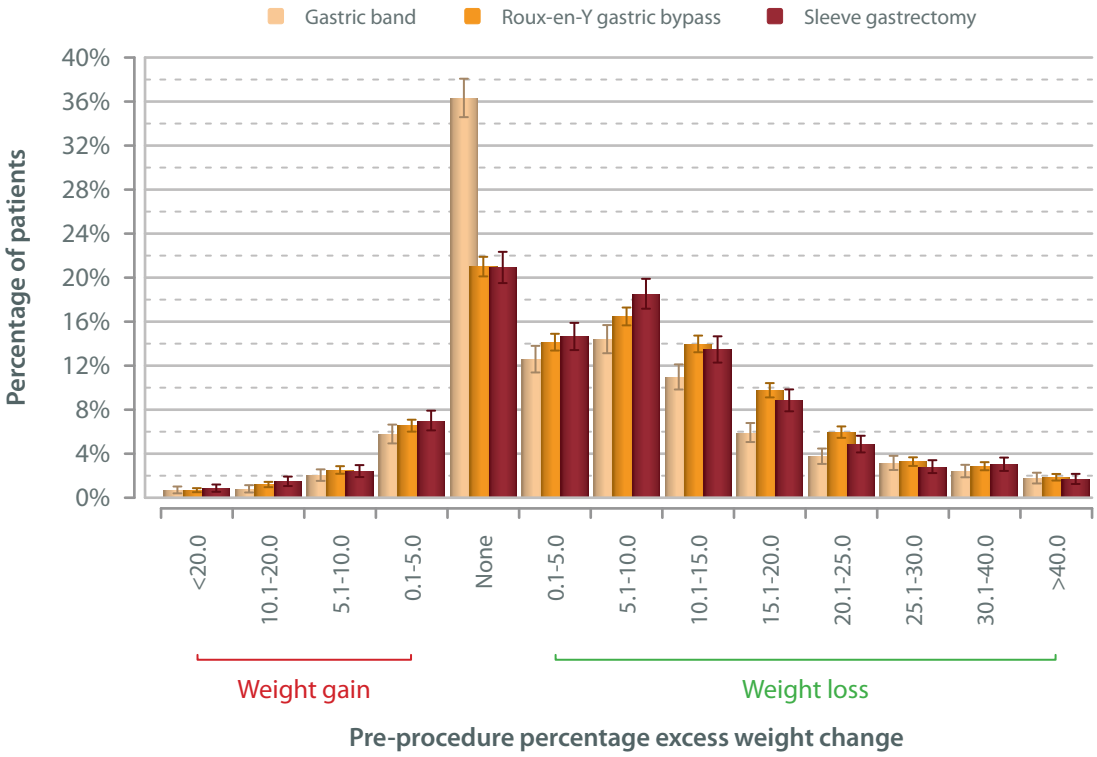
These three approaches are designed to increase the safety and success of subsequent bariatric surgery. The fact that most patients lost weight pre-operatively is a testament to the success of the strategies employed by bariatric surgery multi-disciplinary teams to help patients prepare for surgery.

The data presented in this report do not allow analysis of the success of these approaches in terms of short- and long-term outcomes for patients; more detailed analysis is required. In this general area of data collection, the only constraint on the current NBSR dataset is that the duration over which weight is lost pre-operatively is not recorded.

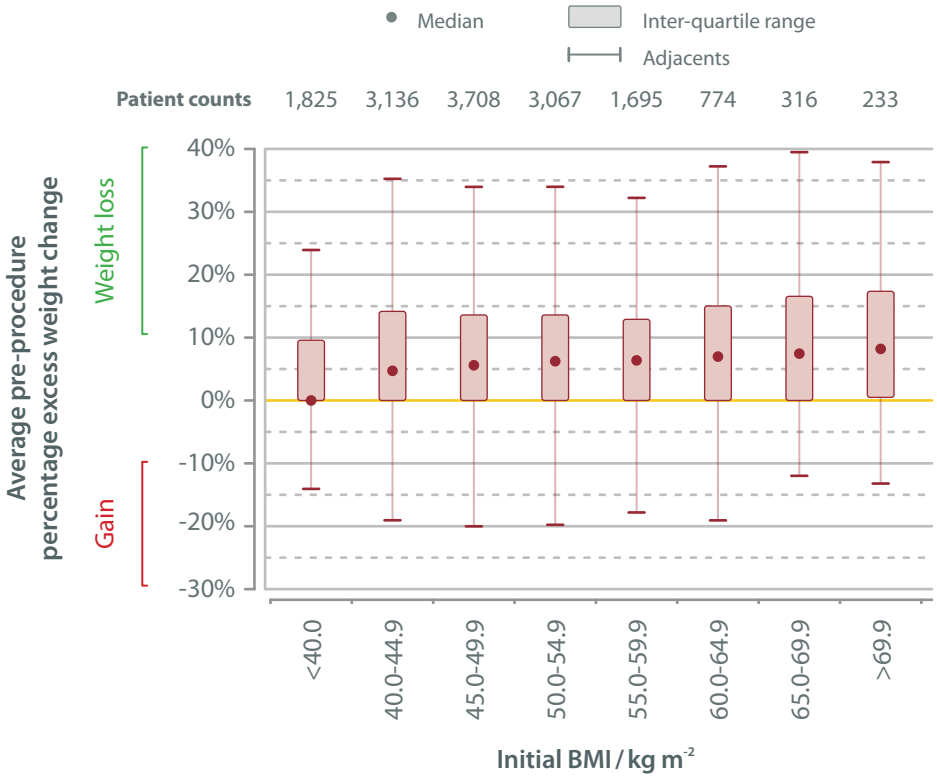
Primary operations: pre-procedure excess weight change; financial years 2011-2013

Excess weight change / %			Operation						
			Gastric band	Roux-en-Y gastric bypass	Sleeve gastrectomy	Gastric balloon	Other	Unspecified	**All**
	Weight gain	<19.9	19	54	26	1	2	0	**102**
		-19.9 to -10.0	22	96	46	8	4	0	**176**
		-9.9 to -5.0	59	204	76	8	2	0	**349**
		-4.9 to -0.1	170	533	224	30	7	0	**964**
	No change		1,077	1,714	672	74	56	0	**3,593**
	Weight loss	0.1 to 5.0	372	1,153	470	46	18	0	**2,059**
		5.1 to 10.0	426	1,344	595	30	34	0	**2,429**
		10.1 to 15.0	324	1,140	432	13	29	0	**1,938**
		15.1 to 20.0	174	796	283	8	11	0	**1,272**
		20.1 to 25.0	110	485	155	3	5	0	**758**
		25.1 to 30.0	92	266	89	4	4	0	**455**
		30.1 to 40.0	70	232	96	0	1	0	**399**
		>40.0	51	150	53	4	2	0	**260**
	Unspecified		667	966	414	65	17	73	**2,202**
	All		**3,633**	**9,133**	**3,631**	**294**	**192**	**73**	**16,956**
	Average loss		6.4%	8.4%	7.7%	3.6%	6.1%		
	95% CI		6.0-6.9%	8.1-8.7%	7.1-8.3%	2.2-5.1%	4.5-7.7%		

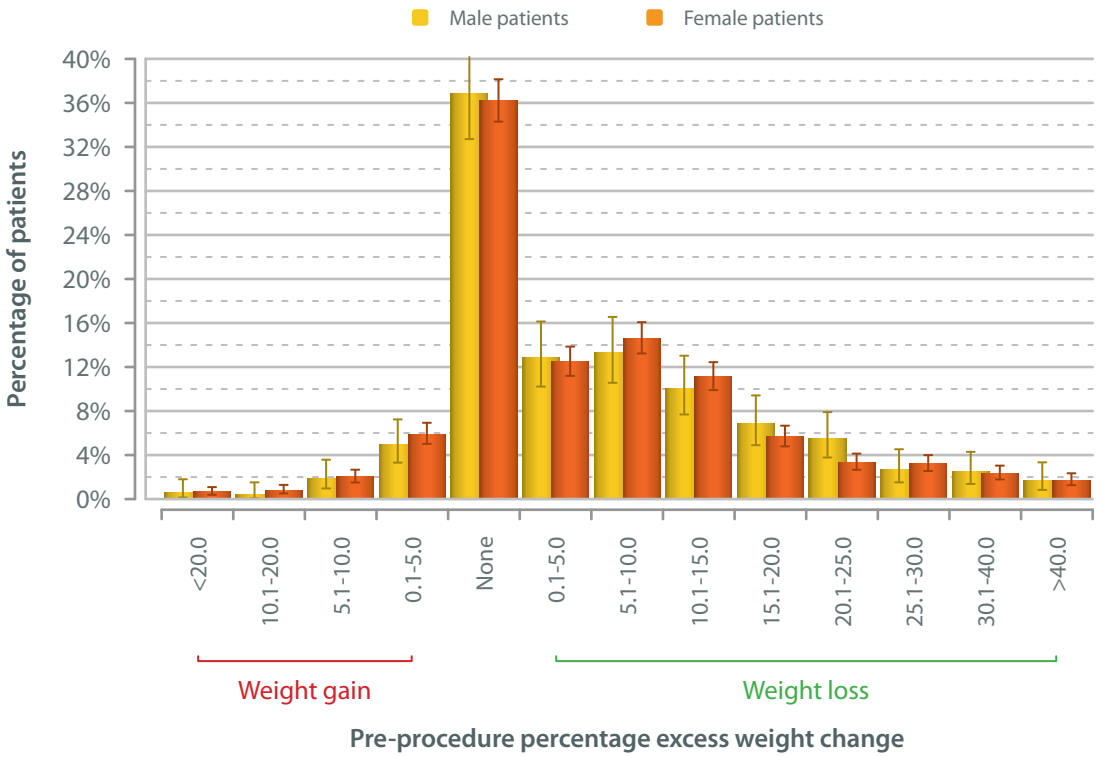
Primary operations: Excess weight change prior to surgery; financial years 2011-2013 (n=14,350)



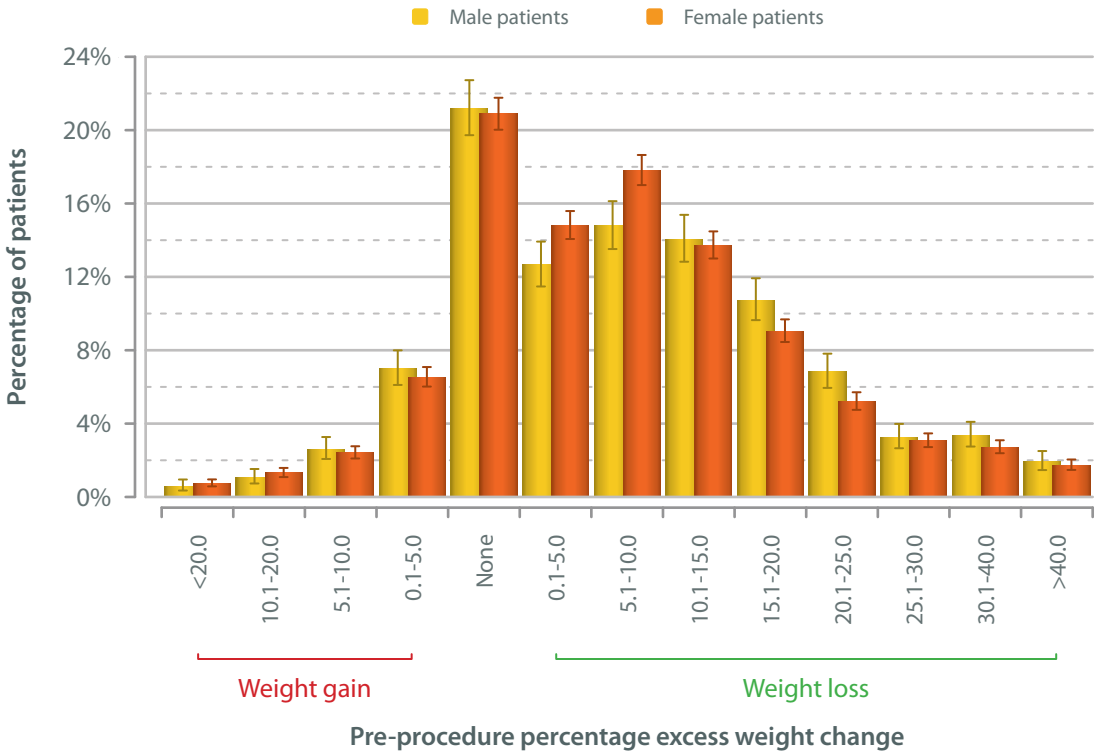
Primary operations: Excess weight change prior to surgery and initial BMI (n=14,755)



Primary gastric band procedures: Excess weight change prior to surgery; financial years 2011-2013 (n=2,966)



Primary Roux-en-Y gastric bypass and sleeve gastrectomy procedures: Excess weight change prior to surgery; financial years 2011-2013 (n=11,384)



The data below demonstrate that patients with higher initial BMIs were more likely to lose weight pre-operatively, and less likely to gain weight compared to lower BMI patients. This relationship was most clearly seen at the extremes of weight loss and gain (<5% gain or >20% weight loss). The reasons for this are unclear, but the previously described approaches of many units with regards to pre-operative weight loss (see page 88) seem likely to play a part. It may be interesting in future reports to look at the effect of weight loss on two key outcomes: first, the risk of developing complications after surgery, and, second, the weight loss achieved after surgery.

Primary operations: pre-procedure excess weight change and initial BMI; financial years 2011-2013

		Initial BMI / kg m^{-2}					
		<40.0	40.0-49.9	50.0-59.9	>59.9	Unspecified	**All**
Excess weight change	<5% gain	105	320	169	33	0	**627**
	0.1-5.0% gain	105	420	350	89	0	**964**
	No change	765	1,652	939	237	0	**3,593**
	0.1-5.0% loss	207	980	692	180	0	**2,059**
	5.1-10.0% loss	204	1,038	934	253	0	**2,429**
	10.1-15.0% loss	147	924	693	174	0	**1,938**
	15.1-20.0% loss	111	615	406	140	0	**1,272**
	20.1-25.0% loss	182	895	579	216	0	**1,872**
	Unspecified	354	777	530	156	385	**2,202**
	All	**2,180**	**7,621**	**5,292**	**1,478**	**385**	**16,956**

Primary operations: Excess weight change prior to surgery and initial BMI; financial years 2011-2013 (n=14,754)

Comorbidities

As noted in the introduction, comorbidity is a term generally used to describe pre-existing, concomitant disease. In the obese population, these diseases are usually directly a consequence of the obese state: the greater the body mass index the greater the prevalence of other medical problems [1]. These conditions can range from metabolic problems such as type 2 diabetes, high blood pressure and high lipid levels in the circulation (which together make up the so-called metabolic syndrome), to joint problems such as arthritis, backache, and limitations in functional status, measured by the inability to climb stairs without resting.

The sheer burden of obesity-related comorbid disease shown in this report is one of its main findings, and belies a popular notion that bariatric surgery is simply a kind of cosmetic surgery. By curing patients of their obese state, bariatric surgery aims to ameliorate or even cure these comorbidities, and so reduce the burden of these diseases upon both individuals and the wider healthcare community.

Nor is bariatric surgery an easy option. Unfortunately, bariatric surgery is the only treatment that has been shown to produce clinically significant and sustained weight loss for these patients, and concomitant comorbidity resolution; if dieting and exercise were the answer, then few would remain obese [2].

There are 4 main reasons why comorbidity data are collected in the NBSR:

- to provide information on overall morbidity rates in this surgical population, which will be useful for health planning.
- to enable clinicians to record health-related comorbidity to demonstrate compliance with international guidelines when operating on patients with a BMI in the range 35-40 kg m^{-2}.
- to risk-stratify outcomes using the Obesity Surgery Mortality Risk Score (OSMRS) [3].
- to provide data upon the rates of improvement of comorbidities post-operatively, which can be used as one way to assess the effectiveness of bariatric surgery.

It might seem surprising that there is no other mechanism within the NHS to collect data on the disease burden of this population of patients. In due course, we expect the NBSR to provide a unique and invaluable source of data that will provide a baseline against which to compare the observed improvement in comorbid disease after surgery. Included in this is a record of the patient's body mass index, which is used by many commissioners as a crude way of determining whether or not an individual patient qualifies for bariatric surgery. Thus, comorbidities are recorded principally for risk assessment and as part of a basic observational record, not for research. The principal elements of the metabolic syndrome and functional assessment are included, with emphasis on brevity and simplicity for rapid and effective data entry. For these reasons, we have not included blood tests, nor other tests such as sleep studies, which assess patients at risk of daytime sleepiness / sleep apnoea. We would have liked to include detailed quality-of-life scores, as these are central to the patient's appreciation of disease burden and treatment outcomes; however, collecting these data is resource- and time-intensive, and we concluded that it would be impractical. Similarly, while there is nearly an unlimited range of comorbidity data that could be collected, we have placed great emphasis on ease of data collection and entry into the registry. So, the fields of data collected and the diseases covered are many fewer than in some similar databases. For example, in the United States of America, the Bariatric Outcomes Longitudinal Database of the Centers of Excellence initiative (BOLD) has 33 comorbidity fields. The structure of the NBSR represents a fine balancing act between collecting too much data (and risking poor engagement with data entry and more incomplete records) and collecting too little data to generate meaningful analysis. The increase with time in the proportion of entries with complete comorbidity data to an impressive rate of over 80% would suggest that a good balance has been achieved.

We have limited questions relating to cardiac disease to the presence or absence of known cardiovascular disease including myocardial infarction, angina, peripheral vascular disease and cerebrovascular disease. The data in this report show a surprisingly high prevalence of atherosclerosis, again indicating the high rates of comorbid disease in the bariatric surgery population. It is worth noting that:

- most patients will be ASA grade II or ASA grade III. The American Society of Anesthesia (ASA) grade is a is a physical status classification system, in use for over 70 years, that has been shown to be a gross predictor of peri-operative outcome (see page 116).
- after much deliberation only observational data on diabetes treatment were included since there is no medical consensus on the definition or treatment of diabetes nor of remission. This approach also reflects, again, the resource implications needed for more detailed data capture and audit *versus* research.

- some of the comorbidities, such as functional status, are categorical and in this report we analyse quantifiable trends over time.
- routine statin therapy is not included as a risk factor. The dyslipidaemia field is designed to accommodate data on hypercholesterolaemia.
- arthritis is included as it affects functional status.
- the registry software will automatically generate an Obesity Surgery Mortality Risk Score [3] for patients undergoing Roux-en-Y gastric bypass. A point is added for each of the following risk factors that are present, up to a maximum of 5 points: age at surgery >45 years, BMI >50 kg m^{-2}, male gender, recorded hypertension, one or more known risk factors for deep vein thrombosis (DVT) / pulmonary embolism (PE). Using the resultant score, complication & mortality rates can be risk-adjusted. It has been shown in the international literature that patients can be risk-stratified according to how many of these risk factors are present, and we present data from the NBSR on the risk groups [2].
- functional status is measured by the ability to climb stairs without resting. The equivalent BOLD data-field was the ability to walk 200 feet (61 m). The latter was chosen to represent the apparent average length of an aisle in a shopping mall in Northern America. We chose to use the ability to climb flights of stairs, as patients in the United Kingdom & Ireland more readily relate to this measure of function.

The paper *Slimmed down Surgery* rightly points out the health economic argument that is strongly in favour of bariatric surgery being more widely available on the NHS [4]. However, despite surgery itself being remarkably cost effective (incremental cost *per* QALY of £2,000-4,000) there is widespread rationing within the NHS, with, historically, some primary care funding bodies (PCTs) failing to follow NICE guidance at all [4,5]. The British Obesity and Metabolic Surgery Society, jointly with 5 Royal Colleges and 4 other professional bodies, has issued guidance on the processes that patients should go through before being referred for surgery and have emphasised that they should not be forced to lose weight as a threshold for a surgery referral [6]. The 18,283 operations recorded in the NBSR for the period 2011-2013 comprise a marked increase over the number of operations performed in 2009-2011, but this still represents only a small fraction (0.85%) of the estimated 2.15 million adults in England who would be eligible to opt for surgery if all commissioning groups (now termed Clinical Commissioning Groups) were to adopt published guidance [7].

What can be done to encourage health commissioners to increase spending for bariatric surgery? The Office of Health Economics report [8] used a novel approach in which they estimated the expected gains arising from unemployed patients going back to work after surgery. Their model found that if 25% of eligible patients received surgery the boost to GDP in the United Kingdom would total £1.3 billion due to increases in paid employment, with an additional £151 million being returned to the economy through reduced benefits costs. Furthermore, recent data suggest that laparoscopic bariatric surgery for diabetes can pay for itself within 26 months of the operation simply by reducing medication costs alone [9]. If the additional economic factors are considered as well, surgery pays for itself within one year [7]. Fourteen months after surgery patients had increased their paid hours worked by 57% and reduced their state benefit claims by 75% [10]. At least 3 other EU countries have shown increases in paid work after surgery [11,12,13]. Obese people also have higher rates of unemployment and consume an ever-expanding proportion of the healthcare budget [14,15]. It is hoped that these and later cost-benefit analyses will convince commissioners of the benefits of bariatric surgery.

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Missing data

Missing data is inevitable when collecting large amounts of comprehensive, clinical information on a large number of patients. However, the amount of missing data can be minimised by a combination of careful registry design and participants who are fully engaged in the data-collection process. The volume of missing data can be a reflection of one or more of a number of factors:

- how readily available / accessible the information is to whoever enters the data.
- how important the clinician believes the data to be.
- the clarity of the data definitions.
- how easy it is to assess the patient's comorbidity.

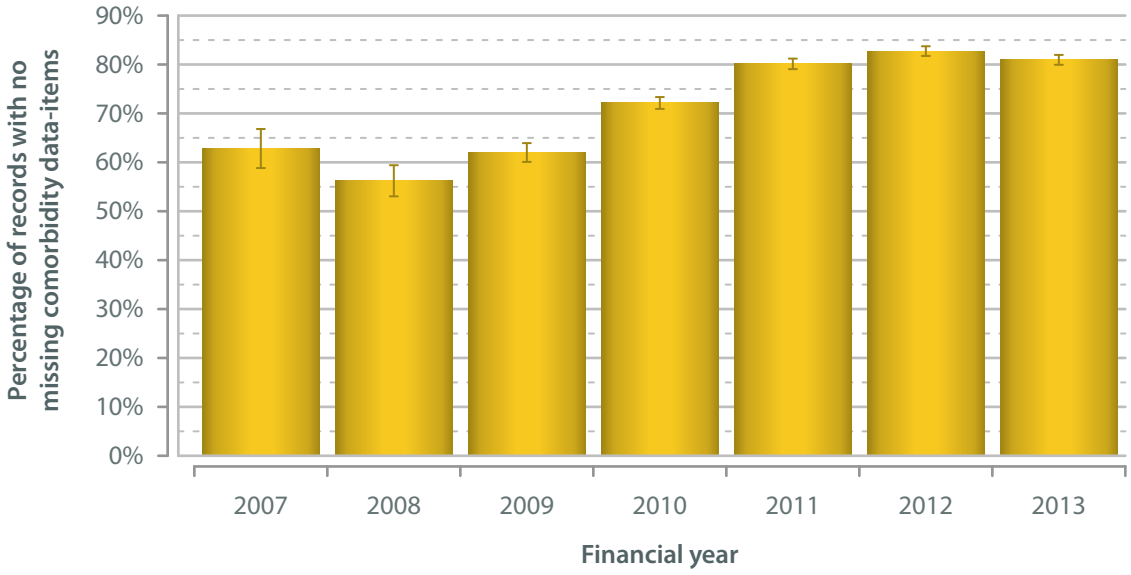
Included in the following analyses are an assessment of the data quality for the pre-operative comorbidity questions concerning: type 2 diabetes, hypertension, dyslipidaemia, atherosclerosis (cardiovascular), sleep apnoea, asthma, functional status, back or leg pain from arthritis, GORD, liver disease, depression and polycystic ovary syndrome. Of course, questions regarding polycystic ovary syndrome are relevant only to female patients: therefore the maximum number of comorbidity data items for males is 11, and 12 for females.

The table below shows that the degree of completeness of the comorbidity data entered into the NBSR has increased with time since the inception of the Registry. In the database entries from the last three full financial years, over 80% had a complete set of comorbidity data recorded, and just over 10% had only one field missing. This is a remarkable and impressive feat given the large number of patients and database entries involved. These figures stand as testament to the widespread acceptance of the NBSR as a valid and useful dataset, and to the commitment of the many contributors to provide high-quality data.

Primary operations: number of missing comorbidity data-items; financial years 2011-2013

		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Number of missing comorbidity data items	0	3,316	81.1%	10,471	81.4%
	1	425	10.4%	1,343	10.4%
	2	49	1.2%	217	1.7%
	3	12	0.3%	43	0.3%
	4	24	0.6%	14	0.1%
	5	7	0.2%	113	0.9%
	6	4	0.1%	21	0.2%
	7	4	0.1%	5	0.0%
	8	2	0.0%	11	0.1%
	9	3	0.1%	6	0.0%
	10	1	0.0%	5	0.0%
	11	240	5.9%	7	0.1%
	12	NA		613	4.8%
	All	**4,087**		**12,869**	

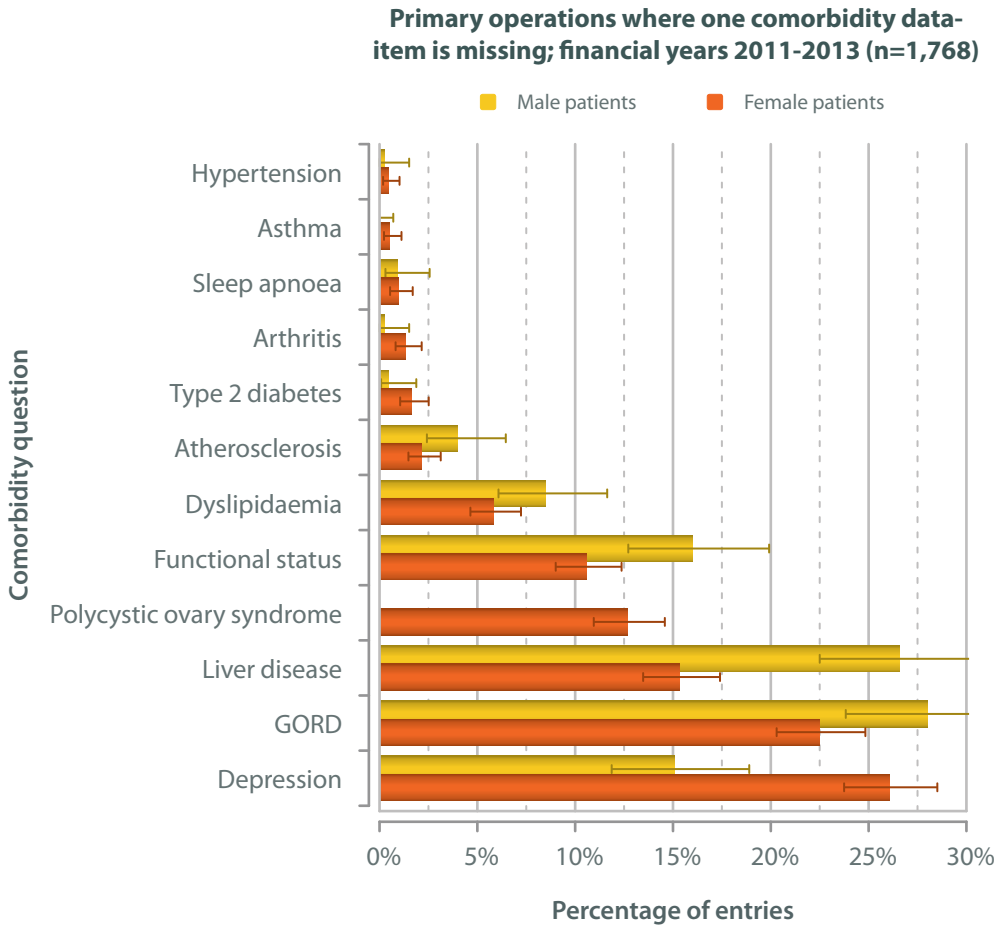
Primary operations:
Changes in comorbidity data-completeness over time (n=26,353)



The following graph shows the frequency with which data on each comorbidity was missing for patient-entries that had only one incomplete comorbidity field.

It is interesting to note that the four most frequently incomplete data fields (polycystic ovary syndrome, liver disease, GORD and depression) are all variables that have little relevance to the assessment of the patients' fitness for anaesthesia and bariatric surgery. Other more completely recorded variables such as hypertension and atherosclerosis *etc.* are much more useful in assessing fitness. This raises the possibility that patients are not being asked about some comorbid conditions as frequently or that these data are simply not being recorded because they are seen as being less important in assessing suitability for surgery.

In the previous NBSR report, functional status was the most frequently missing field, contrasting with the findings of this report which demonstrate a marked improvement in the capture of this *datum*. This may be a reflection of clinicians' increasing understanding of the definitions and relevance of these data, and perhaps also a recognition that a measure of functional status before and after surgery is an important outcome in bariatric surgery.



Number of comorbid conditions

This analysis demonstrates that patients undergoing bariatric surgery are often very unwell, with 64% of patients presenting with three or more serious medical comorbidities.

Over time, the average number of comorbidities recorded *per* patient in the NBSR has increased. This is the case when patients are grouped either by gender or BMI. Whilst the reasons for this are not entirely clear, possible explanations could include: more complete recording of comorbidities as experience with entering data into the NBSR develops, surgeons operating on higher-risk patients as their experience and confidence increases, patients presenting for surgery at a later stage of the disease process due to increasingly restrictive commissioning criteria.

On average, men presented for bariatric surgery with significantly more comorbid conditions ($p<0.001$; one-way ANOVA). This suggests that male patients presented at a later stage in the disease process. The fact that men were older when they presented for surgery has previously been commented upon in this report (pages 72 and 73) and might, in theory, explain the phenomena of increased comorbidity. However, the graphs on page 100-101 seem to refute this hypothesis, as when the data are grouped by both age and gender it becomes clear that for men and women the number of comorbid conditions increased with age, with this effect being no more marked for male patients; in each of the 5 age groups plotted, on average male patients have more comorbidities, significantly more in all but the <30 year-old age group (see overleaf; one-way ANOVA; at age <30 years, $p=0.551$; at age 30-39 years, $p=0.002$; all other age groups plotted, $p<0.001$).

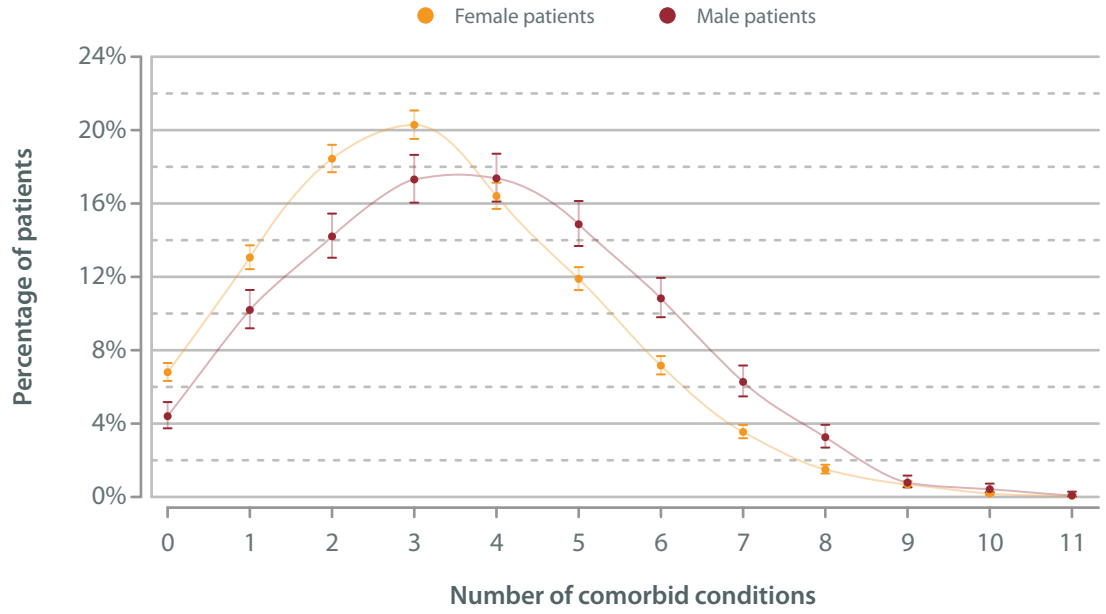
An alternative to the age hypothesis is that the threshold for consideration / acceptance of bariatric surgery may be set higher for male patients; such an elevated threshold could be imposed by either patients or healthcare professionals. We are not aware, however, of any evidence to support this and so this remains conjecture.

However, it is very striking that there is such inequality of access to bariatric surgery. Far more women have surgery than men, but men are much sicker on average. This suggests that fitter patients are gaining access to this valuable resource in preference to those with more significant comorbid disease.

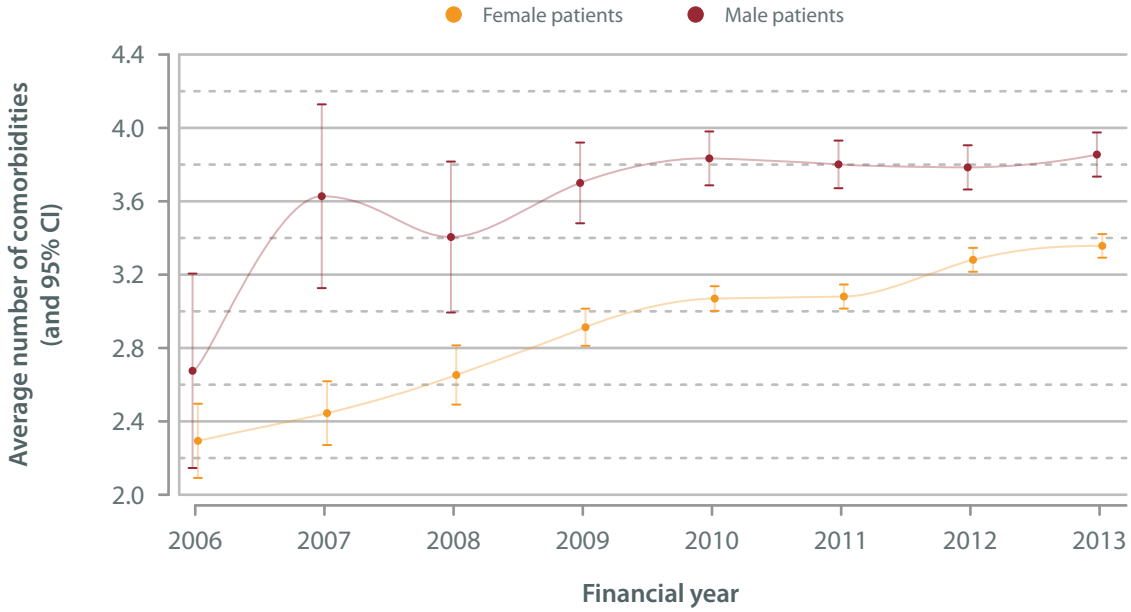
Primary operations where all comorbidity data-items are complete: number of comorbid conditions; financial years 2011-2013

		Gender			
		Male		Female	
Number of comorbid conditions	0	146	4.4%	712	6.8%
	1	338	10.2%	1,367	13.1%
	2	471	14.2%	1,931	18.4%
	3	574	17.3%	2,124	20.3%
	4	576	17.4%	1,718	16.4%
	5	493	14.9%	1,245	11.9%
	6	359	10.8%	750	7.2%
	7	208	6.3%	371	3.5%
	8	108	3.3%	157	1.5%
	9	26	0.8%	71	0.7%
	10	14	0.4%	19	0.2%
	11	3	0.1%	6	0.1%
	All	3,316		10,471	

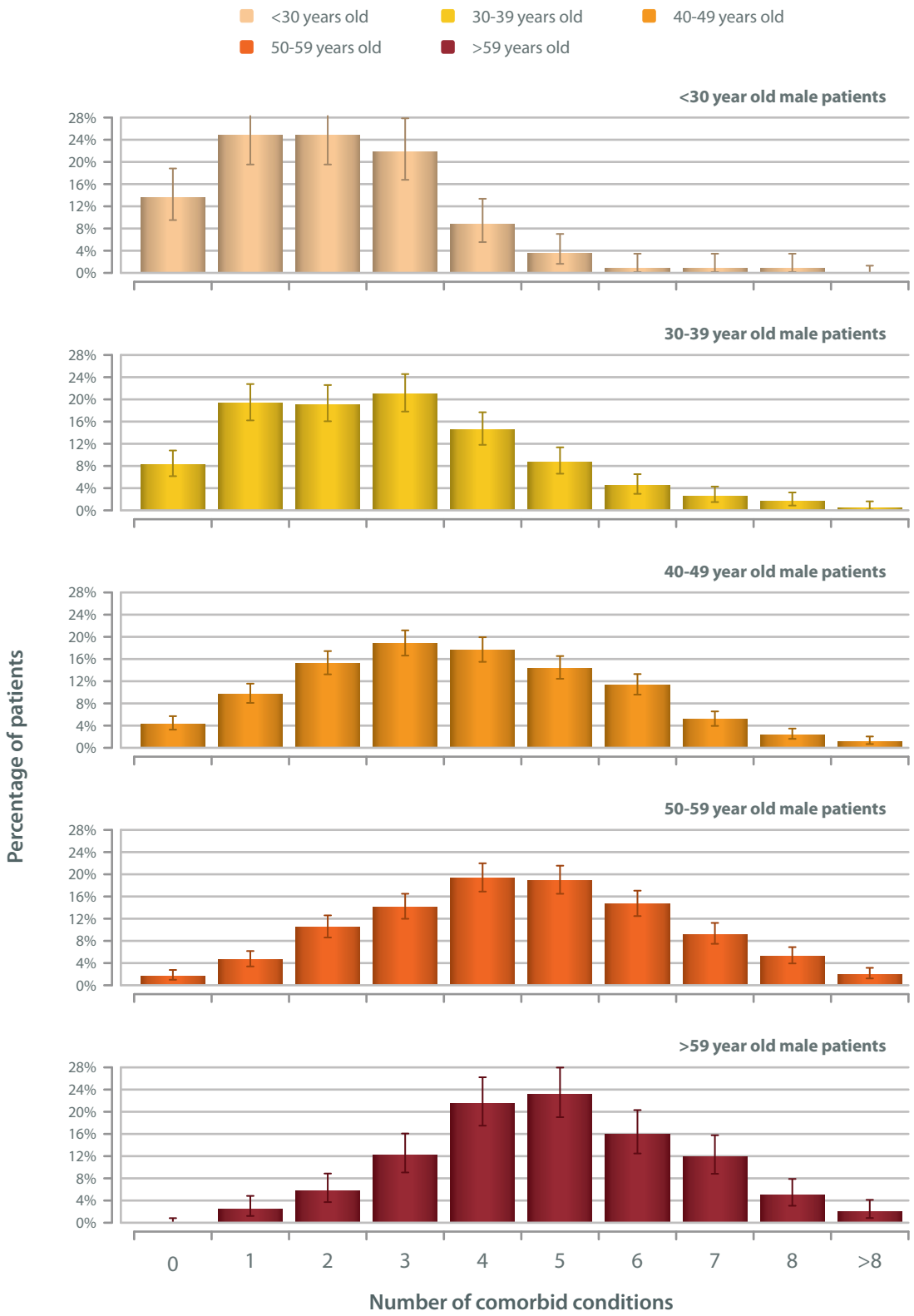
**Primary operations with complete comorbidity data:
Number of comorbidities and gender; financial years 2011-2013 (n=13,787)**



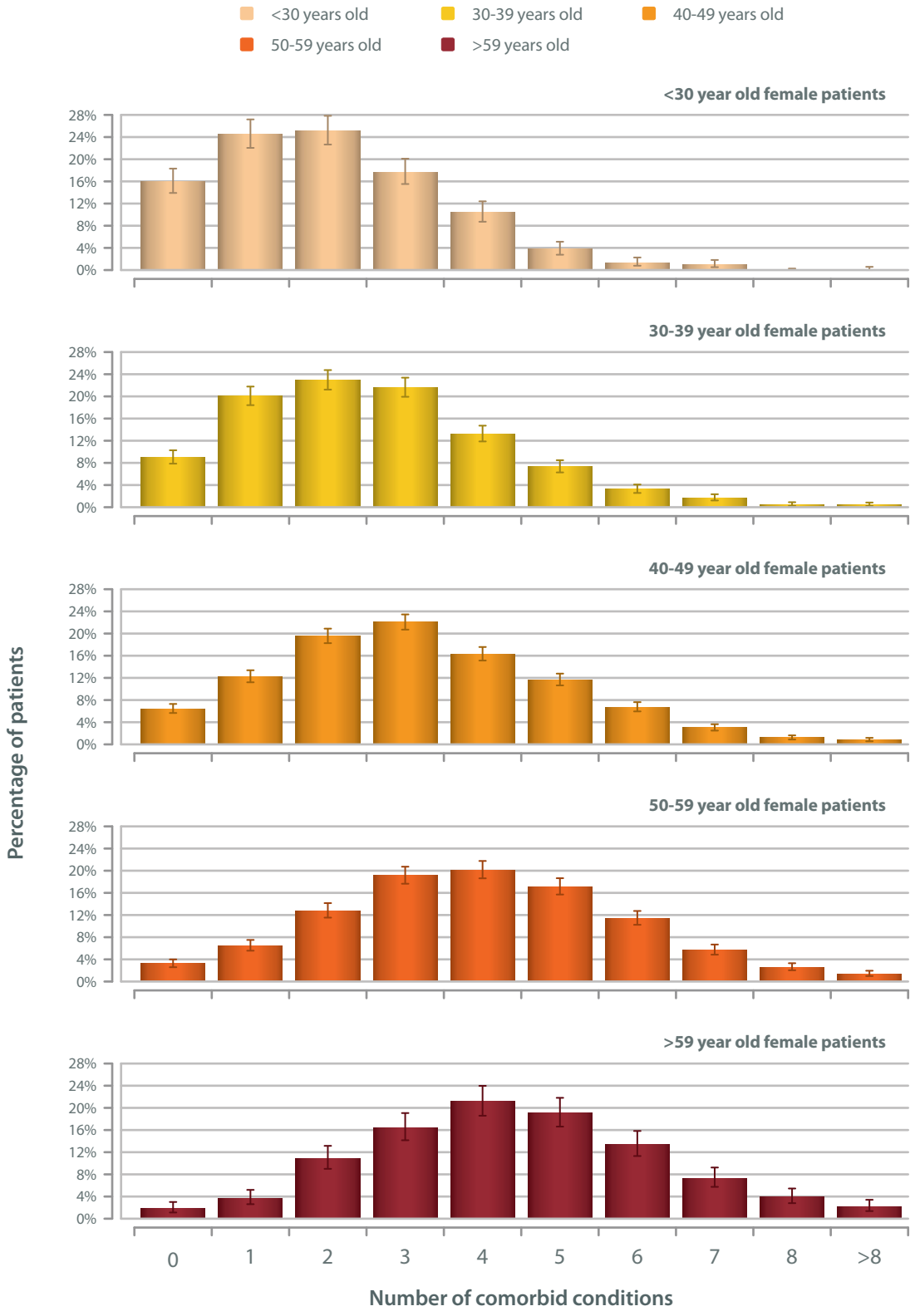
**Primary operations with complete comorbidity data:
Changes in the average number of comorbidities over time (n=20,356)**



Primary operations for male patients with complete comorbidity data: Number of comorbid conditions and age; financial years 2011-2013 (n=3,311)



Primary operations for female patients with complete comorbidity data: Number of comorbid conditions and age; financial years 2011-2013 (n=10,448)



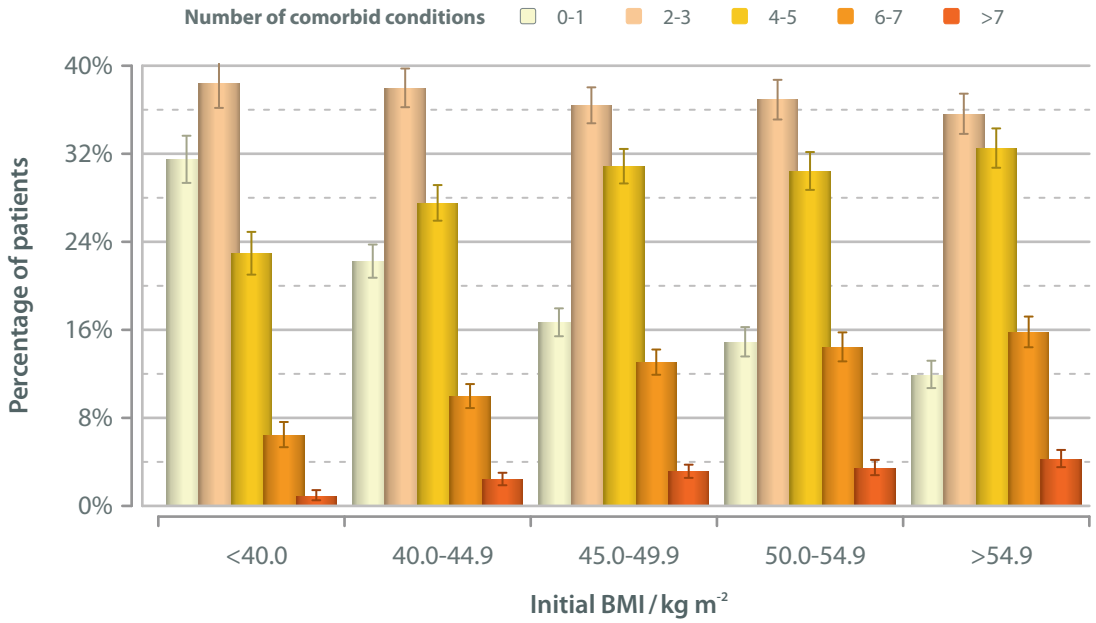
Comorbidity and BMI

It is not surprising to see that increasing BMI was associated with a significant increase in the average number of recorded comorbidities (one-way ANOVA; $p<0.001$). This has been previously reported for patients elsewhere in the world [1]. The data confirm that as the degree of obesity increased its debilitating and life-limiting consequences similarly continued to increase.

Primary operations where all comorbidity data-items are complete: number of comorbid conditions and initial BMI; financial years 2011-2013

		Number of comorbid conditions					
		0-1	2-3	4-5	6-7	>7	**All**
Initial BMI / kg m^{-2}	<40.0	581	709	423	118	16	**1,847**
	40.0-44.9	662	1,132	820	296	71	**2,981**
	45.0-49.9	565	1,235	1,047	442	105	**3,394**
	50.0-54.9	417	1,035	853	404	96	**2,805**
	>54.9	320	958	874	424	114	**2,690**
	Unspecified	18	31	15	4	2	**70**
	All	**2,563**	**5,100**	**4,032**	**1,688**	**404**	**13,787**

Primary operations with complete comorbidity data:
Number of comorbidities and BMI; financial years 2011-2013 (n=13,717)



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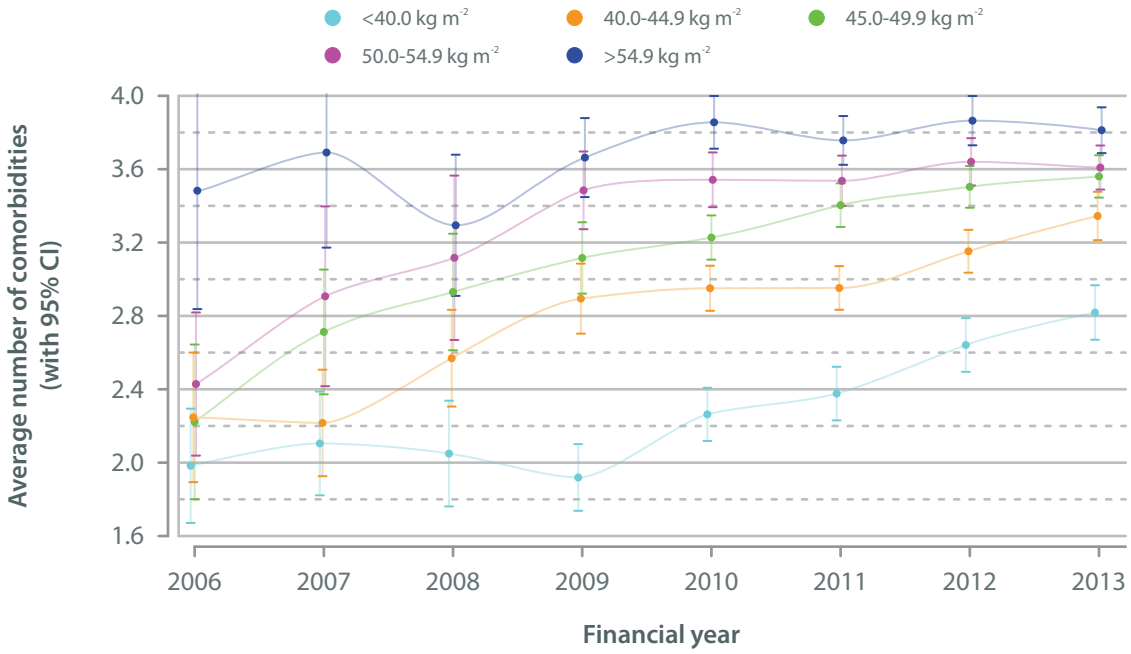
Here is evidence that there is a genuine and sustained increase in the numbers of comorbidities *per* patient, year on year over the last 5-8 years. This increase in the burden of comorbid disease is present across all the BMI groups, which means this effect cannot be simply explained away by the assertion that surgeons are selectively treating more and more patients in the super-obese category.

On average, patients presenting for bariatric surgery are becoming sicker.

Primary operations with complete comorbidity data: The number of comorbid conditions over time and initial BMI; financial years 2011-2013 (n=20,177)



The prevalence of comorbid conditions at presentation

The following table and graph describe the rates of the various comorbidities recorded in the NBSR according to gender.

Poor functional status (defined as an inability to climb three flights of stairs without resting) and arthritis causing back or leg pain were very common, affecting over 70% of both men and women. This is a very important finding to note, as it illustrates the futility of misguided and uninformed suggestions that severe obesity could be effectively addressed by simply increasing the amount of exercise performed by patients.

Most comorbidities (poor functional status, hypertension, type 2 diabetes, dyslipidaemia, sleep apnoea, liver disease and arteriosclerosis) were more common in men than women, whilst the converse is true for GORD, depression and asthma. These data suggest that men may benefit more from bariatric surgery than women. However, despite such high rates of life-limiting problems resulting from their obesity, far fewer men presented for surgery than women (men constituting only 24.1% of all primary surgery; see page 72). The recent increase in the proportion of men accepting surgery, previously described on page 73, offers some hope that awareness of the potential benefits that bariatric surgery can offer to men is becoming increasingly recognized by both male patients and / or healthcare professionals.

Primary operations: details of comorbid conditions at presentation; financial years 2011-2013

		Gender								
		Male				Female				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	significance[i]
Comorbidities[ii]	Arthritis	1,687	2,107	293	55.5%	5,436	6,596	837	54.8%	0.452
	Asthma	3,265	568	254	14.8%	9,624	2,585	660	21.2%	<0.001
	Atherosclerosis	3,402	407	278	10.7%	11,672	496	701	4.1%	<0.001
	Depression	3,081	646	360	17.3%	8,343	3,284	1,242	28.2%	<0.001
	Dyslipidaemia	2,497	1,297	293	34.2%	9,628	2,502	739	20.6%	<0.001
	GORD[iv]	2,483	1,178	426	32.2%	7,358	4,332	1,179	37.1%	<0.001
	Hypertension	1,754	2,084	249	54.3%	7,926	4,294	649	35.1%	<0.001
	Liver disease	3,410	259	418	7.1%	11,272	561	1,036	4.7%	<0.001
	PCOS[v]					10,736	1,094	1,039	9.2%	NA
	Poor functional status[iii]	1,002	2,732	353	73.2%	3,415	8,560	894	71.5%	0.048
	Sleep apnoea	2,303	1,531	253	39.9%	10,273	1,932	664	15.8%	<0.001
	Type 2 diabetes	2,123	1,706	258	44.6%	9,039	3,157	673	25.9%	<0.001

i. χ^2 probability; comparing the incidence amongst the male patient-population with the rate observed in the female patient-population.

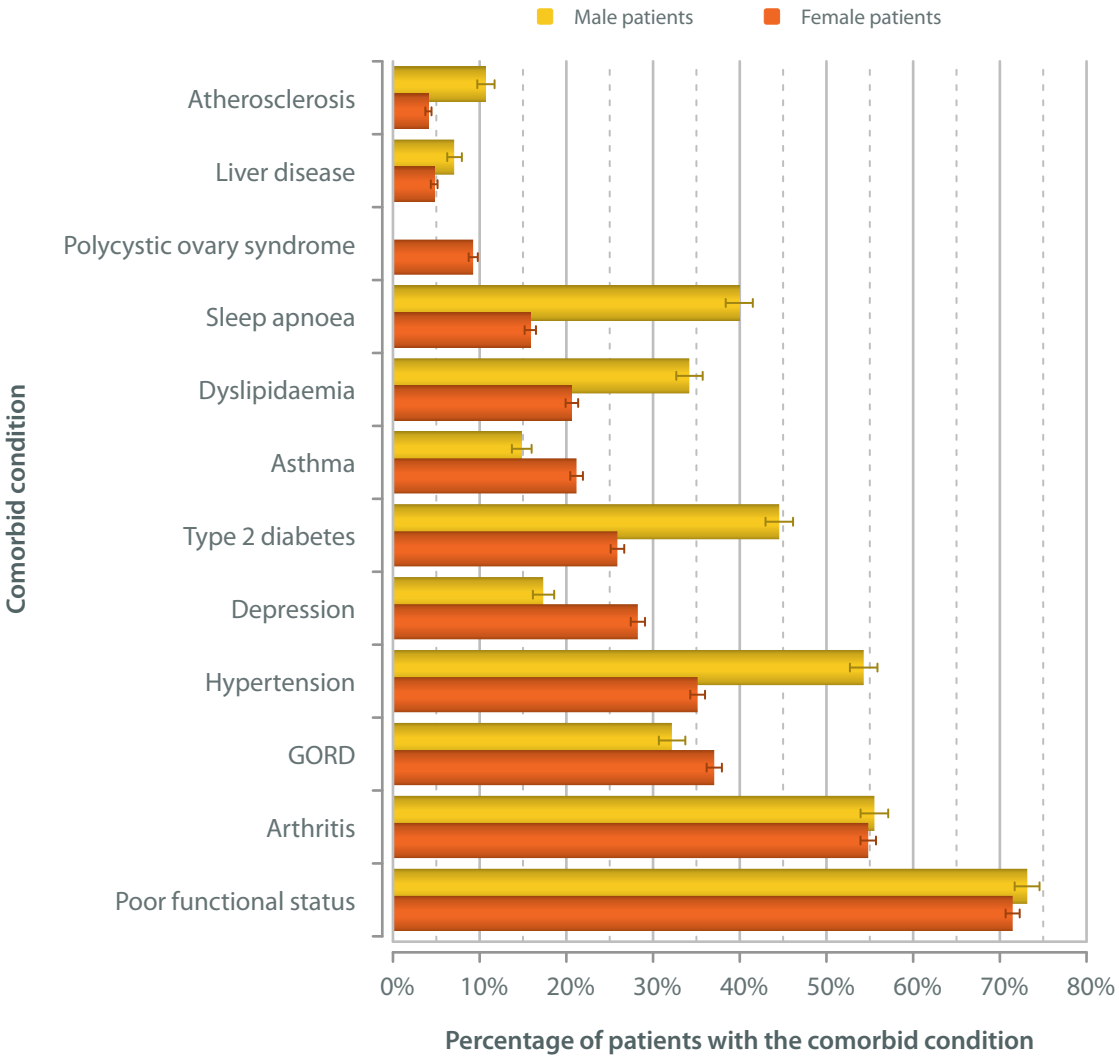
ii. One of the comorbidity questions is only collected for the female patients: *polycystic ovary syndrome*.

iii. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

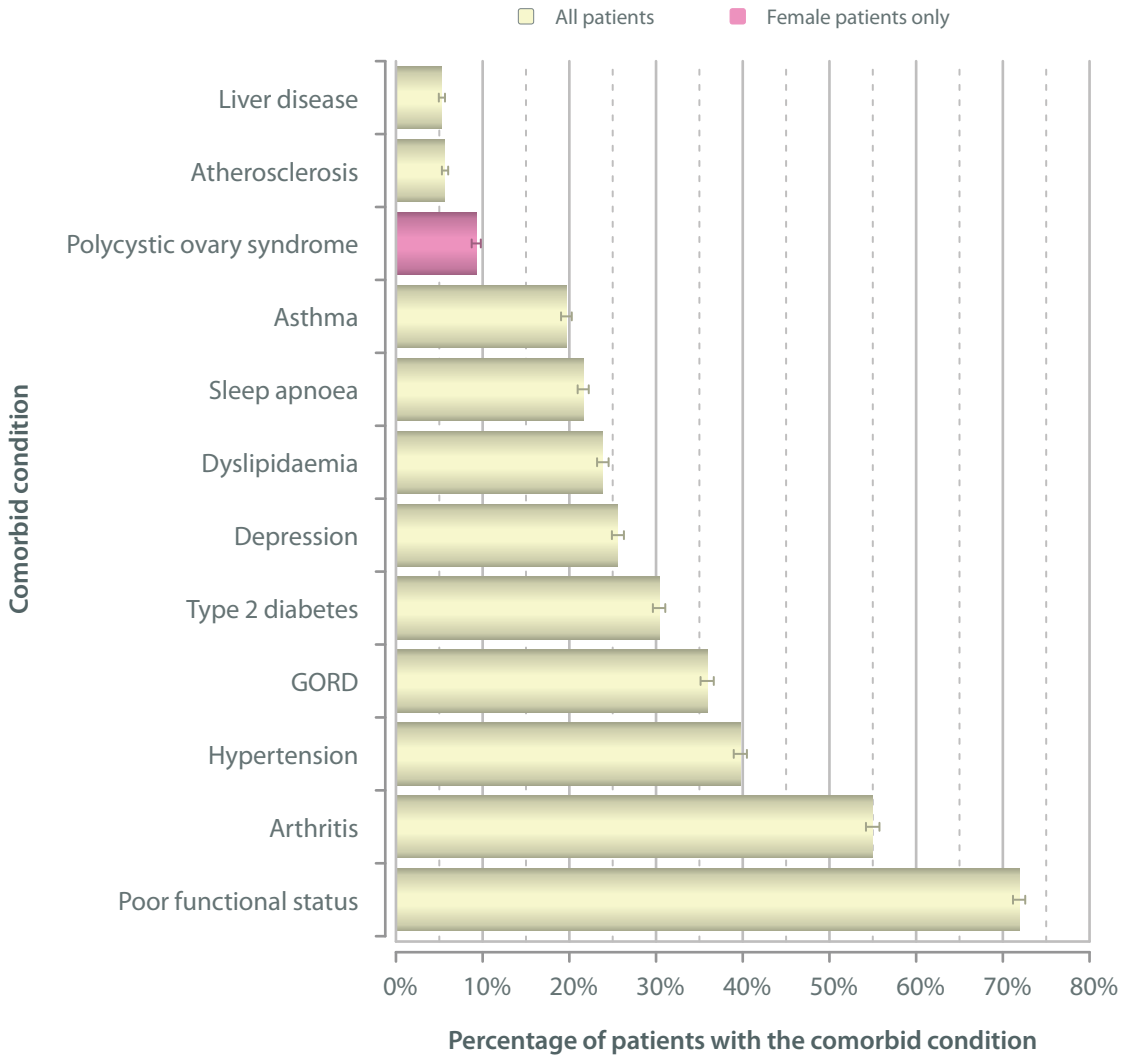
iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

v. Polycystic ovary syndrome.

Primary operations: Gender and the rates of the various comorbid conditions recorded in the database; financial years 2011-2013



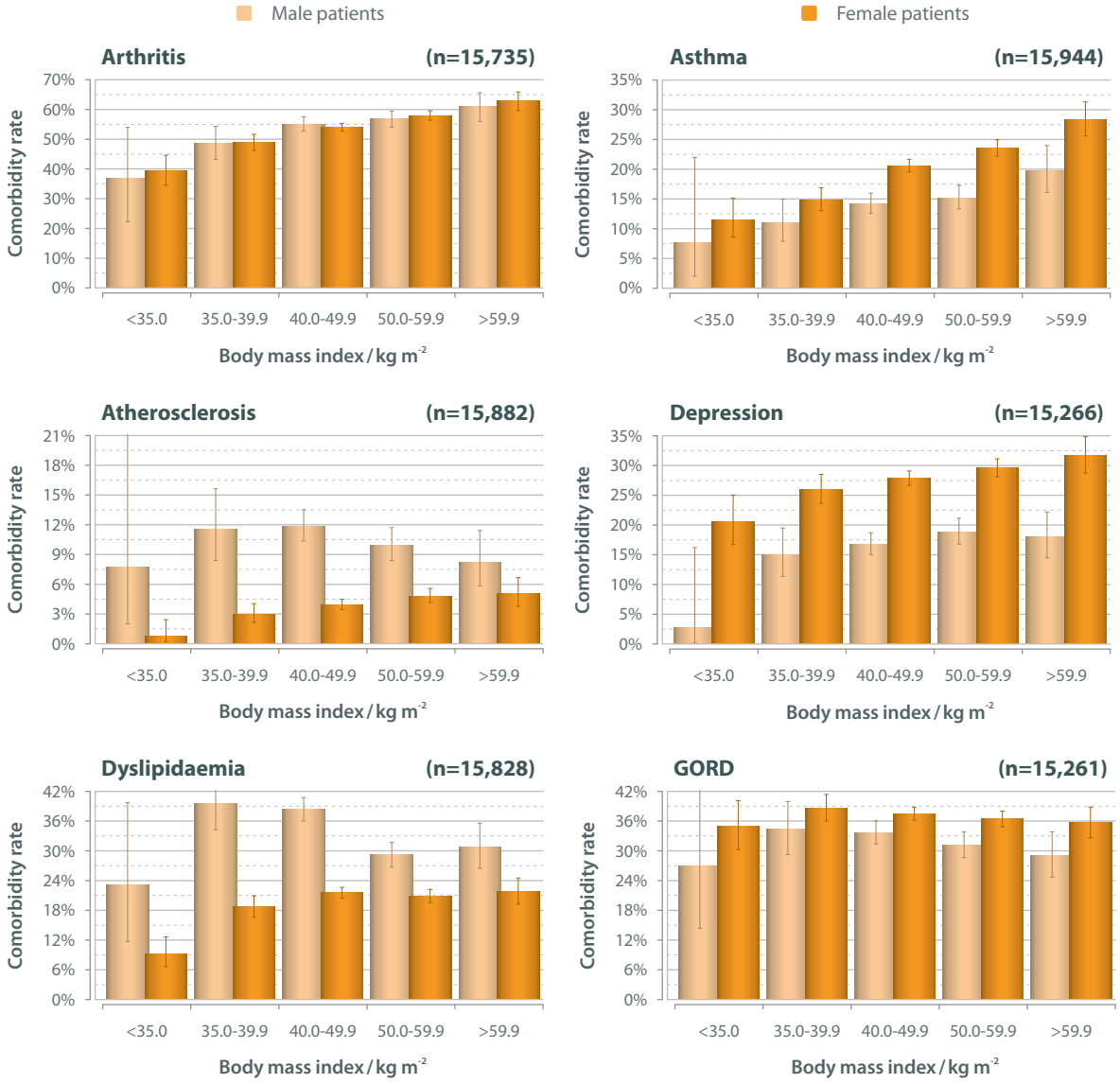
Primary operations: The rates of the various comorbid conditions recorded in the database; financial years 2011-2013



Rates of comorbid conditions, gender and body mass index

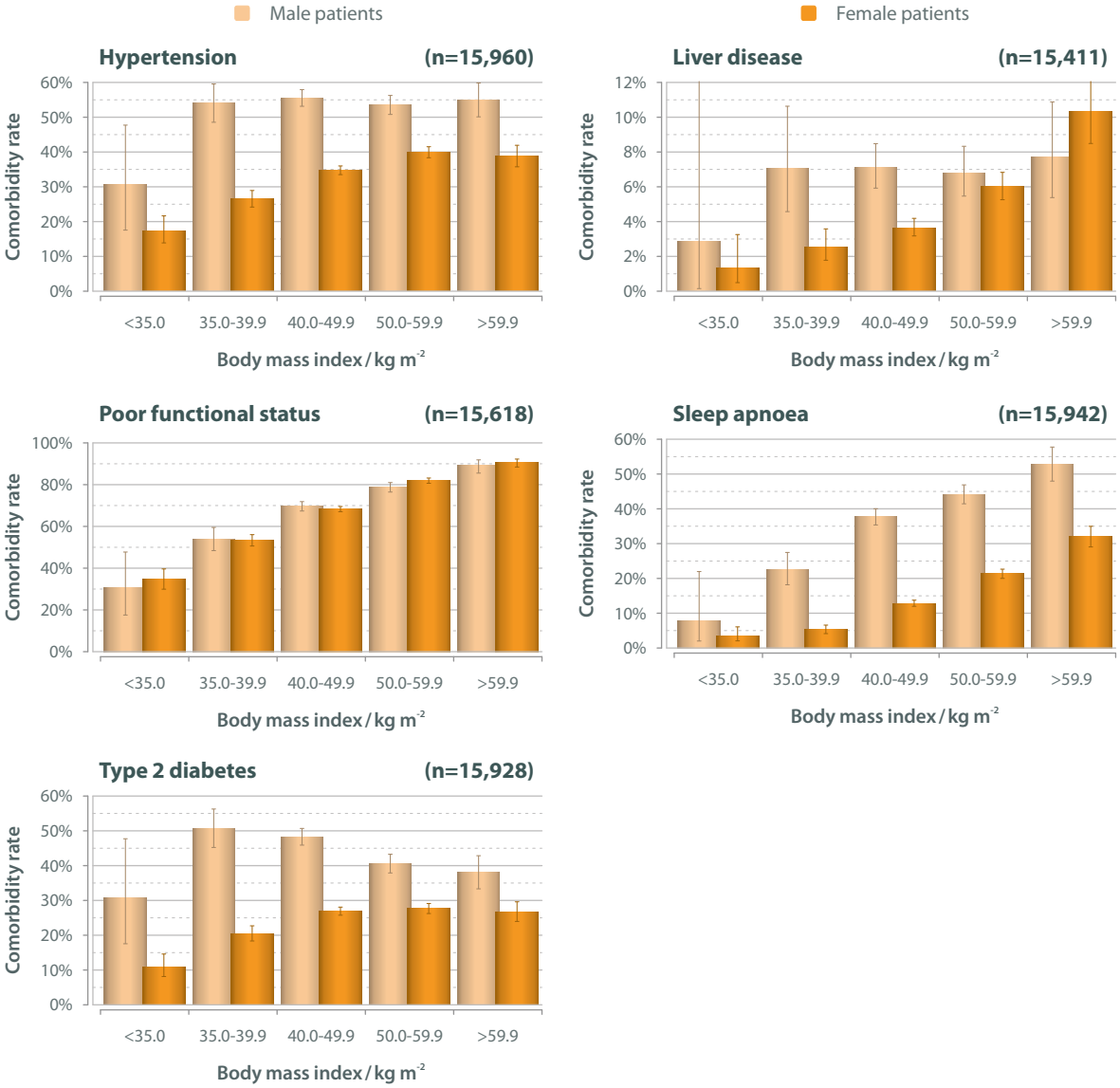
The data presented below illustrate that as BMI increases there is a statistically significant increase in the prevalence of the comorbidities shown, other than GORD, for female patients.

Primary operations: Distributions of the various comorbid conditions for male and female patients according to initial body mass index; financial years 2011-2013



For male patients a similar significant relationship is evident for arthritis, asthma, depression, poor functional status and sleep apnoea; all these comorbidities increase with increasing BMI. However, the converse is true for atherosclerosis, dyslipidaemia and type 2 diabetes; whilst no clear relationship exists between BMI and GORD, hypertension or liver disease (χ^2 test of change over time, $p<0.05$).

Primary operations: Distributions of the various comorbid conditions for male and female patients according to initial body mass index; financial years 2011-2013



Duration of diabetes

The risk of developing type 2 diabetes increases dramatically as BMI increases above 35 kg m^{-2}. Type 2 diabetes has huge implications, not just for the health of individual patients, but also for the healthcare economy: it has been estimated that type 2 diabetes costs Britain's National Health Service £11.7bn *per* year [1], which is around 10% of total NHS expenditure.

One of the most significant beneficial effects of bariatric surgery is its ability to induce remission of type 2 diabetes, which has clear implications for patients and the healthcare economy. It is therefore important to consider this area in more detail in this report.

The duration of patients' type 2 diabetes is an important variable to record, as the longer the patient has been living with the condition the less likely it is that remission will result after bariatric surgery [2]. It is therefore reassuring to see that over 50% of bariatric surgery patients recorded in the NBSR were undergoing surgery within 5 years of the diagnosis of type 2 diabetes, which means that they should stand a good chance of having their diabetes put into remission.

As expected, these data confirm that the longer a patient had been diabetic, the more likely that they will require first oral hypoglycaemic treatment, and later insulin therapy. The type of treatment that a patient requires for their diabetes at the time of bariatric surgery is known to be an important predictor of remission post-operatively [2]; patients who require insulin therapy are less likely to go into remission after surgery compared to those patients whose diabetes is controlled by diet or oral therapy. It is reassuring to see that the majority of patients with type 2 diabetes had surgery whilst they required only dietary or oral hypoglycaemic treatment; only a minority (24.4% of diabetic patients) required insulin therapy pre-operatively.

However, it is not possible to make a generalised statement about when (at what stage after diagnosis) diabetics should be treated, as the relative costs and clinical-effectiveness associated with treating this condition at different stages of the disease process are not yet known.

Primary operations: type of diabetes; financial years 2011-2013

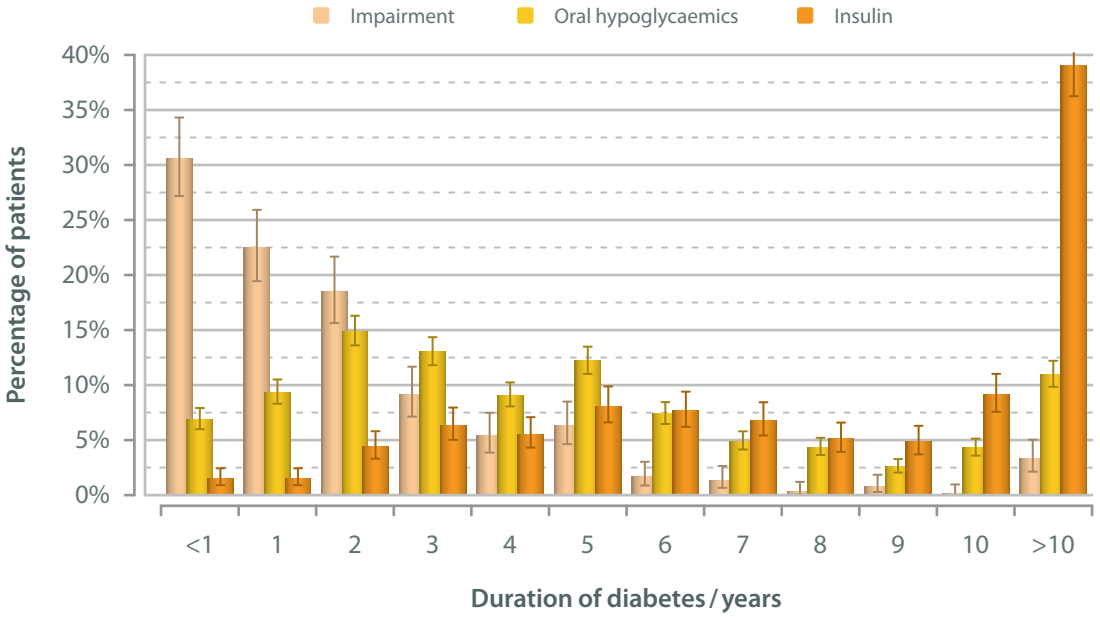
		Type of diabetes			
		Impairment [i]	Oral hypoglycaemics [ii]	Insulin [iii]	**All**
Duration of diabetes	< 1 year	204	191	17	**412**
	1 year	150	259	17	**426**
	2 years	123	413	50	**586**
	3 years	61	361	72	**494**
	4 years	36	252	63	**351**
	5 years	42	338	92	**472**
	6 years	11	205	87	**303**
	7 years	9	136	77	**222**
	8 years	2	121	58	**181**
	9 years	5	72	55	**132**
	10 years	1	119	104	**224**
	>10 years	22	304	444	**770**
	Unspecified	76	163	51	**290**
	All	**742**	**2,934**	**1,187**	**4,863**

i. The patient has impaired glycaemia or impaired glucose tolerance.

ii. The patient is receiving oral hypoglycaemics.

iii. The patient is on insulin treatment for diabetes.

Primary operations: Duration of diabetes; financial years 2011-2013 (n=4,573)



1. Kanavos P *et al.* Diabetes expenditure, burden of disease and management in 5 EU countries. LSE 2012 http://www.lse.ac.uk/LSEHealthAndSocialCare/research/LSEHealth/MTRG/LSEDiabetesReport26Jan2012.pdf.

2. Ramos-Levi, AM *et al.* Statistical models to predict type 2 diabetes remission after bariatric surgery. *Journal of Diabetes*. 2014; **DOI**: 10.1111/1753-0407.12127.

Focus on functional status

As BMI increases the strain and demands placed upon patients' joints and cardiopulmonary systems increase. So, it is not surprising to see that increasing BMI was associated with a decrease in functional status; 71.9% of patients had a significant level of disability in that they were unable to climb 3 flights of stairs without resting.

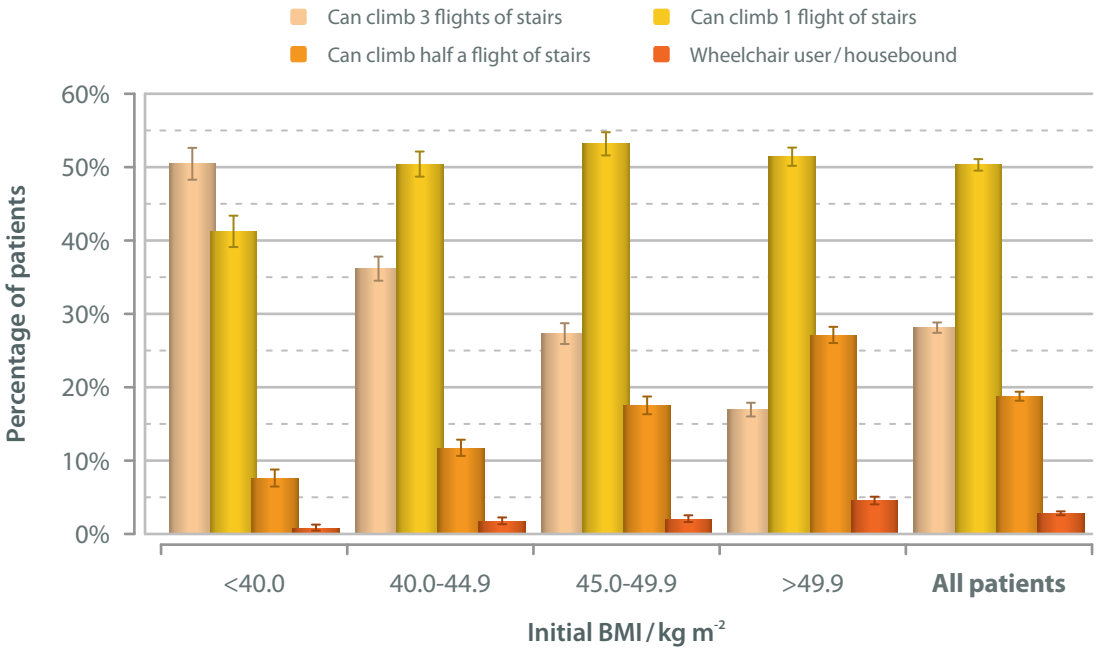
Such high levels of functional restriction confer important consequences upon patients' ability to work and their care requirements, and go some way to explaining the findings of others that up to 58% of bariatric surgery patients are not in paid employment pre-operatively [1]. The economic impact of such disability for individuals and the State is clear.

Primary surgery: functional status and initial BMI; financial years 2011-2013

		Functional status					
		Can climb 3 flights of stairs	Can climb 1 flight of stairs	Can climb half a flight of stairs	Wheelchair user / Housebound	Unspecified	**All**
Initial BMI / kg m^{-2}	<40.0	1,050	858	157	16	96	**2,177**
	40.0-44.9	1,208	1,685	391	58	169	**3,511**
	45.0-49.9	1,059	2,064	679	79	229	**4,110**
	>49.9	1,069	3,247	1,712	286	456	**6,770**
	Unspecified	31	49	9	2	297	**388**
	All	**4,417**	**7,903**	**2,948**	**441**	**1,247**	**16,956**

1. Hawkins S *et al.* Paid work increases and state benefit claims decrease after bariatric surgery. *Obesity Surgery*. 2007; **17**: 434 - 437

Primary operations: Functional status and initial BMI; financial years 2011-2013 (n=15,709)



NICE guidance

The NICE guidance CG43 update is due for release in November 2014 and the following is an extract from the current guidance [1]:

1.2.6 Surgical interventions

This section updates the NICE technology appraisal on surgery for people with morbid obesity (NICE technology appraisal guidance no. 46); see section 6 for details.

Adults and children

1.2.6.1 Bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled:

- they have a BMI of 40 kg m^{-2} or more, or between 35 kg m^{-2} and 40 kg m^{-2} and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months.
- the person has been receiving / will receive intensive management in a specialist obesity service.
- the person is generally fit for anaesthesia and surgery.
- the person commits to the need for long-term follow-up.

1.2.6.2 Severely obese people who are considering surgery to aid weight reduction (and their families as appropriate) should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and / or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and peri-operative mortality.

1.2.6.3 The choice of surgical intervention should be made jointly by the person and the clinician, and taking into account:

- the degree of obesity.
- comorbidities.
- the best available evidence on effectiveness and long-term effects.
- the facilities and equipment available.
- the experience of the surgeon who would perform the operation.

1.2.6.4 Regular, specialist post-operative dietetic monitoring should be provided, and should include:

- information on the appropriate diet for the bariatric procedure.
- monitoring of the person's micronutrient status.
- information on patient support groups.
- individualised nutritional supplementation, support and guidance to achieve long-term weight loss and weight maintenance.

1.2.6.5 Arrangements for prospective audit should be made, so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term.

1.2.6.6 The surgeon in the multi-disciplinary team should:

- have undertaken a relevant supervised training programme.
- have specialist experience in bariatric surgery.
- be willing to submit data for a national clinical audit scheme.

Adults

1.2.6.7 In addition to the criteria listed in 1.2.6.1, bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg m^{-2} in whom surgical intervention is considered appropriate.

1.2.6.8 In people for whom surgery is recommended as a first-line option, orlistat … can be used to maintain or reduce weight before surgery if it is considered that the waiting time … is excessive.

1.2.6.9 Surgery for obesity should be undertaken only by a multi-disciplinary team that can provide:

- pre-operative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s).
- information on the different procedures, including potential weight loss & associated risks.
- regular post-operative assessment, including specialist dietetic and surgical follow-up
- management of comorbidities.
- psychological support before and after surgery.
- information on, or access to, plastic surgery (such as apronectomy) where appropriate.
- access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and seating suitable for patients undergoing bariatric surgery, and staff trained to use them.

1.2.6.10 Surgery should be undertaken only after a comprehensive pre-operative assessment of any psychological or clinical factors that may affect adherence to post-operative care requirements, such as changes to diet.

1.2.6.11 Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive experience because of the high rate of complications and increased mortality.

As shown above, NICE guidelines require that patients must have a BMI >40.0 kg m^{-2} to be eligible for publicly-funded surgery, or have one or more comorbid conditions if their BMI is between 35.0 kg m^{-2} and 40.0 kg m^{-2}. The registry shows that for publicly funded patients, 99.5% satisfied NICE guidance. This compares to 85.2 % for privately funded patients.

The NICE guidance is based on the National Institutes of Health Guidelines from 1991, and, importantly, these guidelines pre-dated both laparoscopic bariatric surgery and also adjustable gastric banding; they were considered appropriate for the period in which they were written, when open surgery was thought to be a high-risk procedure. With the advent of laparoscopic surgery and the constant evolution of surgical practice, many surgeons now feel that the BMI threshold defining suitability for surgery can be lowered. In addition, one of the commercially available gastric bands is licensed for BMI ≥30 kg m^{-2}.

For instance, Asian patients are known to develop diabetes at a lower BMI than their Caucasians counterparts, and there are correspondingly lower thresholds for surgery in other parts of the world [2].

Primary operations where all comorbidities are recorded; financial years 2011-2013: an analysis of the criteria used in NICE Clinical Guidline 43

			Comorbidities recorded		
			None	1 or more	% with no comorbidity
Funding and initial BMI / kg m-2	Publicly funded	<35.0	1	35	2.8%
		35.0-39.9	16	552	2.8%
		>39.9	337	9,417	3.5%
		Unspecified	0	43	0.0%
	Privately funded	<35.0	88	251	26.0%
		35.0-39.9	156	745	17.3%
		>39.9	250	1,861	11.8%
		Unspecified	9	14	39.1%

1. www.nice.org.uk/guidance/cg43

2. Lakdawala M *et al.* Asian Consensus Meeting on Metabolic Surgery. Recommendations for the use of Bariatric and Gastrointestinal Metabolic Surgery for Treatment of Obesity and Type II Diabetes Mellitus in the Asian Population. *Obesity Surgery*. 2010; **20**: 929-36.

ASA grade

The American Society of Anesthesia (ASA) grade [1] is a physical status classification system, in use for over 70 years, that has been shown to be a gross predictor of peri-operative outcome. These graphs show that, as might be expected, there was a significant trend of increasing ASA grade associated with increasing BMI ($p<0.001$; one-way ANOVA). This is to be expected given the previously-presented data that demonstrated a strong association between increasing BMI and an increase in obesity-related comorbid diseases (see previous charts in this section). For both men and women, there is a near linear increase in the proportion of patients with ASA grade III with increasing BMI.

Even amongst the female patient-population, who generally have lower BMIs and fewer obesity-related comorbid conditions than their male counterparts, ASA grade still increased with increasing BMI: nearly one-third of female patients with BMI>50 kg m^{-2} were reported as ASA III.

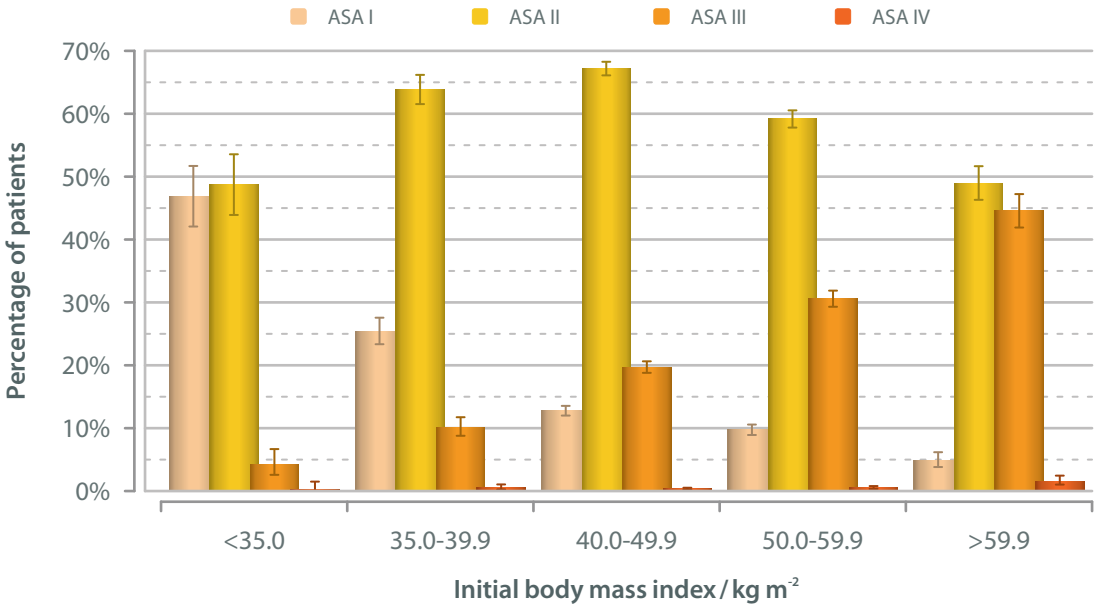
Almost one-quarter of all bariatric surgery (23%) was carried out for a population with ASA grade III (severe systemic disease) or ASA IV (severe systemic disease that is a constant threat to life); these patients are generally considered high risk for elective surgery.

Primary operations: ASA grade, gender and initial BMI; financial years 2011-2013

Gender and initial BMI / kg m^{-2}			ASA grade					
			ASA I	ASA II	ASA III	ASA IV	Unspecified	**All**
	Male	<35.0	11	21	7	1	2	**42**
		35.0-39.9	44	216	58	7	8	**333**
		40.0-49.9	133	1,031	509	12	94	**1,779**
		50.0-59.9	106	700	478	18	89	**1,391**
		>59.9	18	183	196	12	31	**440**
		Unspecified	3	11	15	1	72	**102**
	Female	<35.0	190	188	11	0	15	**404**
		35.0-39.9	383	858	113	2	45	**1,401**
		40.0-49.9	804	3,905	938	14	181	**5,842**
		50.0-59.9	382	2,273	1,058	9	179	**3,901**
		>59.9	49	491	417	10	73	**1,040**
		Unspecified	15	37	11	0	218	**281**

1. Saklad M. Grading of patients for surgical procedures. *Anesthesiology*. 1941; **2**: 281-284.

Primary operations: ASA grade and body mass index; financial years 2011-2013 (n=15,856)



The Edmonton Obesity Staging System

Preceding sections of this report have described the population of bariatric surgery patients entered into the NBSR in terms of their BMI, number of comorbidities and ASA grade. However, each of these classifications has well-recognized limitations: BMI is limited at an individual level as it does not distinguish between lean muscle and fatty tissue; hence, a muscular Olympic athlete or a professional rugby player may have a BMI >35 kg m^{-2}. The number of comorbidities is a rather crude measure as not all carry equal prognostic significance, *e.g.,* a patient with both depression and GORD is unlikely to be as high a surgical risk as a patient with both atherosclerosis and type 2 diabetes treated with insulin, yet both would be classified as having 2 comorbidities. The ASA grading system was developed for use in the general population, and has not been validated as useful in risk stratification for the obese population.

The Edmonton Obesity Staging System (EOSS) [1], is a recent development that ranks obese patients on a 5-point scale that incorporates obesity-related comorbidities and functional status. It has been validated as capable of predicting all-cause mortality for an obese population; but, it cannot be used to predict immediate post-operative mortality. One of the important findings from the EOSS studies is that when patients from the NHANES database were assigned an EOSS score, those without apparent disease did not have poor long-term survival even though they were obese. This contrasts with recent suggestions that there is no such thing as healthy overweight [2].

The Edmonton Obesity Staging System [1] has not been calculated before for a bariatric surgery patient population. However, bariatric teams discussing the risk of not operating with prospective patients could use the score to determine long-term mortality risk. Here, we have used the comorbidity recorded in the NBSR dataset to assign an approximate EOSS score:

4. EOSS stage 4 comprises any one or more of the following patient characteristics:
   i. requires a wheelchair or is housebound.
   ii. has venous oedema with ulceration.
   iii. has had a vena cava filter.
   iv. obesity / hypoventilation syndrome.

3. Assuming no criteria for EOSS stage 4 are met, any one or more of the following qualifies as EOSS stage 3:
   i. diagnosed atherosclerosis.
   ii. sleep apnoea with complications.
   iii. asthma requiring treatment with nebulisers or oral steroids or requiring hospital admission in the last year.
   iv. known arthritis / back or leg pain from arthritis requiring opiates.
   v. non-alcoholic steatohepatosis proven on liver biopsy.

2. Assuming no criteria for EOSS stages 3 and 4 are met, any one or more of the following qualifies as EOSS stage 2:
   i. oral hypoglycaemic or insulin therapy for type 2 diabetes.
   ii. hypertension on treatment.
   iii. dyslipidaemia.
   iv. diagnosis of sleep apnoea or on CPAP / BIPAP.
   v. asthma treated with inhalers.
   vi. can climb half a flight of stairs without resting.
   vii. back or leg pain from arthritis requiring regular medication with non-opitaes.
   viii. daily medication with H2RA / PPI for GORD.
   ix. a prior operation for GORD.
   x. known non-alcoholic fatty liver disease proven on biopsy or hepatology opinion.
   xi. depression on medication.
   xii. on medication for polycystic ovary syndrome (female patients only).

1. Assuming no criteria for EOSS stages 2, 3 and 4 are met, any one or more of the following qualifies as EOSS stage 1:
   i. impaired glycaemia or impaired glucose tolerance.
   ii. intermittent symptoms of back or leg pain from arthritis not treated with medication.
   iii. can climb 1 flight of stairs without resting.
   iv. suspected non-alcoholic fatty liver disease (abnormal LFTs or abnormal ultrasound scan).
   v. diagnosis of polycystic ovary syndrome that is not treated with medication (females only).

0. No criteria for EOSS stages 1-4 are met.

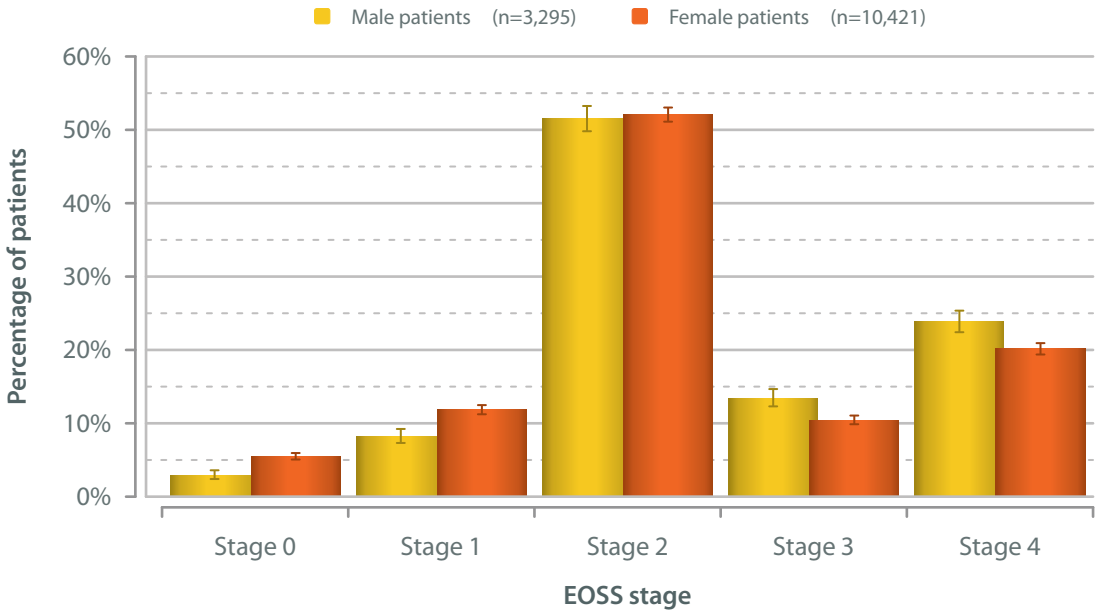
In later years this should allow comparisons to be made between the population's predicted mortality without bariatric surgery and the actual observed mortality rates in the years post-bariatric surgery. It can be seen that the majority of NBSR patients fell into EOSS 2. Male patients tended to have a higher EOSS stage than female patients ($p<0.001$; χ^2 analysis). This finding corroborates earlier findings that men presented for bariatric surgery with higher BMIs and worse comorbidities, suggesting that males tended to present at a later stage of the disease process.

For both male and female patients there has been a tendency for the EOSS stage to increase year on year from 2006. Again, this corroborates data presented earlier demonstrating an increase in the average number of comorbidities with time. Reasons for this are not entirely clear, but it is evident that bariatric surgeons in the United Kingdom are operating on an increasingly unwell group of patients.

Primary operations: Edmonton Obesity Staging System (EOSS) and gender; financial years 2011-2013

		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
EOSS stage	EOSS 0	97	2.9%	572	5.5%
	EOSS 1	271	8.2%	1,234	11.8%
	EOSS 2	1,698	51.5%	5,427	52.1%
	EOSS 3	443	13.4%	1,089	10.5%
	EOSS 4	786	23.9%	2,099	20.1%
	Unspecified	792		2,448	
	All	**4,087**		**12,869**	

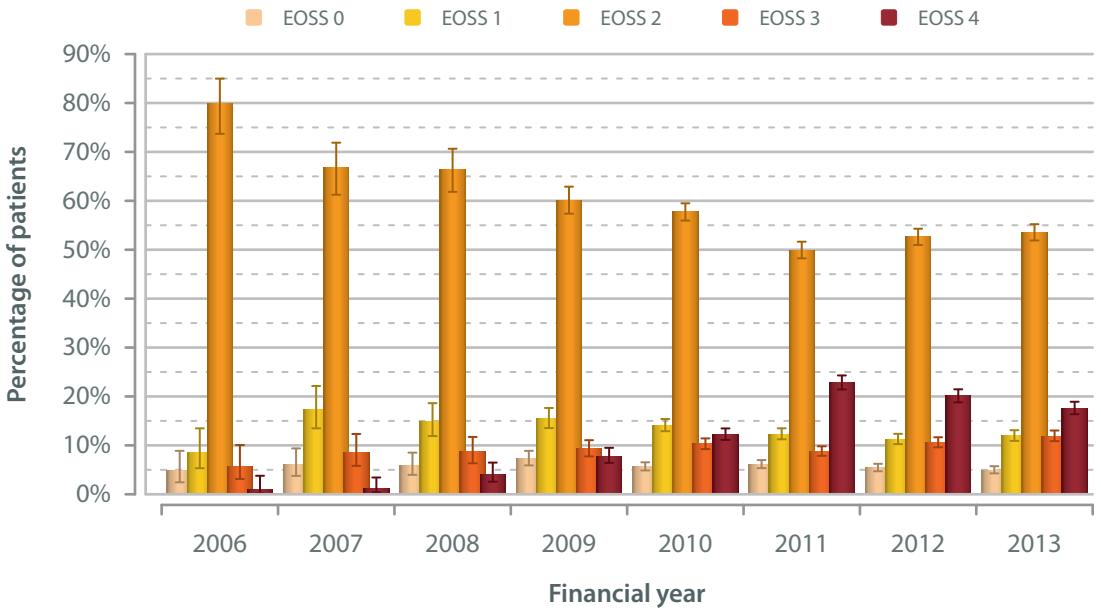
Primary operations: EOSS stage and gender; financial years 2011-2013



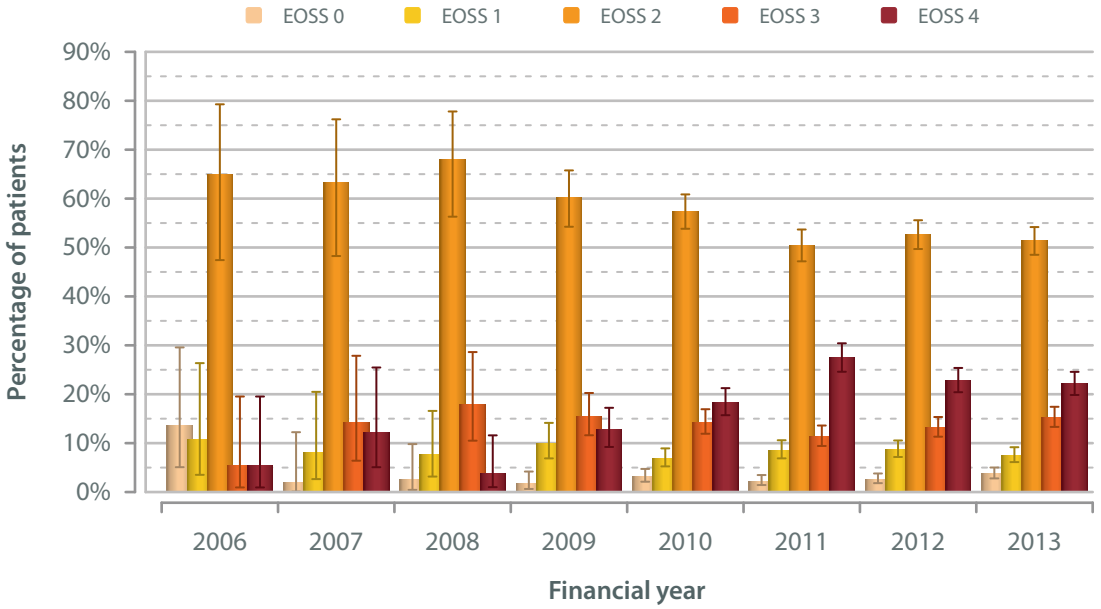
1. Padwal RS, Pajewski NM, Allison DB and Sharma AM. Using the Edmonton obesity staging system to predict mortality in a population-representative cohort of people with overweight and obesity. *Canadian Medical Association Journal*. 2011; **183(14)**: E1059-66.

2. Kramer CK, Zinman B, Retnakaran R. Are Metabolically Healthy Overweight and Obesity Benign Conditions? A Systematic Review and Meta-analysis. Annals of Internal Medicine.

Primary surgery for female patients:
Changes in EOSS distributions over time; financial years 2011-2013 (n=15,711)



Primary surgery for male patients:
Changes in EOSS distributions over time; financial years 2011-2013 (n=4,536)



Younger bariatric surgery patients

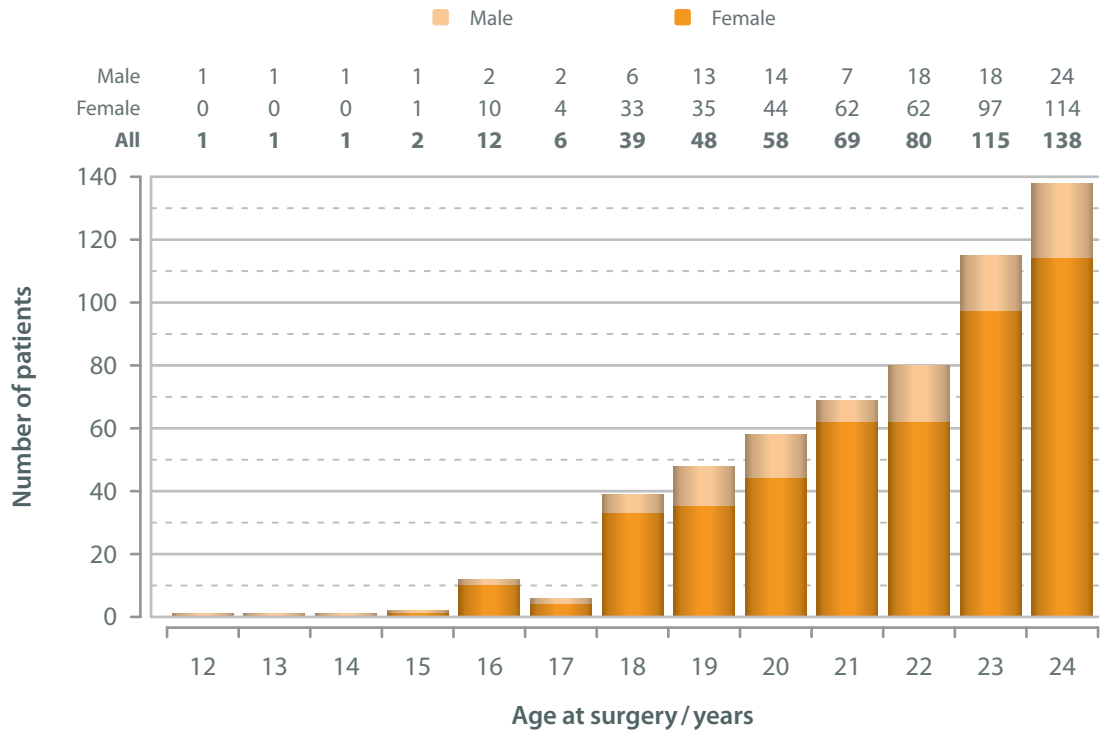
This is the first in-depth description of bariatric surgery in patients under the age of 25 years old in the United Kingdom. Remarkably, there were 62 patients aged ≤18 years having this kind of surgery during the three-year period 2011-2013.

For all those under the age of 25 years, the young patients' initial BMI spanned the range 31-81 kg m^{-2}, with an average of 48.7 kg m^{-2}. The age-specific distributions of initial BMI show that their median BMI generally fell within the range 44-49 kg m^{-2}.

Primary operations: age at operation, gender and BMI; calendar years 2011-2013

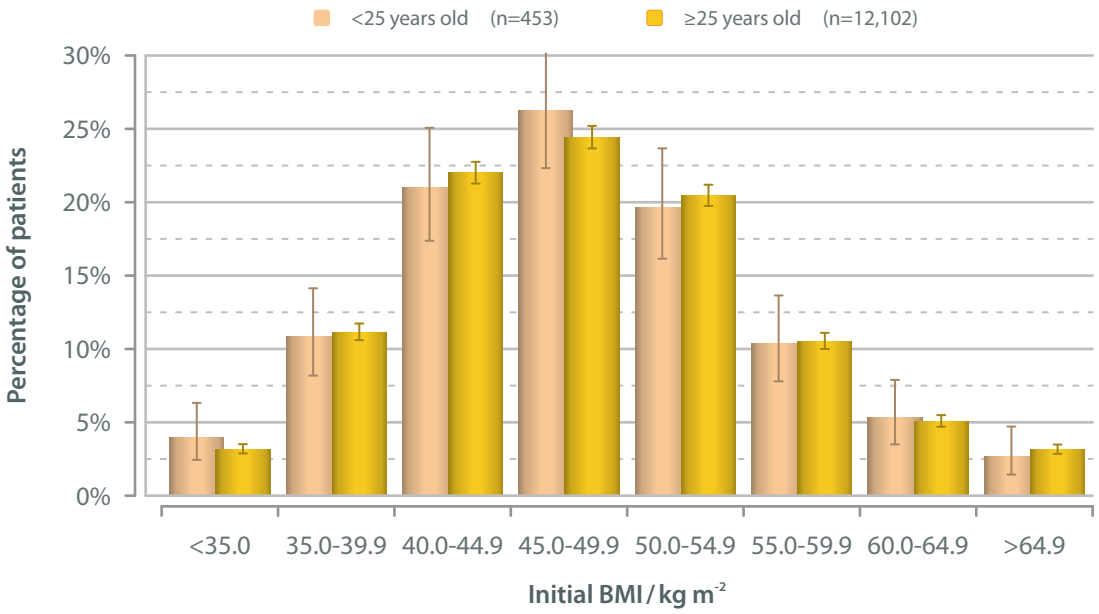
		Gender and age group					
		Male			Female		
		<25 years	≥25 years	Unspecified	<25 years	≥25 years	Unspecified
Initial BMI / kg m^{-2}	<35.0	2	40	0	18	385	1
	35.0-39.9	4	329	0	49	1,350	2
	40.0-44.9	23	725	1	95	2,663	4
	45.0-49.9	28	999	3	119	2,956	5
	50.0-54.9	15	824	0	89	2,476	7
	55.0-59.9	20	532	0	47	1,275	7
	60.0-64.9	6	222	2	24	615	5
	>64.9	8	202	0	12	382	2
	Unspecified	2	100	0	9	271	1
	All	**108**	**3,973**	**6**	**462**	**12,373**	**34**

Primary operations for patients aged <25 years at the time of surgery: Age and gender; calendar years 2011-2013

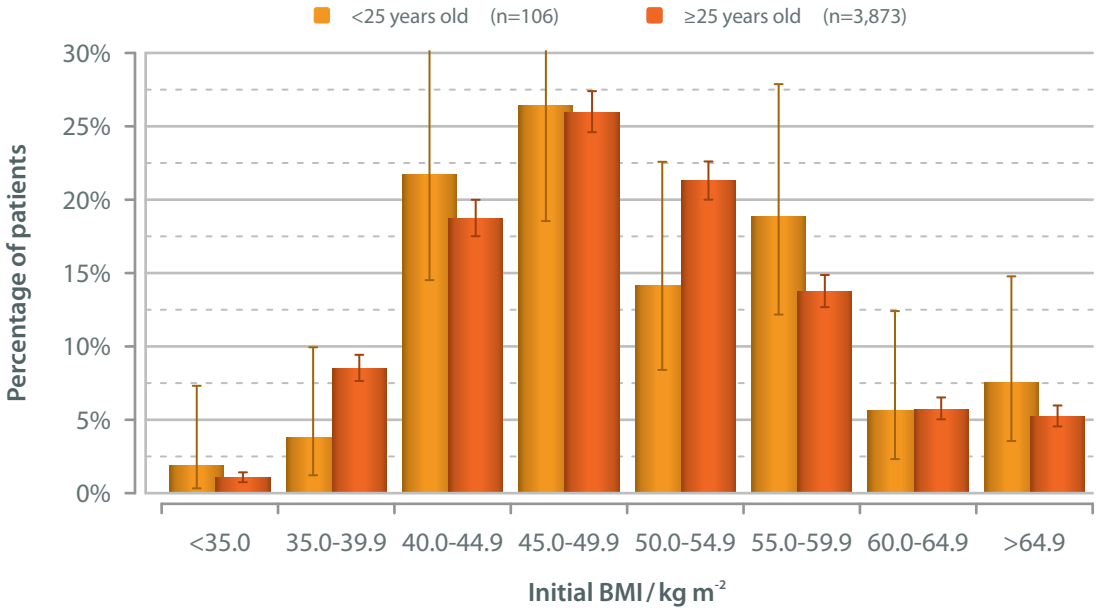


These graphs describe the proportion of patients in each BMI group for the younger patients compared to older patients. It is a reflection on society's failings that these patients had already gained sufficient weight to be broadly comparable to patients who are much older. This is true for both male and female patients. Overall, 39.5% of young male and female patients combined were already classified in the super-obese category with a BMI of 50 kg m^{-2} or more. This represents clear failure of strategies to prevent weight gain in young people.

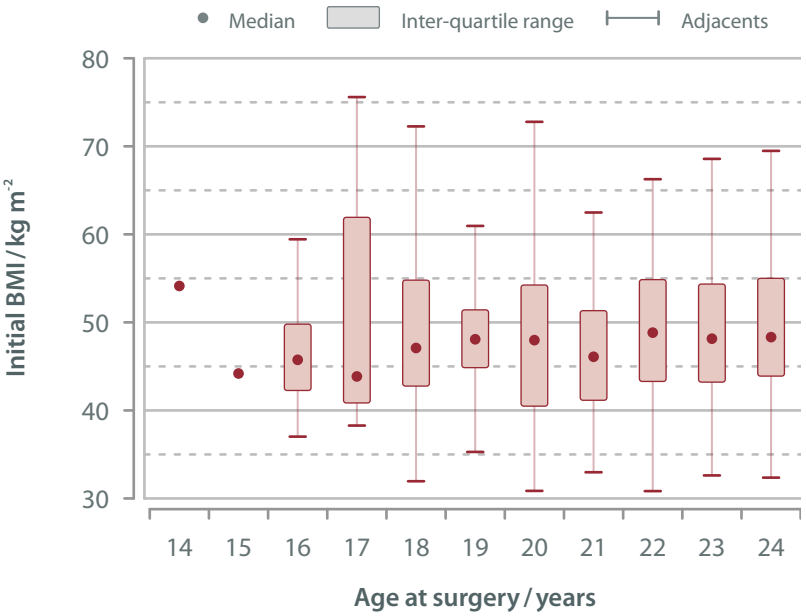
Primary operations for female patients: Initial BMI and age; calendar years 2011-2013



Primary operations for male patients: Initial BMI and age; calendar years 2011-2013



Primary operations for patients aged <25 years at the time of surgery: Initial BMI; financial years 2011-2013



Although the rates of obesity-related comorbid disease in the younger age group are proportionately lower than in the older patients, it is still very worrying that so many of these patients have severe comorbid disease, such as diabetes.

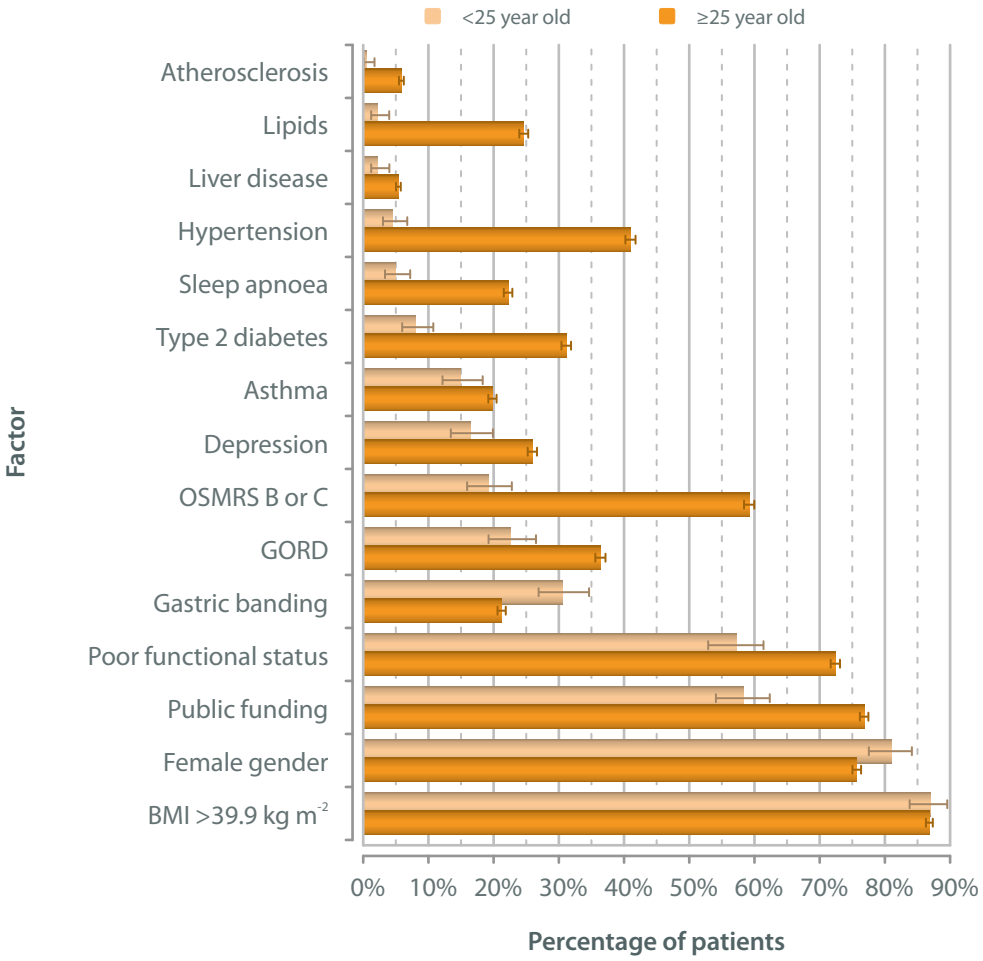
Even more remarkable is the finding that more than half of patients (57.2%) cannot climb 3 flights of stairs. This confirms again the reality that severely overweight teenagers and young adults cannot easily lose weight by exercise: they are too obese even to climb stairs. These findings corroborate the data from the *Early Bird* study in the South-West of England where it was found that obese patients were simply too tired to be able to take exercise.

Primary operations: various factors according to age; calendar years 2011-2013

		Age at operation and presence of the factor							
		<25 years				≥25 years			
		No	Yes	Unspecified	Percentage with the factor	No	Yes	Unspecified	Percentage with the factor
Factor	BMI >39.9	73	486	11	86.9%	2,104	13,871	371	86.8%
	Female	108	462	0	81.1%	3,973	12,373	0	75.7%
	Asthma	465	82	23	15.0%	12,395	3,062	889	19.8%
	Atherosclerosis	544	3	23	0.5%	14,493	899	954	5.8%
	Depression	448	88	34	16.4%	10,949	3,833	1,564	25.9%
	Diabetes	502	44	24	8.1%	10,634	4,807	905	31.1%
	Dyslipidaemia	524	12	34	2.2%	11,573	3,778	995	24.6%
	GORD	413	121	36	22.7%	9,405	5,376	1,565	36.4%
	Hypertension	523	25	22	4.6%	9,131	6,341	874	41.0%
	Liver	521	12	37	2.3%	14,130	804	1,412	5.4%
	Poor functional status	232	310	28	57.2%	4,175	10,956	1,215	72.4%
	Sleep apnoea	519	27	24	4.9%	12,023	3,432	891	22.2%
	OSMRS B or C	431	102	37	19.1%	6,177	8,958	1,211	59.2%
	Band	394	174	2	30.6%	12,821	3,454	71	21.2%
	Public finding	237	331	2	58.3%	3,758	12,456	132	76.8%

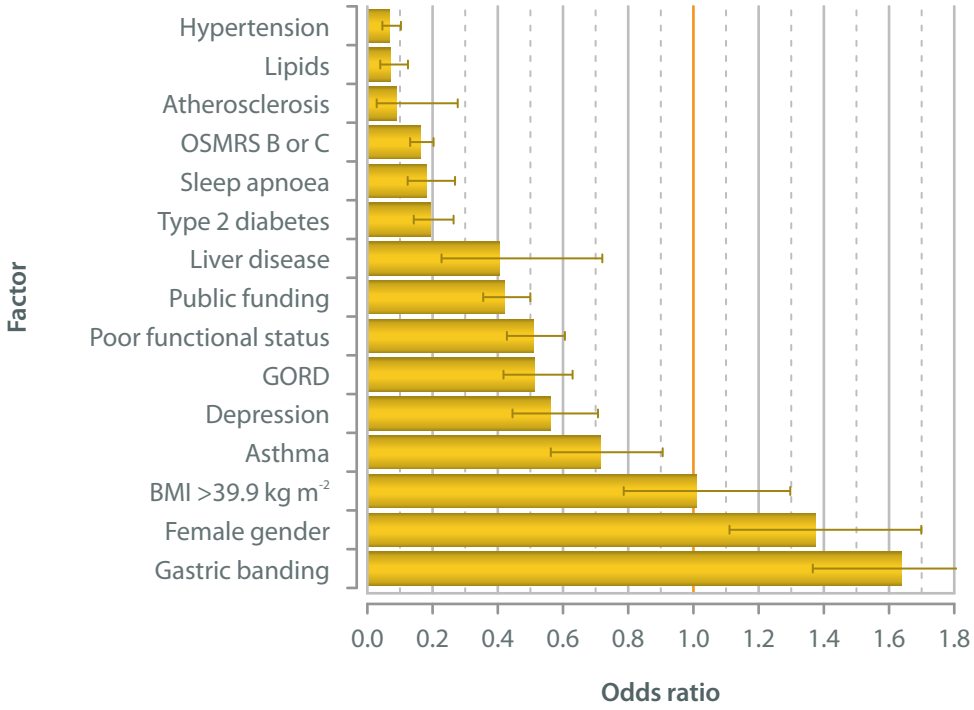
Also very worrying is the observation that almost 1 in 5 of these patients having surgery were in a higher-risk group for operative mortality after surgery, despite the fact that they could not, by definition, have one of the risk factors used for calculating the OSMRS score (aged 45 or over). All these observations are very concerning for teenage and young adult obesity.

Primary operations: Rates of various factors and age; financial years 2011-2013



This graph shows the odd ratios for each factor, comparing the odds of each factor for our young bariatric surgery patients to the rate for those patients aged ≥25 years at the time of surgery. It is interesting to note that there were relatively more females in this age group and that gastric banding was more likely to be the type of operation performed. It is likely that the great advantage of gastric banding here is that it is seen as a least invasive technique that does not rearrange or alter anatomy.

Primary operations: Odd ratios for various factors for patients aged <25 years; financial years 2011-2013



Post-operative complications

Cardiovascular complications

It is not possible to perform any type of surgery without some patients experiencing complications. Bariatric surgery is no exception. From its inception, the NBSR has striven to record a complete set of complications data for all patients. In presenting these data, complications have been grouped as being related to the cardiovascular system or all other complications:

The possible response-options for the cardiovascular complications question are listed on page 293 of this report. The incidences of such cardiovascular complications for all patients in the database were:

- myocardial infarction 3
- stroke 2
- dysrhythmia 34
- pulmonary embolus 3
- deep vein thrombosis 3
- cardiac arrest 3

In the table below that lists the incidences of cardiovascular complications by operation type, all of the above complications have been grouped together as a *yes* response because the incidence of each individual sub-class of complication is very low. Only the difference between cardiovascular complication rates for gastric band procedures and gastric bypass attained statistical significance (p=0.011; χ^2 2×2 contingency table).

Primary operations: cardiovascular complications; financial years 2011-2013

		Cardiovascular complications				
		No	Yes	Unspecified	**All**	Rate (95% CI)
Operation	Gastric band	3,399	3	231	**3,633**	0.1% (0.0-0.3%)
	Roux-en-Y gastric bypass	8,401	30	702	**9,133**	0.4% (0.2-0.5%)
	Sleeve gastrectomy	3,302	10	319	**3,631**	0.3% (0.2-0.6%)
	Duodenal switch & sleeve	8	0	3	**11**	0.0% (0.0-31.2%)
	Gastric balloon	271	2	21	**294**	0.7% (0.1-2.9%)
	Other	157	0	24	**181**	0.0% (0.0-1.9%)
	Unspecified	0	0	73	**73**	NA
	All	**15,538**	**45**	**1,373**	**16,956**	**0.3% (0.2-0.4%)**

Looking at the ASA, BMI and comorbidity data presented earlier in this report, it is clear that the majority of patients undergoing bariatric surgery should be considered as being at a high risk of post-operative complications. In addition, laparoscopic surgery in obese patients is technically demanding in itself. So, it is very reassuring and gratifying to see that post-operative cardiovascular complication rates were very low.

When compared to the data presented in the first NBSR Report it is even more reassuring to see that there has been a significant fall in cardiovascular complication rates, from a previous incidence of 0.6% to the 0.3% shown above (p<0.001; χ^2 2×2 contingency table), despite the previously described increase in the EOSS scores of the patient population.

Although we are aware that most or all hospitals within the NHS do not have data validation clerks and, therefore, the data are self-reported, the results are consistent with internationally published data [1]. Clearly though there may be under-reporting.

1. Hutter MM, Schirmer BD, Jones DB *et al.* First Report from the American College of Surgeons Bariatric Surgery Center Network Laparoscopic Sleeve Gastrectomy has Morbidity and Effectiveness Positioned Between the Band and the Bypass. *Annals of Surgery*. 2011; **254**: 410–422.

Other complications

The possible response options for all other complications are listed on page 293 of this report. The incidences of each such complication for all patients in the database were:

- fluid / electrolyte problems 86
- acute cholecystitis / biliary colic 1
- CBD stones / cholangitis 1
- gastric distention 13
- other abscess / infection / fever 70
- acute renal failure 15
- pneumonia / atelectasis 83
- rhabdomyolysis 4
- urinary tract infection 15
- vomiting / poor intake 96
- wound infection / breakdown 56
- unanticipated transfer to ITU 60

Primary operations: other complications; financial years 2011-2013

		Other complications				
		No	Yes	Unspecified	**All**	Rate (95% CI)
Operation	Gastric band	3,373	25	235	**3,633**	0.7% (0.5-1.1%)
	Roux-en-Y gastric bypass	8,076	261	796	**9,133**	3.1% (2.8-3.5%)
	Sleeve gastrectomy	3,160	114	357	**3,631**	3.5% (2.9-4.2%)
	Duodenal switch & sleeve	8	0	3	**11**	0.0% (0.0-31.2%)
	Gastric balloon	262	12	20	**294**	4.4% (2.4-7.7%)
	Other	147	8	26	**181**	5.2% (2.4-10.3%)
	Unspecified	0	0	73	**73**	NA
	All	**15,026**	**420**	**1,510**	**16,956**	**2.7% (2.5-3.0%)**

Again, it is reassuring and very pleasing that bariatric surgery had very low non-cardiovascular post-operative complication rates despite the fact that it was being performed for quite ill, high-risk patients. The rate of other complications after gastric band procedures was significantly lower than that reported for either gastric bypass or sleeve gastrectomy ($p<0.001$, χ^2 2×2 contingency table).

Combining the cardiovascular and other complications data (where both outcomes are recorded) gave an overall reported composite complication rate of 2.9% (n=15,431; 95% CI: 2.6-3.1%). This low overall rate compares very well with data reported from elsewhere in the world; for example, recent overall post-bariatric surgery complication rates in the USA have been reported as being between 7.3% [1] and 8.0% [2].

Patients who had a gastric banding procedure had a much lower ($p<0.001$; χ^2 2×2 contingency table) combined complication rate (0.8%; n=3,396) than those having either a Roux-en-Y gastric bypass (3.3%; n=8,330) or a sleeve gastrectomy operation (3.5%; n=3,268); the difference between the combined omplication rate for Roux-en-Y gastric bypass and sleeve gastrectomy was not significant ($p=0.589$; χ^2 2×2 contingency table).

1. Birkmeyer N *et al.* Hospital complication rates with bariatric surgery in Michigan. *JAMA*. 2010; **304(4)**: 435 - 442.

2. Dimick JB *et al.* Bariatric surgery complications before vs after implementation of a national policy restricting coverage to centers of excellence. *JAMA*. 2013; **309(8)**: 792 - 799.

Composite complications

A *composite complication* is any one of either the recorded cardiovascular complications or the *other* complications listed above. Both pieces of information must be recorded for the database entry to be classified correctly, so *no* in this instance means neither a cardiovascular complication nor any *other* complications, and *yes* means any one or more of the cardiovascular or *other* complications; if either *datum* is missing, then the status of the derived *composite complication* cannot be determined.

Primary operations: composite complications; financial years 2011-2013

		Composite complication				
		No	Yes	Unspecified	**All**	Rate (95% CI)
Operation	Gastric band	3,369	27	237	**3,633**	0.8% (0.5-1.2%)
	Roux-en-Y gastric bypass	8,053	277	803	**9,133**	3.3% (3.0-3.7%)
	Sleeve gastrectomy	3,153	116	362	**3,631**	3.5% (3.0-4.3%)
	Duodenal switch & sleeve	8	0	3	**11**	0.0% (0.0-31.2%)
	Gastric balloon	259	14	21	**294**	5.1% (2.9-8.6%)
	Other	147	8	26	**181**	5.2% (2.4-10.3%)
	Unspecified	0	0	73	**73**	NA
	All	**14,989**	**442**	**1,525**	**16,956**	**2.9% (2.6-3.1%)**

30-day outcomes

The following table reports on the presence or absence of any recorded complications (such as band slippage, bleeding, leaks, obstructions, *etc.*) or procedure-specific re-operations within 30 days of the patient's primary surgery. An absence of any formally recorded events is treated as if there were no complications.

Primary operations: 30-day outcomes; financial years 2011-2013

		30-day outcomes data		
		Count	30-day complication rate	30-day re-operation rate
Operation	Gastric band	3,633	0.8% (0.6-1.2%)	0.3% (0.2-0.6%)
	Roux-en-Y gastric bypass	9,133	3.1% (2.8-3.5%)	1.9% (1.7-2.3%)
	Sleeve gastrectomy	3,631	2.3% (1.9-2.9%)	1.4% (1.1-1.9%)
	Duodenal switch & sleeve	11	0.0% (0.0-23.8%)	0.0% (0.0-23.8%)
	Gastric balloon	294	0.0% (0.0-1.0%)	0.3% (0.0-2.2%)
	Other	181	0.0% (0.0-1.6%)	0.0% (0.0-1.6%)
	Unspecified	73	0.0% (0.0-4.0%)	0.0% (0.0-4.0%)
	All	**16,956**	**2.4% (2.1-2.6%)**	**1.4% (1.3-1.6%)**

Post-operative in-hospital mortality

Unfortunately any type of major surgery carries some risk of death post-operatively, and bariatric surgery, which is, by its very nature, performed for high-risk patients, is no exception. There were only 11 deaths recorded in the whole registry over the 3 financial years 2011-2013, giving an overall post-operative mortality rate of 0.07% for this period. This is a remarkable result and reflects the safety of bariatric surgery in the United Kingdom. This overall mortality rate compares favourably with data from elsewhere in the world. Large studies from the United States of America report overall mortality rates for bariatric surgery of between 0.1 & 0.3% [1,2], whilst a recent meta-analysis of 259 studies published worldwide reported an overall 30-day mortality rate of 0.08% in randomised controlled trials and 0.22% for observational studies [3].

When operation-specific data are considered, the zero mortality rate recorded in the NBSR for gastric banding, the 0.07% rate for gastric bypass and the 0.15% mortality rate for sleeve gastrectomy all compare very favourably with the results of a recent meta-analysis of international studies, which reported 30-day mortality rates of 0.07-0.38%, 0.08-0.21% and 0.34-6.00% respectively for each kind of operation [3] (RCTs and observational study data). The data are also consistent with a recent Hospital Episode Statistics analysis (data collected by institutions independent of clinicians) by the NBSR Committee where the total number of operations for the 4 financial years 2010- 2013 was estimated at 23,760. There were 25 deaths, equivalent to an overall in-hospital mortality rate of 0.11% [4].

Comparing NBSR mortality rates for each of the three commonest operations, it is clear that gastric banding had the lowest mortality rate (compared to gastric bypass: p=0.191; and to sleeve gastrectomy: p=0.028; both Fisher's exact test). However, it is interesting to note that the mortality rate for sleeve gastrectomy was higher than that for gastric bypass, although this difference was not statistically significant (p=0.198; Fisher's exact test). These data and the similar complication rates of these two operations described in the previous section of this report are contrary to a commonly-held belief amongst patients (and perhaps some surgeons), that sleeve gastrectomy is a safer operation than gastric bypass; the two operations currently seem to be comparable in this regard.

Overall mortality following bariatric surgery recorded in the first NBSR report (0.1%) was higher than in this second report; however, the rates are so low that meaningful comparisons are difficult. Similarly, the rates are so low that it is not possible to draw any meaningful conclusions as to causes of death.

Primary operations: post-operative in-hospital mortality and operation; financial years 2011-2013

		Post-operative in-hospital mortality				
		No	Yes	Unspecified	**All**	Rate (95% CI)
Operation	Gastric band	3,402	0	231	**3,633**	0.00% (0.00-0.09%)
	Roux-en-Y gastric bypass	8,295	6	832	**9,133**	0.07% (0.03-0.17%)
	Sleeve gastrectomy	3,252	5	374	**3,631**	0.15% (0.06-0.38%)
	Duodenal switch & sleeve	8	0	3	**11**	0.00% (0.00-31.23%)
	Gastric balloon	273	0	21	**294**	0.00% (0.00-1.09%)
	Other	155	0	26	**181**	0.00% (0.00-1.91%)
	Unspecified	0	0	73	**73**	NA
	All	**15,385**	**11**	**1,560**	**16,956**	**0.07% (0.04-0.13%)**

1. Birkmeyer NJO. *et al.* Hospital Complication Rates With Bariatric Surgery in Michigan. *JAMA*. 2010; **304(4)**: 435 -442.

2. Smith MD *et al.* 30-day Mortality after Bariatric Surgery: Independently Adjudicated Causes of Death in the Longitudinal Assessment of Bariatric Surgery. *Obesity Surgery*. 2011; **21(11)**: 1687–1692.

3. Chang SH *et al.* The Effectiveness and Risks of Bariatric Surgery An Updated Systematic Review and Meta-analysis, 2003-2012. *JAMA Surgery*. 2014; **149(3)**: 275-87.

4. The United Kingdom National Bariatric Surgery Registry. Publication of surgeon-level data in the public domain for bariatric surgery (2013). http://www.bomss.org.uk/pdf/Bariatric%20Surgeon-Level%20Outcomes%20Data%20Report%202%20July%202013.pdf .

Post-operative stay

Almost all (86%) patients stayed 1 day or less in hospital after a gastric band procedure, and 15% left hospital on the same day as their operation, *i.e.,* these procedures are being performed as day-case surgery.

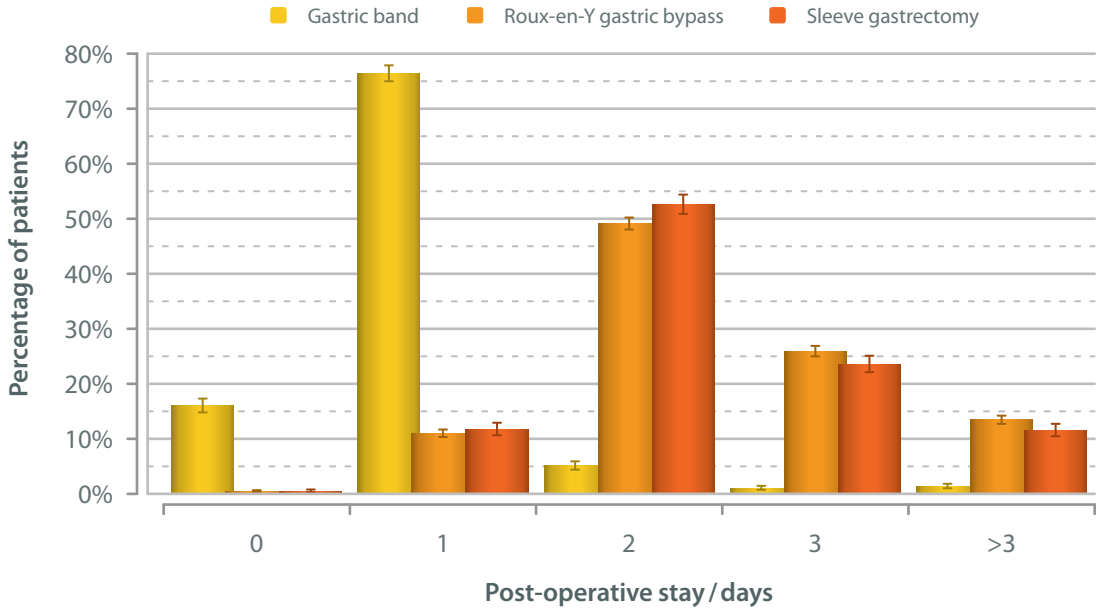
Patients' stay in hospital after gastric bypass and sleeve gastrectomy were very similar: over 75% were discharged by the third day after surgery. There has been a decrease in the average length-of-stay since 2007 (from just over 4 days to under 3 days).

Such short post-operative stay in hospital is only possible because most of the operations were performed using a keyhole / laparoscopic approach, using *enhanced recovery* techniques, with surgeons and anaesthetists becoming increasingly expert and more confident in their skills.

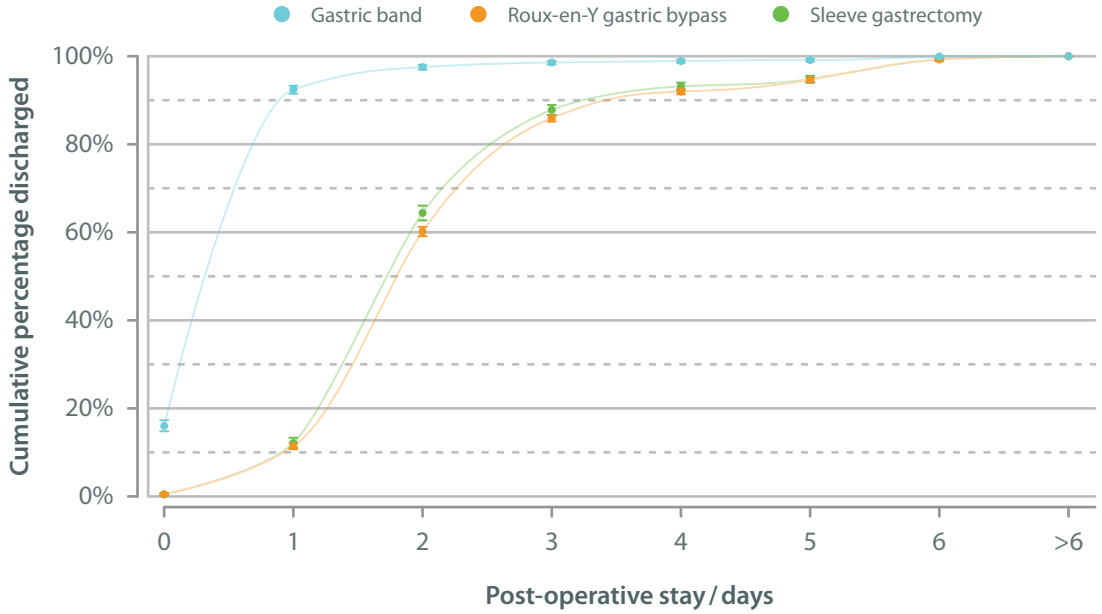
Primary operations: post-operative stay and operation; financial years 2011-2013

		Operation					
		Gastric band	Roux-en-Y gastric bypass	Sleeve gastrectomy	Other	Unspecified	All
Post-operative stay / days	0	540	40	15	154	0	**749**
	1	2,577	900	373	115	0	**3,965**
	2	172	4,021	1,672	93	0	**5,958**
	3	35	2,122	749	39	0	**2,945**
	4	11	498	171	17	0	**697**
	5	8	222	53	2	0	**285**
	>5	27	381	143	9	0	**560**
	Unspecified	263	949	455	57	73	**1,797**
	All	**3,633**	**9,133**	**3,631**	**486**	**73**	**16,956**

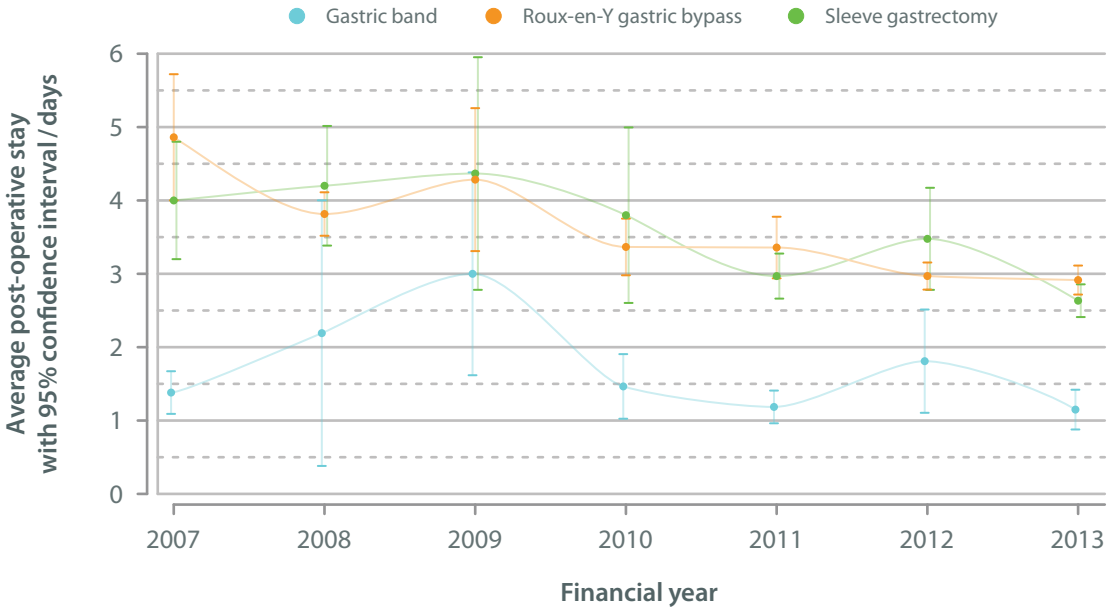
Primary operations: Post-operative stay; financial years 2011-2013 (n=14,730)



Primary operations: Patterns of post-operative stay for the three most common operations; financial years 2011-2013 (n=14,730)



Primary operations: Changes in average post-operative stay over time for the three most common operations (n=22,189)



Follow up data

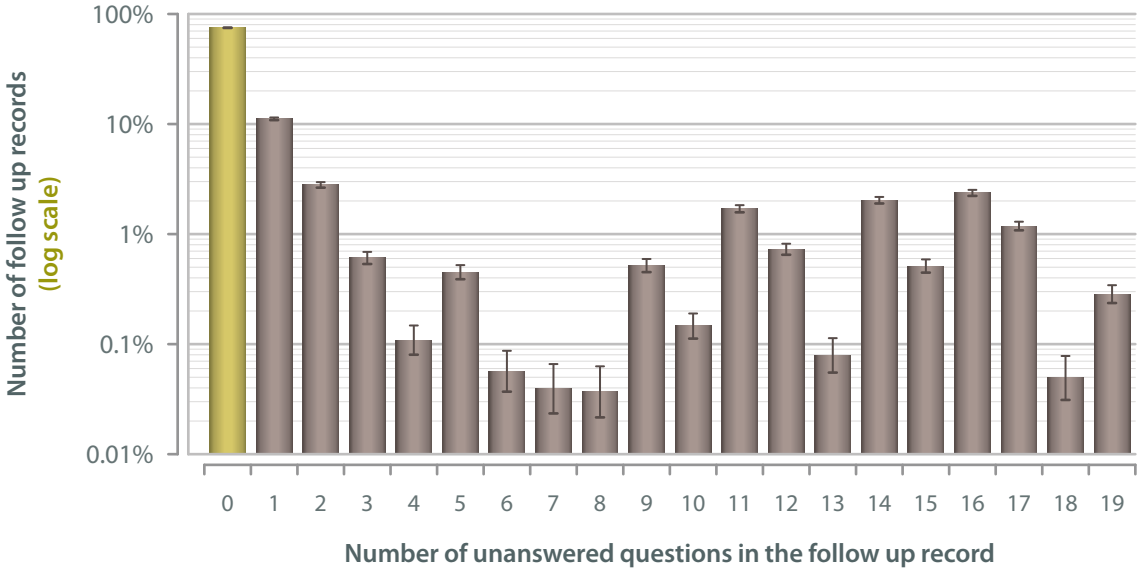
Rationale

Throughout the bariatric surgery literature there are no more than a handful of reports on patients followed for more than 10 years after surgery on an intention-to-treat basis. The reasons for this are varied and include limited patient compliance with follow up, the time and expense needed to capture the data, and the challenge of keeping track of an ever-increasing number of patients over the long term in a busy unit operating on several hundred patients a year. As a result, most units have not been able to actively follow patients up intensively beyond 2 or 3 years. To compound the problem, healthcare funding bodies typically commission the episode of surgery with very limited follow up; for example, the recently published Clinical Commissioning Policy for bariatric surgery performed by the United Kingdom National Health Service (NHS) [1] advocates only 2 years of follow up by surgery providers. Self-evidently, this does not encourage continuity of long-term care. This is despite the fact that follow up data 5-10 years after surgery would be very useful to the NHS, facilitating an assessment of the clinical-effectiveness and cost-effectiveness of these procedures.

The 2014 Weight Assessment and Management Clinics (Tier 3) commissioning guidance [2] stipulates that bariatric physicians and GPs should work together to provide care for patients on the basis of a shared-care model of chronic disease management, and submit data annually to the NBSR. This would provide the infrastructure to capture long-term data so that the question *how much weight is lost long-term on an intention-to-treat basis after bariatric surgery in the NHS?* could be answered. There is currently no other means by which these data could be routinely collected.

The NBSR could be a unique tool for collecting vital public health indices for the NHS, and it is an example of data collection initiated by professional bodies without public funding. There is a long way to go before mechanisms to report weight-loss outcomes become as deeply embedded in the NHS infra-structure as are those for cancer patients.

Completeness of the recorded follow up entries; primary operations recorded in the financial years 2011-2013 (n=40,362 follow up entries)



1. NHS Commissioning Board Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. April 2013. Reference: NHSCB/A05/P/a. http://www.england.nhs.uk/wp-content/uploads/2013/04/a05-p-a.pdf

2. Weight assessment and management clinics (tier 3) http://www.bomss.org.uk/wp-content/uploads/2014/04/Commissioning-guide-weight-assessment-and-management-clinics-published.pdf.

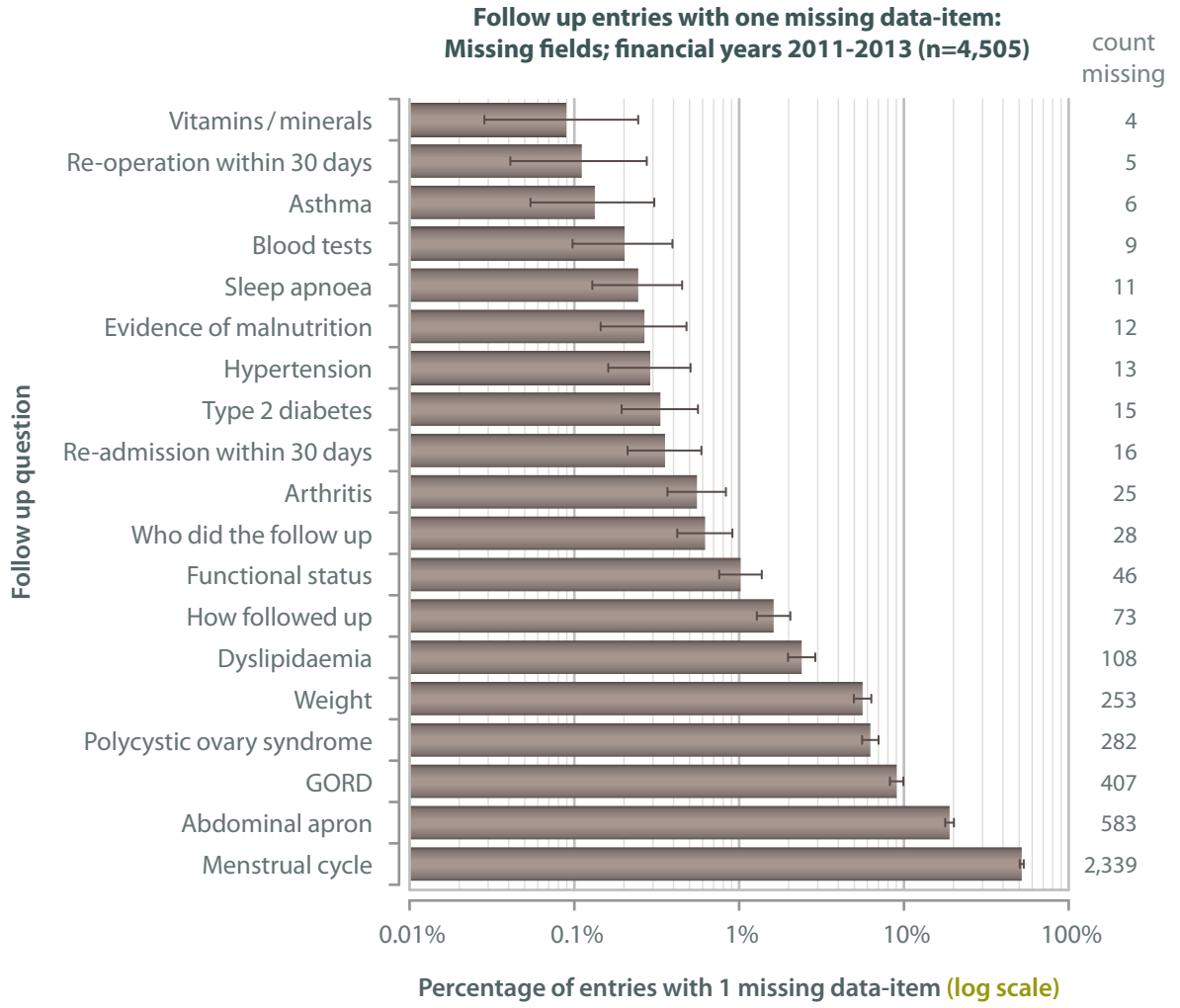
3. Sjöström L. Effects of bariatric surgery on cancer incidence in obese patients in Sweden (Swedish Obese Subjects Study): a prospective, controlled intervention trial. *Lancet Oncology*. 2009; **10**: 653-662.

Bariatric surgery has a powerful preventive effect as far as cancer is concerned [3]. There is a stark contrast between the breadth and depth of the infra-structure that supports surgery to treat cancer, and the relatively meagre resources given to support bariatric surgery, which might help to prevent cancer. There is **no** example of funded follow up after bariatric surgery that extends to anything like 5 years, which is considered the **minimum** timescale over which survival rates should be reported after treatment for cancer.

Over time, analyses of the data in the NBSR will show whether or not the enthusiasts will be able to maintain the momentum behind the registry and continue to enter follow up data on weight and comorbidities for their patients beyond the 3½ year data we have been able to present in this report.

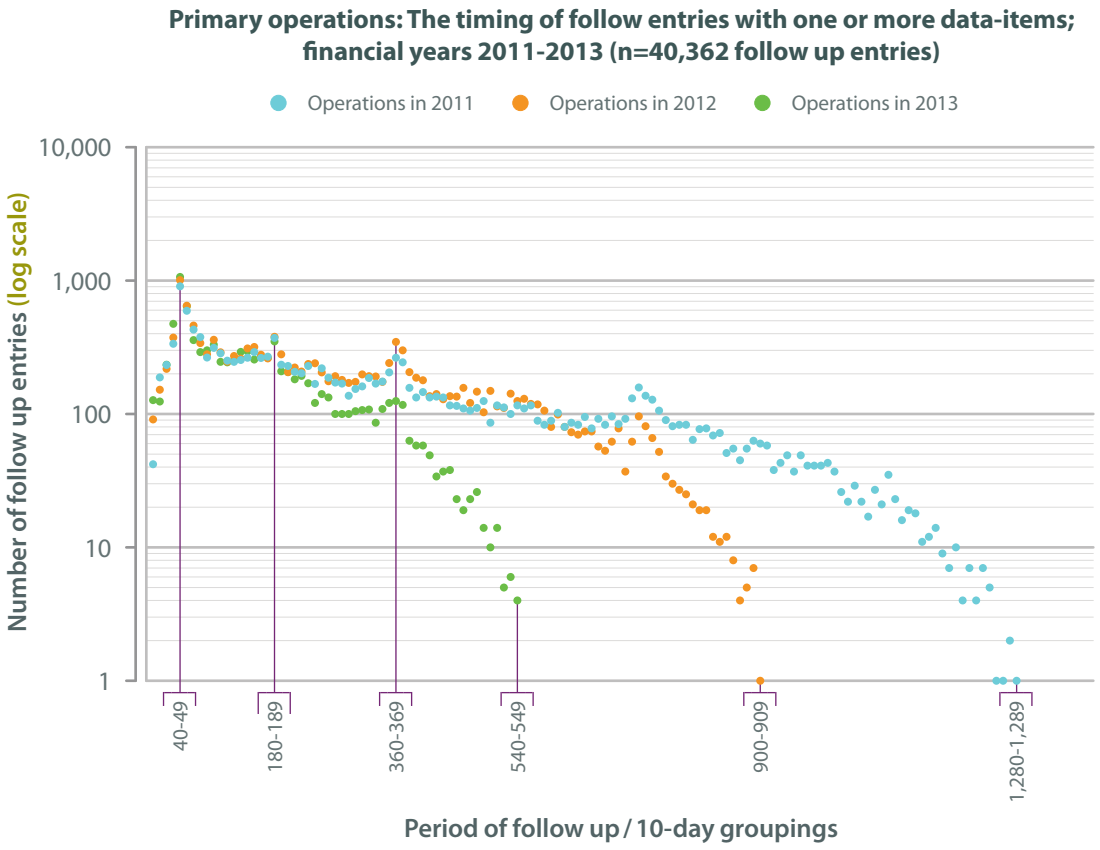
Over 70% of follow up entries into the NBSR were complete, and over 10% of entries lacked only one data-item; this means that 80% of follow up entries had either no missing data or a single data-item missing. These are very encouraging results indicating a high degree of commitment from the contributors, which will facilitate detailed outcome analyses in the future.

The two most commonly missed follow up data-items were menstrual cycle details and abdominal apron symptoms. Both of these items could be seen as being less relevant outcome measures compared to other more functional and / or metabolic issues, hence may be less likely to be asked about by follow up providers.



As one might expect, follow up data were clearly not collected at standardised time periods across bariatric units in the United Kingdom. There were, however, clear peak times for patient reviews at around six weeks (40-49 days), six months (180-189 days) and one year (360-369 days) after the operation. This is not surprising as these are common timings for follow up to occur after many types of surgery.

There appeared to be a rapid drop in the number of follow ups the more distant the time from operation. Some data were still collected beyond 2 years, although not for many patients. For example, for the primary operations performed in the financial year 2011, 30.6% of patients had follow up at 1 year after surgery and 19.0% at 2 years. Operations performed in 2010 could all have 3-year follow up, but only 6% of patients had their weight recorded at 3 years.



These data are very relevant to the NHS setting, and, if recorded, follow up is truly a surrogate for actual follow up, it implies that bariatric units in the NHS do not have the infrastructure yet in place to record their activity. Again, the comparison with the quality of outcomes data in cancer treatment is stark.

Who performed the follow up

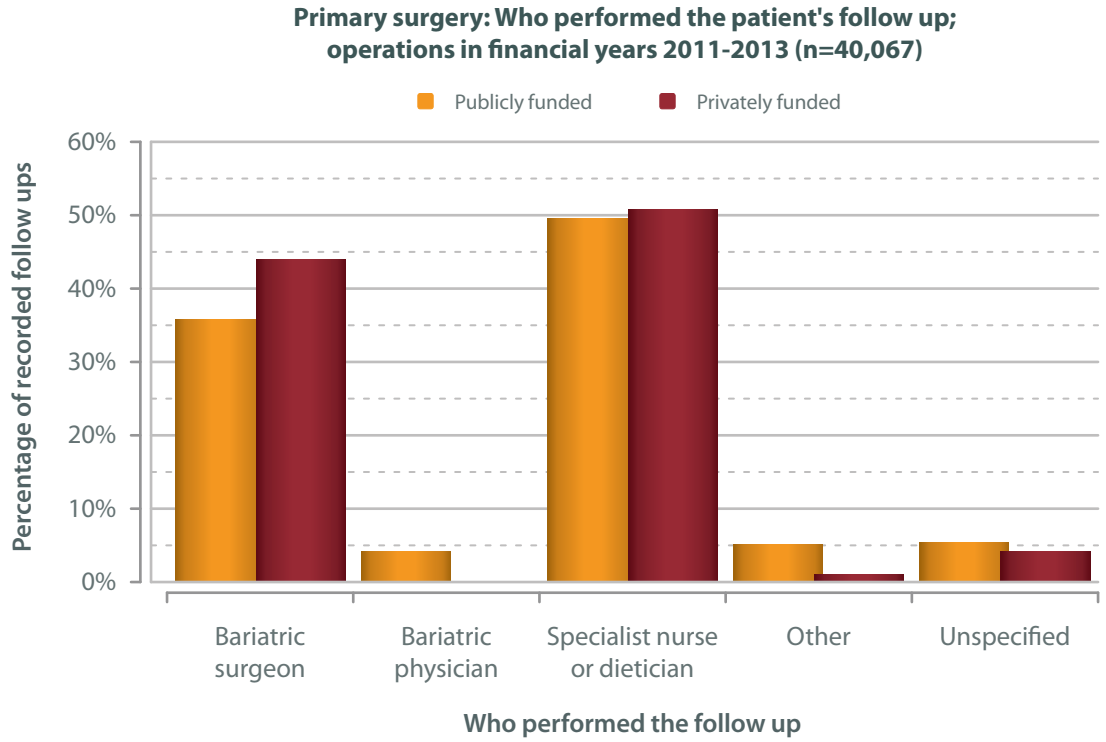
This registry was established by and is maintained by a surgical society. It should be no surprise, then, that most of the follow up entries (91%) originated from surgical clinics conducted by either bariatric surgeons, specialist nurses or dietitians. The small number of follow up entries (3.5%) that resulted from secondary or primary care physician review may also be evidence of a lack of models of follow up care involving such healthcare professionals in the United Kingdom at present.

We note again the importance of processes-of-care evolving so that in a shared care model of chronic disease management, physicians and GPs can work together to submit data annually to the NBSR [1].

Primary operations: who performed the follow up; financial years 2011-2013

		Funding			
		Publicly funded	Privately funded	Unspecified	All
Who performed the follow up	Bariatric surgeon	11,320	3,708	9	**15,037**
	Bariatric physician	1,338	12	1	**1,351**
	Specialist nurse / dietician	15,654	4,279	21	**19,954**
	Other	1,619	83	230	**1,932**
	Unspecified	1,699	355	34	**2,088**
	All	**31,630**	**8,437**	**295**	**40,362**

Counts represent the number of follow up entries



1. Weight assessment and management clinics (tier 3) http://www.bomss.org.uk/wp-content/uploads/2014/04/Commissioning-guide-weight-assessment-and-management-clinics-published.pdf

Excess weight loss

Excess weight loss for the most common operations

The aim of bariatric surgery is to improve the overall health of patients by ameliorating, curing or preventing the development of the many diseases associated with obesity. In this regard weight loss is not a primary aim of surgery. However, weight loss is a convenient and important proxy measure of the effectiveness of surgery.

In order to allow comparisons of the degree of weight loss achieved between patients with differing pre-operative weights, it is common to express weight lost as the percentage of excess weight loss (%EWL; see page 52). The NBSR Committee entirely accepts the limitations of reporting weight loss in this way. Other mechanisms of reporting such as absolute weight loss (kg) or percentage total body weight loss (%) may be preferable. In addition, because of the mathematic variations, the starting weight (kg) should always be stated. As weight is collected as part of the NBSR dataset future reports will allow different ways of reporting these data, as current convention dictates.

The graphs below depict the remarkable success of all three commonly-performed bariatric operations in producing significant and sustained weight loss for up to three years. The degree of excess weight loss was greatest after the Roux-en-Y gastric bypass operation (around 55-70% %EWL), followed by sleeve gastrectomy (55-60% %EWL) and was least after gastric banding (45-55% %EWL). These results are similar to those in the international literature.

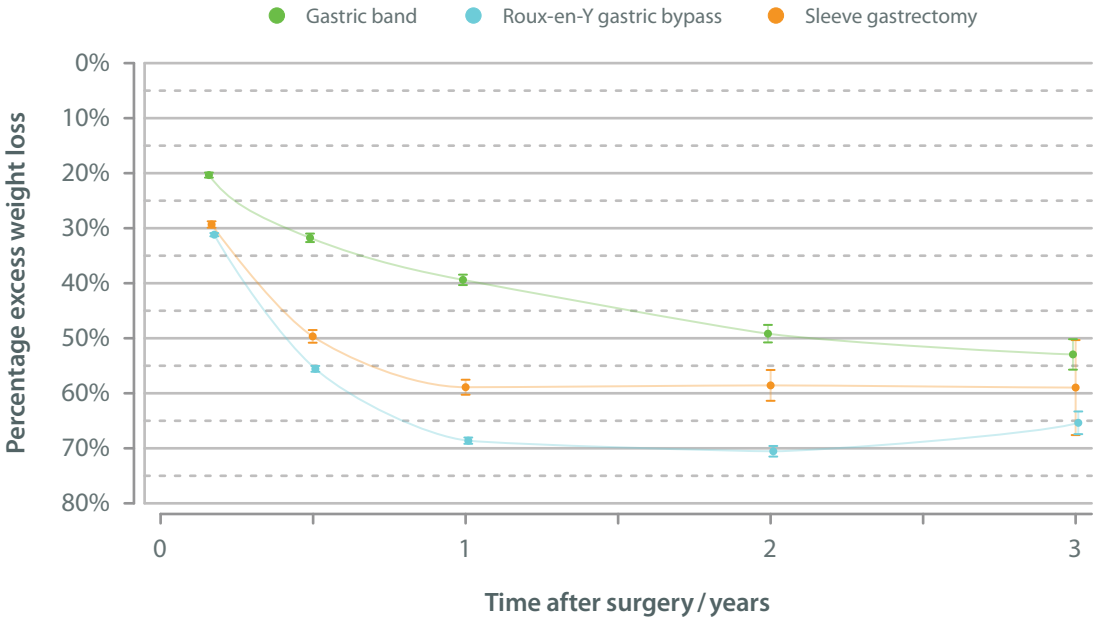
For each kind of operation, on average, men lost less of their excess weight than women; these data are similar to those reported by others. The reason for this difference is unclear, but seems likely to be multi-factoral. For all three common operations, patients with a BMI of less than 50 kg m^{-2} lose more excess weight than those with BMIs greater than 50 kg m^{-2}. This might be seen as evidence in support of a policy of operating on patients at an earlier stage in their disease process.

The last NBSR report detailed weight loss out to 2 years post-surgery; this report is able to report data out beyond 3 years. It is reassuring to see that weight loss was largely sustained over this additional year; indeed, it is interesting to note that for gastric banding weight loss continues up to three years, as would be expected from a review of the published scientific literature on this subject [1,2]. After gastric bypass and sleeve gastrectomy patients' weight loss seemed to plateau one year after the operation, and there was a slight weight regain between two and four years after gastric bypass. As sleeve gastrectomy was only adopted *en masse* more recently in the United Kingdom, the number of patients with follow up exceeding two years is small for this procedure (2%), making assessment of weight loss beyond two years difficult.

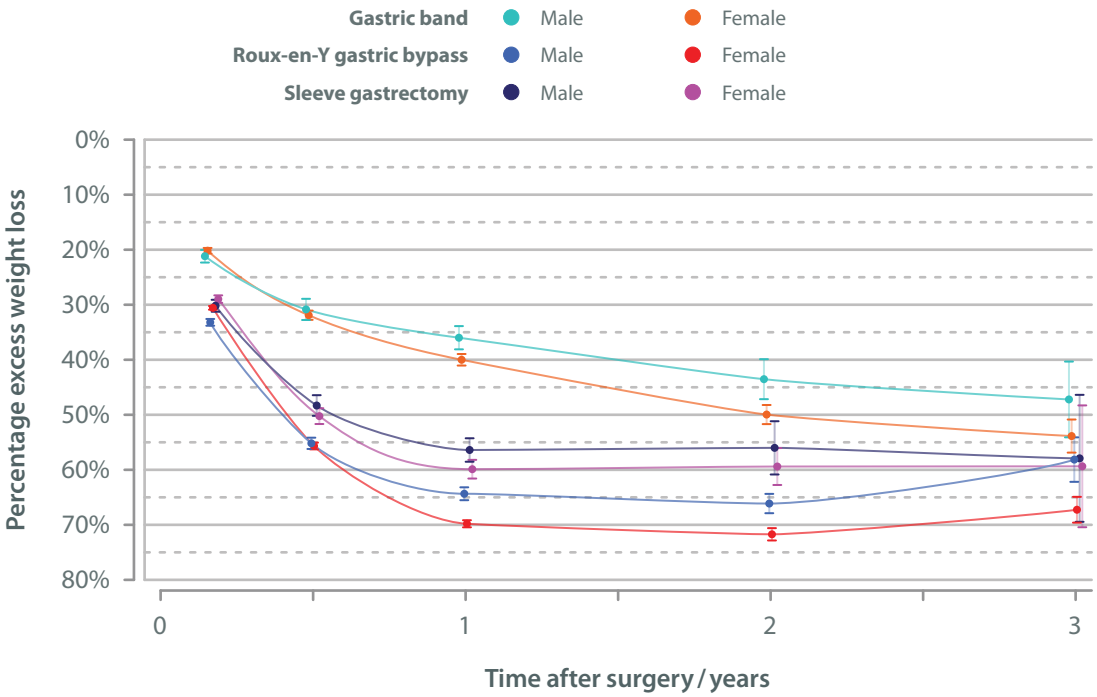
Primary operations: excess weight loss and gender for selected operations; operations in the financial years 2006-2013

			Operation					
			Gastric band		Roux-en-Y gastric bypass		Sleeve gastrectomy	
			EWL (95% CI)	Count	EWL (95% CI)	Count	EWL (95% CI)	Count
Gender & follow up period / months	Male	2	21.2 (1.1)	453	33.2 (0.6)	1,525	30.2 (1.1)	544
		6	30.8 (1.9)	275	55.2 (1.0)	816	48.3 (1.9)	297
		12	36.0 (2.1)	319	64.4 (1.2)	914	56.4 (2.1)	283
		24	43.5 (3.6)	131	66.1 (1.8)	378	56.0 (4.8)	69
		36	47.2 (6.9)	63	58.1 (4.0)	111	57.9 (11.5)	11
	Female	2	20.2 (0.5)	2,360	30.6 (0.3)	4,986	29.0 (0.7)	1,325
		6	31.9 (0.8)	1,574	55.7 (0.6)	2,764	50.2 (1.4)	688
		12	40.0 (1.0)	1,764	69.8 (0.6)	3,264	59.9 (1.7)	716
		24	50.0 (1.7)	935	71.7 (1.1)	1,414	59.4 (3.4)	212
		36	53.9 (3.0)	390	67.3 (2.3)	425	59.4 (11.1)	29

Selected primary operations: Post-operative excess weight loss; operations in financial years 2006-2013



Selected primary operations: Post-operative excess weight loss and gender; operations in financial years 2006-2013



1. O'Brien PE, MacDonald L, Anderson M, Brennan L, Brown WA. Long-Term Outcomes After Bariatric Surgery: Fifteen-Year Follow-Up of Adjustable Gastric Banding and a Systematic Review of the Bariatric Surgical Literature. *Annals of Surgery*. 2013; **257**: 87–94.

2. O'Brien PE, McPhail T, Chaston TB, Dixon JB. Systematic Review of Medium-Term Weight Loss after Bariatric Operations. *Obesity Surgery*. 2006; **16**: 1032-1040.

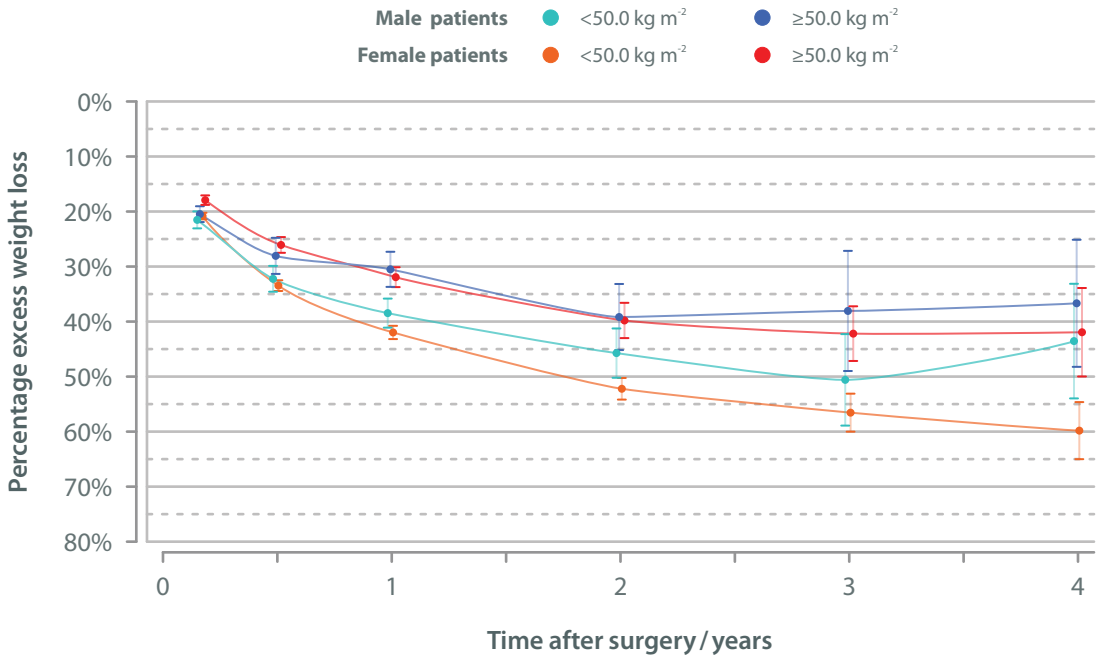
Excess weight loss following gastric band procedures

As noted in the previous report, male patients with higher initial BMI (50 kg m^{-2} or over) tend not to lose as much excess weight as female patients with lower initial BMI (less than 50 kg m^{-2}), although these differences are not significant.

Primary gastric band procedures: excess weight loss, initial BMI and gender; operations in the financial years 2006-2013

Gender & follow up period / months			Initial BMI <50.0 kg m^{-2} EWL (95% CI)	Initial BMI <50.0 kg m^{-2} Count	Initial BMI ≥50.0 kg m^{-2} EWL (95% CI)	Initial BMI ≥50.0 kg m^{-2} Count
	Male	2	21.5 (1.5)	308	20.5 (1.4)	145
		6	32.2 (2.3)	184	28.1 (3.3)	91
		12	38.5 (2.6)	220	30.5 (3.2)	99
		24	45.7 (4.5)	87	39.2 (6.0)	44
		36	50.6 (8.3)	46	38.1 (10.9)	17
		48	43.5 (10.4)	21	36.7 (11.5)	9
	Female	2	20.8 (0.6)	1,836	17.9 (0.9)	524
		6	33.5 (1.0)	1,241	26.1 (1.4)	333
		12	42.0 (1.2)	1,417	31.9 (1.8)	347
		24	52.2 (2.0)	765	39.8 (3.2)	170
		36	56.6 (3.5)	317	42.2 (5.0)	73
		48	59.8 (5.2)	161	41.9 (8.0)	32

Primary gastric band procedures: Post-operative excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



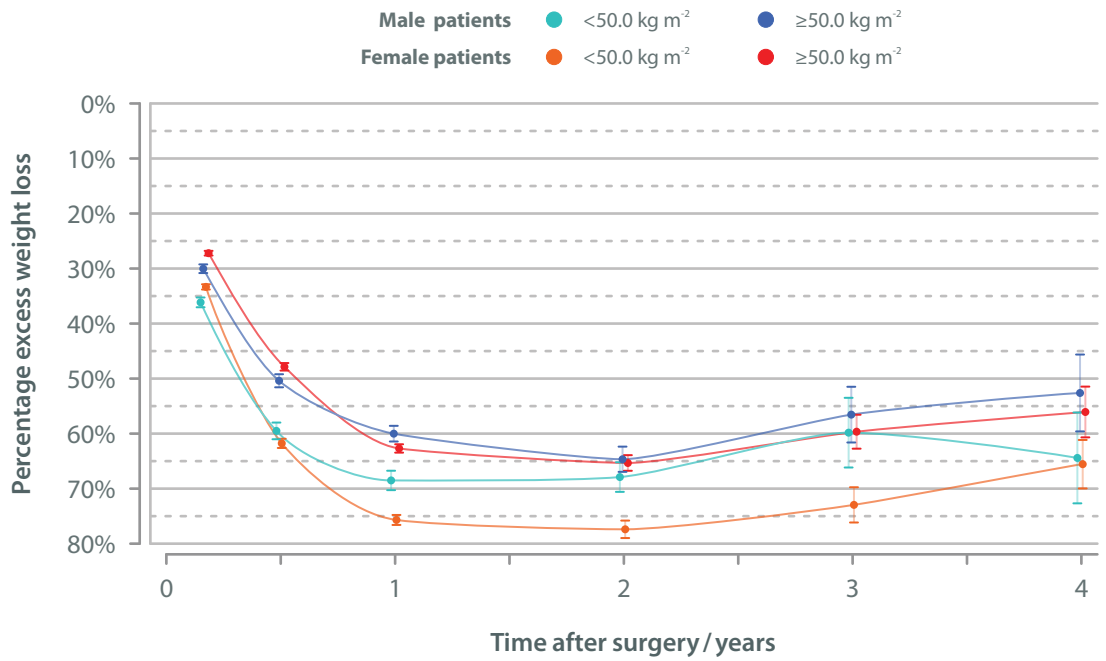
Excess weight loss following Roux-en-Y gastric bypass

Again, the general picture appears to be that male patients with higher initial BMI (50 kg m^{-2} or over) tend not to lose as much excess weight as female patients with lower initial BMI (less than 50 kg m^{-2}), although these differences are not significant. Interestingly, at 3 and 4 years after surgery these patients also appear to be regaining some weight.

Primary Roux-en-Y gastric bypass: excess weight loss, initial BMI and gender; operations in the financial years 2006-2013

Gender & follow up period / months			Initial BMI			
			<50.0kg m^{-2}		≥50.0 kg m^{-2}	
			EWL (95% CI)	Count	EWL (95% CI)	Count
	Male	2	36.1 (0.9)	790	30.0 (0.8)	735
		6	59.5 (1.5)	429	50.4 (1.2)	387
		12	68.5 (1.8)	467	60.0 (1.4)	447
		24	67.9 (2.7)	172	64.7 (2.3)	206
		36	59.8 (6.3)	54	56.6 (5.1)	57
		48	64.4 (8.3)	23	52.6 (7.0)	25
	Female	2	33.3 (0.5)	2,728	27.2 (0.4)	2,258
		6	61.8 (0.8)	1,552	47.9 (0.7)	1,212
		12	75.7 (0.9)	1,786	62.7 (0.8)	1,478
		24	77.4 (1.6)	749	65.3 (1.4)	665
		36	73.0 (3.2)	243	59.7 (3.1)	182
		48	65.6 (4.4)	109	56.1 (4.6)	78

Primary Roux-en-Y gastric bypass: Post-operative excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



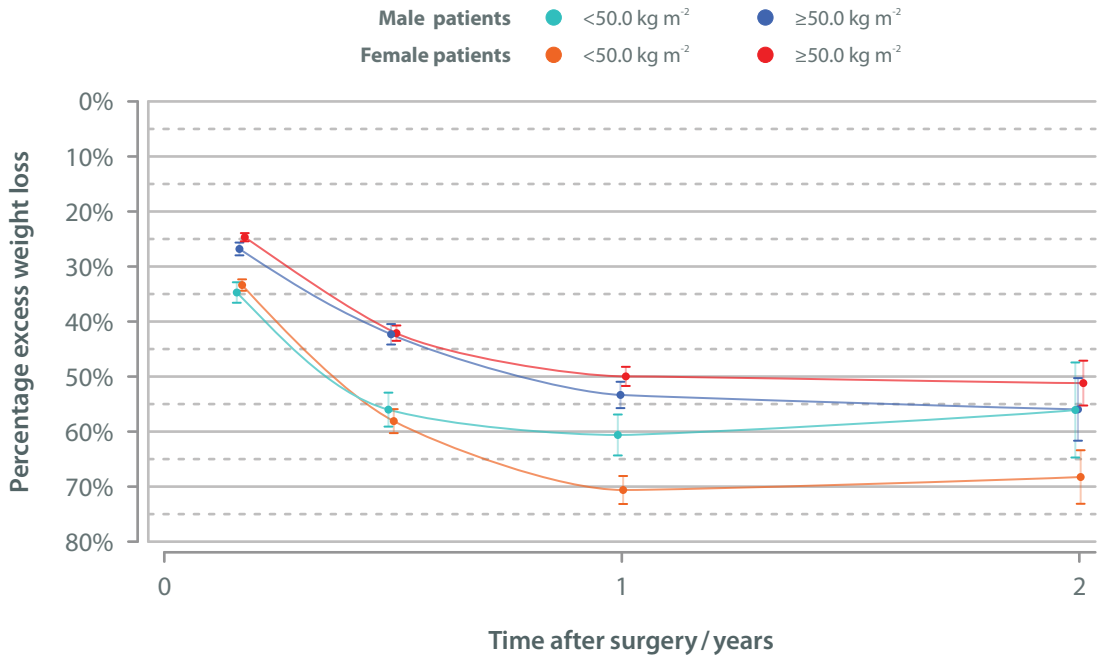
Excess weight loss following sleeve gastrectomy

The excess weight loss one and two years after sleeve gastrectomy appears to be similar to that for patients who have had a gastric bypass; however, as noted above, there are too few patients thus far to show meaningful weight loss data at time periods longer than this.

Primary sleeve gastrectomy: excess weight loss, initial BMI and gender; operations in the financial years 2006-2013

Gender & follow up period / months			Initial BMI			
			<50.0 kg m^{-2}		≥50.0 kg m^{-2}	
			EWL (95% CI)	Count	EWL (95% CI)	Count
	Male	2	34.7 (1.9)	232	26.8 (1.2)	312
		6	56.0 (3.1)	130	42.3 (1.9)	167
		12	60.6 (3.7)	119	53.3 (2.4)	164
		24	56.1 (8.6)	27	56.0 (5.7)	42
	Female	2	33.4 (1.0)	655	24.7 (0.7)	670
		6	58.1 (2.2)	350	42.1 (1.4)	338
		12	70.6 (2.5)	344	50.0 (1.7)	372
		24	68.3 (4.9)	102	51.2 (4.1)	110

Primary sleeve gastrectomy: Post-operative excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



Comorbid disease after surgery

As mentioned on page 138, the aim of bariatric surgery is to improve the overall health of patients by curing, improving or preventing the comorbidities associated with obesity. Hence the rate of resolution of such comorbidities is an important factor to consider when assessing the effectiveness of bariatric surgery.

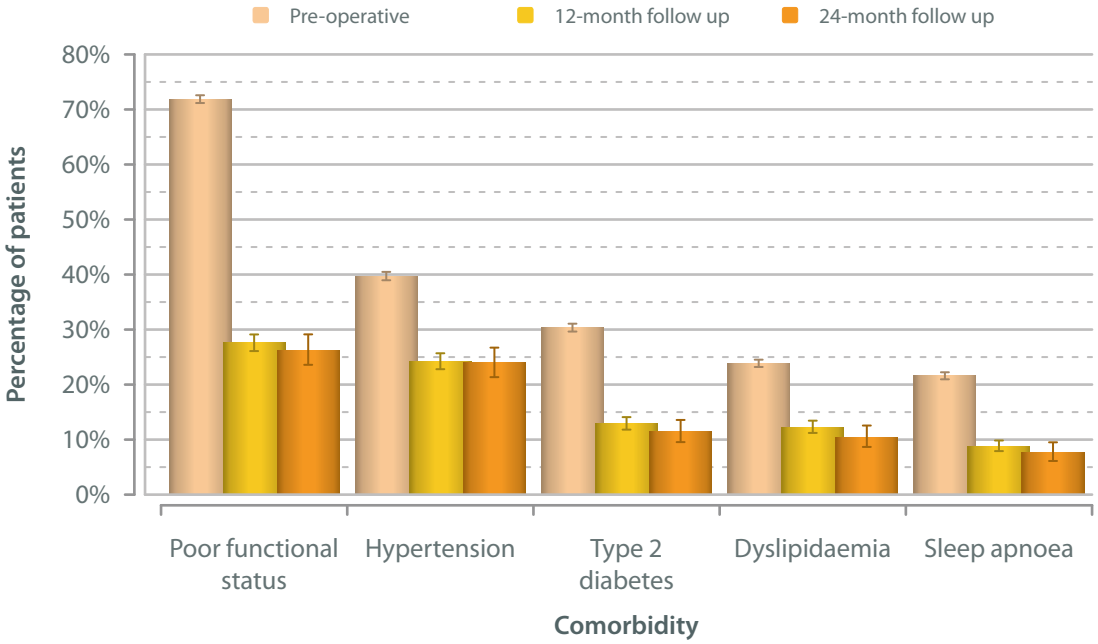
The graphs that follow demonstrate remarkable and statistically significant rates of resolution for all major comorbidities after bariatric surgery. Most cases of resolution occurred within one year of surgery, and resolution rates are maintained or even increase over the second year after surgery. The rates described in this *overview* are for all bariatric operations considered together, individual operation-specific rates of resolution are described in the relevant, operation-specific sections of this report.

Prior to surgery over 70% of men and women had poor functional status; one year after surgery this rate had decreased to under 30%. The NBSR is the only registry we are aware of that records change in functional status over time. There is no other treatment for obesity, or perhaps any other disease, that remotely matches the effects of surgery in terms of providing improvement in functional status for patients.

Other comorbidities also resolved by similarly significant degrees: over 40% of women with high blood pressure had a normal blood pressure one year after surgery (23% resolution for hypertensive men); over 50% of type 2 diabetic men and women experienced resolution within one year; cases of high blood lipid levels also fell by similar amounts within the first year as did the proportion of patients with obstructive sleep apnoea.

The resolution of these life-limiting comorbidities is a remarkable achievement and improves each such patient's quality of life to a large degree. Resolution of these comorbidities also caries very large economic benefits.

Primary operations for all patients:
Comorbid conditions before and after surgery; financial years 2011-2013



Changes in comorbidity rates for female patients

Although there are many missing data points, the overall treatment effect of surgery is such that statistically there is less than a 1 in 1,000 probability that the improvements in these comorbid conditions are due to chance alone.

Primary operations for female patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity				
			Hypertension	Lipids	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	7,926	9,628	3,415	10,273	9,039
		Yes	4,294	2,502	8,560	1,932	3,157
		Unspecified	649	739	894	664	673
		Rate	35.1%	20.6%	71.5%	15.8%	25.9%
	12-month follow up [ii]	No	2,108	2,383	1,904	2,498	2,381
		Yes	547	261	747	153	270
		Unspecified	5,836	5,847	5,840	5,840	5,840
		Rate	20.6%	9.9%	28.2%	5.8%	10.2%
	24-month follow up [iii]	No	625	717	572	750	713
		Yes	162	67	213	37	75
		Unspecified	3,401	3,404	3,403	3,401	3,400
		Rate	20.6%	8.5%	27.1%	4.7%	9.5%
Baseline *versus* 12-month follow up [iv]			<0.001	<0.001	<0.001	<0.001	<0.001
Baseline *versus* 24-month follow up [v]			<0.001	<0.001	<0.001	<0.001	<0.001

i. Pre-operative data.

ii. Data that fall in the period 365 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 365-day point.

iii. Data that fall in the period 730 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 73-day point.

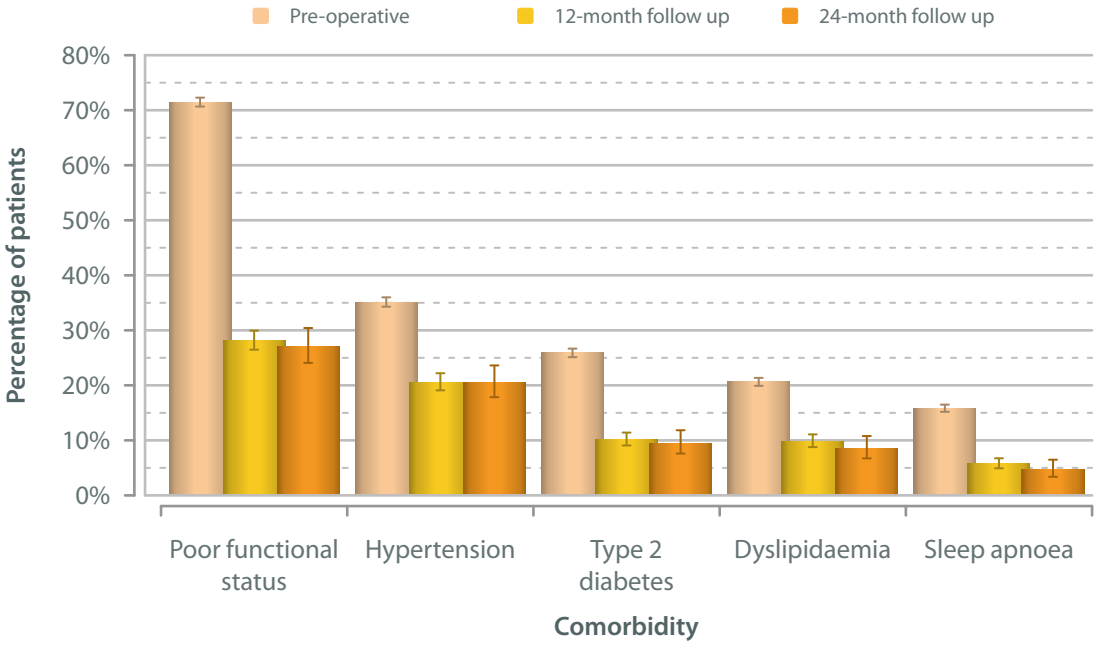
iv. $2 \times 2\ \chi^2$ probability.

v. $2 \times 2\ \chi^2$ probability.

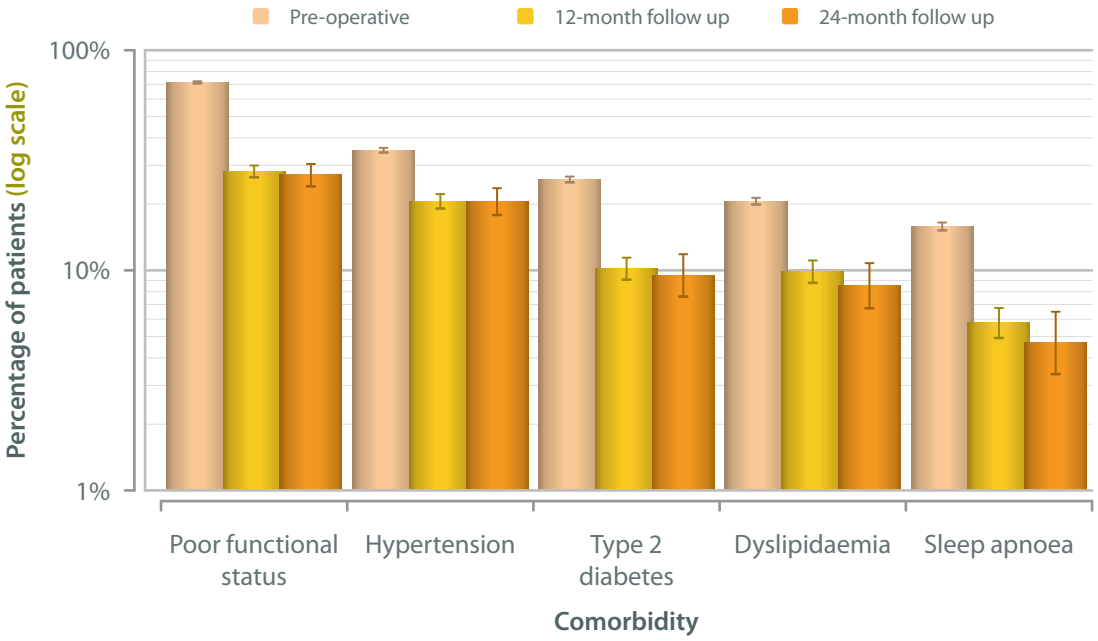
vi. Poor functional status is defined as unable to climb 3 flights of stairs without resting.

This graph shows that the treatment effect of surgery in improving comorbid conditions continues for at least 2 years after surgery.

Primary operations for female patients:
Comorbid conditions before and after surgery; financial years 2011-2013



Primary operations for female patients:
Comorbid conditions before and after surgery; financial years 2011-2013



Changes in comorbidity rates for male patients

Again, the treatment effect of surgery is huge. Although there are many missing data points, the data show that overall there is statistically less than a 1 in 1,000 probability that the improvements in these comorbid conditions is due to chance alone. Surgery improves the patients' comorbid conditions more effectively than any other treatment.

Primary operations for male patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity				
			Hypertension	Lipids	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	1,754	2,497	1,002	2,303	2,123
		Yes	2,084	1,297	2,732	1,531	1,706
		Unspecified	249	293	353	253	258
		Rate	54.3%	34.2%	73.2%	39.9%	44.6%
	12-month follow up [ii]	No	496	616	578	631	608
		Yes	285	159	198	150	173
		Unspecified	1,793	1,799	1,798	1,793	1,793
		Rate	36.5%	20.5%	25.5%	19.2%	22.2%
	24-month follow up [iii]	No	141	182	169	180	180
		Yes	79	38	51	40	40
		Unspecified	978	978	978	978	978
		Rate	35.9%	17.3%	23.2%	18.2%	18.2%
Baseline *versus* 12-month follow up [iv]			<0.001	<0.001	<0.001	<0.001	<0.001
Baseline *versus* 24-month follow up [v]			<0.001	<0.001	<0.001	<0.001	<0.001

i. Pre-operative data.

ii. Data that fall in the period 365 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 365-day point.

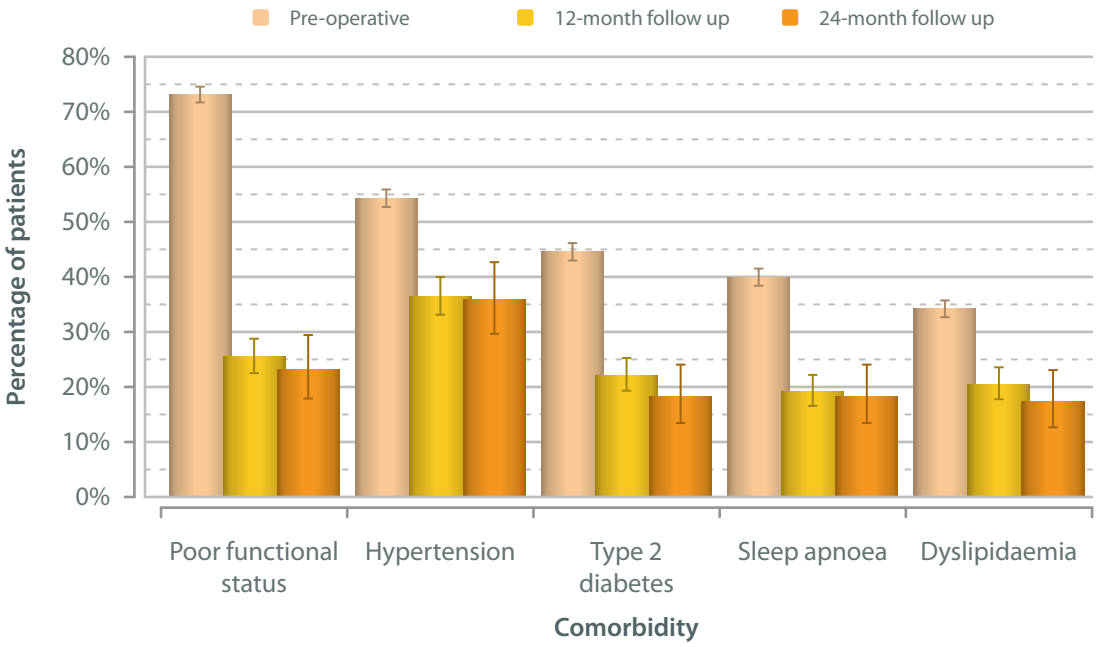
iii. Data that fall in the period 730 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 730-day point.

iv. $2 \times 2\ \chi^2$ probability.

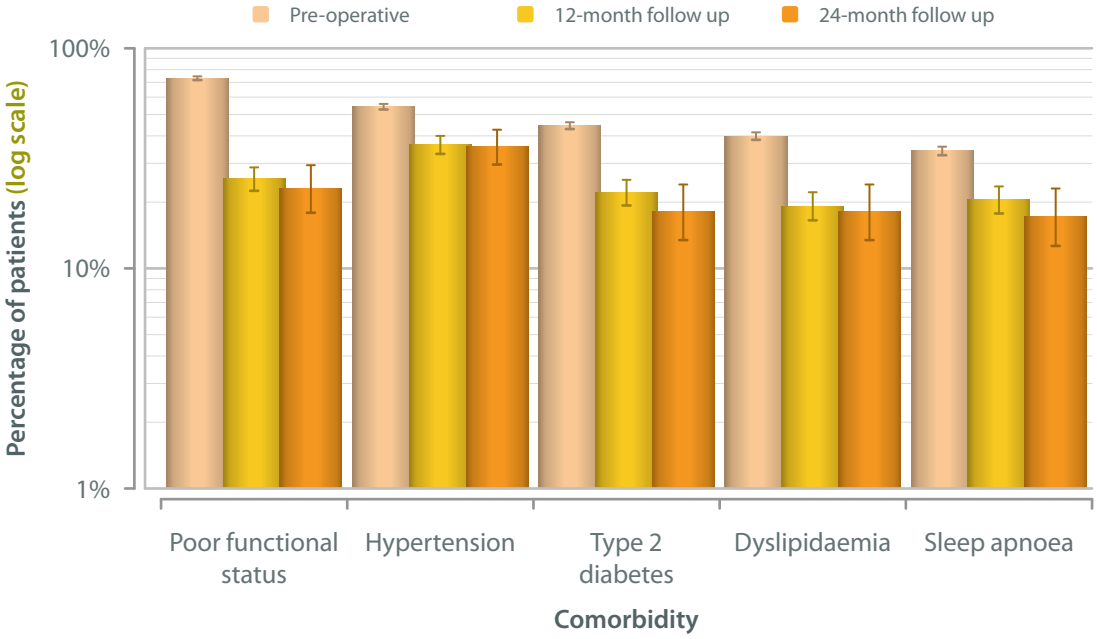
v. $2 \times 2\ \chi^2$ probability.

vi. Poor functional status is defined as unable to climb 3 flights of stairs without resting.

**Primary operations for male patients:
Comorbid conditions before and after surgery; financial years 2011-2013**



**Primary operations for male patients:
Comorbid conditions before and after surgery; financial years 2011-2013**



Changes in functional status

Although the least *medical* of all comorbidities measured, functional status is very important to patients as it contributes greatly to their quality-of-life, employment status and dependence upon carers, *etc.* Over 70% of patients had a decreased functional status pre-operatively; one year after surgery this had dropped to under 26%. This is a remarkable achievement not just for the individual patients, but also for wider society as there will be large economic benefits resulting from these patients' reduced reliance upon State support and return to the workforce.

The degree of decreased functional status can be broken down further into patients who could climb one flight of stairs, half a flight or those who were wheelchair users / housebound. For each such sub-group of patients a large degree of functional improvement was seen: 70.4% of patients pre-operatively limited to 1 flight of stairs could climb three flights at one year post-operation; 85.9% of those limited to half a flight pre-surgery improved post-operatively and 53.8 % of wheelchair or housebound patients saw some improvement in their functional status after their operation.

The functional status of patients in each such sub-group continued to improve up to three years after their operation. Changes in the rates of poor functional status occurred more quickly in patients with less severe obesity (as measured by the Edmonton Obesity Severity Score, EOSS), but even those with the most severe disease (EOSS 4) saw a dramatic improvement.

Primary operations: changes in functional status 12 months after surgery and gender; financial years 2011-2012

			Functional status 12 months after surgery					
			Can climb 3 flights of stairs	Can climb 1 flight of stairs	Can climb half a flight of stairs	Wheelchair user / Housebound	Unspecified	**All**
Gender and pre-operative functional status	**Male**	Can climb 3 flights [i]	187	5	1	0	443	**636**
		Can climb 1 flight [ii]	275	104	8	0	761	**1,148**
		Can climb half a flight [iii]	113	43	17	1	327	**501**
		Housebound [iv]	1	4	2	10	45	**62**
		Unspecified	2	2	1	0	222	**227**
	Female	3 flights	684	25	3	1	1,611	**2,324**
		1 flight	925	374	18	1	2,578	**3,896**
		Half flight	281	168	78	3	908	**1,438**
		Housebound	7	18	18	33	141	**217**
		Unspecified	7	5	0	2	602	**616**

i. Can climb 3 flights of stairs without resting.

ii. Can climb 1 flight of stairs without resting.

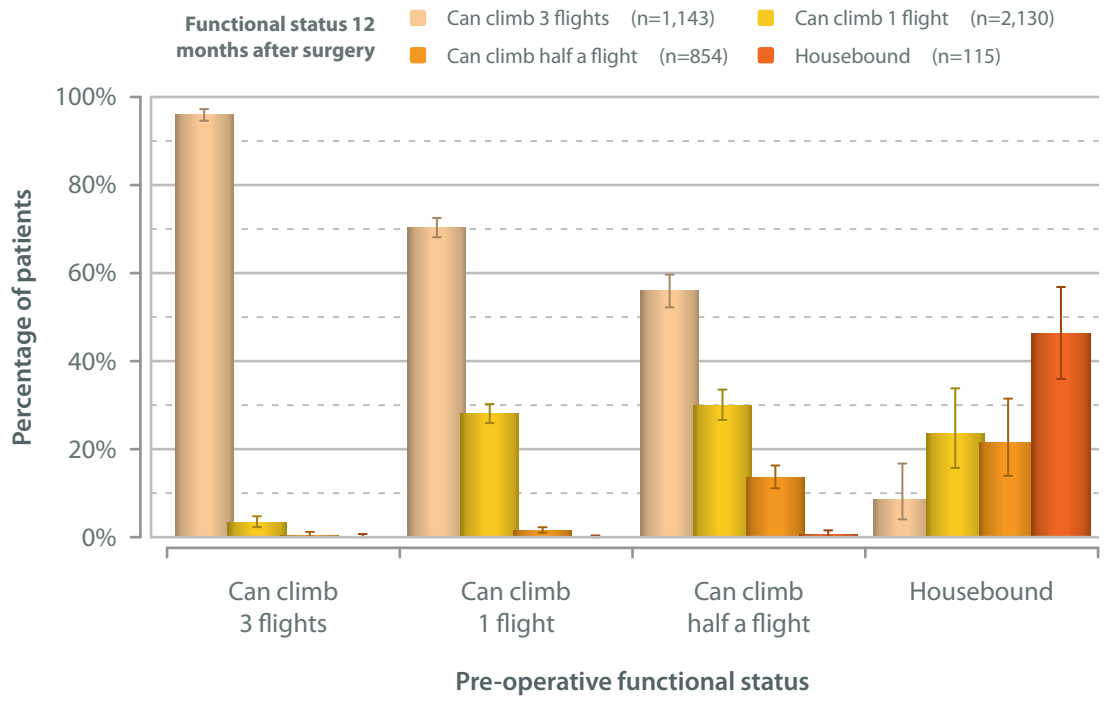
iii. Can climb half a flights of stairs without resting.

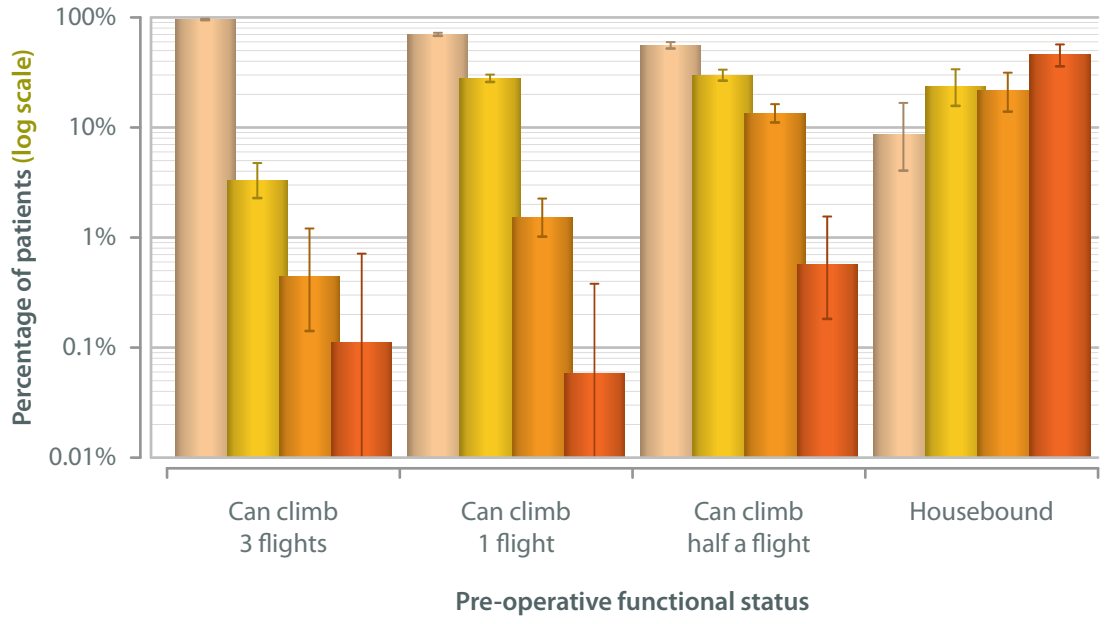
iv. Requires a wheelchair / housebound.

Improvements in functional status have not been studied before on the scale of a national registry. These remarkable data uniquely demonstrate the treatment effect of surgery. There is a *left shift* in the graphs starting with *Can climb 1 flight* and moving across the page to *Housebound*. In each of these graphs it is shown that at one year after surgery patients achieved a more active status, as described above.

In future reports we will be able to analyse whether poor functional status limits the ability of teams to follow up their patients.

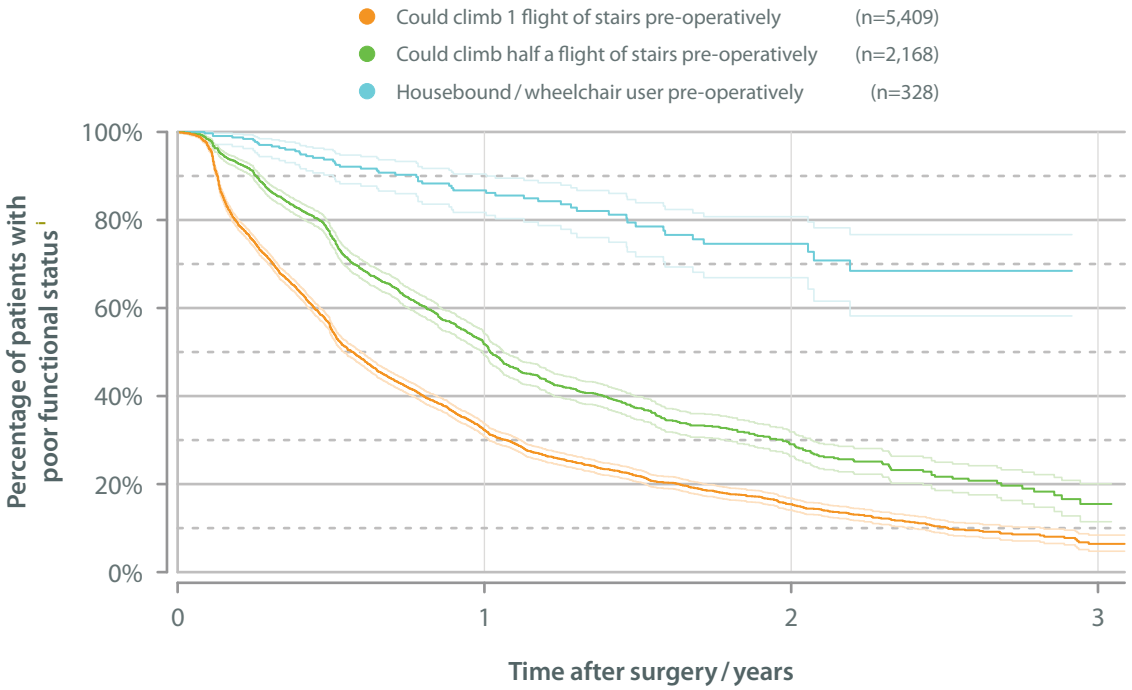
Primary operations: Changes in functional status 12 months after surgery; financial years 2011-2012





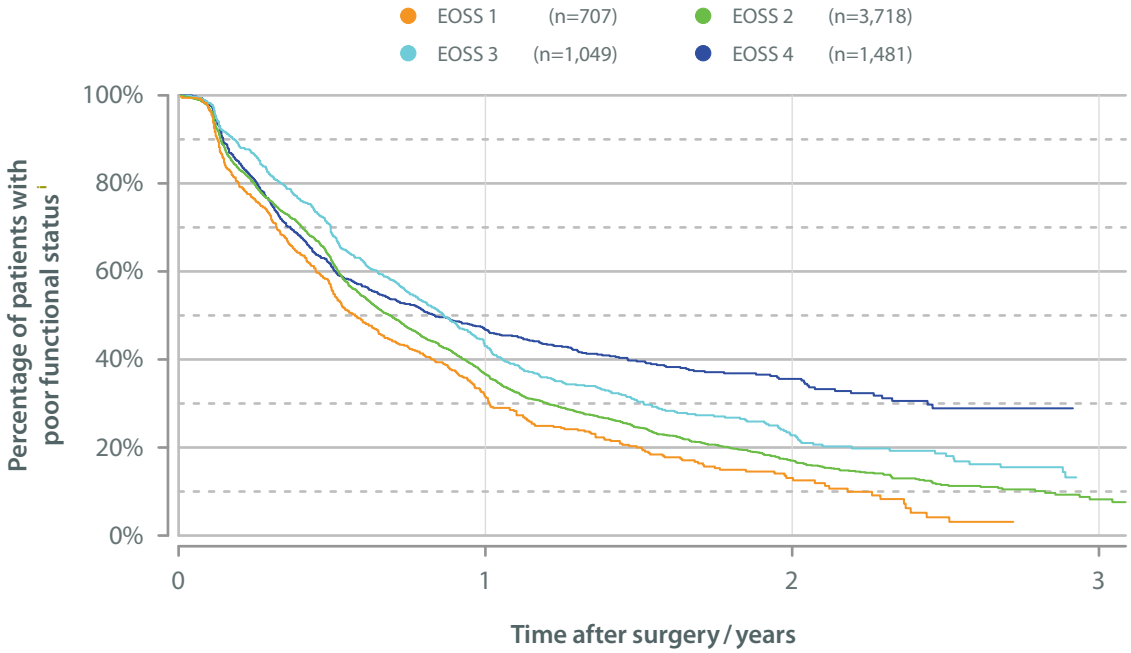
The graph below shows that improvement in functional status continued up to 3 years after surgery. These are remarkable data, again showing the ongoing effect that surgery has on patients at time points after one year.

Primary surgery for patients with poor functional status pre-operatively: Changes in rates of recorded poor functional status [i]; financial years 2011-2013



This graph shows that even the patients with the worst pre-operative comorbid disease status show improvement in functional status that continued beyond 1 and 2 years after surgery. Improvement is most rapid for the patients with the lowest score, *i.e.,* the patients with the lowest level of comorbidity.

Primary surgery for patients with poor functional status pre-operatively: Changes in rates of recorded poor functional status [i]; financial years 2011-2013



i. Poor functional status defined as the inability to climb 3 flights of stairs without resting.

Improvement in diabetes

Type 2 diabetes is a common and significant comorbidity in obese patients. It is expensive to treat and, even with optimum treatment, can result in potentially devastating complications such as myocardial infarctions, stroke, renal failure and peripheral vascular disease. Bariatric surgery has been recognized comparatively recently to be one of the most effective treatments for type 2 diabetes [1]: it is the only treatment with the potential to achieve complete remission / resolution of the condition for significant numbers of patients. In doing so, bariatric surgery can offer significant financial savings to the healthcare economy [2], even when considering the cost of diabetic drugs alone.

The huge cost of treating diabetes has led to much focus on bariatric surgery as an effective treatment. There is good evidence from randomised controlled trials (RCTs) that surgery is superior to medical therapy in improving diabetes control and the metabolic syndrome. Surgery reduces the number of hypoglycaemic medications required, including getting patients off insulin. Simply considering the reduced costs of diabetes treatment, surgery pays for itself within 2-3 years. It also puts many into remission (normal HbA1c, normal fasting glucose, off all medication, relative risk 22.1) and markedly reduces incidence of diabetes compared to matched patients not having surgery. The gastric bypass has been called the equivalent of a *free injection of GLP-1 for life*. The International Diabetes Federation even recommends bariatric surgery as:

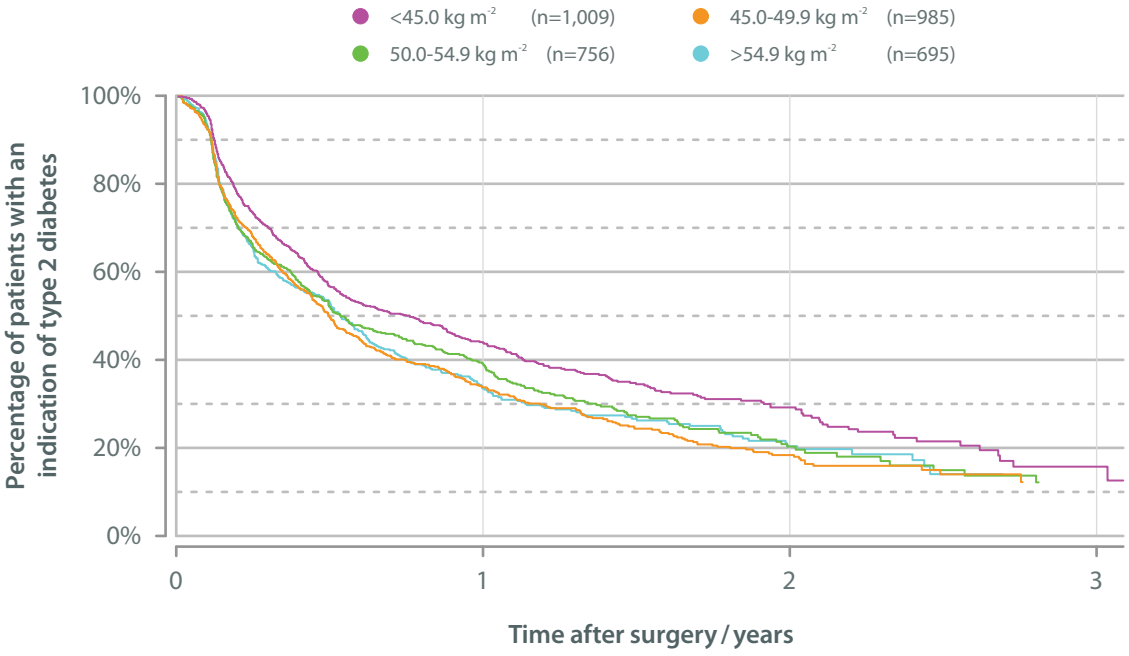
> *… an appropriate treatment for type 2 diabetes and BMI ≥35 not achieving recommended treatment targets with medical therapy, especially where there is other obesity-related comorbidity.*

It is also accepted that the lower BMI threshold for surgery may be reduced by some 2.5 kg m^{-2} for patients from the Asian population, as this ethnic group has a greater susceptibility to diabetes and metabolic syndrome [3-5].

The following charts depict post-operative changes over time in the recorded rates of type 2 diabetes for patients noted to have any clinical indication of diabetes pre-operatively. Each chart demonstrates a substantial and progressive increase in the number of these patients reported as having no clinical indication of diabetes *i.e.,* those noted to be no longer diabetic. At one year post-operation over 60% of previously diabetic patients can be considered to no longer be diabetic, this proportion continues to increase for up to three years. These remarkable results compare well with published results from around the world [6].

Interestingly, the cohort of type 2 diabetic patients with lower pre-surgery BMIs (below 45 kg m^{-2}) have a slower and reduced rate of reversion to a non diabetic state than those with BMIs >45 kg m^{-2} ($p<0.001$; log-rank test). Future NBSR reports will be able to analyse whether this is due to worse diabetes status in those with lower BMIs.

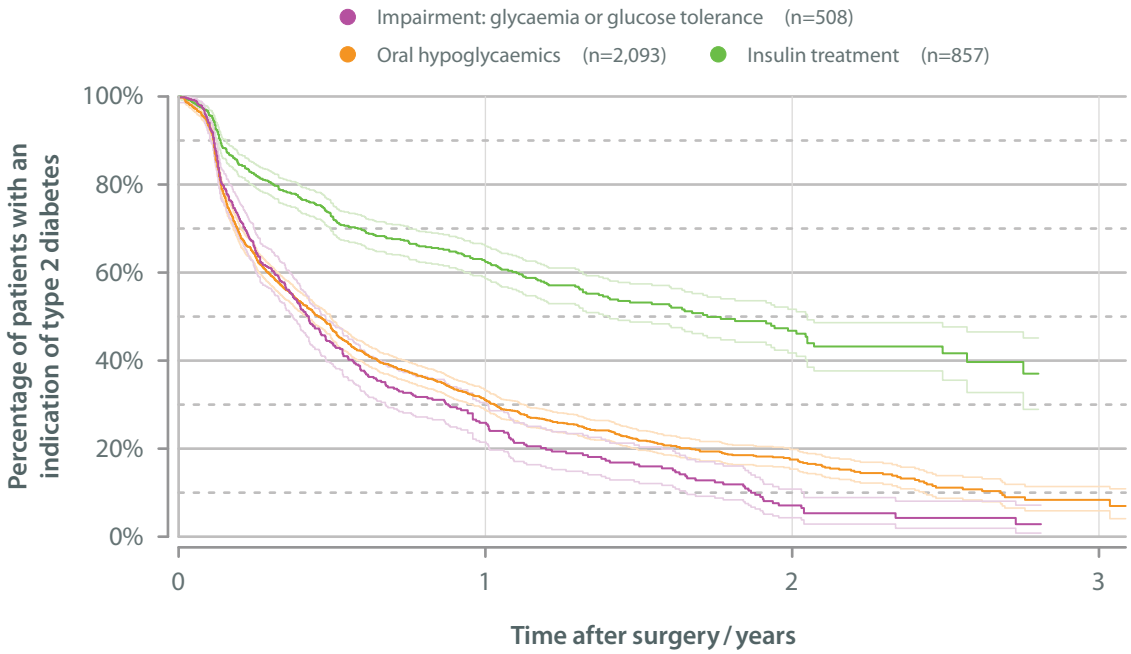
Primary surgery for patients with an indication of diabetes prior to surgery: Changes in rates of recorded diabetes *per* BMI group; financial years 2011-2013



As type 2 diabetes becomes more severe or advanced, the treatment required to control the disease progresses from dietary control (recorded as impairment: glycaemia or glucose tolerance), through oral hypoglycaemics to insulin treatment for the most severely-affected patients. The graph below demonstrates that over a three-year post-operative period the patients requiring insulin before surgery were less likely to revert to a non-diabetic state than patients requiring oral hypoglycaemics ($p<0.001$; long-rank test); this cohort of patients in turn had lower resolution rates than patients treated by diet control alone ($p=0.022$; log-rank test). This has been reported previously [7] and is, perhaps, not surprising, as one might expect any treatment to be less successful the more advanced the condition at the outset.

We believe these are the first data to demonstrate this on the scale of a national *real-world* registry in over 3,000 patients.

Primary surgery for patients with an indication of diabetes prior to surgery: Changes in rates of recorded diabetes *per* type of diabetes group; financial years 2011-2013



1. Schauer PR *et al.* Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes. *New England Journal of Medicine*. 2012; **366(17)**: 1567-1576.

2. Klein S *et al.* Economic Impact of the Clinical Benefits of Bariatric Surgery in Diabetes Patients With BMI ≥35 kg m^{-2}. *Obesity*. 2010; **19(3)**: 581-7.

3. Sjöström L. Review of the key results from the Swedish Obese Subjects (SOS) trial – a prospective controlled intervention study of bariatric surgery. *Journal of Internal Medicine*. 2013; **273**: 219-234.

4. Gloy VL, Briel M, Bhatt DL, Kashyap SR, Schauer PR, Mingrone G *et al.* Bariatric surgery versus non-surgical treatment for obesity. Systematic review and meta-analysis of randomised controlled trials. *BMJ*. 2013; **347**: f5934.

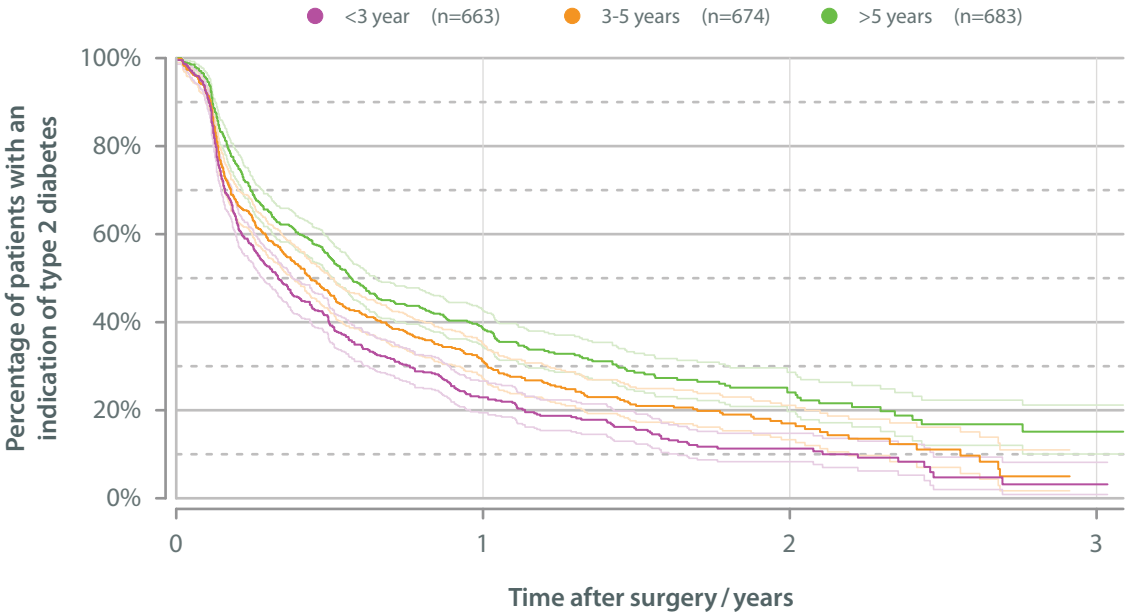
5. Dixon JB, Zimmet P, Alberti KG, Rubino F and on behalf of the International Diabetes Federation Taskforce on Epidemiology and Prevention. Bariatric surgery: an IDF statement for obese Type 2 diabetes. *Diabetic Medicine*. 2011; **28**: 628–642.

6. Buchwald H *et al.* Weight and type 2 diabetes after bariatric surgery: systematic review and meta analysis. *American Journal of Medicine*. 2009; **122(3)**: 248.e5-256.e5.

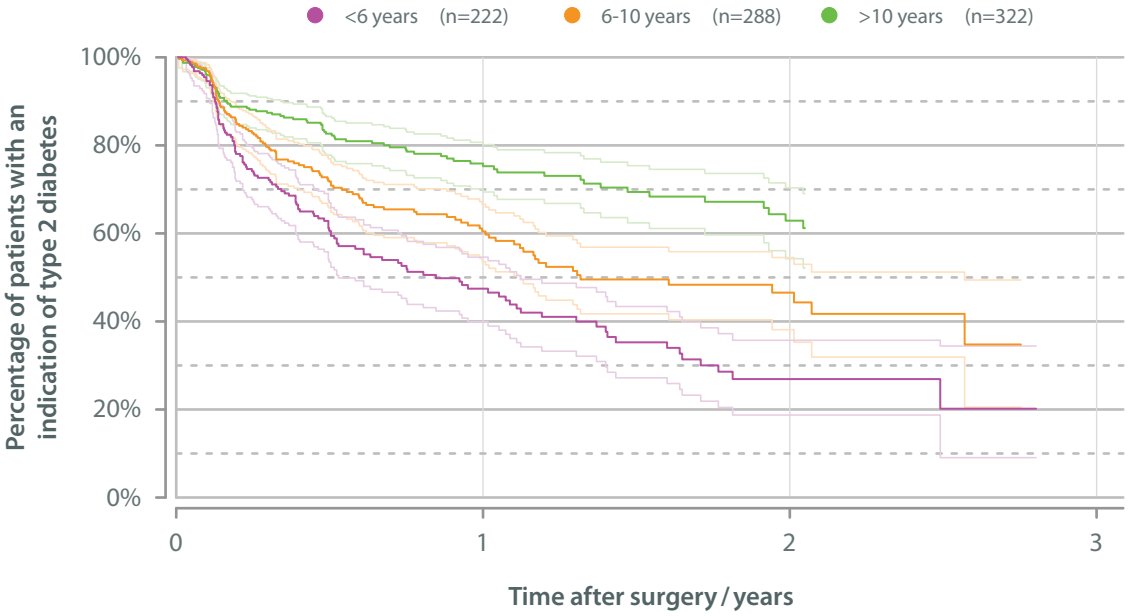
7. Ramos-Levi AM *et al.* Statistical models to predict type 2 diabetes remission after bariatric surgery. *Journal of Diabetes*. 2014; **DOI**: 10.1111 / 1753-0407.12127.

Although not shown here, an analysis of the patients who managed their diabetes using diet control alone showed that their duration of diabetes did not impact on the time to remission of the diabetic state. The two graphs below show that type 2 diabetic patients on pre-operative oral hypoglycaemic treatment and insulin therapy both have a greater likelihood of their diabetes resolving the shorter the duration of their diabetes (hypoglycaemic treatment group: <3 years duration *versus* 3-5 years p=0.002, log-rank test; <3 years *versus* >5 years and 3-5 years *versus* >5 years p<0.001, log-rank test; insulin therapy group: all comparisons different with p<0.001, log-rank test). These are the first data worldwide to demonstrate these changes in such large numbers.

Primary surgery for patients taking oral hypoglycaemics prior to surgery: Changes in rates of recorded diabetes *per* duration of diabetes group; financial years 2011-2013



Primary surgery for patients on insulin therapy prior to surgery: Changes in rates of recorded diabetes *per* duration of diabetes group; financial years 2011-2013

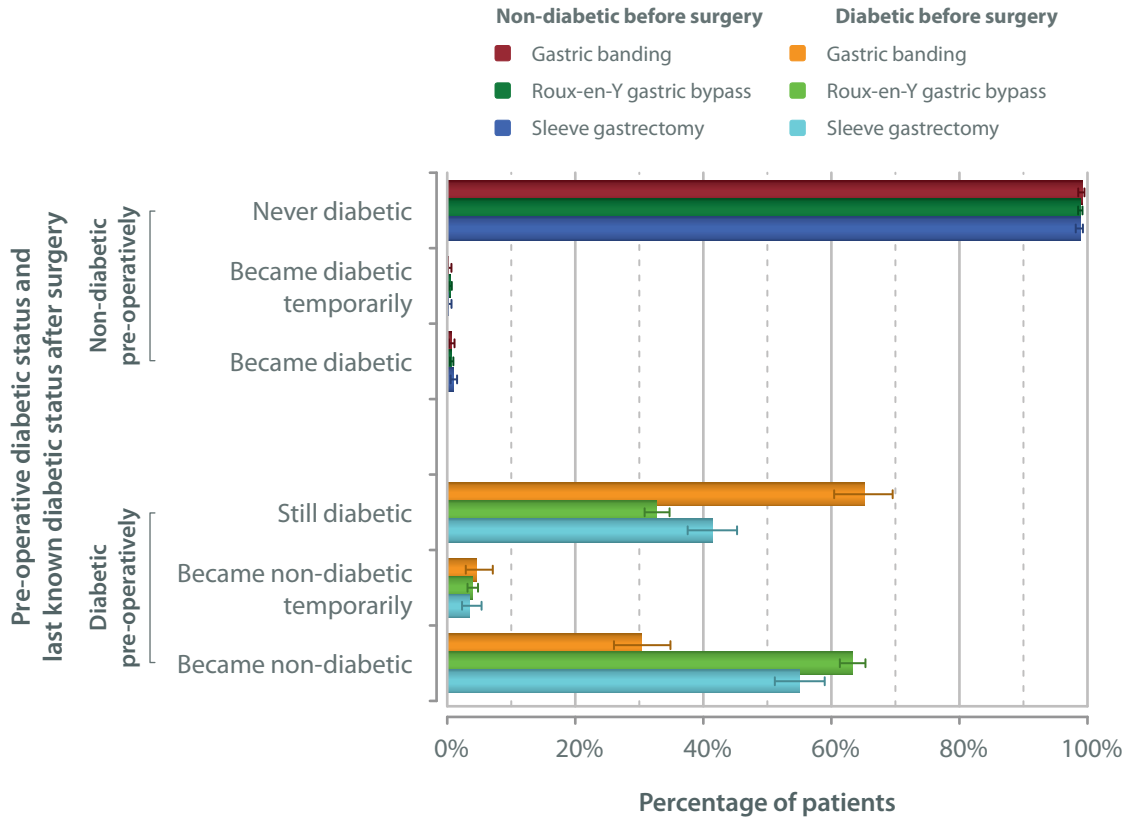


The table and chart below compare post-operative type 2 diabetes resolution rates following the three commonest operations: the gastric bypass operation group were most likely to revert to a non-diabetic state (63.3%), the sleeve gastrectomy group had a 55.1% resolution rate and the group undergoing a gastric band operation were least likely (30.3%) to revert to a non-diabetic state. Similar results have been reported worldwide; however, caution must be used when interpreting these data: in this format they cannot be taken to mean that one operation might be *better* than another. The NBSR data are neither randomised nor matched cohorts, and there are very few published studies that compare the rates of diabetes remission between different operations.

Primary operations: last recorded diabetes data and operation; financial years 2011-2013

			Operation		
			Gastric banding	Roux-en-Y gastric bypass	Sleeve gastrectomy
Diabetic status pre-operatively and at last recorded follow up	No	Never diabetic	1,656	3,878	1,626
		Became diabetic temporarily	4	17	4
		Became diabetic	10	25	15
		Unspecified	1,101	1,657	876
	Yes	Still diabetic	284	746	268
		Became non-diabetic temporarily	20	89	23
		Became non-diabetic	132	1,443	357
		Unspecified	199	850	291

Primary operations: Changes in diabetic status after surgery; financial years 2011-2013 (n=10,597)



Current opinion emphasises that bariatric surgery should be viewed as an adjuvant therapy, which should not be used instead of, but, rather, together with best medical therapy for treating diabetes. In the long- term Swedish Obese Subjects trial it is clear that some patients who were not diabetic before surgery do go on to develop diabetes in future years (although many fewer than in the group that did not have surgery). Future reports will be able to examine the occurrence of *incident diabetes*.

Many clinicians are of the view that remission rates of diabetes may be more dependent upon absolute weight loss, which varies over time between the different operations.

These data demonstrate that type 2 diabetic patients who lost the most weight post-operatively (expressed as a percentage of their pre-operative excess weight) are more likely to experience resolution of their diabetes ($p<0.001$ at each time interval; χ^2-test for trend).

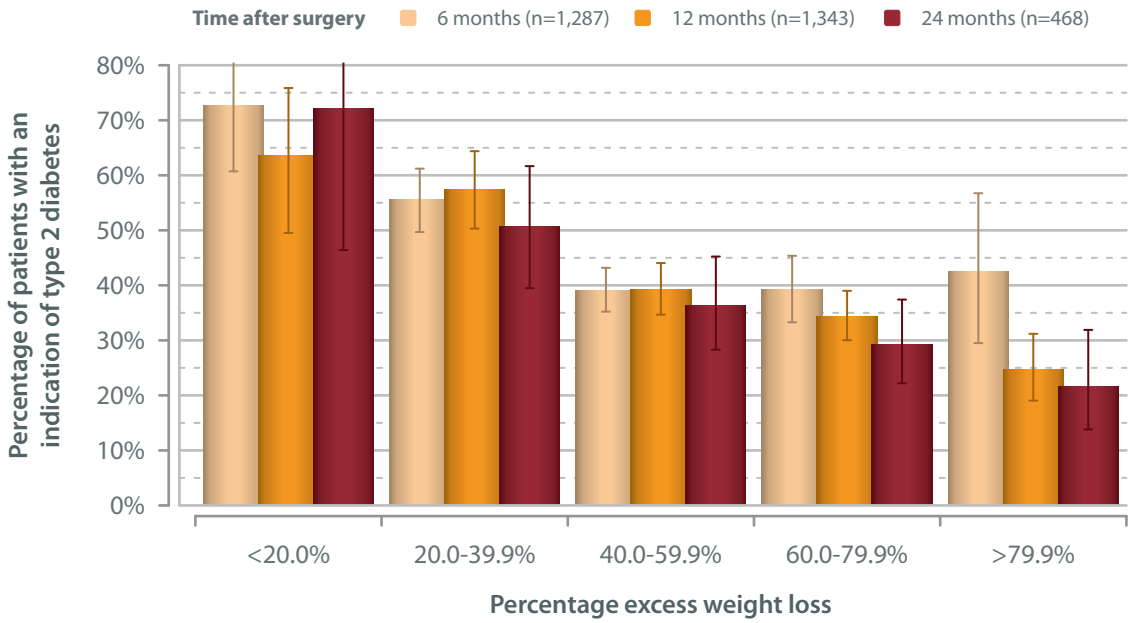
Primary operations for patients with diabetes; financial years 2011-2013

			Diabetic status			
			Non-diabetic	Diabetic	Unspecified	Rate (95% CI)
Time after surgery and percentage excess weight loss	6 months	<20.0	20	53	6	72.6% (60.7-82.1%)
		20.0-39.9	133	166	9	55.5% (49.7-61.2%)
		40.0-59.9	364	234	14	39.1% (35.2-43.2%)
		60.0-79.9	160	103	7	39.2% (33.3-45.4%)
		>79.9	31	23	3	42.6% (29.5-56.7%)
		Unspecified	375	343	2,819	
	12 months	<20.0	20	35	3	63.6% (49.5-75.9%)
		20.0-39.9	85	115	11	57.5% (50.3-64.4%)
		40.0-59.9	263	170	12	39.3% (34.7-44.1%)
		60.0-79.9	294	154	9	34.4% (30.0-39.0%)
		>79.9	156	51	5	24.6% (19.0-31.2%)
		Unspecified	2	4	3,474	
	24 months	<20.0	5	13	0	72.2% (46.4-89.3%)
		20.0-39.9	41	42	6	50.6% (39.5-61.7%)
		40.0-59.9	84	48	2	36.4% (28.3-45.2%)
		60.0-79.9	104	43	3	29.3% (22.2-37.4%)
		>79.9	69	19	1	21.6% (13.8-31.9%)
		Unspecified	5	0	4,378	

This graph indicates that it is weight loss *per* se rather than the time after surgery that is associated with improvement in diabetes. The graph shows the potential of a small dataset to produce influential data from thousands of data entries.

It is important to remember that these data include patients from all 3 of the common operations groups: more work is needed to confirm or refute the observations that weight loss alone could be the important factor in improvement in diabetes.

Primary surgery for patients with an indication of diabetes prior to surgery: Diabetes after surgery and excess weight loss; financial years 2011-2013

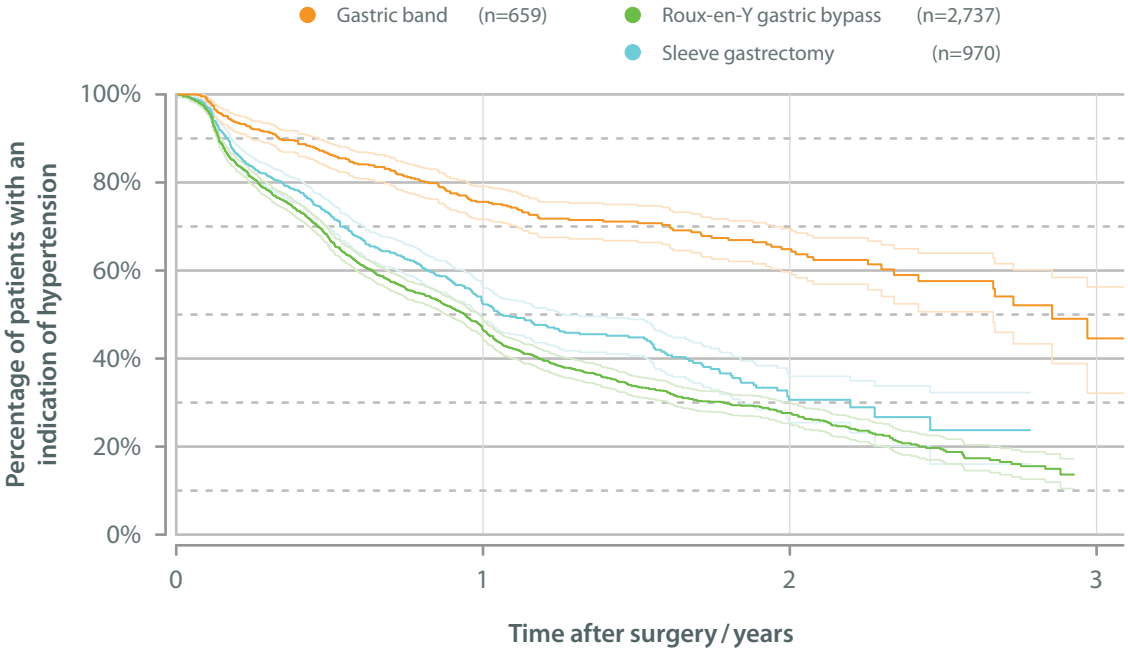


Improvement in hypertension

The graphs below depict a significant and progressive decrease over time in the proportion of pre-operatively hypertensive patients recorded as having hypertension after their operation. Resolution rates were lowest for patients having a gastric band operation. Both gastric bypass and sleeve gastrectomy patients had markedly greater hypertension resolution rates (gastric band *versus* sleeve gastrectomy p<0.001; log-rank test), and gastric bypass had the greatest resolution rate (sleeve gastrectomy *versus* Roux-en-Y gastric bypass; p<0.001; log-rank test).

Bariatric surgery is very effective at reducing the number of anti-hypertensive medications, probably for several years, but the indications are that, over time, as patients get older, they will go back on treatment [1].

Primary surgery for patients with hypertension pre-operatively: Changes in recorded hypertension status and operation; financial years 2011-2013



Reader beware: this chart does not provide evidence that one type of operation is *better* than another. These data are from an observational database, and accurately depict the results from the NBSR, but the patients in each operation group are quite different in terms of their starting weight and their levels of comorbidity.

The only way to determine the relative efficacy of each kind of operation is to do a formal Randomised Controlled Trial (RCT), where the patients in each operation group are matched in terms of their profile (BMI, incidence of comorbid conditions, and so on); such a project is already underway in the United Kingdom (the By-Band RCT) and it will report its findings in the scientific press once the study is complete [2].

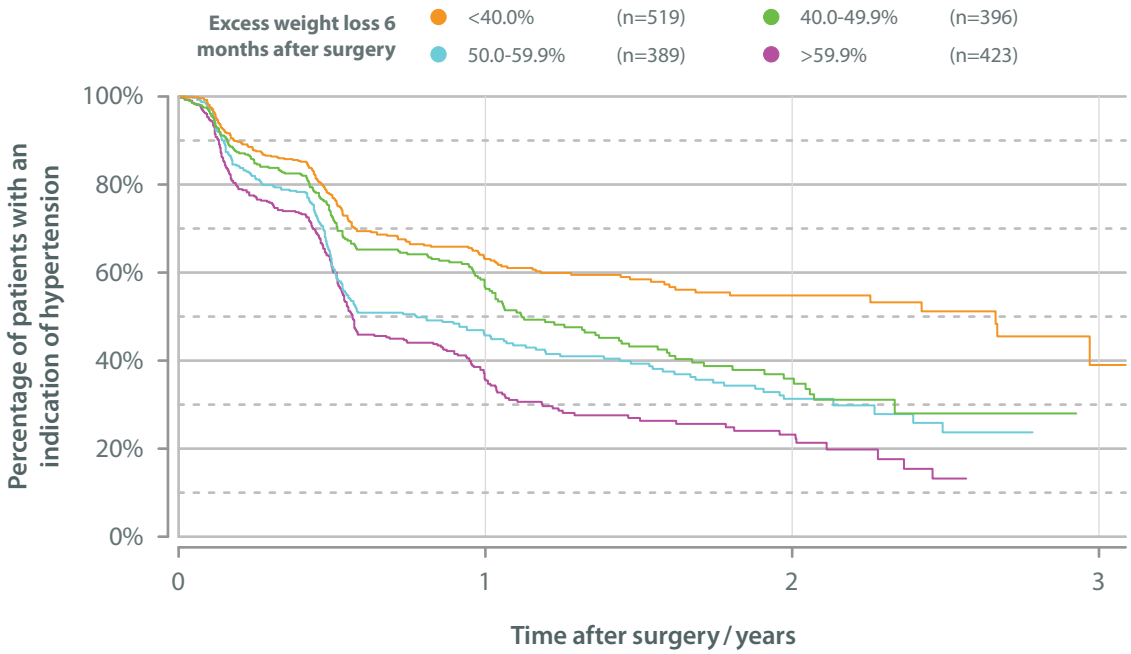
1. Sjostrom l. Review of the key results from the Swedish Obese Subjects (SOS) trial - a prospective controlled intervention study of bariatric surgery. *Journal of Internal Medicine*. 2013; **272**: 219 - 234.

2. Rogers CA, Welbourn R, Byrne J, Donovan JL, Reeves BC, Wordsworth SA et al. The By-Band study: gastric bypass or adjustable gastric band surgery to treat morbid obesity: study protocol for a multi-centre randomised controlled trial with an internal pilot phase. *Trials*. 2014; **15**: 53.

The general pattern of the relationship between the rate of resolution of hypertension and excess weight loss was similar to that reported for resolution of type 2 diabetes: greater post-operative excess weight loss was associated with an elevated rate of resolution. The chart below shows that excess weight loss early after the operation (in this case 6 months) was a good predictor of the rate at which hypertension would go into remission ($p<0.001$ for all comparisons, except 40.0-49.9% %EWL *versus* 50.0-59.9% %EWL, $p=0.019$; and 50.0-59.9% %EWL *versus* >59.9% %EWL, $p=0.010$; log-rank test). As far as we are aware these data have not been demonstrated before.

An analysis of the rates of reported hypertension at 12 months and 24 months after surgery showed that the rates of remission for patients who were previously hypertensive was associated with the percentage excess weight loss at that time (excess weight loss group as *per* analysis of diabetes remission above; $p<0.001$ at each time interval; χ^2-test for trend).

Primary surgery for patients with hypertension pre-operatively: Changes in recorded hypertension status and weight loss at 6 months; financial years 2011-2013



Gastric banding

Clinical quality registers provide one of the best methods for improving safety and quality of healthcare. Key measures for bariatric surgical registers are morbidity and mortality, weight and health outcomes, technical failures of devices, revisions and reversals. Ideally, the database includes all possible participants and events.

The NBSR continues to move towards this aspiration with the percentage participation improving, but the completeness of reporting by each participant is not validated. Without an independent source, such as parallel but separate hospital reporting for identifying events, key outcomes, such as death or major complications, can be missed. Definitions of comorbidities must be according to explicit and accepted standards. The name, model and serial number of all devices, such as gastric bands or stapling instruments, must be recorded and studied in relation to revisional surgery events.

With the above provisos, the data on gastric banding are impressive when compared to published data. Data on 4,075 gastric banding procedures are available for 2011-2013. There have been no deaths and a mere 0.8% complication rate in the first thirty days after surgery. Weight loss at three years after primary band placement is 54% EWL. These figures are equal to best experience worldwide. In the hands of the United Kingdom bariatric surgeon, the gastric band is shown to be a safe and effective weight-loss treatment.

Revisional surgery rates appear low. Leaving out the *legacy* patients first treated prior to 2011, there are just 142 revisions for 3,633 patients, a rate of 3.9%. This is lower than I can achieve and, if accurate, is a credit to the surgery and to the aftercare. These outcomes do not occur without optimal adjustments of the band and instruction on correct eating. Data on device failures or absence of any failures should be explicitly stated.

Notably, 47% of gastric band patients during 2011-2013 were treated privately compared to 15% of bypass and 23% of sleeve patients. The difference is significant, but the reasons are speculative.

Interpretation of the comorbidity data is difficult in the absence of explicit criteria for each diagnosis and some reassurance of its correct application. Certainly, the pre-operative rates of some comorbidities are not quite what we would expect. Nevertheless, overall, a clear health benefit with weight loss is present.

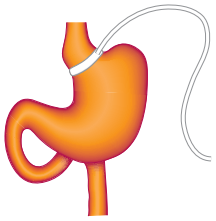
This beautifully-produced report provides copious analyses of data on the gastric band and the other procedures. It is a truly comprehensive document with an exhaustive set of analyses. In due course I would like to see data that focus on the key measures with a high level of integrity.

Paul O'Brien

Emeritus Professor of Surgery, Emeritus Director,

Centre for Obesity Research & Education, Monash University, Melbourne, Australia

The procedure



A gastric band is an adjustable band placed around the stomach, just below the oesophago-gastric junction. The gastric band restricts the passage of textured foods, and is thought to enhance satiety signalling. A balloon on the inside surface of the band can be inflated or deflated by injecting liquid into a chamber placed under the skin, which connects to the band balloon *via* tubing.

This is a simple ambulatory procedure, and is used to adjust restriction and thereby produce gentle weight loss. The following section details the data for this procedure that have been entered in the NBSR.

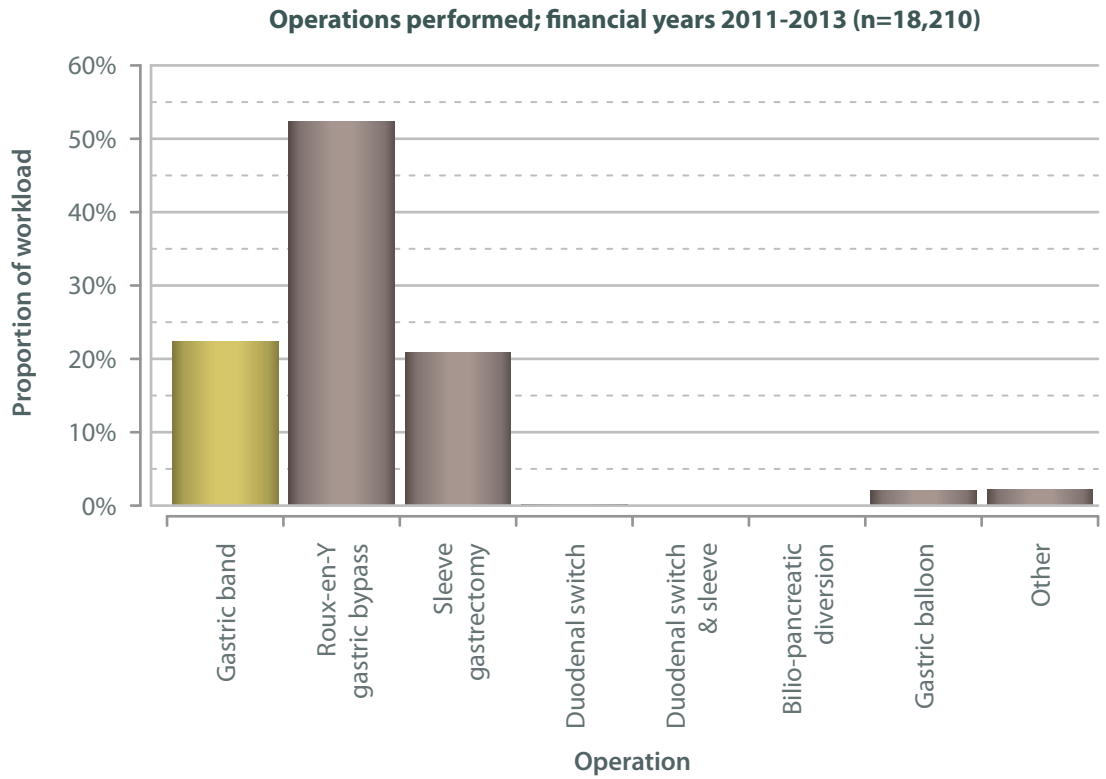
Number of entries in the context of the database

The table below shows that gastric banding is now (almost exactly) level-pegging with sleeve gastrectomy as the joint second most common bariatric surgical procedure performed in the United Kingdom, although this procedure has the highest proportion of revisions.

Type of operation performed; financial years 2011-2013

		Type of surgery					
		Primary	Revision as a primary	Revision	Planned 2nd stage	Unspecified	All
Operation	Gastric band	3,633	295	142	5	0	**4,075**
	Roux-en-Y gastric bypass	9,133	267	86	40	0	**9,526**
	Sleeve gastrectomy	3,631	80	32	54	0	**3,797**
	Duodenal switch	0	7	1	11	0	**19**
	Duodenal switch & sleeve	11	0	0	1	0	**12**
	Bilio-pancreatic diversion	0	5	0	0	0	**5**
	Gastric balloon	294	0	3	89	0	**386**
	Other	181	106	79	24	0	**390**
	Unspecified	73	0	0	0	0	**73**
	All	**16,956**	**760**	**343**	**224**	**0**	**18,283**

As a proportion of all bariatric procedures recorded in the NBSR, the proportion of operations that were gastric banding has fallen year on year over at least the last nine years (see page 68).



Patient profiles

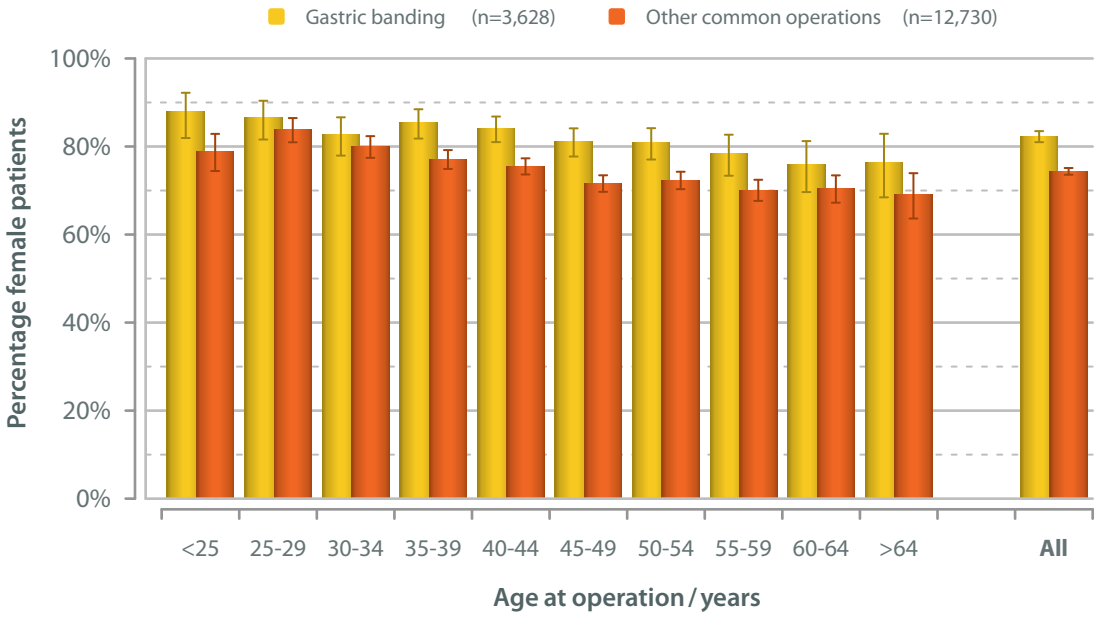
Age and gender

The average age for a female patient undergoing a primary gastric banding procedure was 43.8 years (n=2,984; SE= 0.21 years) , and for a male patient was 46.2 years (n=644; SE= 0.45 years). Notably, over 82% of all gastric banding procedures were performed for female patients.

Primary operations: age and gender distribution for gastric banding *versus* other common procedures; financial years 2011-2013

		Procedure group and gender			
		Gastric banding		Other common procedures [i]	
		Male	Female	Male	Female
Age at operation / years	<25	21	153	80	300
	25-29	34	219	116	604
	30-34	54	258	210	840
	35-39	67	393	349	1,176
	40-44	102	540	528	1,629
	45-49	114	490	642	1,620
	50-54	95	401	557	1,456
	55-59	69	250	430	1,008
	60-64	54	170	254	605
	>64	34	110	101	225
	Unspecified	0	5	6	28
	All	**644**	**2,989**	**3,273**	**9,491**

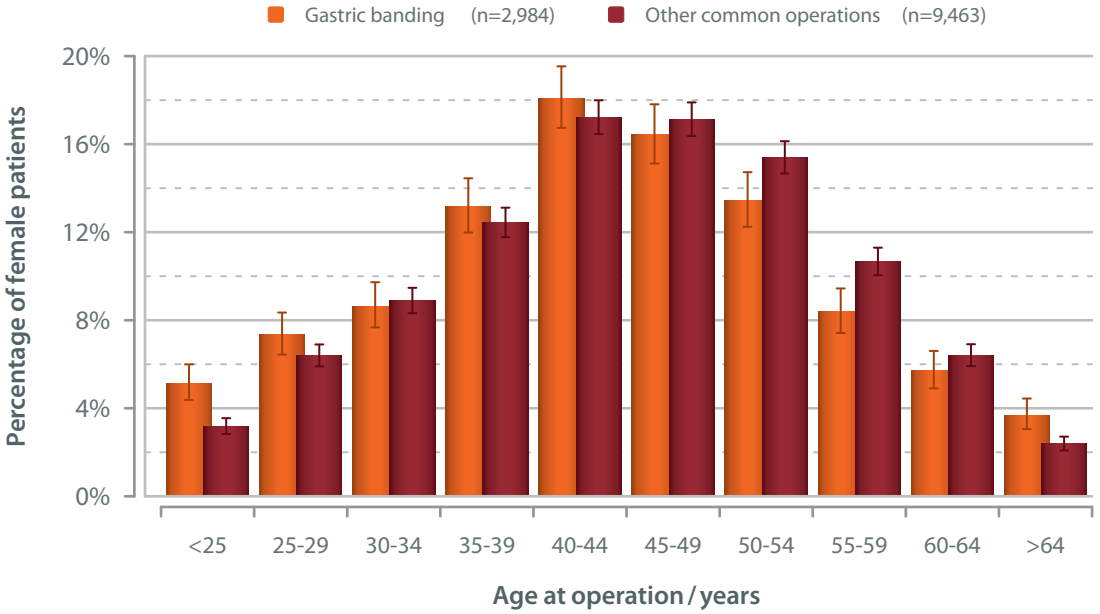
Primary operations: Age and gender; financial years 2011-2013



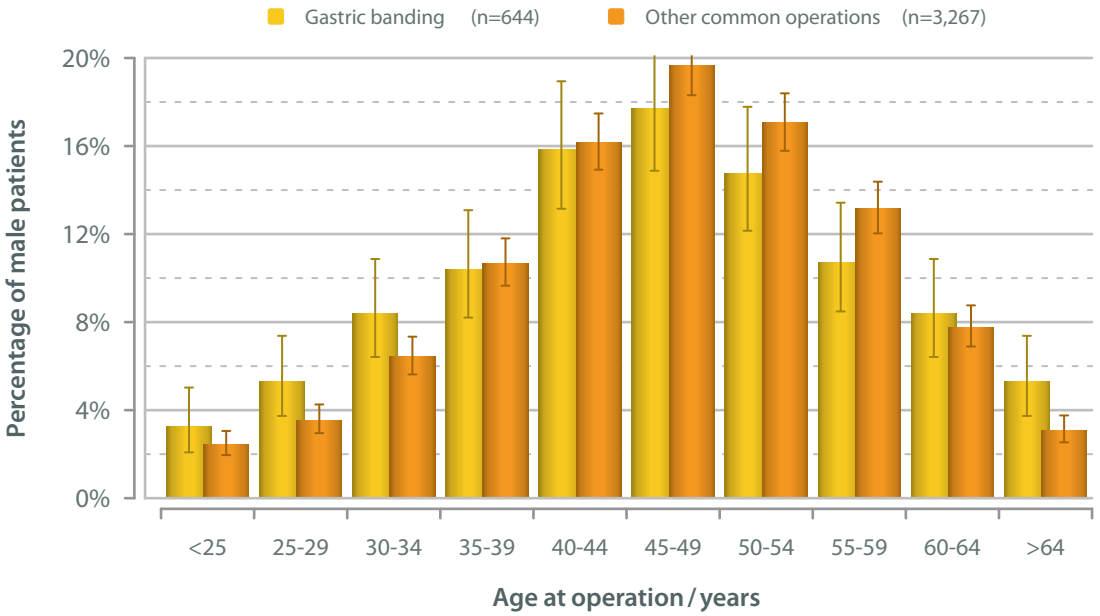
i. Roux-en-Y gastric bypass and sleeve gastrectomy.

The graphs below show the patterns of age distributions for men and women, comparing the patient-populations having gastric banding to those having one of the other two common bariatric procedures. They show that, for both men and women, there is a *leftward shift* in the distribution for the gastric banding patient population compared to the other group, which means that, on the whole, patients who had a gastric banding procedure were younger.

Primary operations for women: Age distributions; financial years 2011-2013



Primary operations for men: Age distributions; financial years 2011-2013



Source of funding

As highlighted in the previous NBSR report, there was a much greater proportion of patients who funded their own surgery in the lower BMI brackets, irrespective of the kind of operation. As BMI increased, operations were more and more likely to have been publicly funded.

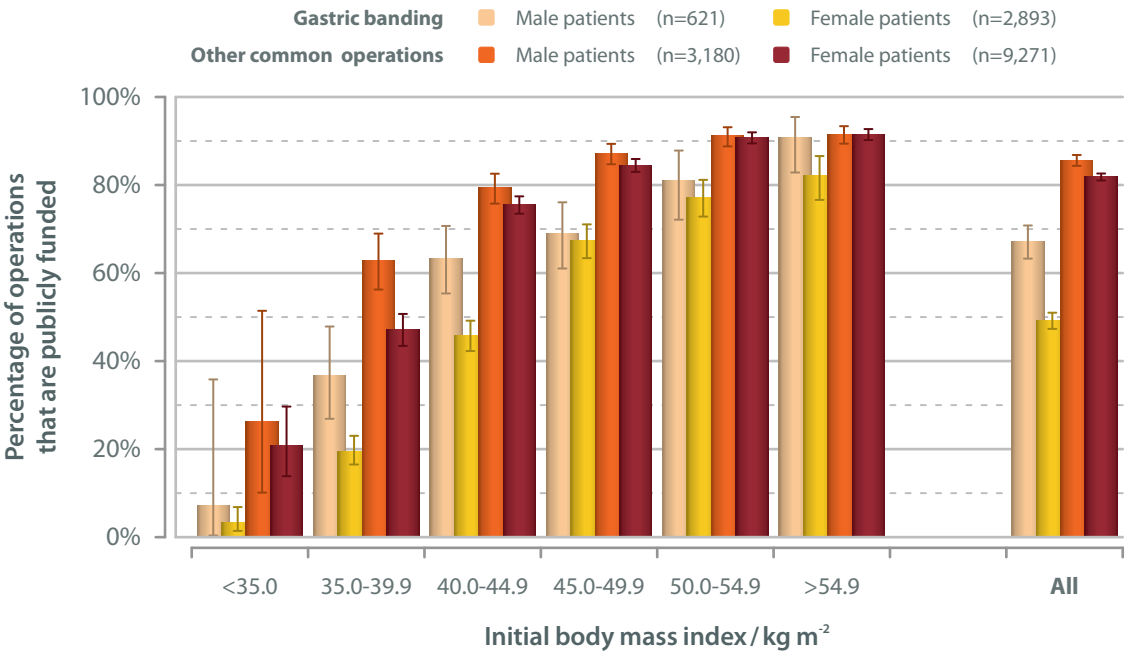
Perhaps this is a reflection of restricted access to surgery for patients with a BMI of <40.0 kg m^{-2}, despite the proven benefits that bariatric surgery would provide. These patients may feel pressured to fund their own treatment.

It also seems that women were much more likely to chose to fund their treatment than men of the same BMI, and the reasons for this are not entirely clear. This gender difference was particularly apparent for the group of patients who had a gastric banding operation.

Primary operations: source of funding, gender and BMI; gastric banding *versus* other common procedures; financial years 2011-2013

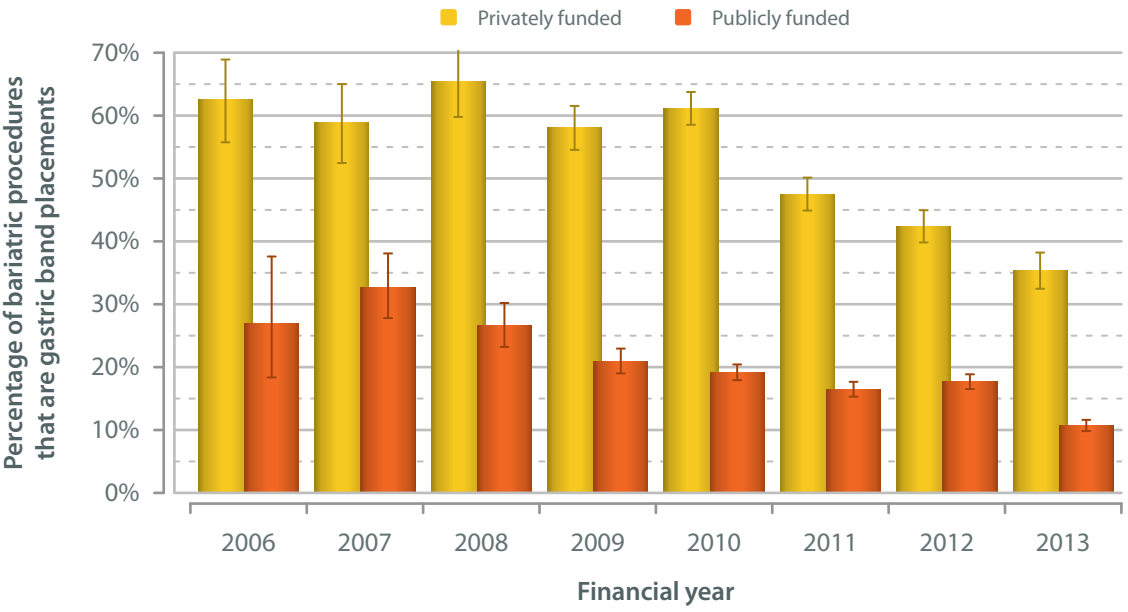
Operation and initial BMI / kg m^{-2}			Gender and source of funding							
			Male				Female			
			Privately funded	Publicly funded	Unspecified	Publicly funded ate	Privately funded	Publicly funded	Unspecified	Publicly funded ate
Gastric banding		<35.0	13	1	0	7.1%	209	7	1	3.2%
		35.0-39.9	55	32	1	36.8%	481	117	3	19.6%
		40.0-44.9	59	102	3	63.4%	449	378	7	45.7%
		45.0-49.9	48	107	4	69.0%	195	402	13	67.3%
		50.0-54.9	20	86	2	81.1%	93	316	9	77.3%
		>54.9	9	89	4	90.8%	44	202	6	82.1%
		Unspecified	1	7	1	87.5%	10	33	14	76.7%
		All	**205**	**424**	**15**	**67.4%**	**1,481**	**1,455**	**53**	**49.6%**
Other common operations		<35.0	14	5	0	26.3%	88	23	2	20.7%
		35.0-39.9	87	147	2	62.8%	397	353	3	47.1%
		40.0-44.9	118	454	0	79.4%	460	1,418	3	75.5%
		45.0-49.9	108	736	1	87.2%	375	2,045	3	84.5%
		50.0-54.9	62	641	0	91.2%	196	1,931	2	90.8%
		>54.9	68	740	2	91.6%	168	1,817	4	91.5%
		Unspecified	5	71	12	93.4%	23	164	16	87.7%
		All	**462**	**2,794**	**17**	**85.8%**	**1,707**	**7,751**	**33**	**82.0%**

Primary operations: Source of funding, initial BMI and gender; financial years 2011-2013



Gastric banding comprises a smaller and smaller proportion of all bariatric surgery in the United Kingdom over time, and this is true for publicly funded operations and privately funded surgery. It will be interesting to see whether or not this trend is sustained over the long term, as the NBSR continues to accumulate data.

Primary operations: Changes in the use of gastric bands over time and source of funding (n= 26,351)



Comorbidity at presentation

Number of comorbid conditions

Gastric banding patients tended to have fewer comorbidities at presentation than other bariatric surgery patients. This may simply be a reflection of a few basic facts:

- patients who had a gastric band were more likely to fund their own surgery, perhaps because they did not qualify for NHS treatment; they could be considered *fitter* than those patients who went down the publicly-funded pathway.
- patients who had a gastric band tended to have a lower BMI; lower BMI is associated with lower rates of comorbid disease.
- patients who had a gastric band were more likely to have treatment earlier in the disease process (they are, on average, younger), reducing the chance for comorbidity to develop.

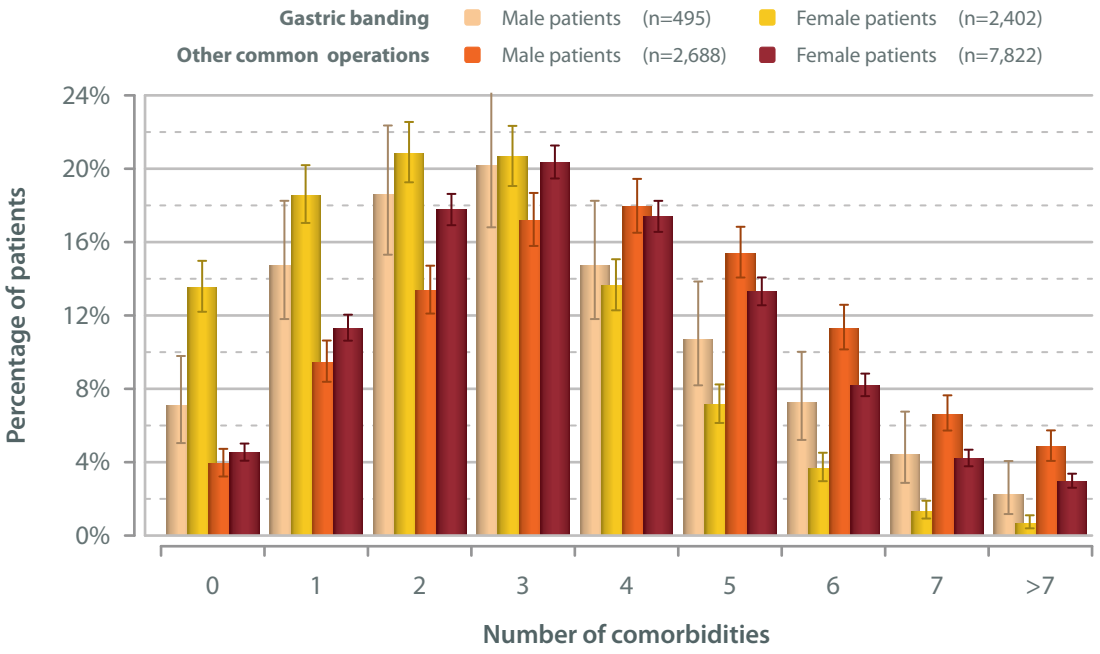
Primary operations: number of comorbid conditions and gender for entries where all comorbidity questions are completed; gastric banding *versus* other common procedures; financial years 2011-2013

		Operation and gender			
		Gastric banding		Other common operations	
		Male	Female	Male	Female
Number of comorbidities	0	35	325	105	354
	1	73	446	254	885
	2	92	501	359	1,389
	3	100	496	462	1,592
	4	73	327	482	1,360
	5	53	171	414	1,040
	6	36	88	304	641
	7	22	32	178	329
	>7	11	16	130	232
	All	**495**	**2,402**	**2,688**	**7,822**

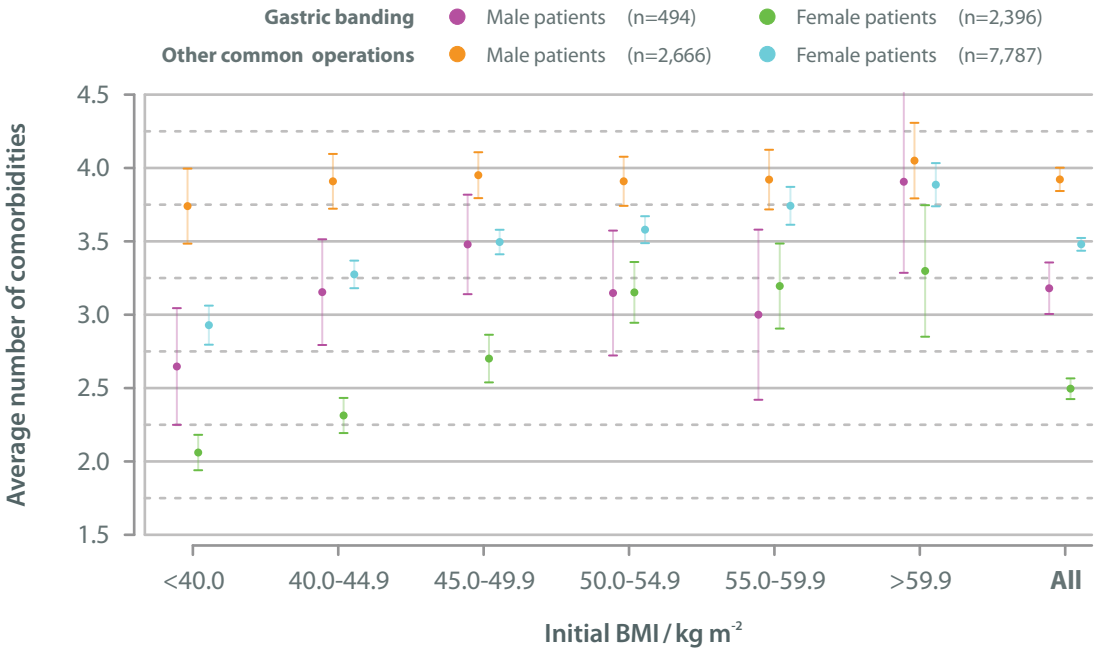
On average, patients undergoing gastric banding have 2.6 comorbid conditions (on average male patients have 3.2, and female patients have 2.5 comorbidities) and patients who have one of the other common bariatric procedures have an average of 3.6 comorbidities (on average male patients have 3.9, and female patients 3.5 comorbidities).

For female patients, as the patient's initial BMI increases the average number of comorbidities also increased. The same relationship was not evident for the male patient-populations.

Primary operations with complete comorbidity data: Number of comorbidities and gender; financial years 2011-2013



Primary operations with complete comorbidity data: Average number of comorbidities, initial BMI and gender; financial years 2011-2013



Comorbidity rates for female patients

Female patients undergoing gastric band surgery had fewer comorbidities than patients undergoing the other common procedures recorded in the NBSR , similar to the findings in the first NBSR report.

All the differences in comorbidity rates for the two groups of female patients were statistically significant.

Primary operations for female patients: details of comorbid conditions at presentation; financial years 2011-2013

		Operation								
		Gastric banding				Other common operations				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	significance[i]
Comorbidities[ii]	Arthritis	1,414	1,372	203	49.2%	3,863	5,085	543	56.8%	<0.001
	Asthma	2,378	441	170	15.6%	7,012	2,072	407	22.8%	<0.001
	Atherosclerosis	2,752	56	181	2.0%	8,622	429	440	4.7%	<0.001
	Depression	2,108	603	278	22.2%	6,039	2,599	853	30.1%	<0.001
	Dyslipidaemia	2,446	356	187	12.7%	6,941	2,082	468	23.1%	<0.001
	GORD[iv]	1,822	878	289	32.5%	5,349	3,354	788	38.5%	<0.001
	Hypertension	2,076	743	170	26.4%	5,641	3,453	397	38.0%	<0.001
	Liver disease	2,662	69	258	2.5%	8,326	482	683	5.5%	<0.001
	PCOS[v]	2,534	206	249	7.5%	7,932	864	695	9.8%	<0.001
	Poor functional status[iii]	1,150	1,555	284	57.5%	2,157	6,814	520	76.0%	<0.001
	Sleep apnoea	2,577	240	172	8.5%	7,437	1,645	409	18.1%	<0.001
	Type 2 diabetes	2,371	444	174	15.8%	6,447	2,627	417	29.0%	<0.001

Although the obvious rates of comorbidities were lower than those reported for the other operations, there is still a significant burden of obesity-related comorbid disease in these female gastric banding patients. It is of concern that even though the patients were generally younger and had a lower initial BMI, some 57.5% of them were still unable to climb 3 flights of stairs without resting.

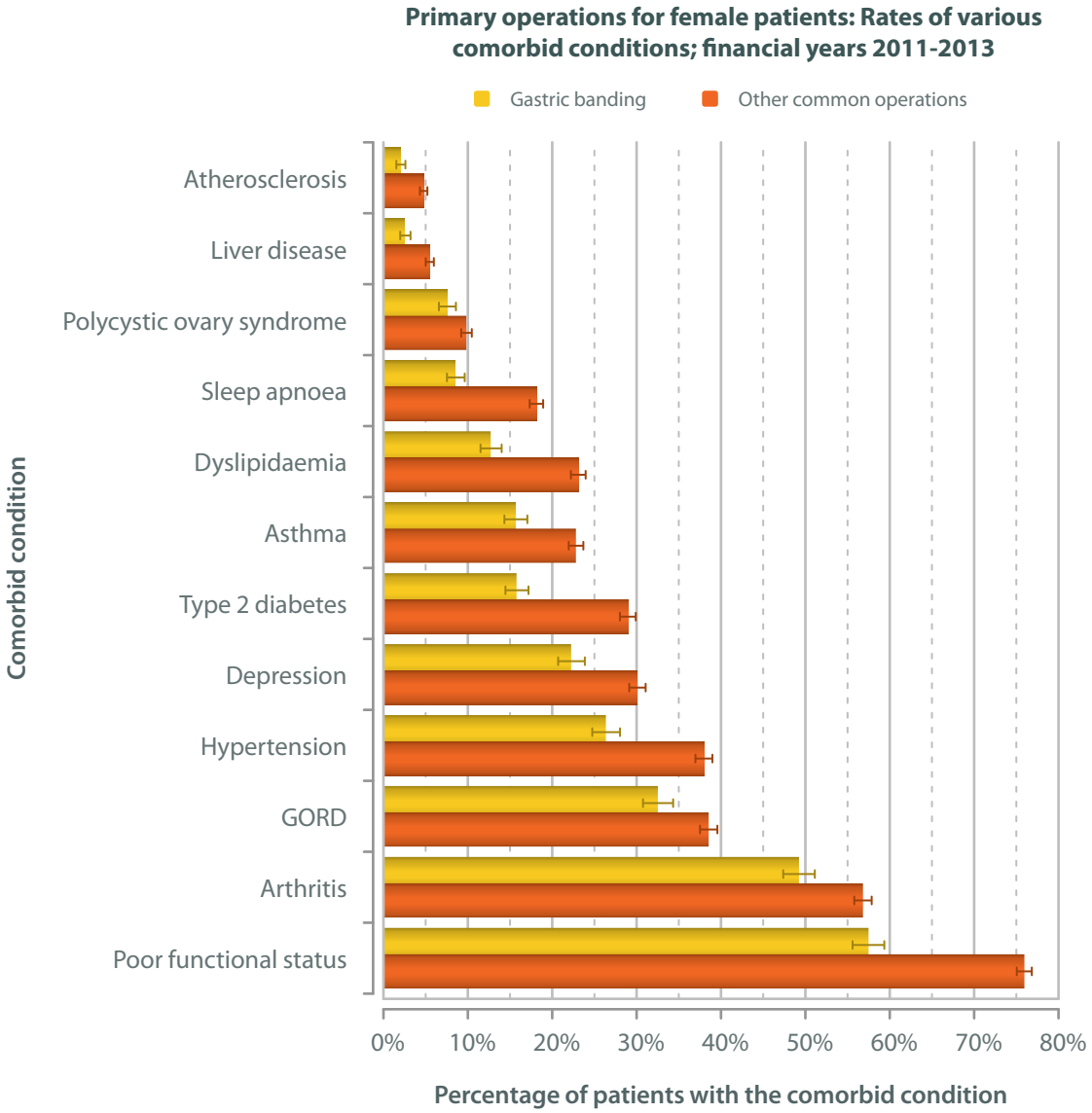
i. χ^2 probability; comparing the incidence amongst the gastric banding patient-population with the rate observed in the *other common operations* patient-population.

ii. One of the comorbidity questions is only collected for the female patients: *polycystic ovary syndrome*.

iii. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

v. Polycystic ovary syndrome.


Primary operations for female patients: Rates of various comorbid conditions; financial years 2011-2013
Gastric banding
Other common operations
Atherosclerosis
Liver disease
Polycystic ovary syndrome
Sleep apnoea
Dyslipidaemia
Asthma
Type 2 diabetes
Depression
Hypertension
GORD
Arthritis
Poor functional status
Comorbid condition
0%
10%
20%
30%
40%
50%
60%
70%
80%
Percentage of patients with the comorbid condition

Comorbidity rates for male patients

Male patients undergoing gastric banding also had fewer comorbidites than their male counterparts undergoing other common bariatric procedures, with one notable exception: rates of atherosclerosis were almost identical for both groups. Hence, gastric banding might be seen as a less risky surgical option for low-risk male patients than other procedures.

The differences in the rates of other comorbidities across these two operation groups were statistically significant, except for the arthritis, GORD and liver disease comorbidities. The difference in the rates of these three comorbidities almost attained statistical significance; it will be interesting to see whether or not these three differences also attain significance as more data are accumulated in the NBSR.

Primary operations for male patients: details of comorbid conditions at presentation; financial years 2011-2013

		Operation								
		Gastric banding				Other common operations				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	significance [i]
Comorbidities [ii]	Arthritis	279	304	61	52.1%	1,339	1,726	208	56.3%	0.070
	Asthma	523	70	51	11.8%	2,621	473	179	15.3%	0.033
	Atherosclerosis	530	62	52	10.5%	2,745	326	202	10.6%	0.976
	Depression	500	73	71	12.7%	2,472	539	262	17.9%	0.003
	Dyslipidaemia	447	142	55	24.1%	1,957	1,103	213	36.0%	<0.001
	GORD [iv]	395	163	86	29.2%	1,998	966	309	32.6%	0.129
	Hypertension	323	268	53	45.3%	1,368	1,732	173	55.9%	<0.001
	Liver disease	532	29	83	5.2%	2,743	223	307	7.5%	0.059
	PCOS [v]									
	Poor functional status [iii]	211	344	89	62.0%	766	2,268	239	74.8%	<0.001
	Sleep apnoea	402	189	53	32.0%	1,822	1,274	177	41.1%	<0.001
	Type 2 diabetes	400	191	53	32.3%	1,651	1,440	182	46.6%	<0.001

i. χ^2 probability; comparing the incidence amongst the male patient-population with the rate observed in the female patient-population.

ii. One of the comorbidity questions is only collected for the female patients: *polycystic ovary syndrome*.

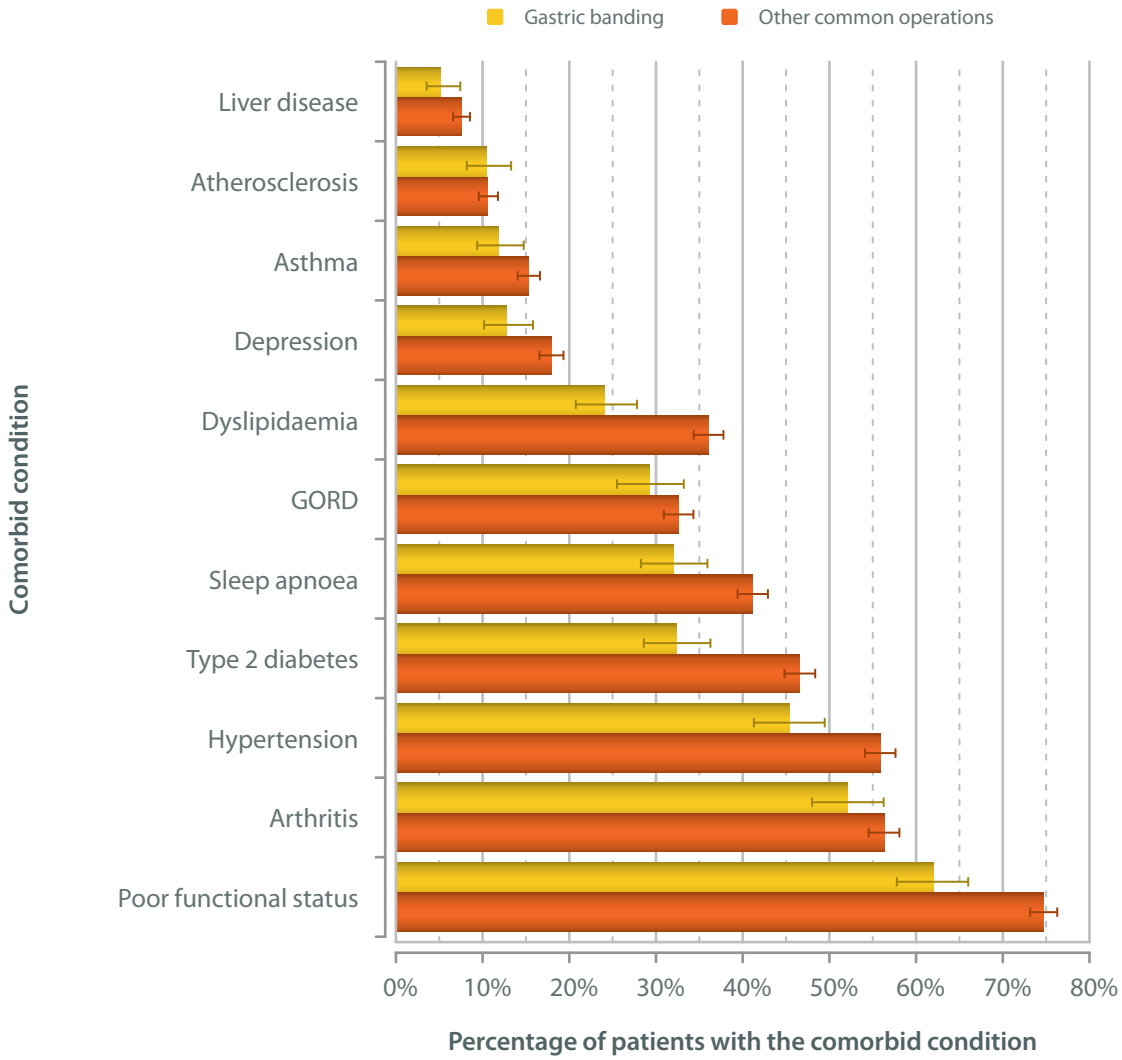
iii. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

v. Polycystic ovary syndrome.

Although the rate of diabetes (32.2%) in these male patients was lower than in those having other operations, it is still much higher than that reported in many international series, where the prevalence of diabetes is often around 20%. Like female gastric banding patients, male patients had very significantly impaired functional status, with 62.0% unable to climb 3 flights of stairs without resting.

Primary operations for male patients: Rates of various comorbid conditions; financial years 2011-2013



Edmonton Obesity Staging System

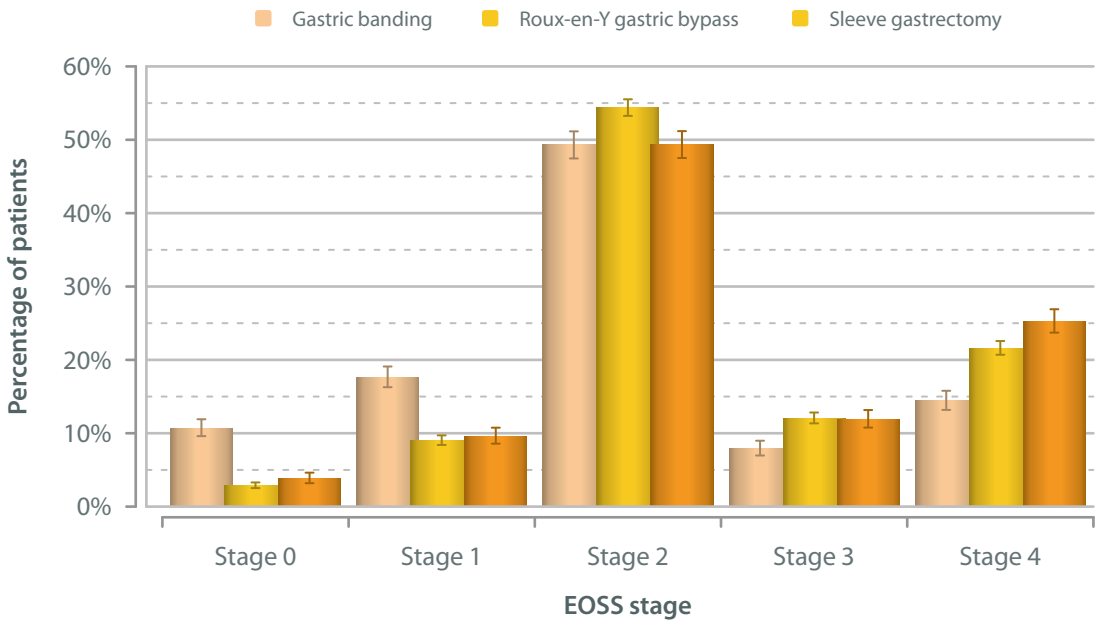
The Edmonton Obesity Staging System (EOSS) gives a global clinical assessment score, which can be used to grade the severity of patients' obesity more effectively than with BMI alone.

On average, patients who had a gastric band procedure tended to have lower EOSS scores than those who had one of the other common bariatric surgical procedures ($p<0.001$ for all inter-operation comparisons). This is further confirmation that the group of patients who had a gastric band placed had fewer comorbidities than the rest of the bariatric surgery patient population.

Primary operations: EOSS distribution and operation; financial years 2011-2013

		Operation					
		Gastric band		Roux-en-Y gastric bypass		Sleeve gastrectomy	
		Count	Percentage	Count	Percentage	Count	Percentage
EOSS stage	EOSS 0	307	10.7%	218	2.9%	112	3.8%
	EOSS 1	506	17.6%	683	9.0%	280	9.6%
	EOSS 2	1,414	49.3%	4,111	54.4%	1,437	49.3%
	EOSS 3	227	7.9%	912	12.1%	347	11.9%
	EOSS 4	414	14.4%	1,634	21.6%	736	25.3%
	Unspecified	765		1,575		719	
	All	**3,633**		**9,133**		**3,631**	

Primary operations: EOSS distributions and operation; financial years 2011-2013



Technical aspects of gastric banding

Gastro-gastric tunnelling sutures

Gastro-gastric tunnel sutures are used to fix the band in front of the stomach; the intention is that this will prevent slippage of the band lower down the stomach.

These data on the use of gastro-gastric tunnelling sutures in gastric band procedures reveal an interesting story. Since the last report there has been an apparent decline in the use of gastro-gastric tunnelling sutures for primary gastric band surgery (the First Registry Report to March 2010 from the NBSR reported a usage rate of 94.8%). We do not know why this should be the case since most surgeons recommend suturing the band in place so as to reduce the risk of slippage occurring in follow up.

Gastric banding: the use of gastro-gastric tunnelling sutures; financial years 2011-2013

		Gastro-gastric tunnelling sutures			
		No	Yes	Unspecified	Rate (95% CI)
Type of operation	Primary	319	3,122	192	90.7% (89.7-91.7%)
	Revision as primary	15	112	168	88.2% (81.0-93.0%)
	Revision	7	26	109	78.8% (60.6-90.4%)
	Planned 2nd stage	0	3	2	100.0% (36.8-100.0%)
	All	**341**	**3,263**	**471**	**90.5% (89.5-91.5%)**

Dissection

In contrast, and exactly as reported in the first NBSR report, there appears to be near universal agreement that the dissection around the lesser curve of the stomach for band placement should go through the window of the lesser *omentum* (so called pars flaccida approach) , rather than a dissection immediately adjacent to the wall of the lesser curve of the stomach (the peri-gastric approach) .

This approach is also recommended to reduce the risk of slippage and band erosion into the stomach.

Gastric banding: dissection; financial years 2011-2013

		Dissection			
		Pars flaccida	Peri-gastric	Unspecified	Rate (95% CI)
Type of operation	Primary	3,436	25	172	99.3% (98.9-99.5%)
	Revision as primary	120	6	169	95.2% (89.5-98.0%)
	Revision	32	1	109	97.0% (82.5-99.8%)
	Planned 2nd stage	3	0	2	100.0% (36.8-100.0%)
	All	**3,591**	**32**	**452**	**99.1% (98.7-99.4%)**

Type of band used

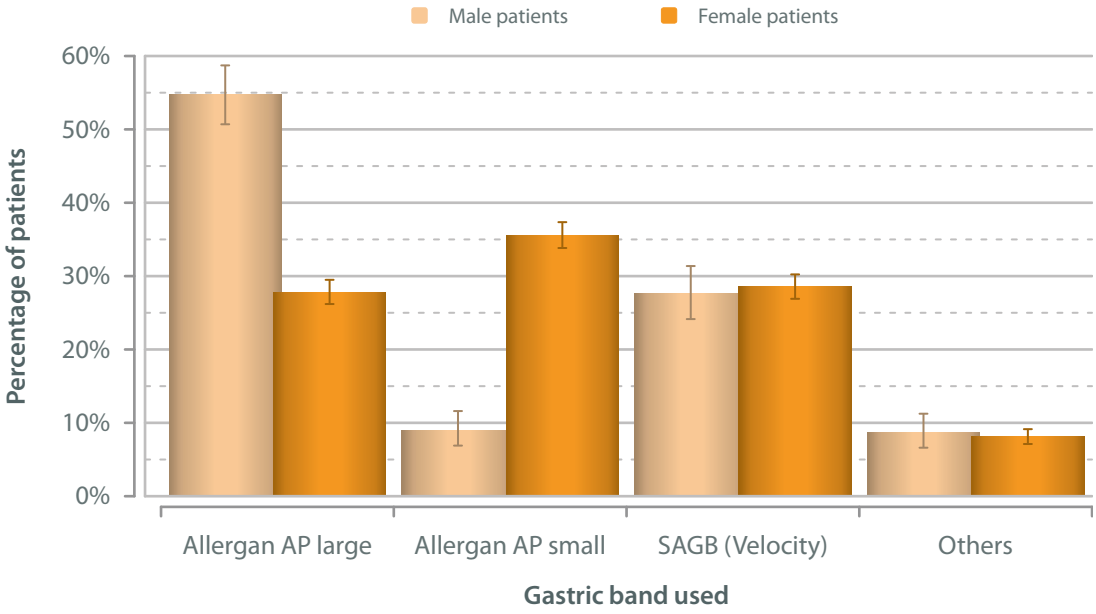
There are a variety of commercially available gastric bands to chose from. There are no consistent data in the literature to suggest that weight loss is any better with one brand of gastric band over another. We do not record in the NBSR why one band is preferred over another for each individual patient.

Primary gastric banding: band used and gender; financial years 2011-2013

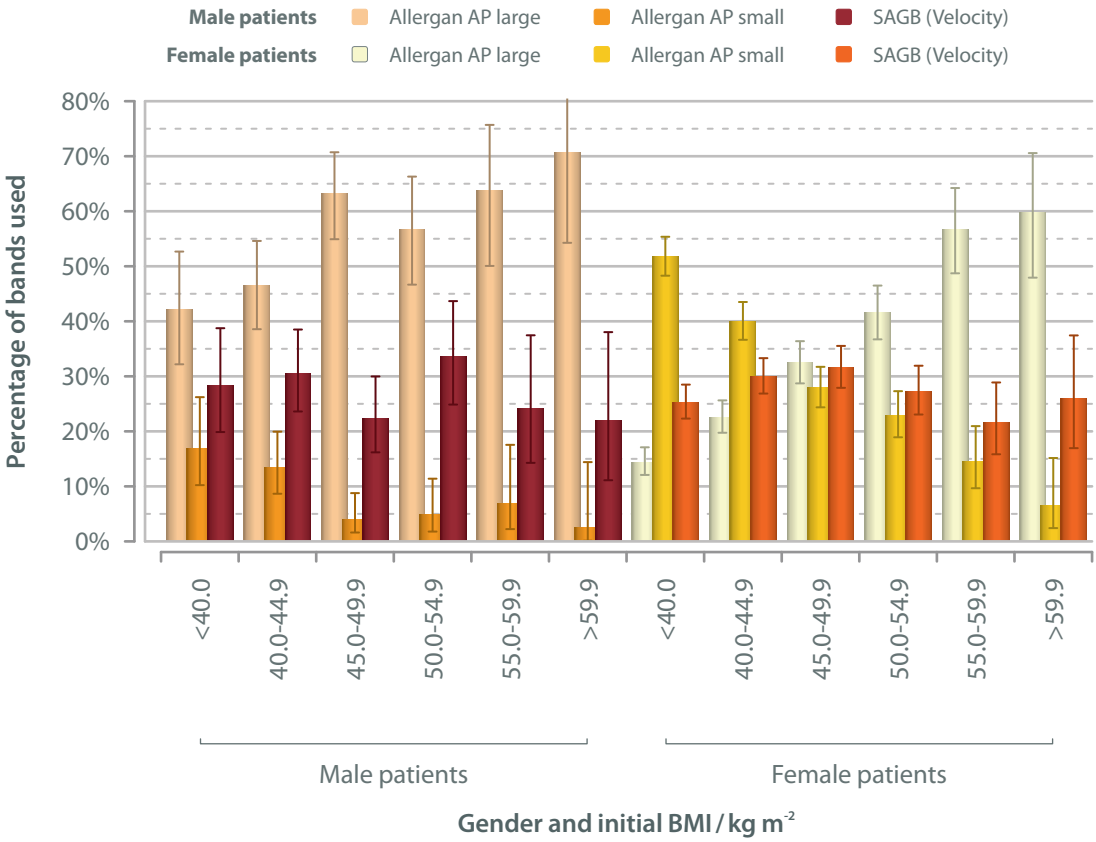
		Gender					
		Male		Female		All	
		Count	Percentage	Count	Percentage	**Count**	**Percentage**
Gastric band used	Allergan AP large [i]	335	54.7%	803	27.8%	**1,138**	**32.5%**
	Allergan AP small [i]	55	9.0%	1,027	35.6%	**1,082**	**30.9%**
	AMI	12	2.0%	39	1.4%	**51**	**1.5%**
	BioEnterics LAP-BAND	0	0.0%	2	0.1%	**2**	**0.1%**
	Bioring (Cousin)	12	2.0%	58	2.0%	**70**	**2.0%**
	Inamed Large	0	0.0%	1	0.0%	**1**	**0.0%**
	Inamed Small	0	0.0%	1	0.0%	**1**	**0.0%**
	MID	7	1.1%	27	0.9%	**34**	**1.0%**
	Minimizer Extra	0	0.0%	2	0.1%	**2**	**0.1%**
	SAGB (Quickclose)	21	3.4%	95	3.3%	**116**	**3.3%**
	SAGB (Velocity)	169	27.6%	824	28.5%	**993**	**28.4%**
	Other	1	0.2%	8	0.3%	**9**	**0.3%**
	Unspecified	32		102		**134**	
	All	**644**		**2,989**		**3,633**	

i. Apollo Endosurgery, Inc. acquired the LAP-BAND® System from Allergan, Inc. in December 2013, including the LAP-BAND AP® small and LAP-BAND AP® large sizes reported in the table and chart above.

Primary gastric banding: Gastric band used and gender; financial years 2011-2013 (n=612 male patients; n=2,887 female patients)



Primary gastric banding: Gastric band used, gender and initial BMI; financial years 2011-2013 (n=607 male patients; n=2,843 female patients)



Additional procedures

The current analyses indicate an increased rate of concomitant hiatus hernia repair, which exceeded 6% of all cases over the last three financial years; perhaps this indicates better recognition of the issue, and an increased enthusiasm to repair this defect before placement of a gastric band.

Gastric banding: additional procedures and type of operation; financial years 2011-2013

		Type of operation			
		Primary		All revisions	
		Count	Percentage	Count	Percentage
Additional procedures	None	3,222	92.8%	339	85.4%
	Cholecystectomy	10	0.3%	3	0.8%
	Hiatus hernia repair	212	6.1%	25	6.3%
	Apronectomy	0	0.0%	0	0.0%
	Other	40	1.2%	31	7.8%
	Unspecified	160		45	
	Number of operations	**3,633**		**442**	

The database allows surgeons to describe the *other* additional procedures in more detail, and this additional information is listed below:

- adhesiolyis and assess fundoplication 1
- adhesiolysis 11
- anterior crural approximation 2
- anterior crural plication 1
- anterior crural repair 1
- anterior crural tightening 1
- anterior cruroplasty 5
- anterior cruroplasty + adhesiolysis 1
- anterior curvaplasty 1
- crural repair 1
- division of adhesions 2
- division of adhesions from prev open cholecystectomy 1
- ex lipoms thigh 1
- gastric plication 1
- hiatus hernia repair 1
- laparoscopic division of adhesions 1
- liver biopsy 2
- liver biopsy - cirrhosis and varices 1
- liver resection haemangioma left lobe 1
- mole removal 1
- removal of slipped band 1
- repair hiatus 1
- repair hiatus hernia 1
- repositioning of slipped band 1
- take down fundoplication 1
- unspecified 4

Post-procedure outcomes

30-day complications

30 / 3,633 (0.8%) patients undergoing a primary gastric banding operation were recorded as having had complication within 30 days of the operation; 7 / 442 (1.6%) patients undergoing a revision procedure were recorded as having had a 30-day complication.

There were no reported deaths for any patient undergoing gastric band surgery in the three financial years ending 2011, 2012 and 2013 (0.0%; n=3,402).

30-day re-operations

12 / 3,633 (0.3%) patients had a re-operation within 30 days of their primary gastric band procedure; and 0 / 442 (0.0%) patients were reported as having had a re-operation within 30 days of their revisional gastric band procedure.

Cardiovascular complications

3 / 3,402 (0.1%) patients had a post-operative cardiovascular complication.

Other complications

25 / 3,398 (0.7%) patients had an *other* post-operative complication.

Primary gastric banding: other complications; financial years 2011-2013

		Other complications			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	787	5	38	0.6% (0.2-1.6%)
	1	1,004	9	43	0.9% (0.4-1.7%)
	2	775	6	43	0.8% (0.3-1.8%)
	3	409	1	11	0.2% (0.0-1.6%)
	4	126	2	2	1.6% (0.3-6.1%)
	5	23	1	0	4.2% (0.2-23.1%)
	Group A	1,791	14	81	0.8% (0.4-1.3%)
	Group B	1,184	7	54	0.6% (0.3-1.3%)
	Group C	149	3	2	2.0% (0.5-6.1%)
	Unspecified	249	1	98	0.4% (0.0-2.6%)
	All	**3,373**	**25**	**235**	**0.7% (0.5-1.1%)**

Follow up data

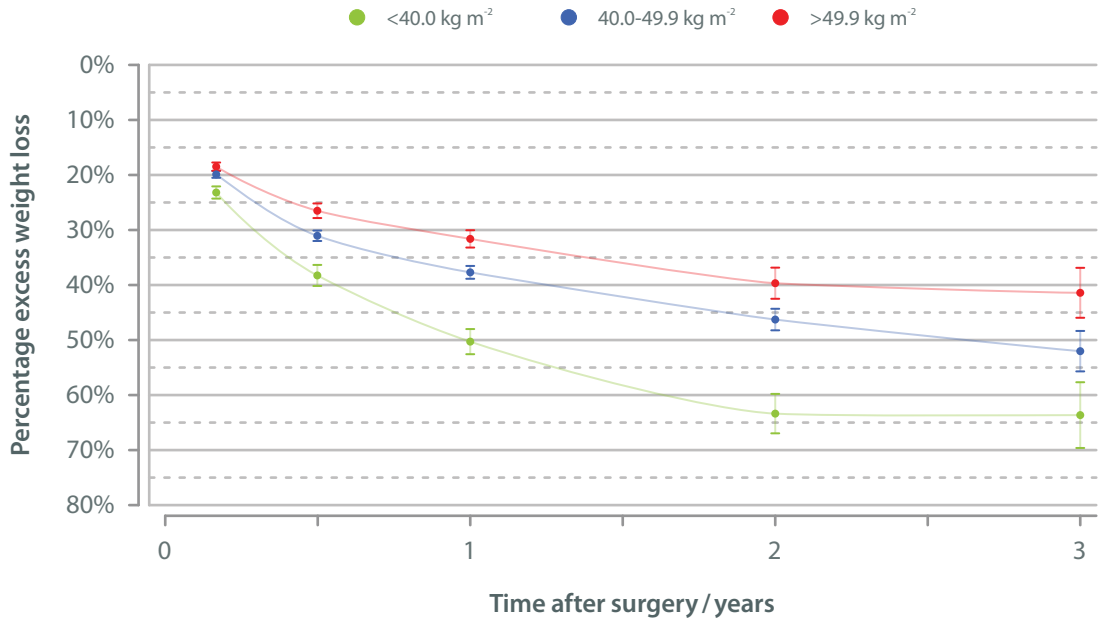
Excess weight loss

Excess weight loss, initial BMI and gender

The following graphs show the percentage excess weight loss after primary gastric banding, stratified according to the patient's initial BMI and gender. The charts demonstrate that there was sustained loss of excess weight across the three years immediately following the operation.

For female patients, the weight loss was progressive throughout the 3-year period. For male patients there was some apparent weight regain in the 3rd year; however, the relatively small numbers of patients in this cohort of male patients with follow up data at 3 years after surgery preclude any definitive assessment of these results at this time. Combined with functional and comorbidity improvements, these data confirm the efficacy of gastric banding as a treatment modality.

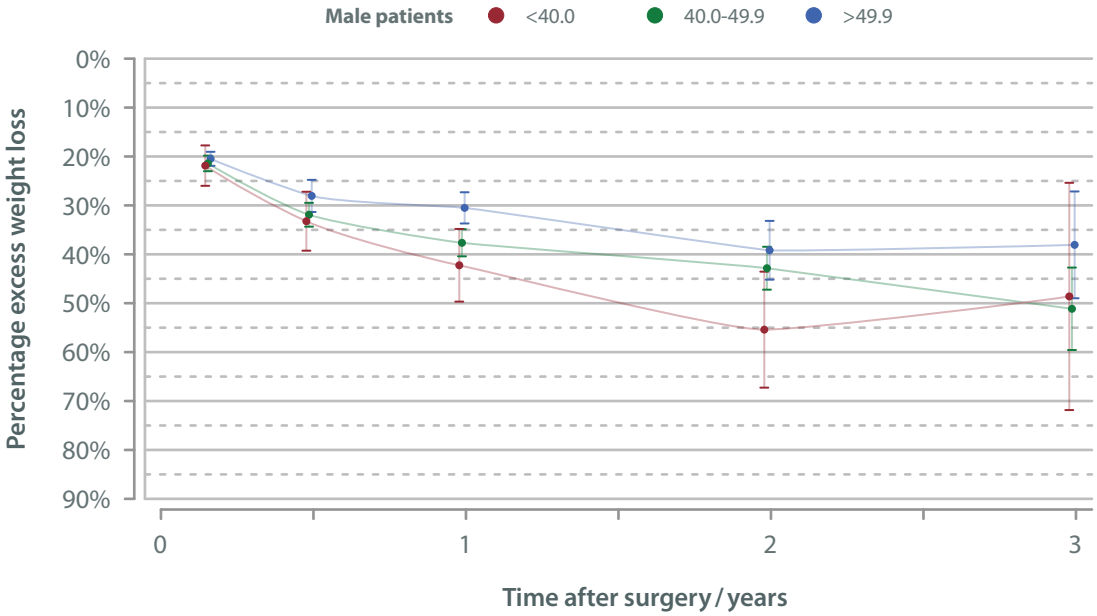
Primary gastric banding: Post-operative excess weight loss and BMI; operations in financial years 2006-2013



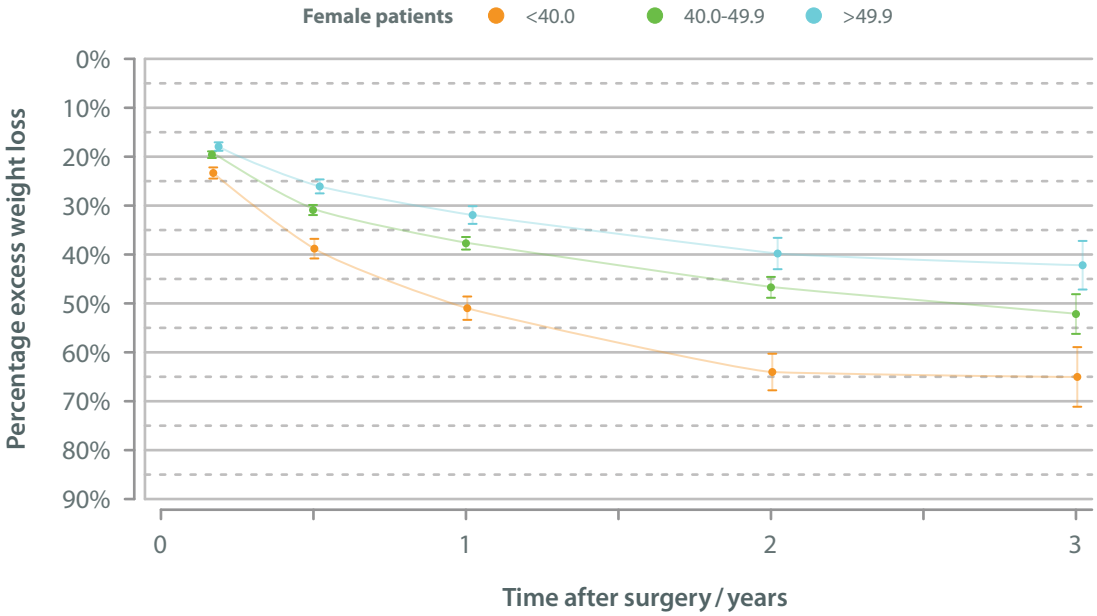
Each kilo of weight lost is more significant in terms of excess weight loss for a patient whose initial BMI was low; their excess weight (the weight over and above what their weight would be if their BMI was 25 kg m^{-2}) is necessarily lower than a patient with a higher initial BMI.

It is important to look at data grouped into initial BMI classes when analysing excess weight loss across different procedure groups, as the patient-populations vary quite significantly in terms of this pre-operative factor.

Primary gastric banding for male patients: Post-operative excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



Primary gastric banding for female patients: Post-operative excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



Excess weight loss and procedure

The registry data show that, in general, there was greater reported excess weight loss for females than males; the reasons for this difference are not clear. Those patients with higher initial BMI had lower percentage excess weight loss mainly due to issues with the calculation of excess weight loss. As previously noted in the report, patients with a BMI of 50 kg m^{-2} or over will typically lose more weight in kg than patients with BMI less than 50 kg m^{-2}, since they have more weight to lose. However, the percentage excess weight loss for the latter patients may be far greater. In reporting weight loss it is always necessary to have also the starting weight of the cohort available.

Primary gastric banding: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

Gender and follow up period / months			Initial BMI / kg m^{-2}		
			<40.0	40.0-49.9	>49.9
Gender and follow up period / months	Male	2	21.9 (±4.1; 69)	21.4 (±1.6; 239)	20.5 (±1.4; 145)
		6	33.2 (±6.0; 44)	31.9 (±2.4; 140)	28.1 (±3.3; 91)
		12	42.2 (±7.4; 39)	37.7 (±2.8; 181)	30.5 (±3.2; 99)
		24	55.4 (±11.9; 20)	42.8 (±4.4; 67)	39.2 (±6.0; 44)
		36	48.6 (±23.2; 10)	51.1 (±8.4; 36)	38.1 (±10.9; 17)
	Female	2	23.3 (±1.1; 605)	19.6 (±0.7; 1,231)	17.9 (±0.9; 524)
		6	38.8 (±2.0; 403)	30.9 (±1.0; 838)	26.1 (±1.4; 333)
		12	51.0 (±2.4; 456)	37.7 (±1.3; 961)	31.9 (±1.8; 347)
		24	64.0 (±3.7; 243)	46.7 (±2.1; 522)	39.8 (±3.2; 170)
		36	65.0 (±6.1; 108)	52.2 (±4.1; 209)	42.2 (±5.0; 73)

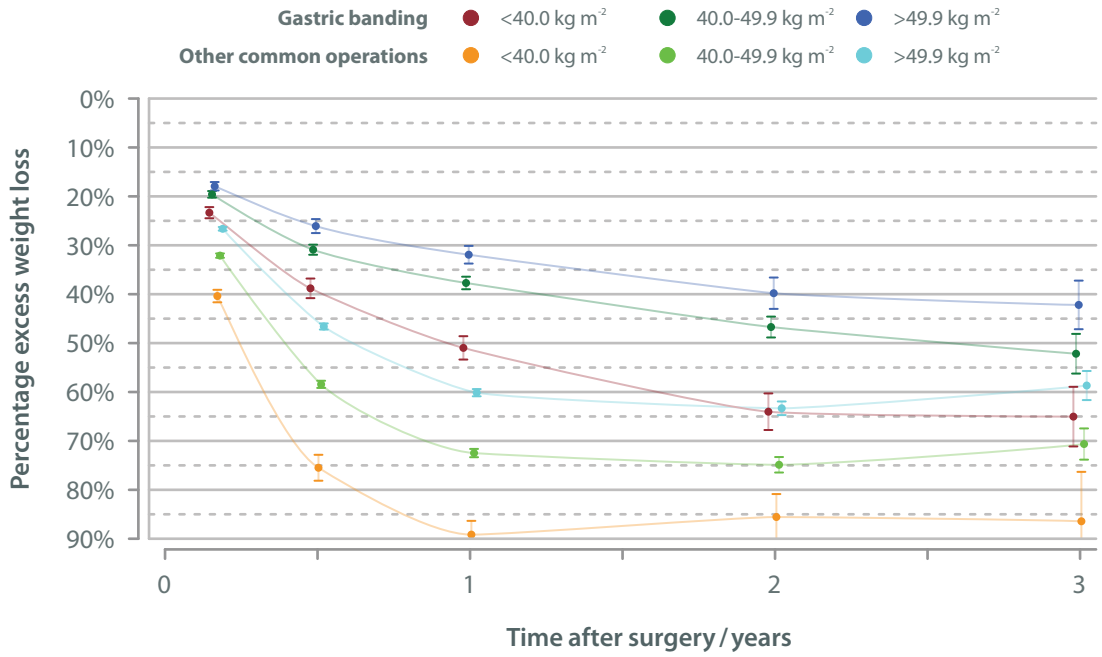
Primary Roux-en-Y gastric bypass / sleeve gastrectomy: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

Gender and follow up period / months			Initial BMI / kg m^{-2}		
			<40.0	40.0-49.9	>49.9
Gender and follow up period / months	Male	2	44.2 (±3.2; 124)	34.7 (±0.8; 898)	29.1 (±0.7; 1,047)
		6	69.9 (±4.7; 79)	56.8 (±1.3; 480)	48.0 (±1.0; 554)
		12	75.7 (±6.1; 61)	65.9 (±1.6; 525)	58.2 (±1.2; 611)
		24	68.7 (±13.2; 14)	66.1 (±2.7; 185)	63.2 (±2.2; 248)
		36	71.1 (±17.2; 3)	58.6 (±6.4; 54)	57.2 (±4.7; 65)
	Female	2	40.4 (±1.3; 503)	32.1 (±0.4; 2,880)	26.6 (±0.4; 2,928)
		6	75.5 (±2.6; 297)	58.4 (±0.7; 1,605)	46.6 (±0.6; 1,550)
		12	89.2 (±2.8; 305)	72.5 (±0.8; 1,825)	60.1 (±0.7; 1,850)
		24	85.6 (±4.7; 113)	74.9 (±1.6; 738)	63.3 (±1.4; 775)
		36	86.4 (±10.1; 39)	70.6 (±3.2; 216)	58.7 (±3.0; 199)

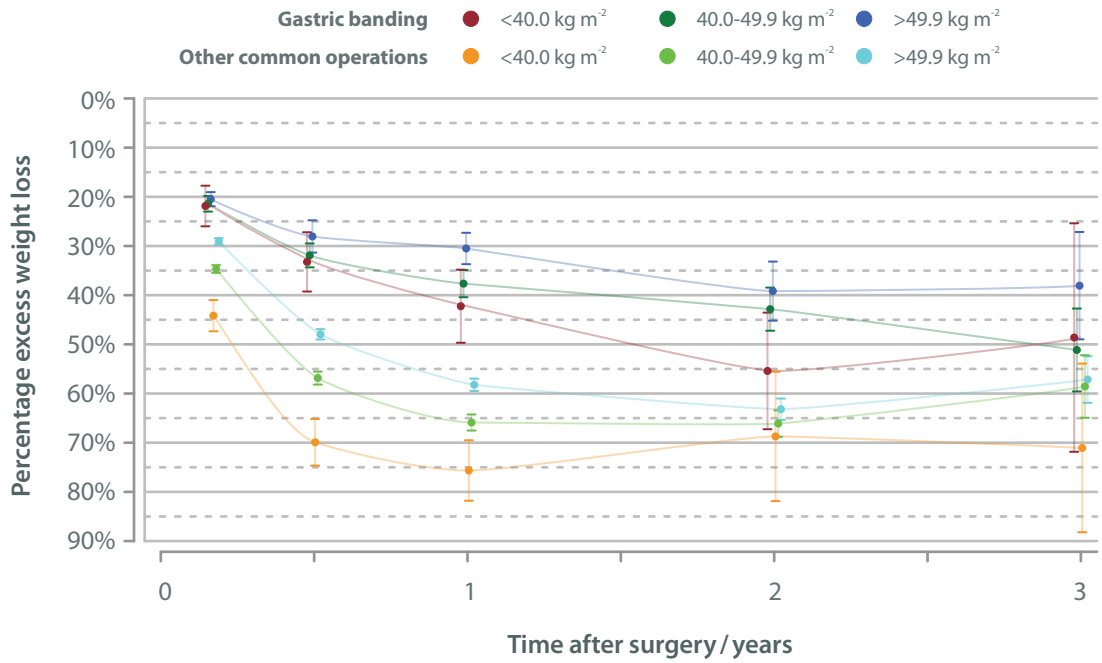
1. Rogers CA, Welbourn R, Byrne J, Donovan JL, Reeves BC, Wordsworth SA et al. The By-Band study: gastric bypass or adjustable gastric band surgery to treat morbid obesity: study protocol for a multi-centre randomised controlled trial with an internal pilot phase. *Trials*. 2014; **15**: 53.

The differences in percentage excess weight loss plotted here come from an observational database. The results are *real* in the sense that they reflect the data in the NBSR, but the patients in each BMI group have not been formally matched as they would have been in a randomised controlled trial (RCT). We will only be able to determine the relative efficacy of each kind of operation once a more formal scientific study has been performed, with the express intention of teasing out this particular question; such a project is already underway in the United Kingdom (the By-Band RCT) and it will report its findings in the scientific press once the study is complete [1].

Primary operations for female patients: Post-operative excess weight loss and initial BMI; operations in the financial years 2006-2013



Primary operations for male patients: Post-operative excess weight loss and initial BMI; operations in the financial years 2006-2013

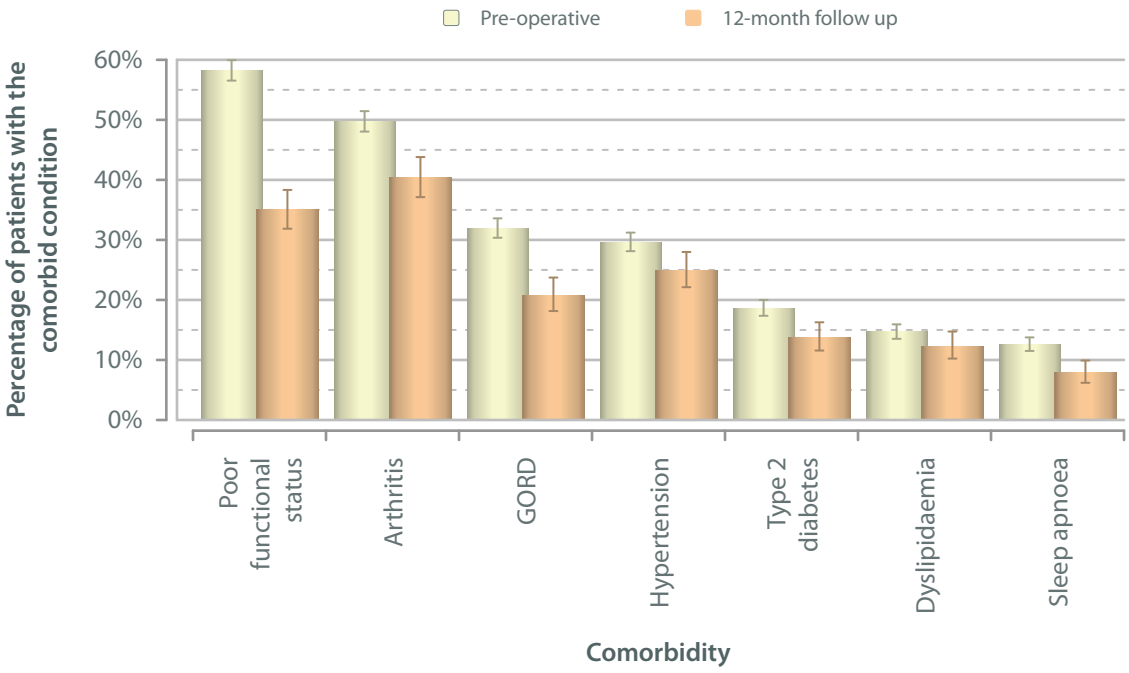


Comorbid disease after surgery

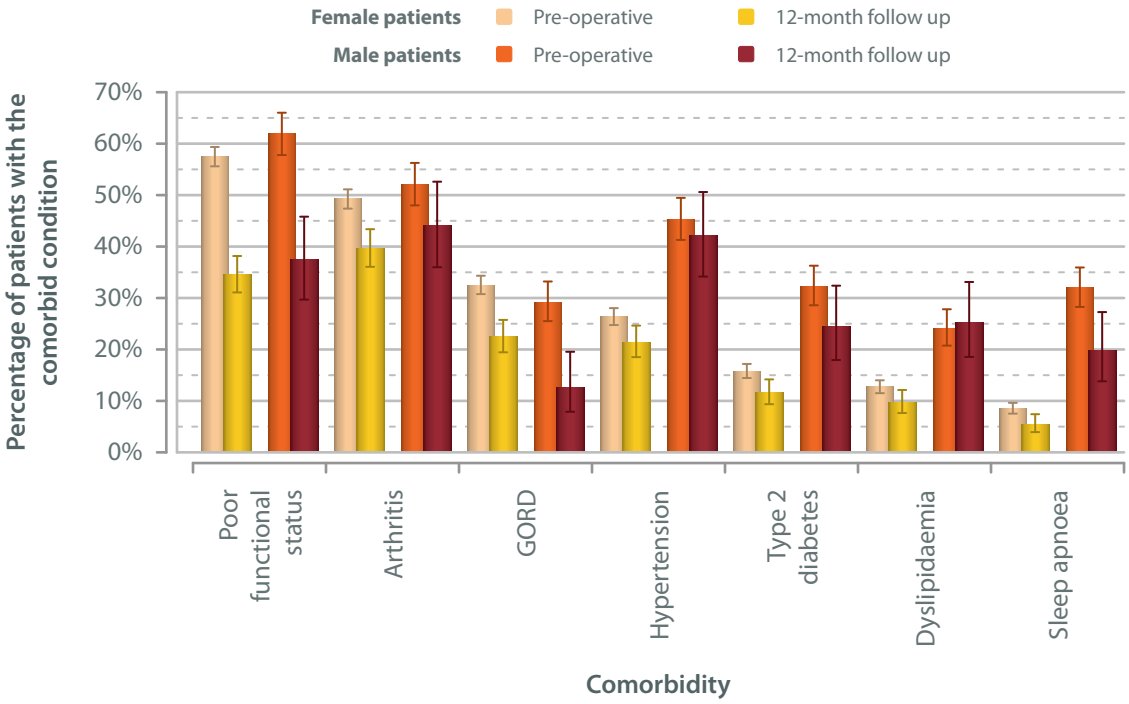
In this second NBSR report, the data are seen to mature; more of the documented comorbidities show statistically significant improvement at 12 months and 24 months after gastric banding.

Encouragingly, functional status showed the greatest magnitude of improvement at both the 12-month and 24-month follow up time-points.

Primary gastric banding: Comorbid conditions before and after surgery; financial years 2011-2013



Primary gastric banding: Comorbid conditions before and after surgery and gender; financial years 2011-2013



Primary gastric banding for female patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

Source of data			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
	Baseline [i]	No	1,414	2,446	1,822	2,076	1,150	2,577	2,371
		Yes	1,372	356	878	743	1,555	240	444
		Unspecified	203	187	289	170	284	172	174
		Rate	49.2%	12.7%	32.5%	26.4%	57.5%	8.5%	15.8%
	12-month follow up [ii]	No	429	645	546	565	470	679	635
		Yes	282	69	158	154	248	39	83
		Unspecified	1,557	1,554	1,564	1,549	1,550	1,550	1,550
		Rate	39.7%	9.7%	22.4%	21.4%	34.5%	5.4%	11.6%
	24-month follow up [iii]	No	143	209	174	172	156	227	207
		Yes	92	27	61	65	82	10	31
		Unspecified	906	905	906	904	903	904	903
		Rate	39.1%	11.4%	26.0%	27.4%	34.5%	4.2%	13.0%
Baseline *versus* 12-month follow up [iv]			<0.001	0.031	<0.001	0.008	<0.001	0.008	0.006
Baseline *versus* 24-month follow up [v]			0.004	0.646	0.046	0.778	<0.001	0.028	0.303

Primary gastric banding for male patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

Source of data			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
	Baseline [i]	No	279	447	395	323	211	402	400
		Yes	304	142	163	268	344	189	191
		Unspecified	61	55	86	53	89	53	53
		Rate	52.1%	24.1%	29.2%	45.3%	62.0%	32.0%	32.3%
	12-month follow up [ii]	No	81	110	124	85	92	118	111
		Yes	64	37	18	62	55	29	36
		Unspecified	315	313	318	313	313	313	313
		Rate	44.1%	25.2%	12.7%	42.2%	37.4%	19.7%	24.5%
	24-month follow up [iii]	No	24	38	39	22	28	36	31
		Yes	23	9	6	25	19	11	16
		Unspecified	154	154	156	154	154	154	154
		Rate	48.9%	19.1%	13.3%	53.2%	40.4%	23.4%	34.0%
Baseline *versus* 12-month follow up [iv]			0.103	0.872	<0.001	0.549	<0.001	0.005	0.082
Baseline *versus* 24-month follow up [v]			0.786	0.555	0.035	0.375	0.006	0.291	0.935

Improvement in diabetes

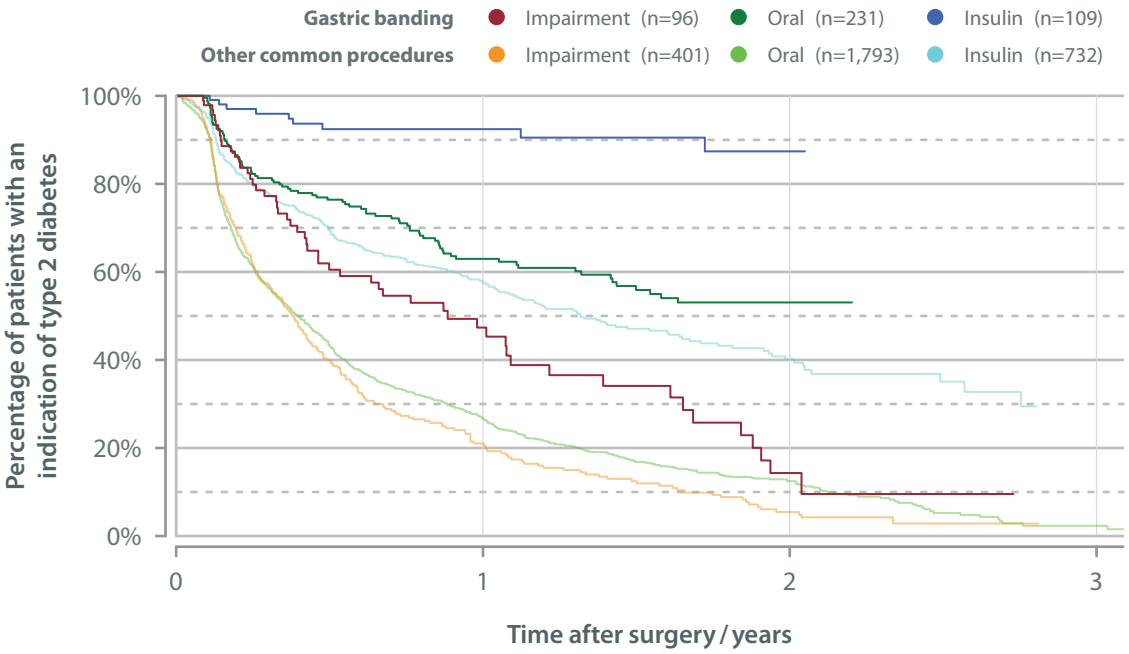
This graph shows the proportion of patients returning to a state of *No indication of diabetes* after gastric banding compared to all other operations, segmented according to BMI.

The data seem to show that the rate of change after gastric banding was lower than that for the other operations (principally gastric bypass and sleeve gastrectomy). However, the results must be interpreted with caution because the population groups were different in a number of ways, and it is possible that factors other than the BMI might have influenced the rate of change (such as different distributions in the duration of diabetes, although the data in the NBSR show that gastric banding patients have a non-significantly shorter duration of diabetes and should therefore have had greater rates of remission; perhaps their reduced weight loss is the explanation for the lower rate of the fall in clinical indications of diabetes).

The data could also be explained by differences in the rates of follow up for privately funded patients. This is an area that has not been explored in the NBSR to date, but it could explain some of the variation seen between gastric banding and the other operations in terms of diabetes improvement.

Please see the previous section (pages 152-157) for a more detailed description and interpretation of the NBSR diabetes data.

Patients recorded as having an indication of type 2 diabetes prior to surgery: Changes in recorded rates of diabetes indications and type of diabetes; operations in financial years 2011-2013



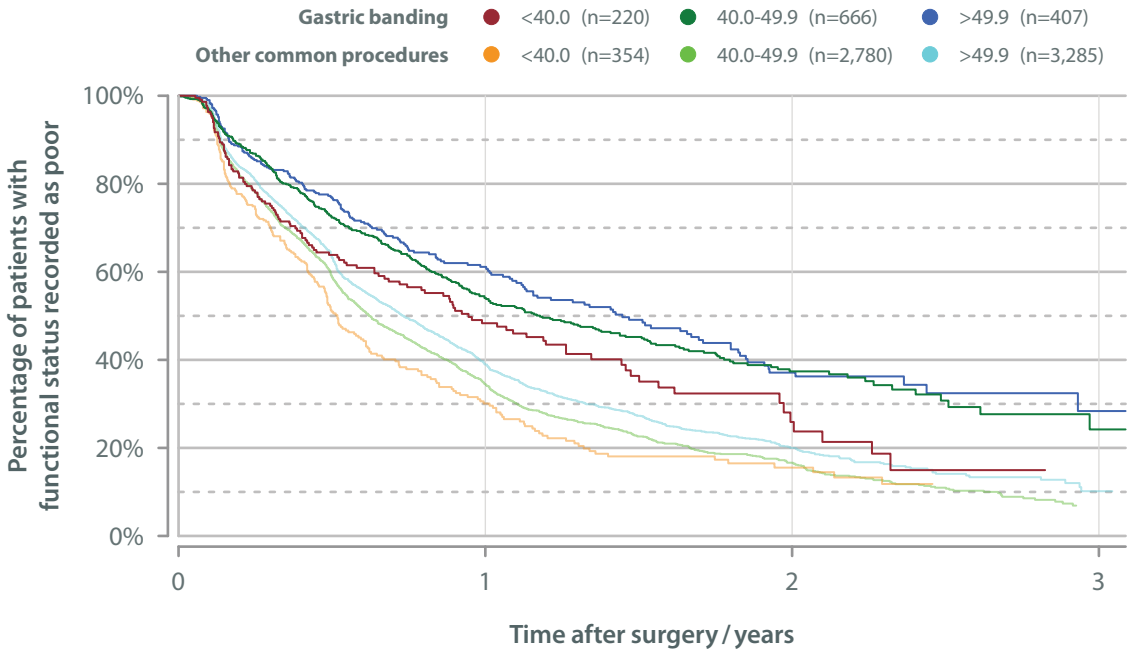
Improvement in functional status

The incidence of poor functional status continued to fall with time after surgery in gastric band patients. The difference between the reported improvement following gastric band surgery as compared to other procedures was evident.

Again, there are probably multiple factors that affect the rate at which patients see improvement in their functional status, some of which are related to the severity of their comorbidities at the time of surgery, including their initial BMI. The patient's initial BMI is not the only factor that determines post-operative improvement in function, which means that these results cannot be interpreted to mean that one kind of surgery is *better* than another.

The remarkable take-home message is that all cohorts of patients see substantial improvement in functional status, irrespective of initial BMI and for all kinds of surgical treatment.

Patients recorded as having poor functional status prior to surgery: Changes in recorded rates of functional status and initial BMI; operations in financial years 2011-2013



Gastric bypass

Bigger data - better answers to bigger questions ?

This Second NBSR Report documents a growth in reported bariatric surgery to over 6,000 operations *per annum* for the current reporting period, 18,283 in all. Of these latter 9,133 were primary Roux-en-Y gastric bypasses (RYGB); an annual figure corresponding to the total for the previous reporting period.

This dramatic growth may represent an encouraging improvement in access to RYGB within the National Health Service: NHS funded procedures have grown modestly from 68% to 76% of the total reported. The numbers also enable the registry to give more reliable answers, but to which questions?

Numerically, RYGB retains its primacy as the *gold standard*, risk-effective operation, accounting for 54% of all primary procedures (previously 56%). Inroads into the total, but not into the proportion of gastric bypasses, come from sleeve gastrectomy and perhaps from single-anastomosis gastric bypass (not recorded separately in the NBSR), operations with their own recognised problems.

RYGB is outstandingly safe (see pages 229-235) in the hands of teams who report, as highlighted in the Executive Summary. The ability of RYGB to induce remission of type 2 diabetes is high (see pages 242-245) and it may particularly suit certain demographic groups (see pages 238-240). Nevertheless, the procedure is not without its own well-documented problems: it is simply that these, their prevention and their remedies are generally well understood.

The exception to this understanding is weight regain (see pages 239-240). Obscure in origin, it challenges our understanding both of the mechanism of gastric bypass and of inability to lose weight in the first place. Set point theory (which would predict weight regain) now enjoys a clear body of supporting evidence and our understanding of entero-endocrine responses, bacterial shift and changes in metabolic rate and mitochondrial function after bypass should consign the volitional theory of weight loss and the traditional description of gastric bypass as *restrictive and malabsorptive* to the archives. Yet much remains a puzzle, especially weight regain.

Despite good animal evidence that bypass subjects segregate into weight maintainers or weight regainers, with differing metabolic responses, the reason remains unknown. Faced with a human regainer we still tend to adduce a behavioural model. Behaviour and biology may both be true (we are not laboratory animals) or variability between our patients may mask an underlying dichotomy. Through good long-term human data with better descriptors the NBSR may give answers, or at least hone the questions to be asked of laboratory models.

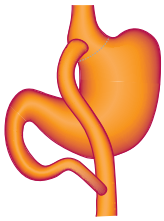
In support of this enterprise there is a need for new data fields (including agreed psycho-behavioural metrics and additional laboratory values), but pressingly also for long term follow-up data in our registry. Private providers must stress the clear guidance on this issue, but the same NHS Commissioners who have so successfully specified audit through the NBSR must also commission meaningful periods of follow up, well beyond the currently wide-spread limit of 2 years.

Alberic Fiennes

European Chapter President IFSO

Number of entries in the database

This operation is widely regarded as the *gold standard* bariatric procedure and is the most commonly performed bariatric procedure globally [1]. There are several variations of this procedure in practice, but they share certain common features. The stomach is partitioned (using surgical staplers) to produce a very small pouch (about 20-30 ml), which effectively functions as the patient's new stomach. The remaining stomach, though it remains in its usual place, is bypassed from the passage of food. The small intestine is then rearranged in a Y shaped arrangement (the so called Roux-en-Y reconstruction, named after the famous Swiss surgeon Cesar Roux) in such a way that food enters it directly from the pouch. A small segment (usually 50-60 cm) of small intestine is also bypassed and a further length (usually 150 cm) rendered largely ineffective for the purposes of absorption. With this small bowel arrangement, bile and pancreatic juices do not usually reach the gastric pouch.



This operation greatly reduces the amount of food that can be eaten and also mildly reduces its absorption, and also significantly reduces the absorption of vitamins, minerals and trace elements. It does not cause significant malabsorption of food. Furthermore, it reduces appetite and has a beneficial effect on type 2 *diabetes mellitus*.

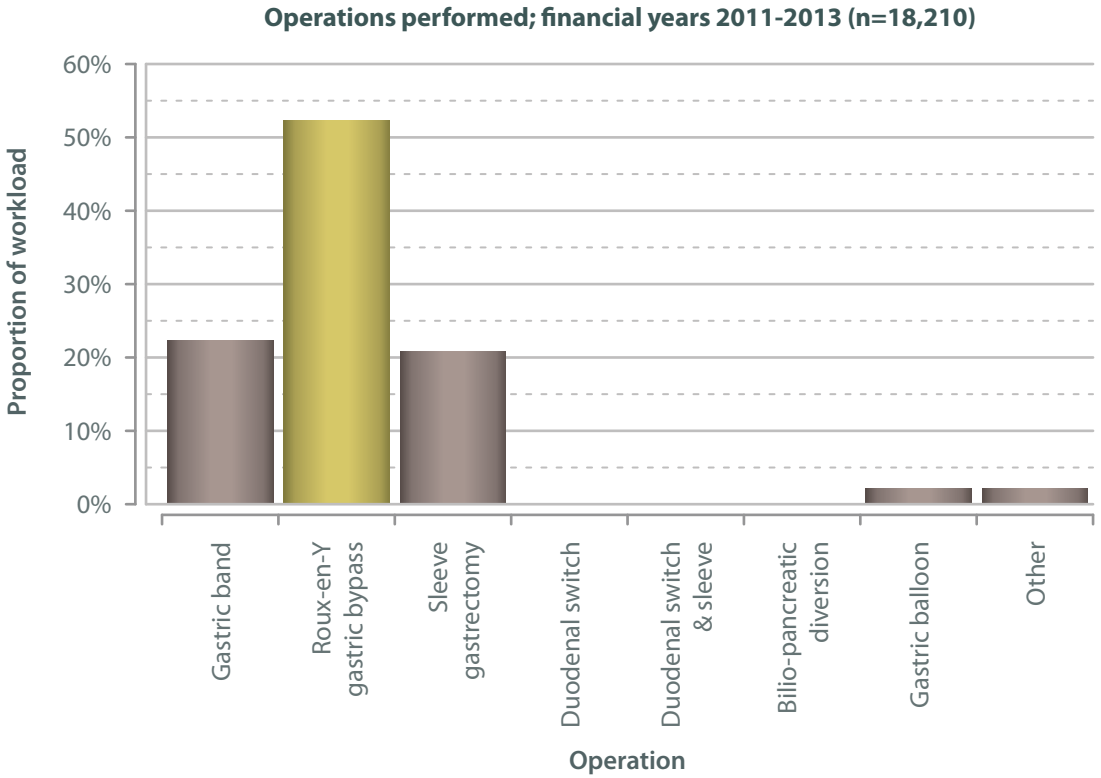
Type of operation performed; financial years 2011-2013

		Type of surgery					
		Primary	Revision as a primary	Revision	Planned 2nd stage	Unspecified	All
Operation	Gastric band	3,633	295	142	5	0	**4,075**
	Roux-en-Y gastric bypass	9,133	267	86	40	0	**9,526**
	Sleeve gastrectomy	3,631	80	32	54	0	**3,797**
	Duodenal switch	0	7	1	11	0	**19**
	Duodenal switch & sleeve	11	0	0	1	0	**12**
	Bilio-pancreatic diversion	0	5	0	0	0	**5**
	Gastric balloon	294	0	3	89	0	**386**
	Other	181	106	79	24	0	**390**
	Unspecified	73	0	0	0	0	**73**
	All	**16,956**	**760**	**343**	**224**	**0**	**18,283**

Roux-en-Y gastric bypass was the commonest operation in the NBSR during this time period and constituted 52.3% of all operations. This is not vastly different from the 54.7% figure seen for Roux-en-Y gastric bypass in the last NBSR report. The vast majority of these (95.9%) were performed as a primary procedure (patients had no previous bariatric surgery). For less than 1% and approximately 0.5% of patients respectively, the operation was a revision (patient had undergone a different bariatric operation in the same unit) and carried out as a planned second stage procedure.

It is worth noting that 2.8% (slight decrease compared to 3.6% last time) of recorded gastric bypass procedures were carried out as a *revision as a primary* (where the original primary surgery was performed in another unit).

1. Buchwald H, Oien DM. Metabolic / Bariatric Surgery Worldwide 2011. *Obesity Surgery*. 2013; **23**: 427-436.


Operations performed; financial years 2011-2013 (n=18,210)
Proportion of workload
60%
50%
40%
30%
20%
10%
0%
Gastric band
Roux-en-Y gastric bypass
Sleeve gastrectomy
Duodenal switch
Duodenal switch & sleeve
Bilio-pancreatic diversion
Gastric balloon
Other
Operation

Patient profiles

Age and gender

Gastric bypass accounted for 56.8% of the three most-commonly recorded bariatric procedures (*i.e.*, Roux-en-Y gastric bypass, sleeve gastrectomy, and gastric banding) in men (n=2,224 / 3,917) and 55.4% of these three procedures in women (n=6,909 / 12,480).

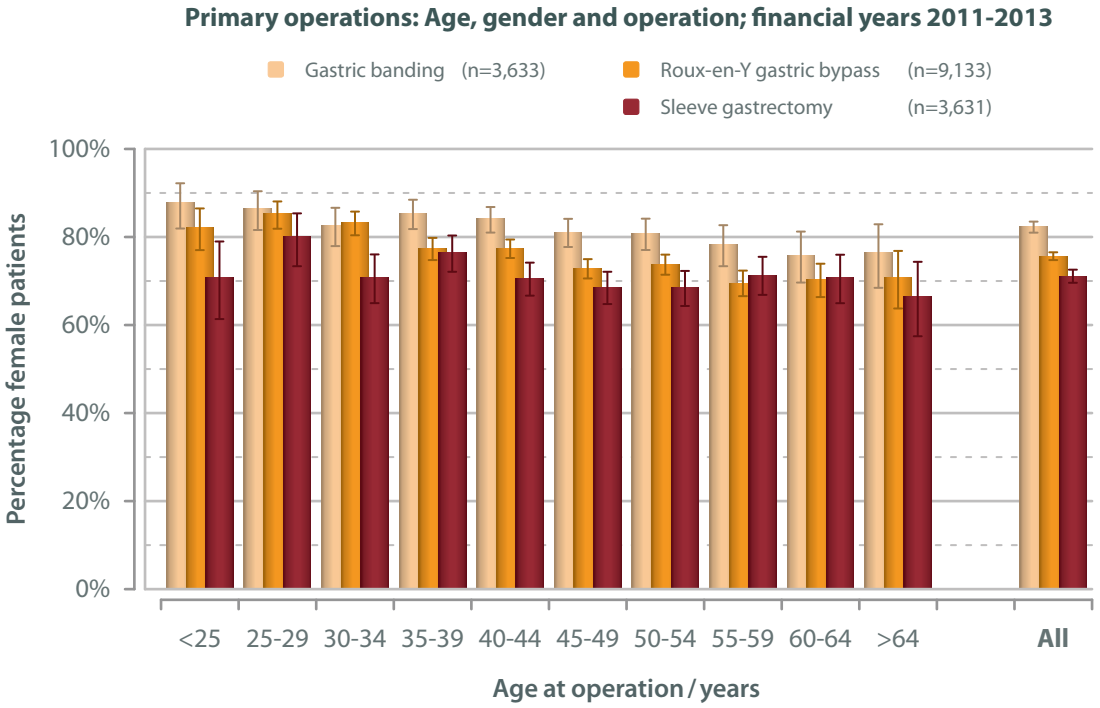
Patients younger than 30 years accounted for 8.8% of all bypasses in this time-period, as opposed to 8.6% quoted in the previous report, representing no significant change. However, the proportion of patients older than 64 years has increased by 50% in this report to 2.2% from 1.4% previously. This may indicate an increasing demand in this age group or an increasing confidence amongst the United Kingdom bariatric surgeons to offer this type of surgery to an older population of patients.

It is also worth noting that with increasing age, the population undergoing Roux-en-Y gastric bypass comprises a higher proportion of men, implying that men present later in life for this type of surgery compared to women.

Primary operations: age, gender and operation; financial years 2011-2013

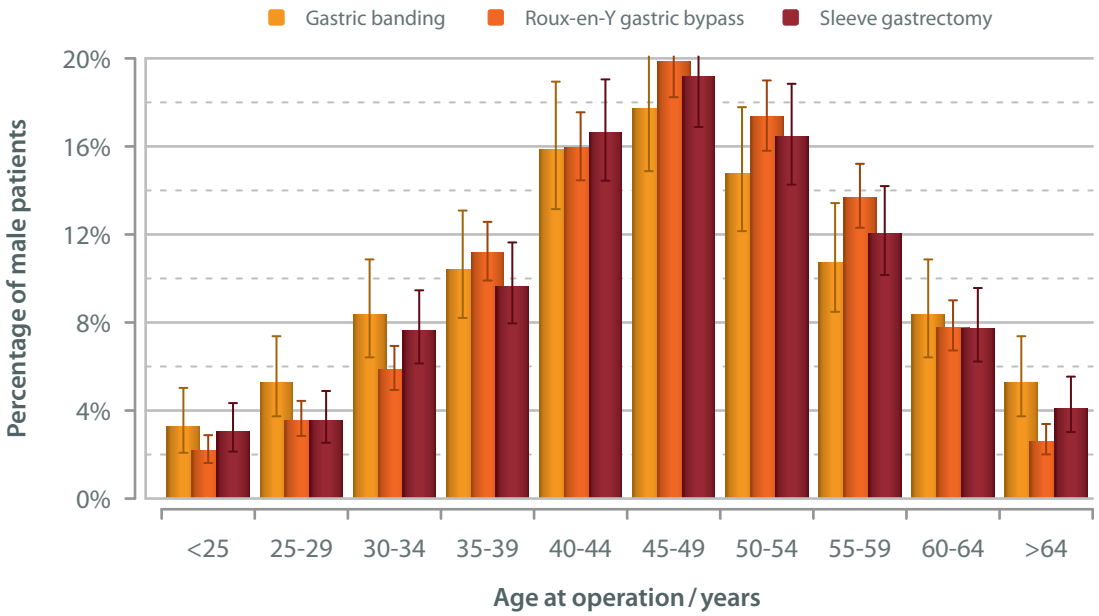
		Operation and gender					
		Gastric banding		Roux-en-Y gastric bypass		Sleeve gastrectomy	
		Male	Female	Male	Female	Male	Female
Age at operation / years	<25	21	153	48	222	32	78
	25-29	34	219	79	456	37	148
	30-34	54	258	130	646	80	194
	35-39	67	393	248	848	101	328
	40-44	102	540	354	1,212	174	417
	45-49	114	490	441	1,182	201	438
	50-54	95	401	385	1,083	172	373
	55-59	69	250	304	694	126	314
	60-64	54	170	173	409	81	196
	>64	34	110	58	140	43	85
	Unspecified	0	5	4	17	2	11
	All	**644**	**2,989**	**2,224**	**6,909**	**1,049**	**2,582**

The demand for gastric bypass (as is the demand for bariatric surgery in general) is highest in middle years of life for both sexes with a steady decrease towards both younger and older age groups.



Roux-en-Y gastric bypass

Primary operations for men: Age distributions; financial years 2011-2013



Primary operations for women: Age distributions; financial years 2011-2013

Source of funding

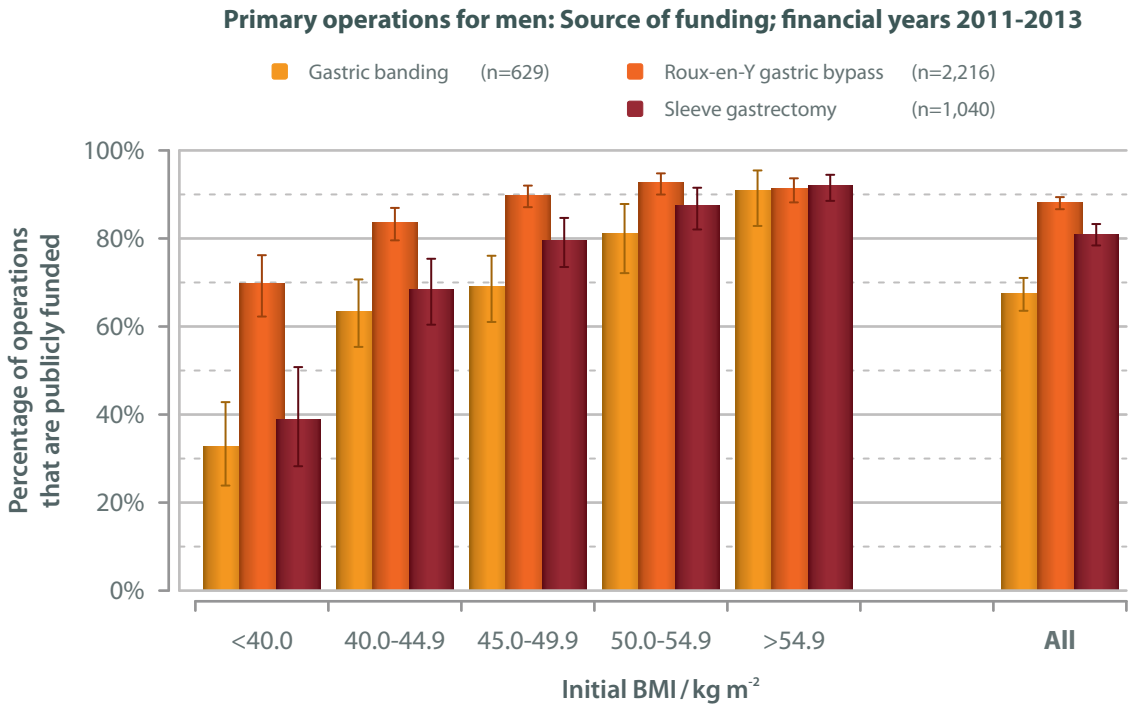
Primary gastric bypass is more likely to be a publicly funded operation, compared to other surgical procedures; 14.8% of primary gastric bypasses were privately funded compared to 47.3% of gastric bands and 22.7% of sleeve gastrectomies. This may be due to the higher cost and surgical complexity of this procedure.

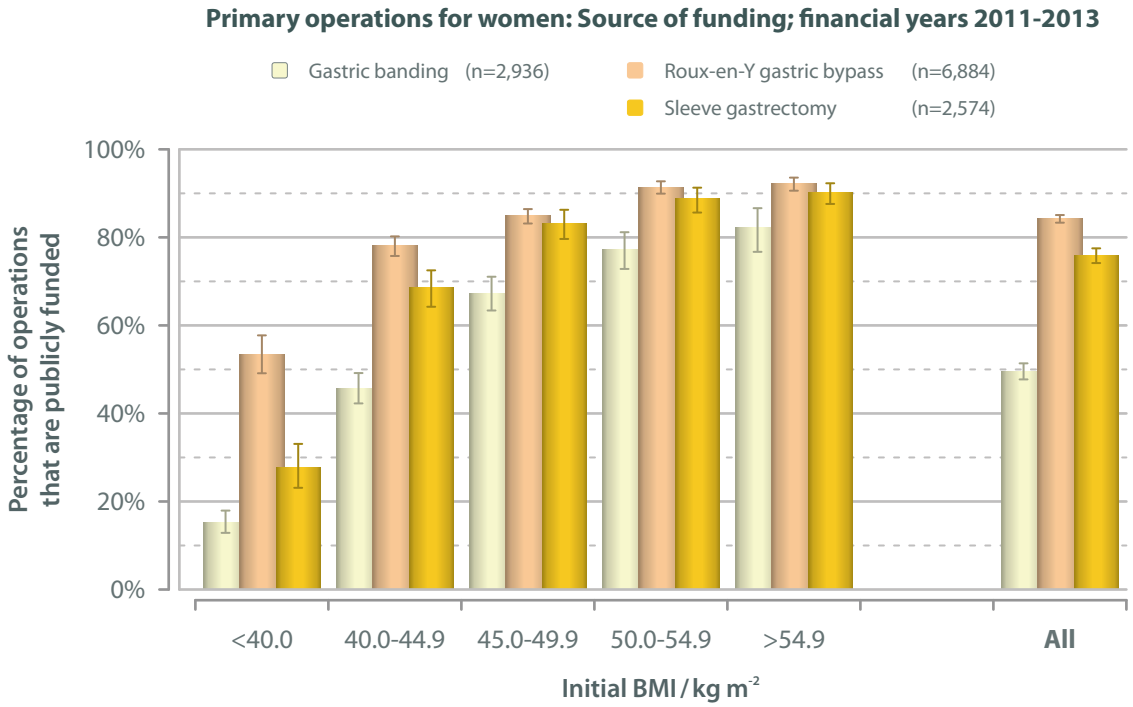
Females are more likely to privately fund a primary gastric bypass procedure than men (15.8% compared to 11.9% of males). The difference was most marked for younger females.

Primary operations: source of funding, gender, operation and initial BMI; financial years 2011-2013

Operation	Initial BMI / kg m^{-2}	Gender and source of funding							
		Male				Female			
		Publicly funded	Privately funded	Unspecified	Rate publicly funded	Publicly funded	Privately funded	Unspecified	Rate publicly funded
Gastric banding	<40.0	33	68	1	32.7%	124	690	4	15.2%
	40.0-44.9	102	59	3	63.4%	378	449	7	45.7%
	45.0-49.9	107	48	4	69.0%	402	195	13	67.3%
	50.0-54.9	86	20	2	81.1%	316	93	9	77.3%
	>54.9	89	9	4	90.8%	203	44	6	82.2%
	Unspecified	7	1	1	87.5%	32	10	14	76.2%
Roux-en-Y gastric bypass	<40.0	124	54	2	69.7%	286	249	2	53.5%
	40.0-44.9	346	68	0	83.6%	1,072	301	3	78.1%
	45.0-49.9	564	64	0	89.8%	1,614	288	3	84.9%
	50.0-54.9	459	36	0	92.7%	1,473	138	1	91.4%
	>54.9	409	39	0	91.3%	1,220	103	2	92.2%
	Unspecified	50	3	6	94.3%	133	7	14	95.0%
Sleeve gastrectomy	<40.0	30	47	0	39.0%	91	236	3	27.8%
	40.0-44.9	108	50	0	68.4%	346	159	0	68.5%
	45.0-49.9	172	44	1	79.6%	431	87	0	83.2%
	50.0-54.9	182	26	0	87.5%	458	58	1	88.8%
	>54.9	332	29	2	92.0%	597	65	2	90.2%
	Unspecified	18	2	6	90.0%	30	16	2	65.2%

Patients with lower BMI were more likely to be privately funded irrespective of gender. Whereas 30.3% and 56.5% of primary gastric bypasses respectively were privately funded in men and women with BMI <40.0 kg m^{-2}, less than 10% of super-obese patients (BMI >50 kg m^{-2}) were privately funded. This may either indicate that obesity is a less acute problem in more affluent sections of the society or that public funding is being restricted to more severe forms of obesity. Since elevated BMI is associated with a more frequent incidence of adverse outcomes, it may also indicate unwillingness on the part of surgeons to undertake riskier work in the private sector.


Primary operations for men: Source of funding; financial years 2011-2013
Gastric banding (n=629)
Roux-en-Y gastric bypass (n=2,216)
Sleeve gastrectomy (n=1,040)
Percentage of operations that are publicly funded
100%
80%
60%
40%
20%
0%
<40.0
40.0-44.9
45.0-49.9
50.0-54.9
>54.9
All
Initial BMI / kg m-2


Primary operations for women: Source of funding; financial years 2011-2013
Gastric banding (n=2,936)
Roux-en-Y gastric bypass (n=6,884)
Sleeve gastrectomy (n=2,574)
Percentage of operations that are publicly funded
100%
80%
60%
40%
20%
0%
<40.0
40.0-44.9
45.0-49.9
50.0-54.9
>54.9
All
Initial BMI / kg m-2

Comorbidity at presentation

Number of comorbid conditions

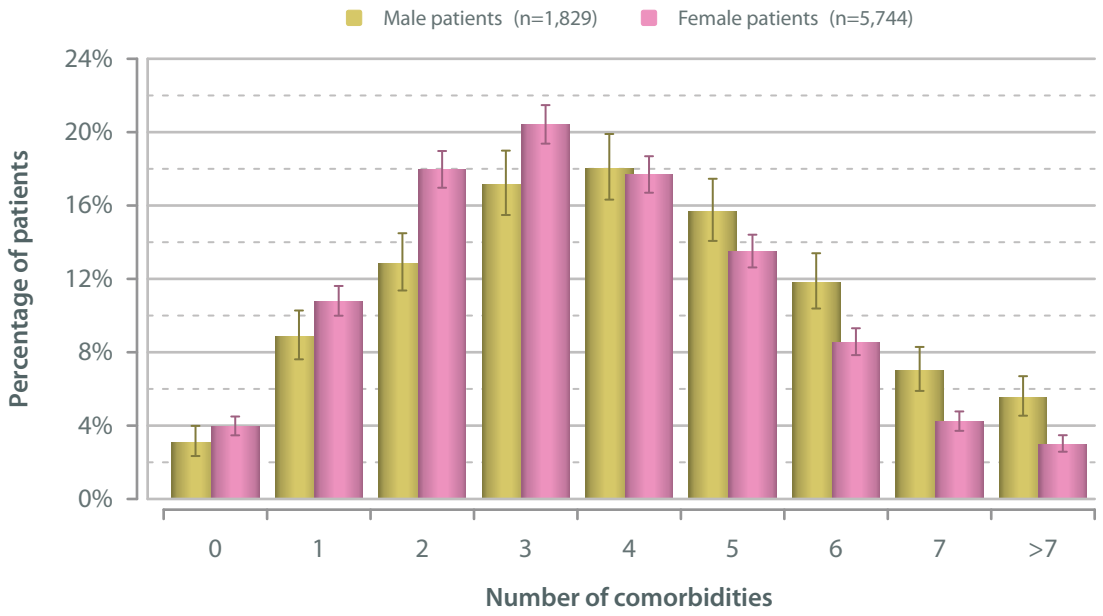
The vast majority of patients undergoing gastric bypass have 3 or more comorbidities (75.2% of men and 67.3% of women).

A higher proportion of men have 4 or more comorbidities compared to women. Conversely, a higher proportion of women have 0-3 comorbidities. This confirms that males undergoing gastric bypass suffer with more comorbidities compared to females ($p<0.001$; χ^2 analysis of numbers of comorbidities as presented below). It is generally recognized that men present later for bariatric surgery and with more severe forms of obesity.

Primary operations: number of comorbid conditions and gender for entries where all comorbidity questions are completed; financial years 2011-2013

		Operation and gender					
		Gastric banding		Roux-en-Y gastric bypass		Sleeve gastrectomy	
		Male	Female	Male	Female	Male	Female
Number of comorbidities	0	35	325	56	227	49	127
	1	73	446	162	619	92	266
	2	92	501	235	1,031	124	358
	3	100	496	314	1,172	148	420
	4	73	327	330	1,015	152	345
	5	53	171	287	775	127	265
	6	36	88	216	491	88	150
	7	22	32	128	242	50	87
	>7	11	16	101	172	29	60
	All	495	2,402	1,829	5,744	859	2,078

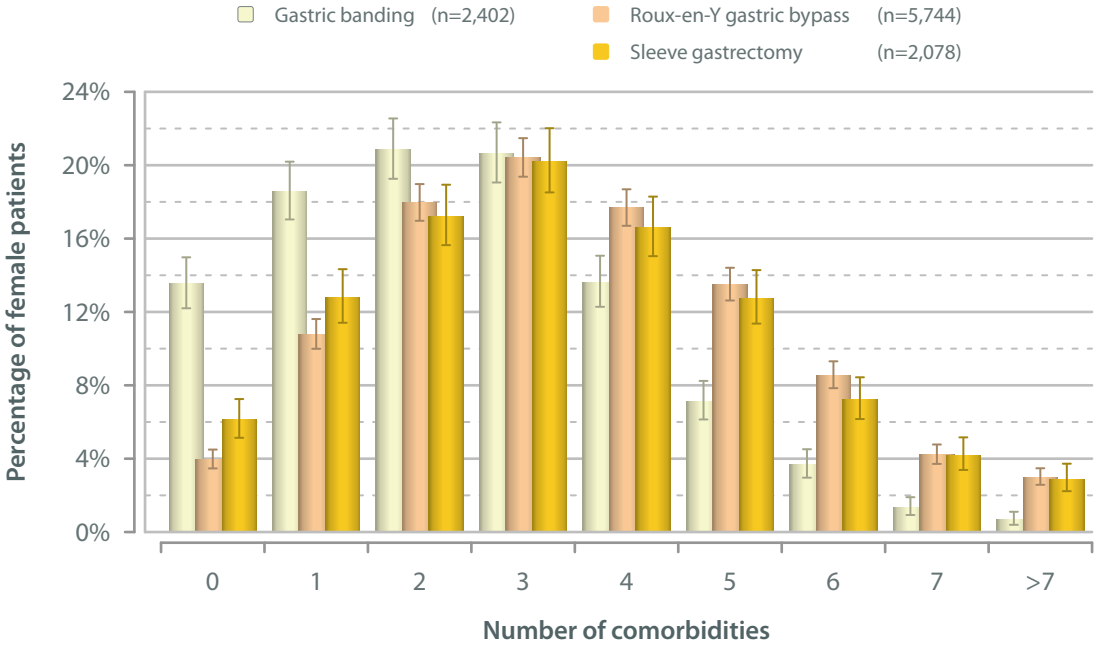
Primary Roux-en-Y gastric bypass operations with complete comorbidity data: Number of comorbidities and gender; financial years 2011-2013



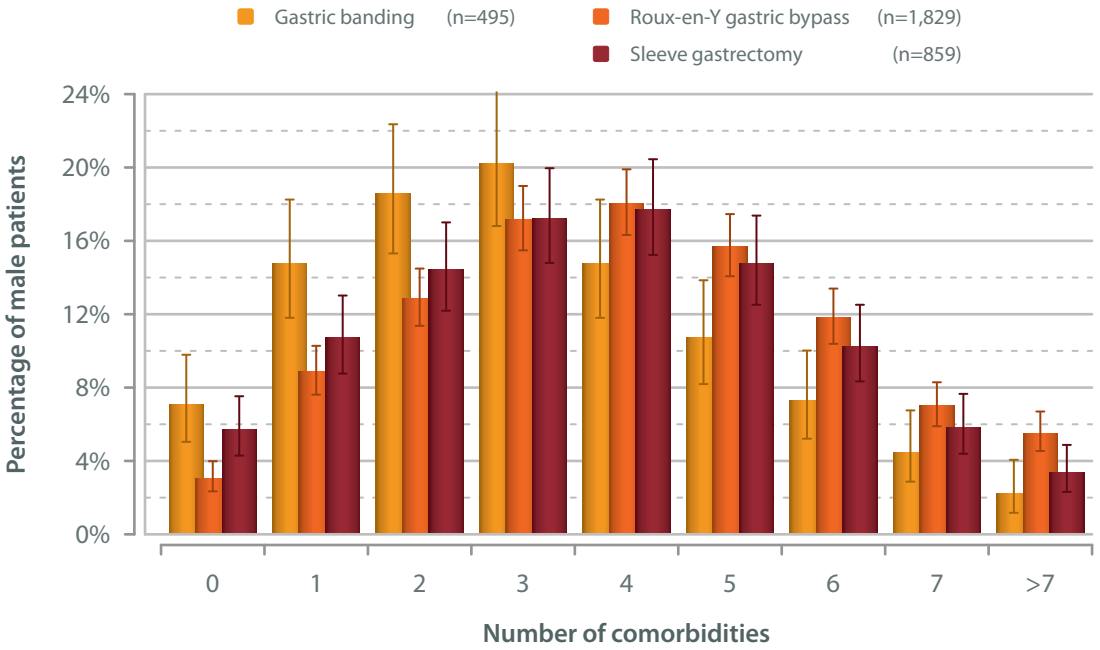
Patients undergoing gastric bypass are more likely to suffer with 4 or more comorbidities compared to those undergoing gastric banding or sleeve gastrectomy. They are also less likely to suffer with 0-2 comorbidities compared to gastric banding and sleeve gastrectomy patients.

Patients with more severe forms of obesity suffering with higher number of comorbidities are more likely to choose or be offered a gastric bypass procedure.

Primary Roux-en-Y gastric bypass operations for women with complete comorbidity data: Number of comorbidities; financial years 2011-2013



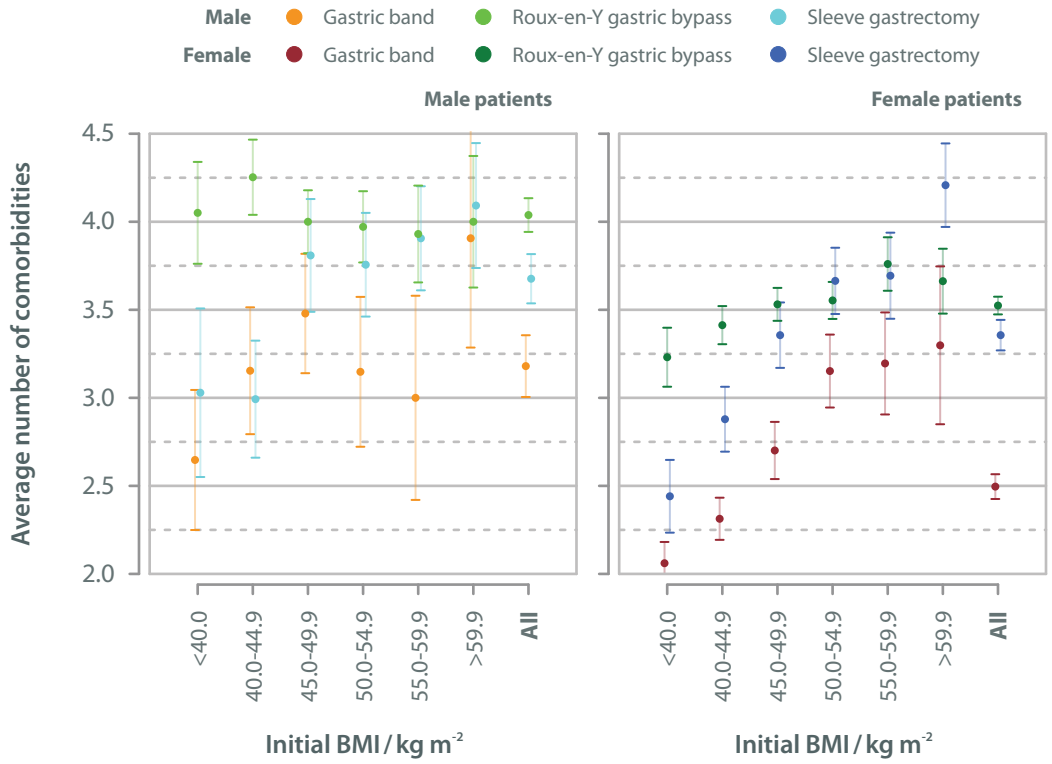
Primary Roux-en-Y gastric bypass operations for men with complete comorbidity data: Number of comorbidities; financial years 2011-2013



Both men and women undergoing gastric bypass have more comorbid disease than those undergoing gastric banding and sleeve gastrectomy. The relative difference in numbers of comorbidities was greater at the lower end of the range of BMIs ; greatest for patients with a BMI less than 40 kg m^{-2}.

On average, a man undergoing gastric bypass has 4 comorbidities, whereas a female patient has 3.5 comorbidities.

Primary operations with complete comorbidity data: Average number of comorbidities, initial BMI and gender; financial years 2011-2013



Comorbidity rates for female patients

For our females patients, those undergoing primary gastric bypass have a significantly greater incidence of each comorbid condition reported here than female patients undergoing gastric banding (p<0.001).

Compared to sleeve gastrectomy patients, these patients were significantly more likely to suffer with GORD (39.8% *versus* 35.2%) and type 2 diabetes (31.1% *versus* 23.3%). This might be taken to indicate that gastric bypass is seen as superior to sleeve gastrectomy for patients with GORD [1] and type 2 diabetes.

Primary operations for female patients: details of comorbid conditions at presentation; financial years 2011-2013

		Operation							
		Roux-en-Y gastric bypass		Gastric banding			Sleeve gastrectomy		
		Comorbidity data recorded	Comorbidity present	Comorbidity data recorded	Comorbidity present	significance [i]	Comorbidity data recorded	Comorbidity present	significance [ii]
Comorbidities [iii]	Arthritis	6,531	57.0%	2,786	49.2%	<0.001	2,417	56.3%	0.563
	Asthma	6,609	22.4%	2,819	15.6%	<0.001	2,475	23.9%	0.130
	Atherosclerosis	6,590	4.5%	2,808	2.0%	<0.001	2,461	5.3%	0.153
	Depression	6,325	30.5%	2,711	22.2%	<0.001	2,313	29.1%	0.235
	Dyslipidaemia	6,569	23.3%	2,802	12.7%	<0.001	2,454	22.5%	0.440
	GORD [iv]	6,362	39.8%	2,700	32.5%	<0.001	2,341	35.2%	<0.001
	Hypertension	6,618	38.3%	2,819	26.4%	<0.001	2,476	37.0%	0.232
	Liver disease	6,426	5.5%	2,731	2.5%	<0.001	2,382	5.5%	0.987
	PCOS [v]	6,421	10.3%	2,740	7.5%	<0.001	2,375	8.5%	0.016
	Poor functional status [vi]	6,528	75.3%	2,705	57.5%	<0.001	2,443	77.7%	0.023
	Sleep apnoea	6,612	18.0%	2,817	8.5%	<0.001	2,470	18.4%	0.708
	Type 2 diabetes	6,605	31.1%	2,815	15.8%	<0.001	2,469	23.3%	<0.001
	All primary operations	**6,909**		**2,989**			**2,582**		

1. Zhang N, Maffei A, Cerabona T, Pahuja A, Omana J, Kaul A. Reduction in obesity-related comorbidities: is gastric bypass better than sleeve gastrectomy? *Surgical Endoscopy*. 2013; **27(4)**: 1273-80.

i. χ^2 probability; comparing the incidence amongst the Roux-en-Y gastric bypass patient-population with the rate observed in the gastric banding patient-population.

ii. χ^2 probability; comparing the incidence amongst the Roux-en-Y gastric bypass patient-population with the rate observed in the sleeve gastrectomy patient-population.

iii. One of the comorbidity questions is only collected for the female patients: *polycystic ovary syndrome*.

iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

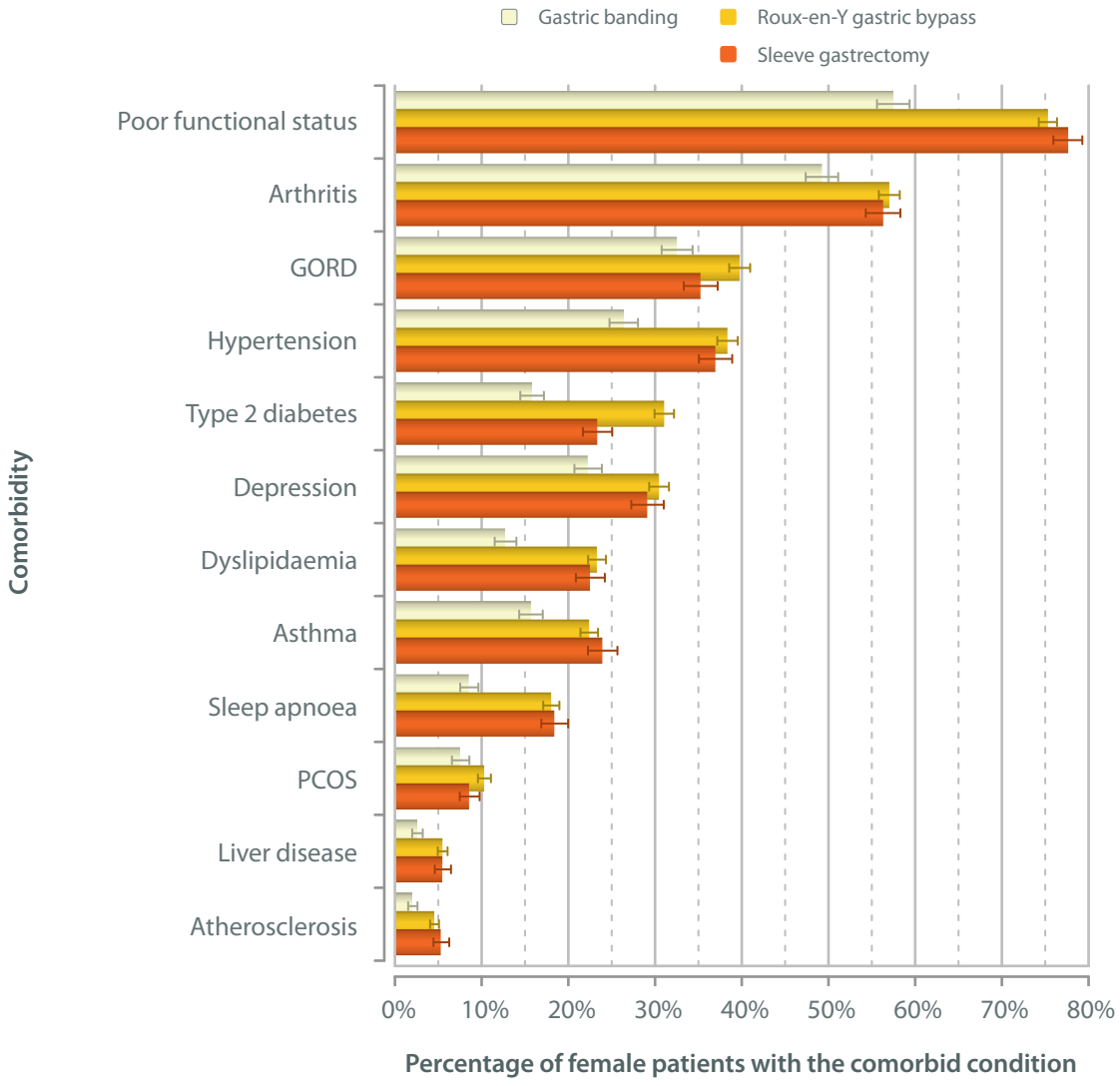
v. Polycystic ovary syndrome.

vi. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

Poor functional status (inability to climb three flights of stairs) was the commonest of the comorbid conditions amongst female patients undergoing gastric bypass (present in 75% of patients), followed, in descending order of incidence, by arthritis, GORD, hypertension, type 2 diabetes, depression, dyslipidaemia, asthma, sleep apnoea, PCOS, liver disease, and atherosclerosis.

Significantly, 40% of patient had GORD, more than a third had hypertension, 30% had type 2 diabetes, and 30% reported depression. Significant weight loss often results in a remarkable improvement in all of these comorbid conditions.

Primary operations for female patients: Rates of various comorbid conditions; financial years 2011-2013



Comorbidity rates for male patients

Male patients undergoing primary gastric bypass had a significantly greater incidence of depression, dyslipidaemia, GORD, hypertension, liver disease, poor functional status, sleep apnoea, and type 2 diabetes when compared to male patients undergoing gastric banding. The incidence of atherosclerosis, dyslipidaemia, GORD, hypertension, sleep apnoea, and type 2 diabetes was significantly greater than in the cohort of men who had a sleeve gastrectomy procedure.

This may indicate that, generally, patients undergoing gastric bypass suffer with more systemic illnesses as a result of their obesity.

Primary operations for male patients: details of comorbid conditions at presentation; financial years 2011-2013

		Operation							
		Roux-en-Y gastric bypass		Gastric banding			Sleeve gastrectomy		
		Comorbidity data recorded	Comorbidity present	Comorbidity data recorded	Comorbidity present	significance [i]	Comorbidity data recorded	Comorbidity present	significance [ii]
Comorbidities [iii]	Arthritis	2,085	56.8%	583	52.1%	0.051	980	55.3%	0.464
	Asthma	2,105	15.1%	593	11.8%	0.053	989	15.8%	0.645
	Atherosclerosis	2,088	11.4%	592	10.5%	0.556	983	8.9%	0.034
	Depression	2,045	18.5%	573	12.7%	0.001	966	16.6%	0.206
	Dyslipidaemia	2,083	38.5%	589	24.1%	<0.001	977	30.8%	<0.001
	GORD [iv]	2,020	34.2%	558	29.2%	0.030	944	29.1%	0.007
	Hypertension	2,109	57.1%	591	45.3%	<0.001	991	53.2%	0.042
	Liver disease	2,017	8.0%	561	5.2%	0.030	949	6.5%	0.186
	PCOS [v]								
	Poor functional status [vi]	2,059	72.8%	555	62.0%	<0.001	975	78.9%	<0.001
	Sleep apnoea	2,109	42.5%	591	32.0%	<0.001	987	38.3%	0.030
	Type 2 diabetes	2,100	51.3%	591	32.3%	<0.001	991	36.6%	<0.001
	All primary operations	**2,224**		**644**			**1,049**		

i. χ^2 probability; comparing the incidence amongst the Roux-en-Y gastric bypass patient-population with the rate observed in the gastric banding patient-population.

ii. χ^2 probability; comparing the incidence amongst the Roux-en-Y gastric bypass patient-population with the rate observed in the sleeve gastrectomy patient-population.

iii. One of the comorbidity questions is only collected for the female patients: *polycystic ovary syndrome*.

iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

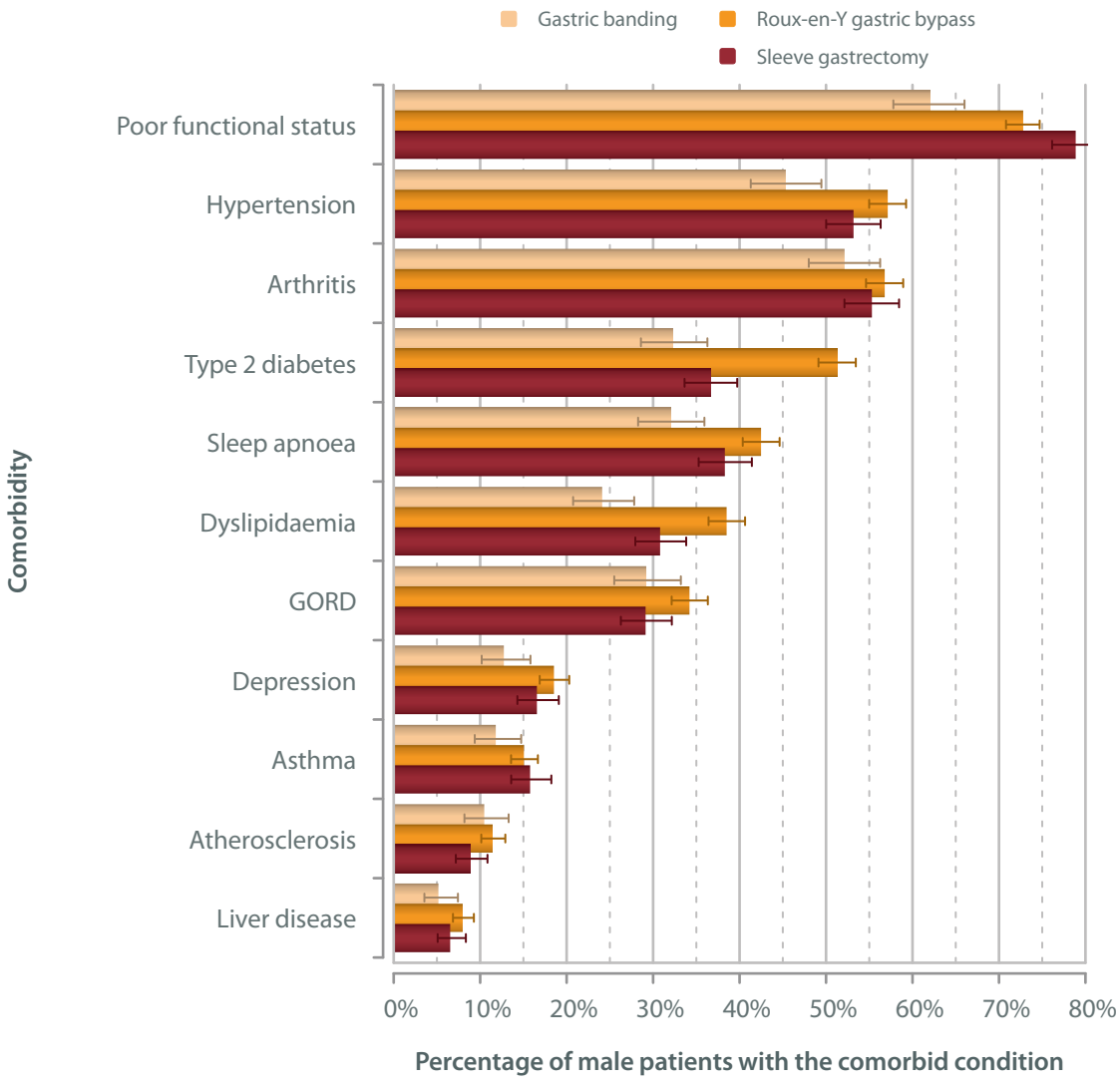
v. Polycystic ovary syndrome.

vi. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

As reported for the female patients above, poor functional status (inability to climb three flights of stairs without resting) was the commonest comorbid condition amongst the men undergoing primary gastric bypass; it was present in more than 70% of patients.

Remarkably, both type 2 diabetes and hypertension had a reported incidence of over 50% in male patients who had a gastric bypass procedure. Dyslipidaemia was reported in nearly 40% of patients. Once again, this indicates that male patients undergoing primary gastric bypass are more likely to suffer with extensive systemic disease caused by their obesity compared to their female counterparts.

Primary operations for male patients: Rates of various comorbid conditions; financial years 2011-2013



Obesity Surgery Mortality Risk Score

The Obesity Surgery Mortality Risk Score (OSMRS) stratifies patients undergoing bariatric surgery into three categories depending on how many of the following risk factors they possess:

- Male gender.
- Age ≥45 years at the time of surgery.
- BMI >50 kg m^2.
- Hypertension.
- Risk factors for deep vein thrombosis / pulmonary embolism.

The patient is ascribed one point for each of the above risk factors and a cumulative score determines, giving a total score in the range zero to five; this score is grouped into one of three categories:

- Group A: score 0-1 (low risk)
- Group B: score 2-3 (moderate risk)
- Group C: score 4-5 (high risk)

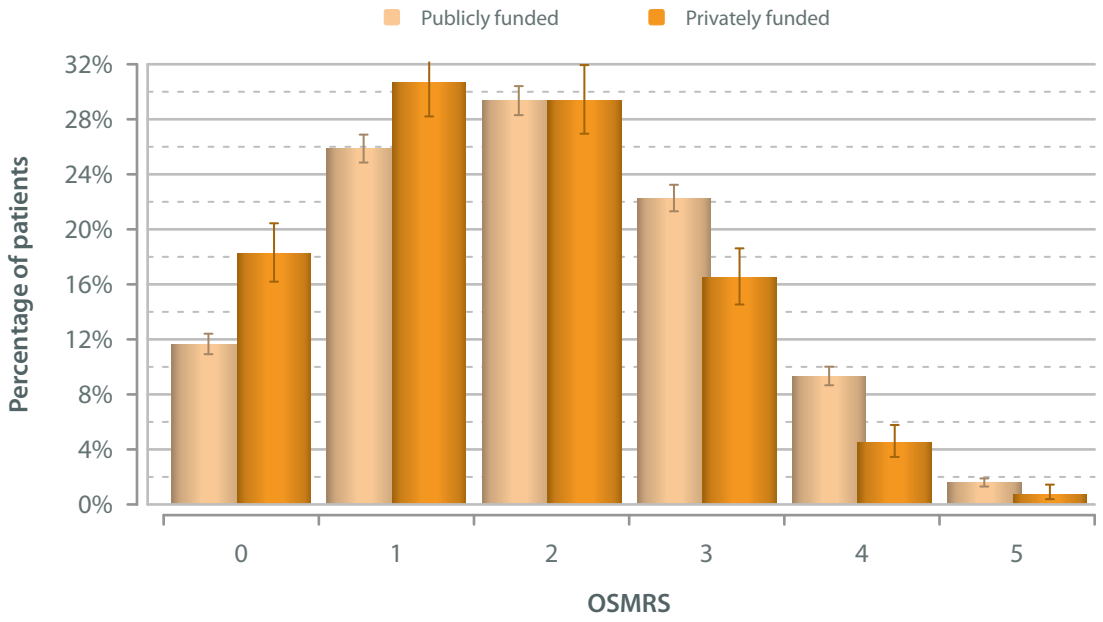
Patients with higher OSMRS, who are at higher risk of post-operative complications and mortality, were more likely to be publicly funded.

Most patients in OSMRS Group C have a Roux-en-Y gastric bypass procedure (860 patients *versus* 154 having gastric banding and 479 having a sleeve gastrectomy); in simple numerical terms, the patient's odds of having a gastric bypass procedure if they are at high risk are 1.36.

The OSMRS distributions according to the source of funding show that more privately funded patients fall into the low risk categories than do the publicly funded patients; the odds on public funding increases with increasing OSMRS (4.2 *versus* 6.2 *versus* 11.4 for groups A, B and C respectively).

This may be due to a number of factors, as discussed above, but does tend to suggest that patients at higher risk are more likely to have access to publicly funded procedures.

Primary Roux-en-Y gastric bypass: OSMRS and source of funding; financial years 2011-2013



For publicly funded patients, gastric bypass was the most commonly performed operation irrespective of risk. In the group of patients who were privately funded, gastric banding was the commonest procedure for low-risk patients (OSMRS 0-1), but for all other OSMRS risk groups, bypass was the operation of choice.

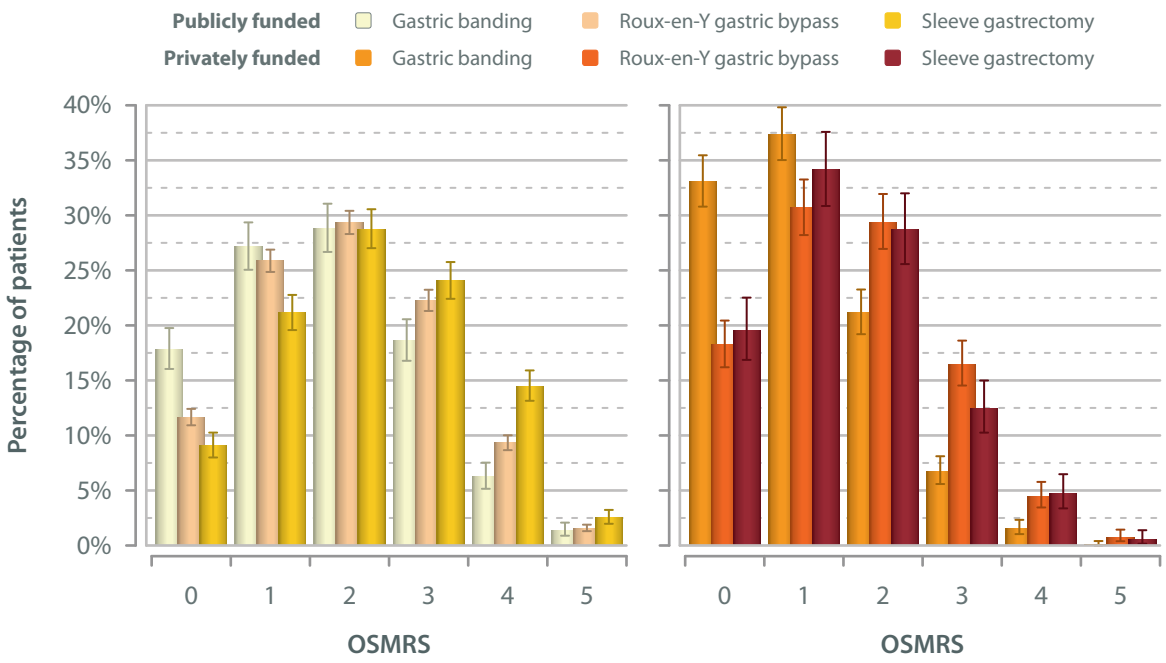
The selection of the most appropriate bariatric surgical procedure for any given patient is a multi-layered process and currently the NBSR is unable to fully describe the reasons for each individual operation.

Primary operations: Obesity Surgery Mortality Risk Score (OSMRS) and source of funding; financial years 2011-2013

Operation and OSMRS			Source of funding			
			Publicly funded		Privately funded	
			Count	Percentage	Count	Percentage
Gastric banding		0	300	17.8%	530	33.1%
		1	457	27.2%	599	37.4%
		2	485	28.8%	339	21.2%
		3	313	18.6%	108	6.7%
		4	105	6.2%	25	1.6%
		5	23	1.4%	1	0.1%
		Group A	757	45.0%	1,129	70.5%
		Group B	798	47.4%	447	27.9%
		Group C	128	7.6%	26	1.6%
		Unspecified	196		84	
Roux-en-Y gastric bypass		0	845	11.6%	240	18.2%
		1	1,876	25.9%	404	30.7%
		2	2,129	29.3%	387	29.4%
		3	1,615	22.3%	217	16.5%
		4	676	9.3%	59	4.5%
		5	114	1.6%	10	0.8%
		Group A	2,721	37.5%	644	48.9%
		Group B	3,744	51.6%	604	45.9%
		Group C	790	10.9%	69	5.2%
		Unspecified	495		33	
Sleeve gastrectomy		0	233	9.1%	154	19.5%
		1	543	21.1%	269	34.1%
		2	739	28.8%	226	28.7%
		3	618	24.0%	98	12.4%
		4	372	14.5%	37	4.7%
		5	65	2.5%	4	0.5%
		Group A	776	30.2%	423	53.7%
		Group B	1,357	52.8%	324	41.1%
		Group C	437	17.0%	41	5.2%
		Unspecified	225		31	

Roux-en-Y gastric bypass

Primary procedures: Operation, source of funding and OSMRS; financial years 2011-2013



Technical aspects of Roux-en-Y gastric bypass

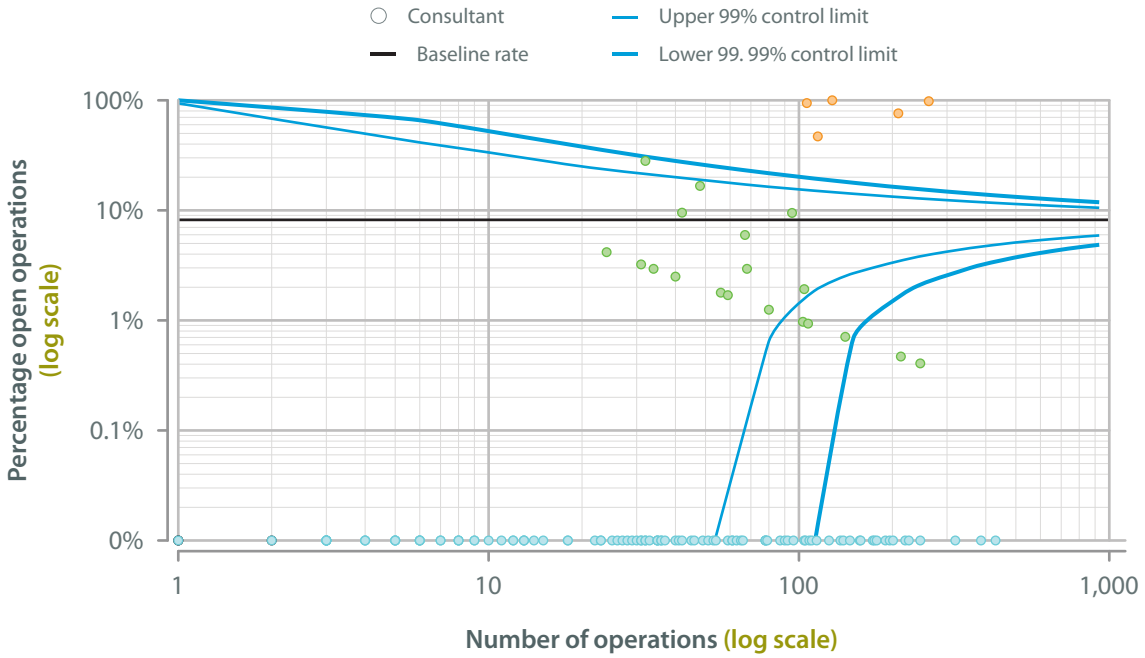
Surgical approach

It is now generally accepted that the laparoscopic approach results in better outcomes for the patient. The adoption of this surgical technique is thought to be one of the major reasons for the explosion in demand for bariatric surgery procedures over the past decade. Laparoscopic gastric bypass remains one of the most technically challenging operations, and requires a high level of surgical skill to perform competently. Dedicated training programs and targeted Fellowships have been very successful in providing more skilled surgeons who will be needed to meet an ever-increasing demand for this service from patients within the United Kingdom.

The United Kingdom has reported a very low conversion-to-open rate for this surgery. Surgeons seem to fall into three distinct groups: those who always perform bypass surgery as a laparoscopic procedure, others who sometimes convert to an open approach (essentially those within the funnel) and a last group who prefer to perform gastric bypass as an open procedure (>40% of the operations they perform). These preferences seem to be largely independent of the number of operations performed.

Future reports could analyse in more detail the results of surgeons who do open surgery *versus* those who perform only laparoscopic surgery.

Primary Roux-en-Y gastric bypass: Funnel plot on open surgery rate for each consultant; financial years 2011-2013 (n=9,121)



Gastric pouch

The vast majority of gastric bypasses were carried out using a vertical lesser curvature based gastric pouch. However, there are surgeons who perform horizontal pouch including fundus. As the number of entries in the NBSR increases and the follow up continues to accumulate, it will be interesting to see if the long-term results for these patients are any different to those with vertical lesser curve based pouch, particularly looking at weight loss observed in follow up.

Roux-en-Y gastric bypass: gastric pouch and type of operation; financial years 2011-2013

		Gastric pouch				
		Vertical [i]	Horizontal [ii]	Unspecified	**All**	Percentage vertical
Type of surgery	Primary	8,129	661	343	**9,133**	92.5%
	Revision as a primary	234	17	16	**267**	93.2%
	Revision	79	1	6	**86**	98.8%
	Planned 2nd stage	40	0	0	**40**	100.0%
	All	**8,482**	**679**	**365**	**9,526**	92.6%

i. Vertical lesser curve pouch.

ii. Horizontal pouch including fundus.

Linear stapler for the gastric pouch

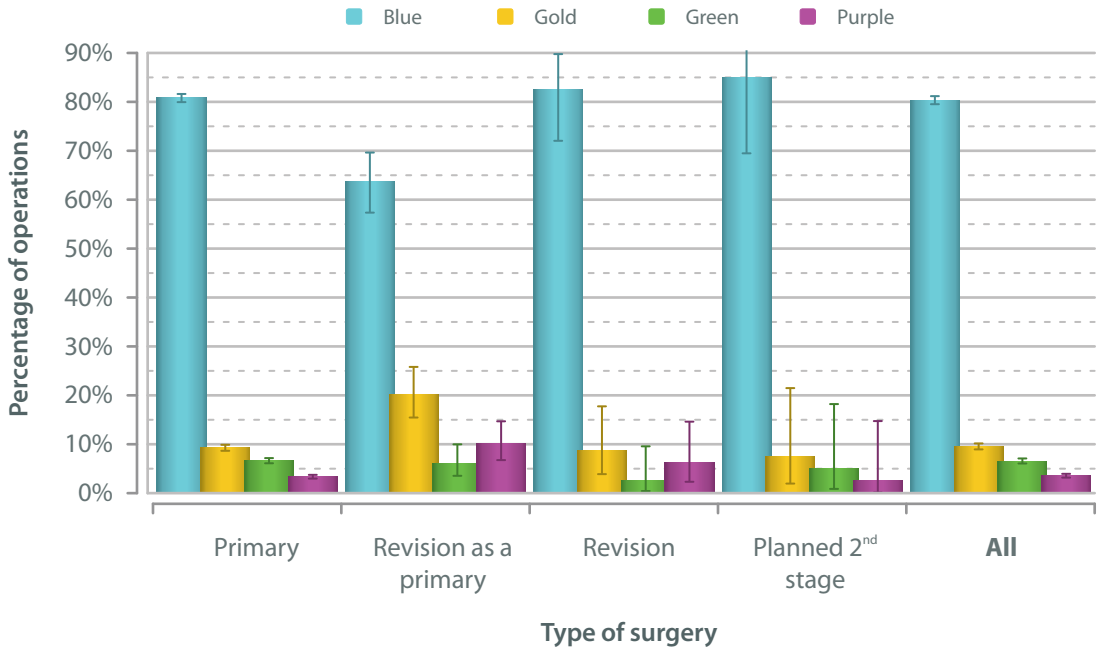
Formation of the gastric pouch is carried out using linear staplers, which seal and divide tissues simultaneously, using multiple rows of staples. These staplers come in a variety of sizes; most surgeons use a blue cartridge for this purpose, as is evident in both the table and chart below. Revisional surgery involves working on thicker, scarred tissues, which are sometimes better dealt with using cartridges that have a greater staple height. This is especially evident in the chart below for the patients having a *revision as a primary* gastric bypass, where the usage rates of the larger gold and purple cartridges are higher than seen in primary surgery, with a concomitant drop in the rate of the use of the blue cartridge.

For a number of operation records (468) the type of staple cartridge used was not recorded. These cases may represent operations performed by surgeons who are using staplers from new manufacturers that are currently not recorded in the NBSR.

Roux-en-Y gastric bypass: linear stapler used in gastric pouch formation and type of surgery; financial years 2011-2013

		Linear stapler					
		Blue	Green	Gold	Purple	Unspecified	**All**
Type of surgery	Primary	7,021	804	575	290	443	**9,133**
	Revision as a primary	158	50	15	25	19	**267**
	Revision	66	7	2	5	6	**86**
	Planned 2nd stage	34	3	2	1	0	**40**
	All	**7,279**	**864**	**594**	**321**	**468**	**9,526**
	Percentage	80.4%	9.5%	6.6%	3.5%		

Roux-en-Y gastric bypass: Linear stapler used for gastric pouch formation (n=9,058)



Reinforcement

A minority of surgeons used material to reinforce staple lines. However, there is currently no robust evidence that the routine use of reinforcement material or fibrin glue reduces bleeding or leak rates after gastric bypass. Since their use does involve additional cost, it is hardly surprising that majority of bypasses were performed without use of any such material. Cost considerations are obviously very important for surgeons working in a publicly funded healthcare system such as the NHS.

Roux-en-Y gastric bypass: reinforcement; financial years 2011-2013

		Type of surgery				
		Primary	Revision as a primary	Revision	Planned 2nd stage	**All**
Reinforcement	None	7,225	203	74	36	**7,538**
	Seamguard	231	12	0	0	**243**
	Peristrips	10	0	1	0	**11**
	Biodesign SLR	5	0	0	0	**5**
	Duet TRS	542	14	1	1	**558**
	Tisseel fibrin glue	7	0	0	0	**7**
	Unspecified	1,116	38	10	3	**1,167**
	All	**9,133**	**267**	**86**	**40**	**9,526**
	Reinforcement rate (95% CI)	9.9% (9.2-10.6%)	11.4% (7.7-16.4%)	2.6% (0.5-10.0%)	2.7% (0.1-15.8%)	**9.8% (9.2-10.5%)**

Method of gastro-jejunostomy formation

The joint between the gastric pouch and the small bowel (gastro-jejunostomy) can be performed using one of three commonly-used techniques:

- linear stapler,
- circular stapler, or
- hand sewn (without use of any staplers).

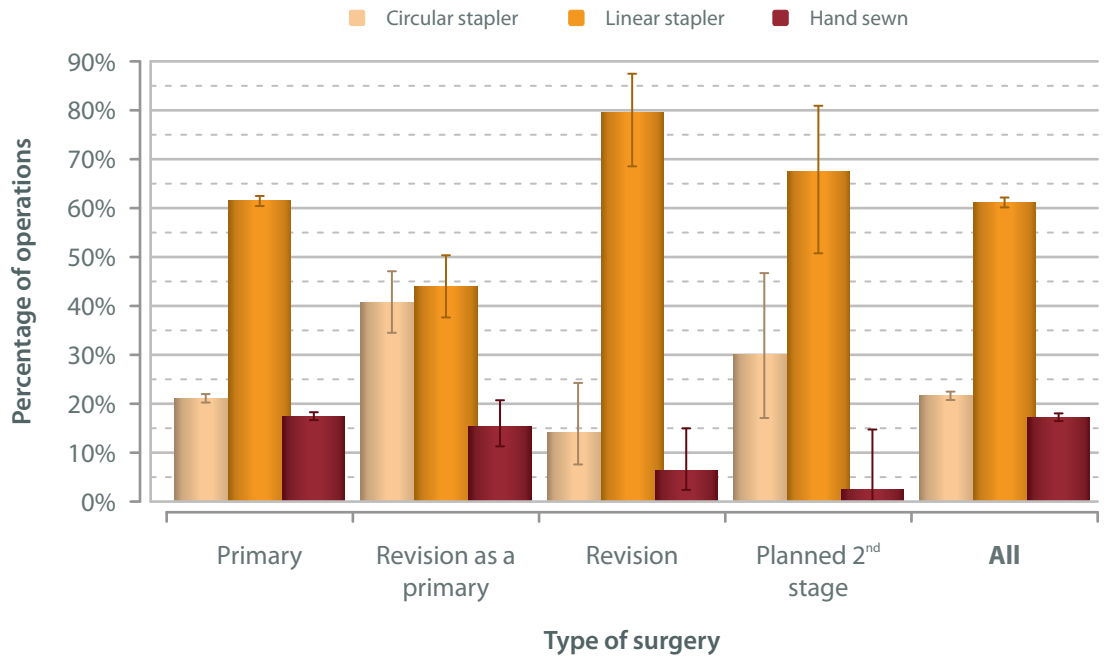
The *linear stapler* technique was the most-commonly recorded technique (61.2%) followed by the *circular stapler* technique (21.6%) and then the *hand sewn* approach (17.2%). The *linear stapler* technique usually involves suture closure of the stapler entry hole.

Proponents of the circular stapler technique believe that calibrating the stoma size is important for reducing dumping and promoting sustained long-term weight loss in these patients. Whether that is indeed the case should become clear in future NBSR reports. The *linear stapler* technique, on the other hand, means that the operation can be performed with a single stapler at a lower cost and at a lower risk of anastomotic narrowing.

Roux-en-Y gastric bypass: method of gastro-jejunostomy formation; financial years 2011-2013

		Method of gastro-jejunostomy formation				
		Circular stapler	Linear stapler	Hand sewn	Unspecified	All
Type of surgery	Primary	1,825	5,316	1,509	483	**9,133**
	Revision as a primary	100	108	38	21	**267**
	Revision	11	62	5	8	**86**
	Planned 2nd stage	12	27	1	0	**40**
	All	**1,948**	**5,513**	**1,553**	**512**	**9,526**

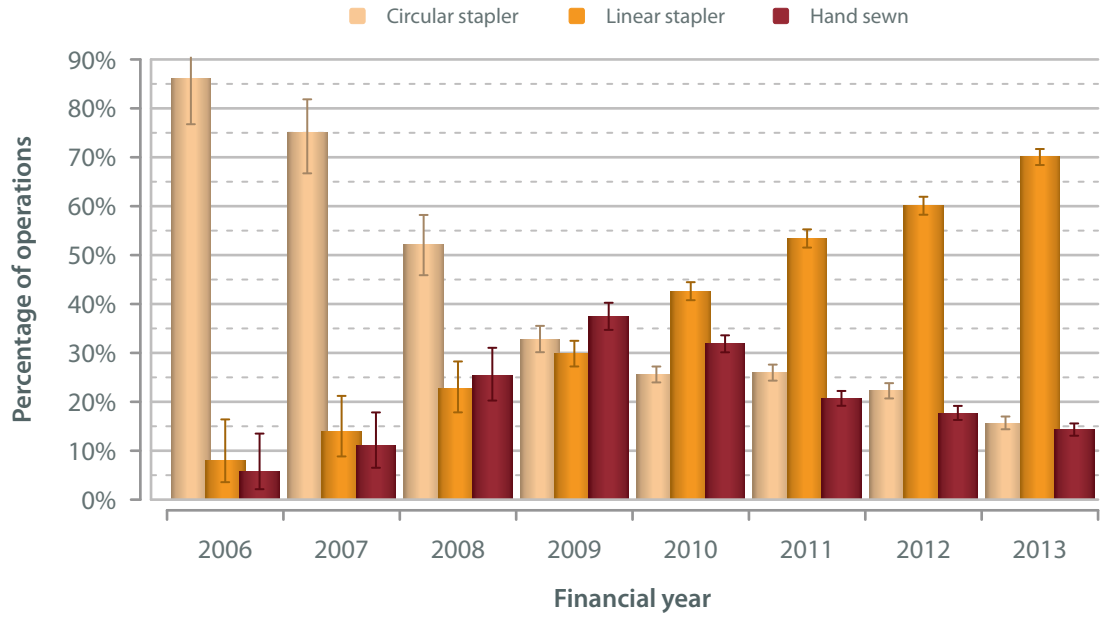
Roux-en-Y gastric bypass: Method of gastro-jejunostomy formation; financial years 2011-2013 (n=9,014)



In 2006, the vast majority of surgeons fashioned their gastro-jejunostomy using circular staplers. Over the following years, the percentage use of circular staplers declined as the use of the linear stapler and hand-sewn techniques increased. By 2009, these three techniques were roughly equally in popularity. Since 2009, use of both the *circular stapler* and *hand sewn* techniques have declined.

This may be due to the fact that the use of circular staplers in this context can be associated with higher stricture (narrowing of the anastomosis) rates. At the same time, concerns regarding a greater risk of dumping syndrome and less weight loss with linear staplers have largely not materialized. However, this change may be related also to the increasing number of surgeons entering data into the NBSR over time and reflect the techniques they were trained to use.

Primary Roux-en-Y gastric bypass:
Changes in gastric pouch jejunostomy over time (n=13,161)



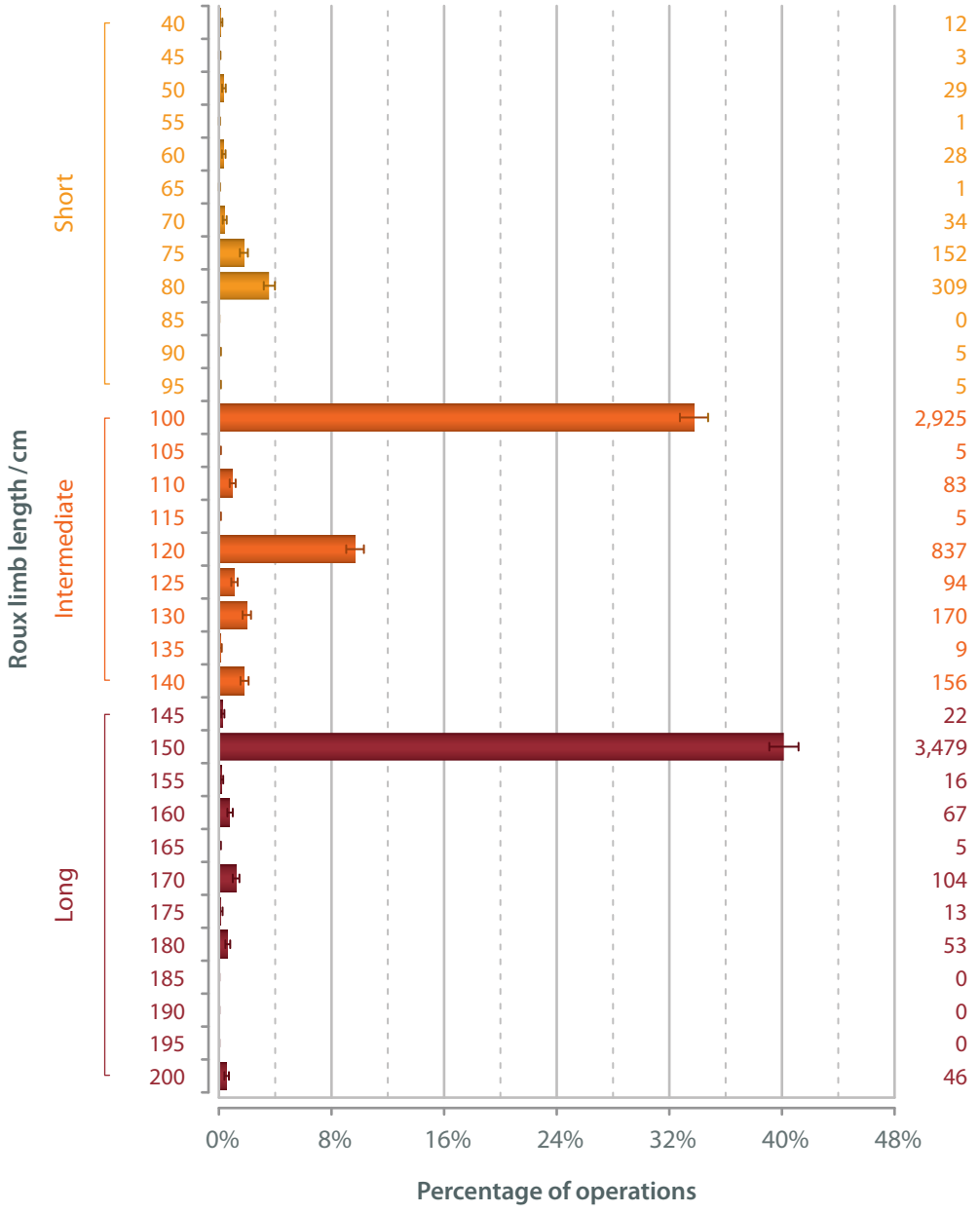
Roux limb

Roux limb length

Though a wide variation exists in the length of the Roux limb (also known as alimentary limb) in primary gastric bypasses, limb lengths of 150 cm (40.1%) and 100 cm (33.7%) were most commonly used. The vast majority of Roux-en-Y Gastric bypass procedures were carried out with a 100-150 cm Roux limb (89.8%). No gastric bypass was performed with a Roux limb longer than 200 cm.

Laparoscopic measurements of bowel length are imprecise, and for standard proximal gastric bypass, minor variation in length of Roux limb does not have significant effect on the final weight loss of patients.

Primary Roux-en-Y gastric bypass: Roux limb length; financial years 2011-2013 (n=8,668)



Roux limb length and initial BMI

There was a tendency towards increasing limb length with increasing BMI of the patient.

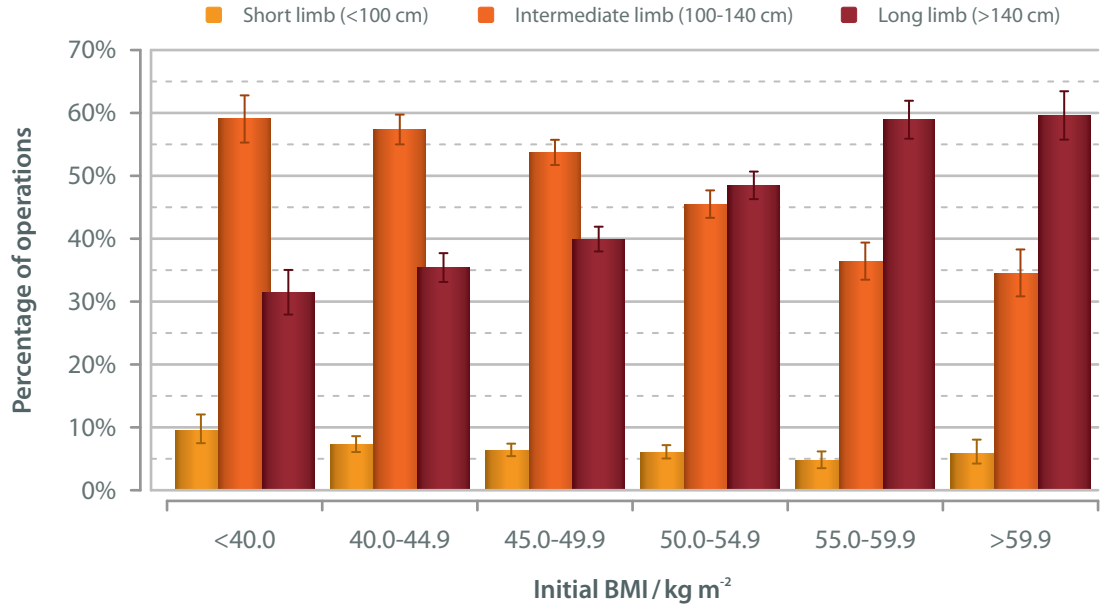
In patients with BMI <40 kg m^{-2}, 31.4% of patients had a long limb bypass (limb length >140 cm) as opposed to 59.7% in those with BMI ≥60 kg m^{-2}. Similarly 9.5% of patients with BMI <40 kg m^{-2} had a short limb bypass (limb length < 100 cm) as opposed to 5.9% of those with a BMI ≥60 kg m^{-2}.

There is some evidence in the literature that limb length becomes an important factor in patients with BMI ≥50 kg m^{-2}. Over time, long-term weight loss data collected in the NBSR should shed more light on the significance of Roux limb length.

Primary Roux-en-Y gastric bypass: Roux limb length and initial BMI; financial years 2011-2013

		Roux limb length				
		Short (<100 cm)	Intermediate (100-140 cm)	Long (>140 cm)	Unspecified	**All**
Initial BMI / kg m^{-2}	<40.0	65	403	214	35	**717**
	40.0-44.9	124	983	606	77	**1,790**
	45.0-49.9	154	1,304	969	106	**2,533**
	50.0-54.9	123	928	989	67	**2,107**
	55.0-59.9	49	382	619	43	**1,093**
	>59.9	38	223	386	33	**680**
	Unspecified	26	61	22	104	**213**
	All	**579**	**4,284**	**3,805**	**465**	**9,133**

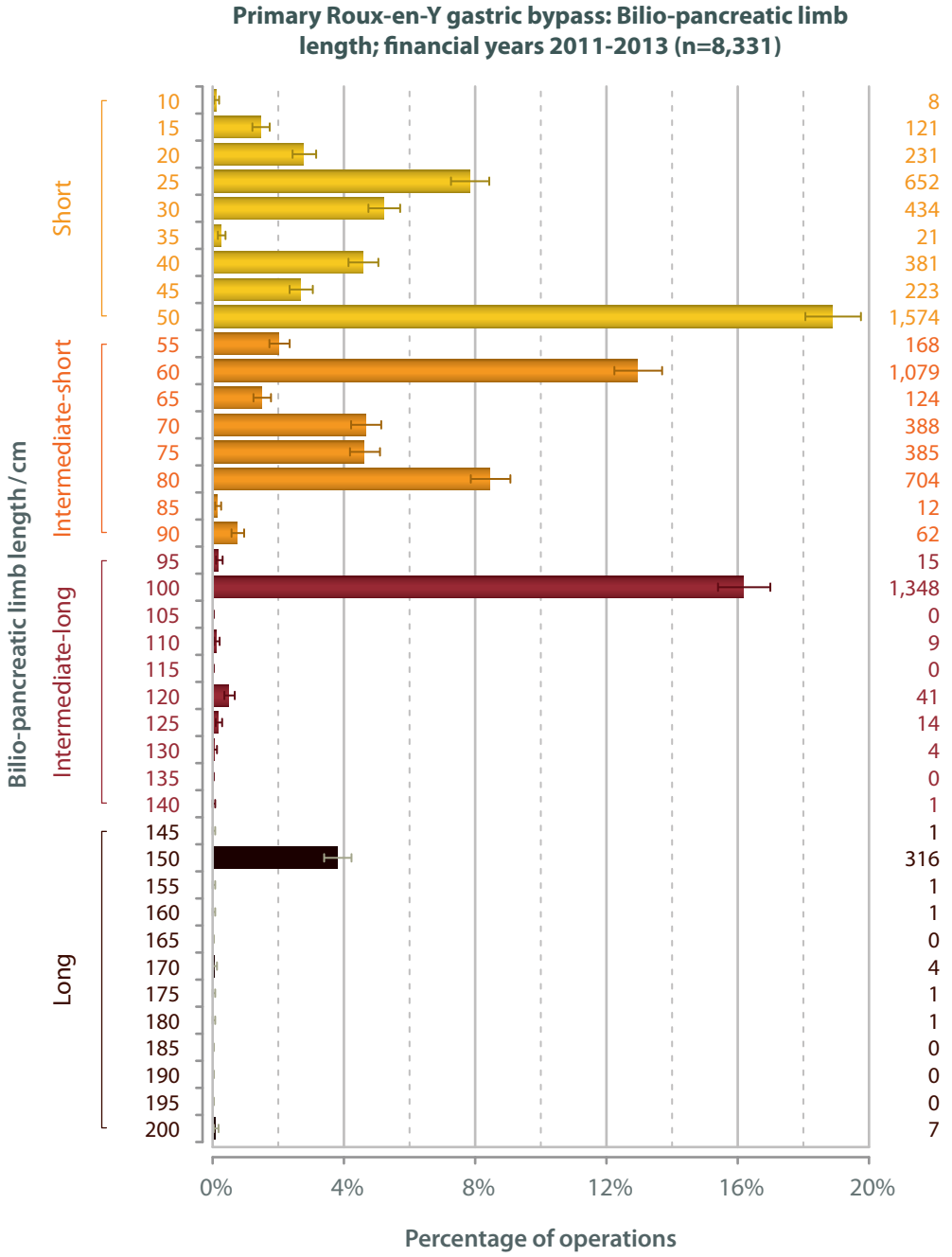
Primary Roux-en-Y gastric bypass: Roux limb length and initial BMI; financial years 2011-2013 (n=8,559)



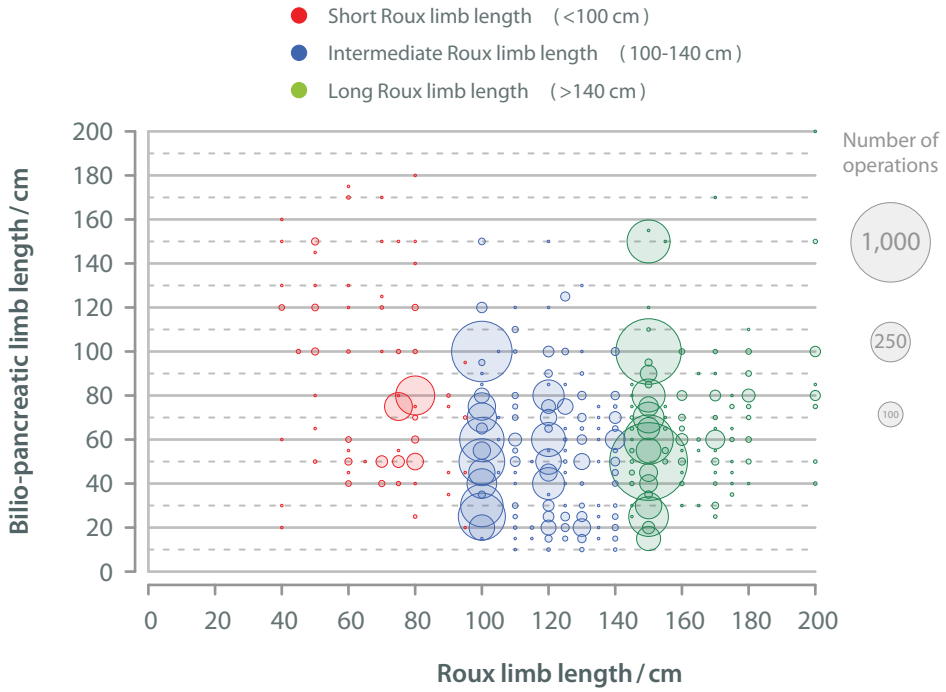
Bilio-pancreatic limb length

The vast majority of gastric bypass procedures were carried out with a bilio-pancreatic limb length of ≤100 cm (range: 10-150 cm). The most commonly-used limb lengths were 50 cm and 100 cm, accounting for 18.9% and 16.2% patients respectively. Interestingly, 17.4% patients had a bilio-pancreatic limb length of ≤30 cm and 3.8% had a limb length of 150 cm.

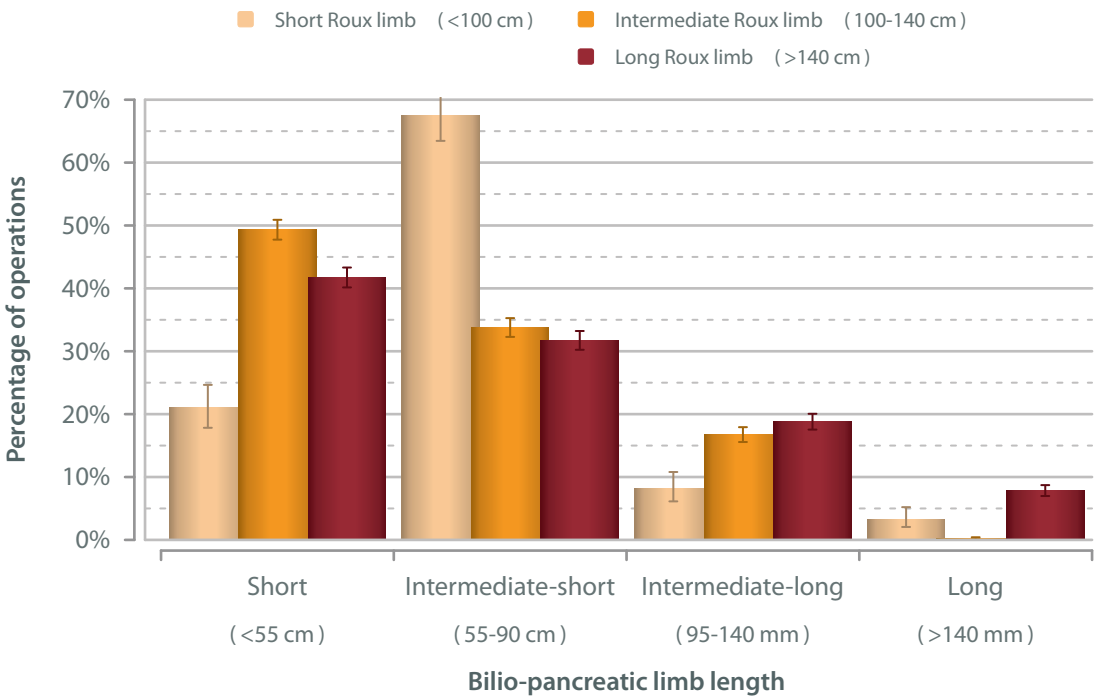
Differences in limb lengths reflect variation in surgical practice, but it may not be possible to completely standardize on this component of the operation as total bowel length and BMI vary significantly from patient to patient.



Primary Roux-en-Y gastric bypass: Roux limb and bilio-pancreatic limb length inter-relationship; financial years 2011-2013 (n=8,288)



Primary Roux-en-Y gastric bypass: Roux limb and bilio-pancreatic limb length inter-relationship; financial years 2011-2013 (n=8,288)



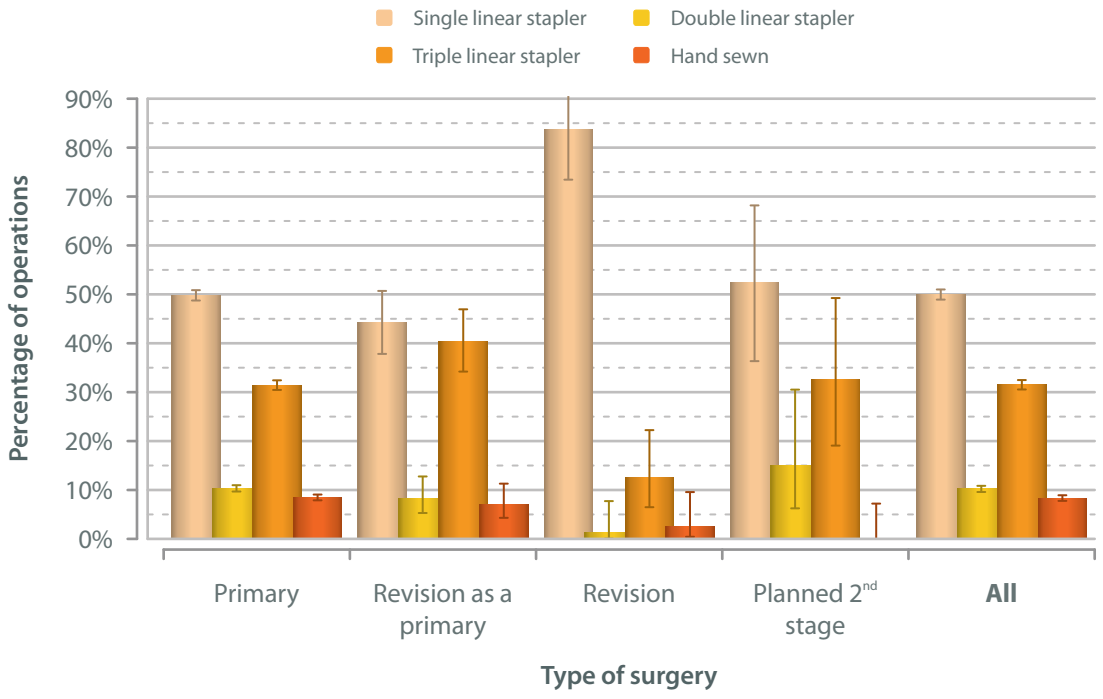
Jejuno-jejunostomy

There are various ways surgeons have performed the jejuno-jejunostomy, but it appears that use of a single linear stapler is the preferred technique, followed in frequency by the triple linear stapler technique.

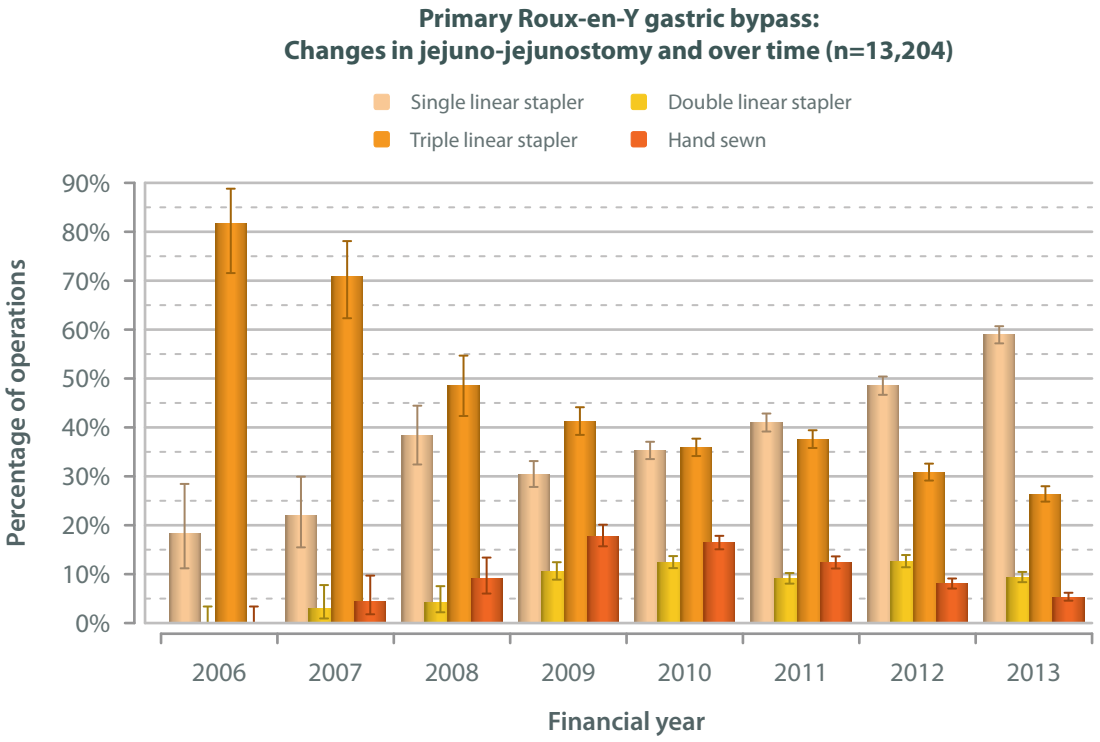
Roux-en-Y gastric bypass: jejuno-jejunostomy; financial years 2011-2013

		Jejuno-jejunostomy					
		Single linear stapler	Double linear stapler	Triple linear stapler	Hand sewn	Unspecified	**All**
Type of surgery	Primary	4,316	894	2,724	733	466	**9,133**
	Revision as a primary	106	20	97	17	27	**267**
	Revision	67	1	10	2	6	**86**
	Planned 2nd stage	21	6	13	0	0	**40**
	All	**4,510**	**921**	**2,844**	**752**	**499**	**9,526**

Roux-en-Y gastric bypass: Jejuno-jejunostomy and type of surgery; financial years 2011-2013 (n=9,027)



Naturally, trends over time may be difficult to interpret as they may involve some biases, as the number of operations recorded in the early years is lower and entered by a smaller number of enthusiastic surgeons. However, there does appear to be a general and sustained trend towards the increasing use of a single linear stapler for the jejuno-jejunostomy. It now accounts for jejuno-jejunostomies in nearly 60% of all primary Roux-en-Y gastric bypass procedures. Triple linear stapler use for jejuno-jejunostomy has fallen from a rate of around 80% to just a little over 25% of cases in the last financial year reported here. There does not seem to have been any change in the rate of complications from different techniques of creating this anastomosis, however.



Linear stapler used

The vast majority of jejuno-jejunostomies are performed using a white stapler cartridge. However, it should be noted that 11.5% were performed using tan cartridges, which were not available at the time of last NBSR report. In future NBSR reports, it will be interesting to look at the complication rates associated with these different stapler cartridges to determine whether or not there are any differences.

Roux-en-Y gastric bypass where a stapler was used: linear stapler employed; financial years 2011-2013

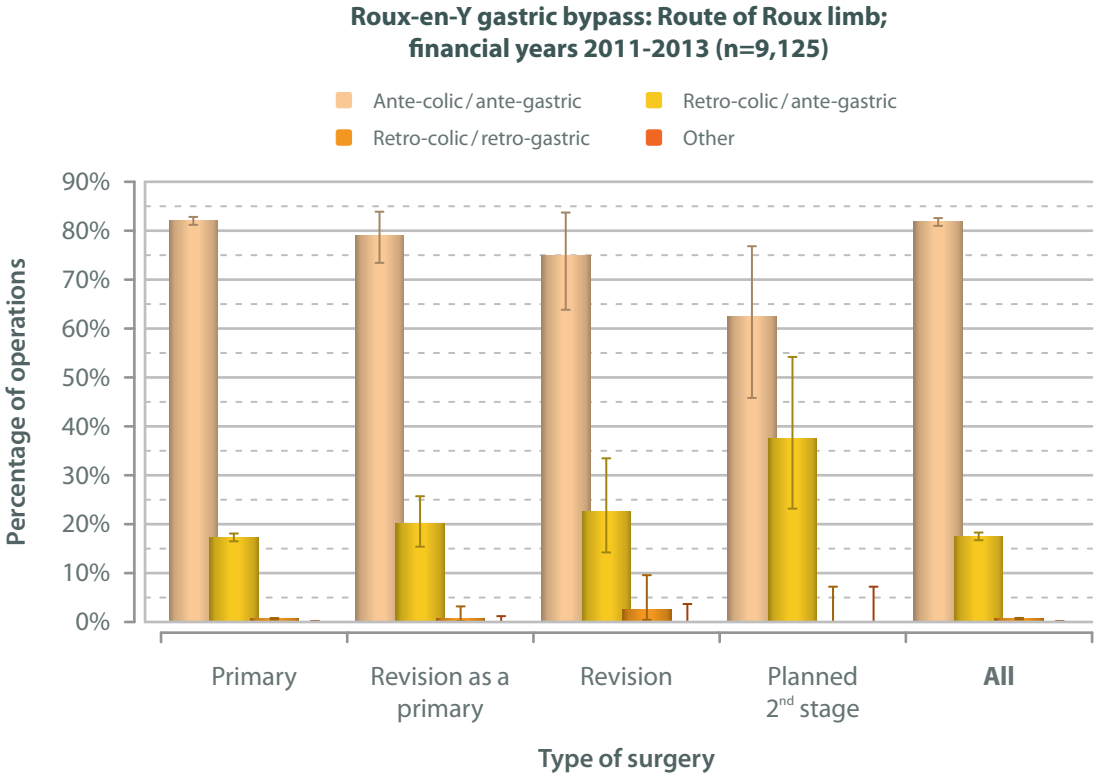
		Linear stapler				
		Blue (1.5 mm)	White (1.0 mm)	Tan (1.0 mm)	Unspecified	**All**
Type of surgery	Primary	328	5,738	772	1,096	**7,934**
	Revision as a primary	22	123	35	43	**223**
	Revision	1	68	6	3	**78**
	Planned 2nd stage	0	31	5	4	**40**
	All	**351**	**5,960**	**818**	**1,146**	**8,275**

Route of Roux limb

The jejunum can be brought up to the gastric pouch in one of several ways, depending on whether the jejunum travels to the pouch in front of or behind the transverse colon and stomach. If it lies in front of the transverse colon, the approach is described as *ante-colic*, whereas if it goes behind the colon it is termed *retro-colic*. Similarly, the relationship to bypassed stomach defines whether it is *ante-gastric* (in front) or *retro-gastric* (behind). More than 80% of all gastric bypasses are performed using the ante-colic ante-gastric approach, with the retro-colic ante-gastric approach accounting for the vast majority of the remainder.

Roux-en-Y gastric bypass: route of Roux limb; financial years 2011-2013

		Type of surgery				
		Primary	Revision as a primary	Revision	Planned 2nd stage	All
Route of Roux limb	Ante-colic / ante-gastric	7,182	197	60	25	**7,464**
	Retro-colic / ante-gastric	1,513	50	18	15	**1,596**
	Retro-colic / retro-gastric	54	2	2	0	**58**
	Other	7	0	0	0	**7**
	Unspecified	377	18	6	0	**401**
	All	**9,133**	**267**	**86**	**40**	**9,526**



Closure of hernia defect

Depending on whether gastric bypass is performed by the ante-colic or retro-colic approach, it leads to the creation of 2 (Petersen's space and jejuno-jejunostomy) or 3 (Petersen's space, jejuno-jejunostomy, and mesocolic) internal defects respectively; internal herniae have been reported at all of these sites. There is currently no consensus amongst surgeons regarding their closure.

Significantly only 3.4% of retro-colic / ante-gastric primary gastric bypass patients did not have any defect closed compared to 35.3% of ante-colic / ante-gastric primary gastric bypass patients. All three defects were closed in more than half (55.3%) of retro-colic / ante-gastric bypass patients. In comparison, both defects were closed in only 22.2% of ante-colic / ante-gastric bypasses. These findings reflect the perception of many surgeons that the ante-colic approach is less likely to result in internal herniae. The NBSR should be able to confirm this in future reports, although we recognise that in the current version of the dataset we have no specific means of recording subsequent internal hernia operations.

Of the ante-colic / ante-gastric approach, 26% patients had Petersen's defect closed, while 47% had the jejuno-jejunostomy defect closed, probably because this defect is a more common site of internal herniae.

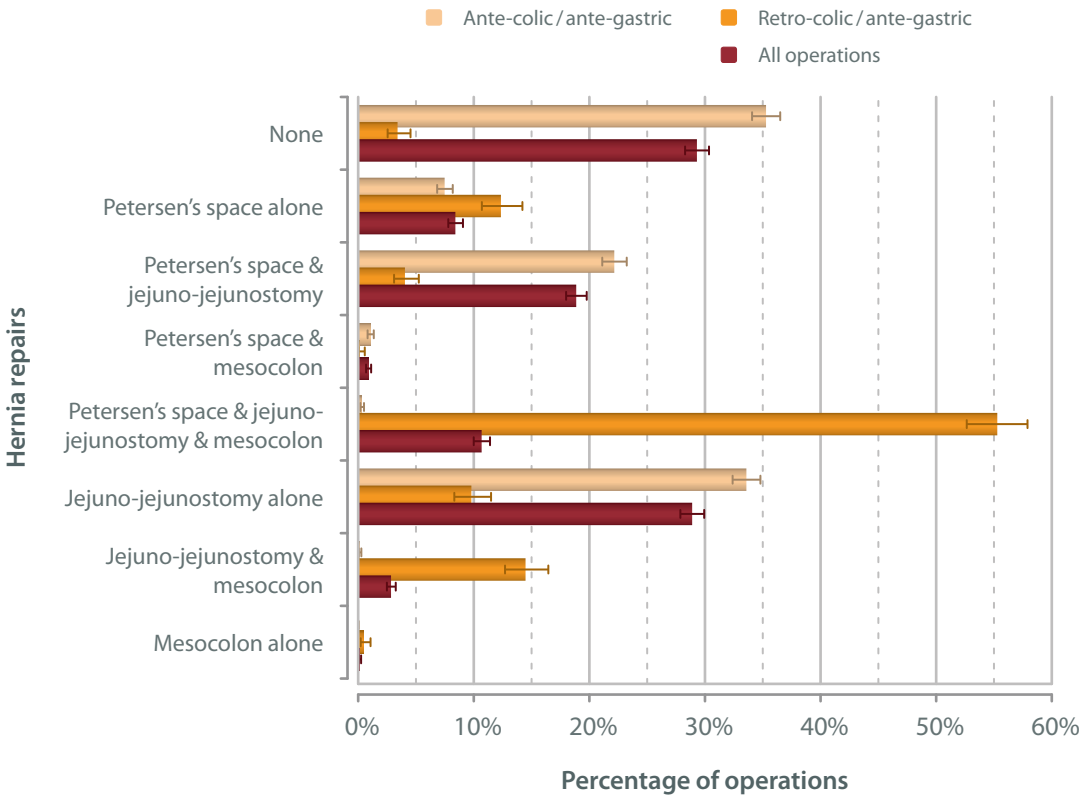
Primary Roux-en-Y gastric bypass: hernia repair and route of Roux limb; financial years 2011-2013

Hernia repair					Route of Roux limb					
	None	Petersen's space	Jenuno-jejunostomy	Mesocolon	Ante-colic / ante-gastric	Retro-colic / ante-gastric	Retro-colic / retro-gastric	Other	Unspecified	**All**
	●				2,118	48	1	3	36	**2,206**
		●			449	174	2	1	7	**633**
		●	●		1,330	57	31	0	2	**1,420**
		●		●	63	2	1	0	0	**66**
		●	●	●	19	779	4	1	1	**804**
			●		2,016	138	8	2	11	**2,175**
			●	●	8	204	1	0	1	**214**
				●	0	7	2	0	1	**10**
	Unspecified				1,179	104	4	0	318	**1,605**
	All				**7,182**	**1,513**	**54**	**7**	**377**	**9,133**

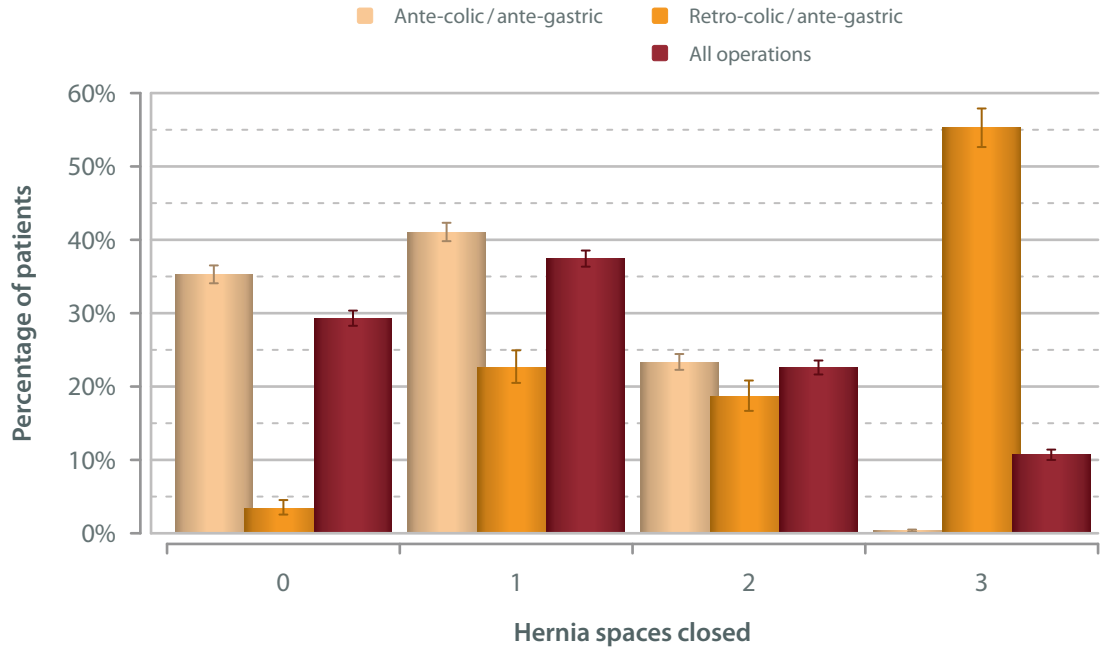
None of the defects was closed in 29.3% of all gastric bypass patients. It would be interesting to see, in future reports, if these patients went on to have a higher rate of internal hernias than the other patients undergoing this procedure.

The wide variation in surgical practice regarding the closure of internal defects probably reflects the absence of any robust level 1 evidence in this area to guide best surgical practice.

Primary Roux-en-Y gastric bypass: closure of hernia defect; financial years 2011-2013 (n=7,528)



Primary Roux-en-Y gastric bypass: closure of hernia defect; financial years 2011-2013 (n=7,528)



Additional procedures

Approximately 11% of patients underwent additional surgical procedures at the time of surgery. Of these, hernia repair (4.6%) and cholecystectomy (2.3%) were most common. This is hardly surprising as obesity is a recognized risk factor for both hernia and gall stones. Adhesiolysis, liver biopsy and band removal accounted for the vast proportion of the remaining additional procedures.

Future reports may investigate the site of hernia repair, *e.g.,* hiatal hernia or umbilical hernia.

Roux-en-Y gastric bypass: additional procedures and type of surgery; financial years 2011-2013

		Additional procedures						
		None	Cholecystectomy	Hernia repair	Apronectomy	Other	Unspecified	**All**
Type of surgery	Primary	6,949	180	340	2	314	1,408	**9,133**
	Revision as a primary	165	3	18	0	28	57	**267**
	Revision	59	0	5	0	8	14	**86**
	Planned 2nd stage	24	1	4	0	4	8	**40**
	All	**7,197**	**184**	**367**	**2**	**354**	**1,487**	**9,526**
	Primary	90.0%	2.3%	4.4%	0.0%	4.1%		
	Revision as a primary	78.6%	1.4%	8.6%	0.0%	13.3%		
	Revision	81.9%	0.0%	6.9%	0.0%	11.1%		
	Planned 2nd stage	75.0%	3.1%	12.5%	0.0%	12.5%		
	All	**89.5%**	**2.3%**	**4.6%**	**0.0%**	**4.4%**		

- (with densely icarcerated omentum & division of dense omental adhesions in sac 1
- 4x attempt to insert mirena coil by gynae consultant 1
- a roeu-en-o was created which was recognised and revised. 1
- a stitch to the crura 1
- adhesiolysis 82
- adhesiolysis - previous hysterectomy 1
- adhesiolysis - previous incisional hernia mesh repair 1
- adhesiolysis and fobi ring 1
- adhesiolysis from previous laparotomy wound for twisted bowel 1
- adhesiolysis from previous surgery and incarcerated incisional hernia 1
- adhesiolysis, drain to anastomosis site 1
- adhesiolysis, reversal of gastro-jejunostomy, partial gasrtectomy 1
- adhesiolysis-extensive adhesions from hysterectomy 3 yrs ago 1
- adhesionolysis & repair of umblical hernia 1
- anterior cruroplasty 5
- band removal 22
- bougie caught in stapler thus gastrojejunostomy carried out hand sewn 1
- bowel polyp removal 1
- common bile duct exploration 1
- diagnostic laparoscopy 2

• division of adhesions	32
• division of adhesions from lap umbilical hernia re	1
• division of adhesions to mesh epigastric hernia repair	1
• division of adhesions, repair of serosal tear	1
• division of dense diaphragmatic adhesions	1
• division of dense intestinal adhesions (converted to open procedure)	1
• division of omental adhesions	6
• division of omental adhesions and small bowel resection	1
• division of omental adhesions to umblical hernia	1
• division of omental of omental adhesiona	1
• division of omentum	2
• division of peritoneal and omental adhesions	1
• divison of adhesions	2
• endrometerial biopsy (research)	1
• excision of abdo wall lipoma	1
• excision of gist of the posterior wall of the fundus	1
• excision of intragastric lesion	1
• excision of small 5mm stromal tumour from fundus serosa (for hp)	1
• gastric balloon removal	1
• gastroscopy	1
• giant lipoma excision	1
• hiatal closure, single suture	1
• hiatus hernia repair	1
• huge hiatus hernia repair (with crural approximation)	1
• laparoscopic adhesiolysis	35
• liver biopsy	39
• liver biopsy - as very thick enlarged liver	1
• liver biopsy and umb hernia repair	1
• liver biopsy, adhesiolysis	1
• liver, omental, subcut fat and muscle biopsies	1
• massive hiatus hernia repair	1
• mesomeseitreic closed	1
• moderate sized hiatus hernia - crural repair done	1
• no gall bladdder stones retrieved	1
• note previous fundoplication so should be in higher risk category	1
• oesophagopexy	1
• ogd	1
• ogd + adhesiolysis	1
• omental adenolysis	1
• omental adhesiolysis and transection	1
• omental adhesiolysis from previous laparotomy scar for ectopic pregnancy	1
• omental adhesiolysis from the previous appendicectomy scar	1
• omental adhesiolysis- prev lscs scar	1
• omentum stuck in paraumbilical hernia - divided	1
• ometal adhesiolysis - previous lscs scar	1
• on table og, repair of damage of small bowel,	1
• on table ogd	1
• open left inguinal hernia repair	1
• open repair of hernia	1
• open repair of hernia & division of dense intra-abdominal adhesions	1

- partial gastrectomy 1
- prev - oopherectomy for cancer- incidental pelvic cysts excised 1
- previous band removal (foreign band) 1
- proximal gastrectomy for large gist tumour arising from goj & upper gi endoscopy (on table) 1
- r / o intragastric balloon 1
- reduction and repair of internal hernia through congenital defect in small bowel mesentry (part of roux limb) 1
- reduction of previous nissen 2
- re-laparoscopy 1
- re-laparoscopy, suture haemostasis of bleeding from omentum, spenectomy and partial gastrectomy 1
- removal balloon 1
- removal gastric band (ami) 1
- removal of abdominal wall papilloma 1
- removal of band and removal of pseudocapsule encircling the stomach as a tight band intself 1
- removal of old gastroplasty band 1
- removal old gastroplasty band 1
- remove gastric balloon 1
- reoperation to retrieve lost jacques catheter tube around lesser omentum (from 1st op) 3h later on same day 1
- repair hiatus hernia 1
- repair of abdo wall (epigastric) 1
- repair of congenital mesocolic hernia 1
- repair of diaphragmatic hernia, division of adhesions 1
- repair of hiatus hernia 1
- repair of hole in stomach 1
- repair of incisional & umbilical hernia with physiomesh & division of omental adhesions 1
- resection of small bowel (hernia repair abandoned) 1
- resection of the fundus 1
- reversal of nissen fundoplication 1
- small bowel resection (incarcerated in recurrent umbilical hernia) 1
- small epigastric hernia incidental mass suture repair 1
- splenectomy 2
- study biopsies, adhesionlysis 1
- take down of previous fundoplication 1
- tear oversewn and bleeding stopped with harmonic scalpel 1
- umblical hernia repair, adhesionolysis 1
- undoing the previous anterior fundoplication, repairing large hiatus defect, extensice adhesiolysis 1
- unwrapping of previous lap nissen fundoplication 1
- use of floseal to control bleeding from splenic capsule tear at the omental adhesion site. kept in icu as an hdu patient precautionarily for observation due to intra op bleeding 1
- wedge resection of gastric fundus gist 1
- with excision of paraoesophageal lipoma 1
- with incarcerated omentum with division of dense omental adhesions in sac 1
- with incarcerated omentum, with division of dense omental adhesions in sac 1
- with incarcerated omentum, with division of omental adhesions in sac 1
- unspecified 19

Post-procedure outcomes

30-day complications

Leaks, bleeding, and bowel obstruction were the three major early reported complications after gastric bypass (*i.e.,* complications seen within the first 30 days after the operation).

The overall operative complication rate was 3.1% for primary procedures, and 4.6% for revisional bypass surgery, both of which would be considered very respectable figures for such a technically demanding operation. As expected, revisional bypass was associated with a higher rate of leak than primary gastric bypass (1.3% *versus* 0.6%; p=0.163; χ^2 2×2 contingency table). The rates of bleeding and bowel obstruction were the same in both groups (1.3% and 0.5% respectively).

Roux-en-Y gastric bypass: 30-day complications; financial years 2011-2013

Type of surgery and 30-day complications			Complications		
			None recorded	Yes	Rate (95% CI)
	Primary	**Any complication**	**8,846**	**287**	**3.1% (2.8-3.5%)**
		Leak	9,080	53	0.6% (0.4-0.8%)
		Bleeding	9,012	121	1.3% (1.1-1.6%)
		Obstruction	9,088	45	0.5% (0.4-0.7%)
		Other	9,033	100	1.1% (0.9-1.3%)
	All revisions	**Any complication**	**375**	**18**	**4.6% (2.8-7.3%)**
		Leak	388	5	1.3% (0.5-3.1%)
		Bleeding	388	5	1.3% (0.5-3.1%)
		Obstruction	391	2	0.5% (0.1-2.0%)
		Other	383	10	2.5% (1.3-4.8%)

30-day re-operations

The 30-day re-operation rate (patients who undergo re-operations within the first 30 days after the gastric bypass) is widely used as an indicator of morbidity after any surgical procedure. The re-operation rate for primary gastric bypass was 1.9%, and 2.5% following revisional bypass. These outcome rates indicate a remarkable level of safety for this procedure in the United Kingdom.

As expected, diagnostic laparoscopy, refashioning of anastomosis, control of bleeding, drainage and enteral feeding tube placement account for a significant proportion of these procedures.

Roux-en-Y gastric bypass: 30-day re-operations; financial years 2011-2013

Type of operation and re-operation performed			30-day re-operation			
			No	Yes	Unspecified	Rate (95% CI)
Primary		**Any re-operation**	**8,955**	**178**	**0**	**1.9% (1.7-2.3%)**
		Refashioning anastomosis	9,097	33	3	0.4% (0.3-0.5%)
		Attention to bleeding area	9,101	29	3	0.3% (0.2-0.5%)
		Hernia repair	9,114	16	3	0.2% (0.1-0.3%)
		Drain replacement	9,095	35	3	0.4% (0.3-0.5%)
		Gastrostomy	9,117	13	3	0.1% (0.1-0.3%)
		Enteral feed	9,121	9	3	0.1% (0.0-0.2%)
		Laparoscopy	9,098	32	3	0.4% (0.2-0.5%)
		Other	9,066	64	3	0.7% (0.5-0.9%)
All revisions		**Any re-operation**	**383**	**10**	**0**	**2.5% (1.3-4.8%)**
		Refashioning anastomosis	391	2	**0**	0.5% (0.1-2.0%)
		Attention to bleeding area	391	2	0	0.5% (0.1-2.0%)
		Hernia repair	392	1	0	0.3% (0.0-1.6%)
		Drain replacement	390	3	0	0.8% (0.2-2.4%)
		Gastrostomy	392	1	0	0.3% (0.0-1.6%)
		Enteral feed	391	2	0	0.5% (0.1-2.0%)
		Laparoscopy	393	0	0	0.0% (0.0-0.8%)
		Other	389	4	0	1.0% (0.3-2.8%)

Cardiovascular complications

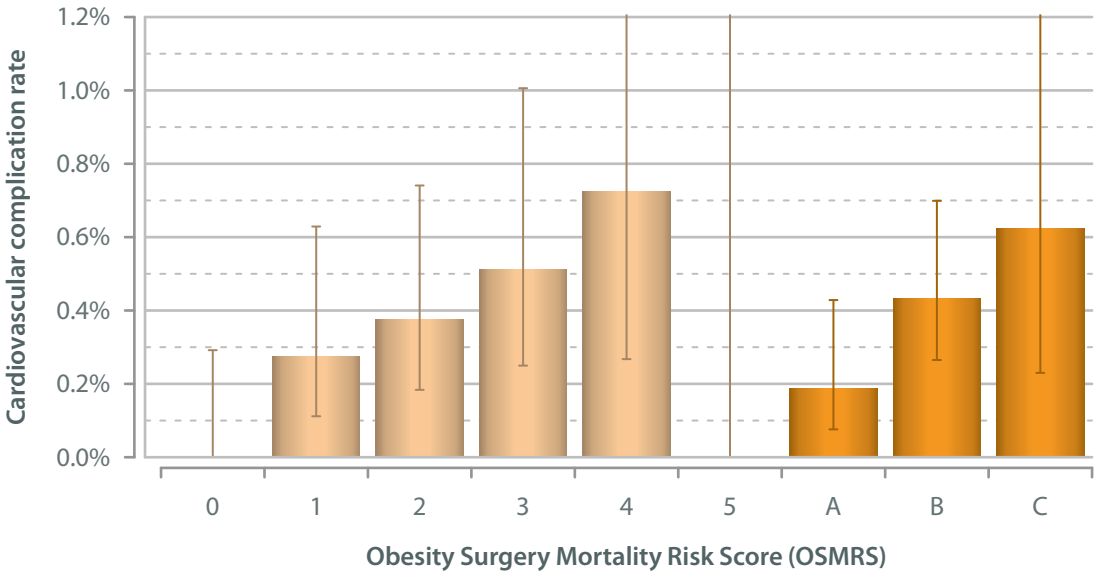
The OSMRS (see page 206) was originally intended to predict a patient's risk of mortality after bariatric surgery; more recently it has also been found to be a useful predictor of post-operative morbidity [1].

In the NBSR data, there was a gradual increase in the reported cardiovascular complication rate with increasing OSMRS. Group C patients (4 or 5 risk factors) had a cardiovascular complication rate of 0.6%, compared to 0.4% in Group B (2 or 3 risk factors) and 0.2% in Group 1 (0 or 1 risk factors); the difference across these three ordered groups is significant ($p<0.027$; χ^2-test for trend).

Primary Roux-en-Y gastric bypass: cardiovascular complications and OSMRS; financial years 2011-2013

		Cardiovascular complications			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	1,025	0	61	0.0% (0.0-0.3%)
	1	2,179	6	96	0.3% (0.1-0.6%)
	2	2,383	9	128	0.4% (0.2-0.7%)
	3	1,751	9	74	0.5% (0.2-1.0%)
	4	684	5	47	0.7% (0.3-1.8%)
	5	112	0	12	0.0% (0.0-2.6%)
	Group A	3,204	6	157	0.2% (0.1-0.4%)
	Group B	4,134	18	202	0.4% (0.3-0.7%)
	Group C	796	5	59	0.6% (0.2-1.5%)
	Unspecified	267	1	284	0.4% (0.0-2.4%)
	All	**8,401**	**30**	**702**	**0.4% (0.2-0.5%)**

Primary Roux-en-Y gastric bypass: Post-operative cardiovascular complications and OSMRS; financial years 2011-2013 (n=8,163)



1. Sarela AI, Dexter SP, McMahon MJ. Use of the obesity surgery mortality risk score to predict complications of laparoscopic bariatric surgery. *Obesity Surgery*. 2011; **21(11)**: 1698-703.

Other complications

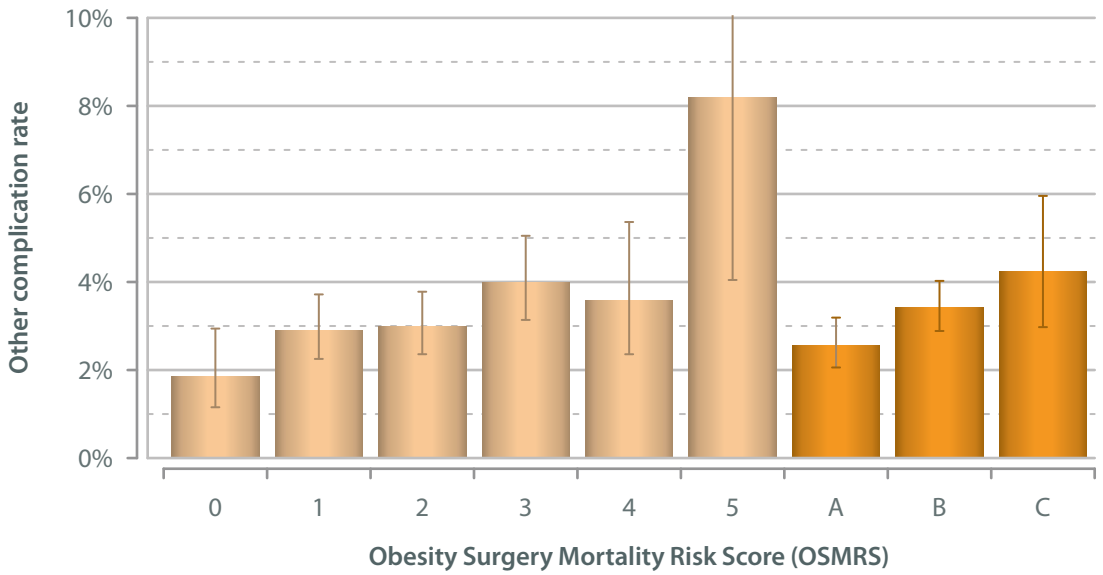
The same general pattern was also evident in the relationship between OSMRS rate and other complications after primary gastric bypass: the complication rate rises with increasing OSMRS. Group A patients had the lowest complication rate of 2.4%, compared to 3.6% and 4.2% respectively for Group B and Group C. The trend across these three groups is significant (p=0.006; χ^2-test for trend).

Interestingly, there was a sudden leap in the *other* complication rate from 3.6% in patients with an OSMRS score of 4 to 8.2% in those with a score of 5. These data give surgeons and multi-disciplinary teams some idea about where to focus their efforts. Appropriate procedure selection and efforts to maximize pre-operative weight loss for those with BMI>50 kg m^{-2} (the only modifiable risk factor of the five included in the OSMRS) may prove useful in reducing complication rates.

Primary Roux-en-Y gastric bypass: other complications and OSMRS; financial years 2011-2013

		Other complications			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	1,004	19	63	1.9% (1.2-2.9%)
	1	2,110	63	108	2.9% (2.3-3.7%)
	2	2,303	71	146	3.0% (2.4-3.8%)
	3	1,661	69	104	4.0% (3.1-5.0%)
	4	646	24	66	3.6% (2.4-5.4%)
	5	101	9	14	8.2% (4.0-15.4%)
	Group A	3,114	82	171	2.6% (2.1-3.2%)
	Group B	3,964	140	250	3.4% (2.9-4.0%)
	Group C	747	33	80	4.2% (3.0-6.0%)
	Unspecified	251	6	295	2.3% (1.0-5.3%)
	All	**8,076**	**261**	**796**	**3.1% (2.8-3.5%)**

Primary Roux-en-Y gastric bypass: Other post-operative complications and OSMRS; financial years 2011-2013 (n=8,080)



Combined cardiovascular and other complications

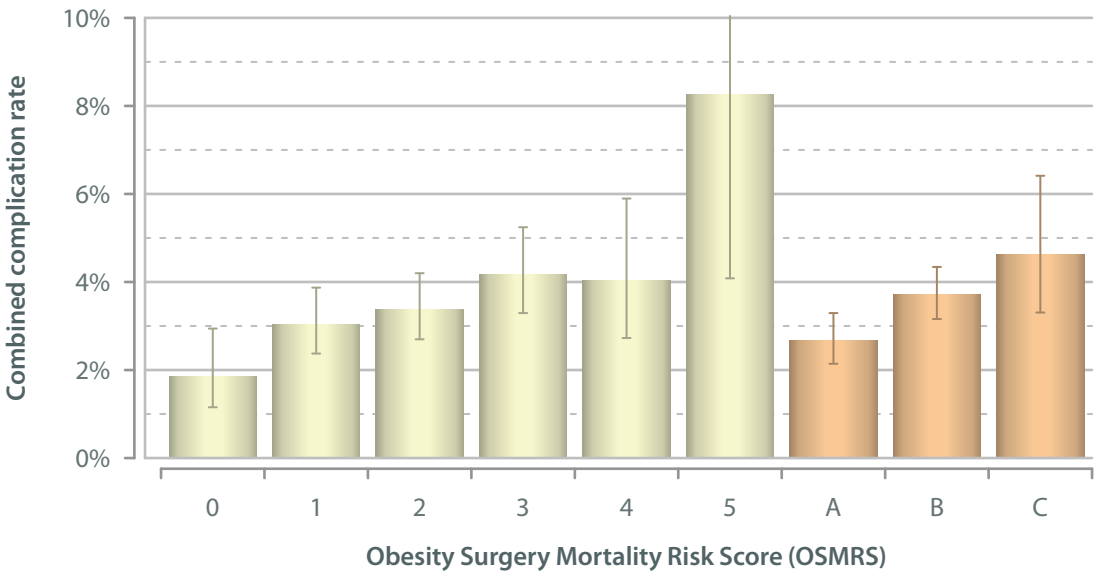
This chart shows that when the cardiovascular complications and *other* complications were assessed *in tandem* to produce a *combined* complication rate, there was an increase in the derived, *combined* complication rate with increasing OSMRS. This trend is highly significant (p=0.002 across groups A-C, and p<0.001 across the six ordered scores 0-5; χ^2-test for trend). Thus patients with a score of 4 or 5 (Group C) have a 4.6% risk of developing one of these complications. This is the first time that we have presented a composite complication rate for patients recorded in the NBSR as having gastric bypass.

Future reports will be able to examine whether other risk factors such as diabetes increase the complication rates.

Primary Roux-en-Y gastric bypass: combined cardiovascular and other complications and OSMRS; financial years 2011-2013

		Any complication			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	1,004	19	63	1.9% (1.2-2.9%)
	1	2,107	66	108	3.0% (2.4-3.9%)
	2	2,293	80	147	3.4% (2.7-4.2%)
	3	1,657	72	105	4.2% (3.3-5.2%)
	4	642	27	67	4.0% (2.7-5.9%)
	5	100	9	15	8.3% (4.1-15.5%)
	Group A	3,111	85	171	2.7% (2.1-3.3%)
	Group B	3,950	152	252	3.7% (3.2-4.3%)
	Group C	742	36	82	4.6% (3.3-6.4%)
	Unspecified	250	4	298	1.6% (0.5-4.3%)
	All	**8,053**	**277**	**803**	**3.3% (3.0-3.7%)**

Primary Roux-en-Y gastric bypass: Combined post-operative complications and OSMRS; financial years 2011-2013 (n=8,076)



Mortality

With a total of 6 deaths during this time period, the NBSR recorded a mortality rate of 0.07% for gastric bypass.

As expected, Group C patients had a much higher mortality at 0.26% (still not much more than what one would expect after a cholecystectomy) compared to 0.05% with Group B patients and 0.03% with Group A patients. The numbers of deaths are so very low that none of the apparent differences in mortality rates between the three OSMRS groups reaches statistical significance (Fisher's exact test). Figures for individual scores are much lower than initially suggested when this score was conceived [1]. A very low complication and mortality rate with bariatric surgery may have played a major role behind the exponentially increasing demand for this type of surgery within United Kingdom.

Significantly mortality approaches 1% for those patients where all the 5 risk factors are present. The number of these patients is low in the NBSR (n=107) suggesting perhaps that surgeons are preferentially offering other less risky procedures to these patients at highest risk. It would seem a sensible approach to offer lower risk procedures to the highest risk patients so as to reduce post-operative mortality risk to a minimum.

Roux-en-Y gastric bypass: post-operative mortality and OSMRS; financial years 2011-2013

		Post-operative mortality			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	1,019	0	67	0.00% (0.00-0.29%)
	1	2,161	1	119	0.05% (0.00-0.30%)
	2	2,367	2	151	0.08% (0.01-0.34%)
	3	1,724	0	110	0.00% (0.00-0.17%)
	4	672	1	63	0.15% (0.01-0.96%)
	5	107	1	16	0.93% (0.05-5.80%)
	Group A	3,180	1	186	0.03% (0.00-0.20%)
	Group B	4,091	2	261	0.05% (0.01-0.20%)
	Group C	779	2	79	0.26% (0.04-1.03%)
	Unspecified	245	1	306	0.41% (0.02-2.60%)
	All	**8,295**	**6**	**832**	**0.07% (0.03-0.17%)**

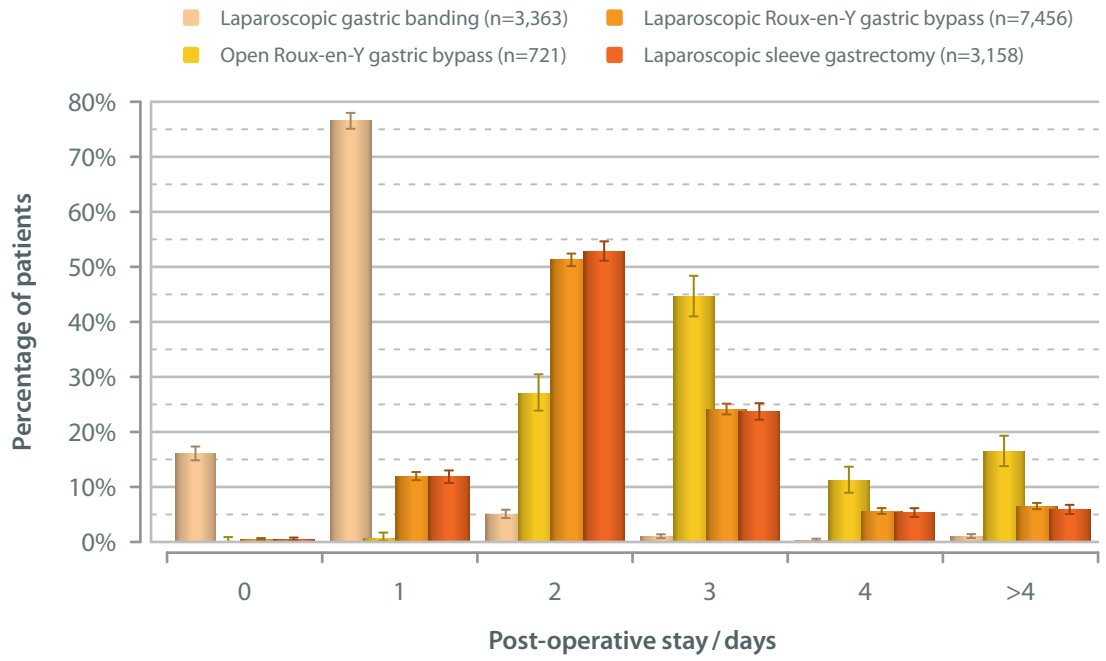
1. DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. *Surgery for Obesity & Related Disease*. 2007; **3(2)**: 134-40.

Post-operative stay

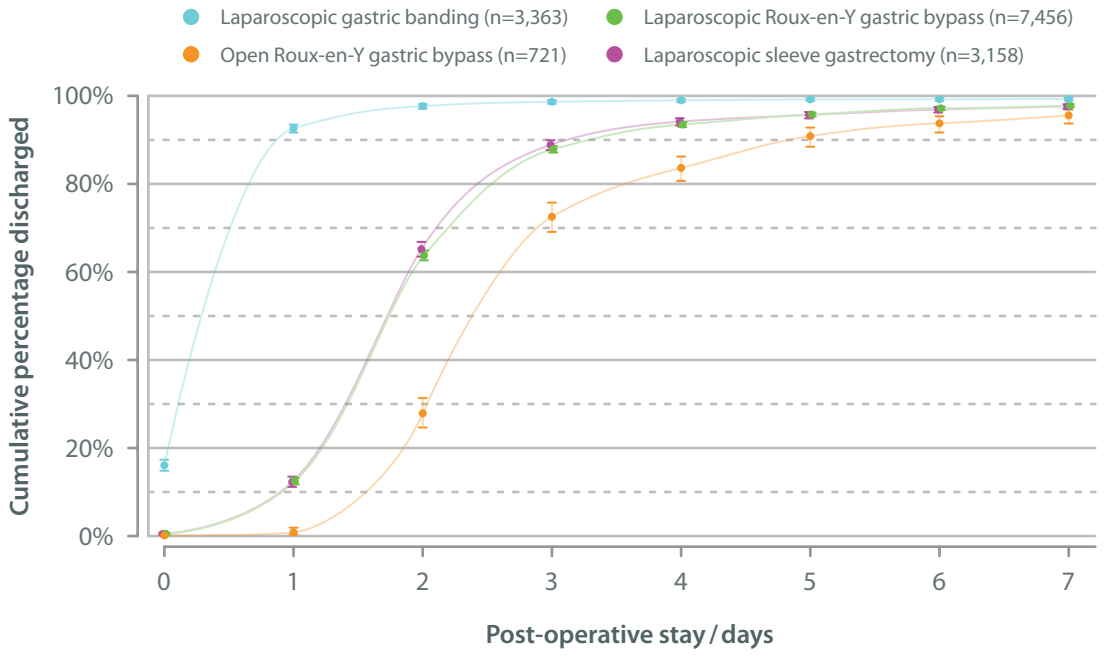
Post-operative stay after laparoscopic gastric bypass is similar to that after laparoscopic sleeve gastrectomy, but, as expected, longer than after laparoscopic gastric banding. Hospital stay was longer for patients undergoing open Roux-en-Y gastric bypass ($p<0.001$; χ^2 test), but these procedures accounted for a minority (8%) of all the bypass procedures recorded in the NBSR.

It is worth noting that over 50% of laparoscopic gastric bypass patients stayed in the hospital for just 2 days and a further 25% stayed for just 3 days. Equally noteworthy are the 10% of gastric bypass patients whose hospital stay was a meagre 1 day. Shorter hospital stay has multiple benefits in terms of improving the patient's overall experience and reducing the cost of care.

Primary operations: Post-operative stay; financial years 2011-2013



Primary operations: Post-operative stay; financial years 2011-2013



Follow up data

Excess weight loss

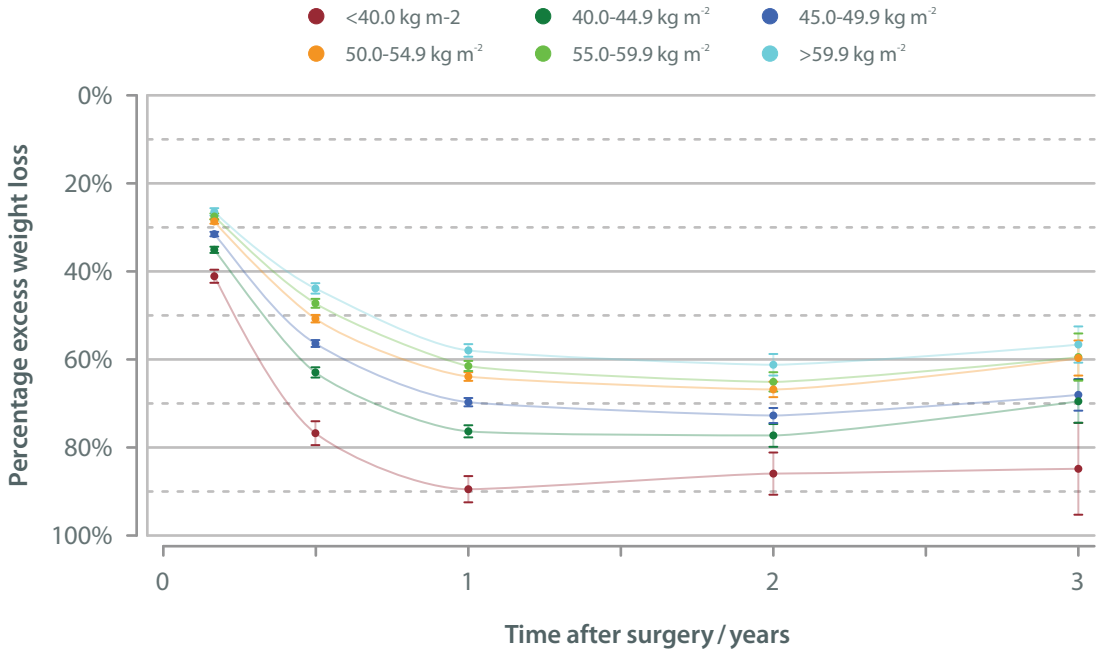
Excess weight loss and initial BMI

These data show that, as expected, patients with the lowest initial BMI have the greatest percentage excess weight loss at each time point after surgery. This is not surprising as they have the least excess weight to lose (see page 180 for a further explanation of this). However, even the heaviest patients who were available for follow up still recorded an average loss of more than 50% of their excess weight. These data are in accord with reports from the international scientific literature.

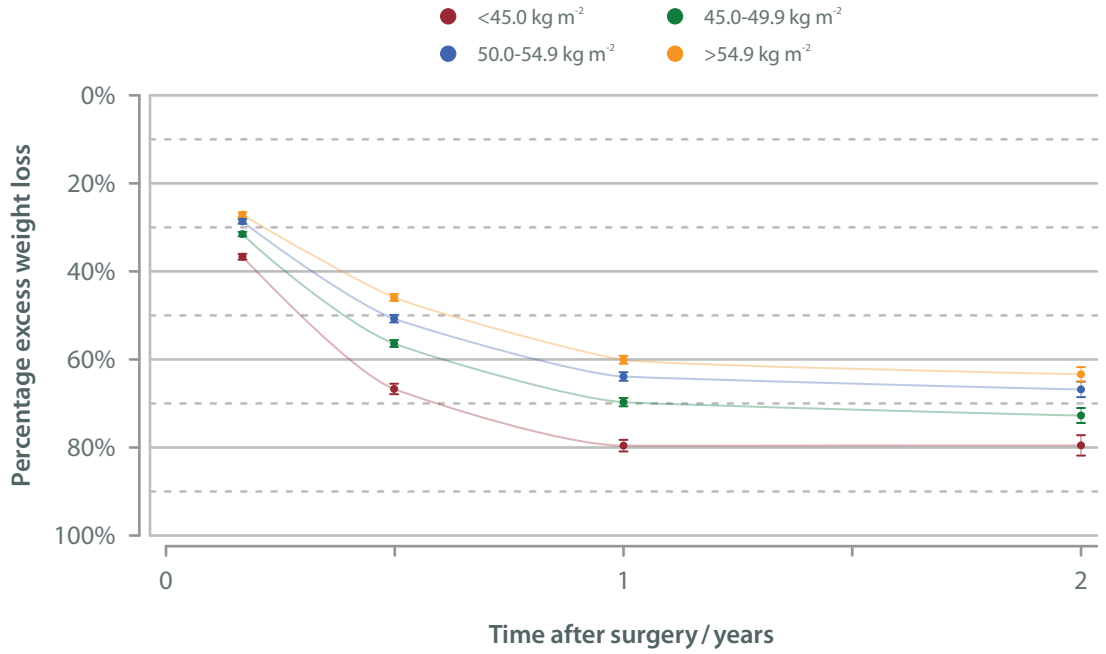
Primary Roux-en-Y gastric bypass: percentage excess weight loss (95% CI; count) and initial BMI; operations in the financial years 2006-2013

Follow up period / months	Initial BMI / kg m^{-2} <40.0	40.0-44.9	45.0-49.9	50.0-54.9	55.0-59.9	>59.9
2	41.1 (±1.5; 439)	35.1 (±0.7; 1,228)	31.5 (±0.5; 1,851)	28.6 (±0.5; 1,566)	27.5 (±0.7; 839)	26.5 (±0.8; 588)
6	76.8 (±2.7; 256)	62.9 (±1.2; 684)	56.4 (±0.8; 1,041)	50.7 (±0.9; 845)	47.3 (±1.0; 460)	43.9 (±1.2; 294)
12	89.5 (±3.0; 254)	76.3 (±1.4; 771)	69.7 (±0.9; 1,228)	63.9 (±1.0; 1,006)	61.5 (±1.1; 555)	58.0 (±1.4; 364)
24	85.9 (±4.8; 102)	77.3 (±2.6; 289)	72.7 (±1.7; 530)	66.8 (±1.8; 455)	65.1 (±2.2; 233)	61.2 (±2.4; 183)
36	84.8 (±10.4; 35)	69.5 (±4.9; 110)	68.0 (±3.6; 152)	59.7 (±4.0; 113)	59.5 (±5.4; 71)	56.6 (±4.1; 55)

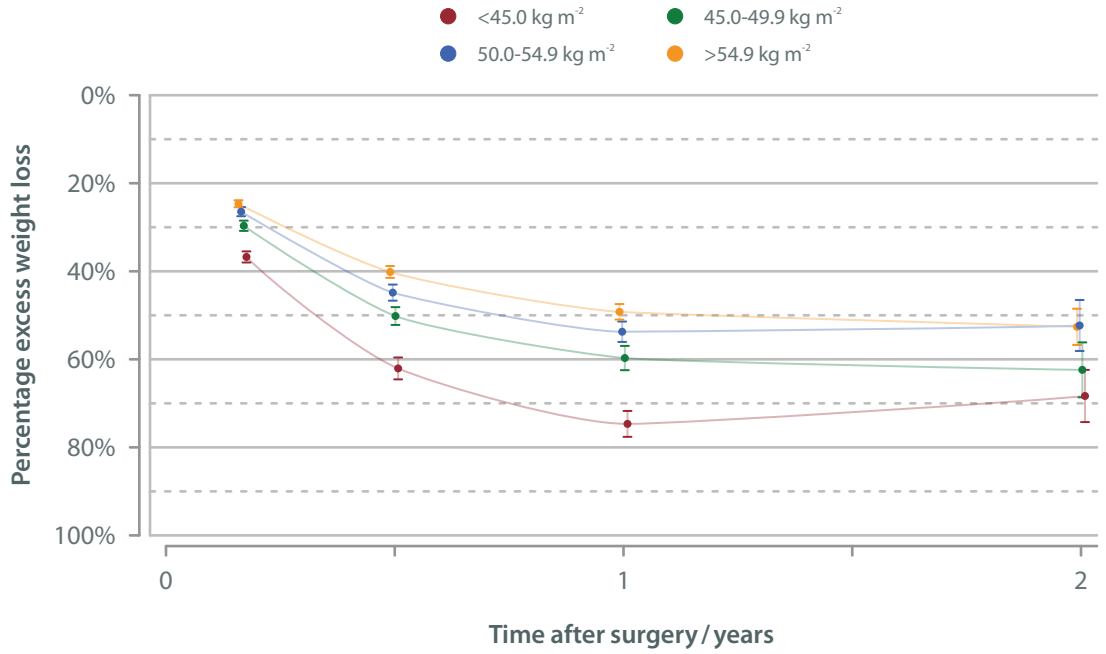
Primary Roux-en-Y gastric bypass for all patients: Post-operative excess weight loss and initial BMI; operations in the financial years 2006-2013



Primary Roux-en-Y gastric bypass: Excess weight loss and initial BMI; operations in the financial years 2006-2013



Primary sleeve gastrectomy: Excess weight loss & initial BMI; operations in the financial years 2006-2013



Excess weight loss, initial BMI and gender

This section compare excess weight loss by initial BMI, adjusted for gender.

As expected, patients with a higher BMI had a lower excess weight loss, although female patients had a greater weight loss compared to male patients at all time-points.

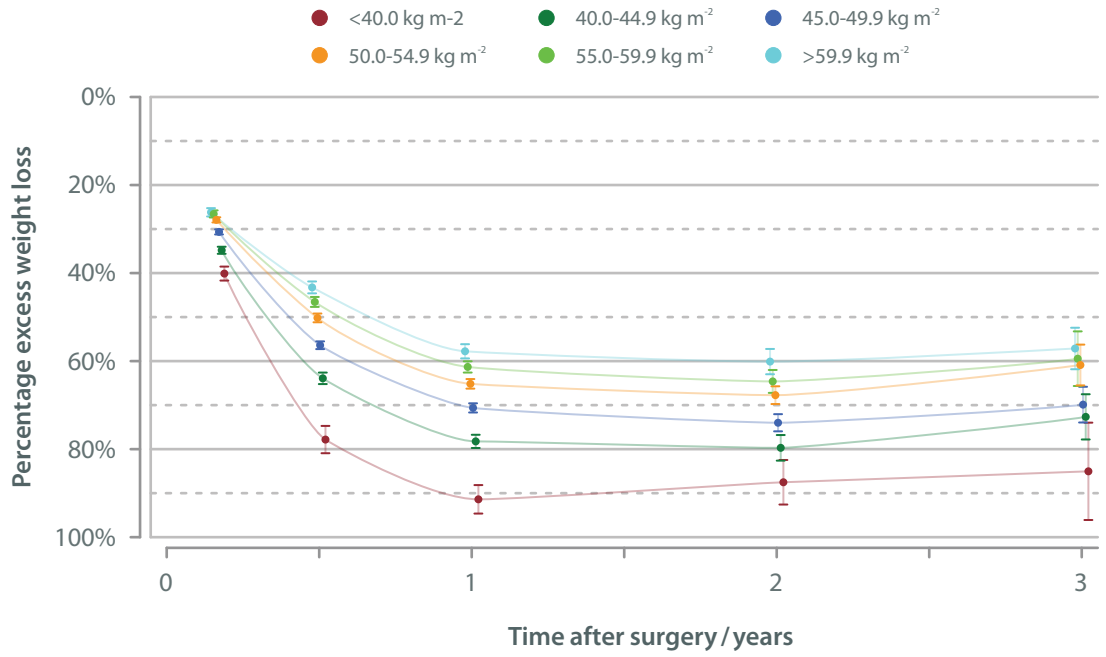
As with almost all bariatric surgery procedures, most of the weight loss was seen within the first 12 months after surgery, with peak excess weight loss of 60%-90% achieved between 12-24 months.

Primary Roux-en-Y gastric bypass: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

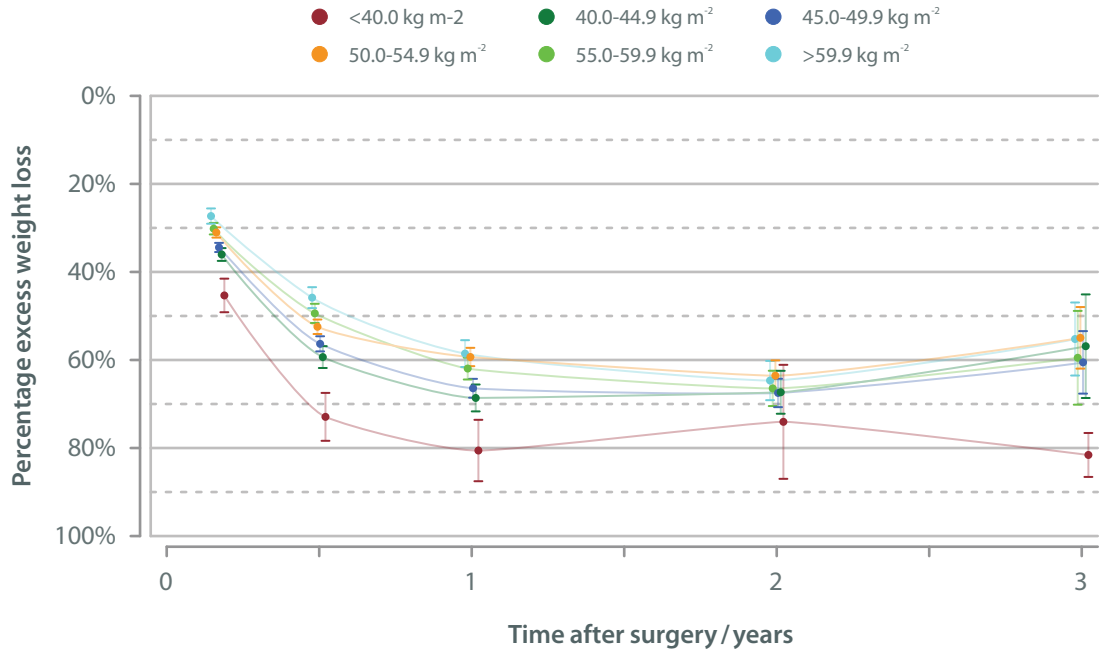
Gender and follow up period / months			Initial BMI					
			<40.0	40.0-44.9	45.0-49.9	50.0-54.9	55.0-59.9	>59.9
	Female	2	40.1 (±1.6; 356)	34.8 (±0.8; 949)	30.7 (±0.6; 1,423)	27.9 (±0.6; 1,201)	26.6 (±0.8; 615)	26.2 (±0.9; 442)
		6	77.8 (±3.1; 200)	63.9 (±1.3; 540)	56.4 (±0.9; 812)	50.2 (±1.0; 639)	46.6 (±1.1; 348)	43.3 (±1.3; 225)
		12	91.4 (±3.2; 209)	78.2 (±1.5; 618)	70.6 (±1.0; 959)	65.2 (±1.1; 786)	61.3 (±1.3; 413)	57.8 (±1.6; 279)
		24	87.5 (±5.1; 90)	79.7 (±2.9; 232)	74.0 (±1.9; 427)	67.7 (±2.0; 354)	64.6 (±2.6; 172)	60.1 (±2.9; 139)
		36	85.0 (±11.1; 33)	72.7 (±5.1; 88)	69.9 (±4.1; 122)	60.9 (±4.6; 90)	59.5 (±6.2; 52)	57.1 (±4.7; 40)
	Male	2	45.3 (±3.8; 83)	36.0 (±1.5; 279)	34.4 (±1.0; 428)	31.0 (±1.2; 365)	30.2 (±1.3; 224)	27.3 (±1.7; 146)
		6	72.9 (±5.4; 56)	59.3 (±2.5; 144)	56.3 (±1.7; 229)	52.5 (±1.6; 206)	49.4 (±2.2; 112)	45.8 (±2.4; 69)
		12	80.6 (±7.0; 45)	68.6 (±3.1; 153)	66.4 (±2.1; 269)	59.3 (±2.1; 220)	61.9 (±2.5; 142)	58.5 (±3.0; 85)
		24	74.1 (±13.0; 12)	67.3 (±4.9; 57)	67.5 (±3.2; 103)	63.6 (±3.5; 101)	66.5 (±4.0; 61)	64.7 (±4.5; 44)
		36	81.6 (±5.0; 2)	56.9 (±11.8; 22)	60.5 (±7.1; 30)	55.0 (±7.0; 23)	59.5 (±10.7; 19)	55.2 (±8.3; 15)

The percentage weight loss following gastric bypass is greater in those with a lower starting BMI, but all patients demonstrate some weight regain at 36 months after surgery. This is in keeping with the published literature, where the weight loss at 3-4 years after gastric banding is found to be equivalent to that after bypass. However, it is important to remember that the scientific literature is also clear that the health gains from gastric bypass continue for many years despite some weight regain.

Primary Roux-en-Y gastric bypass for female patients: Post-operative excess weight loss and initial BMI; operations in the financial years 2006-2013



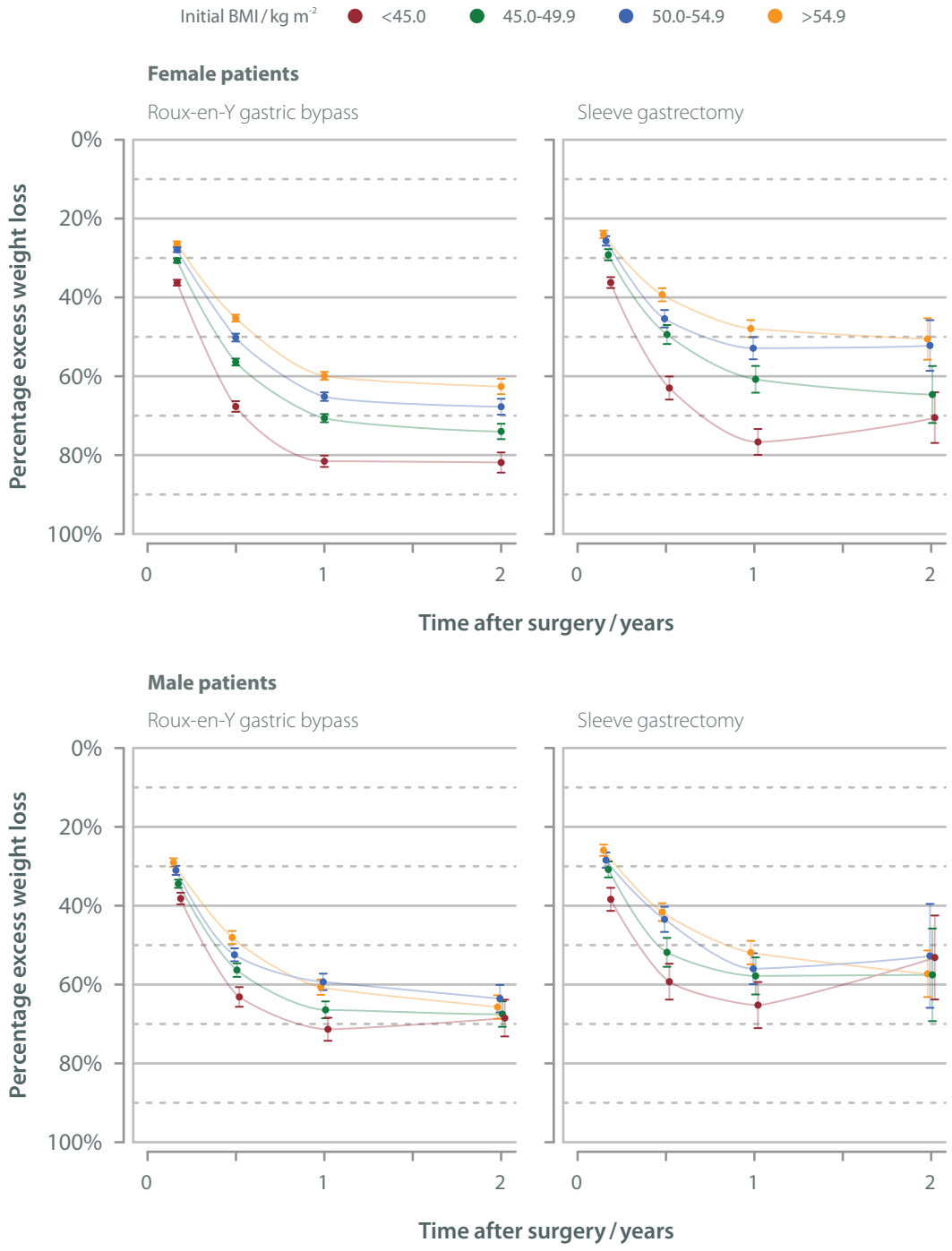
Primary Roux-en-Y gastric bypass for male patients: Post-operative excess weight loss and initial BMI; operations in the financial years 2006-2013



Excess weight loss and procedure

The percentage weight loss following gastric bypass is greater in those with lower starting BMI, but some patient groups demonstrate a little weight regain at 24 months after surgery.

Primary operations: Excess weight loss, operation, gender and initial BMI; operations in the financial years 2006-2013



Primary Roux-en-Y gastric bypass: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

Gender and follow up period / months			Initial BMI / kg m^{-2}			
			<45.0	45.0-49.9	50.0-54.9	>54.9
	Male	2	38.2 (±1.5; 362)	34.4 (±1.0; 428)	31.0 (±1.2; 365)	29.0 (±1.1; 370)
		6	63.1 (±2.5; 200)	56.3 (±1.7; 229)	52.5 (±1.6; 206)	48.1 (±1.6; 181)
		12	71.3 (±2.9; 198)	66.4 (±2.1; 269)	59.3 (±2.1; 220)	60.7 (±1.9; 227)
		24	68.5 (±4.7; 69)	67.5 (±3.2; 103)	63.6 (±3.5; 101)	65.7 (±3.0; 105)
	Female	2	36.3 (±0.7; 1,305)	30.7 (±0.6; 1,423)	27.9 (±0.6; 1,201)	26.4 (±0.6; 1,057)
		6	67.7 (±1.3; 740)	56.4 (±0.9; 812)	50.2 (±1.0; 639)	45.3 (±0.9; 573)
		12	81.6 (±1.4; 827)	70.6 (±1.0; 959)	65.2 (±1.1; 786)	59.9 (±1.0; 692)
		24	81.9 (±2.6; 322)	74.0 (±1.9; 427)	67.7 (±2.0; 354)	62.6 (±1.9; 311)

Primary sleeve gastrectomy: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

Gender and follow up period / months			Initial BMI / kg m^{-2}			
			<45.0	45.0-49.9	50.0-54.9	>54.9
	Male	2	38.4 (±2.9; 120)	30.8 (±2.0; 112)	28.4 (±2.0; 109)	25.9 (±1.4; 203)
		6	59.3 (±4.6; 73)	51.8 (±3.7; 57)	43.5 (±3.2; 63)	41.6 (±2.3; 104)
		12	65.2 (±5.8; 45)	57.8 (±4.7; 74)	56.0 (±3.9; 58)	51.9 (±3.0; 106)
		24	53.1 (±10.7; 9)	57.5 (±11.7; 18)	52.7 (±13.2; 12)	57.3 (±5.9; 30)
	Female	2	36.2 (±1.4; 389)	29.2 (±1.4; 266)	25.7 (±1.2; 270)	24.0 (±0.9; 400)
		6	63.0 (±2.9; 224)	49.4 (±2.4; 126)	45.4 (±2.2; 155)	39.3 (±1.7; 183)
		12	76.7 (±3.3; 213)	60.8 (±3.4; 131)	52.9 (±2.8; 154)	47.9 (±2.2; 218)
		24	70.5 (±6.4; 63)	64.6 (±7.2; 39)	52.2 (±6.4; 43)	50.5 (±5.3; 67)

Comorbid disease after surgery

There was significant resolution of all of the 7 major comorbid conditions recorded in the following table for female patients; resolution was significant at both the 1-year and 2-year follow up intervals. Improvement in these health conditions is one of the biggest drivers for bariatric surgery in United Kingdom; not only does it vastly improve an individual patient's quality-of-life, but it also reduces dramatically expenditure on their healthcare in the longer term. In cost terms, bariatric surgery is one of the very few medical interventions which, in addition to being hugely valuable to patients, also pays for itself.

Quite remarkably, the incidence of type 2 diabetes for female patients falls from 31.1% prior to the operation, to 9.8% and 8.1% at 1-year and 2-year follow up respectively. These data extend the known benefits of surgery from 1 year for most of the recorded comorbidities (2 years for diabetes) reported in the first NBSR report to a timescale of 2 years. These are important findings that commissioners of public health services need to see.

Primary Roux-en-Y gastric bypass operations for female patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	2,807	5,039	3,833	4,080	1,611	5,421	4,554
		Yes	3,724	1,530	2,529	2,538	4,917	1,191	2,051
		Unspecified	378	340	547	291	381	297	304
		Rate	57.0%	23.3%	39.8%	38.3%	75.3%	18.0%	31.1%
	12-month follow up [ii]	No	890	1,335	1,170	1,187	1,109	1,397	1,328
		Yes	571	135	269	288	364	75	145
		Unspecified	3,074	3,065	3,096	3,060	3,062	3,063	3,062
		Rate	39.1%	9.2%	18.7%	19.5%	24.7%	5.1%	9.8%
	24-month follow up [iii]	No	303	425	376	384	359	438	422
		Yes	154	33	76	75	98	21	37
		Unspecified	1,869	1,868	1,874	1,867	1,869	1,867	1,867
		Rate	33.7%	7.2%	16.8%	16.3%	21.4%	4.6%	8.1%
Baseline *versus* 12-month follow up [iv]			<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Baseline *versus* 24-month follow up [v]			<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

i. Pre-operative data.

ii. Data that fall in the period 365 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 365-day point.

iii. Data that fall in the period 730 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 730-day point.

iv. $2 \times 2\ \chi^2$ probability.

v. $2 \times 2\ \chi^2$ probability.

vi. Poor functional status is defined as unable to climb 3 flights of stairs without resting.

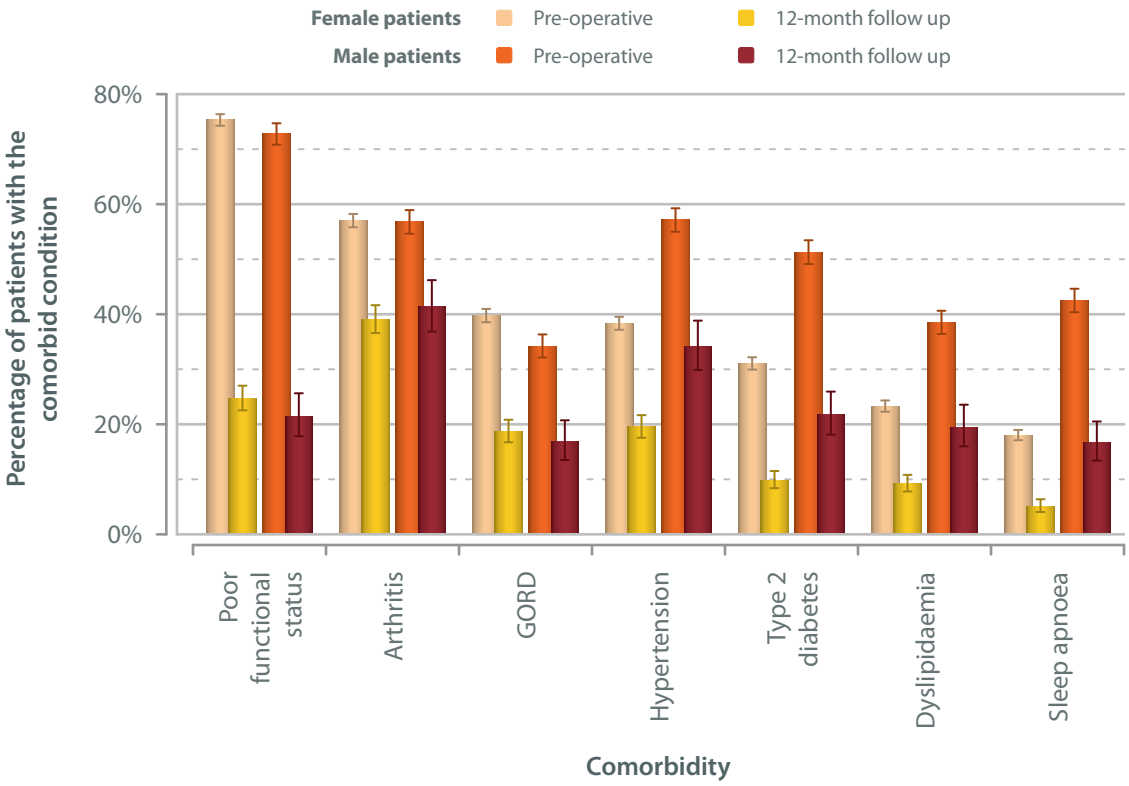
Men undergoing gastric bypass had a similar dramatic improvement in their comorbid conditions. Statistically significant resolution was noted at both 1-year and 2-year follow up for all the conditions recorded in the following table. Compared to the baseline incidence, at the point of 2-year follow up the rate of hypertension amongst male patients had fallen from 57.1% to 30.9%, and the rate of type 2 diabetes had fallen from 51.3% to 13.7%. From a financial perspective these are potentially very important findings.

Primary Roux-en-Y gastric bypass operations for male patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	901	1,281	1,329	904	560	1,213	1,023
		Yes	1,184	802	691	1,205	1,499	896	1,077
		Unspecified	139	141	204	115	165	115	124
		Rate	56.8%	38.5%	34.2%	57.1%	72.8%	42.5%	51.3%
	12-month follow up [ii]	No	260	359	366	296	351	375	352
		Yes	184	87	74	154	96	75	98
		Unspecified	966	964	970	960	963	960	960
		Rate	41.4%	19.5%	16.8%	34.2%	21.5%	16.7%	21.8%
	24-month follow up [iii]	No	81	117	123	96	113	117	120
		Yes	57	22	16	43	26	22	19
		Unspecified	584	583	583	583	583	583	583
		Rate	41.3%	15.8%	11.5%	30.9%	18.7%	15.8%	13.7%
Baseline *versus* 12-month follow up [iv]			<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Baseline *versus* 24-month follow up [v]			0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Comparison between genders demonstrates similar incidences of locomotor problems and GORD, with similar improvements at 1-year follow up. Male patients had more recorded metabolic comorbidities than female patients, with similar percentage improvements 1 year after surgery.

Primary Roux-en-Y gastric bypass: Comorbid conditions before and after surgery and gender; financial years 2011-2013



Further analysis of the patients with type 2 diabetes pre-operatively revealed that resolution rates of this condition depended on the severity of disease pre-operatively. Though significant improvements were seen in all groups of patients, those patients on insulin therapy pre-operatively generally had the lowest rates of resolution; patients on oral hypoglycaemics prior to surgery had better resolution of their condition, but those who reported just impaired glycaemia had the best rates of resolution. Whereas more than 70% of those on insulin were no longer diabetic close to 3 years after surgery, almost all of the other diabetic patients had gone into remission by the same point in time.

Similar dramatic improvements were also seen in the functional status of patients after surgery, with a similar inter-relationship between pre-operative severity of disease and rates of resolution at 3-year follow up.

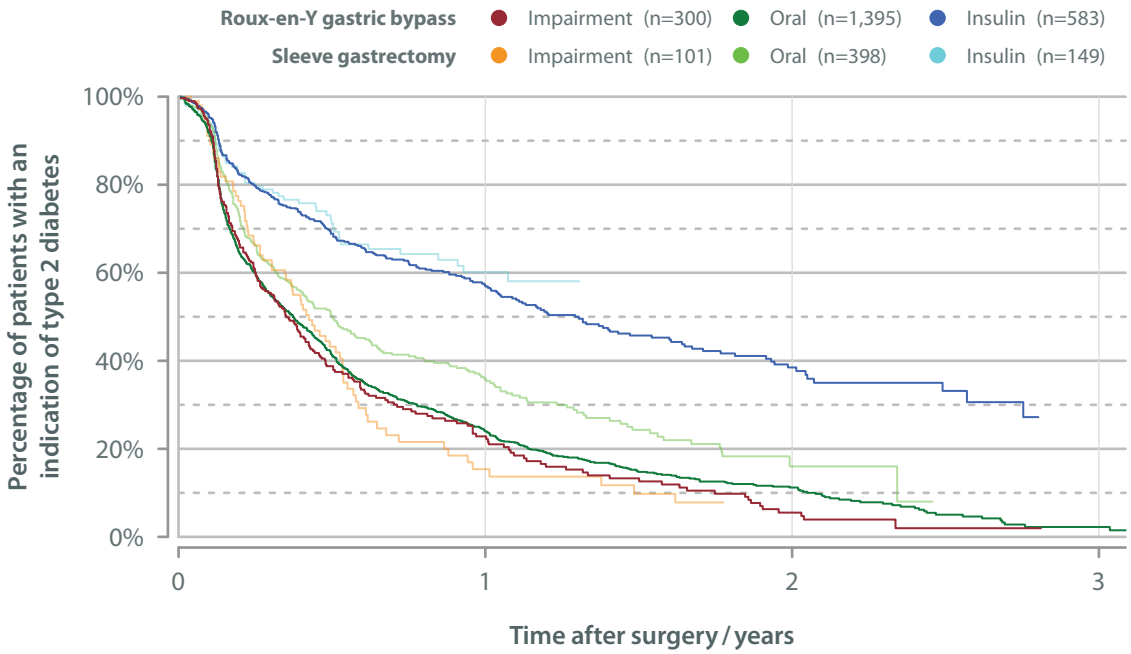
In general, patients undergoing gastric bypass did slightly better than those undergoing sleeve gastrectomy across the board. Sleeve gastrectomy is generally regarded as less effective than bypass for resolution of type 2 diabetes [1] but it does also carry a lower risk of peri-operative morbidity and mortality.

Further work, including randomised controlled trials (RCTs), are needed to compare gastric bypass with sleeve gastrectomy in more detail.

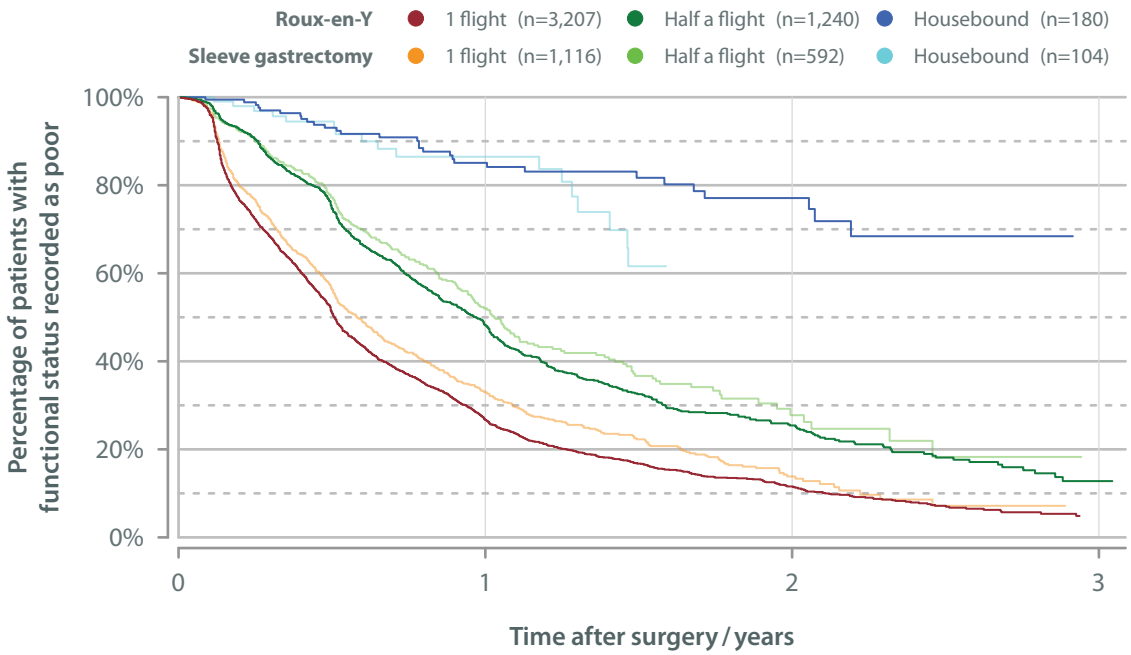
1. Li JF, Lai DD, Ni B, Sun KX. Comparison of laparoscopic Roux-en-Y gastric bypass with laparoscopic sleeve gastrectomy for morbid obesity or type 2 diabetes mellitus: a meta-analysis of randomized controlled trials. *Canadian Journal of Surgery*. 2013; **56(6)**: E158-64.

Whilst there are some apparent differences between resolution rates between procedure types, two things must be borne in mind: firstly, all patients groups exhibit significant improvement; and, secondly, these groups are drawn from an observational database, and the patients in each group have not been matched up as they would have been in a formal, randomised controlled trial. These analyses do not provide formal evidence of the relative efficacy of the different kinds of bariatric operation; only a properly-organised scientific study would be able to provide that kind of information.

Patients recorded as having an indication of type 2 diabetes prior to surgery: Changes in recorded rates of diabetes indications and type of diabetes; operations in financial years 2011-2013



Primary surgery for patients with poor functional status pre-operatively: Changes in rates of recorded poor functional status; financial years 2011-2013



Sleeve gastrectomy

I remember my first reading of the first edition of the NBSR database report of the British Obesity and Metabolic Surgery Society, it was a revelation. I was in Doha, Qatar at the time, re-engineering a struggling bariatric surgical team to make it a regional center of excellence, and had received a package sent to me by Alberic Fiennes, with a personal letter attached. It was the most beautiful and comprehensive review of a registry on bariatric surgery I had ever seen, even though the follow up on certain procedures was short due to the novelty. Such a comprehensive report was not existent in the US type of compulsory databases, which are mostly used for administrative and insurance purposes. Therefore, the expectation is higher for the second edition of 2014.

Concerning the sleeve gastrectomy data presented, it is evident that one observes a 4-fold raise in the numbers of this procedure in United Kingdom, somewhat parallel other countries like the USA. However, only 27% of procedures in 2013 are sleeve gastrectomy as opposed to 42 % in the same year in USA, and therefore we might see more in 2014-2015. British surgeons might choose this procedure for male patients, with a BMI >50 kg m^{-2}. This is, in our experience, inadequate in the long-term, and those patients should be considered as part of a 2-stage plan, as sleeve gastrectomy as a primary operation is mostly effective for patients with BMI <50 kg m^{-2}. It is interesting that the registry has been able to collect the staple height of cartridges used. There is a tendency in the last year to use higher staple heights and buttress materials, in attempts to decrease leaks, and more often in men and patients with higher recorded initial BMI. The use of smaller bougies (32 Fr and below) is decreasing and we may see fewer leaks as a result. Hiatal hernia is still performed infrequently at 3.7%, and we are likely to see this percentage to go up with experience (in very experienced surgeons 10-40%), as this may decrease the incidence of post-operative GORD, which seems unchanged.

A post-operative stay of 2-3 days, makes me think that these patients are treated as if they had had a gastric bypass, although their post-operative recovery is lesser. There is room for improvement here as, with experience, patients could be discharged one day earlier. Resolutions of comorbidities and weight loss parallel results for gastric bypass, although most data for sleeve are up to 2 years only. Nevertheless, the leak rate is lower than expected at overall 0.8% (and parallels the evolution of laparoscopic gastric bypass), and I must congratulate British surgeons for their meticulous tissue techniques.

Michel Gagner

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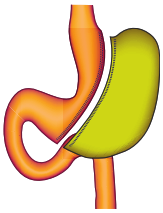
Senior Consultant, Hopital du Sacre Coeur, Montreal, Quebec, Canada

President, Clinique Michel Gagner, MD, Inc.

Director of the IFSO Global Registry

President, IFSO 2014 - 19th World Congress of IFSO, Montreal, Canada

Number of entries in the database

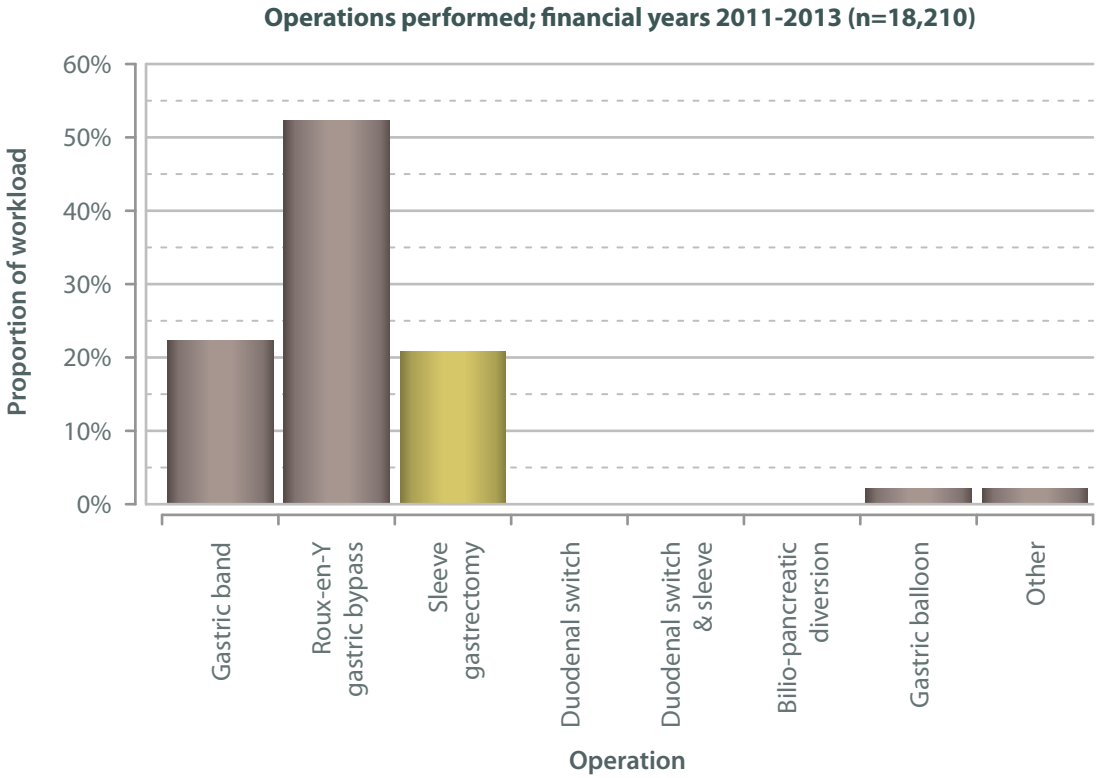


Sleeve gastrectomy comprised 20.8% of the operations entered in the National Bariatric Surgery Registry during the period 2011-2013. The vast majority of operations were performed as a definitive weight loss operation; only a very small proportion was formed with a pre-determined intent for subsequent intestinal re-arrangement or as part of a duodenal switch procedure.

Notably, the proportion of sleeve gastrectomies, as part of the total bariatric workload that was performed during 2011-2013, was quite similar to that of adjustable gastric banding (22.3%).

Type of operation performed; financial years 2011-2013

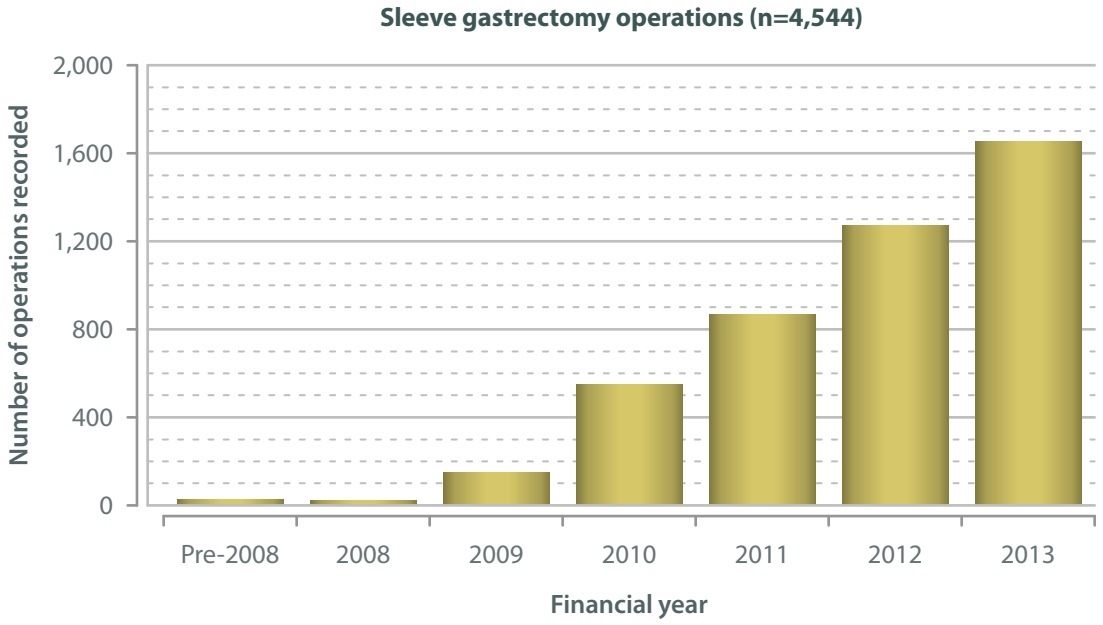
		Type of surgery					
		Primary	Revision as a primary	Revision	Planned 2nd stage	Unspecified	All
Operation	Gastric band	3,633	295	142	5	0	**4,075**
	Roux-en-Y gastric bypass	9,133	267	86	40	0	**9,526**
	Sleeve gastrectomy	3,631	80	32	54	0	**3,797**
	Duodenal switch	0	7	1	11	0	**19**
	Duodenal switch & sleeve	11	0	0	1	0	**12**
	Bilio-pancreatic diversion	0	5	0	0	0	**5**
	Gastric balloon	294	0	3	89	0	**386**
	Other	181	106	79	24	0	**390**
	Unspecified	73	0	0	0	0	**73**
	All	**16,956**	**760**	**343**	**224**	**0**	**18,283**

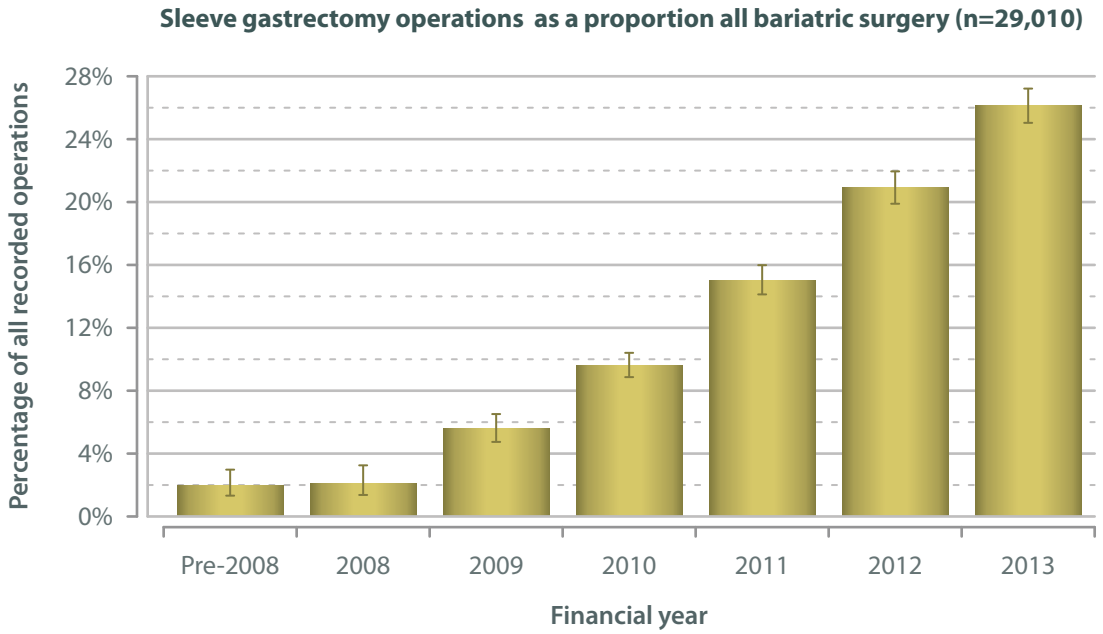

Operations performed; financial years 2011-2013 (n=18,210)
Proportion of workload
60%
50%
40%
30%
20%
10%
0%
Gastric band
Roux-en-Y gastric bypass
Sleeve gastrectomy
Duodenal switch
Duodenal switch & sleeve
Bilio-pancreatic diversion
Gastric balloon
Other
Operation

Changes in the number of operations over time

From 2008 through to 2013, sleeve gastrectomy as a proportion of all bariatric surgery has gone up by approximately five percentage points each year (2.1% in 2008; 5.6% in 2009; 9.6% in 2010; 15.0% in 2011; 20.9% in 2012; and 26.1% in2013).

The increase in popularity of the sleeve gastrectomy, as a definitive bariatric operation, appears to be at the expense of a steady and corresponding decrease in adjustable gastric banding. If all operations in the registry (26,817 operations since the pre-2006 inception of data entry) are considered, the trajectory of total recorded number of adjustable bands crossed over that for sleeve gastrectomies during the 2012-2013 financial year, such that bands now form the smallest group amongst the three commonly performed operations that are recorded in the registry.





Patient profiles

Age and gender

Men comprised 28.9% of the patients who had a primary sleeve gastrectomy during the period 2011-2013. In comparison, 24.4% of Roux-en-Y gastric bypass operations and 17.7% of adjustable gastric band operations were performed on men.

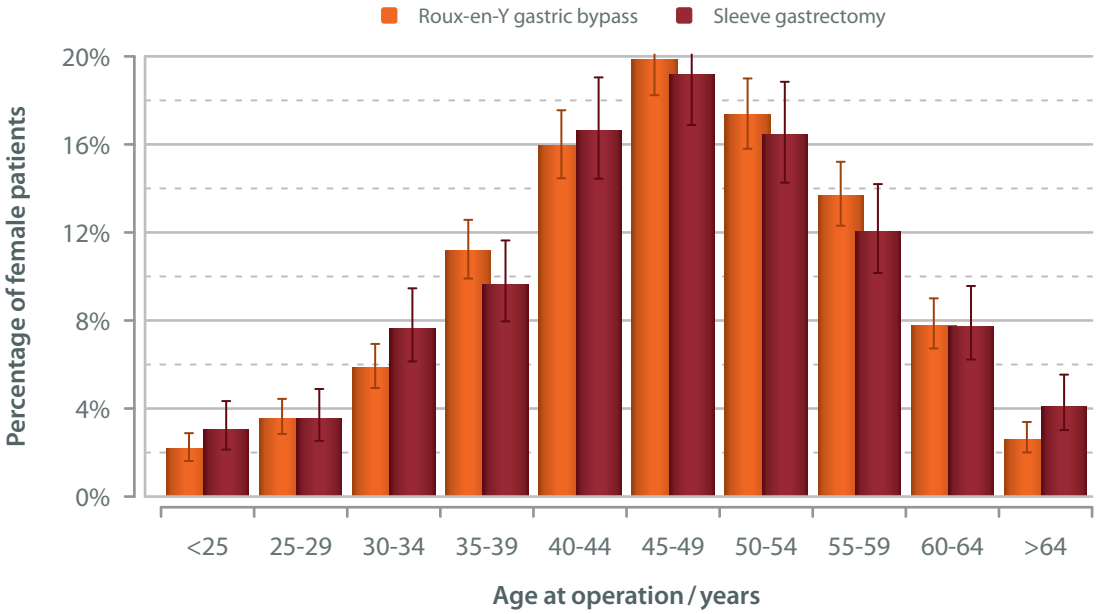
The majority of male sleeve gastrectomy patients had a BMI ≥50 kg m^{-2}; in contrast, the majority of men who had an adjustable gastric band or Roux-en-Y gastric bypass had BMI <50 kg m^{-2} (see 84). Thus, it is likely that the clustering of super-obese male patients for sleeve gastrectomy reflects the surgeons' preference for an operation that is technically simpler and is perceived to have a lower risk of post-operative complications than Roux-en-Y gastric bypass.

For female patients, there did not appear to be any association between BMI and the choice of Roux-en-Y gastric bypass or sleeve gastrectomy. However, there did appear to be a selection bias related to age: in each of the 5-year age brackets up to and including the 50-54 year-old group, the proportion of women having a sleeve gastrectomy rather than another kind of bariatric operation was around 19%, whereas the rate of sleeve gastrectomy in female patients over the age of 54 was a little over 24%. There does not appear to be any such corresponding age-related procedure selection bias in the male patient population. It may be that sleeve gastrectomy was preferred in older, post-menopausal women in an attempt to avoid the added risk of increased osteoporosis that is specifically associated with gastric bypass.

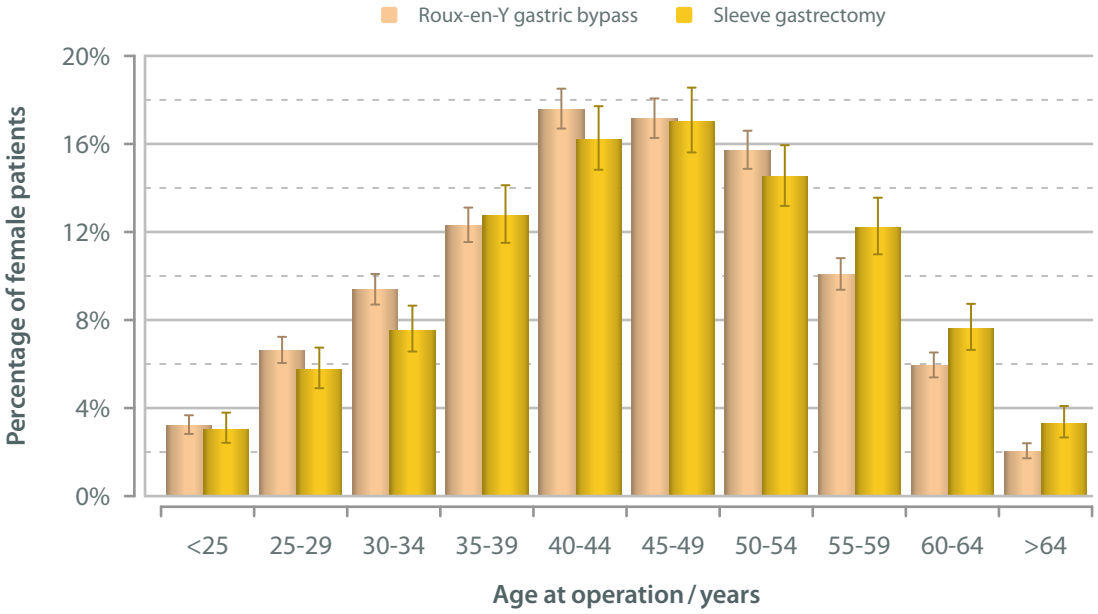
Primary operations: age, gender and operation; financial years 2011-2013

		Operation and gender					
		Gastric banding		Roux-en-Y gastric bypass		Sleeve gastrectomy	
		Male	Female	Male	Female	Male	Female
Age at operation / years	<25	21	153	48	222	32	78
	25-29	34	219	79	456	37	148
	30-34	54	258	130	646	80	194
	35-39	67	393	248	848	101	328
	40-44	102	540	354	1,212	174	417
	45-49	114	490	441	1,182	201	438
	50-54	95	401	385	1,083	172	373
	55-59	69	250	304	694	126	314
	60-64	54	170	173	409	81	196
	>64	34	110	58	140	43	85
	Unspecified	0	5	4	17	2	11
	All	**644**	**2,989**	**2,224**	**6,909**	**1,049**	**2,582**

Primary operations for men: Age distributions; financial years 2011-2013



Primary operations for women: Age distributions; financial years 2011-2013



Source of funding

During 2011-2013, the vast majority of sleeve gastrectomies were publicly funded (although, the proportion of publicly funded patients in the Roux-en-Y gastric bypass group was greater than that for sleeve gastrectomy).

Notably, the sub-group of publicly funded male sleeve gastrectomy patients had the highest average BMI amongst the 12 sub-groups formed by grouping according to gender, type of operation and funding; they were followed by publicly funded female sleeve gastrectomy patients (see 87). Not surprisingly, all publicly funded patients had significantly higher BMI than privately funded patients.

Technical aspects of sleeve gastrectomy

Surgical approach

Almost all (99.5%) primary sleeve gastrectomies were performed laparoscopically. In contrast, about 8% of primary Roux-en-Y gastric bypass operations were performed by conventional open surgery. It is remarkable that laparoscopic surgery was accomplished almost universally in a group of generally higher-risk sleeve gastrectomy patients (heavier men and older women).

Linear stapler

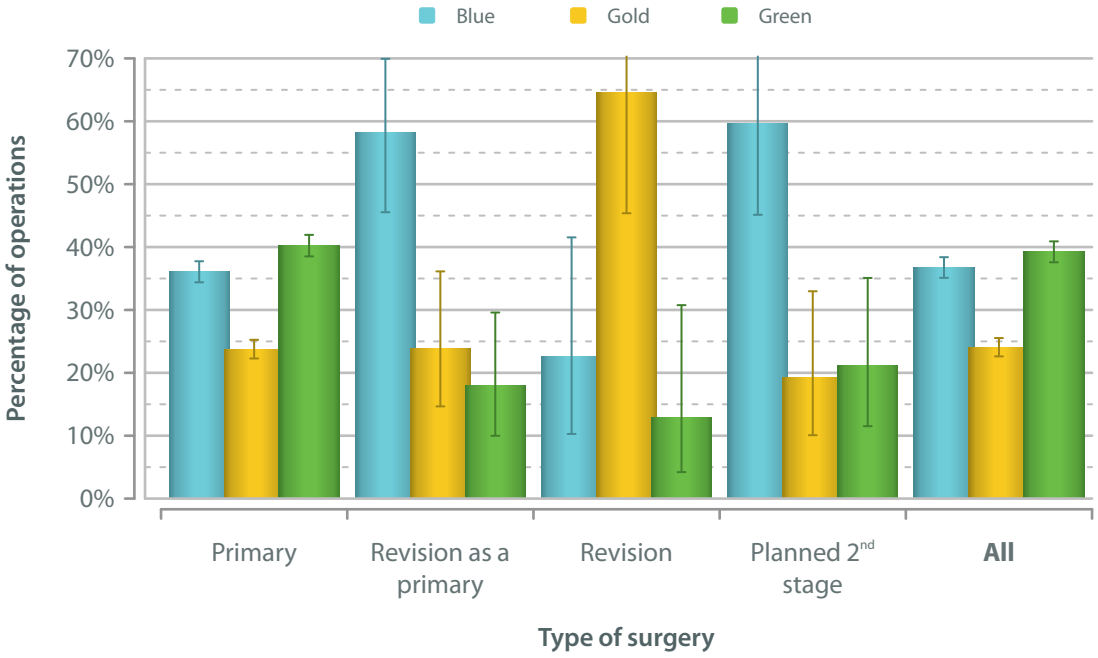
For primary sleeve gastrectomies, the preferred staple-height appears to be fairly similarly distributed between blue (40%) and green (36%) stapler cartridges. In contrast, for revisonal laparoscopic sleeve gastrectomy, only a minority (less than 20%) of surgeons used blue stapler cartridges; the greater staple-height in green or gold cartridges appeared to be preferred for the thicker tissues that are likely to be encountered in revisional surgery.

From the financial year 2010 onwards, there appears to be a clear trend of decreasing usage of green stapler cartridges, with corresponding increases in the usage of blue and gold cartridges.

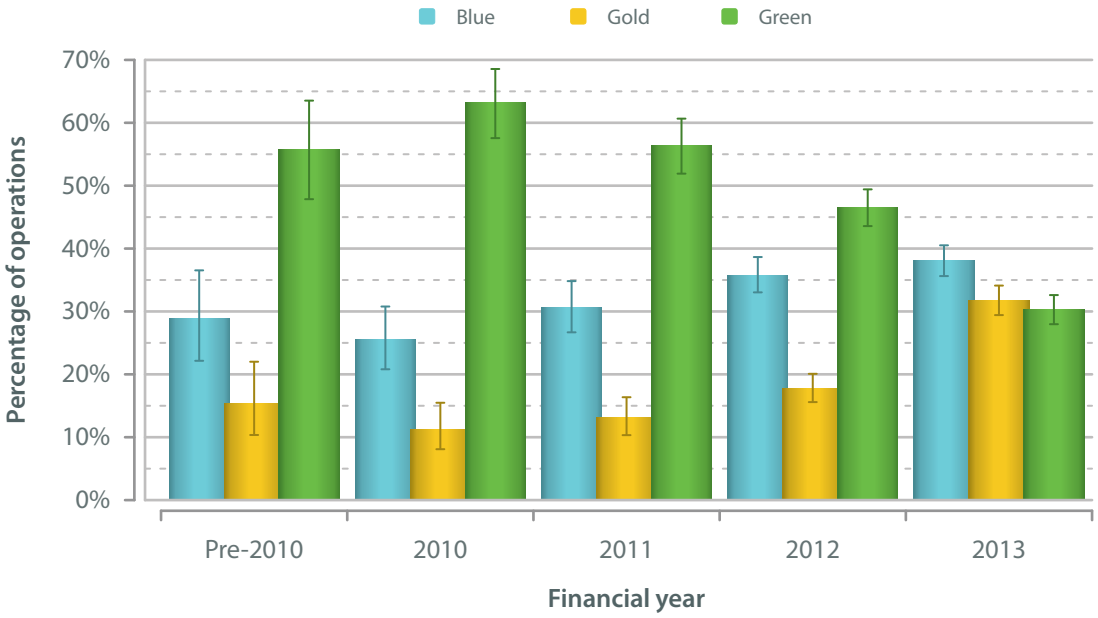
Sleeve gastrectomy: linear stapler used in gastric pouch formation and type of operation; financial years 2011-2013

		Linear stapler				
		Green	Gold	Blue	Unspecified	**All**
Type of surgery	Primary	1,159	763	1,293	416	**3,631**
	Revision as a primary	39	16	12	13	**80**
	Revision	7	20	4	1	**32**
	Planned 2nd stage	31	10	11	2	**54**
	All	**1,236**	**809**	**1,320**	**432**	**3,797**
	Primary	36.0%	23.7%	40.2%		
	Revision as a primary	58.2%	23.9%	17.9%		
	Revision	22.6%	64.5%	12.9%		
	Planned 2nd stage	59.6%	19.2%	21.2%		
	All	36.7%	24.0%	39.2%		

Sleeve gastrectomy: Linear stapler used for gastric pouch formation and type of surgery; financial years 2011-2013 (n=3,365)



Primary sleeve gastrectomy: Linear stapler used for gastric pouch formation (n=3,365)



Reinforcement

During the period 2011-2013, the majority of surgeons (58%) reinforced the staple-line. The three most common reinforcement modalities were the Duet TRS (20%), suturing (16%) and Seamguard (12%).

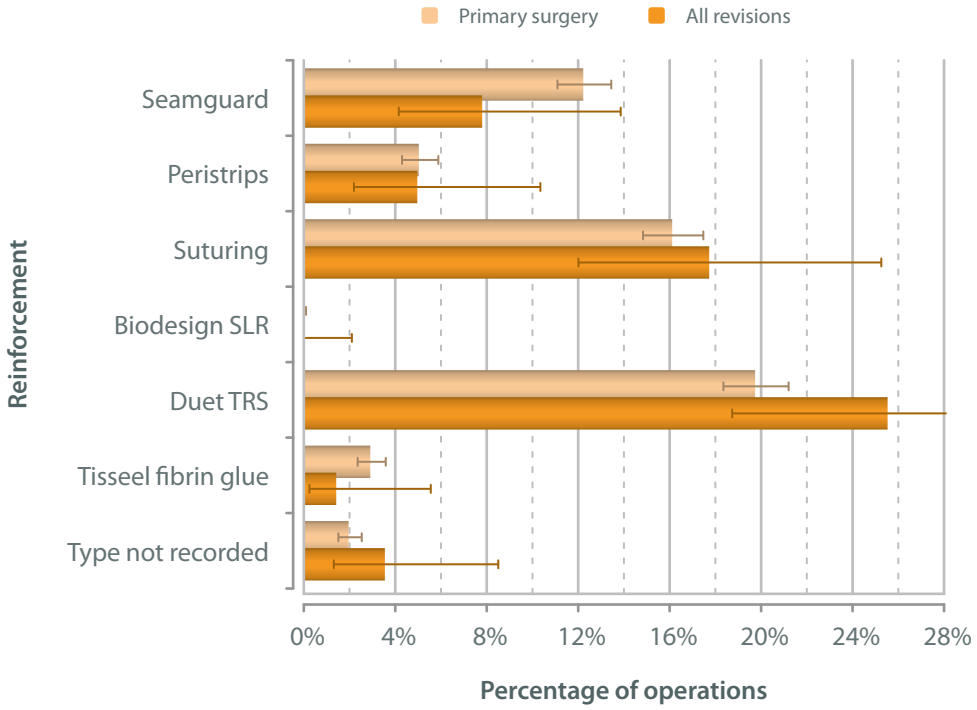
There was a definite decrease in the use of reinforcement in the year 2013: about 50% of surgeons reinforced the staple line during this year as compared to reinforcement prevalence of 60-65% during previous years.

Interestingly, there were no significant differences in the usage of reinforcement between primary and revisional procedures.

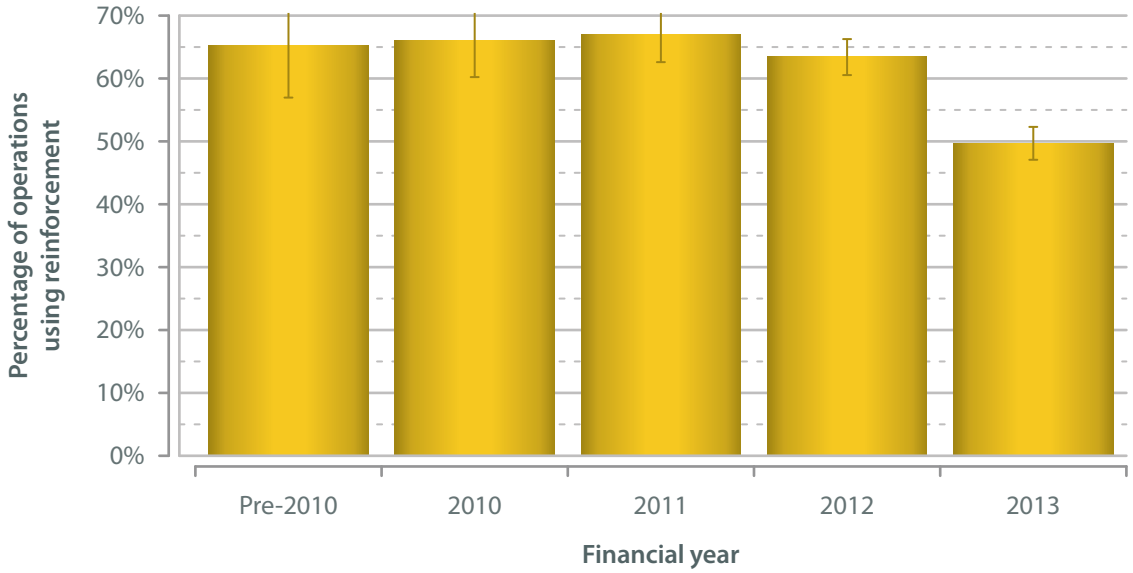
Sleeve gastrectomy: staple line reinforcement of the gastric pouch; financial years 2011-2013

		Type of surgery				
		Primary	Revision as a primary	Revision	Planned 2nd stage	**All**
Type of reinforcement	None	1,299	25	12	19	**1,355**
	Seamguard	374	7	2	2	**385**
	Peristrips	154	3	1	3	**161**
	Suturing	493	7	12	6	**518**
	Biodesign SLR	0	0	0	0	**0**
	Duet TRS	604	13	3	20	**640**
	Tisseel fibrin glue	89	2	0	0	**91**
	Type not recorded	60	4	1	0	**65**
	Unspecified	571	20	1	4	**596**
	Patient denominator	**3,631**	**80**	**32**	**54**	**3,797**
	None	42.5%	41.7%	38.7%	38.0%	**42.3%**
	Seamguard	12.2%	11.7%	6.5%	4.0%	**12.0%**
	Peristrips	5.0%	5.0%	3.2%	6.0%	**5.0%**
	Suturing	16.1%	11.7%	38.7%	12.0%	**16.2%**
	Biodesign SLR	0.0%	0.0%	0.0%	0.0%	**0.0%**
	Duet TRS	19.7%	21.7%	9.7%	40.0%	**20.0%**
	Tisseel fibrin glue	2.9%	3.3%	0.0%	0.0%	**2.8%**
	Type not recorded	2.0%	6.7%	3.2%	0.0%	**2.0%**

Sleeve gastrectomy: Staple line reinforcement; financial years 2011-2013 (n=3,201)



Primary sleeve gastrectomy: Reinforcement rates over time (n=3,501)



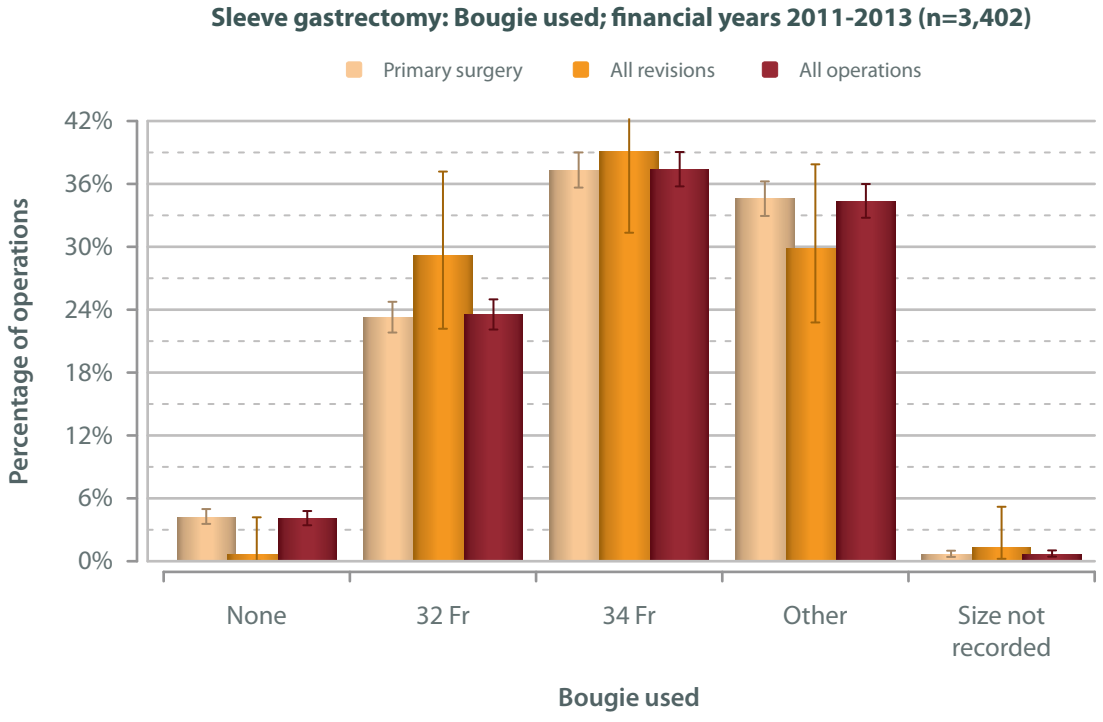
Bougie used

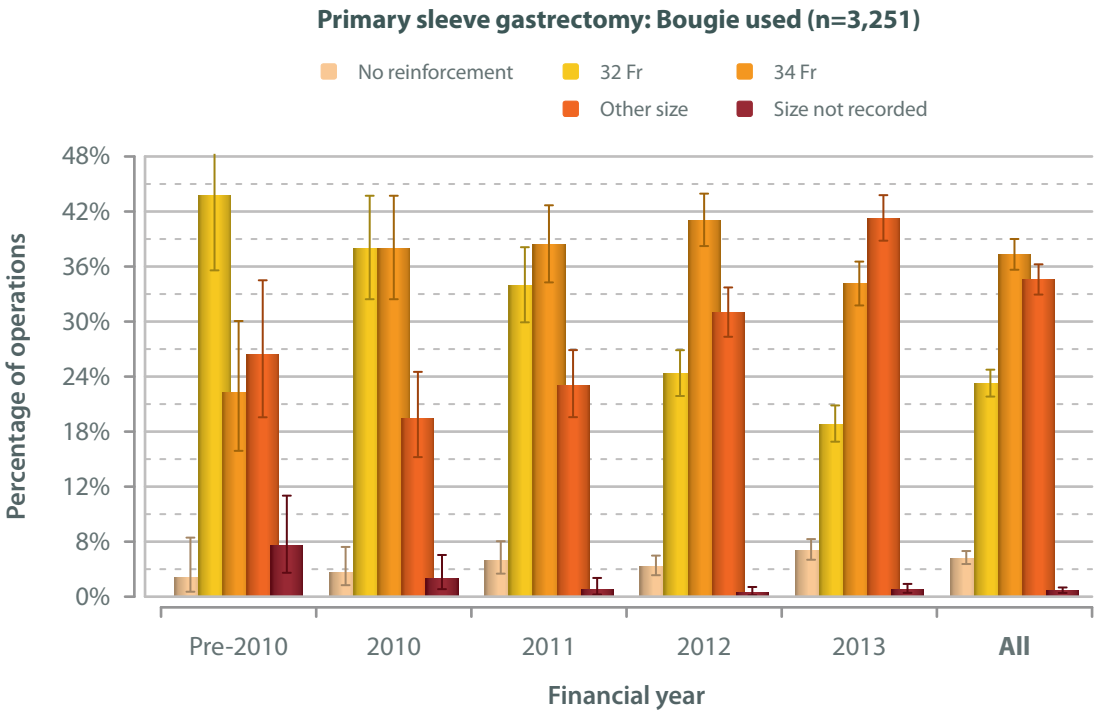
Only a small minority of operations (4%) did not include the use of a bougie to calibrate the sleeve gastrectomy. The most commonly used bougie size was 34 Fr (37%), followed by 32 Fr (23%).

There has been a steady decrease in the usage of a 32 Fr bougie from the pre-2010 era to 2013, with a corresponding increase in the use of bougies measuring other than 32 Fr or 34 Fr.

Sleeve gastrectomy: bougie used; financial years 2011-2013

		Type of surgery				
		Primary	Revision as a primary	Revision	Planned 2nd stage	**All**
Bougie used	No	137	1	0	0	**138**
	32 Fr	756	19	2	23	**800**
	34 Fr	1,213	30	8	21	**1,272**
	Other	1,124	17	21	7	**1,169**
	Size not recorded	21	1	0	1	**23**
	Unspecified	380	12	1	2	**395**
	All	**3,631**	**80**	**32**	**54**	**3,797**
	No	4.2%	1.5%	0.0%	0.0%	**4.1%**
	32 Fr	23.3%	27.9%	6.5%	44.2%	**23.5%**
	34 Fr	37.3%	44.1%	25.8%	40.4%	**37.4%**
	Other	34.6%	25.0%	67.7%	13.5%	**34.4%**
	Size not recorded	0.6%	1.5%	0.0%	1.9%	**0.7%**




Primary sleeve gastrectomy: Bougie used (n=3,251)
No reinforcement
32 Fr
34 Fr
Other size
Size not recorded
Percentage of operations
48%
42%
36%
30%
24%
18%
12%
8%
0%
Pre-2010
2010
2011
2012
2013
All
Financial year

Additional procedures

Hiatus hernia repair was performed during 3.7% of primary sleeve gastrectomies. Considering that a diagnosis of GORD was recorded in 35% of patients, it is possible that hiatus hernias are not being repaired in a sizeable number of patients.

Sleeve gastrectomy: additional procedures and type of surgery; financial years 2011-2013

		Additional procedures						
		None	Cholecystectomy	Hernia repair	Apronectomy	Other	Unspecified	**All**
Type of surgery	Primary	2,848	44	116	1	135	497	**3,631**
	Revision as a primary	46	0	5	0	16	13	**80**
	Revision	23	1	1	0	2	5	**32**
	Planned 2nd stage	28	1	0	0	20	5	**54**
	All	**2,945**	**46**	**122**	**1**	**173**	**520**	**3,797**
	Primary	90.9%	1.4%	3.7%	0.0%	4.3%		
	Revision as a primary	68.7%	0.0%	7.5%	0.0%	23.9%		
	Revision	85.2%	3.7%	3.7%	0.0%	7.4%		
	Planned 2nd stage	57.1%	2.0%	0.0%	0.0%	40.8%		
	All	**89.9%**	**1.4%**	**3.7%**	**0.0%**	**5.3%**		

Details of *other* additional procedures

• adhesiolysis	16
• adhesiolysis - previous splenectomy	1
• adhesiolysis + crural / hiatal repair	1
• anterior cruroplasty	1
• band removal	6
• balloon removal	6
• biopsy of peritoneal nodule	1
• crural approximation	1
• division of adhesions	4
• endoscopic removal of intragastric balloon	1
• excision of gist+repair of umbilical hernia	1
• hiatus hernia repair	1
• lap band removal	1
• laparoscopic adhesionalysis	1
• laparoscopic wide excision of antral tumour	1
• leak at fundus oversewn	1
• liver biopsy	5
• liver biopsy & tissue excision	1
• ogd	1
• ogd+removal of gastric balloon	5
• open excision of large lipoma in abdomen wall	1
• permacol mesh repair of adbominal wall with component separation (ramirez technique)	1
• previous laparoscopic cholecystectomy	1
• splenectomy	2
• blank (no data recorded)	112

Post-procedure outcomes

30-day complications, re-operations and mortality

Leakage and bleeding were reported after 0.8% and 0.7% of primary sleeve gastrectomies respectively, and 1.2% and 1.2% of revisional operations. The incidence of re-operation was 1.4% after primary operations and 2.4% after revisional surgery.

The reported incidence of post-operative cardiovascular complications (including venous thromboembolism) was similar for sleeve gastrectomy and Roux-en-Y gastric bypass (0.3% *versus* 0.4%, respectively). The incidence of other complications also appeared similar across these two procedure groups (3.5% *versus* 3.1%).

Notably, the incidence of post-operative mortality was about twice as high with laparoscopic sleeve gastrectomy than with Roux-en-Y gastric bypass (0.15% *versus* 0.07%; although this is not *statistically significant*; p=0.499; Fisher's exact test). The mortality data are consistent with the observations that the patients at generally higher-risk for post-operative adverse events are being selected for sleeve gastrectomy.

Sleeve gastrectomy: 30-day complications; financial years 2011-2013

Type of surgery and 30-day complications			Complications		
			None recorded	Yes	Rate (95% CI)
	Primary	**Any complication**	**3,547**	**84**	**2.3% (1.9-2.9%)**
		Leak	3,601	30	0.8% (0.6-1.2%)
		Bleeding	3,605	26	0.7% (0.5-1.1%)
		Obstruction	3,631	0	0.0% (0.0-0.1%)
		Other	3,592	39	1.1% (0.8-1.5%)
	All revisions	**Any complication**	**161**	**5**	**3.0% (1.1-7.3%)**
		Leak	164	2	1.2% (0.2-4.7%)
		Bleeding	164	2	1.2% (0.2-4.7%)
		Obstruction	166	0	0.0% (0.0-1.8%)
		Other	165	1	0.6% (0.0-3.8%)

Although we have not presented a formal analysis of the treatment of sleeve leaks in this report, the placement of drains is highly suggestive of treatment for this very purpose, together with an attempt at repair of the gastric suture line, which usually dehisces at the angle of His (the top end of the gastric sleeve / tube). Leaks are thought to occur in this location due to pressure from a functional contracting gastric *antrum*, together with an intact pylorus (the outlet valve of the stomach), creating a high pressure system.

Also, we plan to remove diagnostic laparoscopy only as a complication in future reports, as this may be considered a first-line minimally invasive test by some surgeons in contrast to CT scanning in patients suspected of having a complication.

Sleeve gastrectomy: 30-day re-operations; financial years 2011-2013

Type of operation and re-operation performed			30-day re-operation			
			No	Yes	Unspecified	Rate (95% CI)
	Primary	**Any re-operation**	**3,580**	**51**	**0**	**1.4% (1.1-1.9%)**
		Refashioning anastomosis	3,631	0	0	0.0% (0.0-0.1%)
		Attention to bleeding area	3,618	13	0	0.4% (0.2-0.6%)
		Hernia repair	3,630	1	0	0.0% (0.0-0.2%)
		Drain replacement	3,610	21	0	0.6% (0.4-0.9%)
		Gastrostomy	3,629	2	0	0.1% (0.0-0.2%)
		Enteral feed	3,631	0	0	0.0% (0.0-0.1%)
		Repair gastric line staple	3,619	12	0	0.3% (0.2-0.6%)
		Laparoscopy	3,624	7	0	0.2% (0.1-0.4%)
		Other	3,618	13	0	0.4% (0.2-0.6%)
	All revisions	**Any re-operation**	**162**	**4**	**0**	**2.4% (0.8-6.4%)**
		Refashioning anastomosis	166	0	0	0.0% (0.0-1.8%)
		Attention to bleeding area	166	0	0	0.0% (0.0-1.8%)
		Hernia repair	166	0	0	0.0% (0.0-1.8%)
		Drain replacement	163	3	0	1.8% (0.5-5.6%)
		Gastrostomy	166	0	0	0.0% (0.0-1.8%)
		Enteral feed	166	0	0	0.0% (0.0-1.8%)
		Repair gastric line staple	165	1	0	0.6% (0.0-3.8%)
		Laparoscopy	166	0	0	0.0% (0.0-1.8%)
		Other	165	1	0	0.6% (0.0-3.8%)

Post-operative complications

Individual complications

In this table we have reported on cardiovascular and *other* complications together. *Other* complications were the most frequent. Even so, the rate of in-hospital mortality after surgery is very low.

The data are similar to those recorded for primary gastric bypass surgery, where the rate of cardiovascular complications was 0.4% and *other* complications 3.1% (see page 231); a further analysis showed that the rate of *composite* complications (cardiovascular and / or *other*) after Roux-en-Y gastric bypass was 3.3%. Statistically there is no difference between this and the composite complication rate recorded for sleeve gastrectomy, which was 3.5%.

Sleeve gastrectomy: post-operative complications; financial years 2011-2013

Type of surgery and post-operative complications			Complications			
			No	Yes	Unspecified	Rate (95% CI)
	Primary	Cardiovascular	3,302	10	319	0.3% (0.2-0.6%)
		Other	3,160	114	357	3.5% (2.9-4.2%)
		In-hospital mortality	3,252	5	374	0.2% (0.1-0.4%)
	All revisions	Cardiovascular	141	0	25	0.0% (0.0-2.1%)
		Other	136	5	25	3.5% (1.3-8.5%)
		In-hospital mortality	140	0	26	0.0% (0.0-2.1%)
	All	**Cardiovascular**	**3,443**	**10**	**344**	**0.3% (0.1-0.6%)**
		Other	**3,296**	**119**	**382**	**3.5% (2.9-4.2%)**
		In-hospital mortality	**3,392**	**5**	**400**	**0.1% (0.1-0.4%)**

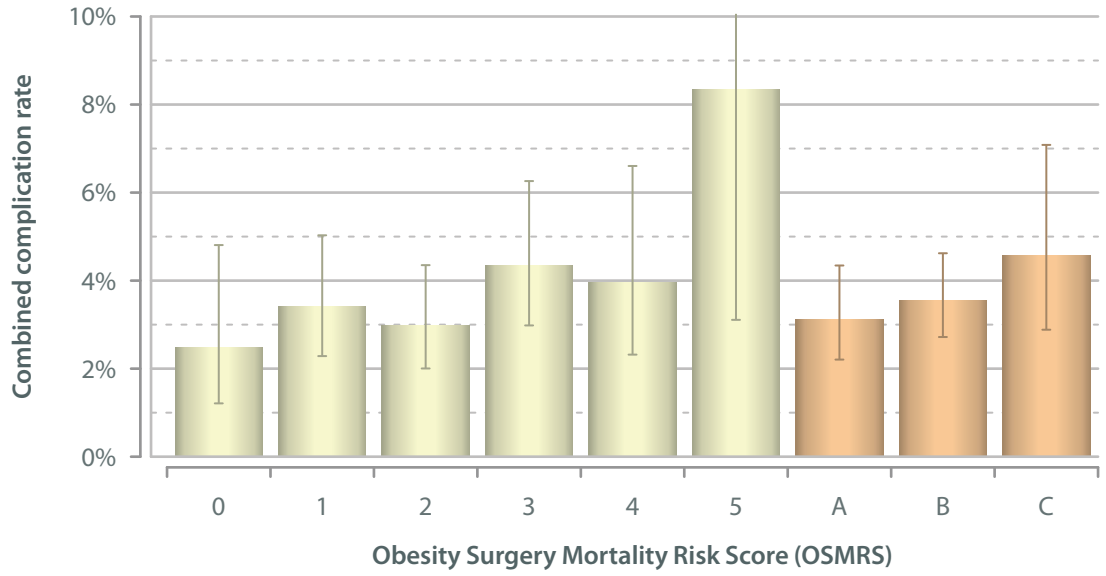
Combined cardiovascular and other complications

In this section we have analysed the combined cardiovascular complications and *other* complications as a *composite complication rate*. The chart below shows that the derived, combined complication rate rose with rising OSMRS, although this trend did not attain statistical significance (p=0.179; χ^2-test for trend). So, a patient with all 5 risk factors used in the OSMRS has an 8.3% risk of a *composite* complication, and the clinician can use this information as part of the decision-making and consent process.

Primary sleeve gastrectomy: combined cardiovascular and other complications and OSMRS; financial years 2011-2013

		Any complication			
		No	Yes	Unspecified	Rate (95% CI)
OSMRS	0	355	9	25	2.5% (1.2-4.8%)
	1	736	26	50	3.4% (2.3-5.0%)
	2	882	27	58	3.0% (2.0-4.4%)
	3	638	29	51	4.3% (3.0-6.3%)
	4	363	15	32	4.0% (2.3-6.6%)
	5	55	5	9	8.3% (3.1-19.1%)
	Group A	1,091	35	75	3.1% (2.2-4.3%)
	Group B	1,520	56	109	3.6% (2.7-4.6%)
	Group C	418	20	41	4.6% (2.9-7.1%)
	Unspecified	124	5	137	3.9% (1.4-9.3%)
	All	**3,153**	**116**	**362**	**3.5% (3.0-4.3%)**

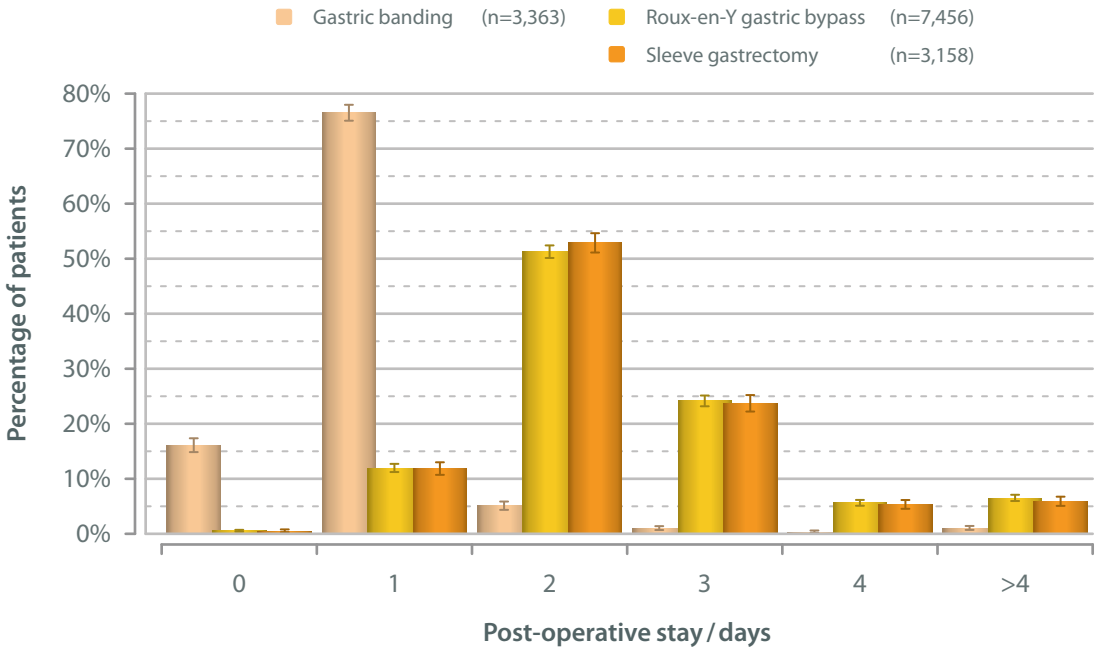
Primary sleeve gastrectomy Combined post-operative complications and OSMRS; financial years 2011-2013 (n=3,140)



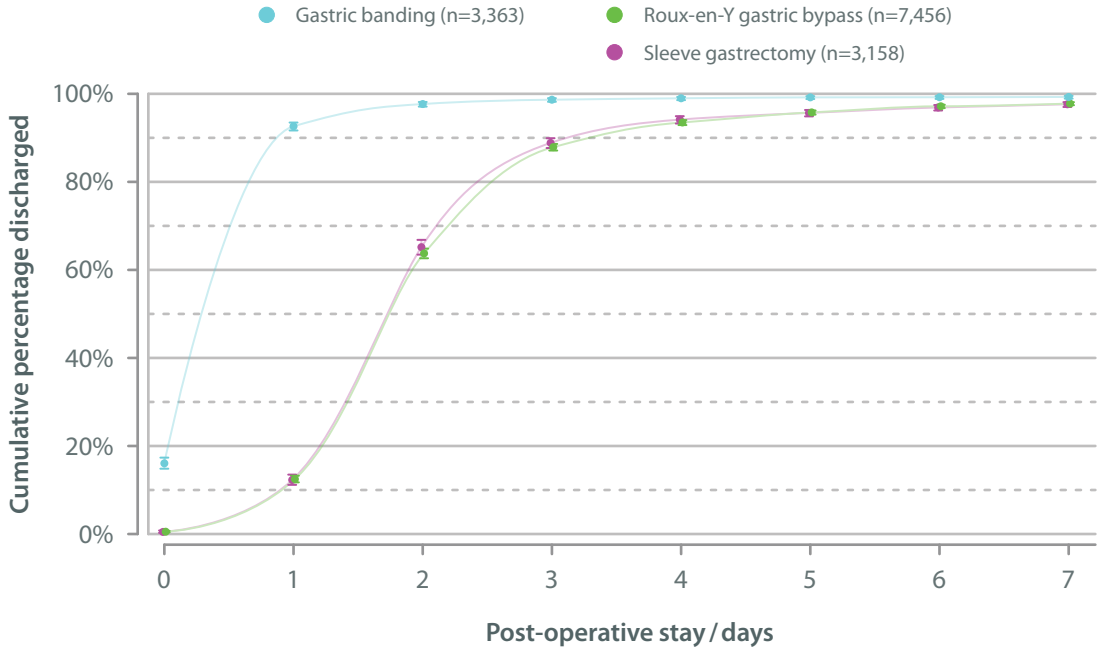
Post-operative stay

In this graph we see that the length-of-stay after sleeve gastrectomy surgery is similar to that for gastric bypass, and longer than that reported after gastric banding. Despite their advanced comorbidity, more than half of sleeve gastrectomy patients are still going home within 48 hours, indicating fast, enhanced recovery is possible with laparoscopic surgery.

Primary laparoscopic surgery: Post-operative stay and operation; financial years 2011-2013



Primary laparoscopic operations: Post-operative stay; financial years 2011-2013



Follow up data

Excess weight loss, initial BMI and gender

Meaningful data on weight loss after sleeve gastrectomy are currently only available up to 24-month follow-up. In general, for both genders and all BMI sub-groups, maximum excess weight loss appears to be achieved by 12 months post-operatively. There may be some sub-group specific patterns for weight regain or further weight loss during the second 12 months, but robust inferences cannot be derived from the data presently available.

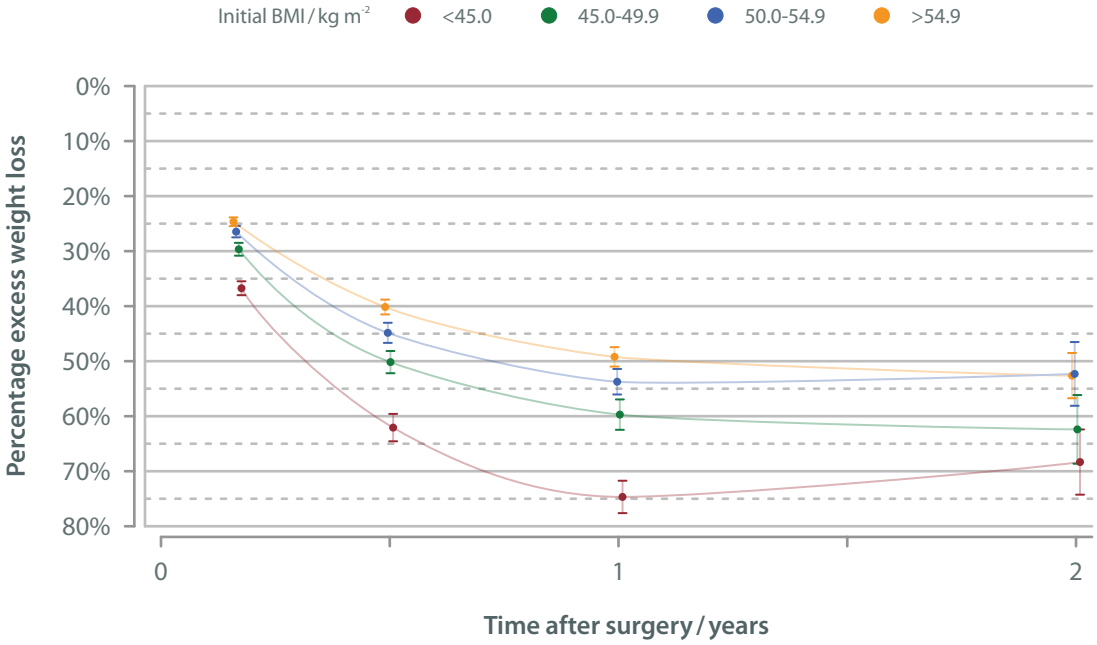
Interestingly, male patients have a similar excess weight loss at 24 months follow-up irrespective of their starting BMI. In contrast, female patients with BMI >50 kg m^{-2} have lost considerably less excess weight at 24 months than those with BMI <50 kg m^{-2}.

Primary sleeve gastrectomy: percentage excess weight loss (95% CI; count), gender and initial BMI; operations in the financial years 2006-2013

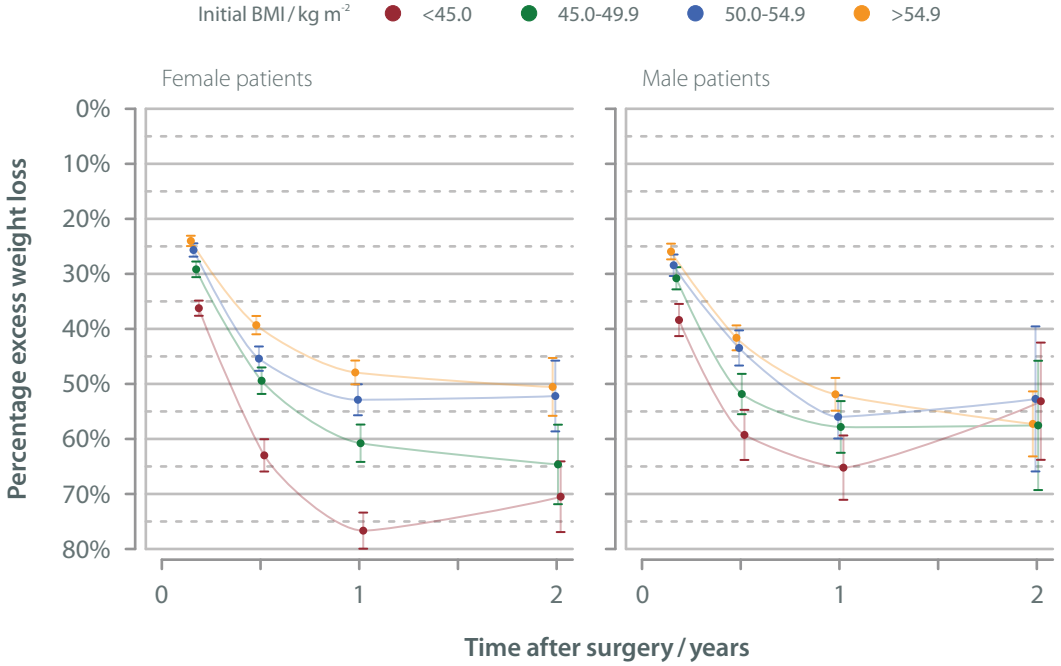
Gender and follow up period / months			Initial BMI / kg m^{-2}			
			<45.0	45.0-49.9	50.0-54.9	>54.9
	Female	2	36.2 (1.4; 389)	29.2 (1.4; 266)	25.7 (1.2; 270)	24.0 (0.9; 400)
		6	63.0 (2.9; 224)	49.4 (2.4; 126)	45.4 (2.2; 155)	39.3 (1.7; 183)
		12	76.7 (3.3; 213)	60.8 (3.4; 131)	52.9 (2.8; 154)	47.9 (2.2; 218)
		24	70.5 (6.4; 63)	64.6 (7.2; 39)	52.2 (6.4; 43)	50.5 (5.3; 67)
	Male	2	38.4 (2.9; 120)	30.8 (2.0; 112)	28.4 (2.0; 109)	25.9 (1.4; 203)
		6	59.3 (4.6; 73)	51.8 (3.7; 57)	43.5 (3.2; 63)	41.6 (2.3; 104)
		12	65.2 (5.8; 45)	57.8 (4.7; 74)	56.0 (3.9; 58)	51.9 (3.0; 106)
		24	53.1 (10.7; 9)	57.5 (11.7; 18)	52.7 (13.2; 12)	57.3 (5.9; 30)
	All patients	2	36.7 (1.3; 509)	29.7 (1.2; 378)	26.5 (1.0; 379)	24.7 (0.8; 603)
		6	62.1 (2.5; 297)	50.2 (2.0; 183)	44.9 (1.8; 218)	40.2 (1.4; 287)
		12	74.7 (2.9; 258)	59.7 (2.8; 205)	53.7 (2.3; 212)	49.2 (1.8; 324)
		24	68.3 (5.9; 72)	62.4 (6.2; 57)	52.3 (5.8; 55)	52.6 (4.1; 97)

As explained previously, it is important to remember that for each kilo of post-operative weight-loss a patient with a smaller initial BMI has a greater calculated percentage **excess** weight loss as their excess weight was relatively smaller at the outset.

Primary sleeve gastrectomy: Excess weight loss and initial BMI; operations in the financial years 2006-2013



Primary sleeve gastrectomy: Excess weight loss, gender and initial BMI; operations in the financial years 2006-2013



Comorbid disease after surgery

There was a significant reduction in the prevalence of most comorbidities at follow-up intervals of 12 months or 24 months.

Female patients reported significant improvements in all comorbidities except arthritis at 24-month follow up. This may be because sleeve gastrectomy was more likely to be performed in older females in whom arthritis is well established. However, remarkable resolution of type 2 diabetes, dyslipidaemia and sleep apnoea occurred within 1 year of surgery.

Primary sleeve gastrectomy for female patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	1,056	1,902	1,516	1,561	546	2,016	1,893
		Yes	1,361	552	825	915	1,897	454	576
		Unspecified	165	128	241	106	139	112	113
		Rate	56.3%	22.5%	35.2%	37.0%	77.7%	18.4%	23.3%
	12-month follow up [ii]	No	248	376	300	335	297	394	390
		Yes	181	54	126	95	132	36	39
		Unspecified	1,015	1,014	1,018	1,014	1,015	1,014	1,015
		Rate	42.2%	12.6%	29.6%	22.1%	30.8%	8.4%	9.1%
	24-month follow up [iii]	No	47	82	68	67	55	83	82
		Yes	42	7	20	22	33	6	7
		Unspecified	501	501	502	501	502	501	501
		Rate	47.2%	7.9%	22.7%	24.7%	37.5%	6.7%	7.9%
Baseline *versus* 12-month follow up [iv]			<0.001	<0.001	0.027	<0.001	<0.001	<0.001	<0.001
Baseline *versus* 24-month follow up [v]			0.111	0.002	0.021	0.025	<0.001	0.008	0.001

i. Pre-operative data.

ii. Data that fall in the period 365 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 365-day point.

iii. Data that fall in the period 730 ± 61 days after the operation. The follow-up entry used in the analysis is that datum that is nearest in time to the 730-day point.

iv. $2 \times 2\ \chi^2$ probability.

v. $2 \times 2\ \chi^2$ probability.

vi. Poor functional status is defined as unable to climb 3 flights of stairs without resting.

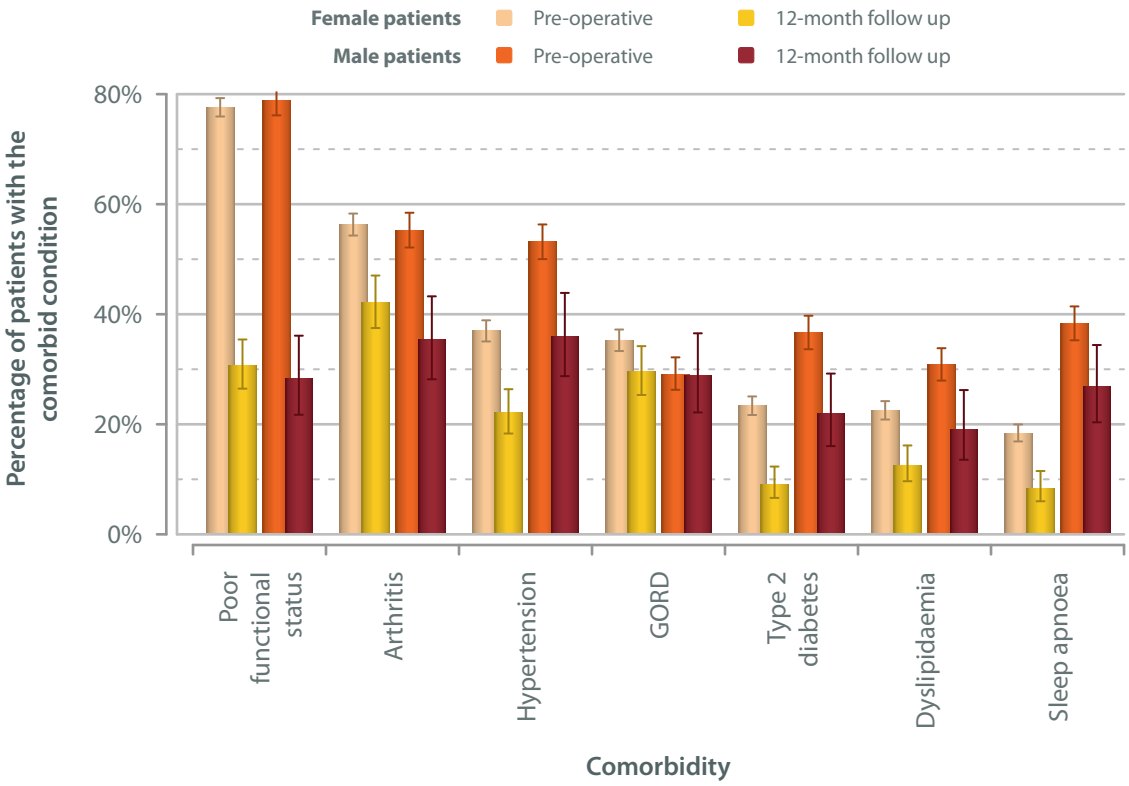
Male patients tended to have more comorbid conditions prior to surgery. Interestingly, while metabolic conditions improved significantly in the first year, there was no significant improvement in GORD symptoms for male patients at follow-up intervals of 12 months and 24 months. Future reports will be able to examine the data to determine whether or not improvement in GORD symptoms is associated with repair of any hiatal defect (hiatus hernia) at the time of primary sleeve gastrectomy.

Primary sleeve gastrectomy for male patients: comorbid conditions pre-operatively and at follow up; financial years 2011-2013

			Comorbidity						
			Arthritis	Dyslipidaemia	GORD	Hypertension	Poor functional status [vi]	Sleep apnoea	Type 2 diabetes
Source of data	Baseline [i]	No	438	676	669	464	206	609	628
		Yes	542	301	275	527	769	378	363
		Unspecified	69	72	105	58	74	62	58
		Rate	55.3%	30.8%	29.1%	53.2%	78.9%	38.3%	36.6%
	12-month follow up [ii]	No	106	131	116	105	116	120	128
		Yes	58	31	47	59	46	44	36
		Unspecified	428	430	429	428	430	428	428
		Rate	35.4%	19.1%	28.8%	36.0%	28.4%	26.8%	22.0%
	24-month follow up [iii]	No	20	25	23	21	25	25	26
		Yes	11	6	8	10	6	6	5
		Unspecified	192	192	192	192	192	192	192
		Rate	35.5%	19.4%	25.8%	32.3%	19.4%	19.4%	16.1%
Baseline *versus* 12-month follow up [iv]			<0.001	0.003	0.987	<0.001	<0.001	0.006	<0.001
Baseline *versus* 24-month follow up [v]			0.046	0.244	0.841	0.034	<0.001	0.051	0.031

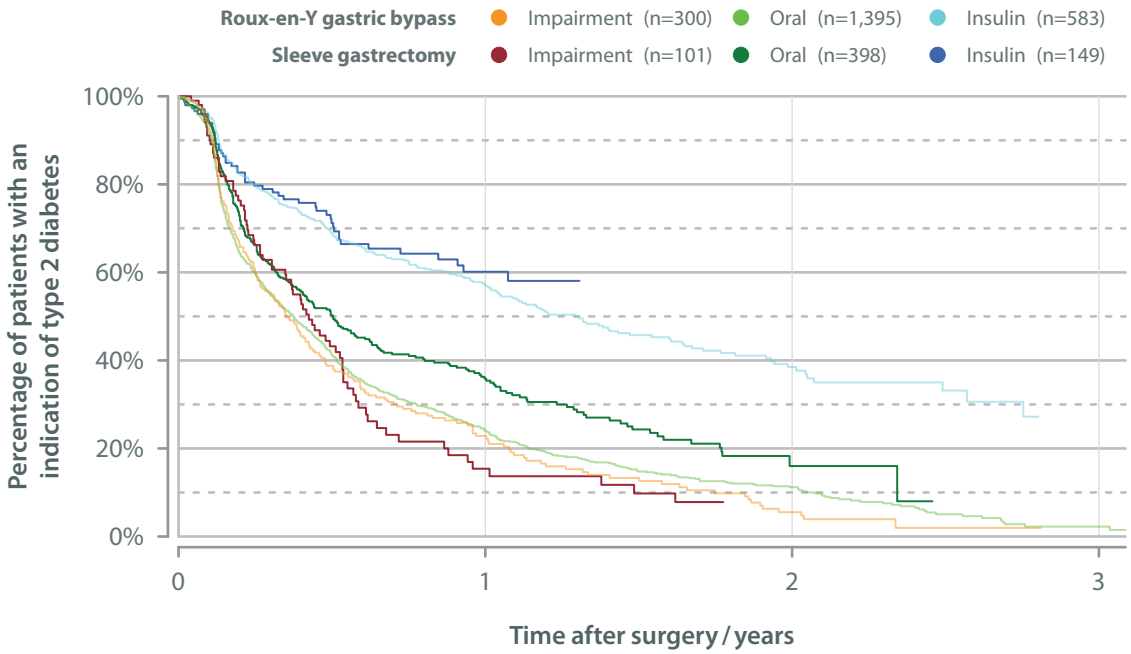
All comorbidities improved within one year of sleeve gastrectomy, except for GORD. This is significant given that reflux is a recognised complication of sleeve gastrectomy and fewer than 4% patients underwent hiatus hernia repair.

Primary sleeve gastrectomy: Comorbid conditions before and after surgery and gender; financial years 2011-2013



Rates of resolution of diabetes are similar following sleeve gastrectomy and gastric bypass. However, caution should be used in interpreting any differences in the rates of improvement of comorbidities, especially diabetes, between the operations recorded in the NBSR since patients were not randomised into these treatment groups, and the groups are very different in terms of their risk profiles.

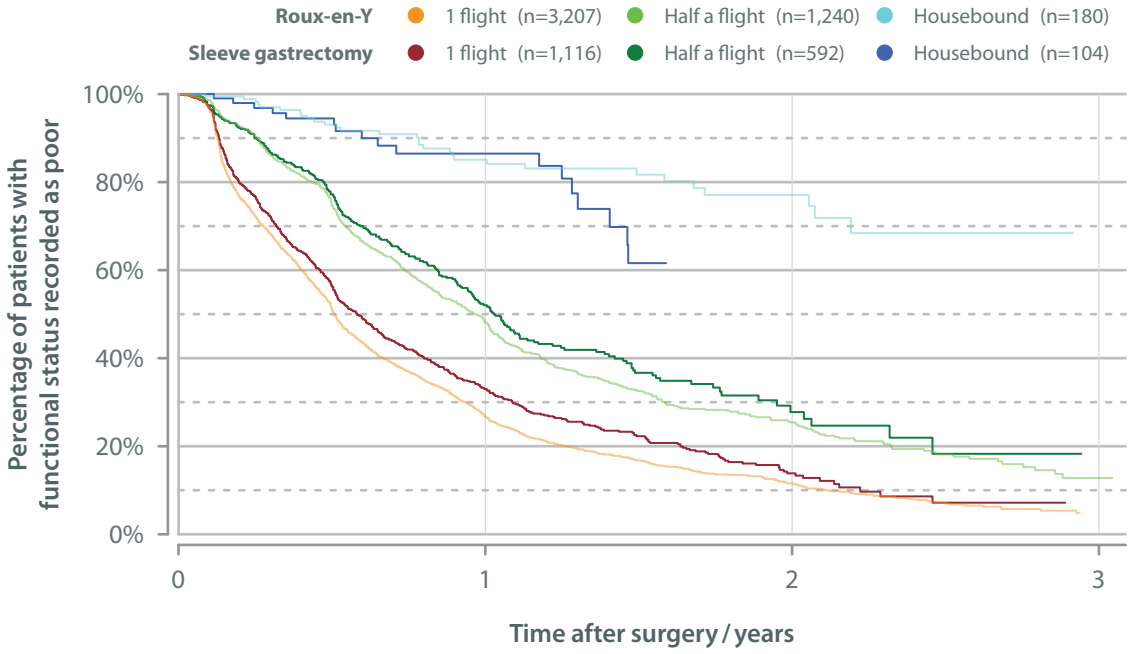
Patients recorded as having an indication of type 2 diabetes prior to surgery: Changes in recorded rates of diabetes indications and type of diabetes; operations in financial years 2011-2013



The following chart on the improvement in functional status after these two bariatric operations is the first of its kind on the scale of a national registry. No other treatments apart from bariatric surgery can demonstrate anything like these effects on patients with severe obesity.

Primary surgery for patients with poor functional status pre-operatively: Changes in rates of recorded poor functional status; financial years 2011-2013

(poor functional status is the inability to climb 3 flights of stairs)



Appendices

Database form

Form A

UK National Bariatric Surgery Registry

Initial data

Page 1; Version 2.1 (01/01/2009)

Demographics and other identifiers

Unique patient-identifier	
Date of birth	dd / mm / yyyy
Gender	○ Male ○ Female
Ethnic origin	○ Caucasian ○ Chinese ○ Asian ○ Afro-Caribbean ○ African ○ Other ○ Not recorded

Registry data

Admission and clinical history

Date of operation	dd / mm / yyyy			
Weight when first seen	kg	or	st	lb
Height	m	or	ft	in
Funding category	○ Publicly funded ○ Self-pay ○ Private insurer			
Source of referral	○ GP ○ Self referral ○ Secondary care			

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Form B

UK National Bariatric Surgery Registry

Baseline comorbidity data

Page 1; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier

Date of operation dd / mm / yyyy

Baseline comorbidity

For questions where only one option may be selected (identified by radio buttons or drop-down lists), choose the worst option that applies

ASA grade
- ASA I
- ASA II
- ASA III
- ASA IV

Type 2 diabetes
- No indication of type 2 diabetes
- Impaired glycaemia or impaired glucose tolerance
- Oral hypoglycaemics
- Insulin treatment

Duration of type 2 diabetes
- <1 year
- 1 year
- 2 years
- 3 years
- 4 years
- 5 years
- 6 years
- 7 years
- 8 years
- 9 years
- 10 years
- >10 years

Hypertension
- No indication of hypertension or on no treatment
- Hypertension on treatment

Lipids
- No indication of dyslipidaemia
- Dyslipidaemia

Cardiovascular
- No indication of atherosclerosis
- Diagnosis of atherosclerosis

Sleep
- No diagnosis or indication of sleep apnoea
- Diagnosis of sleep apnoea; on CPAP / BIPAP
- Sleep apnoea with complications

Asthma
- No diagnosis or indication
- Treated with inhalers
- Treatment with nebulisers or oral steroids, or requiring hospital admission in last year

Functional status
- Can climb 3 flights of stairs without resting
- Can climb 1 flight of stairs without resting
- Can climb half a flight of stairs without resting
- Requires wheelchair / house-bound

Known risk for pulmonary embolus
- No known risk factor
- History or risk factor of DVT / PE
- Venous oedema with ulceration
- Vena cava filter
- Obesity / hypoventilation syndrome

Back or leg pain from arthritis
- No symptoms
- Intermittent symptoms; no medication
- Regular medication with non-opiates
- Known arthritis / requiring opiates
- Back / joint operation done / recommended pending weight loss
- Failed previous back operation / joint replacement

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Form B

UK National Bariatric Surgery Registry

Baseline comorbidity data

Page 2; Version 2.1 (01/01/2009)

Unique patient-identifier

Date of operation dd / mm / yyyy

Baseline comorbidity ...

GORD (Gastro-oesophageal acid reflux, heartburn or hiatus hernia)
- ○ No symptoms
- ○ Intermittent symptoms; no medication
- ○ Intermittent medication
- ○ Daily medication; H2RA / PPI
- ○ Previous anti-reflux operation

Liver disease
- ○ No indication of liver disease
- ○ Suspected NAFLD
- ○ Known NAFLD
- ○ NASH
- ○ Cirrhosis liver disease

Polycystic ovary syndrome [i]
- ○ No indication / diagnosis; no medication
- ○ Diagnosis of PCOS; no medication
- ○ PCOS on medication
- ○ Infertility

Menstrual [i]
- ○ Regular menstrual cycle
- ○ Irregular / infrequent periods
- ○ Menorrhagia
- ○ Amenorrhea
- ○ Previous hysterectomy
- ○ Post menopausal

Depression
- ○ No indication of depression
- ○ Depression on medication

Abdominal apron
- ○ No symptoms
- ○ Known intertrigo
- ○ Apron so large it interferes with walking
- ○ Recurrent cellulitis / ulceration
- ○ Surgical treatment required
- ○ Apronectomy

Smoking
- ○ Never smoked
- ○ Ex-smoker
- ○ Rarely
- ○ Occasionally
- ○ Up to 20 cigarettes / day
- ○ More than 20 cigarettes / day

Weight-loss drugs or devices used before surgery
- ○ None
- ☐ Orlistat
- ☐ Sibutramine
- ☐ Intra-gastric balloon
- ☐ Rimonabant
- ☐ Topiramate
- ☐ VLCD (very low calorie diet)

Most recent weight - today's weight If possible

Date of most recent weight dd / mm / yyyy

Most recent weight kg or st lb

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i. Please only complete this question for female patients.

Form B

UK National Bariatric Surgery Registry
Baseline comorbidity data
Page 3; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Dataset definitions

These entries appear as hover prompts in the live database.

ASA grade

- ASA I — Healthy; no medical problems
- ASA II — Mild systemic disease
- ASA III — Severe systemic disease, but not incapacitating
- ASA IV — Severe systemic disease that is a constant threat to life

Lipids

- Dyslipidaemia — Only for high lipids / cholesterol; does not include routine statin therapy

Cardiovascular

- Diagnosis of atherosclerosis — Includes angina, MI, CABG, stroke, claudication

Sleep

- No … — No witnessed apnoea and no daytime sleepiness
- CPAP — Continuous positive airways pressure
- BIPAP — Bi-level positive airways pressure
- Sleep apnoea … — Pulmonary hypertension and / or right heart failure secondary to lung disease

Liver disease

- No indication … — LFTs normal and normal U/S scan
- Suspected NAFLD — Non-alcoholic fatty liver disease suspected by abnormal LFTs or abnormal U/S scan
- Known NAFLD — Non-alcoholic fatty liver disease proven on liver biopsy or hepatology opinion
- NASH — Non-alcoholic steatohepatosis proven on liver biopsy
- Cirrhosis — Proven on liver biopsy or clinical features or hepatology opinion

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Form C

UK National Bariatric Surgery Registry

Operation section

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier

Date of operation dd / mm / yyyy

Most recent weight - today's weight If possible

Date of most recent weight dd / mm / yyyy

Most recent weight kg or st lb

Operation record

Surgical assistant
- ○ None
- ○ Consultant
- ○ Registrar (year 4+)
- ○ Registrar (year 1-3)
- ○ BST
- ○ Staff grade
- ○ Fellow
- ○ Specialist nurse
- ○ Other

Type of operation
- ○ Primary
- ○ Revision as primary procedure (in your hands)
- ○ Revision
- ○ Planned second stage

Operative approach
- ○ Laparoscopic
- ○ Lap converted to open
- ○ Endoscopic
- ○ Open

Operation
- ○ Gastric band
- ○ Roux-en-Y gastric bypass
- ○ Sleeve gastrectomy
- ○ Duodenal switch
- ○ Duodenal switch with sleeve
- ○ Bilio-pancreatic diversion
- ○ Revisional gastric band surgery
- ○ Gastric balloon placement / retrieval
- ○ Other

Details of other operation

For revisions previous operation type
- ○ Gastric band
- ○ Roux en Y gastric bypass
- ○ Sleeve gastrectomy
- ○ Duodenal switch with sleeve
- ○ Bilio-pancreatic diversion
- ○ Vertical banded gastroplasty
- ○ Other
- ○ Not known at this time

Details of other prior operation

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Form D

UK National Bariatric Surgery Registry

Gastric band procedure

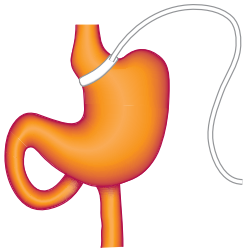
Page 1; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier

Date of operation dd / mm / yyyy

Gastric band



Gastric band

- ○ Allergan AP large
- ○ Allergan AP small
- ○ AMI
- ○ BioEnterics LAP-BAND
- ○ Bioring (Cousin)
- ○ Heliogast
- ○ MID
- ○ Minimizer Extra
- ○ SAGB (Quickclose)
- ○ SAGB (Velocity)
- ○ Other

Dissection

- ○ Pars flaccida
- ○ Peri-gastric

Gastro-gastric tunneling sutures

- ○ No
- ○ Yes

Additional procedures

- ○ None
- ☐ Cholecystectomy
- ☐ Hernia repair
- ☐ Apronectomy
- ☐ Other

Details of other additional procedures

Type of hernia repair

- ☐ Hiatus hernia
- ☐ Umbilical
- ☐ Ventral
- ☐ Incisional

Gastric banding complications

Date of complication / re-operation dd / mm / yyyy

Reason for re-operation

- ○ Slippage
- ○ Infection
- ○ Perforation
- ○ Bleeding
- ○ Other

Details of other reason for re-operation

Post-op re-operation performed

- ☐ Band slippage; re-positioned
- ☐ Band removed
- ☐ Attention to port / tubing

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Form E

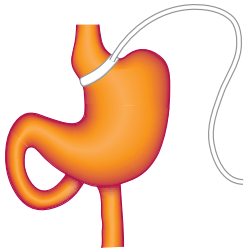
UK National Bariatric Surgery Registry

Revisional gastric band procedure

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Revisional gastric band surgery



Reason for revisional gastric band operation	☐ Band intolerance ☐ Erosion ☐ Pouch / oesophageal dilatation ☐ Slippage ☐ Perforation	☐ Port / tubing / technical band problem ☐ Infection ☐ Bleeding ☐ Other
Details of other reason for revision		
Revisional gastric band operation performed	○ Band repositioned ○ Band removed	○ Band replaced ○ Attention to port or tubing
Endoscopic band removal	○ No	○ Yes
Where previous operation done	○ Public hospital in GB & I ○ Private hospital in GB & I	○ Public hospital abroad ○ Private hospital abroad
Gastric band	○ Allergan AP large ○ Allergan AP small ○ AMI ○ BioEnterics LAP-BAND ○ Bioring (Cousin) ○ Heliogast	○ MID ○ Minimizer Extra ○ SAGB (Quickclose) ○ SAGB (Velocity) ○ Other
Dissection	○ Pars flaccida	○ Peri-gastric
Gastro-gastric tunneling sutures	○ No	○ Yes
Additional procedures	○ None ☐ Cholecystectomy ☐ Hernia repair	☐ Apronectomy ☐ Other
Hernia repair	☐ Hiatus hernia ☐ Ventral	☐ Incicsional ☐ Umbilical
Details of other additional procedures		

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Form E

UK National Bariatric Surgery Registry

Revisional gastric band procedure

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier

Date of operation dd / mm / yyyy

Complications for this new gastric banding procedure

Date of complication / re-operation dd / mm / yyyy

Reason for re-operation

- ○ Slippage
- ○ Infection
- ○ Perforation
- ○ Bleeding
- ○ Other

Details of other reason for re-operation

Post-op re-operation performed

- ☐ Band slippage; re-positioned
- ☐ Band removed
- ☐ Attention to port / tubing

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Form F

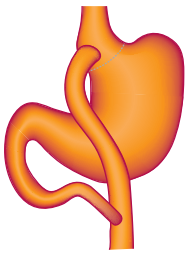
UK National Bariatric Surgery Registry

Bypass procedure

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier		
Date of operation		dd / mm / yyyy

Roux-en-Y



Gastric pouch	○ Vertical lesser curve pouch	○ Horizontal pouch incl. fundus
Banded gastric bypass	○ No	○ Yes
Linear stapler for gastric pouch	○ Green (2.0mm) ○ Gold (1.8 mm)	○ Blue (1.5 mm)
Reinforcement	○ None ☐ Seamguard ☐ Peristrips	☐ Biodesign SLR ☐ Duet TRS
Gastric pouch-jejunostomy	○ Circular stapler	○ Linear stapler ○ Hand sewn
Bilio-pancreatic limb length	cm	in the range 10-200 cm in 5 cm increments
Roux limb length	cm	in the range 40-200 cm in 5 cm increments
Jejuno-jejunostomy	○ Triple linear stapler ○ Double linear stapler	○ Single linear stapler ○ Hand sewn
Stapler used	○ Blue (1.5 mm) ○ White (1.0 mm)	○ Tan (1.0 mm)
Route of Roux limb	○ Ante-colic / ante-gastric ○ Retro-colic / ante-gastric	○ Retro-colic / retro-gastric ○ Other
Closure of hernia defects	○ Not done ☐ Petersen's space	☐ Jejuno-jejunostomy ☐ Mesocolon
Additional procedures	○ None ☐ Cholecystectomy ☐ Hernia repair	☐ Apronectomy ☐ Other
Details of other additional procedures		
Type of hernia repair	☐ Hiatus hernia ☐ Umbilical	☐ Ventral ☐ Incisional

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Form F

UK National Bariatric Surgery Registry

Bypass procedure

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Roux-en-Y complications

Date of complication / re-operation	dd / mm / yyyy
Complication	☐ Leak ☐ Obstruction ☐ Bleeding ☐ Other
Details of other reason for re-operation	
Re-operation	○ No ○ Yes
Leak location	○ Gastrojejunostomy ○ Gastric remnant ○ Jejuno-jejunostomy ○ Other
Details of other leak location	
Probable source of bleeding	☐ GI tract ☐ Intra-abdominal ☐ Other
Details of other source of bleeding	
Treatment of bleeding	○ No transfusion needed ○ Blood transfusion
Cause of bowel obstruction	○ Petersen's hernia ○ Anastomotic anatomy ○ Mesenteric anastomosis defect ○ Adhesions ○ Mesocolic defect ○ Other
Details of other cause of obstruction	
Treatment of obstruction	○ Settled conservatively ○ Endoscopic dilatation
Re-operation performed	☐ Re-fashioning anastomosis ☐ Gastrostomy ☐ Attention to bleeding area ☐ Enteral feeding ☐ Hernia repair ☐ Laparoscopy only ☐ Drain replacement ☐ Other
Details of other re-operation performed	
Approach for re-operation	○ Laparoscopic ○ Laparoscopic converted to open ○ Open

Dataset definitions

These entries appear as hover prompts in the live database.

Cause of bowel obstruction

- Petersen's space — Defined as small bowel hernia posterior to Roux limb
- Mesocolon — Defined as Roux limb hernia through transverse mesocolon

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Form G

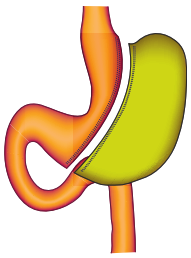
UK National Bariatric Surgery Registry

Sleeve gastrectomy

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Sleeve gastrectomy



Linear stapler for sleeve (please enter the pre dominant stapler used)	○ Green (2.0 mm)	○ Gold (1.8 mm) ○ Blue (1.5 mm)
Staple line reinforcement	○ No	○ Yes
Type of reinforcement	☐ Seamguard ☐ Peristrips ☐ Suturing	☐ Biodesign SLR ☐ Duet TRS
Bougie used	○ No	○ Yes
Bougie size	○ 32 Fr ○ 34 Fr	○ Other
Other Bougie size	Fr	
Additional procedures	○ None ☐ Cholecystectomy ☐ Hernia repair	☐ Apronectomy ☐ Other
Details of other additional procedures		
Type of hernia repair	☐ Hiatus hernia ☐ Umbilical	☐ Ventral ☐ Incisional

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Form G

UK National Bariatric Surgery Registry

Sleeve gastrectomy

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Sleeve gastrectomy complications

Date of complication / re-operation	dd / mm / yyyy
Complication	☐ Staple line leak ☐ Bleeding ☐ Other
Details of other reason for re-operation	
Re-operation	○ No ○ Yes
Leak location	○ Gastric sleeve ○ Other
Details of other leak location	
Treatment of staple line leak	☐ Attention to leaking area ☐ Enteral feeding ☐ Percutaneous drain ☐ Other
Details of other Tx of staple line leak	
Probable source of bleeding	☐ GI tract ☐ Intra-abdominal ☐ Other
Details of other source of bleeding	
Treatment of bleeding	○ No transfusion needed ○ Blood transfusion
Re-operation performed	☐ Repair gastric line staple ☐ Attention to bleeding area ☐ Gastrostomy ☐ Hernia repair ☐ Laparoscopy only ☐ Drain replacement ☐ Other
Details of other re-operation performed	
Approach for re-operation	○ Laparoscopic ○ Laparoscopic converted to open ○ Open

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Form H

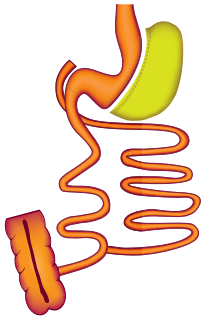
UK National Bariatric Surgery Registry

Duodenal switch procedure

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier		
Date of operation		dd / mm / yyyy

Duodenal switch



Duodeno-ileal anastomosis	○ Circular stapler ○ Linear stapler	○ Hand sewn
Stapler used (Duodeno-ileal anastomosis)	○ Blue	○ White
Ileo-ileal anastomosis	○ Triple linear stapler ○ Double linear stapler	○ Single linear stapler ○ Hand sewn
Stapler used (Ileo-ileal anastomosis)	○ Blue (1.5)	○ White (1.0)
Common channel limb length	75, 100 or 125 cm	please circle the appropriate option
Alimentary channel limb length	100, 150, 200 or 250 cm	please circle the appropriate option
Closure of hernia defects	○ Not done	☐ Duodeno-ileostomy defect ☐ Ileo-ileostomy defect
Additional procedures	○ None ☐ Cholecystectomy ☐ Hernia repair	☐ Apronectomy ☐ Other
Details of other additional procedures		
Type of hernia repair	☐ Hiatus hernia ☐ Umbilical	☐ Ventral ☐ Incisional

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Form H

UK National Bariatric Surgery Registry

Duodenal switch procedure

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Duodenal switch complications

Date of complication / re-operation	dd / mm / yyyy
Complication	☐ Leak ☐ Obstruction ☐ Bleeding ☐ Other
Details of other reason for re-operation	
Re-operation	○ No ○ Yes
Leak location	○ Gastric remnant ○ Ileo-ileal ○ Gastro-ileal ○ Other
Details of other leak location	
Probable source of bleeding	☐ GI tract ☐ Intra-abdominal ☐ Other
Details of other source of bleeding	
Treatment of bleeding	○ No transfusion needed ○ Blood transfusion
Cause of bowel obstruction	○ Petersen's hernia ○ Anastomotic anatomy ○ Mesenteric anastomosis defect ○ Adhesions ○ Mesocolic defect ○ Other
Details of other cause of obstruction	
Treatment of obstruction	○ Settled conservatively ○ Endoscopic dilatation
Re-operation performed	☐ Re-fashioning anastomosis ☐ Attention to bleeding area ☐ Enteral feeding ☐ Hernia repair ☐ Laparoscopy only ☐ Drain replacement ☐ Other
Details of other re-operation performed	
Approach for re-operation	○ Laparoscopic ○ Laparoscopic converted to open ○ Open

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Form I

UK National Bariatric Surgery Registry

Bilio-pancreatic diversion

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier		
Date of operation		dd / mm / yyyy

Bilio-pancreatic diversion

Distal gastrectomy proximal linear stapler	○ Green (2.0 mm)	○ Gold (1.8 mm) ○ Blue (1.5 mm)
Staple line reinforcement	○ No	○ Yes
Type of reinforcement	○ None ☐ Seamguard ☐ Peristrips	☐ Biodesign SLR ☐ Duet TRS ☐ Other
Other type of reinforcement		
Distal gastrectomy duodenal linear stapler	○ Blue (1.5 mm)	○ White (1.0 mm)
Gastro-ileal anastomosis	○ Circular stapler ○ Linear stapler	○ Hand sewn
Ileo-ileostomy	○ Tripler linear stapler ○ Double linear stapler	○ Single linear stapler ○ Hand sewn
Stapler used	○ Blue (1.5 mm)	○ White (1.0 mm)
Common channel limb length	75, 100 or 125 cm	please circle the appropriate option
Alimentary channel limb length	100, 150, 200 or 250 cm	please circle the appropriate option
Route of alimentary limb	○ Ante-colic	○ Retro-colic
Closure of hernia defects	○ Not done ☐ Gastro-ileostomy defect	☐ Ileo-ileostomy defect
Additional procedures	○ None ☐ Cholecystectomy ☐ Hernia repair	☐ Apronectomy ☐ Other
Details of other additional procedures		
Type of hernia repair	☐ Hiatus hernia ☐ Umbilical	☐ Ventral ☐ Incisional

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Form I

UK National Bariatric Surgery Registry

Bilio-pancreatic diversion

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier

Date of operation dd / mm / yyyy

Bilio-pancreatic diversion complications

Date of complication / re-operation dd / mm / yyyy

Complication
- ☐ Leak
- ☐ Bleeding
- ☐ Obstruction
- ☐ Other

Details of other reason for re-operation

Re-operation
- ○ No
- ○ Yes

Leak location
- ○ Gastric remnant
- ○ Gastro-ileal
- ○ Ileo-ileal
- ○ Other

Details of other leak location

Probable source of bleeding
- ☐ GI tract
- ☐ Intra-abdominal
- ☐ Other

Details of other source of bleeding

Treatment of bleeding
- ○ No transfusion needed
- ○ Blood transfusion

Cause of bowel obstruction
- ○ Petersen's hernia
- ○ Mesenteric anastomosis defect
- ○ Mesocolic defect
- ○ Anastomotic anatomy
- ○ Adhesions
- ○ Other

Details of other cause of obstruction

Treatment of obstruction
- ○ Settled conservatively
- ○ Endoscopic dilatation

Re-operation performed
- ☐ Re-fashioning anastomosis
- ☐ Attention to bleeding area
- ☐ Hernia repair
- ☐ Drain replacement
- ☐ Enteral feeding
- ☐ Laparoscopy only
- ☐ Other

Details of other re-operation performed

Approach for re-operation
- ○ Laparoscopic
- ○ Laparoscopic converted to open
- ○ Open

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Form J

UK National Bariatric Surgery Registry

Balloon placement / retrieval

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Balloon placement / removal

Balloon placement or removal	○ Balloon placement	○ Balloon removal
Placed gastric balloon	○ Allergan BIB	○ Heliosphere
Fill volume	○ 500 ml ○ 550 ml ○ 600 ml	○ 650 ml ○ 700 ml ○ Other
Other fill volume	ml	

Gastric balloon placement / retrieval complications

Date of complication / re-operation		
Complication	☐ Leak ☐ Bleeding	☐ Obstruction ☐ Other
Details of other reason for re-operation		
Re-operation	○ No	○ Yes
Leak location	○ Gastric remnant ○ Gastro-ileal	○ Ileo-ileal ○ Other
Details of other leak location		
Probable source of bleeding	☐ GI tract ☐ Intra-abdominal	☐ Other
Details of other source of bleeding		
Treatment of bleeding	○ No transfusion needed	○ Blood transfusion
Cause of bowel obstruction	○ Petersen's hernia ○ Mesenteric anastomosis defect ○ Mesocolic defect	○ Anastomotic anatomy ○ Adhesions ○ Other
Details of other cause of obstruction		
Treatment of obstruction	○ Settled conservatively	○ Endoscopic dilatation
Re-operation performed	☐ Re-fashioning anastomosis ☐ Attention to bleeding area ☐ Hernia repair ☐ Drain replacement	☐ Enteral feeding ☐ Laparoscopy only ☐ Other
Details of other re-operation performed		
Approach for re-operation	○ Laparoscopic ○ Laparoscopic converted to open ○ Open	

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Form K

UK National Bariatric Surgery Registry

Post-operative course and discharge

Page 1; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier	
Date of operation	dd / mm / yyyy

Post-operative course & discharge

Cardiovascular complications

- ○ None
- ☐ MI
- ☐ Stroke
- ☐ Dysrhythmia
- ☐ PE
- ☐ DVT
- ☐ Cardiac arrest

Other complications

- ○ None
- ☐ Fluid / electrolyte problems
- ☐ Acute cholecystitis / biliary colic
- ☐ CBD stones / cholangitis
- ☐ Gastric distention
- ☐ Other abscess/infection/fever
- ☐ Acute renal failure
- ☐ Pneumonia / atelectasis
- ☐ Rhabdomyolysis
- ☐ UTI
- ☐ Vomiting / poor intake
- ☐ Wound infection/breakdown
- ☐ Unanticipated transfer to ITU

Date of discharge / in-hospital death dd / mm / yyyy

Discharge to

- ○ Home
- ○ Another hospital
- ○ Deceased
- ○ Other [iv]

Details of other discharge destination

Cause of death

- ○ PE
- ○ Cardiac
- ○ Leak
- ○ Bleed
- ○ Pneumonia
- ○ Other [v]

Details of other cause of death

Dataset definitions

These entries appear as hover prompts in the live database.

Other complications

• Rhabdomyolysis	Defined as CPK >5,000
• Acute renal failure	Defined as oliguria / anuria
• Pneumonia / atelectasis	Defined as significant CXR changes + fever
• UTI	Urinary tract infection
• Wound infection / breakdown	Defined as cellulitis + fever

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iv. Please complete the following question *Details of other discharge destination*

v. Please complete the following question *Details of other cause of death*

Form L

UK National Bariatric Surgery Registry

Follow up

Page 1; Version 2.1 (01/01/2009)

Unique patient-identifier	
Date of follow up	dd / mm / yyyy

Follow up data

Follow up visit details

Weight	kg or st lb
Patient re-admitted within 30 days of index operation	○ No ○ Yes
Reason for re-admission	
Patient re-operated within 30 days of index operation	○ No ○ Yes
Reason for reoperation	
Patient known to have died since discharge or in follow up	○ No ○ Yes
Cause of death	
How followed up	○ Hospital clinic ○ Other clinic ○ Other in person; phone or electronic contact ○ Did not attend follow up / uncontactable
Who did follow up	○ Bariatric surgeon ○ Bariatric physician ○ Specialist nurse / dietician ○ Other
Details of other person who did follow up	
Vitamins / minerals: patient taking appropriate supplements	○ No ○ Yes ○ No recommendation made
Blood tests: patient having regular appropriate monitoring	○ No ○ Yes ○ No recommendation made
Clinical evidence of malnutrition	○ No ○ Yes

Follow up comorbidity

Type 2 diabetes	○ No indication of type 2 diabetes ○ Impaired glycaemia or impaired glucose tollerance ○ Oral hypoglycaemics ○ Insulin treatment
Hypertension	○ No indication of hypertension / previous hypertension now off treatment ○ Hypertension on treatment

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Form L

UK National Bariatric Surgery Registry

Follow up

Page 2; Version 2.1 (01/01/2009)

NBSR NATIONAL BARIATRIC SURGERY REGISTRY

Unique patient-identifier

Date of follow up dd / mm / yyyy

Follow up comorbidity continued …

Lipids
- ○ No indication of dyslipidaemia
- ○ Dyslipidaemia

Sleep
- ○ No diagnosis or indication of sleep apnoea
- ○ Diagnosis of sleep apnoea; on CPAP / BIPAP
- ○ Sleep apnoea with complications

Asthma
- ○ No diagnosis or indication
- ○ Treated with inhalers
- ○ Treatment with nebulisers or oral steroids, or requiring hospital admission in last year

Functional status
- ○ Can climb 3 flights of stairs without resting
- ○ Can climb 1 flight of stairs without resting
- ○ Can climb half a flight of stairs without resting
- ○ Requires wheelchair / house-bound

Back or leg pain from arthritis
- ○ No symptoms
- ○ Intermittent symptoms; no medication
- ○ Regular medication with non-opiates
- ○ Known arthritis / requiring opiates
- ○ Back / joint operation done / recommended pending weight loss
- ○ Failed previous back operation / joint replacement

GORD (Gastro-oesophageal acid reflux, heartburn or hiatus hernia)
- ○ No symptoms
- ○ Intermittent symptoms; no medication
- ○ Intermittent medication
- ○ Daily medication; H2RA / PPI
- ○ Previous anti-reflux operation

Polycystic ovary syndrome [i]
- ○ No indication / diagnosis; no medication
- ○ Diagnosis of PCOS; no medication
- ○ Treatment with single medication
- ○ Treatment with multiple medications
- ○ Infertility

Menstrual [i]
- ○ Regular menstrual cycle
- ○ Irregular / infrequent periods
- ○ Menorrhagia
- ○ Amenorrhea
- ○ Previous hysterectomy
- ○ Post-menopausal

Abdominal apron
- ○ No symptoms
- ○ Known intertrigo
- ○ Apron so large it interferes with walking
- ○ Recurrent cellulitis / ulceration
- ○ Surgical treatment required
- ○ Apronectomy

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vi. Please only complete this question for female patients.

The Second National Bariatric Surgery Registry Report

The NHS has finite resources, and many question the use of public funding to pay for bariatric (weight loss) surgery for people with severe and complex obesity. Patients and commissioners also rightly want to know the results of their operations. The Second NBSR Report 2014 is the authoritative reference for bariatric surgery in the United Kingdom, and the data show the quality of surgery in more than 18,000 patients operated between 2010 and 2013. The dramatic improvement in obesity-related diseases such as type 2 diabetes suggests that the funding has been money well spent.

… this second report demonstrates the commitment of British surgeons to share their data in the interests of understanding and improving the quality of care they offer. It describes the state of the art in 2014. The pooling of so much data will help define the place of surgery for people debilitated by obesity and will, in time, help to refine surgical strategies and even unravel the mystery of why this surgery has such an instantaneous, profound and beneficial effect on diabetes, another scourge of our society. In short, this report is a tribute to the professionalism of the British Obesity & Metabolic Surgery Society.

Prof. Sir Bruce Keogh
Medical Director of the National Health Service in England

Patients are often inquisitive as to a surgeon's experience in a particular procedure, and this report goes a long way to reassuring patients about their chosen surgeon. I recommend all patients considering surgery to look at the information it contains regarding their surgeon and to discuss it with them.

Mr Ken Clare
Chair of Trustees Weight Loss Surgery Information and Support (WLSinfo)

The report provides very detailed insights into changing patterns among those having bariatric operations and the procedures that they are undergoing, and the overall early outcomes achieved.

Prof. John Dixon
NHMRC Senior Research Fellow, Adjunct Professor, Primary Care Research, Monash University
Head of Clinical Obesity Research, Baker IDI Heart and Diabetes Institute, Melbourne, Australia

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