The United Kingdom National Bariatric Surgery Registry

First Registry Report to March 2010

Prepared by

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Alberic Fiennes MS FRCS
on behalf of the NBSR Data Committee

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For and on behalf of the NBSR Data Committee

Mr Michael Rhodes
Mr Peter Sedman

The Association of Laparoscopic Surgeons

Mr Simon Dexter
Mr Bruce Tulloh

The Association of Upper GI Surgeons

Mr Alberic Fiennes
Mr Marcus Reddy

The British Obesity & Metabolic Surgery Society

and on behalf of all the contributors (see pages 10-11) whose contributions cannot be over-valued.

The Association of Laparoscopic Surgeons (ALSGBI), the Association of Upper GI Surgeons (AUGIS) and the British Obesity & Metabolic Surgery Society (BOMSS) operate the National Bariatric Surgery Registry (NBSR) as a consortium in partnership with Dendrite Clinical Systems Limited. The Societies also gratefully acknowledge the assistance of Dendrite Clinical Systems for:

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Executive summary

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

In overview:

- 84 surgeons from 86 hospitals recorded 8,710 operations; 7,045 in the financial years 2009 & 2010.
- 68.8% operations were funded by the National Health Service; 30.9% were independently funded and a tiny proportion were paid for by private insurers.
- Data are analysed for 3,817 gastric bypass procedures, 2,132 gastric band operations and 588 sleeve gastrectomy operations.
- The observed in-hospital mortality rate after primary surgery was 0.1% overall (and just 0.2% for gastric bypass), much lower than that for many other planned operations.
- The recorded surgical complication rate overall for primary operations was 2.6 %.
- 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.
- 80% of patients were discharged by the third post-operative day, indicating the efficient use of resource.

At the time of primary surgery:

- 24.9% of all patients had a high level of co-existing disease.
- 27.5% had type 2 diabetes
- 16.5% were on treatment for sleep apnoea.
- 69.0% of all patients had some functional impairment, *i.e.,* they could not manage to climb 3 flights of stairs without resting.

Follow-up data is derived from some 12,000 follow-up entries for the 2009 & 2010 patients

One year after surgery:

- On average, patients lost 57.8% of their excess weight (43.2% for gastric banding, 67.8% for gastric bypass & 54.0% for sleeve gastrectomy).
- Almost half of patients 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.
- 60.2% of patients with sleep apnoea were able to come off treatment.

Two years after surgery:

- 85.5% 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.

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. Once established in adults it constitutes a dysregulated state of physiology and reversal is not primarily a voluntary or behavioural process.
- Among comparisons of age, weight, level of co-morbidity, gender, *etc.*, the data also show that the benefit for certain co-morbidities is greater the earlier surgical treatment is undertaken. This has implications for the prioritisation of treatment.
- Bariatric surgery greatly and highly cost-effectively improves the health of obese patients, much more so than other treatments.

Foreword

Around the world the delivery and funding of healthcare is being challenged by demographic changes and lifestyle diseases. Chief among these is the sweeping obesity epidemic which brings with it an increase in diabetes, heart disease, stroke and some cancers, each of which imposes an additional demand on healthcare services.

Prevention is always better than cure, but commercial and advertising pressures along with personal freedoms and expectations mean that life is not that easy either for the individual or for healthcare policy makers.

Most people have strong views on sex, politics and religion and sadly also on other people's obesity. It is either all their fault and society owes them nothing or at the other extreme the obese are victims of the food and drinks industry or government policy. These views colour the spectrum of perceptions over the provision of bariatric surgery in the NHS.

But for decades our NHS has picked up the failings of human nature, personal choice, and public health endeavours to influence human behaviour. Think seat belts, think smoking, think alcohol. Bariatric surgery is simply the latest response to an inevitable healthcare demand imposed largely by personal choice.

The surgery described in this report is technically complicated and potentially risky. The benefits have been described over the last few years from specialist centres and the risks addressed by larger studies with few of them describing long-term follow-up.

This report is a tribute to British surgery. It describes a national practice of experienced and emerging teams, demonstrates a professional commitment to hard nosed analysis of results and a commitment to understanding the longer term impact of their interventions on those they seek to help.

Apart from demonstrating the professionalism of the contributors, this report starts to lay the foundations for a proper economic analysis of the benefits of this sort of surgery which will help us determine in an evidence based way where this surgery should fit within our overall healthcare system. The reported data seem to support international literature indicating reversal of comorbidities which may, in the longer term, lead to healthcare cost savings.

This report describes outstanding national results, debunking the perception that this surgery carries a significant mortality. However, there is a risk that as demand grows and more, and less experienced surgeons take up this surgery that the results could deteriorate. So, I am of the clear view that contributing complete and accurate data on all patients to this database should be a prerequisite for any surgeon or institution wishing to embark on or continue undertaking such surgery. After all, in my view, if you can't describe what you're doing and define how well you're doing it, you have no right to be doing it at all.

Bruce Keogh

Medical Director of the National Health Service in England

From the Chairman of the Data Committee and President of BOMSS

It is an honour to present this first Annual Report of the NBSR, as it has been a privilege to chair the NBSR Data Committee since its inception at the end of 2008.

The registry is operated as a consortium by BOMSS, AUGIS and ALS. By early 2008 the bariatric community in Britain had been wrestling for some years with the establishment of a national audit registry. It deserves to be said here, at the outset, that without the initiative, drive and financial commitment shown by the Association of Laparoscopic Surgeons the registry would not have come into being when it did. The vision and generosity with which ALS invited AUGIS and BOMSS to join as equal partners set the scene for what has proved to be a harmonious and fruitful tripartite collaboration, and this is to the singular credit of Michael Parker, President of the ALS at the time.

The creation of the registry database, the choice of dataset and of the embedded functionality have been the solo achievement of Richard Welbourn, working with the programmers and analysts at Dendrite Clinical Systems. The scale of this work cannot be overvalued, nor can the good nature and responsiveness with which they have faced the inevitability of not *pleasing all of the people all of the time*.

In playing my own very small part in the preparation of this report I have become intensely aware of the experience, patience and tireless skill of the senior personnel at Dendrite, most notably, but not exclusively, Robin Kinsman, Chief Data Analyst, and Peter Walton, Managing Director. Theirs has been a truly professional and accomplished act. It has been the greatest pleasure to work closely with them and with Richard Welbourn, as well as with my colleagues on the Data Committee as a whole.

The Data Committee has worked hard, meeting on numerous occasions - always under the pressure of busy professional lives. We have dealt with difficult issues of confidentiality, of professional duty and of securing trust and participation. We have dealt jointly with well-intended enquiries that inadvertently threatened these integrities and we have fought and extinguished a few unexpected if minor fires. I am indebted for the enthusiasm and hard work displayed by all committee members, just as the Committee in turn owes gratitude to our parent Societies for their trust and support. The release of the present Report represents the summation of that commitment.

However, there would be no report without the trust and enthusiasm shown by contributing clinical teams and their host institutions. It is the Committee's belief that we have currently achieved about 80% participation by all bariatric surgeons practising in the United Kingdom. The exceptionally low mortality and morbidity, together with the weight-loss and co-morbidity resolution reported in the following pages is a tribute to their skill.

By proxy and on their behalf the Data Committee would like to thank firstly the Royal College of Surgeons of England for its invaluable institutional and professional support and secondly all those industrial partners whose financial support has made the process possible at all.

Sincere thanks are also due to Jenny Treglohan and her colleagues at The Association of Surgeons, who have provided tireless administrative support.

The nature of the current pandemic of Severe and Complex Obesity, the associated science and the professional imperatives arising are considered elsewhere in this book, together with a brief appraisal of current bariatric treatment. At this point, however, the final word must be for our patients, past and future: we thank them for the confidence placed in us.

L*et all* who read this report bear witness that people locked into Severe and Complex Obesity are not the undeserving weak, as they are often branded, but the victims, in their phalanxes, of an often misunderstood but lethal disease of civilisation – perhaps the biggest disease of the early 21st Century.

Alberic GTW Fiennes

Chairman, NBSR Data Committee; President, the British Obesity & Metabolic Surgery Society

From the President of AUGIS

I congratulate the NBSR Data Committee under the leadership of Alberic Fiennes, on this magnificent achievement of bringing this first Annual Report of the National Bariatric Surgery Registry to fruition. This has been a signal achievement of which BOMSS and its partner Societies should be rightly proud.

The management of our obesity epidemic is increasingly challenging. The surgery is complex and frequently demanding, and the delivery of the service under threat by NHS reorganisation. In order to continue to develop this service, it is imperative for surgeons to demonstrate the benefits and outcomes of the treatments that they are providing. As we know, although improving, reliance on Hospital Episode Statistics (HES) data within the NHS does not provide sufficient accuracy to map a rapidly evolving service such as bariatric surgery. Because of the wide variations in NHS commissioning, a large part of the provision of bariatric surgery has to take place in the private sector. Whether this increases or decreases as we enter the uncertainties of GP-led commissioning remains to be seen. Furthermore, those who have led the development of bariatric surgery have done so against the uncertain background of reorganisation in oesophago-gastric surgery around the provision of cancer services. Therefore, for the bariatric surgery community to have produced this national register is both timely and impressive.

The NBSR data committee has worked tirelessly under Alberic's chairmanship, dealing with delicate and sensitive issues, and to have achieved 80% participation in the first annual report is I believe unique in the recent history of such large scale national registers. I can only hope that the bariatric community will continue to support the NBSR, and I can assure all involved of AUGIS's lasting support.

Lastly, on behalf of AUGIS, I would like to thank Richard Welbourn for his tireless work along with Robin Kinsman and Peter Walton at Dendrite Systems, as well as Alberic and his colleagues on the Data Committee, for their considerable achievement. I wish them all well for the future of this project.

Graeme Poston

President, Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

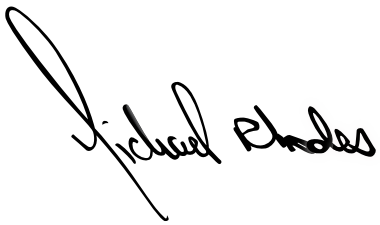
From the President of ALS

It has been a privilege to work on behalf of ALS with my colleagues in AUGIS and BOMSS to help establish the National Bariatric Surgery Registry. The unique status of bariatric surgery during the last decade makes the registry a very timely initiative. From well under a 1,000 cases *per annum* in the year 2000, the annual prevalence of bariatric surgery approaches 10,000 in 2010. Not only has there been a ten-fold increase in the delivery of this surgery, but varied commissioning around the United Kingdom means that approaching 50% of cases are performed in the private sector. This was just one of several reasons why many bariatric surgeons felt some form of registry would enable them to audit and benchmark their work for the benefit of Commissioners and public alike. In doing so this report represents the *coming of age* of bariatric surgery in the United Kingdom, as Professor Higa has so kindly emphasised in his appraisal on page 8.

My role in the whole process has been a minor one. It is correct, as Alberic Fiennes has noted, that ALS under my predecessor Michael Parker and myself, took the first initiative by approving initial financial support for the project. It was however always fundamental to our aim to move to an equal partnership with our sister societies. The fruits of the titanic task undertaken by Richard Welbourn could only properly be delivered into a single, truly shared forum that would unite the bariatric community and look forward.

It has thus been a special delight to represent ALS on the NBSR steering committee. As my close colleague Alberic mentions, the remarkably smooth working of this tripartite group has been as important an achievement as the operation of the registry itself. Equal representation from AUGIS, ALS and BOMSS should encourage all surgeons involved with bariatric care to feel ownership of this registry, which professionally is theirs, not ours.

I would add my personal thanks to Richard Welbourn, Dendrite and my fellow ALS, BOMSS and NBSR committee members – all have worked together to make this first report possible. My final plea would be that all surgeons who undertake bariatric work endeavour to add their data to the database. This will provide the most accurate and powerful dataset with which to represent the achievements of United Kingdom bariatric surgery.



Michael Rhodes

President, Association of Laparoscopic Surgeons of Great Britain & Ireland

A transatlantic view

The epidemic of obesity can no longer be ignored. Once perceived as penance for the sins of economically developed countries, it has attacked poorer, less advanced cultures with the same level of aggression.

Obesity is a global disease of unprecedented proportions, insidious in its penetrance, devastating in its consequences; not only through lives lost, but through its global effects on the economy. Through agriculture, domestication of livestock, genetic manipulation and chemical engineering, we have succeeded in replacing starvation with an equally harmful form of malnutrition - obesity.

Treatment of this disease is surprisingly difficult given the obvious, naive answer: *eat less, exercise more*. Despite evidence for the futility of this *dictum* and for the effectiveness of our surgical interventions, universal acceptance of surgical treatment has been elusive. Perhaps understandable, as we, ourselves, have little evidence as to the pathophysiology of our interventions or precise long-term outcomes - and even less insight as to which operations will give the best performance in a given patient.

In the United States, as well as other countries, bariatric surgery registries have failed to capture enough data to be of significance. We, as surgeons, suffer from the same lack of insight as our critics – had we universally participated in such programs from the beginning, think how different the landscape would be today. The importance of the contribution made by longitudinal endeavors such as the Swedish Obese Subjects study cannot be over-emphasized.

Data derived from Center of Excellence programs will not have the broad, long-range answers to the global questions that plague us. Surgeons will retire, programs will close as new ones emerge, and patients will change insurance or simply move to a new town. It is not feasible to rely upon a single practice to keep track of every patient forever. By contrast it is possible for a health care system to keep track of every patient who has had a bariatric / metabolic procedure and this should be among the highest of priorities.

The NBSR is an important step in this direction. Every surgeon who performs a bariatric / metabolic procedure should consider participation a mandatory part of this specialty.

Kelvin D Higa

Past President, American Society for Metabolic and Bariatric Surgery

Clinical Professor of Surgery, University of California, San Francisco, USA

Director, Minimally Invasive and Bariatric Surgery, Fresno Heart and Surgical Hospital

An historical view

A small band of surgeons

We have not done well in the conquest of chronic disease. In spite of intensive, costly research at all levels we still lack effective medicines for severe obesity, diabetes, hypertension and crippling arthritis. The fight against obesity is a good example. The futility of our approaches has been painfully evident to doctors for a long time. Even as early as 1991, the National Institute of Health's Consensus Conference on Gastrointestinal Surgery of Obesity, concluded that diets, exercise, behavioral modification and drugs were ineffective in patients who were severely obese.

Who would have guessed that full and durable remission could be attained in all of these diseases? Simultaneously? Who would have guessed that these breakthroughs would not come from sophisticated laboratories but, instead, from ordinary operating rooms, operations that did not depend on the invention of new technologies, but involved the classic approaches of gastro-intestinal surgery invented a century ago.

The story began in the 1950s when a small band of surgeons at the University of Minnesota, frustrated by futility of obesity treatments, wondered whether the weight loss induced by bowel resections might offer a reasonable approach. There were a number of false starts, including the disastrous intestinal bypasses and gastric wraps, but with time and the leadership of Ed Mason and Henry Buchwald, better procedures including the gastric bypass and gastric banding were developed, operations that produced massive, durable weight loss. Appropriately, the new technology was named *bariatric* surgery after the Greek word, *baros*, for weight.

By the 1980s, however, it became evident that the operations also produced outcomes that were even more important than weight loss. The gastric bypass, for example, led to full and durable remission of diabetes in 83% of the subjects with similar reversals of the other manifestations of the metabolic syndrome including hypertension, sleep apnea, non-alcoholic steatotic hepatitis (NASH), gastroesophageal reflux (GERD), Pickwickian syndrome, pseudotumor cerebri, and polycystic ovary syndrome. As a result, the specialty was appropriately renamed *metabolic and bariatric surgery*.

Even these major breakthroughs, however, were not enough for the small band of surgeons who were now confronted with complaints that the operations were far too dangerous for the severely obese who were, certainly high-risk subjects. This challenge, stridently issued in the press and courtrooms, was also rapidly resolved in less than five years with the establishment of a Centers of Excellence program by the American Society for Metabolic and Bariatric Surgery (ASMBS) and managed by the Surgical Review Corporation (SRC) a non-profit, independent organization. By 2010, 425 hospitals in the United States plus other affiliates in other countries were delivering bariatric surgery with a 90-day mortality of 0.11%, far safer than reported for other abdominal operations and at the same level as first-time deliveries in the United States.

The small band, however, now grown to about 2,000 surgeons in the United States is still restless. Currently, less that 1% of individuals who could benefit have access to the surgery, even though the bariatric operations not only resolve their diseases, but also reduce the cost of their medications and let them go back to work. The challenge now is to overcome the bias against obesity and those who are the victims of this terrible metabolic failure. The small band will win that challenge as well.

Let me express my delight that our colleagues in the United Kingdom National Bariatric Surgery registry are on the same path with a similar dedication to some of the most unfortunate citizens in our countries. Good luck in your endeavors.

Walter J Pories

Professor of Surgery, Biochemistry, Sport and Exercise Medicine

Brody School of Medicine, East Carolina University, USA

Contributors

Contributions were received from the following hospitals:

- Alexandra Hospital, Cheadle
- Ayr Hospital
- Barking, Havering & Redbridge Univ. Hospitals
- Berkshire Independent Hospital, Reading
- Birkdale Clinic, Rotherham
- Birmingham Heartlands Hospital
- BMI Albyn Hospital
- BMI Chelsfield Park Hospital, Orpington
- BMI Droitwich Spa Hospital
- BMI Park Hospital, Nottingham
- BMI Thornbury Hospital, Sheffield
- Bon Secours Hospital, Cork
- Bradford Teaching Hospitals
- Castle Hill Hospital, Hull
- Chelsea and Westminster Hospital, London
- Circle Bath Hospital
- Claremont Hospital, Sheffield
- Cromwell Hospital, London
- Crosshouse Hospital, Kilmarnock
- Derby Hospitals NHS Trust
- Derriford Hospital, Plymouth
- Dolan Park Hospital, Bromsgrove
- Duchy Hospital, Cornwall
- Gloucestershire Royal Hospital, Gloucester
- Hexham General Hospital
- Homerton University Hospital, London
- Hope Hospital, Salford
- Hull & East Riding Hospital
- King's College Hospital, London
- Lanarkshire University Hospital
- Leeds Hospitals
- Luton & Dunstable Hospital
- Manchester Royal Infirmary
- Mid Yorks NHS Trust, Dewsbury & District
- Musgrove Park Hospital, Taunton
- Norfolk & Norwich University Hospital
- North Tyneside Hospital, Tyne & Wear
- Northumbria Hospital
- Nuffield Hospital, Bournemouth
- Nuffield Hospital, Brentwood
- Nuffield Hospital, Cheltenham
- Nuffield Hospital, Derby
- Nuffield Hospital, Leeds
- Nuffield Hospital, Plymouth
- Nuffield Hospital, Taunton
- Princess Elizabeth Hospital, Guernsey
- Princess Royal Hospital, Telford
- Princess Royal University Hospital, Orpington
- Priory Hospital, Birmingham
- Ramsey Winfield Hospital, Gloucester
- Royal Berkshire Hospital, Reading
- Royal Bournemouth Hospital
- Royal Cornwall Hospital, Truro
- Royal Infirmary Edinburgh
- Salisbury Hospital
- Sarum Road Hospital, Winchester
- Sheffield Teaching Hospitals
- Spire Bushey Hospital, Watford
- Spire Gatwick Park Hospital, Horley
- Spire Hull & East Riding Hospital
- Spire Leeds Hospital
- Spire Manchester Hospital
- Spire Murrayfield Hospital, Edinburgh
- Spire Norwich Hospital
- Spire Parkway Hospital, Nottingham
- Spire Regency Hospital, Macclesfield
- Spire Southampton Hospital
- Spire Washington Hospital
- St Anthony's Hospital, Cheam
- St George's Hospital, London
- St James's University Hospital, Leeds
- St Mary's Hospital, London
- Stobbhill Hospital, Glasgow
- St Richard's Hospital West Sussex, Chicester
- Sunderland City Hospital
- Sunderland Royal Hospital
- The Shelburne Hospital, High Wycombe
- University College Hospital, London
- University Hospital North Staffordshire
- Whittington Hospital, London
- York Hospitals NHS Foundation Trust

and from the following consultant surgeons:

- Roger **Ackroyd**
- Marco **Adamo**
- Sanjay **Agrawal**
- Anselm **Agwunobi**
- Ahmed **Ahmed**
- Basil **Ammori**
- Luigi **Angelini**
- Shaun **Appleton**
- Ian **Bailey**
- Shlok **Balupuri**
- Andrew **de Beaux**
- Ian **Beckingham**
- Gianluca **Bonanomi**
- Michael **Booth**
- Michael **van den Bossche**
- Duff **Bruce**
- James **Byrne**
- Richard **Byrom**
- Avril **Chang**
- Chandra **Cheruvu**
- Carol **Craig**
- Ravindra **Date**
- Nick **Davies**
- Fionnuala **Davison**
- Bart **Decadt**
- Thomas **Dehn**
- Simon **Dexter**
- Evangelos **Efthimiou**
- Shamsi **El-Hasani**
- Marwan **Farouk**
- Adeshina Sergei **Fawole**
- Alberic **Fiennes**
- Ian **Finlay**
- Nadi **Hakim**
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- Dugal **Heath**
- David **Hewin**
- Joe **Horner**
- Prashant K **Jain**
- Vigyan **Jain**
- Andrew **Jenkinson**
- Jamie **Kelly**
- David **Khoo**
- Yashwant **Koak**
- Richard **Krysztopik**
- Paul **Leeder**
- Alan **Li**
- David **Mahon**
- Kesava Reddy **Mannur**
- Mike **McMahon**
- Vinod Sreedhara **Menon**
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- Kirtik **Patel**
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- George **Vassilikostas**
- Andrew **Wan**
- Richard **Welbourn**
- Timothy John **Wheatley**
- Douglas **Whitelaw**
- Wingzou **Wong**
- Sean **Woodcock**

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Roux-en-Y gastric bypass

Obesity, bariatric surgery and the NBSR

Obesity and bariatric surgery

Bariatric Surgery is surgical treatment to promote health improvement in people who suffer from *severe and complex obesity* (so-called *morbid obesity*).

It is considered for individuals who either have a Body Mass Index (BMI) of at least 40 kg m^{-2} in its own right or who have a BMI 35 kg m^{-2} or greater with serious health consequences, who have been unable to lose weight by other means. A BMI in the range 18.5-25.0 kg m^{-2} is considered by the World Health Organisation to be *normal*, depending on race and gender.

As Professor Pories has pointed out, in honouring this report with his generous review (see page 9), it is just 50 years since American surgeon John Payne undertook his first successful weight reducing operations. Whether he appreciated the prophecy that can now be read into his pioneering work is uncertain.

The road travelled since then, however, has seen the world engulfed by a pandemic of overweight and obesity. The WHO reports that worldwide more individuals are affected by these conditions than by undernourishment [1].

England (see FIgure 1), Wales, Scotland and Ireland all have adult obesity rates that are amongst the highest in Europe [2]. Epidemiological evidence suggests the rate of obesity will only increase over the coming decades (see Figure 2) [3]. The Foresight report estimates that by the year 2050 60% of men, 50% of women and 25% of children will be obese [4]. Apart from prevention, there is little evidence that medical interventions can reverse the problem of *severe and complex obesity* once it is present [5].

FIgure 1 OECD data: The rise in the proportion of the population that are overweight [2]

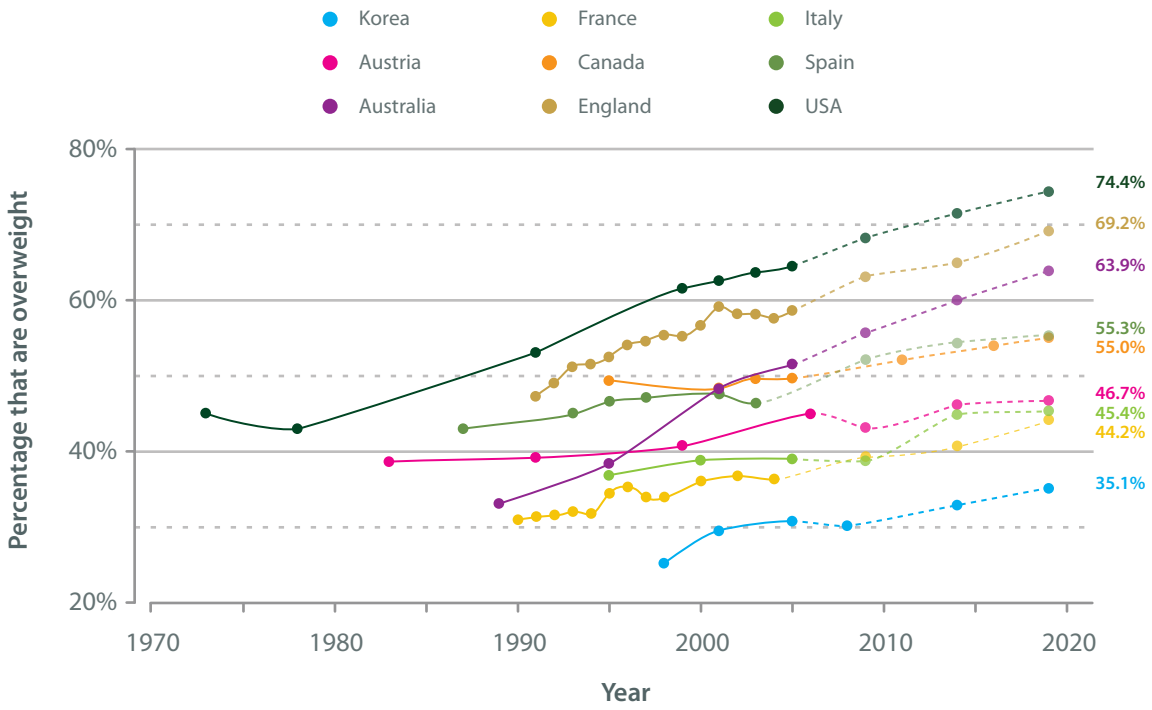
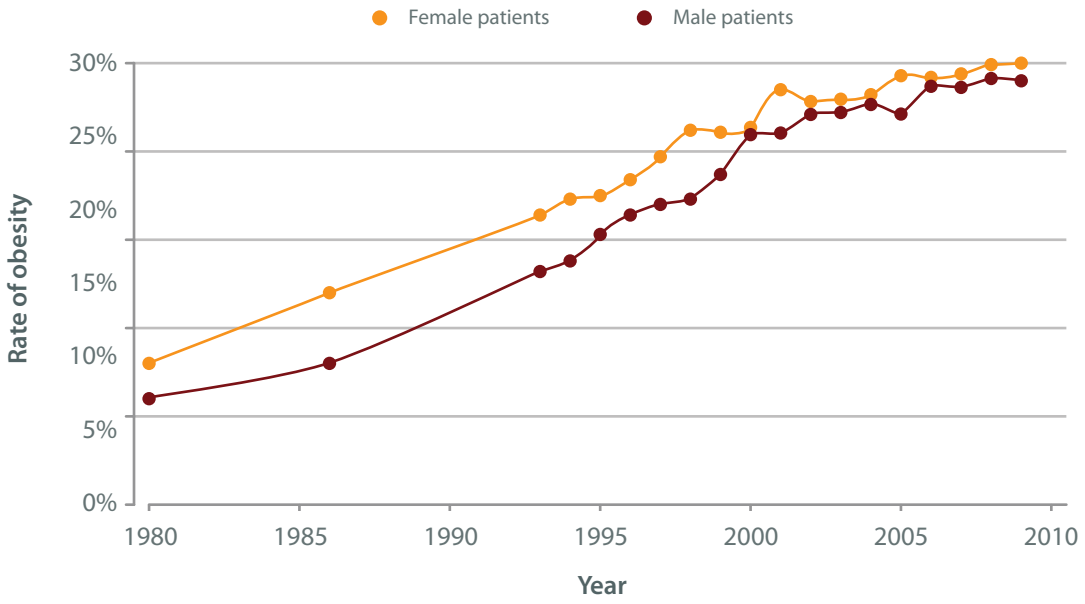


Figure 2 **Changes in obesity in England over time** [3]



Effects on the economy

Estimates for the United Kingdom conclude that treatment of the end-consequences of obesity alone costs the health economy £5 billion *per* year, and that this is set to double in real terms by 2050 [4]. This figure does not apply to treating the disease itself to ameliorate the underlying condition (so-called *secondary prevention*) and simply indicates the unavoidable cost of doing nothing. In the long term primary prevention, to arrest the onset of this overweight in susceptible groups, must be the answer, but currently no such strategy has been shown to be effective, so that at least 2 generations of affected individuals will, untreated, now suffer the personal health consequences and contribute to this cost burden. This affects the wider economy too [5].

As will be shown later, surgery to facilitate weight loss is outstandingly the most effective [4] (see Figure 6) and cost-effective [7] means of secondary prevention. There are well-founded, long-standing, internationally-supported guidelines to identify those who would benefit. This guidance has been repeatedly fully endorsed in the United Kingdom by the National Institute for Health and Clinical Excellence (NICE) [8].

From an *obesity pool* that is steadily growing, these guidelines identify, in the broadest terms, about 1 million United Kingdom adults whose condition might best be termed one of *severe and complex obesity*, and who could thus benefit from surgery. As the present report shows, rather less than 1% of these people underwent surgery in the last 2 years. If these figures were applied, for example, to symptomatic coronary artery disease, the cause for concern becomes immediately clear.

Effects on the individual

Being overweight (a BMI greater than 25 kg m^{-2}) and being obese (a BMI of 30 kg m^{-2} or more) are both associated with a high risk of developing other diseases, of which type 2 diabetes, hypertension and obstructive sleep apnoea are only the most renowned. These conditions are usually termed *comorbidities*, a misnomer since they do not exist by accident alongside the *overweight*, but as its direct consequence.

As BMI rises above 35 kg m^{-2}, the risk of developing these conditions increases dramatically (see Figure 3 and Figure 4) [9, 10]. The consequences are not just a matter of life-expectancy [11] (see Figure 5). Given a lifetime treatment cost for type 2 diabetes usually quoted at £3,000 *per annum*, there are clearly also major impacts on the health economy.

These are figures on a truly disturbing scale and which demand effective action.

Figure 3 **Age-adjusted risk of diabetes by BMI group** [9, 10]

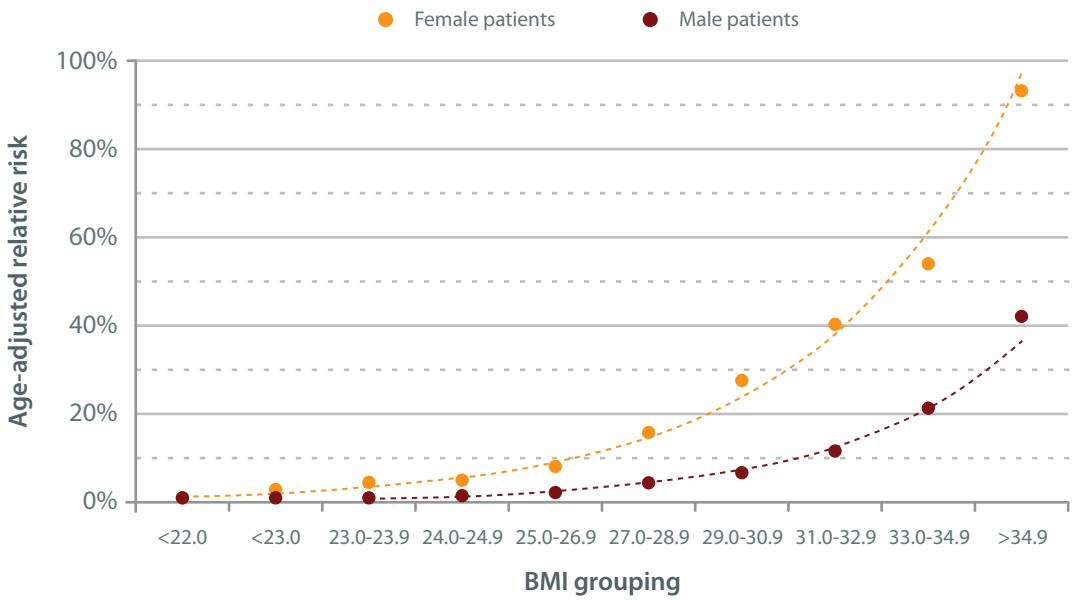


Figure 4 **Unadjusted cumulative mortality** [5]

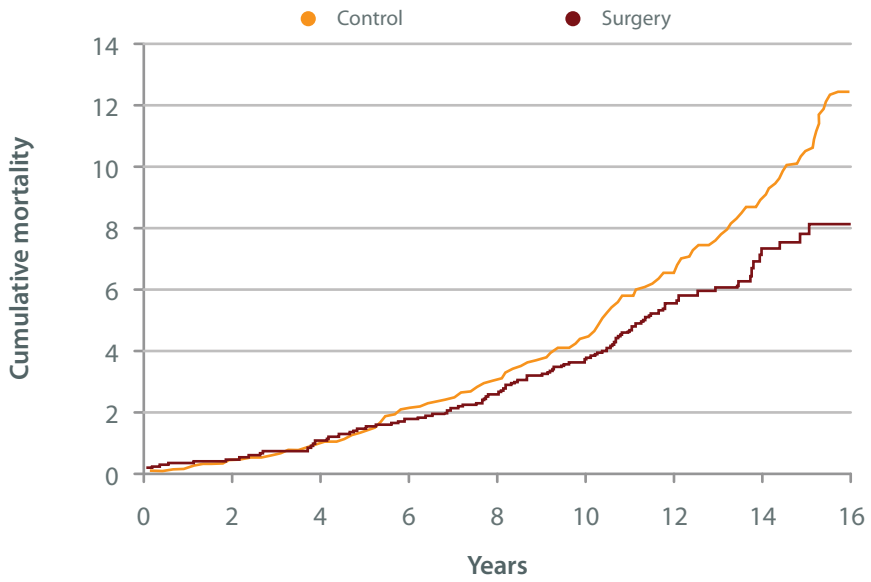
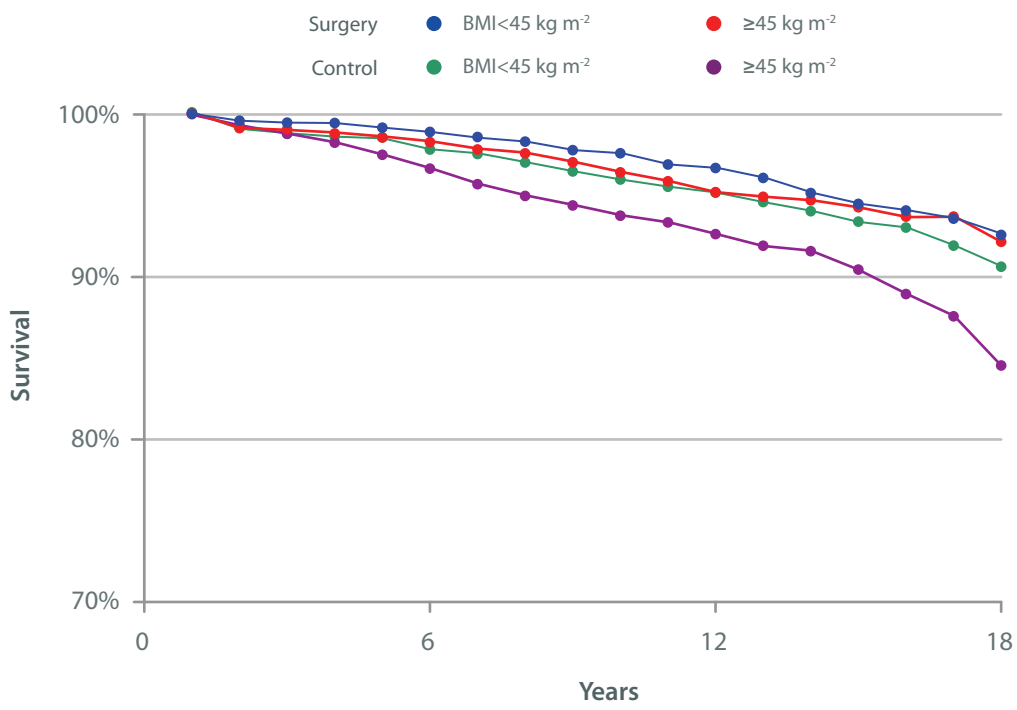


Figure 5 Survival according to BMI in the surgery group and the control group [10]



Lay and professional perceptions of severe obesity

It is often believed that the sufferers of *severe and complex obesity* are in some way less deserving of clinical care because their condition is *self-inflicted*, and because their inability to lose substantial weight denotes lack of will-power: if only they would pull themselves together and eat less over a long period, all would be well.

It is of course correct that people become overweight because they have, over time, eaten more than they needed, although this excess is often much smaller than imagined. A wide variety of reasons lie behind this. They include environmental issues, over which we have little individual personal control (the lack of chronic disease ravaging our energy stores, the ubiquitous, heavily marketed availability of cheap high-quality food). There are also personal behavioural, lifestyle and psychological issues over which we *may* have a greater degree of individual influence.

However, being self-inflicted, from this point of view, does not distinguish *severe and complex obesity* from any other disease of civilisation, such as coronary artery disease, hypertension or chronic obstructive pulmonary disease.

The analogy is strong, because what results is a disease state in which reversing the causative process does restore normality. The body's function is dysregulated so that the sufferer is locked-in to their new body weight by a powerful physiological barrier. Appeals to overcome this barrier by will-power and altered behaviour are just as ill-informed (and therefore unprofessional) as it would be to suggest blood pressure could be permanently, decisively lowered or narrowed coronary arteries be widened by these means:

Firstly, it should be remembered that, whilst an average lean person can vary their weight (and usually but not always maintain it) voluntarily by the amount they wish, these are small variations. To suppose that the severely overweight person can simply vary their weight 10 times as much (and maintain it) by the same means is not rational. Everyone can hold their breath for a minute, but who can hold it for 10? It is important to recognise eating as a vital life-preserving function: if it were under limitless voluntary control it would be uniquely unlike any other such function.

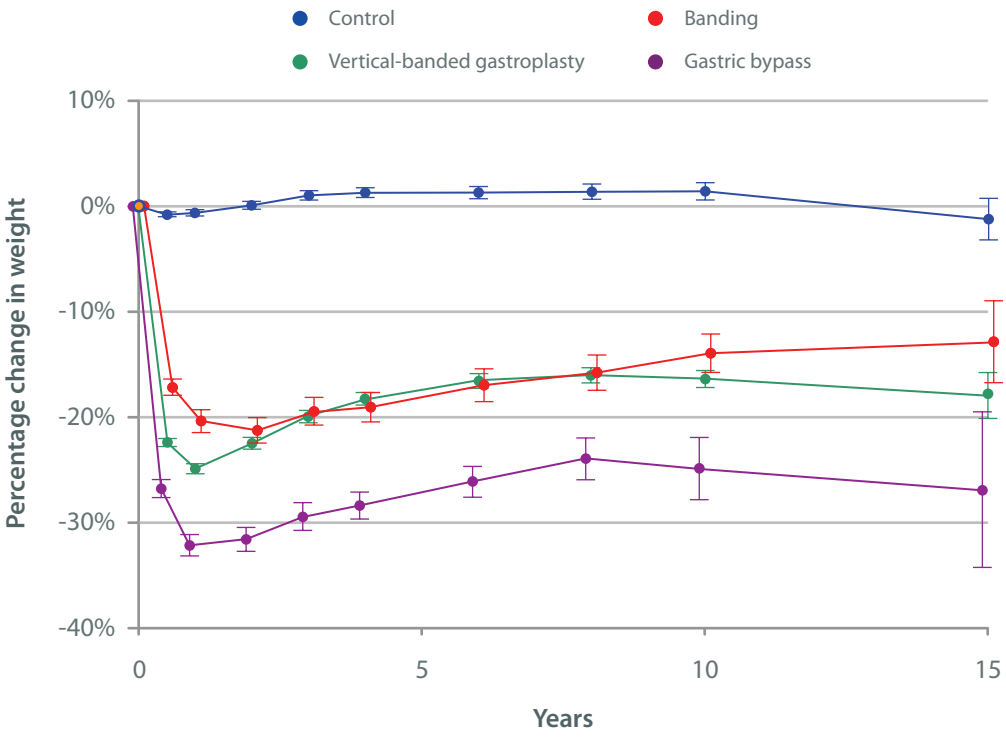
Secondly, the same lean person usually maintains their weight accurately, automatically and largely unconsciously over many years without any active intentional measures. There is now a large body of clinical evidence, gathered over years from around the world, to suggest that the very overweight are in the grip of exactly the same accurate, automatic mechanism (*i.e.*, energy homeostasis), but that it is permanently and irreversibly re-set to the new body weight. This, not moral weakness, explains the inability of behaviour modification programs to achieve

lasting major reduction in caloric intake. Even surgery may not lower the set point, but it is capable of falsifying the signal in the associated control pathway.

Thirdly, it is now known that the normal intestinal hormone mechanism that limits food intake at mealtimes is absent once *severe and complex obesity* has been established for any real length of time – probably also permanently so. This hormone (peptide YY 3-36) is normally released once eating starts and can be shown to be an appetite suppressant (as well as a powerful regulator of metabolism) in both lean and overweight people [12]. Once again, the evidence is lacking that voluntary measures would restore this (or that there is any credible way in which they could). By contrast, certain types of bariatric surgery result in an artificial, early and above normal hormonal response, which explains their beneficial effect on weight and metabolism.

Thus, *severe and complex obesity* represents a disease state [13] of disordered physiological regulation. Pathological change results from a mismatch of evolved constitution and created environment. Bariatric surgery is the only known effective treatment and a highly cost-effective treatment for this disease, which is no less deserving of healthcare attention than is any other disease of civilisation. The correct treatment for this disease is a real bargain for the health economy and for wider society [5, 7, 14].

Figure 6 Mean percent weight change over a 15-year period in the control group and the surgery group, according to the method of bariatric surgery [5]



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11. Adams T *et al*. Long-Term Mortality after Gastric Bypass Surgery. *New England Journal of Medicine*. 2007; **357:** 753-761.
12. Batterham *et al*. Gut hormone PYY3-36 physiologically inhibits food intake. *Nature*. 2002; **418:** 650-654.
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The patient journey

Bariatric surgery is only one episode in the management of the chronic lifetime disease that is obesity. The schematic on the facing page shows the complexity of the journey that obese patients have to take to in order to reach bariatric surgical treatment. The NBSR has been specifically designed to cover the patient's journey from the time that they have been accepted for surgery, the detail of which can be found on pages 194-213 of this report. It captures data on concomitant obesity-related disease (comorbidity), weight and previous medical weight treatments. Data on type of operation, technical details of the each operation, medical and surgical complications and follow-up are also collected. The registry has built-in functionality that enables data collection on all re-operations, planned staged procedures and revisions, as well as long-term assessment of clinical outcomes.

NICE guidance (see page 84) states that patients referred for bariatric surgery should have a full multi-disciplinary assessment and evidence that a medical weight management programme has been tried for at least 6 months. There is no evidence as yet that a patient who progresses through a full medical assessment is likely to have a better weight-loss outcome, but getting each patient as fit as possible before surgery makes obvious clinical sense. Thus, for instance, many patients with daytime sleepiness will need testing for sleep apnoea, as this could require treatment before surgery. Part of the work-up will include a so-called *liver diet*, which is a low calorie diet intended to deplete the liver of fat and carbohydrate stores, which makes it smaller in preparation for surgery. Very rarely a patient may have a previously undiagnosed endocrine disorder, which is responsible for their weight problem that is only identified during the work up for surgery.

Not all patients referred to a medical obesity clinic for management of obesity-related disease will want to have bariatric surgery, and, in fact, may not qualify for surgery according to NICE guidance. Depending on local resources, some surgical units may not have access to a dedicated medical obesity clinic, and in order to assess local variations in the provision of such services data on the source of referrals to bariatric surgical team are being collected in the NBSR.

Typically a Bariatric Care Team involves medical obesity physicians (often endocrinologists), dieticians, specialist nurses, psychologists, respiratory physicians, anaesthetists and surgeons. Busy units need an administrator to meld the process of care. Other necessary members of the team include dedicated operating theatre and recovery staff. Critical care nurses and ward staff need to be experienced in the needs of bariatric patients. Care protocols for surgery and anaesthetics need to be standardised, and these may include details of the specific operation steps, post-operative analgesia, and policies on deep vein thrombosis (DVT) / pulmonary embolus (PE) prophylaxis.

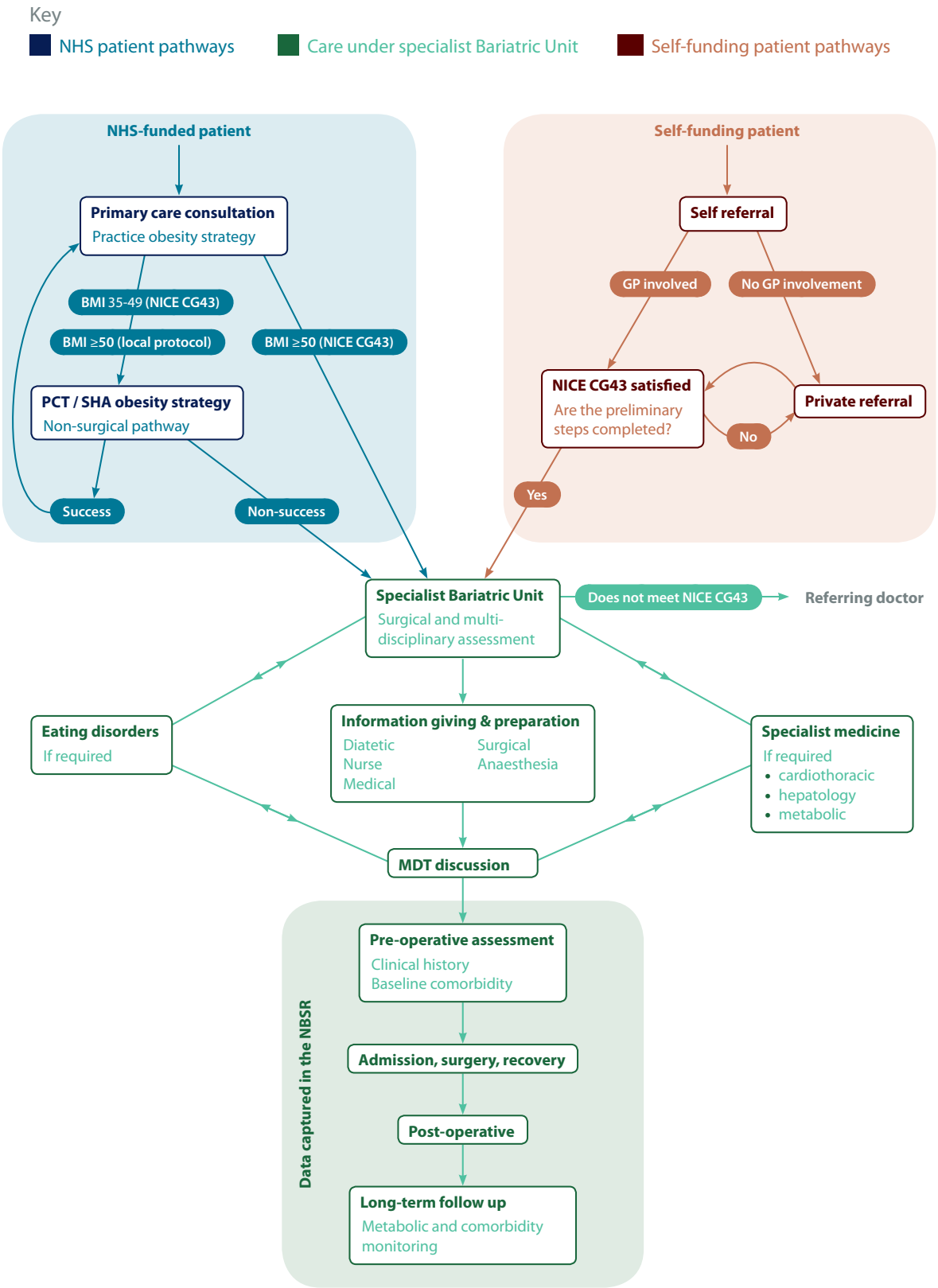
Outsize physical infrastructure is also needed: operating tables and transfer mattresses, electric beds, computed tomography (CT) and magnetic resonance imaging (MRI) scanners capable of accommodating patients sometimes weighing well over 200 kg. All staff who come into contact with bariatric patients need to be sensitive to their needs, as one casual comment can destroy a patient's confidence and undermine the whole process of care.

Some patients referred into medical obesity clinics may opt to persevere with trying to make lifestyle changes alone. When a patient is referred for surgery part of the process involves detailed education about the outcomes that might be expected from the different operations. The risks of surgery should be carefully discussed so that each patient can make an informed choice between the different operations that may be recommended. There is no formal information on why patients in the United Kingdom choose one kind of operation over another; however, drivers probably include cultural and surgical preference, media information and peer pressure. Similar to the standard process of care for cancer patients, multi-disciplinary Bariatric Care Teams hold regular meetings so that individual team members have the opportunity to discuss every patient in preparation for surgery.

1. The Betsy Lehman Report. Massachusetts. http://www.mass.gov/Eeohhs2/docs/dph/patient_safety/weight_loss_executive_report_dec07.pdf.

2. Kelly J. Best care recommendations for weight loss surgery. *Obesity Research*. 2005; **13:** 227-233.

The bariatric / metabolic surgery patient journey diagram



For further information on the NICE guidance CG43 see pages 84-85.

How surgery helps with weight loss

To maintain weight, the body needs a fixed amount of food energy *per* day. This amount can be estimated accurately for any given age, weight, gender and body make-up. If the body gets more than this amount, it increases its fat stores. If the body gets less, these stores get used up.

Reducing Intake

All surgical weight-loss procedures act by limiting the amount of food that gets into the body through the digestive system: stomach and intestines. This limitation could occur in any of three ways:

1. Simple mechanical restriction of intake capacity (much like a stopcock or throttle).
2. Reduction in the drive to eat (less appetite – more fullness).
3. Reduction of absorption into the body of food that passes through the intestines.

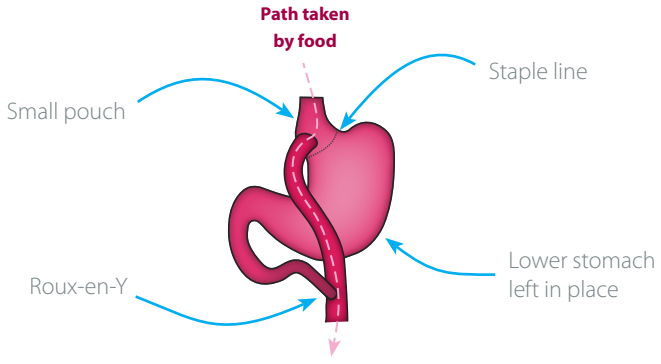
Most practical operations offer a combination of some or all of these basic mechanisms.

The choice of operation

The following gives an overview of the 4 most commonly recognised operations. Each of these has advantages and disadvantages, so careful discussion of the risks / benefits of surgery is required both at multi-disciplinary team meetings (MDTs) and with the patient.

Gastric bypass

How it works: In this procedure the stomach is divided and stitched (by very small staples) to produce a small pouch (about 30 ml, similar to that in gastric banding). The rest of the stomach remains in the body. The intestine is rearranged so that food enters it directly, bypassing both the rest of the stomach and an initial length of intestine. These are reconnected to the remaining intestine lower down (*Roux-en-Y*).



Diagrammatic representation of a Roux-en-Y gastric bypass procedure

The operation significantly reduces the amount of food that can be eaten. It mildly reduces the amount of fat that can be absorbed from the food that is eaten. It has a direct effect that reduces appetite and this effect also improves type 2 diabetes

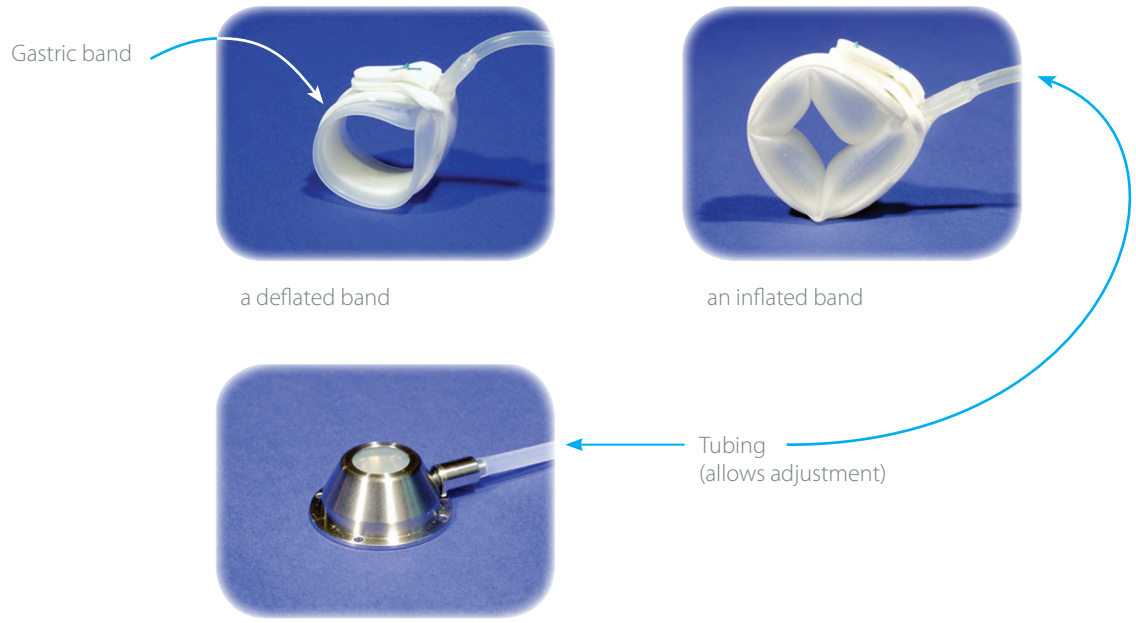
Advantages: Gastric bypass is an effective operation for producing good weight-loss with less requirement for a major change in eating habits and with lower long-term risks than other operations. It requires relatively little in the way of follow-up, but this cannot be ignored. In cases of diabetes it may be the best option.

Disadvantages: The risk at the time of surgery is greater than for simpler operations, although the risks of remaining overweight may be greater. It is irreversible and the patient must take vitamin supplements every day after their surgery.

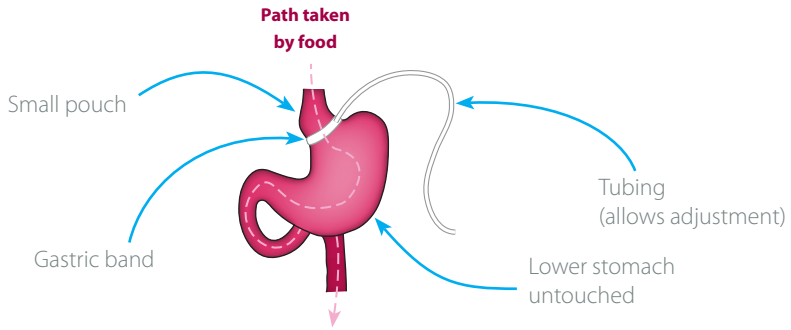
Gastric banding

How it works: A gastric band is a synthetic ring, which is placed around the extreme upper stomach.

A Swedish Adjustable Gastric Band (SAGB)



The result is a small pouch of about 25 ml above the band, which restricts intake capacity for solid food. A balloon on the inside surface of the band can be inflated or deflated by injecting liquid through the skin into a chamber placed under the skin (port). This simple ambulatory procedure is used to adjust restriction and produce gentle weight loss.



Diagrammatic representation of a gastric band in place

Advantages: The adjustable gastric band procedure is the safest and simplest procedure at the time of operation. This, and the feeling that nothing permanently harmful has been done to the stomach are seen by many as its great advantage.

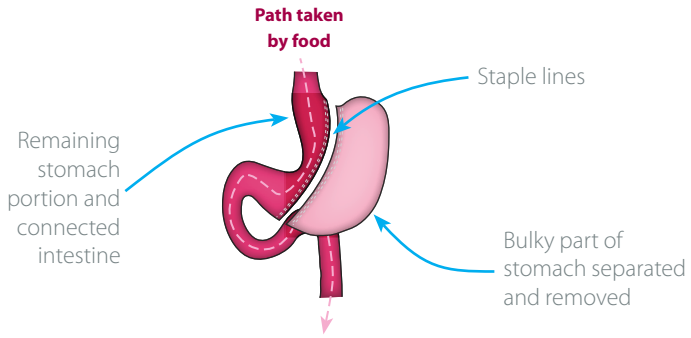
Disadvantages: However, although it works well for most patients, it does not do so in every case. In the longer term, problems may arise which mean about 10-20% of patients may need a further operation, one-third of these as an emergency. It may not reduce appetite.

It may best suit those who seek participation in a process of change and it may be least suitable for those who cannot change or who desire complete freedom in eating.

Patients must be prepared to attend hospital for regular follow-up checks – frequently to begin with.

Sleeve gastrectomy

How it works: In this procedure the bulky part of the stomach is separated from the rest with a long staple line and removed, leaving a narrow tube of stomach connecting the gullet to the first part of the intestine. Normal continuity is preserved, but the capacity for solid food is seriously limited. The part of the stomach that is removed produces a signalling chemical called *ghrelin* that makes people feel empty. Therefore there is also usually a reduction in appetite. The long-term weight loss is often enough, but if not, a further conversion procedure can be added later.



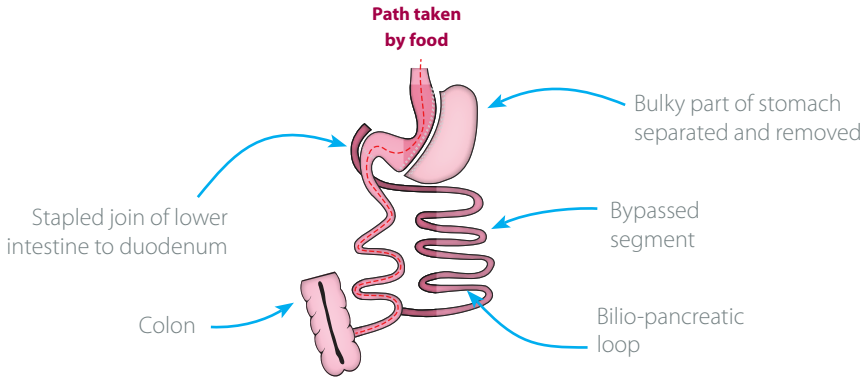
The basics of a sleeve gastrectomy procedure

Advantages: Sleeve gastrectomy is an effective operation for producing good weight-loss and can be regarded as a single-step procedure or as stage 1 of a more complicated operation in heavier patients. On its own it may be sufficient for patients with a BMI 40-50 kg m^{-2}. It is simpler than a gastric bypass, but in cases of diabetes it may be just as effective. Intestinal absorption is not interfered with, so there may be less need for long-term vitamin supplementation. Some other complications of gastric bypass will also not occur. It requires relatively little in the way of follow-up, but this cannot be ignored.

Disadvantages: The long-term weight maintenance is less well proven than for gastric bypass. In patients who are more severely overweight it may not provide enough weight-loss on its own, so further surgery may be needed later. The effect on patients with severe acid reflux is not clearly established. The risk at the time of surgery is greater than for simpler operations, such as gastric banding, although the risks of remaining overweight may be greater. It is also an irreversible procedure.

Duodenal switch

How it works: In this operation the stomach is reduced in volume to some extent, usually by a sleeve gastrectomy (see above), but some patients will already have had some other stomach-reducing procedure. The purpose is to partly moderate the total intake volume.



Duodenal switch diagram

The intestine is divided once about 4 cm beyond the stomach and again 2.5 m from the large bowel. It is re-connected, so that food only passes through a very short section of the duodenum before reaching the lower intestine. The rest of the small bowel, containing bile and digestive juice, is reconnected just 1 m above the large bowel. As a result there is fixed limit to absorbing carbohydrate (starch) and fat. This imposes a fixed calorie intake capacity and so fixes the final weight.

Advantages: Duodenal switch is the most effective operation for producing weight-loss and offers the best long-term weight maintenance. It allows a relatively normal volume intake capacity later on and the weight loss occurs however much is eaten.

Disadvantages: The risk at the time of surgery is greater than for simpler operations, although the risks of remaining overweight may be greater. The stomach reduction component may be irreversible. Patients who eat more fat than can be absorbed will get significant foul-smelling diarrhoea. Eating more starch than can be absorbed results in passage of foul wind. Patients who eat within these limits may get few digestive disturbances. Patients who eat beyond the limits will get the same weight loss, but will suffer these *social* side effects and are at much greater risk of long-term nutritional harm. These nutritional effects may force re-operation. The patient must take vitamin supplements every day after their surgery and careful follow-up is required.

A note on the conventions used throughout this report

There are a number of 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 tend to 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 operations (see the example below, which is a modified version of the table presented on page 52).

Primary operations: age and gender distributions

		Gender			
		Male	Female	Unspecified	**All**
Age at operation / years	<25	40	193	0	**233**
	25-29	43	319	0	**362**
	30-34	92	489	0	**581**
	35-39	174	815	0	**989**
	40-44	205	943	0	**1,148**
	45-49	264	935	0	**1,199**
	50-54	201	686	0	**887**
	55-59	155	465	0	**620**
	60-64	81	263	0	**344**
	>64	34	78	0	**112**
	Unspecified	3	5	0	**8**
	All	**1,292**	**5,191**	**0**	**6,483**

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 the age 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 red 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: <25, 25-29,30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64 and >64 years ; 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.

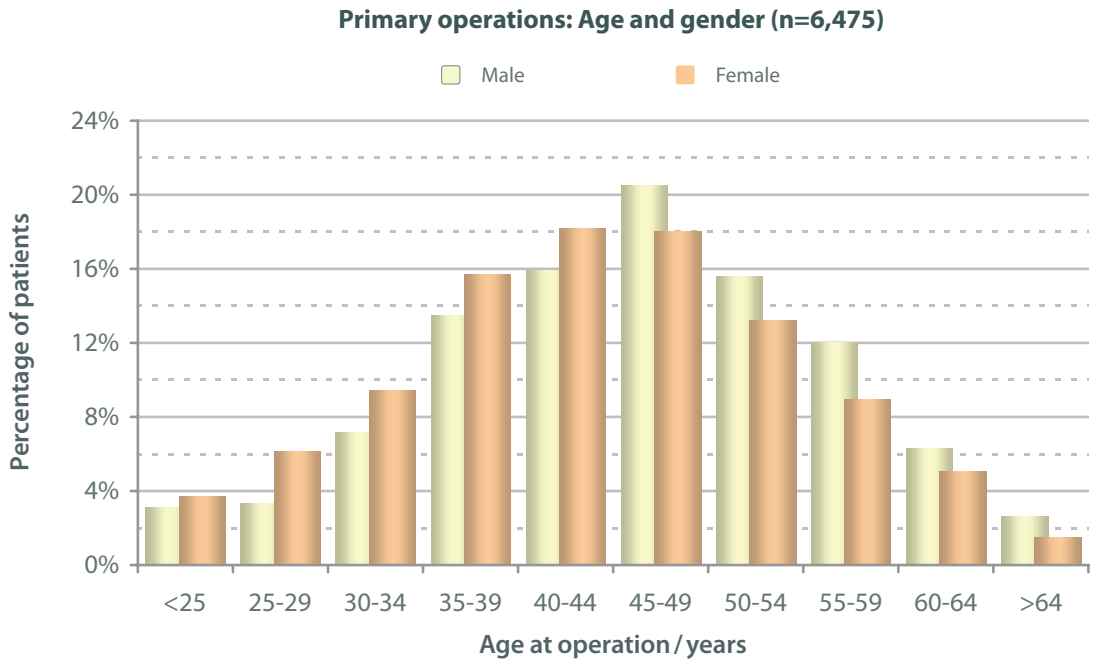
Conventions used in graphs

The basic principles applied when preparing graphs for the first NBSR 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 on page 52 (reproduced below in a slightly modified format), only the entries where both the patient's age and gender are known are included in the analysis; this comes to 6,549 patient-entries (84 + 90 + 180 + 212 + 267 + 204 + 158 + 117 male patients and 514 + 497 + 823 + 953 + 946 + 690 + 469 + 345 female patients; the 8 entries with unspecified data are excluded from the chart as are all those entries in the database where the operation is not a primary operation).



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 66 for more details and explanation).

Excess weight loss

Excess weight loss is defined as:

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

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 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 timeline 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 timeline 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 timeline 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 23 fields in the database that are absolutely required for meaningful data collection:

Section	Question
Add a new patient (3)	Date of birth
	Date of operation
	Patient's gender
Initial information (3)	Patient's height
	Patient's weight
	Funding category
Baseline comorbidity (8)	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 (4)	Operating Surgeon
	Type of operation
	Operative approach
	Operation
Post-operative course & discharge (5)	Cardiovascular complications
	Other complications
	Discharge date
	Discharge destination
	Are the data complete

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.

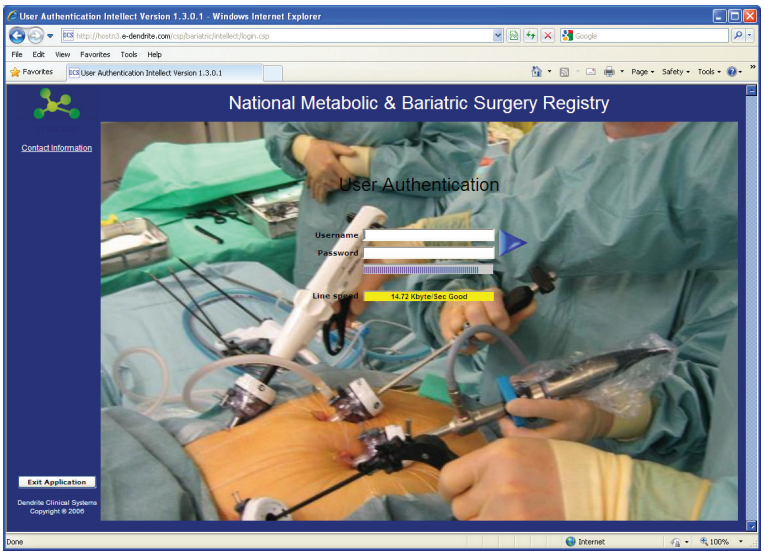
How the NBSR web registry works

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 / Carelink 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 194-213). 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.

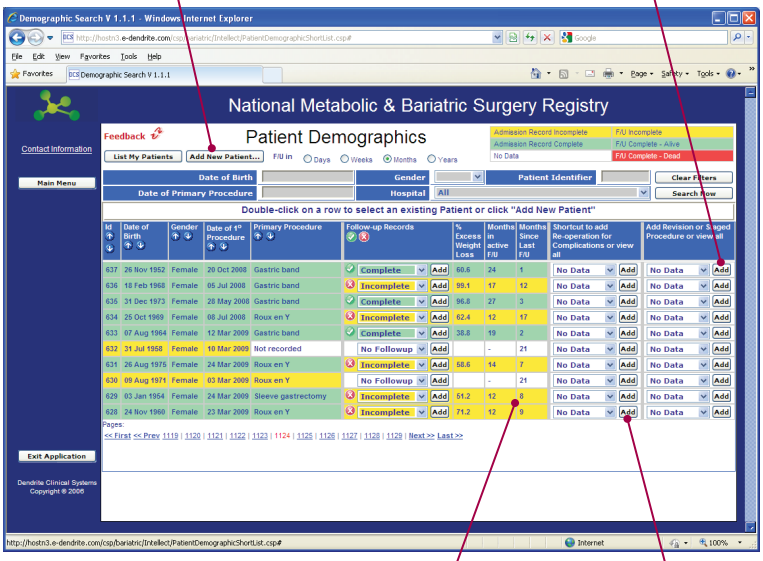
The patient data are anonymised to comply with United Kingdom Data Protection laws, such that the only information required to create a new record or to identify an existing patient-entry are the *date-of-birth*, *gender* and *date-of-operation*. Each line in the demographic screen listing represents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

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

Complications

Access pages for recording surgical complications, if applicable.

Tracking data

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

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

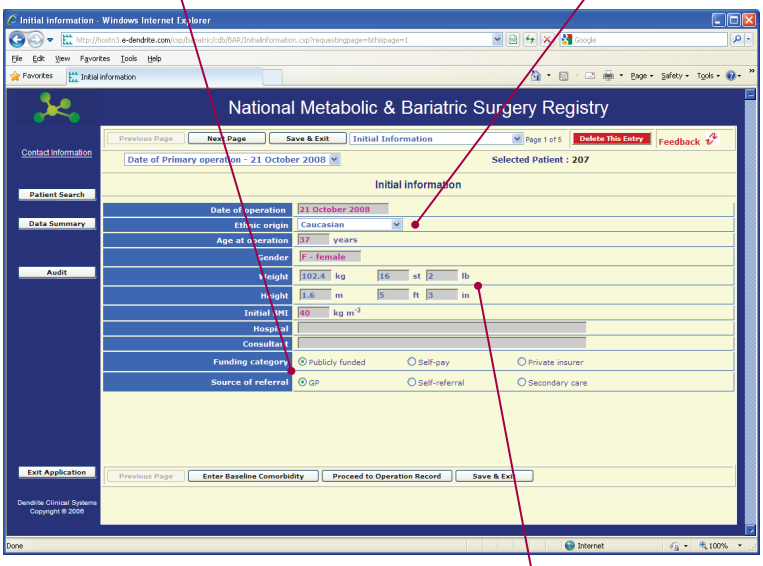
- use of simple radio buttons, multi-choice tick boxes and drop down lists, presenting only validated choice options.
- free-text boxes are limited as much as possible (to aid future data analysis).
- widespread use of hover-tip prompts to provide extra information to guide users on the most suitable response-options to select (see Appendices page 215 *Database tooltips*).
- 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.

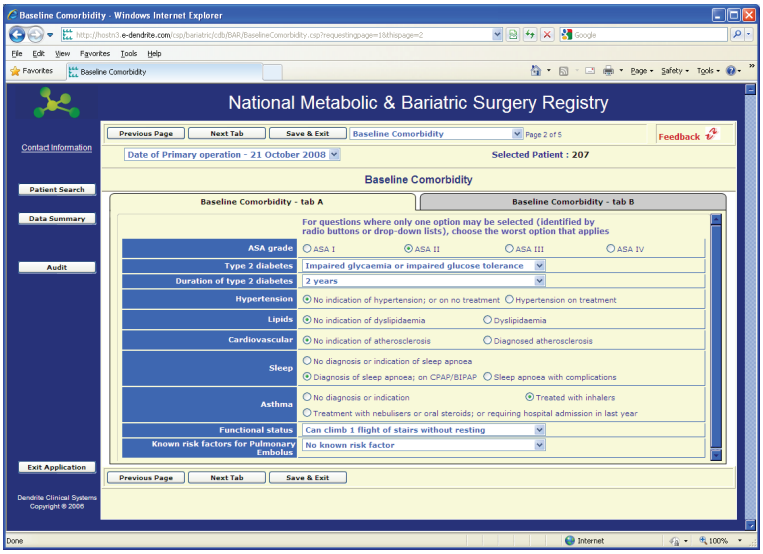


Initial information screen

Numeric fields

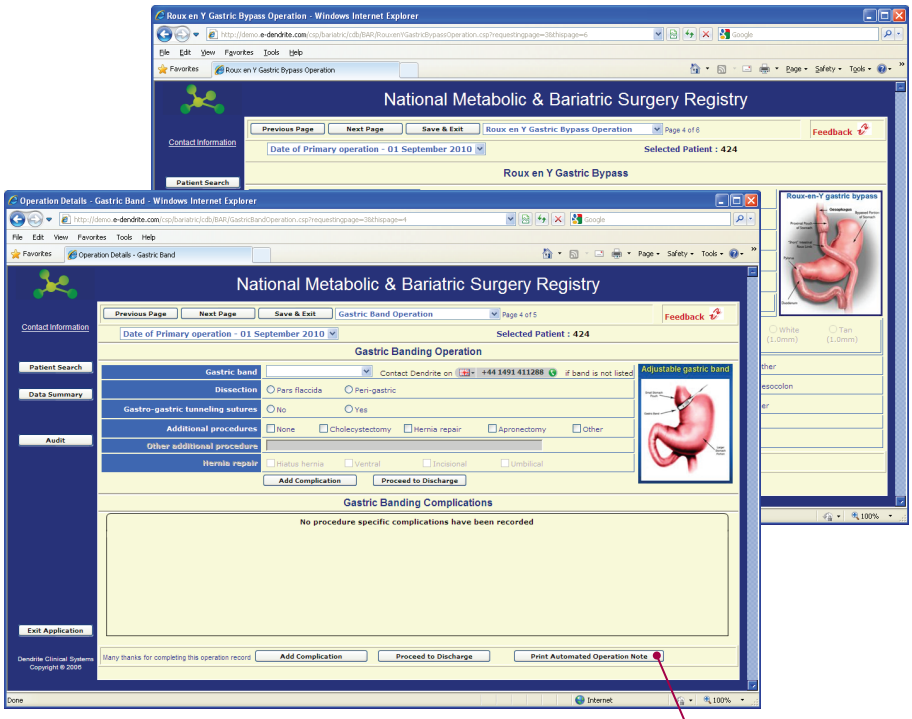
Height & weight data may be entered in either metric or imperial boxes; if entered as metric the imperial boxes auto-populate, and *vice versa*. Both have validation to ensure nonsense values are not accepted.

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.



Comorbidity data

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:



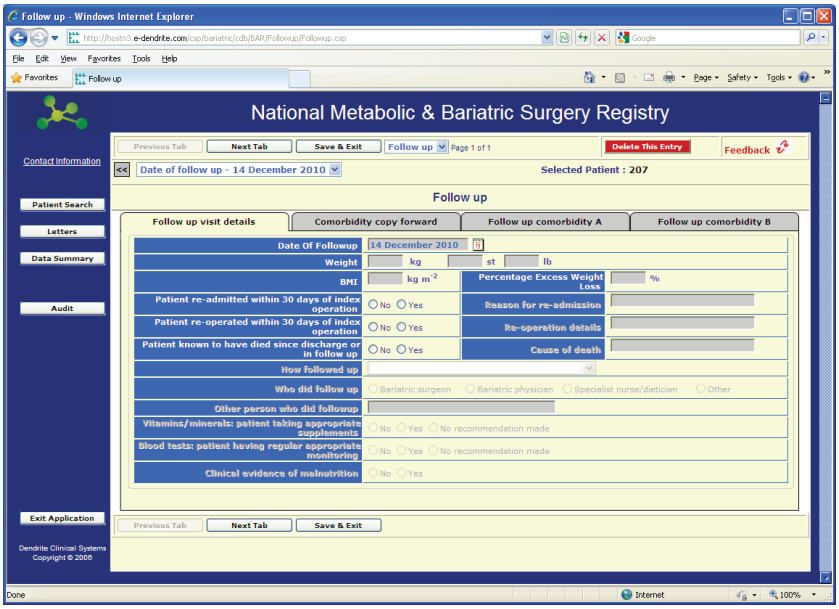
Operation data screens

Automated operation note

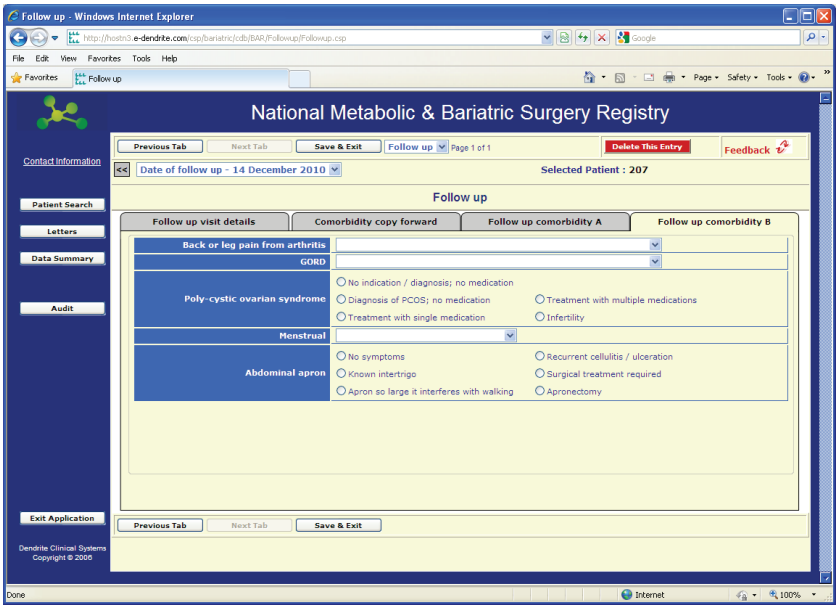
Click here to generate an html operation note.

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.

Example auto-generated follow-up letter

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

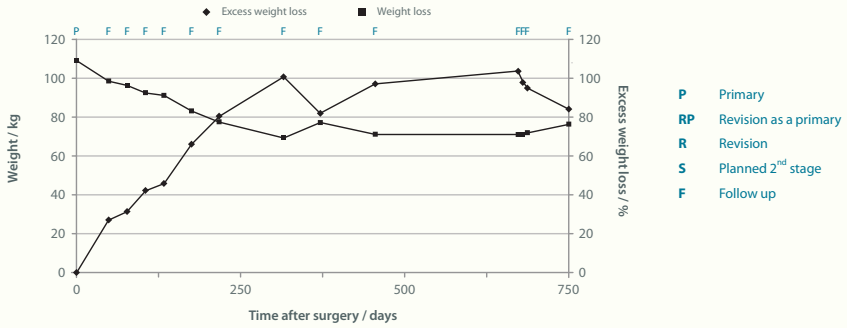
Pre-op weight: 109 kg
Pre-op BMI: 38.9 kg m^{-2}

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

Database overview

Database overview

Introduction

The United Kingdom & Ireland are facing an epidemic of obesity, and their populations have some of the highest rates of obesity in the world today. Accumulating international evidence suggests that bariatric surgery has much to offer these patients, yet only a fraction of those who could benefit currently receive surgery. Good surgical safety and outcomes data are essential if we are to persuade commissioners to increase the provision of bariatric surgery.

Developing the NBSR registry from ground-up required extensive consultation within the multi-disciplinary environment to agree an optimum minimum dataset. The Dendrite Clinical Systems team, led by Peter Walton, Robin Kinsman and Graeme Smith (the lead programmer), then created the web database to match our requirements. The registry went live in January 2009 and has to date already accumulated over 14,000 clinical records in a very short period of time. It is estimated that this probably represents coverage of about 80% of United Kingdom bariatric surgical practice. This is by any account a national registry success story, but there is still much to do. Recruitment of 100% of practice is the ultimate goal along with capture of life-long follow-up data.

We are aware of the high standards set by other registries. The first NBSR was created by Dr Edward Mason in the United States of America, and was active from 1986 to 2001, collecting data on 38,000 patients with an impressive published 30-day mortality rate of 0.24% [1]. The United States and Canada continue to lead the way with current bariatric surgery registries. The US Bariatric Outcomes Longitudinal Database opened in 2007 and has already accumulated some 300,000 patients, with 12,000 patients being entered each month [2]. The Michigan Bariatric Surgery Collaborative has already published hospital- and surgeon-volume data, and outcomes on 15,000 patients [3], and the McGill / Quebec provincial database has generated well-cited papers [4]. In Europe there are several examples of national registries with limited follow-up data, and the IFSO (International Federation of Surgery for Obesity) European Chapter is setting up a Centre of Excellence programme with a linked registry [5]. To date, the NBSR has some of the largest and most detailed published follow-up outside the United States of America and Canada.

A great advantage of this NBSR registry is that it is Internet-based, and so it can be accessed from any hospital computer. Using structured clinical questions we can assess improvement over time of the patients' obesity-related disease. Limitations of any clinical registry include possible under-reporting, but a large body of complete data-records presented in this current report suggests integrity of data entry in the NBSR.

While most of the other data-fields are clinically obvious, we have made arbitrary distinctions for planned second stage and revision operations (see the *Glossary* on page 32). There is a section on revisional gastric band surgery, and we explain the rationale for this also on page 32. An explanation of the obesity-related disease data (comorbidity) that we are collecting is included on page 70. For ease of use and to encourage participation we have not included detailed laboratory results, as the principle aim was to collect good-quality surgical audit data.

This first report of our NBSR analyses data on more than 7,000 operations in the period April 2008 - March 2010. We believe that the data in the report will add to the accumulating evidence that bariatric surgery is very safe and tremendously beneficial for a population that has much obesity-related disease. The data from this and subsequent reports could have a major impact on the willingness of the NHS to commission bariatric surgery.

This report is a tribute to the commitment and enthusiasm of the 86 bariatric surgeons in the United Kingdom and Ireland who have contributed their data.

Richard Welbourn

Richard Welbourn, on behalf of the NBSR Committee

1. http://www.healthcare.uiowa.edu/Surgery/ibsr/30-day%20Mort%20Present_files/frame.htm
2. http://www.surgicalreview.org/SRCBold/history.aspx accessed Nov 2010
3. Birkmeyer NJO *et al*. Hospital Complication Rates With Bariatric Surgery in Michigan. *Journal of the American Medical Association*. 2010; **304:** 435-442.
4. Christou NV *et al*. Surgery Decreases Long-term Mortality, Morbidity, and Health Care Use in Morbidly Obese Patients. *Annals of Surgery*. 2004; **240(3):** 416–424.
5. http://www.eac-bs.com/eacbs/en/6/60.html

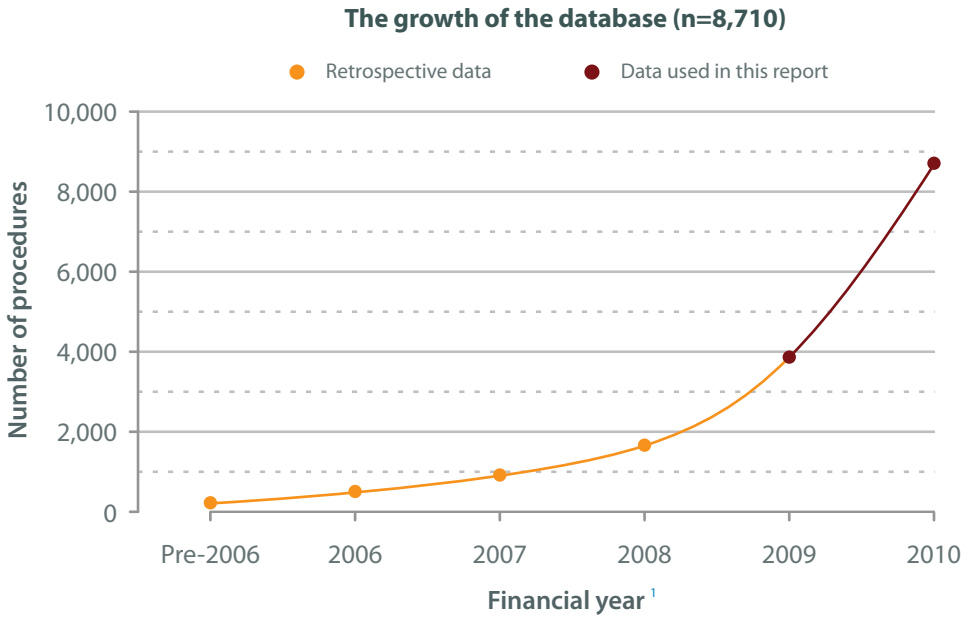
Growth of the database

Since its inception, the volume of data in the NBSR has expanded rapidly and significantly. The table and chart below detail the number of operations recorded in the registry at the time the data were extracted from the main database for the purposes of assembling thus report (1st November 2010). The registry was formally launched in January 2009 and since that time additions to the registry have been both prospective and retrospective (by the enthusiasts). The data from the financial year 2009-2010 are clearly the most complete since they were all added to the registry after its launch, and we believe that the data for this year represent around 70-80% of all the bariatric operations that were performed in the United Kingdom over that period. This is a remarkable feat for such a *young* registry, and all the contributors and organisational team should be congratulated on their efforts.

To ensure that all the subsequent tables and charts in this report present information on the most up-to-date clinical practice and contemporary outcomes for patients, we have limited all the following analyses to the financial years 2008-2009 and 2009-2010 (over 80% of the data in the registry).

Number of entries in the database

		Data	
		Count	Percentage
Financial year ending	Pre-2006	226	2.6%
	2006	282	3.2%
	2007	412	4.7%
	2008	745	8.6%
	2009	2,201	25.3%
	2010	4,844	55.6%
	All	**8,710**	



1. The financial year ending refers to the year in which the financial year, running from April to March, ends; the financial year April 2009 – March 2010 is therefore referred to as 2010.

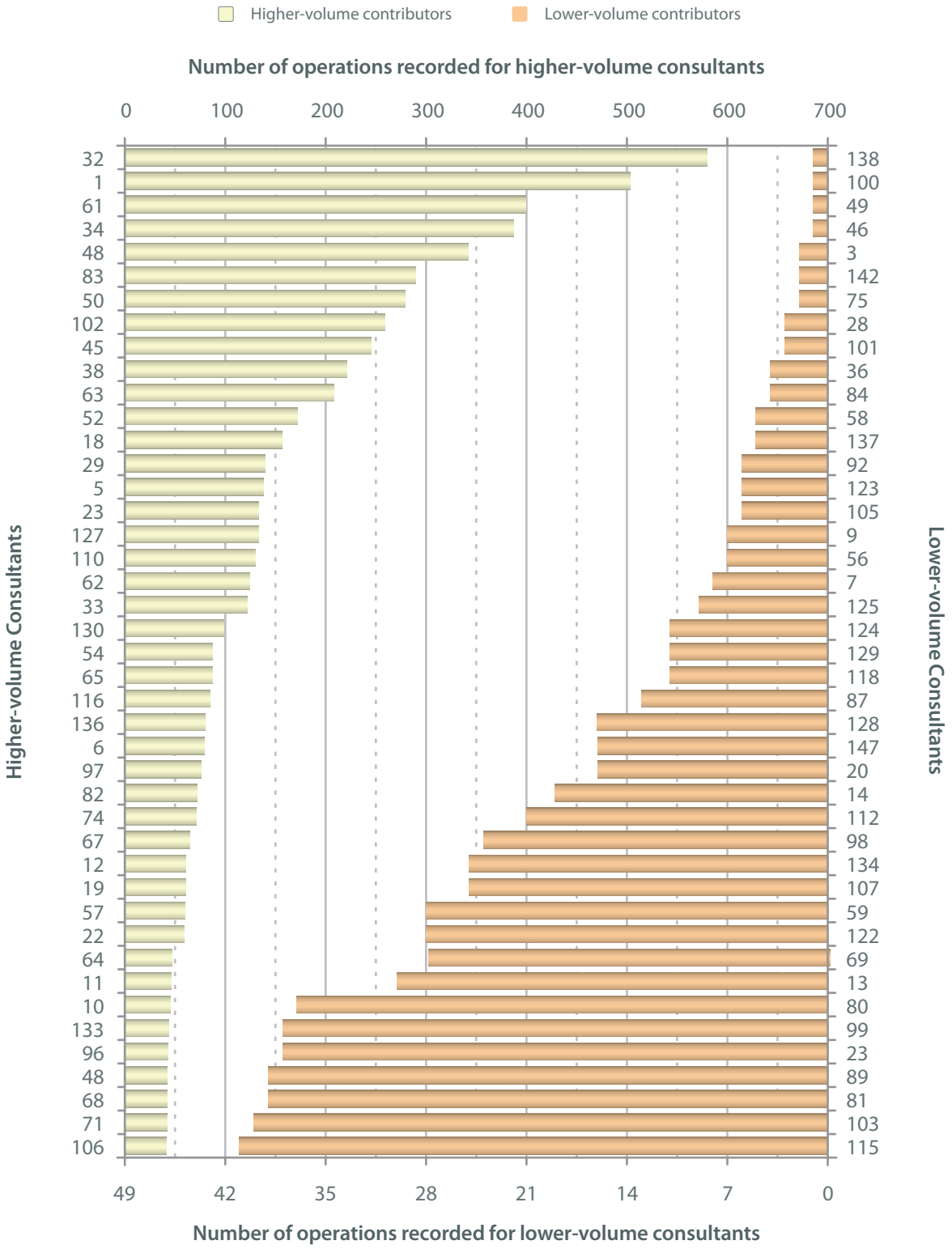
Number of entries submitted

Number of entries for each consultant

The number of operations reported for each consultant may or may not be a true reflection of the number of operations performed by that consultant in the period under analysis; it depends on the time at which the surgeon joined as a contributor to the registry and their enthusiasm for entering data. The volumes reported for consultants who have been contributors for the lifetime of the registry will (more likely) truly represent their practice, whereas those consultants who joined some time after the launch of the National Bariatric Surgery Registry (NBSR) will appear to have performed relatively fewer operations, unless they have entered both their prospective and retrospective data.

There were contributions from 86 consultants covering operations performed over the financial years 2009-2010. The submissions by each Consultant surgeon have been ranked according to the number of operations that they have recorded over the period under analysis. Consultants are identified simply by a code-number. The data are presented with the distribution simply divided in two equal halves, by volume of surgery. Being in either the *higher-volume* or the *lower-volume* group is not intended to indicate any measure of quality.

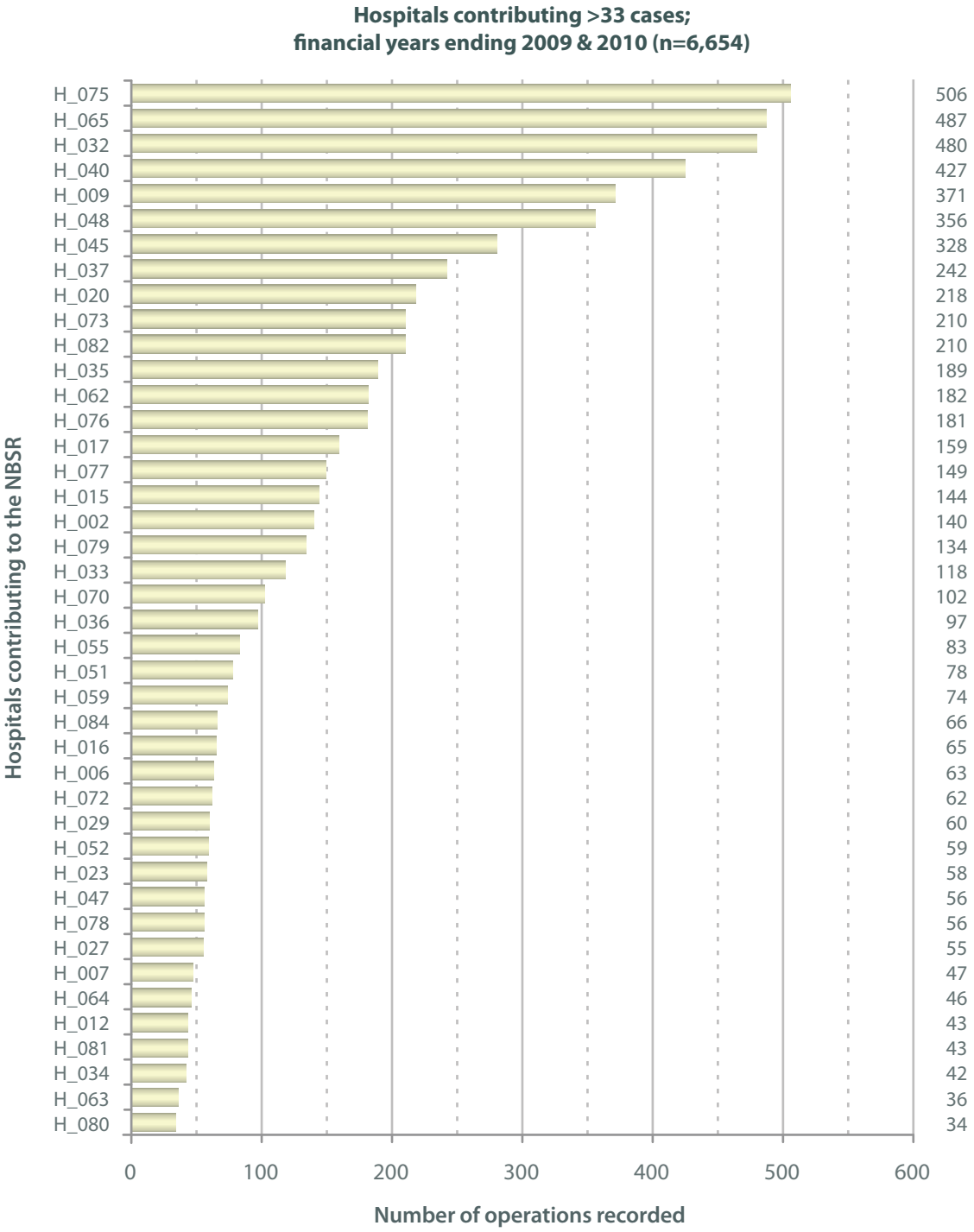
Consultants actively contributing to the NBSR; financial years ending 2009 & 2010 (n=7,045)



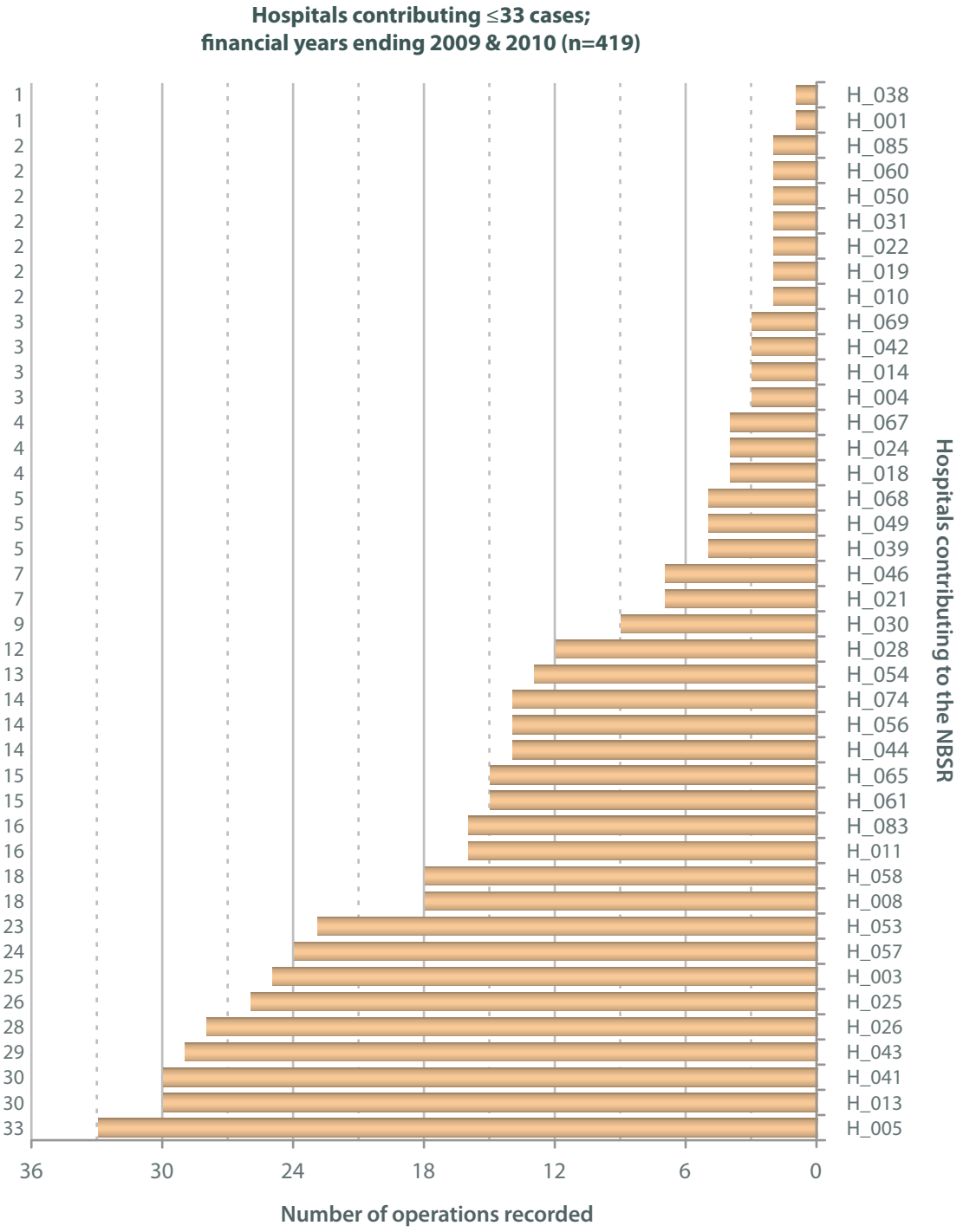
Number of submissions by hospital

The following charts list the number of cases by hospital (note the codes are anonymised). Setting an arbitrary cutoff of >30 and ≤30 operations divides the distribution into two approximately equal sub-groups.

In the same way that the number of operations reported for each consultant may or may not be a true reflection of the total number of operations they performed, it follows that the number of procedures reported for each hospital may or may not accurately reflect the volume of bariatric surgery performed at that centre.



In the same way that the National Adult Cardiac Surgery Database [1] grew from humble beginnings to a point where it acquired comprehensive data on all the cardiac surgical procedures performed in the NHS in the United Kingdom, the hope is that, eventually, all bariatric surgeons in the United Kingdom will sign up as contributors to the NBSR and enter data on all the operations that they perform; then the power and validity of all the analyses coming from this registry will increase greatly.



1. Bridgewater B, Kinsman R, Walton P and Keogh B. Demonstrating quality: The Sixth National Adult Cardiac Surgery database report. ISBN 1-903968-23-2. Published by Dendrite Clinical Systems Ltd, Henley-on-Thames, Oxfordshire, United Kingdom.

Type of procedures performed

Operation and type of surgery

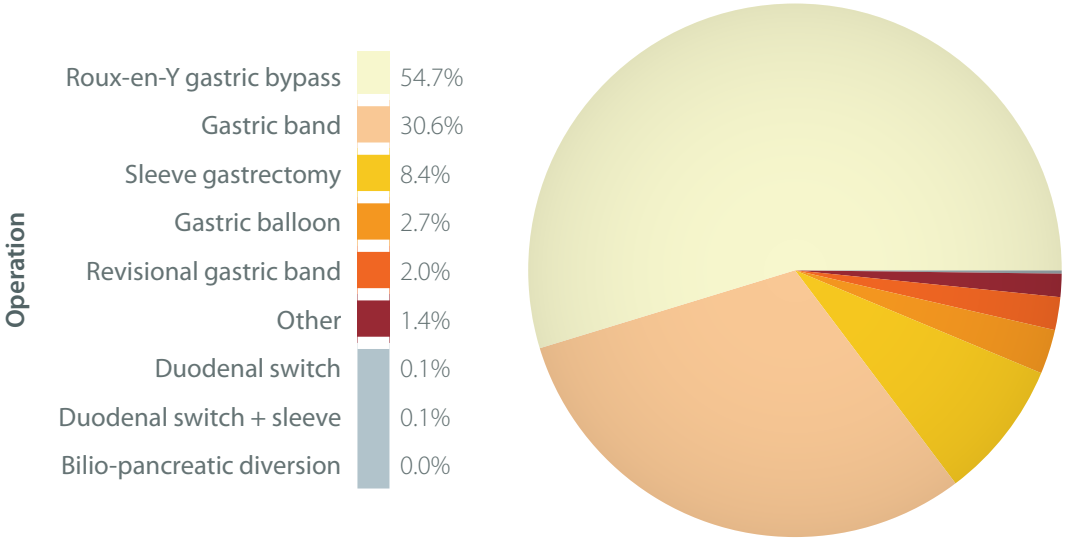
More than 85% of the operations recorded in the NBSR were Roux-en-Y gastric bypass (RYGB) or gastric banding. This proportion is very similar to the published global casemix for bariatric surgery. The proportion of bypass was slightly higher and banding slightly lower than that reported across the rest of Europe. However, the proportion of each was similar to current estimates of surgery rates in United States of America / Canada [1].

Type of operation performed

		Type of surgery					
		Primary	Revision	Revision as a primary	Planned 2nd stage	Unspecified	All
Operation	Gastric band	2,131	0	0	0	1	**2,132**
	Roux-en-Y gastric bypass	3,626	33	136	22	0	**3,817**
	Sleeve gastrectomy	543	5	25	14	1	**588**
	Duodenal switch	0	0	0	9	0	**9**
	Duodenal switch + sleeve	2	0	2	0	0	**4**
	Bilio-pancreatic diversion	1	0	0	0	0	**1**
	Revisional gastric band	0	54	83	2	0	**139**
	Gastric balloon	112	8	5	63	0	**188**
	Other	25	24	37	12	0	**98**
	Unspecified	43	1	0	0	25	**69**
	All	**6,483**	**125**	**288**	**122**	**27**	**7,045**

1. Buchwald H. Metabolic / Bariatric Surgery Worldwide 2008. *Obesity Surgery.* 2009; **19:** 1605-1611.

**Operations performed;
financial years ending 2009 & 2010 (n=6,976)**



Operation and approach

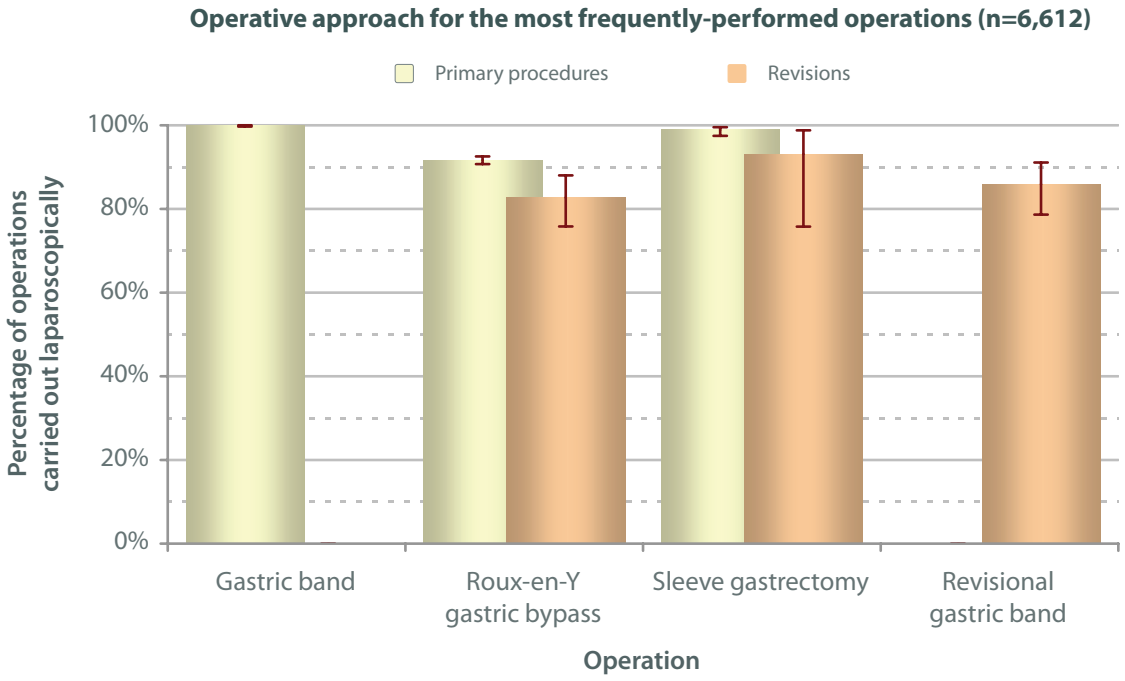
Every primary gastric band operation, with one exception, was performed by laparoscopic, or keyhole surgery, which, due to the absence of large incisions, enables faster recovery. Over 90% of Roux-en-Y gastric bypass (RYGB) operations were also performed laparoscopically. RYGB is a technically much more challenging operation that has a significant learning curve, and it is not surprising that a number of these operations were performed as open surgery, especially if the operation was a revision of a previous bariatric operation such as a gastric band. Almost all primary sleeve gastrectomies were laparoscopic, as were more >90% of revisions.

Operation performed, type of surgery and operative approach

		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	2,124	1	6	0	0	0	0	0	0
	Roux-en-Y gastric bypass	3,319	301	6	134	28	7	22	0	0
	Sleeve gastrectomy	535	6	2	27	2	1	14	0	0
	Duodenal switch	0	0	0	0	0	0	9	0	0
	Duodenal switch + sleeve	1	1	0	0	2	0	0	0	0
	Bilio-pancreatic diversion	0	0	1	0	0	0	0	0	0
	Revisional gastric band	0	0	0	116	19	2	2	0	0
	Gastric balloon	111	0	1	13	0	0	63	0	0
	Other	20	4	1	38	23	0	10	2	0
	Unspecified	1	0	42	1	0	0	0	0	0
	All	**6,111**	**313**	**59**	**329**	**74**	**10**	**120**	**2**	**0**

Percentage of operations performed laparoscopically for each kind of operation and type of surgery

		Type of surgery and approach		
		Primary	All revisions	Planned 2nd stage
Operation	Gastric band	100.0% (99.7-100.0%)	NA	NA
	Roux-en-Y gastric bypass	91.7% (90.7-92.6%)	82.7% (75.8-88.0%)	100.0% (87.3-100.0%)
	Sleeve gastrectomy	98.9% (97.5-99.5%)	93.1% (75.8-98.8%)	100.0% (80.7-100.0%)
	Duodenal switch	NA	NA	100.0% (71.7-100.0%)
	Duodenal switch + sleeve	50.0% (2.7-97.3%)	0.0% (0.0-77.6%)	NA
	Bilio-pancreatic diversion	NA	NA	NA
	Revisional gastric band	NA	85.9% (78.6-91.1%)	100.0% (22.4-100.0%)
	Gastric balloon	100.0% (97.3-100.0%)	100.0% (79.4-100.0%)	100.0% (95.4-100.0%)
	Other	83.3% (61.8-94.5%)	62.3% (48.9-74.1%)	83.3% (50.9-97.1%)
	Unspecified	100.0% (5.0-100.0%)	100.0% (5.0-100.0%)	NA
	All	**95.1%** (94.6-95.6%)	**81.6%** (77.4-85.2%)	**98.4%** (93.6-99.7%)


Operative approach for the most frequently-performed operations (n=6,612)
Primary procedures
Revisions
Percentage of operations carried out laparoscopically
100%
80%
60%
40%
20%
0%
Gastric band
Roux-en-Y gastric bypass
Sleeve gastrectomy
Revisional gastric band
Operation

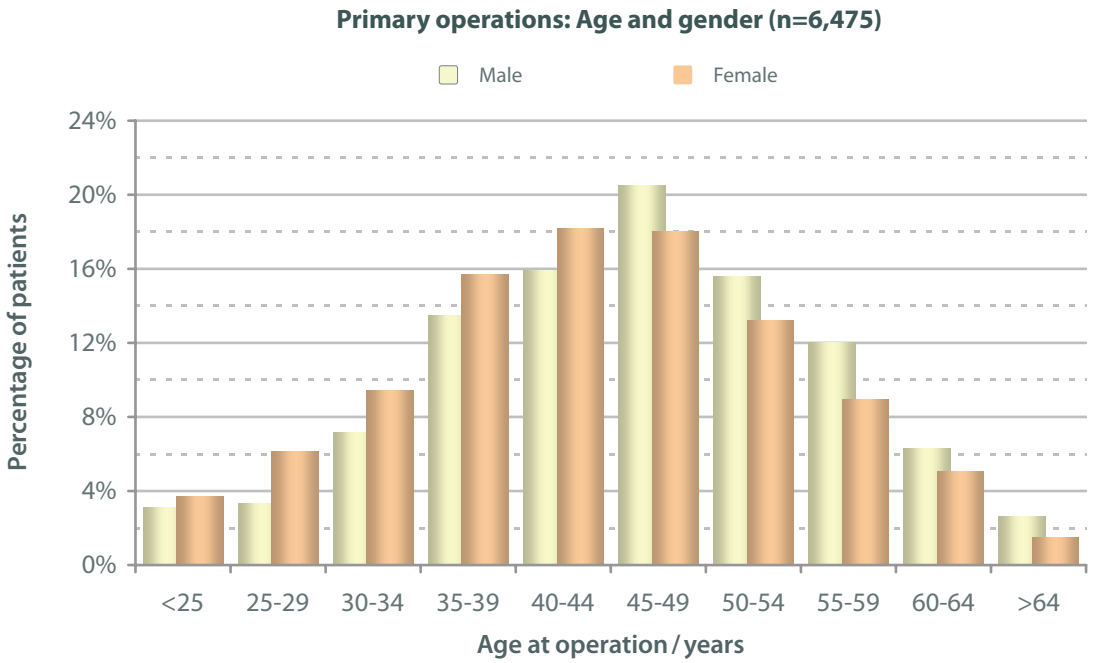
Gender

Age and gender

The NBSR data demonstrate that four-fifths of patients are women. This almost exactly mirrors the male-female ratio in nearly every other reported series worldwide. The reasons for this gender bias are not fully understood.

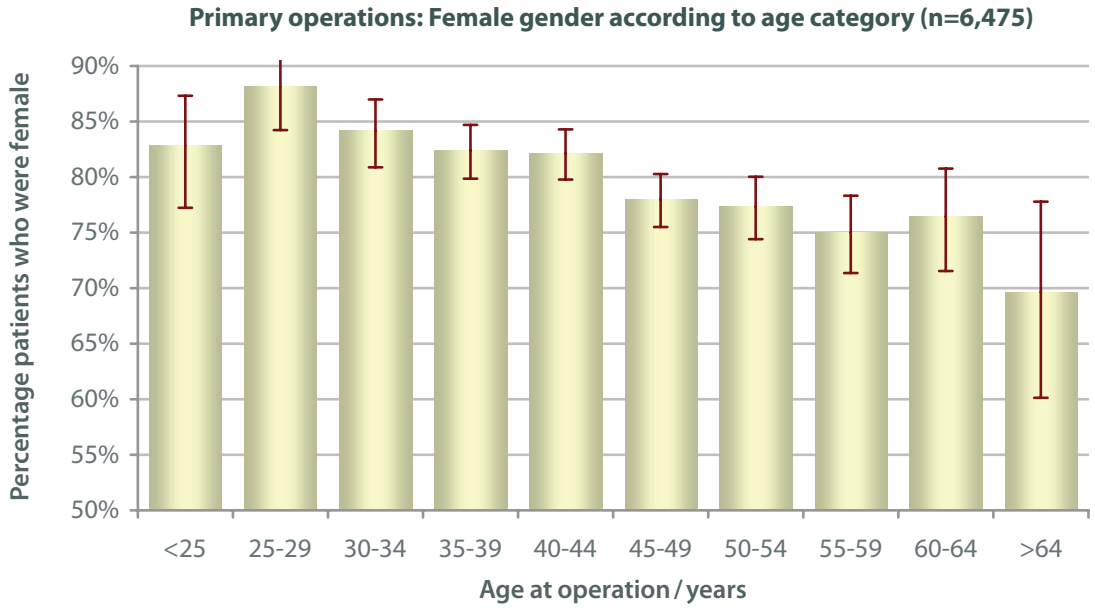
Primary operations: age and gender distributions

		Gender				
		Male	Female	Unspecified	**All**	Proportion female
Age at operation / years	<25	40	193	0	**233**	82.8%
	25-29	43	319	0	**362**	88.1%
	30-34	92	489	0	**581**	84.2%
	35-39	174	815	0	**989**	82.4%
	40-44	205	943	0	**1,148**	82.1%
	45-49	264	935	0	**1,199**	78.0%
	50-54	201	686	0	**887**	77.3%
	55-59	155	465	0	**620**	75.0%
	60-64	81	263	0	**344**	76.5%
	>64	34	78	0	**112**	69.6%
	Unspecified	3	5	0	**8**	62.5%
	All	**1,292**	**5,191**	**0**	**6,483**	80.1%



Transforming the data allows us to demonstrate that there is a significant decrease in the proportion of female patients with increasing age (there is significant variation in the gender profile with age: $\chi^2 \Rightarrow p<0.001$), excluding patients in the <25 year-old age-bracket. In general, the rate falls from 88.1% female patients in the 25-29 year-olds to 62.5% in the >64 year-old group (there is also a significant difference in gender when comparing patients ≤44 years of age versus >44 years of age: $\chi^2 \Rightarrow p<0.001$).

This clearly suggests that women are more likely to come for surgery at an earlier age, for any number of reasons: perhaps there are more cultural drivers for women to want to reduce their weight, perhaps because they are more prepared to fund their surgery, perhaps they wish to start or extend their families. Whatever the reasons, bariatric surgeons are dealing with more women than men, and studies in other surgical specialties have shown that women are sometimes at greater risk of adverse events following surgery.

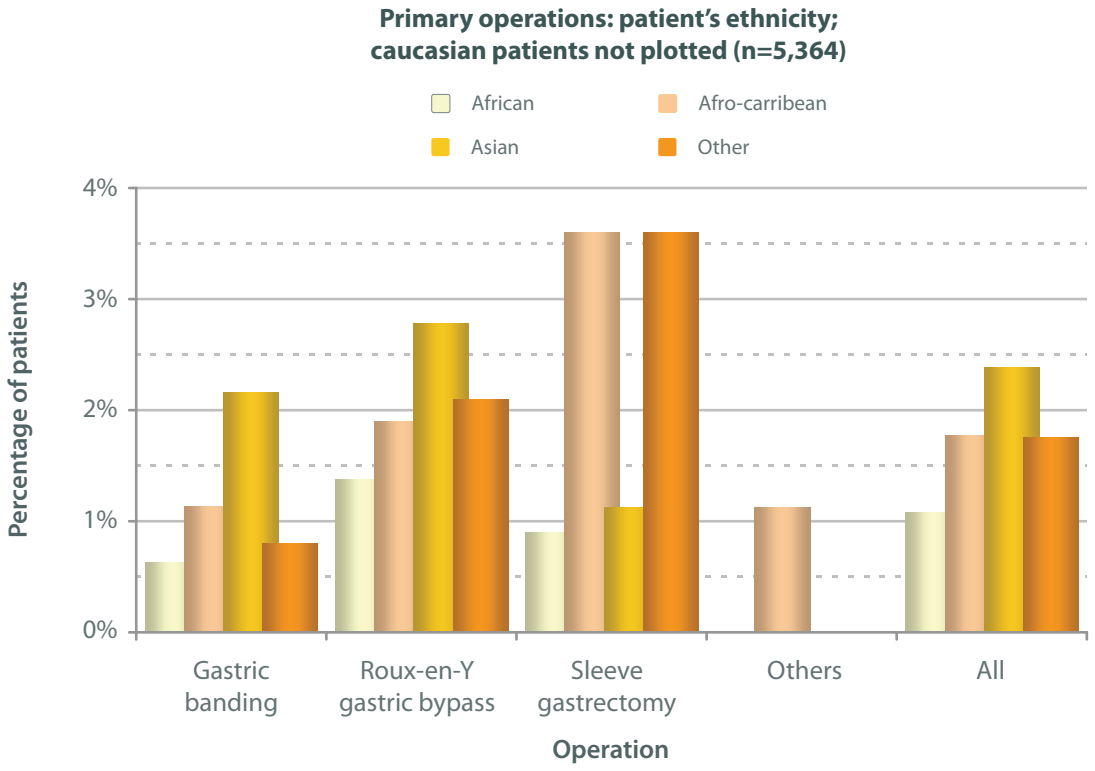


Ethnicity

These data from the NBSR are preliminary results from what is in truth a very small subset of the whole cohort of patients with severe obesity. At first sight, many ethnic groups are under-represented in terms of frequency of surgery, but, as more data are accumulated in the NBSR , the frequency of comorbidities in these groups will become more apparent.

Primary operations: patient's ethnicity

		Ethnicity						
		African	Afro-carribean	Asian	Caucasian	Others	Unspecified	All
Operation	Gastric band	11	20	38	1,676	14	372	**2,131**
	Roux-en-Y gastric bypass	42	58	85	2,804	64	573	**3,626**
	Sleeve gastrectomy	4	16	5	403	16	99	**543**
	Duodenal switch	0	0	0	0	0	0	**0**
	Duodenal switch + sleeve	0	0	0	1	0	1	**2**
	Bilio-pancreatic diversion	0	0	0	1	0	0	**1**
	Gastric balloon	0	1	0	68	0	43	**112**
	Other	0	0	0	18	0	7	**25**
	Unspecified	1	0	0	18	0	24	**43**
	All	**58**	**95**	**128**	**4,989**	**94**	**1,119**	**6,483**



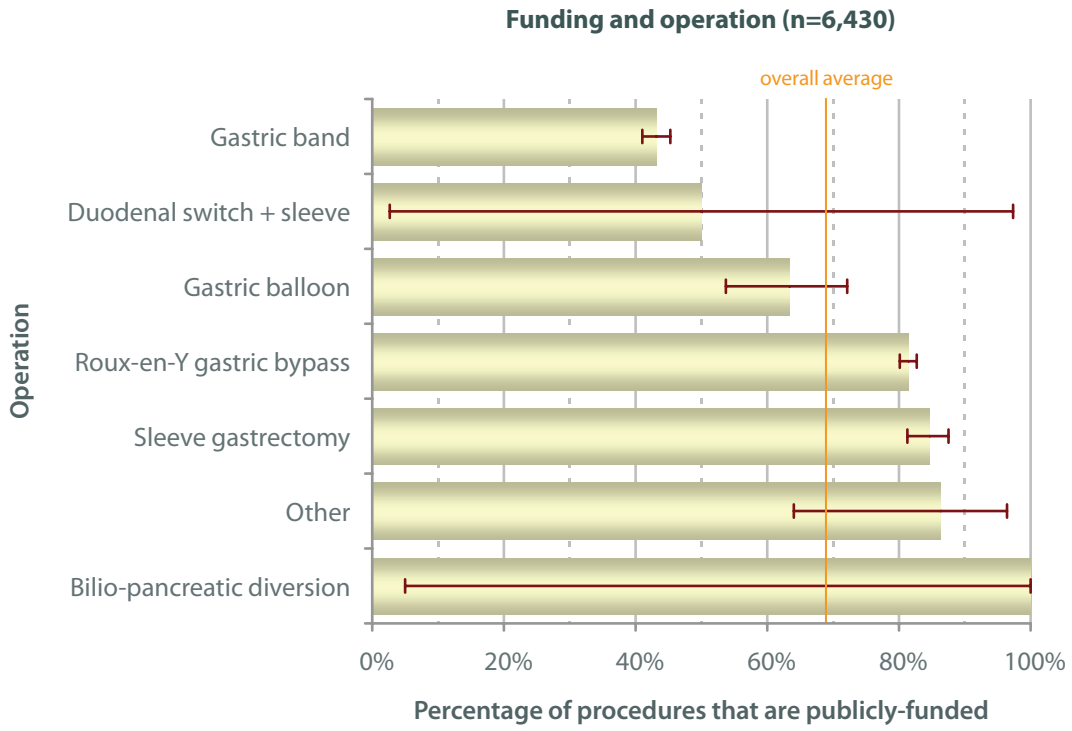
Funding

Funding and operation

On average 68.8% of procedures were publicly-funded; for the three most common procedures, this ranges from 43.1% for gastric banding procedures to 81.4% for Roux-en-Y gastric bypass & 84.7% for sleeve gastrectomy.

Type of operation and source of funding

		Funding				
		Publicly funded	Self-pay	Private insurer	Unspecified	All
Operation	Gastric band	917	1,207	2	5	**2,131**
	Roux-en-Y gastric bypass	2,924	653	13	36	**3,626**
	Sleeve gastrectomy	458	82	1	2	**543**
	Duodenal switch	0	0	0	0	**0**
	Duodenal switch + sleeve	1	1	0	0	**2**
	Bilio-pancreatic diversion	1	0	0	0	**1**
	Revisional gastric band	0	0	0	0	**0**
	Gastric balloon	71	40	1	0	**112**
	Other	19	3	0	3	**25**
	Unspecified	33	3	0	7	**43**
	All	**4,424**	**1,989**	**17**	**53**	**6,483**



Funding, age and gender

There is a great deal of information in this table. It reminds us that there are four times as many women as men coming to bariatric surgery. It also demonstrates that the ratio of publicly funded to privately funded surgery is almost 4:1 for male patients as opposed to only 2:1 for female patients; this is a significant difference ($\chi^2 \Rightarrow p<0.001$). In the light of the fact that the rates of obesity are currently almost identical for men and women in the United Kingdom (see page 19), this result begs two questions: firstly, why do men come for bariatric surgery so less frequently than women and, secondly, why are men less prepared to fund their own surgery?

For the female population, there is a slight increase in the proportion of operations that are publicly funded with increasing age, whereas amongst the male patients there is a distinct difference in the rate of publicly funded surgery for those under the age of 35 (*circa* 65%) and those 35 years of age and older (*circa* 80%).

This speaks of issues around patient choice and / or gender-specific barriers to accessing bariatric surgery, and possibly to risk-averse behaviour on the part of the male population in the United Kingdom, although there are no firm data to support these assertions. There is some evidence here, however, that publicly-funded provision is being restricted, at least in part, to older patients, who, in general, have more obesity-related comorbidity.

Primary operations: source of funding according to age and gender

		Gender and funding					
		Male			Female		
		Publicly funded	Privately funded	Unspecified	Publicly funded	Privately funded	Unspecified
Age at operation	<25	26	14	0	96	96	1
	25-29	28	15	0	199	118	2
	30-34	60	31	1	318	165	6
	35-39	142	31	1	544	267	4
	40-44	160	44	1	601	334	8
	45-49	211	52	1	630	296	9
	50-54	163	34	4	468	210	8
	55-59	127	26	2	323	142	0
	60-64	66	15	0	182	79	2
	>64	28	6	0	46	29	3
	Unspecified	2	1	0	4	1	0
	All	**1,013**	**269**	**10**	**3,411**	**1,737**	**43**

Primary operations: Source of funding, age and gender (n=6,422)

Height, weight and body mass index

Height and gender

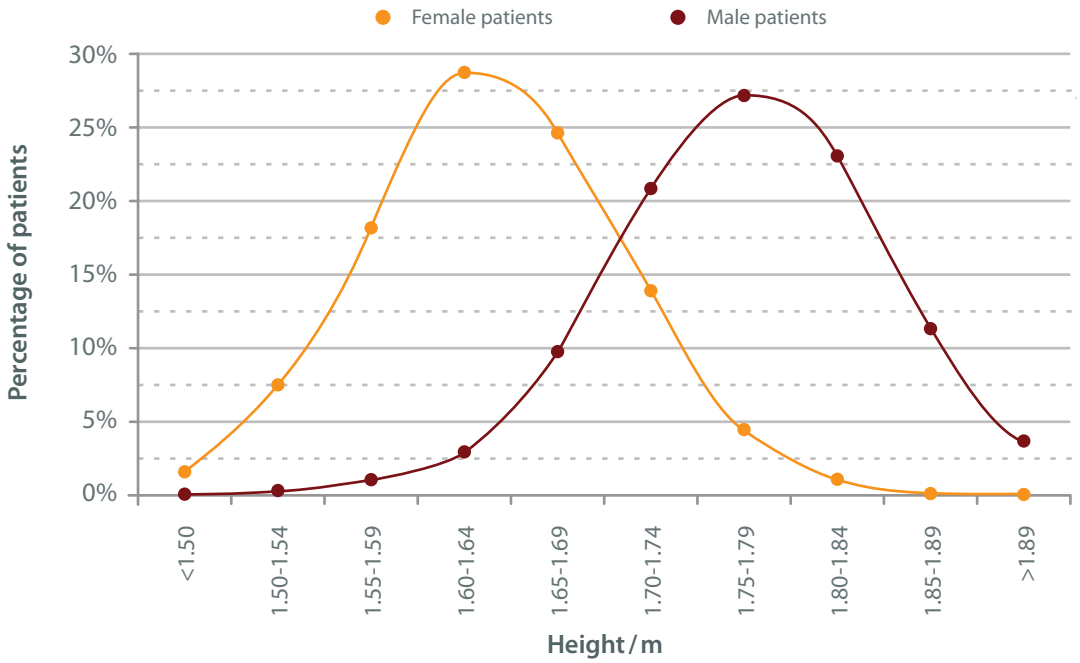
This analysis clearly shows that the male and female patients coming for bariatric surgery are very different in terms of their height: on average, the male patients are significantly taller than the female patients.

This height distribution is exactly what one would expect when comparing men's and women's heights in the general population from the United Kingdom (Health Survey for England 2008: average height for men was 1.753 m and 1.616 m for women). On average, taller people tend to be heavier than their shorter compatriots, so simply comparing people's mass is problematic, hence the need for more sophisticated comparisons.

Primary operations: height and gender distributions

		Gender			
		Male	Female	Unspecified	All
Height / m	<1.50	1	79	0	**80**
	1.50-1.54	4	371	0	**375**
	1.55-1.59	13	898	0	**911**
	1.60-1.64	36	1,420	0	**1,456**
	1.65-1.69	119	1,217	0	**1,336**
	1.70-1.74	254	687	0	**941**
	1.75-1.79	331	221	0	**552**
	1.80-1.84	281	54	0	**335**
	1.58-1.89	138	6	0	**144**
	>1.89	45	3	0	**48**
	Unspecified	70	235	0	**305**
	All	**1,292**	**5,191**	**0**	**6,483**

Primary operations: Height and gender distributions (n=6,178)



Weight and gender

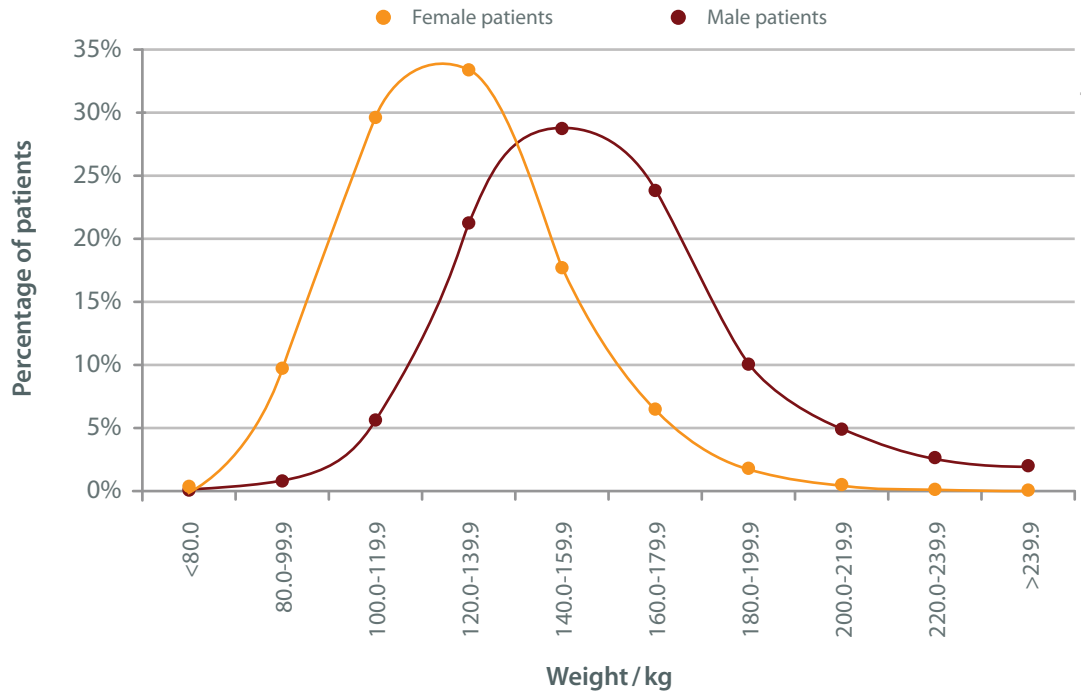
As would be expected, the distribution of initial weight for patients in the NBSR are quite unlike those for the general populations: these men and women have a much higher body mass compared to the nation's average (Health Survey for England: in 2008 the average weight for an adult man was 83.6 kg, and 70.2 kg for an adult woman).

Only by using a body mass index calculation, is it possible to estimate the excess weight for each patient, *i.e.,* the extent to which the individual's weight exceeds a pre-defined norm, given their height.

Primary operations: weight and gender distributions

		Gender			
		Male	Female	Unspecified	All
Weight / kg	<80.0	1	19	0	**20**
	80.0-99.9	10	490	0	**500**
	100.0-119.9	70	1,496	0	**1,566**
	120.0-139.9	264	1,680	0	**1,944**
	140.0-159.9	357	891	0	**1,248**
	160.0-179.9	296	327	0	**623**
	180.0-199.9	125	91	0	**216**
	200.0-219.9	61	26	0	**87**
	220.0-239.9	33	7	0	**40**
	>239.9	25	4	0	**29**
	Unspecified	50	160	0	**210**
	All	**1,292**	**5,191**	**0**	**6,483**

Primary operations: Weight and gender distributions (n=6,273)



Body mass index and gender

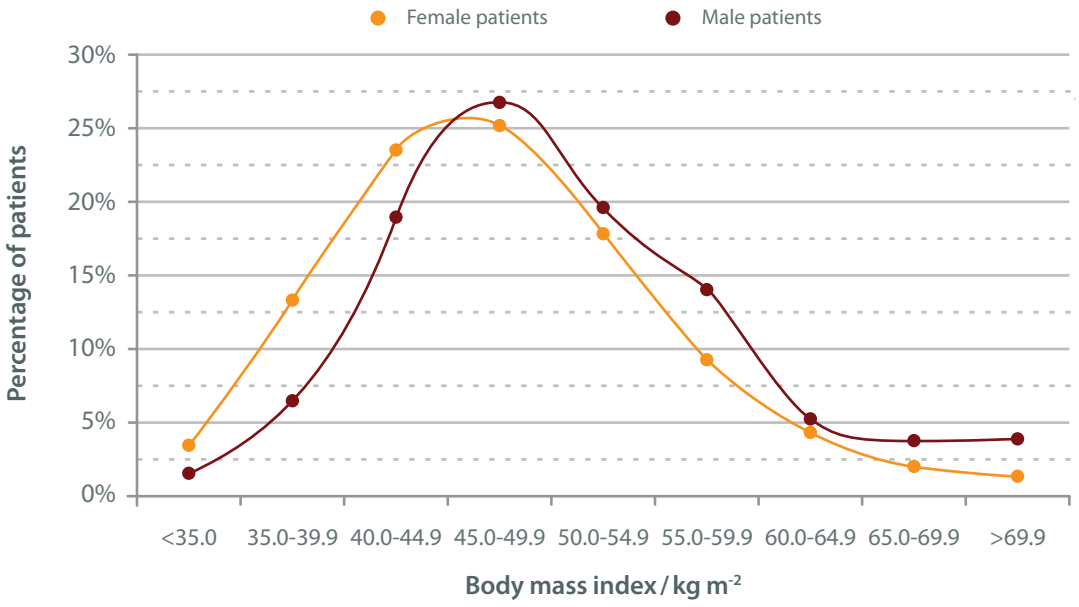
The known differences in height between men and women is one of the reasons clinicians need a measure like the body mass index, which is a value derived from a person's height and weight according to the formula previously described on page 32. The body mass index allows us to evaluate weight with reference to predetermined norms, and allows us to compare men and women on a sensible basis.

This analysis shows that the relative distributions of body mass index for male and female patients undergoing bariatric surgery are less divergent than the height distributions for the same groups. However, there are still significantly more men in the higher BMI groupings, *i.e.*, men undergoing bariatric surgery are, as a group, generally more over-weight ($\chi^2 \Rightarrow p<0.001$).

Primary operations: body mass index and gender distributions

		Gender			
		Male	Female	Unspecified	All
Body mass index / kg m^{-2}	<35.0	19	171	0	**190**
	35.0-39.9	79	658	0	**737**
	40.0-44.9	231	1,162	0	**1,393**
	45.0-49.9	326	1,244	0	**1,570**
	50.0-54.9	239	881	0	**1,120**
	55.0-59.9	171	458	0	**629**
	60.0-64.9	64	214	0	**278**
	65.0-69.9	46	100	0	**146**
	>69.9	47	67	0	**114**
	Unspecified	70	236	0	**306**
	All	**1,292**	**5,191**	**0**	**6,483**

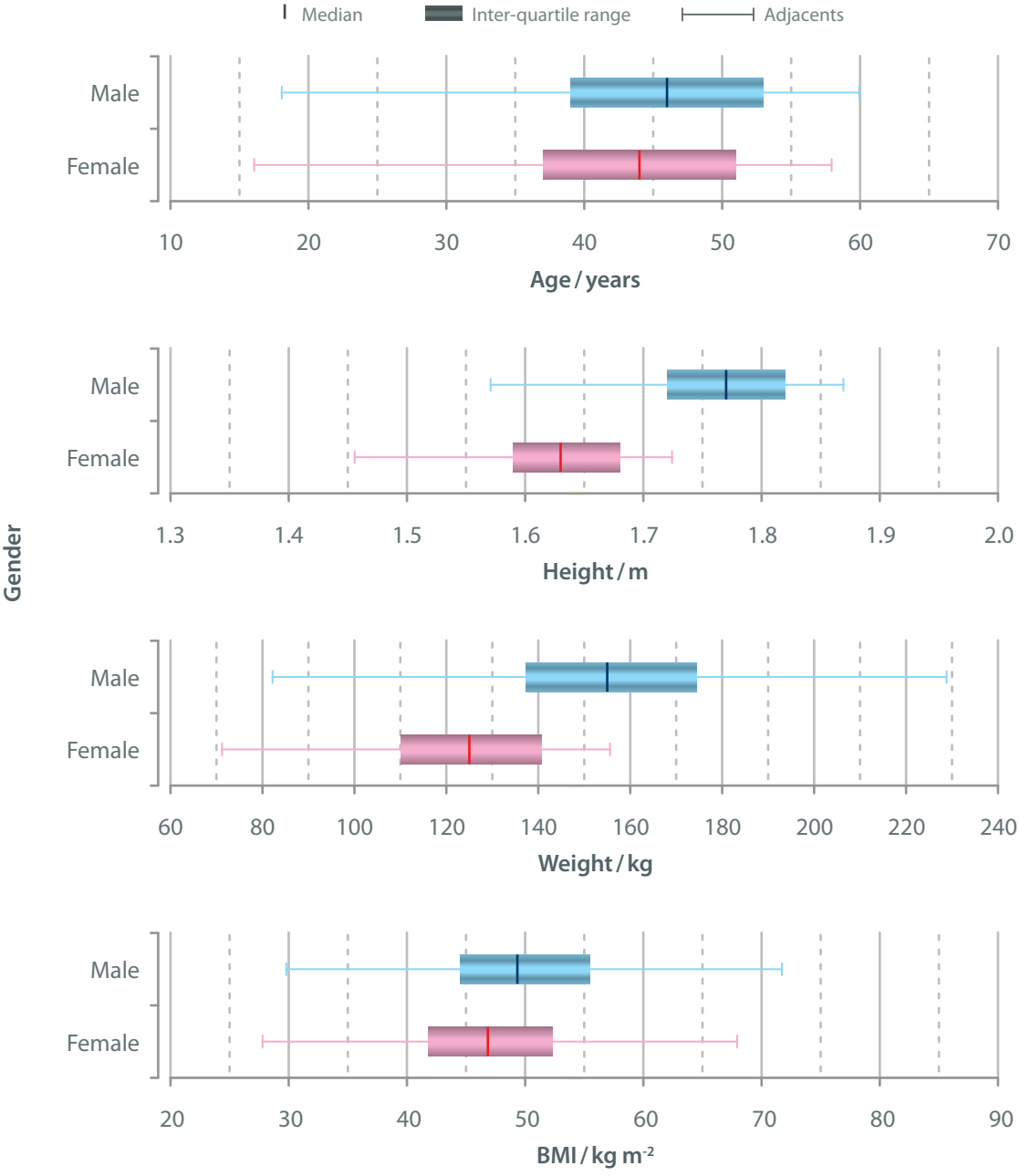
Primary operations: BMI and gender distributions (n=6,177)



Summary statistics on age, height, weight and BMI for patients undergoing a primary operation

		Count	Average	Median	Range (min-max)	IQR (Lower-Upper)
Age at surgery (years)	Male	1,289	45.8	46	15 – 72	39 – 53
	Female	5,186	43.5	44	16 – 74	37 – 51
Height (m)	Male	1,222	1.769	1.77	1.48 – 1.98	1.72 – 1.82
	Female	4,956	1.633	1.63	1.28 – 1.91	1.59 – 1.68
Weight (kg)	Male	1,242	158.5	155.0	75.0 – 338.0	137.4 – 174.4
	Female	5,031	127.2	125.0	71.0 – 273.1	110.2 – 140.6
BMI (kg m^{-2})	Male	1,222	50.6	49.3	22.4 – 103.5	44.5 – 55.5
	Female	4,955	47.7	46.8	27.7 – 100.2	41.8 – 52.3

Primary operations: Basic statistics on age, height, weight & BMI and gender



Body mass index, operation and gender

The following chart and table present data for the three most-commonly recorded procedures in the registry; the analyses have segmented body mass index into 10 kg m^{-2} groups that start at <40.0 kg m^{-2} and extend up to >69.9 kg m^{-2}; these groupings were chosen simply because they generate analyses that provide as much information as possible, with as much economy as possible.

The chart shows that there are considerably more female patients in the smaller BMI groups than men for each procedure type, suggesting that women come to surgery earlier in the disease process than men, irrespective of the type of surgery they eventually elect to undergo.

It is also apparent that irrespective of gender, patients having a Roux-en-Y gastric bypass procedure have, on average, a greater BMI than patients having a gastric band, and that sleeve gastrectomy patients, on average, have an even higher BMI. This implies that gastric banding is a procedure that is deemed suitable for the patients in the early stages of their disease, whereas for patients with a greater body mass index, with more extensive excess-weight and, concomitantly, with more obesity-related comorbid conditions, a more definitive and long-term solution is indicated.

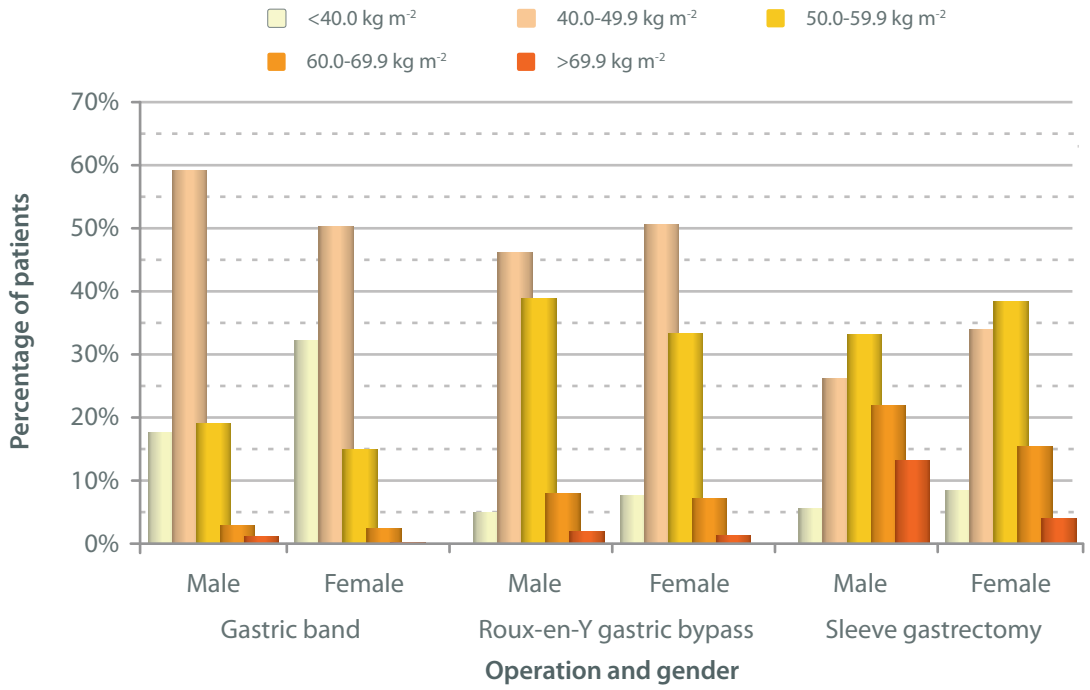
Primary operations: body mass index, operation and gender

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	48	161	52	8	3	22
		Roux-en-Y gastric bypass	37	348	295	60	15	27
		Sleeve gastrectomy	9	42	53	35	21	7
		Gastric balloon	4	5	5	5	4	9
		Other	0	0	2	1	4	1
		Unspecified	0	1	3	1	0	4
	Female	Gastric band	565	881	261	42	2	86
		Roux-en-Y gastric bypass	207	1,386	912	196	36	107
		Sleeve gastrectomy	30	121	137	55	14	19
		Duodenal switch + sleeve	0	1	0	0	0	1
		Bilio-pancreatic diversion	0	0	1	0	0	0
		Gastric balloon	23	6	14	17	12	8
		Other	3	4	4	1	1	4
		Unspecified	1	7	10	3	2	11

Primary operations: average body mass index (and standard error), operation and gender

		Gender					
		Male		Female		All	
Operation	Gastric band	46.3	(0.44)	43.8	(0.17)	**44.2**	**(0.16)**
	Roux-en-Y gastric bypass	50.6	(0.28)	49.3	(0.14)	**49.6**	**(0.13)**
	Sleeve gastrectomy	56.5	(0.90)	52.2	(0.49)	**53.5**	**(0.45)**
	Duodenal switch + sleeve	NA		42.8	(0.00)	**42.8**	**(0.00)**
	Bilio-pancreatic diversion	NA		53.5	(0.00)	**53.5**	**(0.00)**
	Gastric balloon	54.7	(3.30)	52.6	(1.95)	**53.1**	**(1.68)**
	Other	69.9	(5.02)	50.6	(3.86)	**57.3**	**(3.67)**
	Unspecified	53.1	(2.99)	52.4	(2.41)	**52.5**	**(2.04)**

Primary operations: Operation, gender and body mass index (n=6,032)



Body mass index, operation and funding

The following charts show that patients whose surgery is publicly-funded have a significantly greater BMI than their privately-funded counterparts ($p<0.001$), which is largely accounted for by the fact that women who undergo publicly-funded surgery have a significantly higher BMI than the women who fund their own surgery ($p<0.001$).

The reasons for the these observations are not entirely clear, but one possible explanation could be the higher thresholds for access to surgery for publicly-funded patients [1].

Primary operations: body mass index, operation and source of funding

			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	75	477	228	36	4	97
		Roux-en-Y gastric bypass	119	1,362	1,058	223	46	116
		Sleeve gastrectomy	11	130	174	85	34	24
		Duodenal switch + sleeve	0	0	0	0	0	1
		Bilio-pancreatic diversion	0	0	1	0	0	0
		Gastric balloon	0	2	16	22	14	17
		Other	1	4	5	2	5	2
		Unspecified	1	6	12	4	2	8
	Privately funded	Gastric band	537	564	85	13	1	9
		Roux-en-Y gastric bypass	124	355	142	31	5	9
		Sleeve gastrectomy	28	33	15	5	1	1
		Duodenal switch + sleeve	0	1	0	0	0	0
		Gastric balloon	27	9	3	0	5	0
		Other	2	0	0	0	0	1
		Unspecified	0	1	0	0	0	2

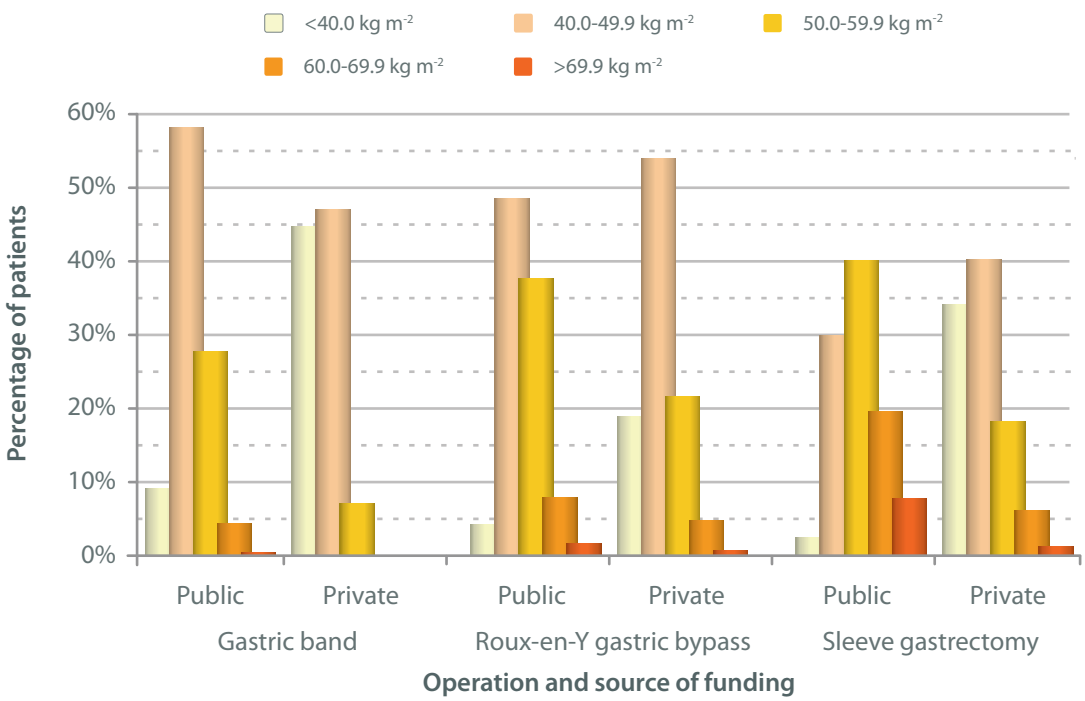
Primary operations: average BMI (count; 95% CI) for selected operations according to the source of funding

		Funding		
		Publicly funded	Private	p [i]
Operation	Gastric band	47.7 (674; 3.11)	41.4 (1,074; 2.19)	0.197
	Roux-en-Y gastric bypass	50.1 (2,165; 2.17)	46.2 (551; 4.60)	0.271
	Sleeve gastrectomy	53.9 (296; 8.74)	43.9 (60; 13.24)	0.305
	All	**50.6 (4,159; 1.98)**	**43.2 (1,984; 2.30)**	**<0.001**

iIndependent samples t-test

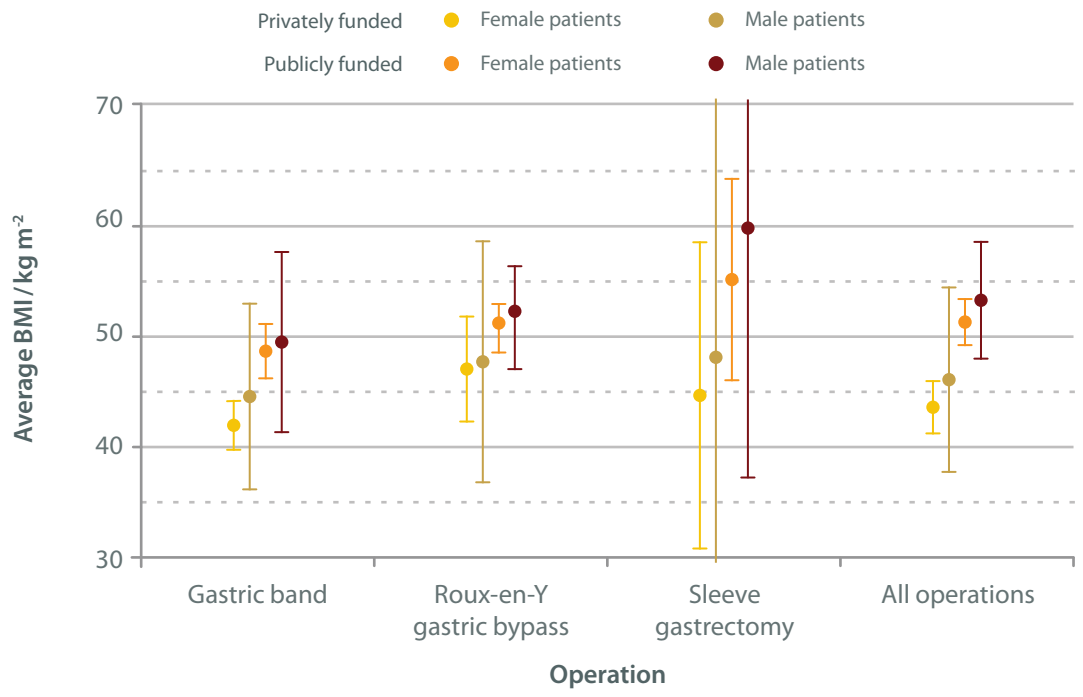
1. McCartney M. Slimmed down surgery. *BMJ.* 2010; **341:** c5499.

Primary operations: Operation, funding and body mass index (n=6,001)



There is a significantly lower average BMI for women choosing to have privately funded surgery as opposed to the women having publicly funded treatment ($p<0.001$), but no other comparisons attain significance.

Primary operations: Average BMI (with 95% confidence intervals) and operation for publicly and privately funded procedures



Weight-loss prior to surgery

A *initial BMI* is calculated from the patient's weight at first consultation. This is the first BMI entry into the database. Surgeons then have the option of also entering the patient's weight at the point immediately before surgery, which, then enables us to estimate weight loss prior to surgery.

These data show that there are a substantial number of patients who lose weight, in some cases a significant amount of weight, prior to surgery. These are the first international data to show that Bariatric Care Teams have successfully used strategies to help patients lower their BMI before surgery. However, it is not universal practice to apply this strategy, although having a BMI over 50 kg m^{-2} is considered to be an independent risk factor for post-operative complications and mortality following gastric bypass [1]. The fact that some patients gain weight needs to be seen in this light.

Primary operations: pre-procedure excess weight change

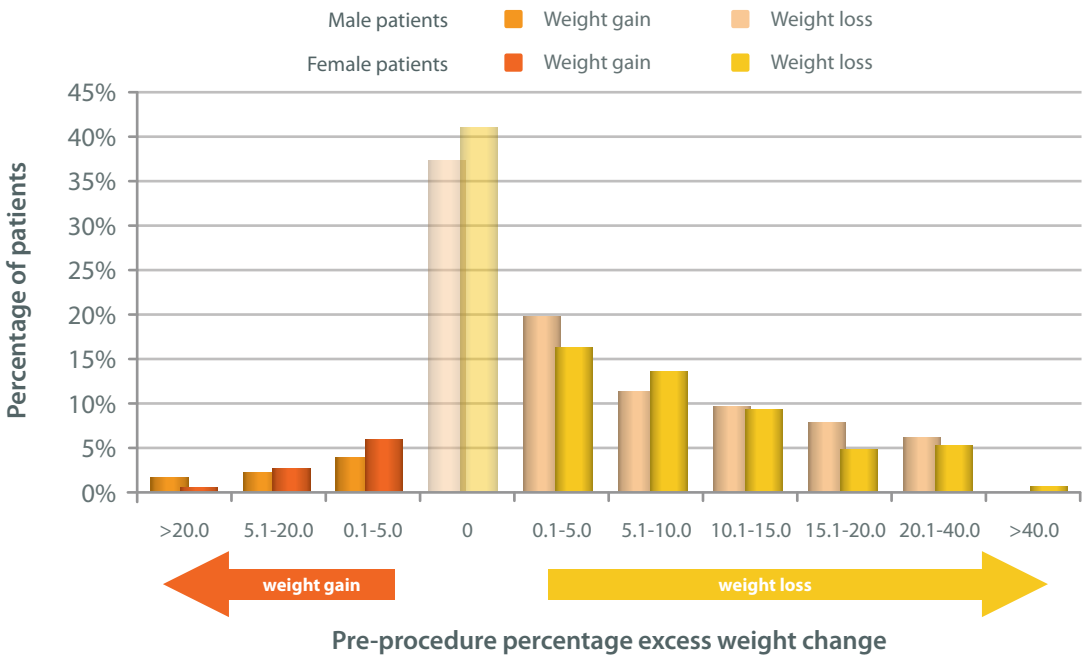
		Operation							
		Gastric band	Roux-en-Y gastric bypass	Sleeve gastrectomy	Duodenal switch with sleeve	Bilio-pancreatic diversion	Gastric balloon	Other	Unspecified
Excess weight change / %	>20.0 % gain	9	17	2	0	0	3	0	0
	5.1-20.0% gain	36	106	21	0	0	1	3	0
	0.1-5.0% gain	79	183	39	0	0	5	4	0
	No change	559	881	112	0	0	24	6	0
	0.1-5.0% loss	231	420	73	0	1	10	1	0
	5.1-10.0% loss	183	381	57	0	0	4	2	0
	10.1-15.0% loss	129	285	45	1	0	5	0	0
	15.1-20.0% loss	71	166	25	0	0	2	0	0
	20.1-40.0% loss	75	205	24	0	0	0	1	0
	>40.0% loss	8	14	1	0	0	0	0	0
	Unspecified	751	968	144	1	0	58	8	43
	All	**2,131**	**3,626**	**543**	**2**	**1**	**112**	**25**	**43**
	Average loss	4.4%	5.3%	4.6%	10.1%	0.1%	-1.4%	0.7%	
	95% CI	±0.04%	±0.04%	±0.09%	NA	NA	±0.95%	±0.25%	

Overall 50.5% of gastric banding patients and 55.3% of Roux-en-Y gastric bypass patients lose some weight before surgery. In contrast, 49.5% and 44.7% respectively fail to lose any weight before surgery, and in fact 9.0% and 11.5% respectively actually gain weight. Although the so-called *liver diet* is widely-considered important immediately prior to surgery, these are the first national registry data to demonstrate results from real-world practice of encouraging bariatric surgery patients to lose weight before their surgery. The average excess weight loss achieved before surgery in those who lost weight was 10.5%. Overall the increase in excess weight amongst those who gained weight was 7.2 %.

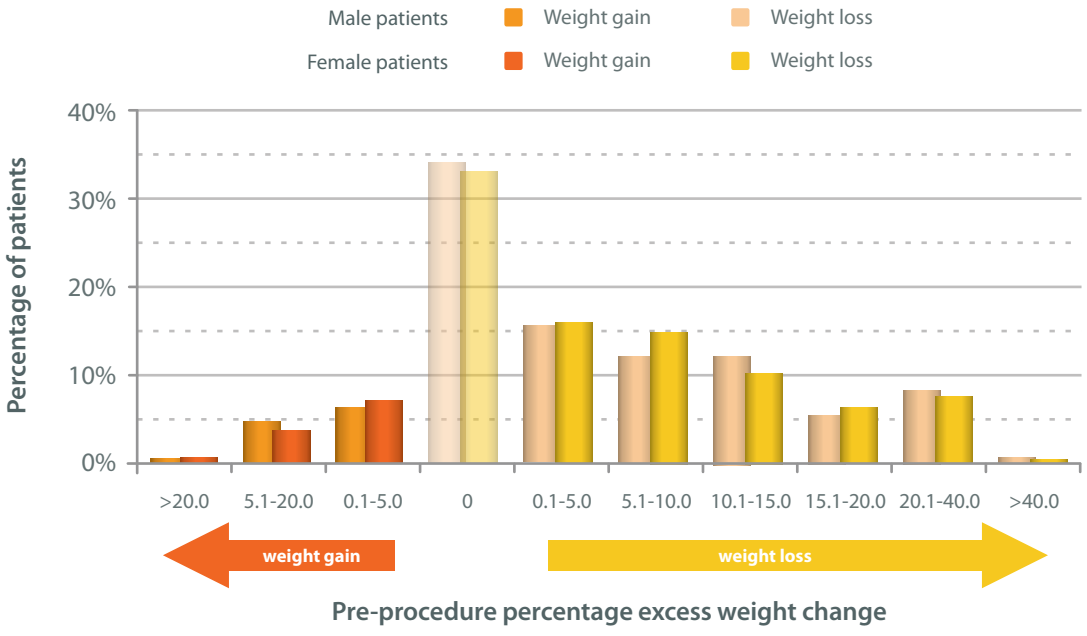
In future reports we should be able to determine whether or not weight loss immediately before surgery has an impact upon surgical complication rates and / or long-term weight loss.

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 and Related Diseases.* 2007; **3(2):** 134-40.

**Primary gastric band procedures:
Excess weight change prior to surgery (n=1,380)**

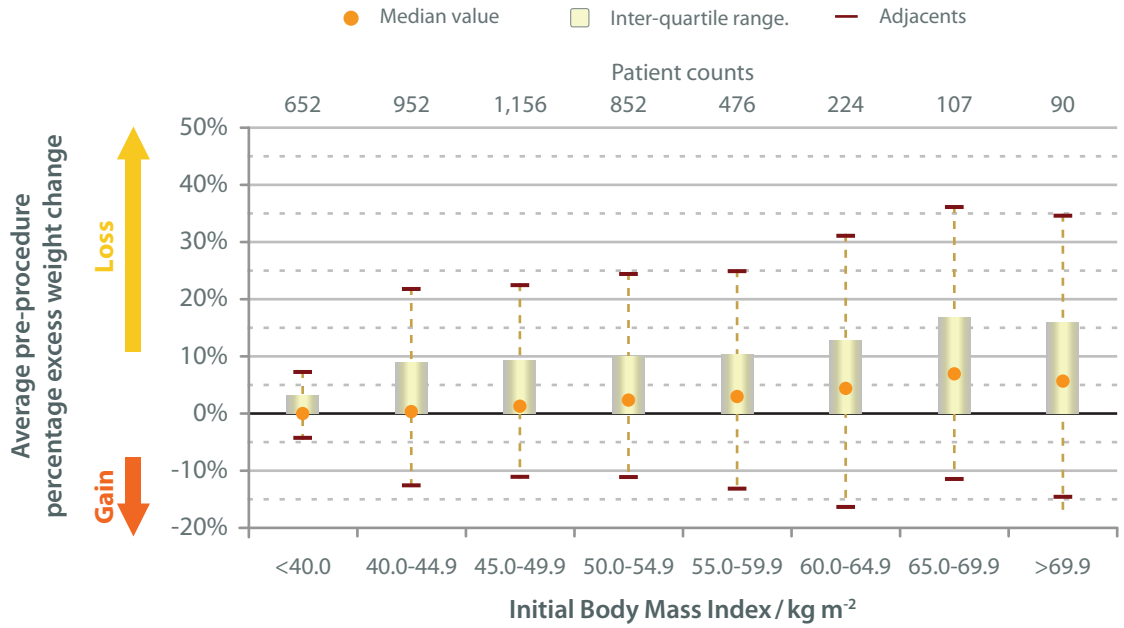


**Primary Roux-en-Y gastric bypass operations:
Excess weight change prior to surgery (n=2,658)**



The chart clearly shows that there is a relationship between the *initial BMI* and the extent of weight-loss before surgery (ANOVA $p<0.001$). This is in keeping with attempts to help patients get ready for surgery, to reduce their anaesthetic and surgical risk.

Primary procedures: Excess weight change prior to surgery and initial BMI (n=4,509)



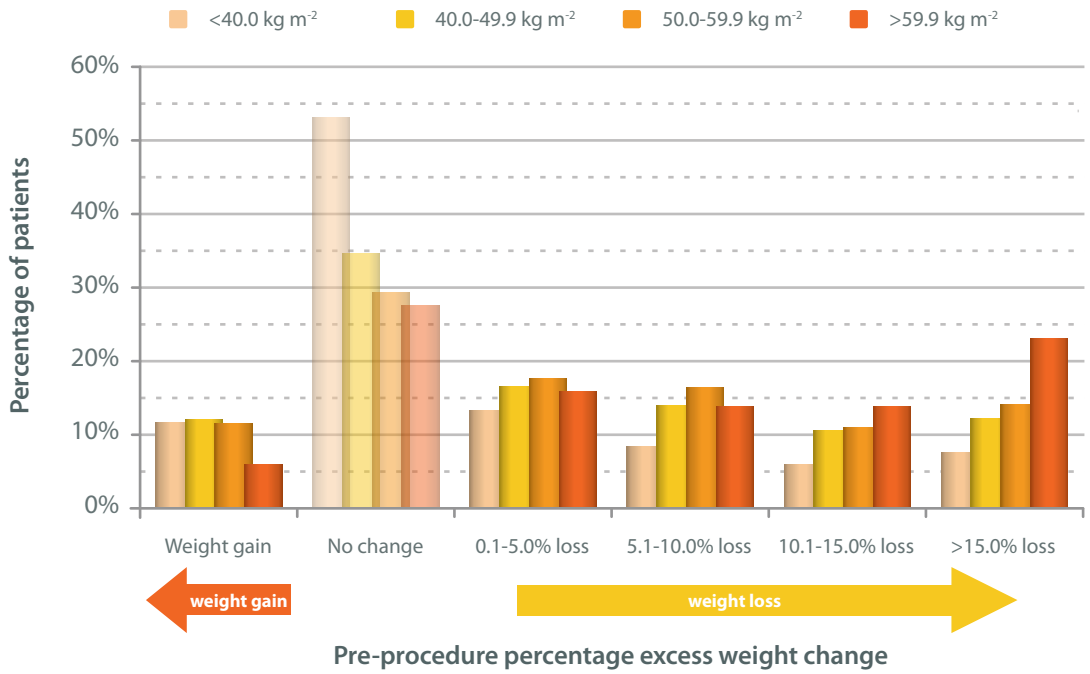
Further analysis of the excess-weight-loss data show that the patients with the lowest initial BMI are more likely to gain weight prior to surgery than patients with a higher BMI. In fact, as BMI increases it seems that fewer patients gain weight before surgery, and more & more patients lose >15% of their excess weight.

The likely, but unproven, explanation for this is that Bariatric Care Teams are trying to reduce the operative risk in the highest risk patients by reducing their BMI before surgery.

Primary operations: pre-procedure excess weight change and initial body mass index

Excess weight change / %	Initial Body Mass Index / kg m^{-2}				
	<40.0	40.0-49.9	50.0-59.9	>59.9	Unspecified
Weight gain	76	254	153	25	0
No change	347	730	389	116	0
0.1-5.0% loss	87	348	234	67	0
5.1-10.0% loss	55	296	218	58	0
10.1-15.0% loss	39	222	146	58	0
>15.0% loss	49	258	188	97	0
Unspecified	274	855	421	117	306
All	**927**	**2,963**	**1,749**	**538**	**306**

Primary procedures: Excess weight change prior to surgery and initial BMI (n=4,510)



Comorbidities

As noted in the introduction, comorbidity is a term generally used to describe concomitant disease. In the obese population, this disease is usually directly a consequence of the obese state: the greater the body mass index the greater the prevalence of other medical problems [1]. These 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 shown by the inability to climb stairs.

The sheer burden of obese-related disease shown in this report is one of its main findings and belies a popular notion that bariatric surgery is an easy option or *just cosmetic surgery*. No one chooses to be diabetic or not to be able to climb stairs – if dieting were the answer then few would remain obese.

There are 3 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) [2].

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 an 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 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. Only as time passes will we know whether or not we have the balance right.

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 II or III.
- after much deliberation only observational data on diabetes treatment are included since there is no medical consensus on definitions or treatment of diabetes or of remission. This approach also reflects, again, the resource implications needed for more detailed data entry and audit *versus* research.
- some of the comorbidities, such as functional status, are categorical and therefore could generate 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 record will generate an Obesity Surgery Mortality Risk Score (de Maria) 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 stratified for risk 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 is 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 [3]. 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 some PCTs failing to follow NICE guidance at all [3,4]. The 3,642 patients who had surgery in NHS England in 2009-2010 represent a small fraction, 0.33%, of those eligible opting for surgery if all PCTs were to adopt the guidance [5].

What can be done to encourage health commissioners to increase spending for bariatric surgery? The recent Office of Health Economics (OHE) report used a novel approach in which they estimated the expected gains arising from unemployed patients going back to work after surgery. The model found that if 25% of eligible patients (140,000) received surgery the boost to the GDP would total £1.3 billion due to increases in paid employment, with an additional £151 million being returned to the economy by reducing benefits costs. Further, recent data suggest that laparoscopic bariatric surgery for diabetes can pay for itself within 26 months simply by reducing medication costs alone [6]. If the additional economic factors are considered instead, surgery pays for itself within one year [5].

14 months after surgery patients had increased their paid hours worked by 57% and reduced their state benefit claims by 75% [7]. At least 3 other EU countries have shown increases in paid work after surgery [8,9,10]. Obese people also have higher rates of unemployment and consume an ever-expanding proportion of the healthcare budget [11,12]. It is hoped that cost-benefit analyses will convince commissioners of the benefits of bariatric surgery.

1. Belle SH *et al*. The Relationship of BMI with Demographic and Clinical Characteristics in the Longitudinal Assessment of Bariatric Surgery (LABS). *Surgery for Obesity and Related Diseases.* 2008; **4(4):** 474–480.
2. 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 and Related Diseases.* 2007; **3(2):** 134-40.
3. McCartney M. Slimmed down surgery. *BMJ.* 2010; **341:** c5499.
4. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, Clegg AJ. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technology Assessment.* 2009; **13(41):** 1-214.
5. Office of Health Economics. Shedding the pounds. 2010; www.rcseng.ac.uk / news / docs / BariatricReport.pdf.
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7. Hawkins SC, Osborne A, Finlay IG, Alagaratnam S, Edmond JR, Welbourn R. Paid work increases and state benefit claims decrease after bariatric surgery. *Obesity Surgery.* 2007; **17:** 434-7.
8. van Gemert WG, Adang EM, Greve JW *et al*. Quality of life assessment of morbidly obese patients: effect of weight-reducing surgery . *American Journal of Clinical Nutrition.* 1998; **67:** 197–201.
9. Narbro K, Agren G *et al*. Sick leave and disability pension before and after treatment for obesity: a report from the Swedish Obese Subjects (SOS) study. *International Journal of Obesity.* 1999; **23:** 619-624.
10. Andersen JR, Aasprang A, Bergsholm P, Sletteskog N, Våge V and Natvig GK. Health-Related Quality of Life and Paid Work Participation after Duodenal Switch. *Obesity Surgery.* 2010; **20:** 340-345.
11. Suhrcke M, McKee M, Arce RS, Tsolova S, Mortensen J *et al*. Investment in health could be good for Europe's economies. *BMJ.* 2006; **333:** 1017-1019.
12. Lenzer J. Obesity related illness consumes a sixth of the US healthcare budget. *BMJ.* 2010; **341:** c6014.

Missing data

Missing data is an almost inevitable consequence of the process of trying to collect comprehensive clinical data, but a consequence that 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: type 2 diabetes, hypertension, dyslipidaemia, atherosclerosis (cardiovascular), sleep apnoea, asthma, functional status, back or leg pain from arthritis, GORD, liver disease, depression and polycystic ovarian syndrome.

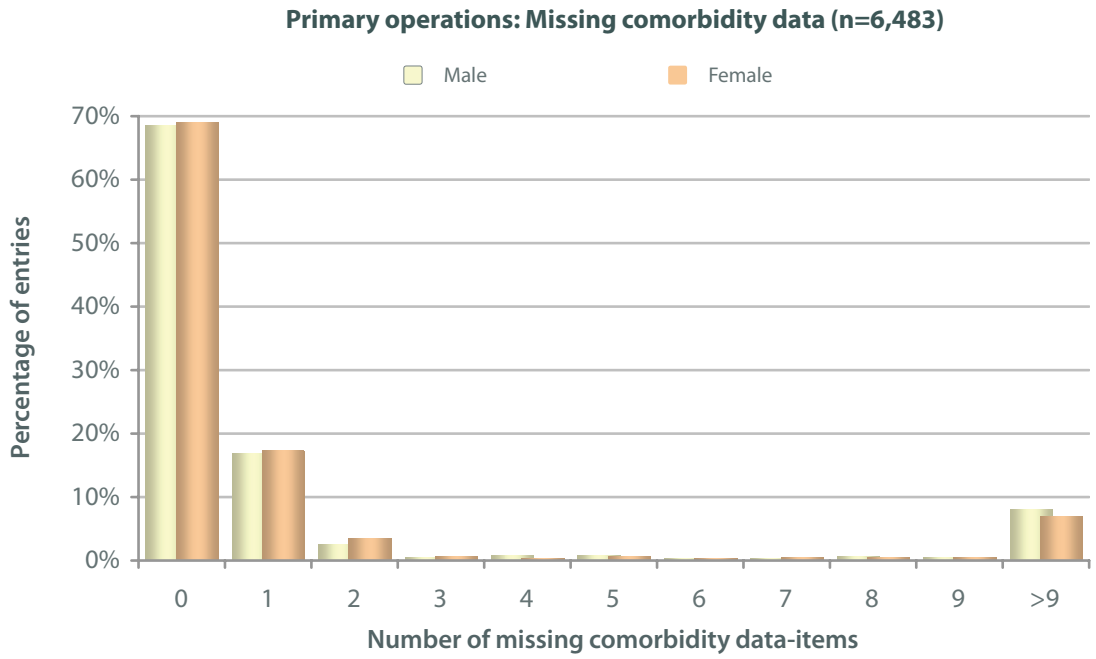
>68% of all records have no missing comorbidity data at all, and just under 17% have only one field missing. This is an astonishingly impressive achievement for a newly-developed registry, considering the number of operations for which data have been entered, and speaks of the commitment of the contributors to providing high-quality data, and to the acceptance of the NBSR as a valid and valuable dataset. The most-frequently missing *datum* in entries where only one data-item is unanswered is *Functional status* [1]. The reasons for this are not yet apparent.

When the NBSR Committee come to review this current dataset, as must happen as part of the general over-sight and good governance of the registry, missing data will be a major consideration that will inform decisions about which questions should be retained, edited or removed from the registry.

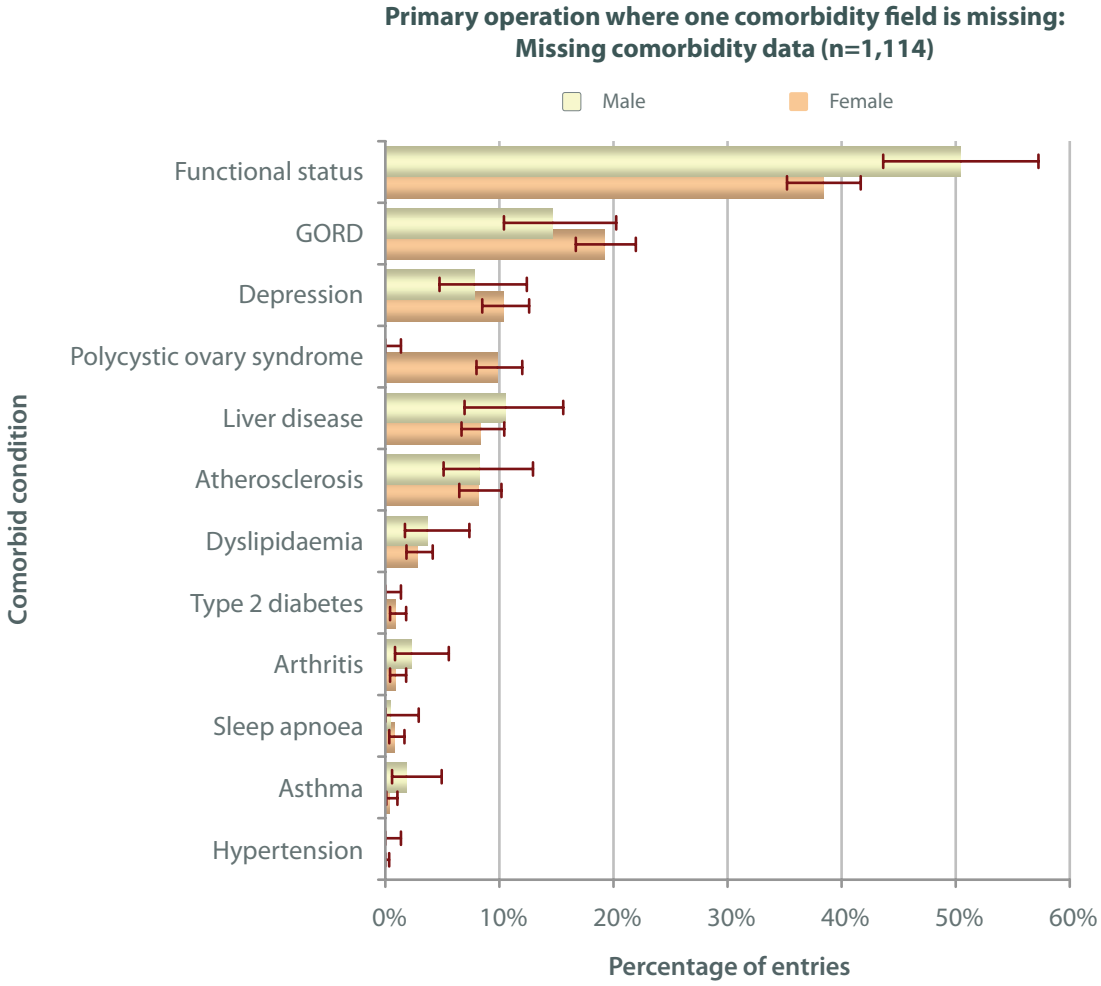
Primary operations: number of missing comorbidity data-items

		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Number of missing data-items [2]	0	886	68.6%	3,581	69.0%
	1	218	16.9%	896	17.3%
	2	32	2.5%	180	3.5%
	3	7	0.5%	36	0.7%
	4	10	0.8%	13	0.3%
	5	10	0.8%	34	0.7%
	6	5	0.4%	18	0.3%
	7	5	0.4%	21	0.4%
	8	9	0.7%	22	0.4%
	9	7	0.5%	28	0.5%
	10	3	0.2%	17	0.3%
	11	100	7.7%	17	0.3%
	12			328	6.3%
	All	**1,292**		**5,191**	

1. Acquiring data on the patient's functional status requires that the clinician asks the patient how many flights of stairs they can manage without resting. In general, these data cannot be gleaned from the patient's notes, which may explain the relatively high rate of missing data. It is agreed that this is an important comorbid condition.
2. One of the quoted comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome. Therefore, the maximum number of missing comorbidity data-items for male patients is 11, whereas the maximum number of missing data-items for female patients is 12.



Ranked according to the rate of missing data in registry-entries for female patients with only one comorbidity question unanswered (being the greatest portion of the data in the registry), this chart clearly shows that *Functional status* is missing most often. Completeness for other fields is very good.



Number of comorbid conditions

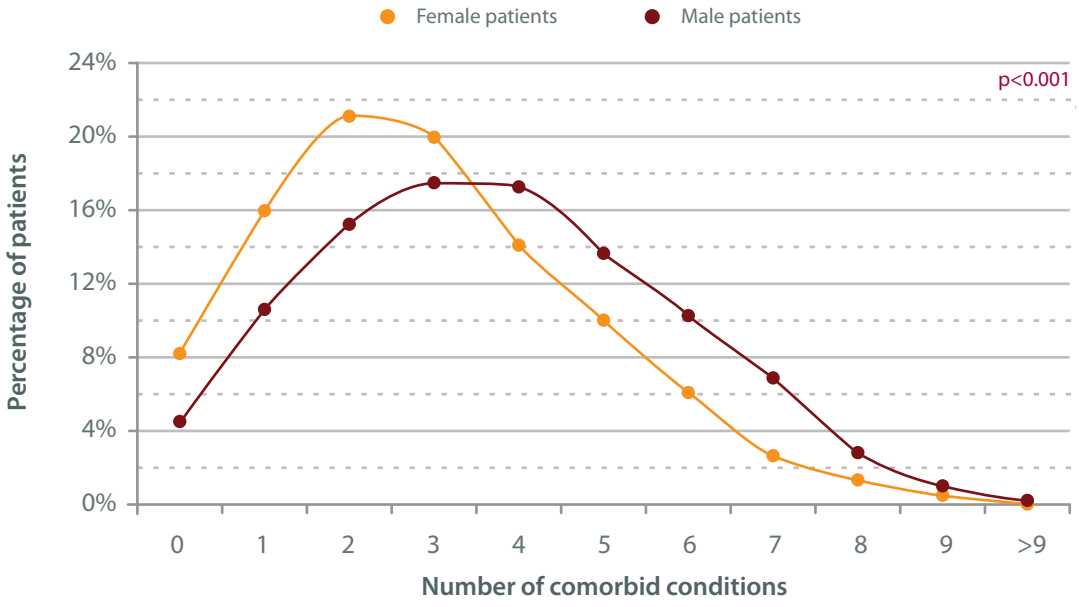
This analysis shows that men present with more comorbid conditions than women (χ^2 analysis $\Rightarrow p<0.001$). One theory to explain this is that this might be the fact that men present for surgery at a later age, and age is known to be associated with increasing comorbidity. However, the charts on the facing page discount this theory when the number of comorbidites is presented broken down by age and gender. It can be seen that when age is added as a dimension of the analysis, men present with relatively more comorbid conditions than women in particular for the older age bands.

Primary operations where all comorbidity questions are completed: number of comorbid conditions

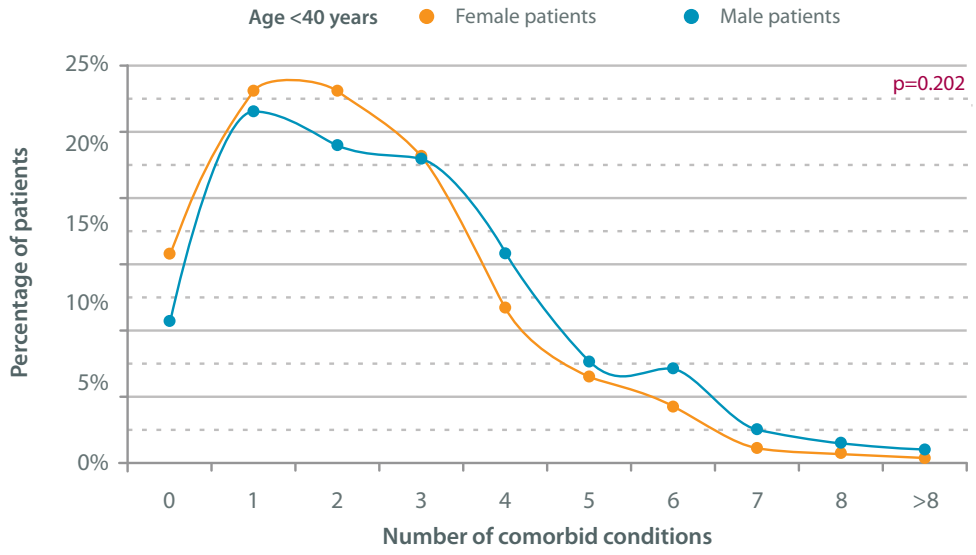
		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Number of comorbidities[i]	0	40	4.5%	294	8.2%
	1	94	10.6%	572	16.0%
	2	135	15.2%	756	21.1%
	3	155	17.5%	715	20.0%
	4	153	17.3%	505	14.1%
	5	121	13.7%	359	10.0%
	6	91	10.3%	218	6.1%
	7	61	6.9%	95	2.7%
	8	25	2.8%	48	1.3%
	9	9	1.0%	18	0.5%
	10	1	0.1%	1	0.1%
	11	1	0.1%	0	0.0%
	All	**886**		**3,581**	

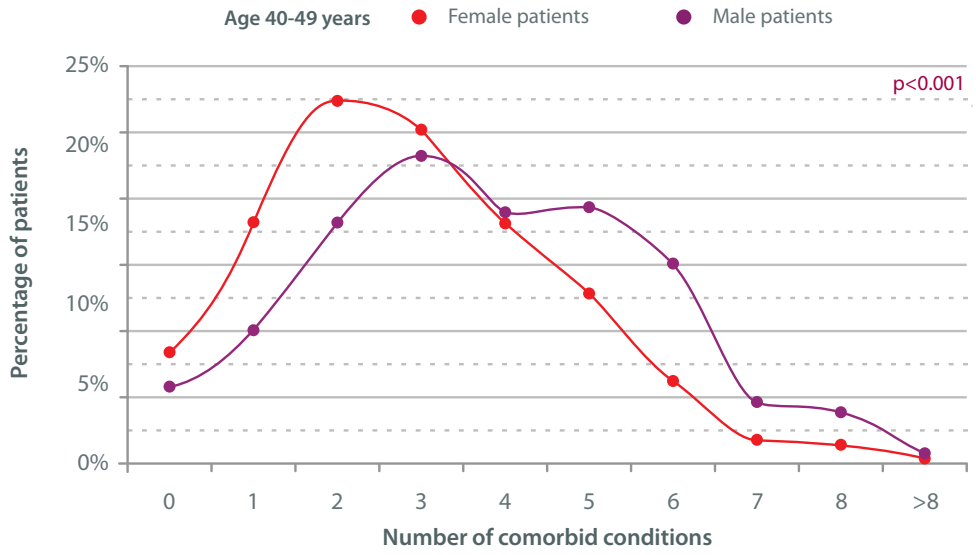
i. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovarian syndrome. Therefore, the maximum number of missing comorbidity data-items for male patients is 11, whereas the maximum number of missing data-items for female patients is 12.

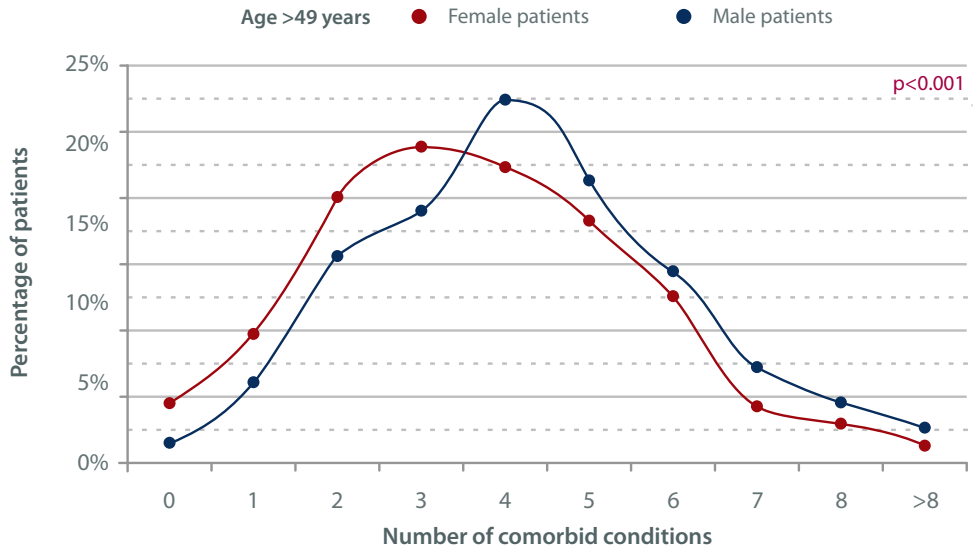
Primary operations with complete comorbidity data: Number of comorbidities and gender (n=4,467)



Primary operations with complete comorbidity data: Number of comorbidities, age and gender (n=4,409)







Database overview

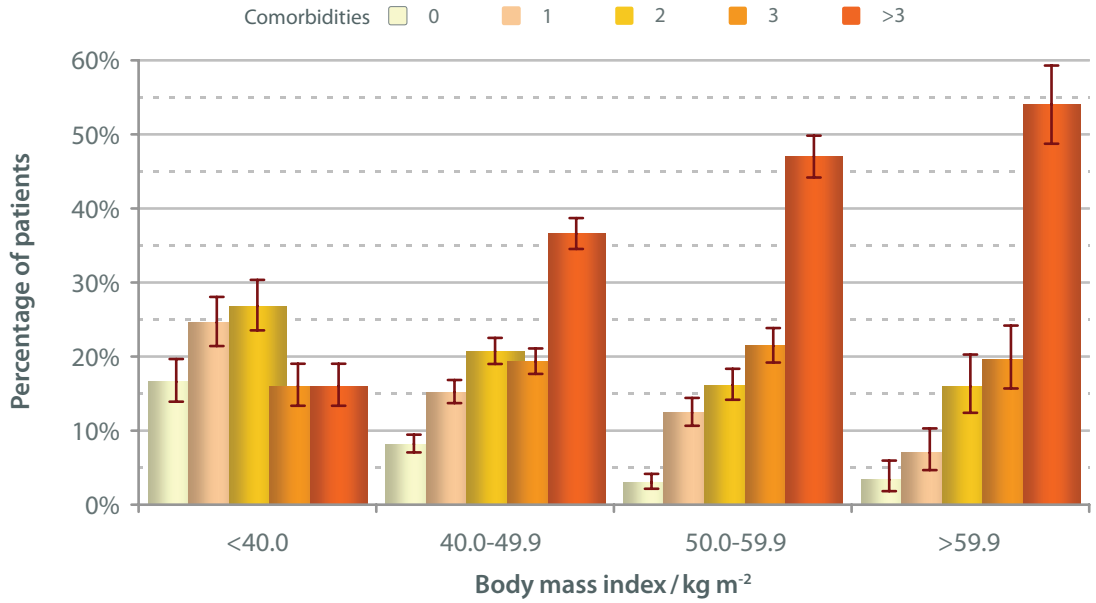
Comorbidity and BMI

These are among the first national registry data to show that increasing BMI correlates with increasing numbers of recorded comorbidities, confirming the debilitating nature of severe obesity. More than two-thirds of patients with a BMI of >50 have three or more obesity-related comorbid diseases. The data are in keeping with published reports of increasing comorbidity as BMI rises [1].

Primary operations where all comorbidity questions are completed: number of comorbid conditions and body mass index

		Initial Body Mass Index / kg m^{-2}				
		<40.0	40.0-49.9	50.0-59.9	>59.9	Unspecified
Number of comorbidities	0	112	171	37	12	2
	1	166	318	153	25	4
	2	181	433	199	57	21
	3	108	404	264	70	24
	>3	108	765	579	193	61
	All	**675**	**2,091**	**1,232**	**357**	**112**

Primary operations with complete comorbidity data:
Number of comorbidities and body mass index (n=4,355)



1. Belle SH *et al.* The Relationship of BMI with Demographic and Clinical Characteristics in the Longitudinal Assessment of Bariatric Surgery (LABS). *Surgery for Obesity and Related Diseases.* 2008; **4(4):** 474–480.

Prevalence of comorbid conditions at presentation

The following chart and table show the rates of patients' comorbid conditions at presentation by gender:

- both men and women have high rates of poor *functional status* (75.0% and 67.6%) and *arthritis* (54.0% 53.9%).
- the relative rates of *back or leg pain due to arthritis* and *GORD* occur at similar rates in both male and female patient populations.
- most conditions are more common amongst men: poor functional status, hypertension, type 2 diabetes, dyslipidaemia, sleep apnoea, liver disease and atherosclerosis.
- the rates of the remaining comorbidities are significantly higher amongst the female patients: depression and asthma; the reasons for these apparently higher rates in women are not fully understood.

Primary operations: details on comorbid conditions

		Gender and presence of comorbid condition								
		Male				Female				
		Absent	Present	Unspecified	Rate	Absent	Present	Unspecified	Rate	Significance [i]
Comorbidities [ii]	Type 2 diabetes	668	509	115	43.2%	3,656	1,131	395	23.6%	<0.001
	Hypertension	587	598	107	50.5%	3,312	1,517	362	31.4%	<0.001
	Dyslipidaemia	827	323	142	28.1%	3,962	745	484	15.8%	<0.001
	Atherosclerosis	993	133	166	11.8%	4,475	176	540	3.8%	<0.001
	Sleep apnoea	738	427	127	36.7%	4,195	548	448	11.6%	<0.001
	Asthma	982	176	134	15.2%	3,828	932	431	19.6%	<0.001
	Functional status [iii]	257	769	266	75.0%	1,372	2,865	954	67.6%	<0.001
	Arthritis	529	621	142	54.0%	2,181	2,547	463	53.9%	0.963
	GORD [iv]	792	319	181	28.7%	3,079	1,436	676	31.8%	0.050
	Liver disease	1,033	80	179	7.2%	4,434	170	587	3.7%	<0.001
	Depression	922	206	164	18.3%	3,373	1,231	587	26.7%	<0.001
	PCOS [v]					4,166	390	635	8.6%	NA

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

ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome.

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

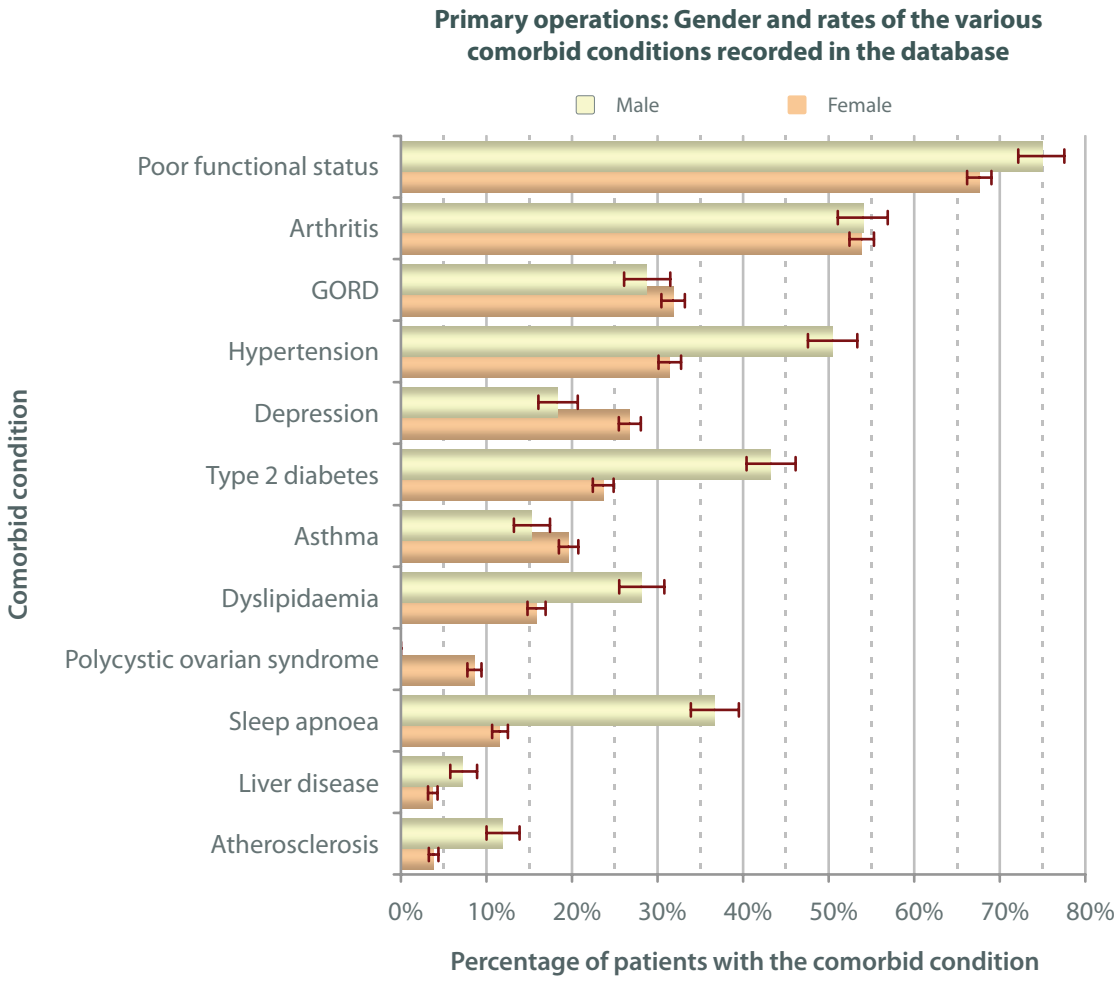
iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

v. Polycystic ovarian syndrome.

The comorbidities in the following chart are ordered according to the rates calculated for female patients.

Fully two-thirds of these bariatric surgery patients have poor functional status, *i.e.,* they cannot climb 3 flights of stairs without resting. Moreover, more than half of the patients report arthritic symptoms. These findings illustrate that the suggestion these patients should simply increase exercise as a means of losing weight is misguided.

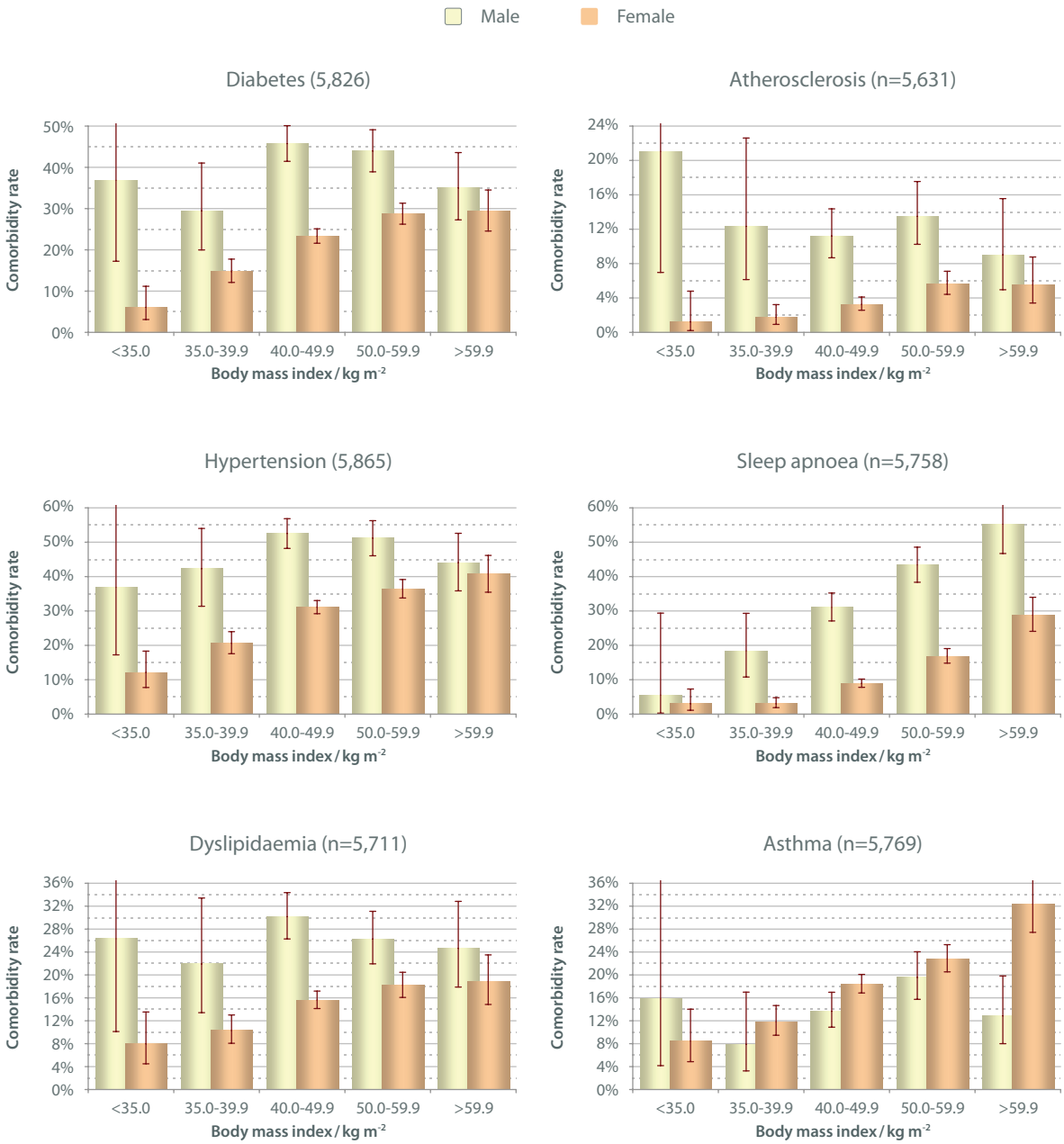
Forty-three percent of male patients were diabetic, which is much higher than the proportion of diabetic patients in most analyses from similar databases around the world (*circa* 20%). The reasons for this are not known, but it seems very likely that males with diabetes, hypertension and sleep apnoea are being favoured for public funding.



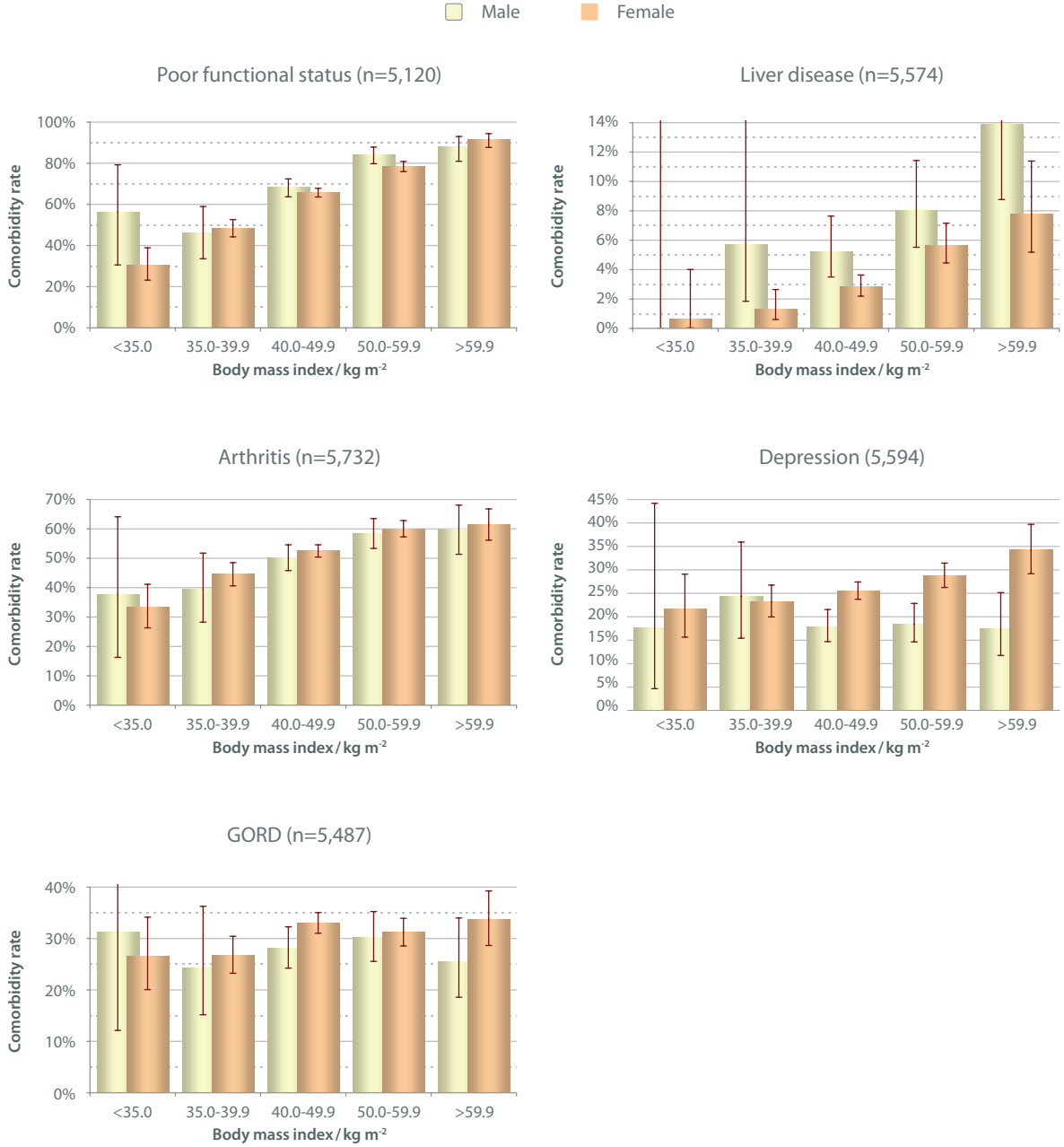
Rates of comorbid conditions, gender and body mass index

Even allowing for the fact that male patients are generally older and, on average, have a higher body mass index, the rates of comorbid conditions are much higher in men than women for every condition, with the exception of arthritis and reflux disease (where there is little or no difference), and depression and asthma (where females have relatively high rates of disease). It is possible that the high rate of publicly-funded surgery for male patients recorded in the registry can be explained by their (significantly) high levels of obesity-related comorbidity.

Primary operations: Distributions of the various comorbid conditions for male and female patients according to initial body mass index



Primary operations: Distributions of the various comorbid conditions for male and female patients according to initial body mass index



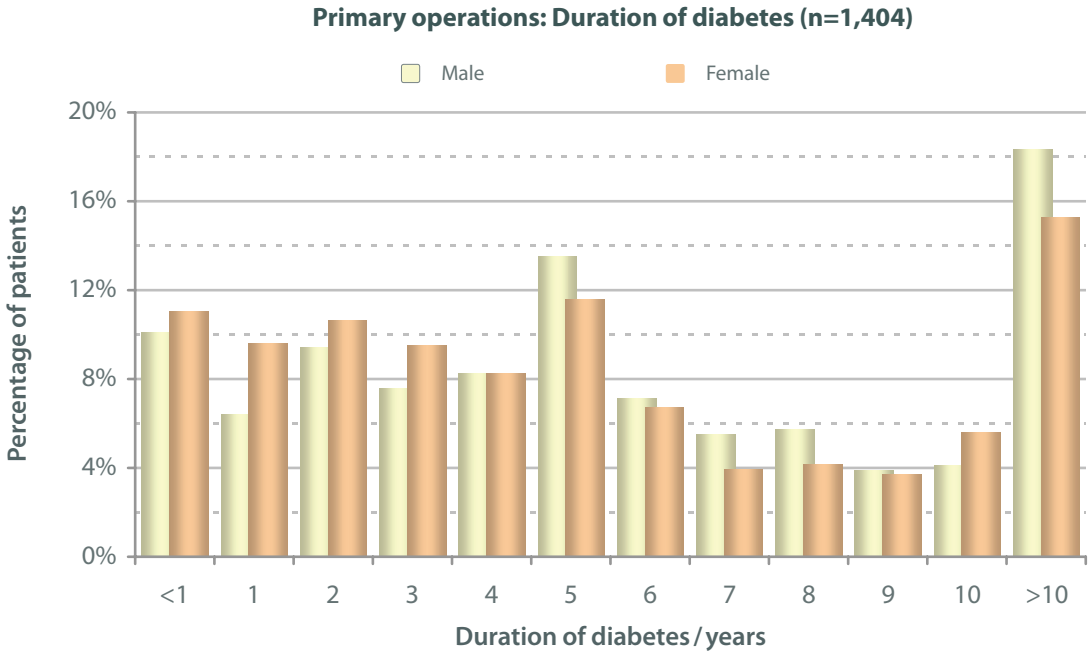
Detailed data on diabetes

Diabetes duration and gender

It is important that contributors record the duration of the patients' type 2 diabetes as it is considered likely that the longer the condition is present, the less likely they are to go into remission after surgery. If this is the case, then being able to track the duration of diabetes and medication usage after surgery is important from the perspective of resource utilisation when considering the wider public health implications for delivering diabetic care to the population.

Primary operations where the patient is reported as having diabetes: duration of diabetes

		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Duration of symptoms / years	<1	44	10.1%	107	11.1%
	1	28	6.4%	93	9.6%
	2	41	9.4%	103	10.6%
	3	33	7.6%	92	9.5%
	4	36	8.3%	80	8.3%
	5	59	13.5%	112	11.6%
	6	31	7.1%	65	6.7%
	7	24	5.5%	38	3.9%
	8	25	5.7%	40	4.1%
	9	17	3.9%	36	3.7%
	10	18	4.1%	54	5.6%
	>10	80	18.3%	148	15.3%
	Unspecified	73		163	
	All	**509**		**1,131**	



Type of diabetes and duration of diabetes

As might be expected, the analyses below shows that the longer the duration of diabetes, the more likely the requirement for insulin therapy. Longitudinal analysis later on in this report show that there is significant improvement in patients' reported diabetic status after surgery, and this has profound implications for both the patient-wellbeing and to the health service overall in terms of significant cost-savings and demand on diabetic services.

Primary operations: type of diabetes and duration of diabetes

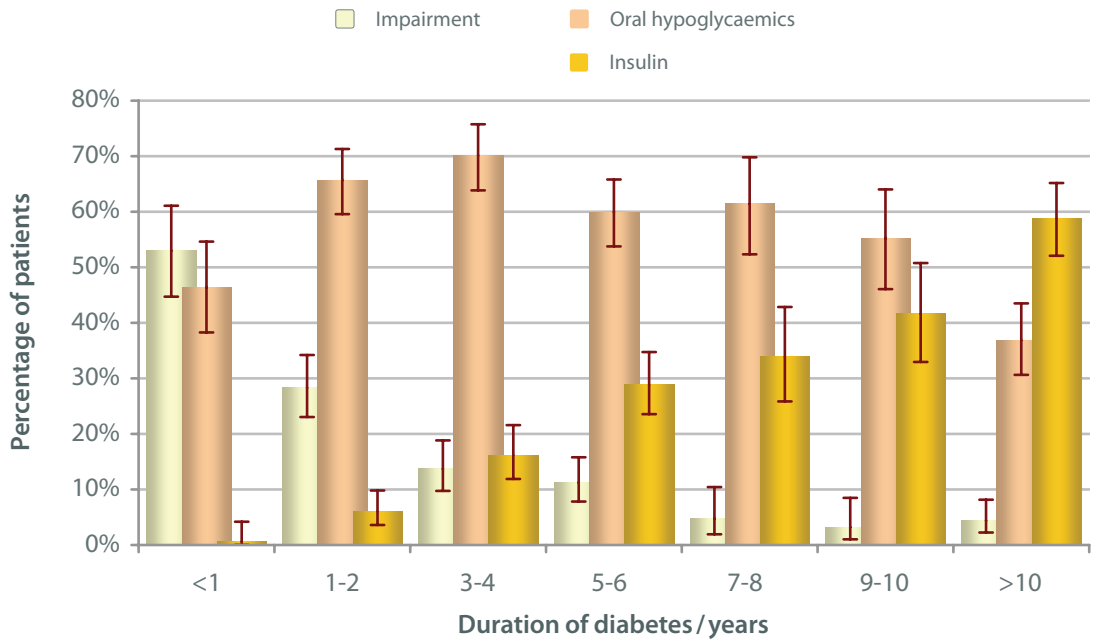
		Type of diabetes			
		Impairment [i]	Oral hypoglycaemics [ii]	Insulin [iii]	**All**
Duration of diabetes / years	<1 year	80	70	1	**151**
	1-2 years	75	174	16	**265**
	3-4 years	33	169	39	**241**
	5-6 years	30	160	77	**267**
	7-8 years	6	78	43	**127**
	9-10 years	4	69	52	**125**
	>10 years	10	84	134	**228**
	Unspecified	50	149	37	**236**
	All	**288**	**953**	**399**	**1,640**

i Patient has impaired glycaemia or impaired glucose tolerance.

ii Patient is receiving oral hypoglycaemics.

iii Patient is on insulin treatment for diabetes. See page 195

Primary operations:
Type of diabetes according to the duration of diabetes (n=1,404)



NICE guidance

The following is an extract from the NICE guidance on obesity (www.nice.org.uk/guidance/cg43):

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 or 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 postoperative 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 and 40.0 kg m^{-2}. The registry shows that for publicly funded patients, 99.6 % satisfied NICE guidance. This compares to 86.8 % 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.

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 [1].

Primary operations where all comorbidities are recorded: an analysis of the criteria used in NICE Clinical Guideline 43

Funding and inital BMI / kg m^{-2}		Number of comorbidities recorded		
		0	1 or more	% with no comorbidities
Publicly funded	<35.0	1	6	14.3%
	35.0-39.9	3	112	2.6%
	>39.9	107	2,612	3.9%
	Unspecified	0	105	0.0%
Privately funded	<35.0	37	91	28.9%
	35.0-39.9	71	354	16.7%
	>39.9	113	846	11.8%
	Unspecified	2	5	28.6%

1. 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, that has been shown to be a gross predictor of peri-operative outcome. These graphs shows that, as might be expected, the general trend is that as the BMI increases so does the ASA grade (men: χ^2 analysis $\Rightarrow p<0.001$; women: χ^2 analysis $\Rightarrow p<0.001$), very likely corresponding to the increase in obesity-related comorbid disease that coincides with increasing BMI (see previous charts in this section).

Even amongst the female patient-population, who in general have lower BMIs and fewer obesity-related comorbid conditions than their male counterparts, the ASA grade still increases with BMI: nearly one-third of female patients with BMI>50 are reported as ASA III.

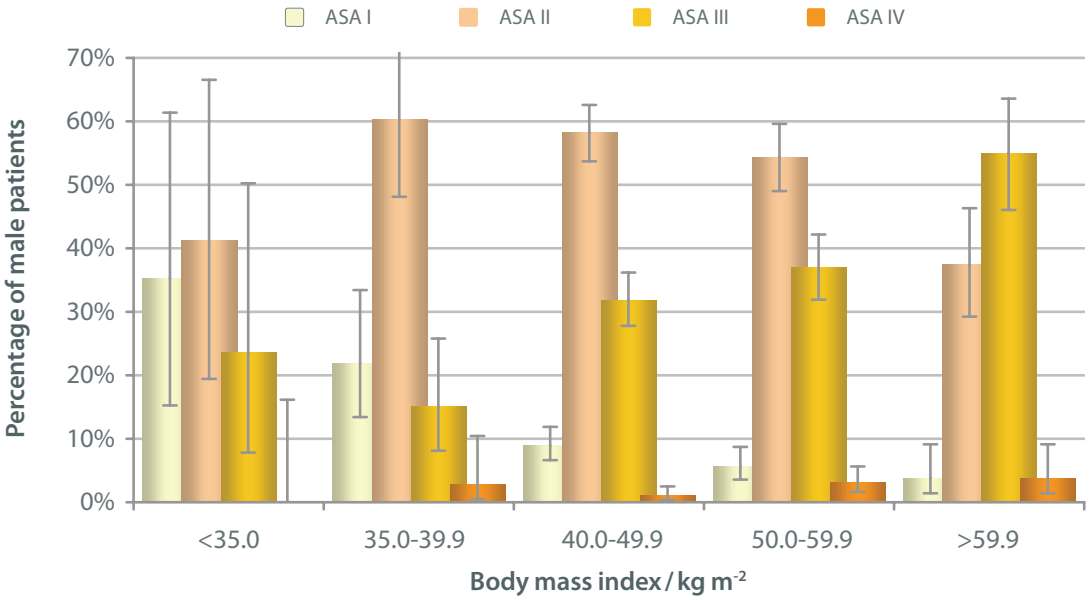
The data confirm that a large proportion of surgery (24.9%) is being carried out on a population with ASA grade III or ASA IV, generally considered high risk for elective surgery.

Primary operations: ASA grade, gender and body mass index

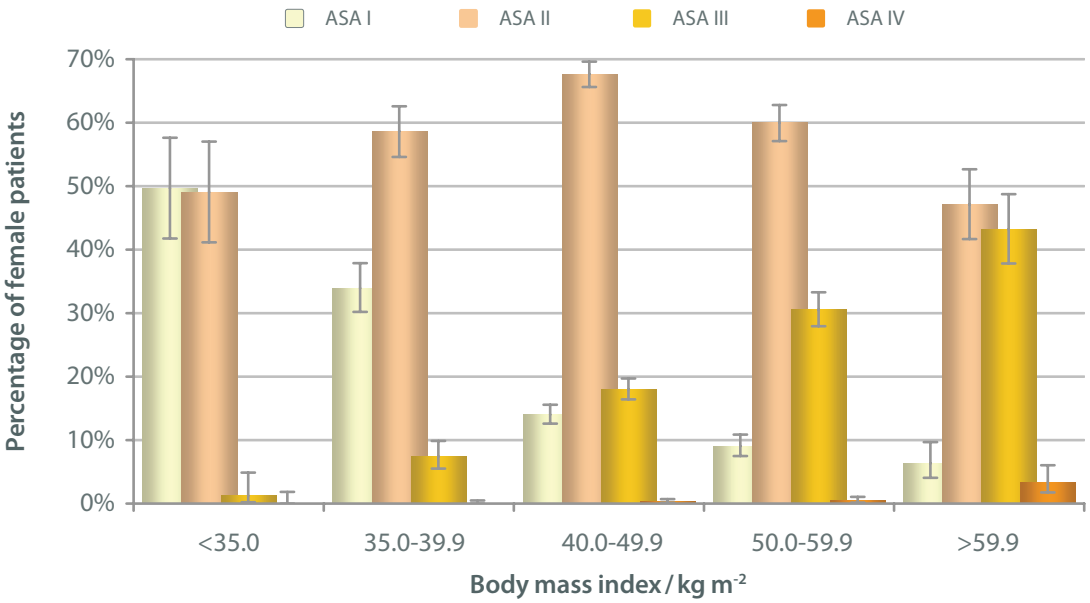
			ASA grade				
			ASA I	ASA II	ASA III	ASA IV	Unspecified
Gender and body mass index / kg m^{-2}	Male	<35.0	6	7	4	0	2
		35.0-39.9	16	44	11	2	6
		40.0-49.9	44	287	157	5	64
		50.0-59.9	20	193	131	11	55
		>59.9	5	49	72	5	26
		Unspecified	1	17	12	1	39
	Female	<35.0	80	79	2	0	10
		35.0-39.9	206	356	45	0	51
		40.0-49.9	302	1,458	388	7	251
		50.0-59.9	106	703	358	5	167
		>59.9	21	156	143	11	50
		Unspecified	17	68	36	0	115

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

**Primary operations for male patients:
ASA grade and body mass index (n=1,069)**



**Primary operations for female patients:
ASA grade and body mass index (n=4,426)**



Post-operative outcomes

Cardiovascular complications

The response-options for the *Cardiovascular complications* question in the database are (see page 211):

- none.
- myocardial infarction (MI; n=2).
- stroke (n=0).
- dysrhythmia (n=23).
- pulmonary embolus (PE; n=4).
- deep-vein thrombosis (DVT; n=3).
- cardiac arrest (n=5).

In the following table all the positive response-options (anything other than *None*) have been grouped together to create the *Yes* response because each specific complication is so rarely reported.

Primary operations: cardiovascular complications and operation

		Cardiovascular complications			
		No	Yes	Unspecified	Rate (95% CI)
Operation	Gastric band	1,877	3	251	0.2% (0.0-0.5%)
	Roux-en-Y gastric bypass	3,140	27	459	0.9% (0.6-1.3%)
	Sleeve gastrectomy	493	5	45	1.0% (0.4-2.5%)
	Duodenal switch + sleeve	2	0	0	0.0% (0.0-77.6%)
	Bilio-pancreatic diversion	0	0	1	NA
	Gastric balloon	90	0	22	0.0% (0.0-3.3%)
	Other	17	0	8	0.0% (0.0-16.2%)
	Unspecified	2	0	41	0.0% (0.0-77.6%)
	All	**5,621**	**35**	**827**	0.6% (0.4-0.9%)

Despite the fact that majority of patients presenting for bariatric surgery are considered *high-risk* from an ASA perspective, and that laparoscopic surgery on obese patients is technically demanding in itself, it is gratifying to see that post-operative cardiovascular complication rates are generally very low.

Other complications

The response-options for the *Other complications* question in the database are (see page 211):

- none.
- fluid / electrolyte problems (n=19).
- acute cholecystitis / biliary colic (n=0).
- CBD stones / cholangitis (n=0).
- gastric distension (n=2).
- other abscess / infection / fever (n=21).
- acute renal failure (n=8).
- pneumonia / atelectasis (n=21).
- rhabdomyolysis (n=0).
- urinary tract infection (UTI; n=7).
- vomiting / poor intake (n=38).
- wound infection / breakdown (n=20).
- unanticipated transfer to ITU (n=13).

Primary operations: other complications and operation

		Other complications			
		No	Yes	Unspecified	Rate (95% CI)
Operation	Gastric band	1,863	19	249	1.0% (0.6-1.6%)
	Roux-en-Y gastric bypass	3,073	88	465	2.8% (2.3-3.4%)
	Sleeve gastrectomy	483	14	46	2.8% (1.6-4.8%)
	Duodenal switch + sleeve	2	0	0	0.0% (0.0-77.6%)
	Bilio-pancreatic diversion	0	0	1	NA
	Gastric balloon	89	1	22	1.1% (0.1-6.9%)
	Other	16	0	9	0.0% (0.0-17.1%)
	Unspecified	2	0	41	0.0% (0.0-77.6%)
	All	**5,528**	**122**	**833**	2.2% (1.8-2.6%)

For these *high-risk* patients, with challenging comorbid disease, undergoing a technically demanding procedure, it is, again, pleasing to see that the rates of post-operative complication classified as *other* are also generally very low.

Mortality

There were only 7 deaths recorded in the entire registry. This is a remarkable achievement, and reflects the safety of bariatric surgery.

The zero mortality recorded for gastric banding, the 0.22% mortality for gastric bypass and the zero mortality from sleeve gastrectomy compare favourably with the best published international data. Other externally collected data from the United Kingdom (Hospital Episode Statistics data) found that the mortality from gastric bypass for 2000-08 was 0.5% – a time before data collection in the NBSR had started.

In the United States, the LABS consortium [1] reported 0% mortality (0 / 1,198) for gastric banding, 0.2% (6 / 2,975) for laparoscopic gastric bypass and 2.3% (9 / 437) for open gastric bypass. The United States Centers of Excellence program published 0.14% overall mortality in 57,918 patients [2].

Primary operations: post-operative mortality and operation

		Post-operative mortality			
		No	Yes	Unspecified	Rate (95% CI)
Operation	Gastric band	1,878	0	253	0.0% (0.0-0.2%)
	Roux-en-Y gastric bypass	3,132	7	487	0.2% (0.1-0.5%)
	Sleeve gastrectomy	493	0	50	0.0% (0.0-0.6%)
	Duodenal switch + sleeve	2	0	0	0.0% (0.0-77.6%)
	Bilio-pancreatic diversion	0	0	1	NA
	Gastric balloon	88	0	24	0.0% (0.0-3.3%)
	Other	17	0	8	0.0% (0.0-16.2%)
	Unspecified	2	0	41	0.0% (0.0-77.6%)
	All	**5,612**	**7**	**864**	0.1% (0.1-0.3%)

1. Flum D *et al.* Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery. The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. *New England Journal of Medicine.* 2009; **361:** 445-54.

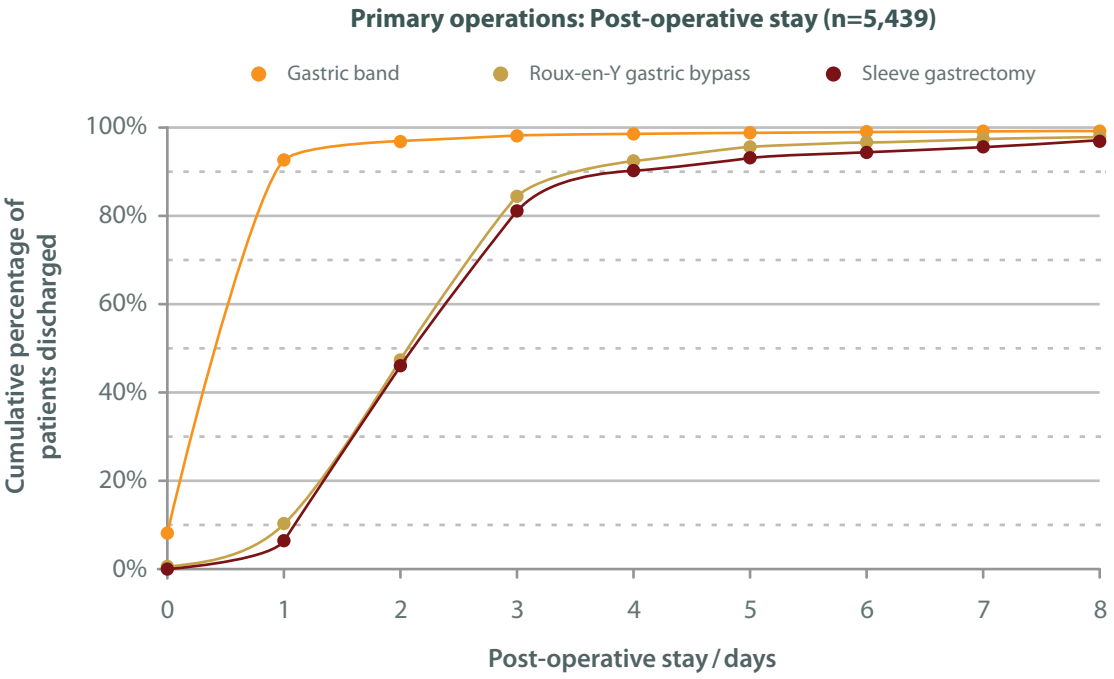
2. Belle SH *et al.* The Relationship of BMI with Demographic and Clinical Characteristics in the Longitudinal Assessment of Bariatric Surgery (LABS). *Surgery for Obesity and Related Diseases.* 2008; **4(4):** 474–480.

Post-operative stay

As expected, nearly all gastric band patients stay 1 day or less in hospital. Despite being a major procedure for patients with severe obesity-related disease, 80% or more of bypass patients are discharged by day 3. This remarkably short in-hospital stay is almost certainly due to the surgery being performed *via* a laparoscopic approach and surgeons being sufficiently confident in their operative technique.

Primary operations: post-operative length-of-stay for each of the operation groups

		Operation							
		Gastric band	Roux-en-Y gastric bypass	Sleeve gastrectomy	Duodenal switch with sleeve	Bilio-pancreatic diversion	Gastric balloon	Other	Unspecified
Post-operative stay / days	0	151	19	0	0	0	34	2	1
	1	1,567	301	31	0	0	18	7	0
	2	77	1,150	191	0	0	10	2	0
	3	24	1,150	169	0	0	10	2	0
	4	8	249	44	1	0	7	1	0
	5	5	98	14	1	0	3	0	0
	6	5	33	8	0	0	3	0	0
	7	2	25	4	0	0	1	2	0
	8	0	14	6	0	0	1	0	0
	>8	15	64	15	0	0	0	0	0
	Unspecified	277	523	61	0	1	25	9	42
	All	**2,131**	**3,626**	**543**	**2**	**1**	**112**	**25**	**43**
	>30-day stay rate	0.65%	0.74%	0.83%	0.0%	0.0%	0.0%	0.0%	0.0%



Database overview

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 the time and expense needed to capture the data, and the ever-increasing challenge of keeping track of patients over the long term in a busy unit that is operating on several hundred patients a year. For instance, the resources needed to see gastric band patients in a timely fashion in the surgical clinic and adjust their bands appropriately inevitably means that there is often little opportunity (even though there may be the will) to keep on following the patients well after 2 or 3 years. Follow-up data over 5-10 years after surgery, however, would be very useful to the NHS, facilitating an assessment of procedures on an intention-to-treat basis.

To compound the problem, healthcare funding bodies typically commission the episode of surgery with very limited follow-up; for example, one post-operative clinic visit at 6 weeks following a gastric bypass, and 4 follow-ups or follow-up to 6 months post-surgery, whichever comes sooner, following gastric banding. Self-evidently this does not encourage continuity of long-term care, as general practitioners or secondary care physicians are not usually funded to see the patients thereafter. Although band adjustment is a skill that is easily learnt, the process of devolved care only works when the GP is funded to do the follow-up, as in Australia, for example, where outstanding results are obtained.

Even with other bariatric operations such as gastric bypass, where there is no band to adjust, obtaining follow-up data is just as problematic. With patients treated for cancer data on survival are recorded in the background without clinicians necessarily being aware; there is no similar mechanism in the NHS for recording progression of weight loss and remission of obesity-related disease. This makes the NBSR an 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 embedded as deeply into the NHS infrastructure as those for cancer patients.

Bariatric surgery seems to have a powerful preventive effect as far as cancer is concerned, so there is a notable contrast between the extent of the infrastructure that supports surgery to treat obesity-related cancer and that of the surgery that might prevent it [1]. To take the analogy further, there is no example of funded follow-up after bariatric surgery that extends to anything like 5 years, which is the minimum timescale usually used to report survival rates after cancer treatments. Over time, analyses of the data in the NBSR will show whether or not the enthusiasts will be able maintain the momentum behind the registry and continue to enter follow-up data on weight and comorbidity for their patients beyond the 2-year data we have been able to present in this report.

International bodies suggest that surgeons should strive to be aware of the outcome of 75% of their patients on an annual basis for 5 years. Thus the US Centers of Excellence programme mandates this standard as one of its criteria for recognition [2]. The International Federation of Surgery for Obesity and Metabolic Disorders (IFSO) has published similar guidelines, which units must adhere to in order to meet IFSO's *standards for excellence* [3]. In this first NBSR report we have not presented follow-up analyses for individual units, but this is something that could be addressed in future reports.

1. 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.

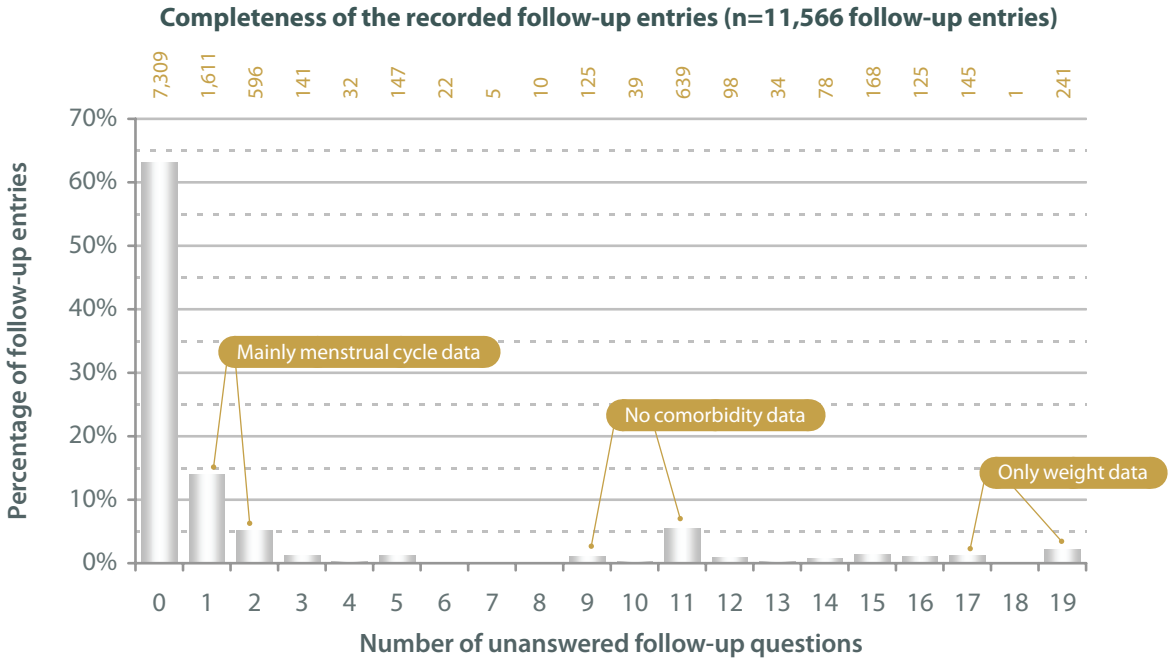
2. www.surgicalreview.org

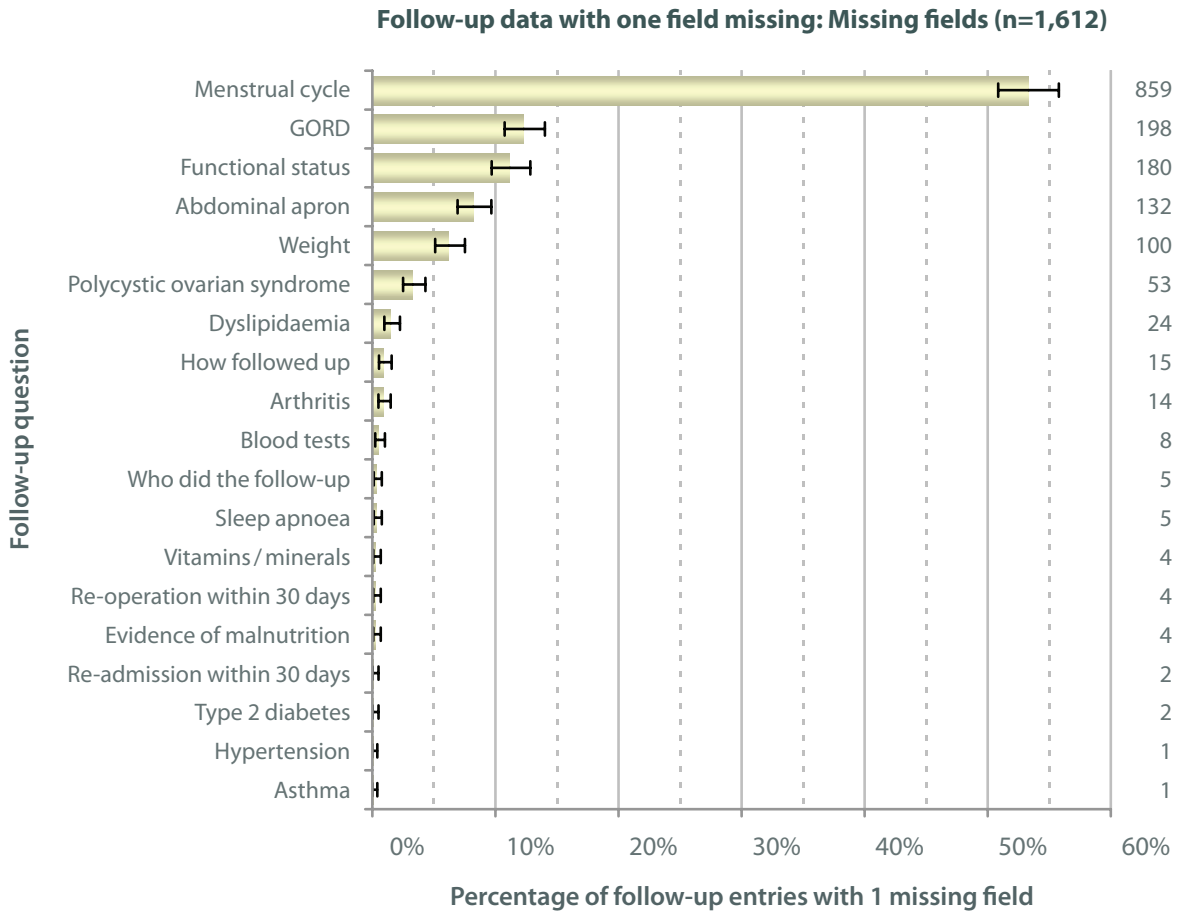
3. Melissas J. IFSO Guidelines for Safety, Quality, and Excellence in Bariatric Surgery. *Obesity Surgery.* 2008; **18(5):** 497-500.

There are essentially 20 core questions in the follow-up section of the NBSR, the answers to some of which are qualified by answers to subsequent (conditional) questions (see pages 212-213). The core questions are:

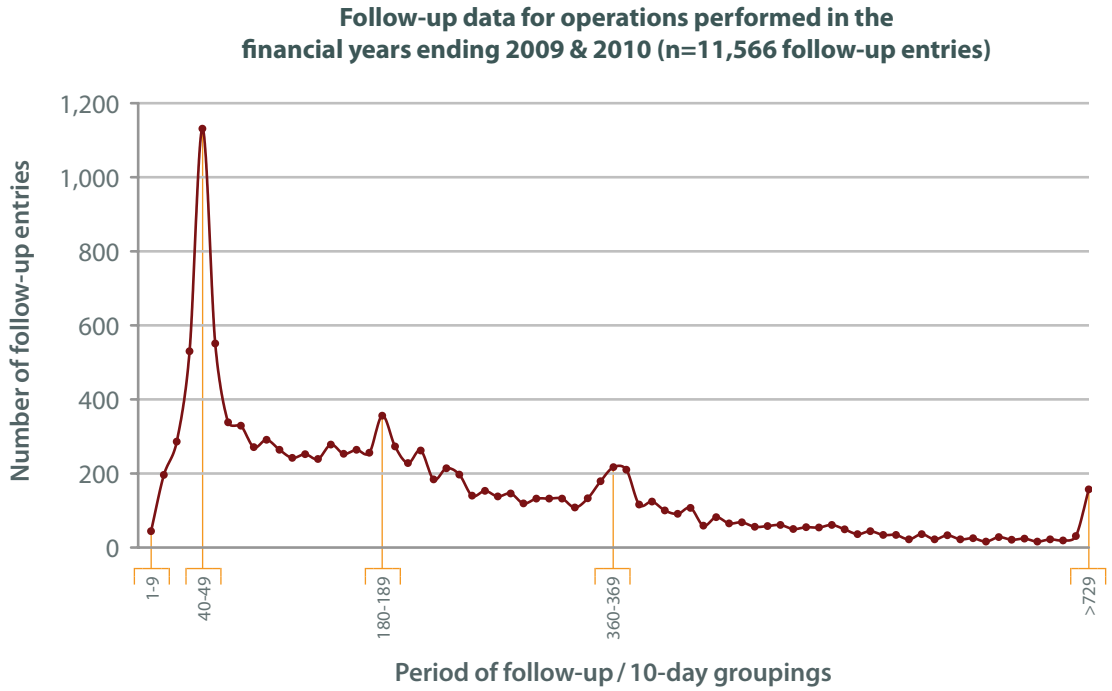
1. Patient's weight.
2. Patient re-admitted within 30 days of the index operation.
3. Patient re-operated within 30 days of the index operation.
4. Patient known to have died since discharge or in follow-up.
5. How was the patient followed up.
6. Who did the follow-up.
7. Vitamins / minerals: patient taking appropriate supplements.
8. Blood tests: patient having regular appropriate monitoring.
9. Clinical evidence of malnutrition.
10. Type 2 diabetes.
11. Hypertension.
12. Dyslipidaemia.
13. Sleep apnoea
14. Asthma.
15. Functional status.
16. Back or leg pain from arthritis.
17. Gastro-oesophageal acid reflux, heartburn or hiatus hernia (GORD).
18. Polycystic ovarian syndrome (female patients only).
19. Menstrual cyle (female patients only).
20. Abdominal apron.

As the following chart shows, the vast majority of follow-up entries have no more than 2 missing data-items. It is extremely encouraging that over 60% of follow-up entries have complete data entry, indicating a high degree of commitment. Future reports should be able to tease out differences in the ways that follow-up is carried out between different providers.





It is clear from the chart below that the acquisition of follow-up data is not regularised across the United Kingdom. There are several peaks in the distribution: at 40-49 days after the procedure, *circa* 6 months post-surgery, and then around the first anniversary of the operation. Otherwise, there appears to be a slowly diminishing percentage of total follow-up data the more distant from the timing of the patient's surgery.

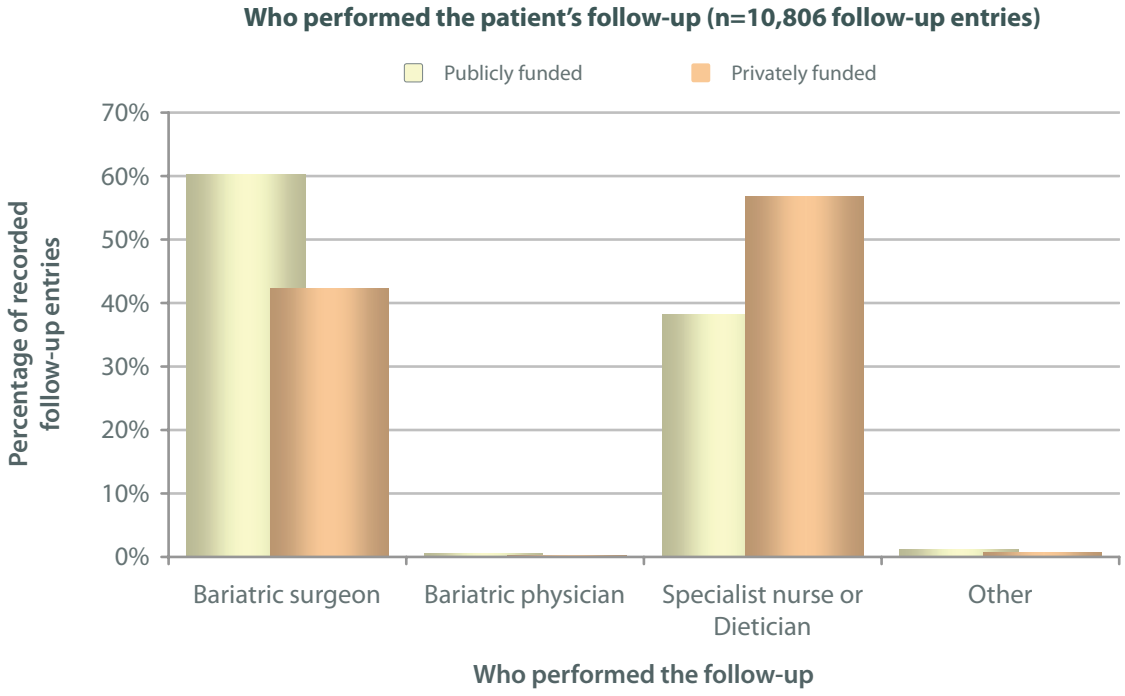


Who performed the follow-up

The only mechanism within the National Health Service to record weight loss after bariatric surgery globally is *via* this registry; therefore it is not surprising that most of the follow-up entries were performed in the surgical clinic. As yet there is no evidence in the registry of any models-of-care involving secondary - or primary-care physicians carrying out follow-up for these patients, and arranging for the relevant data to be entered onto the system.

Source of follow-up data: person recorded as performing follow-up; counts of follow-up entries

		Funding			
		Publicly funded	Privately funded	Unspecified	**All**
Who did the follow-up	Bariatric surgeon	3,723	1,957	7	**5,687**
	Bariatric physician	36	11	0	**47**
	Specialist nurse / dietician	2,359	2,622	7	**4,988**
	Other	68	30	0	**98**
	Unspecified	457	289	0	**746**
	All	**6,643**	**4,909**	**14**	**11,566**



Excess weight loss

When considering these data, which contrast percentage excess weight loss (%EWL) after gastric band and gastric bypass operations, it is important to consider the following:

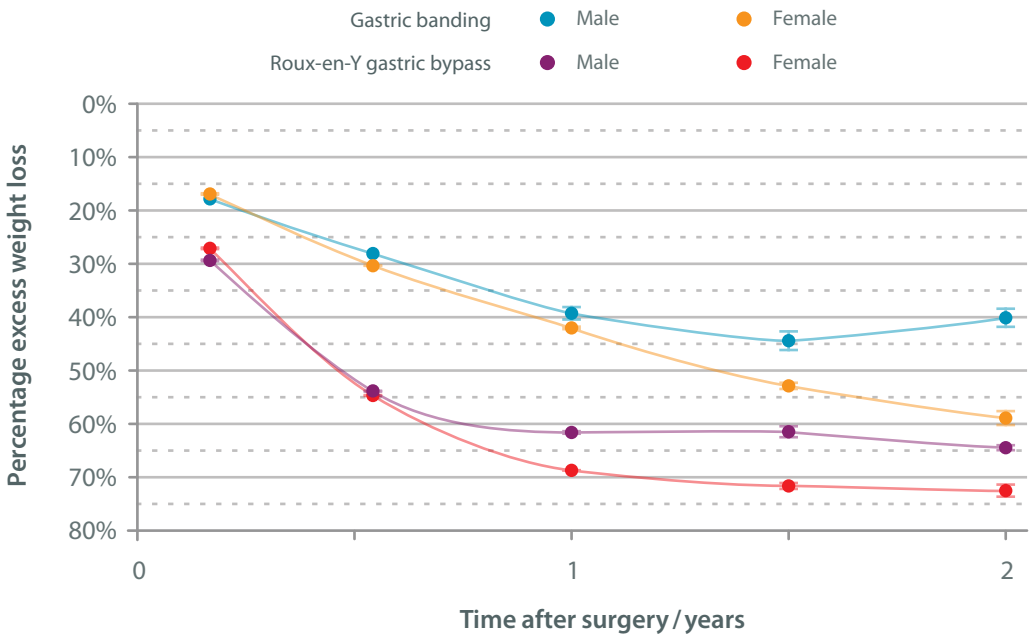
1. They may not be indicative of %EWL finally reached or maintained (*e.g.*, after 5 years).
2. It is often held that weight loss after gastric banding may continue for as long as 3 years.
3. Successful weight loss after gastric banding may be more dependent on lifestyle support than after gastric bypass.
4. Change in diet or lifestyle may be less readily adopted by men than by women.
5. It is now understood that gastric bypass, unlike gastric banding, induces a hormonally-mediated appetite-suppressant effect that may:
    a. explain its apparently greater early effectiveness at inducing weight loss.
    b. explain its efficacy at early and partly weight-independent effectiveness at inducing remission of the Metabolic Syndrome.
    c. conversely explain why remission of the Metabolic Syndrome after gastric banding depends purely on the weight-loss actually achieved.
6. Finally that the well-being of men and women arises not from weight loss alone. The latter is only an easy proxy for the more relevant but more testing parameters of:
    a. resolution of co-morbidity.
    b. improvement in quality of life (QoL).

In other words, the real comparisons should be the relationships between QoL (and its improvement) and co-morbidity improvement. There are no internationally accepted measures for this ratio (see also page 78).

In the first 2 years after surgery, excess weight loss was recorded as being greater following gastric bypass surgery than after gastric banding procedures.

The following charts also shows that women lose more weight than men on average. Women continued to lose weight in the period 1-2 years after gastric banding, whereas men's excess weight loss stabilised at around 40-45% in the same period. These data are comparable to the published international literature.

Selected primary operations: Post-operative excess weight loss



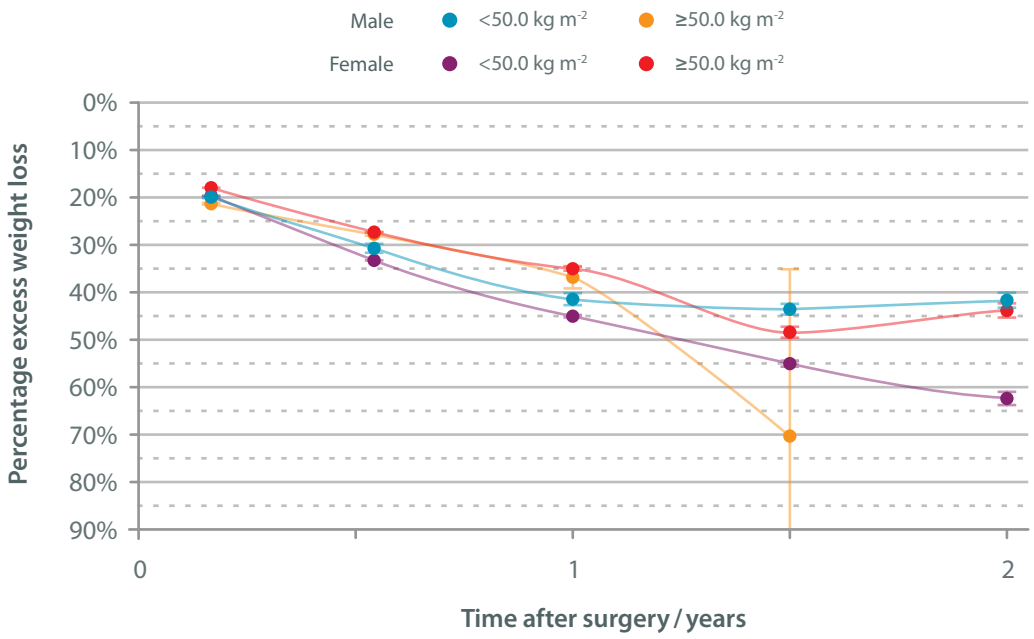
Excess weight loss after primary gastric banding surgery

		Gender					
		Male			Female		
		% EWL [i]	95% CI [ii]	Count	% EWL	95% CI	Count
Follow-up period	2 months	20.3	0.008	111	19.4	0.002	731
	6 months	30.1	0.018	92	32.3	0.005	675
	1 year	40.9	0.027	55	43.5	0.009	512
	1.5 years	45.8	0.038	24	53.9	0.016	239
	2 years	41.7	0.037	6	59.7	0.030	119

i Excess weight loss

ii Confidence interval

Primary gastric banding: Post-operative excess weight loss and BMI



Counts of patients under analysis at each time interval

Male	<50.0 kg m^{-2}	85	73	48	22	6
Male	≥50.0 kg m^{-2}	26	19	7	2	0
Female	<50.0 kg m^{-2}	604	564	433	199	102
Female	≥50.0 kg m^{-2}	127	111	79	40	17

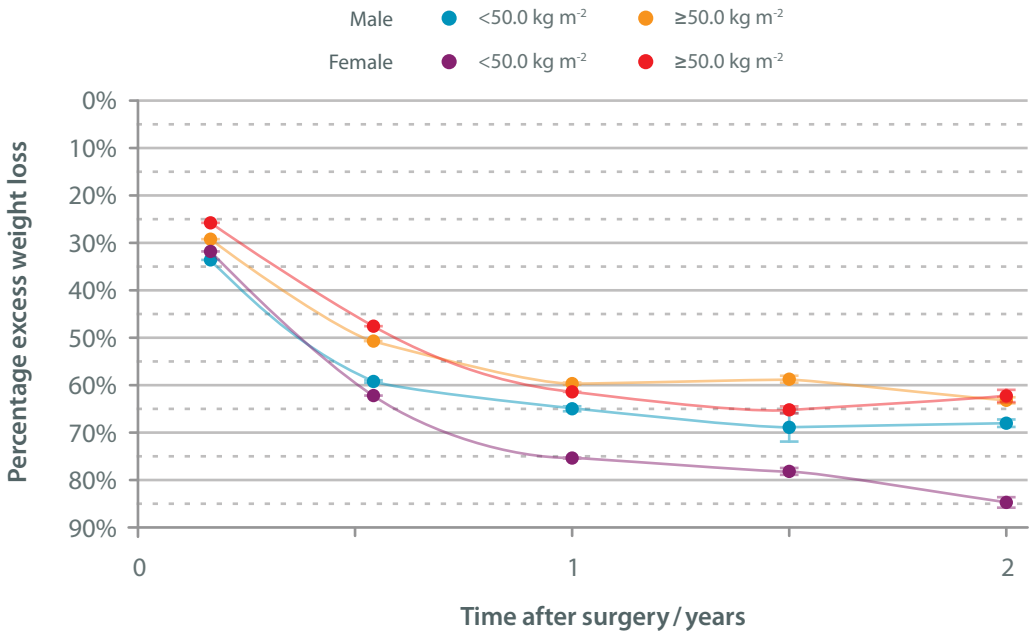
Excess weight loss after primary Roux-en-Y gastric bypass surgery

		Gender					
		Male			Female		
		% EWL	95% CI	Count	% EWL	95% CI	Count
Follow-up period	2 months	31.3	0.002	378	29.2	0.001	1,426
	6 months	54.8	0.006	274	55.7	0.004	1,073
	1 year	62.3	0.009	178	69.1	0.005	707
	1.5 years	62.2	0.025	47	72.0	0.016	171
	2 years	65.1	0.014	18	72.8	0.027	81

i Excess weight loss

ii Confidence interval

Primary Roux-en-Y gastric bypass: Post-operative excess weight loss & BMI



Counts of patients under analysis at each time interval

Male	<50.0 kg m-2	183	133	89	16	7
Male	≥50.0 kg m-2	195	141	89	31	11
Female	<50.0 kg m-2	801	594	392	89	38
Female	≥50.0 kg m-2	625	479	315	82	43

Comorbid disease after surgery

This is an overview of the main findings in follow-up. Strikingly, 7 out of every 10 patients had limited functional ability prior to surgery - that is, they were unable to climb 3 flights of stairs without resting. In addition, a third of patients initially had high blood pressure, over a quarter of patients had diabetes, nearly 1 in 5 had high blood lipid levels, and 1 in 6 experienced sleep apnoea. At one year after their operation, the improvement in each of these was dramatic and was highly statistically significant. It is very likely that huge economic benefit can result as the patients come off their treatment.

For the full list of comorbidities and their resolution after each of the most commonly performed procedures see pages 124 (gastric banding section), 168 (Roux-en-Y gastric bypass section) and 190 (sleeve gastrectomy section).

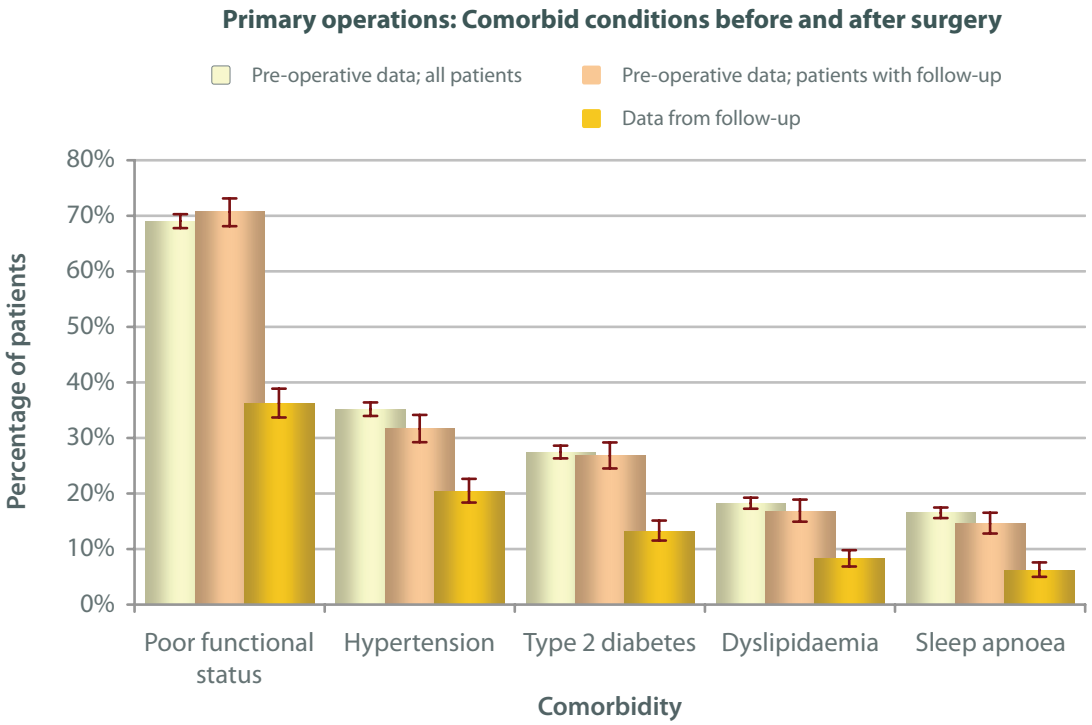
Primary operations: comorbid conditions pre-operatively and 12 months after surgery [i]

Source of data				Comorbidity				
				Type 2 diabetes	Hypertension	Dyslipidaemia	Sleep apnoea	Functional status [ii]
Source of data	All patients	Pre-operative data	No	4,333	3,899	4,789	4,933	1,629
			Yes	1,640	2,115	1,068	975	3,634
			Unspecified	510	469	626	575	1,220
			Rate	27.5%	35.2%	18.2%	16.5%	69.0%
	Patients with followup data	Pre-operative data	No	1,036	968	1,167	1,208	384
			Yes	379	448	236	206	926
			Unspecified	6	4	10	5	42
			Rate	26.8%	31.6%	16.8%	14.6%	70.7%
		12-month follow-up data [i]	No	1,233	1,130	1,297	1,332	862
			Yes	188	290	116	87	490
			Unspecified	0	0	0	0	0
			Rate	13.2%	20.4%	8.2%	6.1%	36.2%
			Significance [iii] (χ^2 probability)	<0.001	<0.001	<0.001	<0.001	<0.001

i. The data used to determine the incidence of the risk factor fall in the defined time-period 365 ± 91 days. The follow-up entry used in the analysis is that row of data that is nearest in time to the 365-day point.

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

iii. Comparing the pre-operative incidence to the 12-month follow-up incidence in the patients with follow-up data.


Primary operations: Comorbid conditions before and after surgery
Pre-operative data; all patients
Pre-operative data; patients with follow-up
Data from follow-up
Percentage of patients
80%
70%
60%
50%
40%
30%
20%
10%
0%
Poor functional status
Hypertension
Type 2 diabetes
Dyslipidaemia
Sleep apnoea
Comorbidity

Improvement in diabetes

These data on changes in the rates of the clinical indication of diabetes post-bariatric surgery are the first published registry data from the United Kingdom on this subject. For the cohort of patients with a diagnosis of diabetes prior to surgery, there is a progressive and substantial increase over time in the number of patients reported as having *No indication of type 2 diabetes* in follow-up. This represents profound potential cost savings to the National Health Service, when bariatric surgery is under consideration for obese diabetic patients.

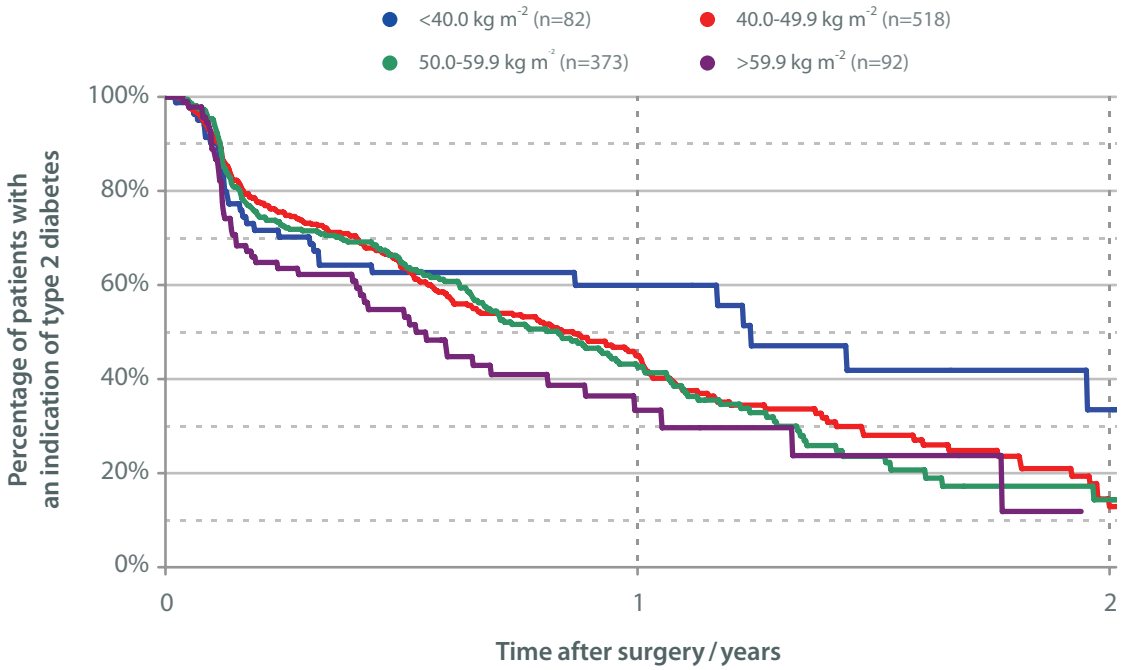
In the initial dataset, the question called *Type 2 diabetes* records the patient's status as one of the following:

- no indication of type 2 diabetes,
- impaired blood sugar / impaired glucose tolerance,
- oral hypoglycaemics,
- insulin treatment.

All the following charts on changes in the report rates of clinical indications of diabetes after surgery utilise the data for the group of patients who had a clinical indication of diabetes prior to surgery (anything other than *No indication of type 2 diabetes*). The charts shows that for these patients, lower starting BMIs are associated with a slower and reduced reversion to lack of any clinical indication of diabetes (statistical comparisons between the various curves: <40.0 kg m^{-2} versus >59.9 kg m^{-2}: p=0.024; no other comparisons attain significance. Log rank, Mantel Cox).

These results suggest favourable comparison with recently-published results from an international study [1], which demonstrated that the time taken to recover the costs of surgery after a laparoscopic, bariatric procedure by considering just the reduction in the consumption of medications used to control diabetes was only 26 months.

Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and BMI



1. Klein S *et al*. Economic Impact of the Clinical Benefits of Bariatric Surgery in Diabetes Patients With BMI ≥35 kg m^{-2}. *Obesity*. 2010

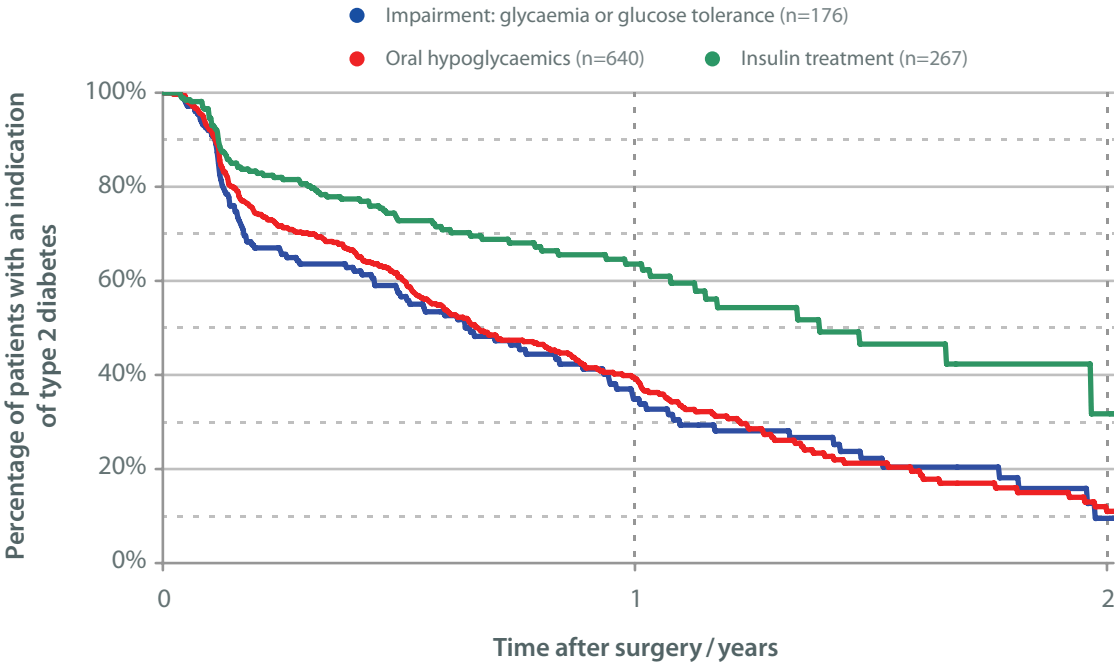
This chart tracks the change in diabetic status recorded in follow-up, split into three cohorts:

- impaired glycaemia / impaired glucose tolerance at presentation.
- oral hypoglycaemics at presentation.
- insulin treatment at presentation.

It confirms that over a two-year period post-surgery, those who presented on insulin tend to revert to a state of *No indication of diabetes* less frequently than other patients with diabetes (Impairment versus Oral: p=0.507; Impairment versus Insulin: p<0.001; Oral versus Insulin: p<0.001); these are the first national registry data to demonstrate such a finding.

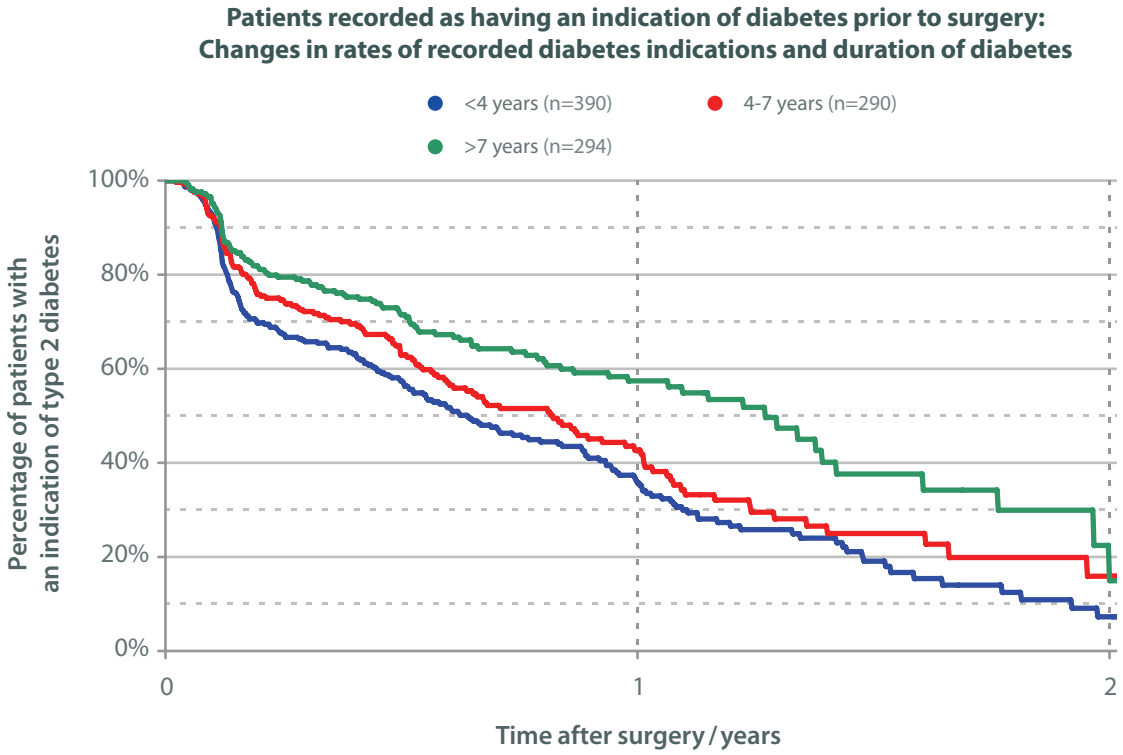
Patients on insulin generally have more advanced diabetes and have had the condition for longer, which may explain the slower reversion rate.

Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and type of diabetes



The chart below shows that the longer patients have had diabetes the less likely they are to be reported as having no indication of diabetes post-surgery (statistical comparisons between the various curves: <4 versus 4-7: p=0.051; <4 versus >7: p<0.001; 4-7 versus >7: p=0.005. Log rank, Mantel Cox):

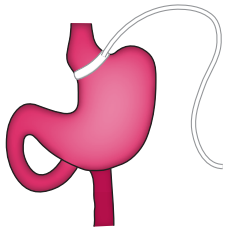
While this finding is consistent with the published literature from case series, these are possibly the first national registry data to confirm this observation anywhere in the world.



Gastric banding

Gastric banding

Number of entries in the context of the database

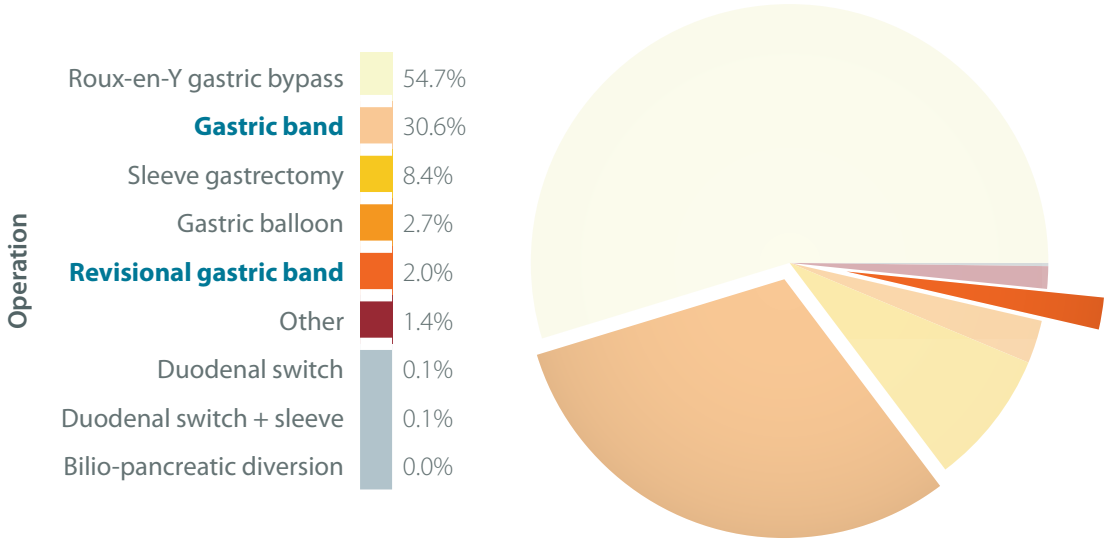


In a gastric banding procedure a synthetic ring is placed around the extreme upper portion of the stomach. The band restricts intake capacity for solid food. A balloon on the inside surface of the band can be inflated or deflated by injecting liquid through the skin into a chamber placed under the skin that connects to the balloon *via* port 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.

Type of operation performed

		Type of surgery					
		Primary	Revision	Revision as a primary	Planned 2nd stage	Unspecified	All
Operation	Gastric band	2,131	0	0	0	1	**2,132**
	Roux-en-Y gastric bypass	3,626	33	136	22	0	**3,817**
	Sleeve gastrectomy	543	5	25	14	1	**588**
	Duodenal switch	0	0	0	9	0	**9**
	Duodenal switch + sleeve	2	0	2	0	0	**4**
	Bilio-pancreatic diversion	1	0	0	0	0	**1**
	Revisional gastric band	0	54	83	2	0	**139**
	Gastric balloon	112	8	5	63	0	**188**
	Other	24	24	37	12	0	**98**
	Unspecified	43	1	0	0	25	**69**
	All	**6,483**	**125**	**288**	**122**	**27**	**7,045**

Operations performed (n=6,976)



Patient profiles

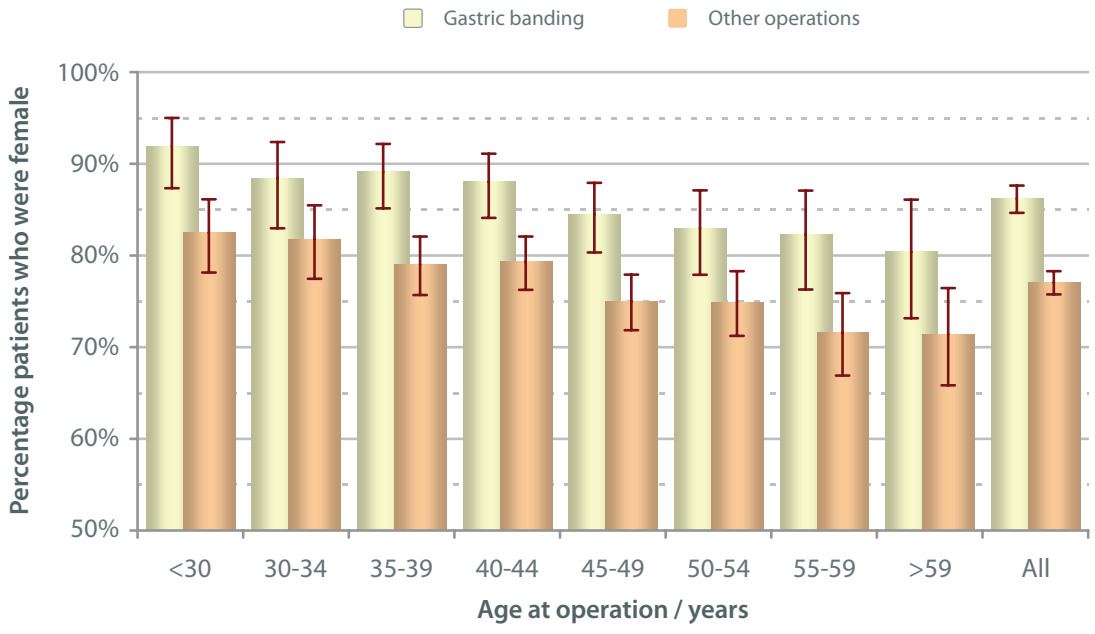
Age and gender

The average age for a female patient undergoing a primary gastric banding procedure was 43.3 years (n=1,836; SE=0.25 years), and for a male patient 46.4 years (n=293; SE=0.63 years).

Primary gastric banding: age and gender distributions

		Gender			
		Male	Female	Unspecified	**All**
Age at operation / years	<30	18	205	0	**223**
	30-34	23	176	0	**199**
	35-39	36	295	0	**331**
	40-44	43	316	0	**359**
	45-49	58	316	0	**374**
	50-54	47	229	0	**276**
	55-59	37	172	0	**209**
	60-64	17	97	0	**114**
	>64	14	30	0	**44**
	Unspecified	1	1	0	**2**
	All	**294**	**1,837**	**0**	**2,131**

Primary operations: Age and gender distributions (n=6,440)



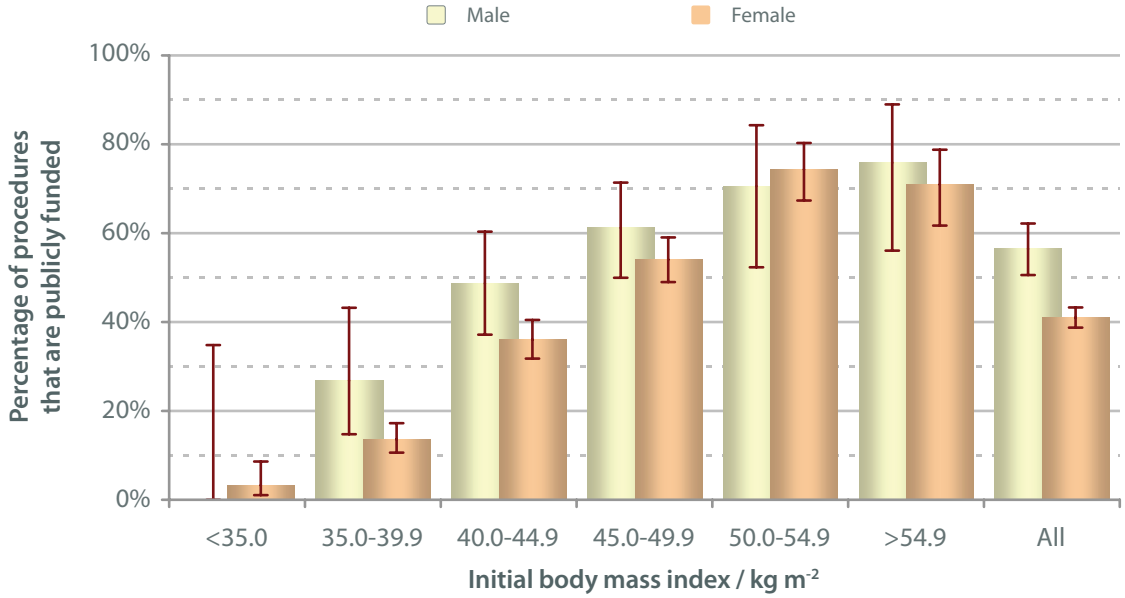
Source of funding

As previously noted, patients having a gastric band procedure tended to self-fund, especially in the lower BMI range. In contrast, although revisional band surgery is performed much less frequently, as recorded so far in the registry, a much greater proportion of these procedures were publicly funded.

Gastric banding procedures: source of funding according to initial BMI and gender

Procedure & initial body mass index / kg m^{-2}		Gender and funding					
		Male			Female		
		Funding known	Funding unspecified	Publicly funded rate	Funding known	Funding unspecified	Publicly funded rate
Gastric band	<35.0	7	0	0.0%	123	1	3.3%
	35.0-39.9	41	0	28.6%	441	0	13.6%
	40.0-44.9	76	0	48.7%	486	1	36.0%
	45.0-49.9	85	0	61.2%	394	0	54.1%
	50.0-54.9	34	0	70.6%	187	0	74.3%
	>54.9	29	0	75.9%	117	1	70.9%
	Unspecified	22	0	90.9%	84	2	91.7%
Revisional gastric band	<35.0	0	0	NA	16	0	75.0%
	35.0-39.9	0	0	NA	14	0	71.4%
	40.0-44.9	0	0	NA	13	0	76.9%
	45.0-49.9	3	0	66.7%	4	0	75.0%
	50.0-54.9	0	0	NA	2	0	100.0%
	>54.9	1	0	100.0%	2	0	100.0%
	Unspecified	1	8	80.0%	26	49	92.3%

Gastric banding: Source of funding, initial body mass index and gender (n=2,126)



Comorbid conditions at presentation

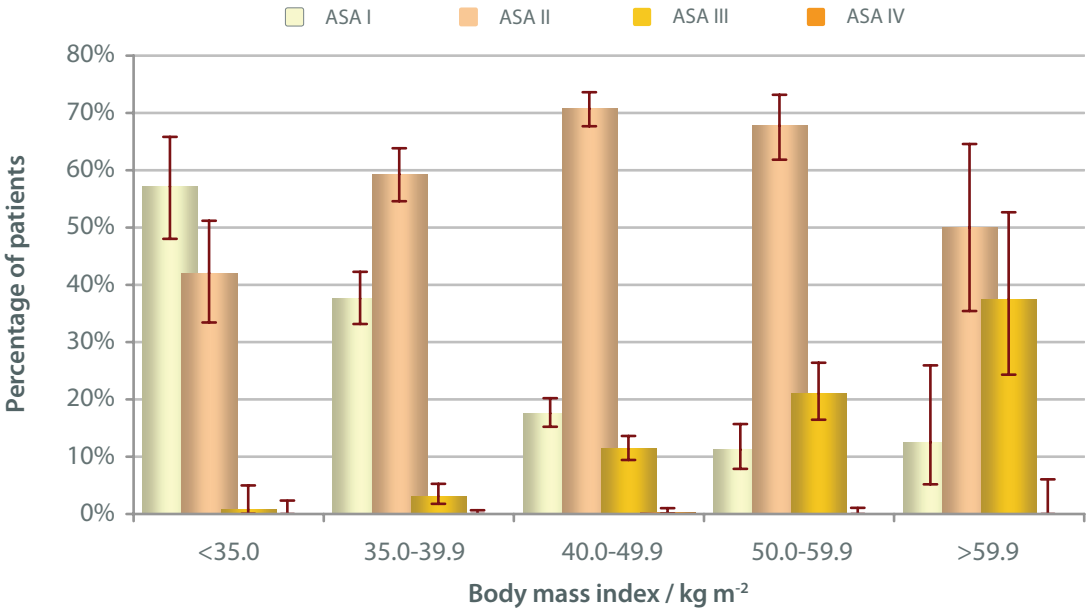
ASA grade

The ASA grade of gastric banding patients was predominantly recorded as either ASA I or ASA II; in contrast, the patients recorded in the NBSR as undergoing either gastric bypass or a sleeve gastrectomy generally had a higher ASA grade. When comparing rates of mortality or post-operative complications across the different kinds of bariatric operations it is important risk stratify the data, so as to make more reasonable comparisons. Using a pre-operative assessment systems such as the ASA grade means that the patients can be sub-divided into groups that have a similar pre-operative risk of an adverse event, which then allows comparisons of outcome rates to be made on a reasonable basis, genuinely comparing like for like.

Gastric banding procedures: ASA grade and initial body mass index

Gender and body mass index / kg m^{-2}		ASA grade				
		ASA I	ASA II	ASA III	ASA IV	Unspecified
Gastric band	<35.0	72	53	1	0	5
	35.0-39.9	170	268	14	0	30
	40.0-49.9	164	660	106	3	109
	50.0-59.9	31	187	58	0	37
	>59.9	6	24	18	0	7
	Unspecified	13	31	16	0	48
Revisional gastric band	<35.0	7	5	0	0	4
	35.0-39.9	6	7	0	0	1
	40.0-49.9	1	14	2	0	3
	50.0-59.9	0	2	0	0	0
	>59.9	0	1	1	0	1
	Unspecified	2	1	1	0	80

Primary gastric banding: ASA grade and initial body mass index (n=1,835)



Number of comorbid conditions

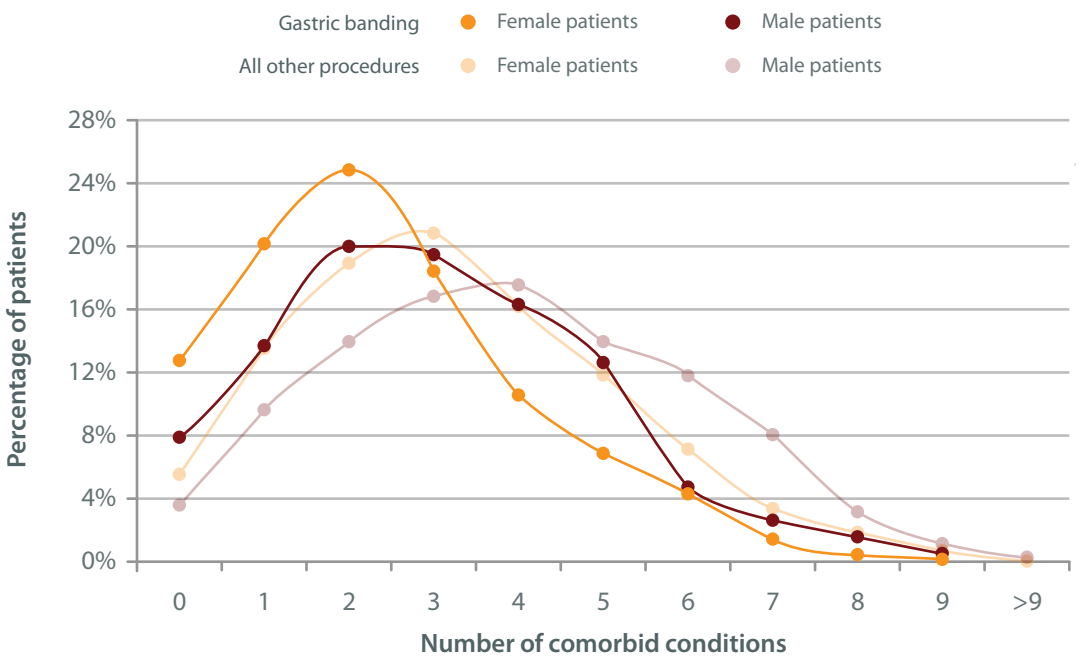
These data confirm that patients choosing to undergo a gastric banding operation have significantly fewer comorbid conditions than the rest of the patients in the registry. This is consistent with female patients choosing to have surgery at an earlier stage in their disease process, before they have developed more serious and extensive comorbidities.

Primary gastric banding: operations where all comorbidity questions are completed: number of comorbid conditions

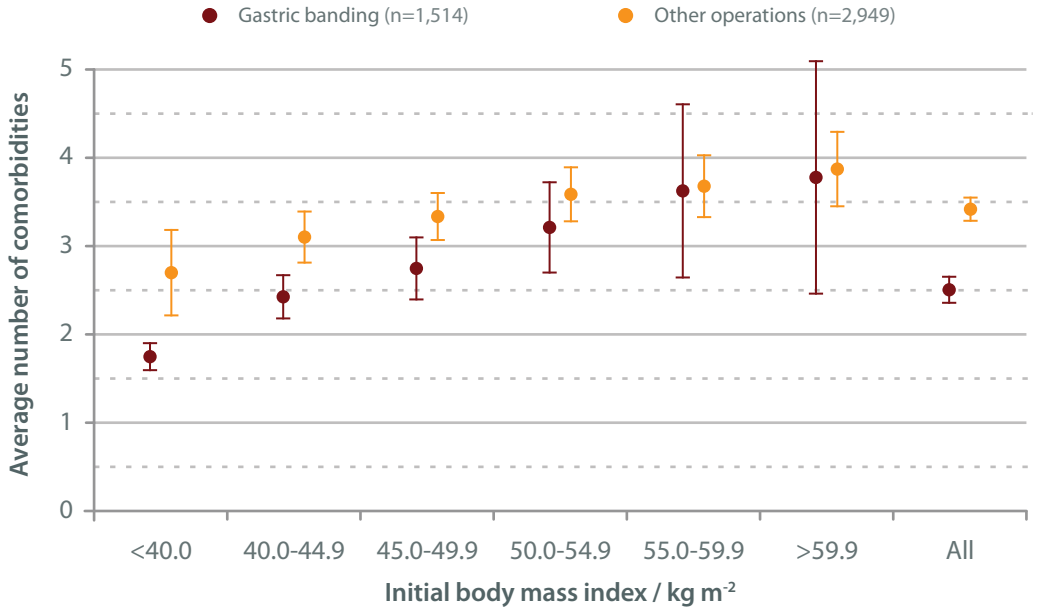
		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Number of comorbidities[i]	0	15	7.9%	169	12.8%
	1	27	14.2%	267	20.2%
	2	38	20.0%	329	24.8%
	3	37	19.5%	244	18.4%
	4	31	16.3%	140	10.6%
	5	24	12.6%	91	6.9%
	6	9	4.7%	57	4.3%
	7	5	2.6%	19	1.4%
	8	3	1.6%	6	0.5%
	9	1	0.5%	2	0.2%
	10	0	0.0%	0	0.0%
	11	0	0.0%	0	0.0%
	All	**190**		**1,324**	

i. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome. Therefore, the theoretical maximum number of missing comorbidity data-items for male patients is 11, whereas the maximum number of missing data-items for female patients is 12.

Primary operations with complete comorbidity data: Number of comorbidities and gender



Primary gastric banding operations with complete comorbidity data: Average number of comorbidities (with 95% confidence interval) and BMI



Comorbidity rates

Patients having a gastric banding procedure had fewer of each of the recorded obesity-related conditions, except for reflux disease and polycystic ovarian syndrome, compared to patients undergoing other procedures recorded in the NBSR.

Despite this, patients having a gastric banding procedure still have a considerable burden of disease. For instance, 60% were unable to climb 3 flights of stairs without resting and half had some form of limiting arthritis.

Primary operations: details on comorbid conditions

		Operation								
		Gastric banding				Other procedures				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	Significance [i]
Comorbidities [ii]	Type 2 diabetes	1,693	315	123	15.7%	2,636	1,324	349	33.4%	<0.001
	Hypertension	1,480	540	111	26.7%	2,415	1,573	321	39.4%	<0.001
	Dyslipidaemia	1,693	269	169	13.7%	3,091	798	420	20.5%	<0.001
	Atherosclerosis	1,883	67	181	3.4%	3,580	242	487	6.3%	<0.001
	Sleep apnoea	1,815	167	149	8.4%	3,116	806	387	20.6%	<0.001
	Asthma	1,697	299	135	15.0%	3,109	808	392	20.6%	<0.001
	Functional status [iii]	721	1,068	342	59.7%	907	2,562	840	73.9%	<0.001
	Arthritis	968	1,006	157	51.0%	1,739	2,161	409	55.4%	0.001
	GORD [iv]	1,303	576	252	30.7%	2,565	1,177	567	31.5%	0.562
	Liver disease	1,888	35	208	1.8%	3,576	214	519	5.6%	<0.001
	Depression	1,515	415	201	21.5%	2,777	1,022	510	26.9%	<0.001
	PCOS [v]	1,536	127	174	7.6%	2,628	263	429	9.1%	0.101

i. χ^2 probability; comparing the incidence amongst the gastric banding patients with the patients undergoing other primary procedures.

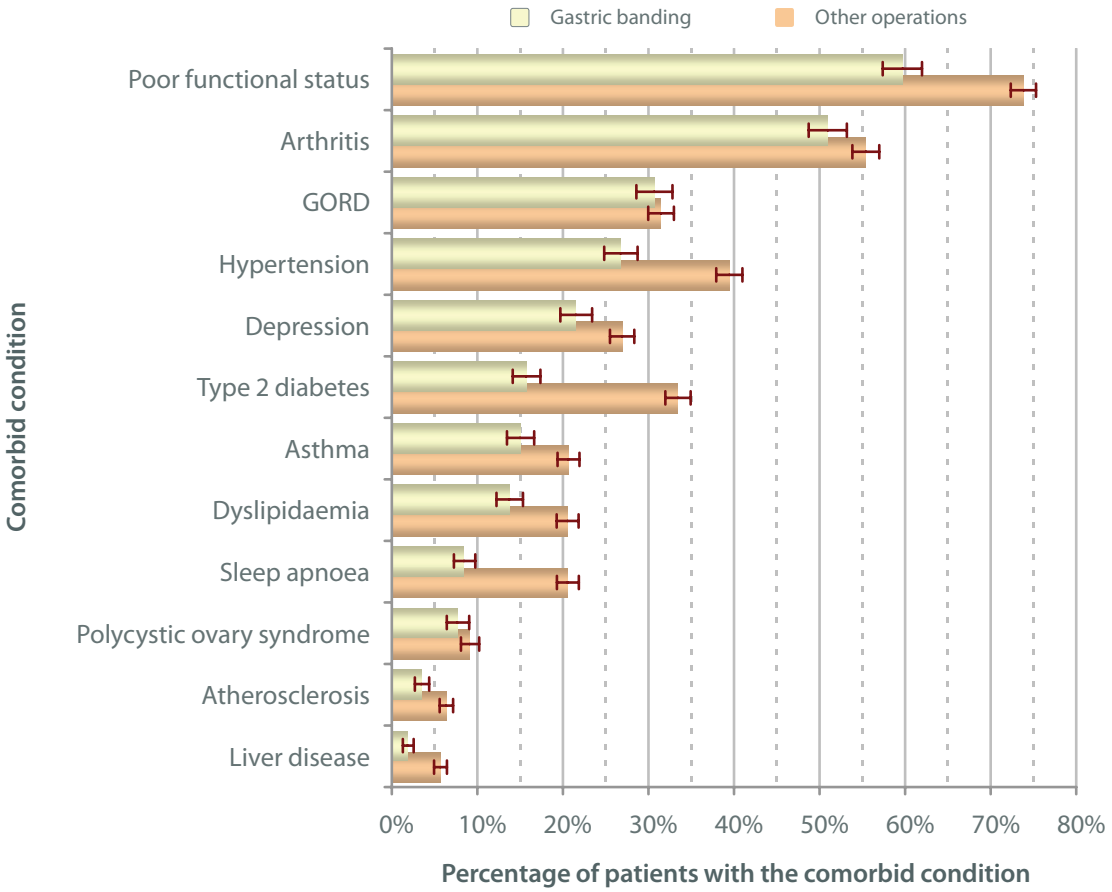
ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome.

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 ovarian syndrome.

Primary gastric banding operations: Rates of the various comorbid conditions recorded in the database

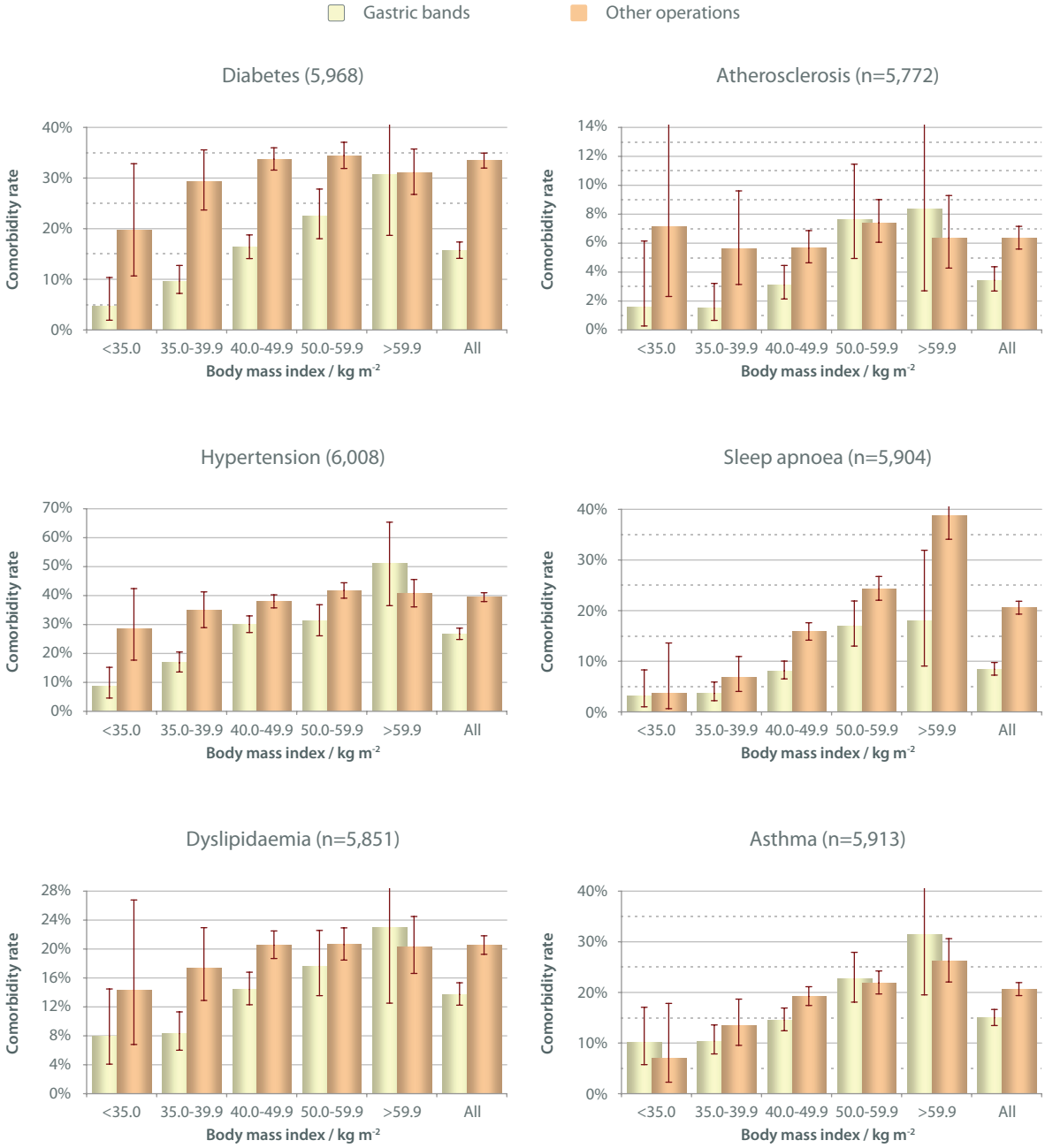


Rates of comorbid conditions, gender and body mass index

These graphs show the prevalence of each comorbidity grouped by BMI. As expected, the general picture is one where the burden of comorbid disease increases with increasing BMI.

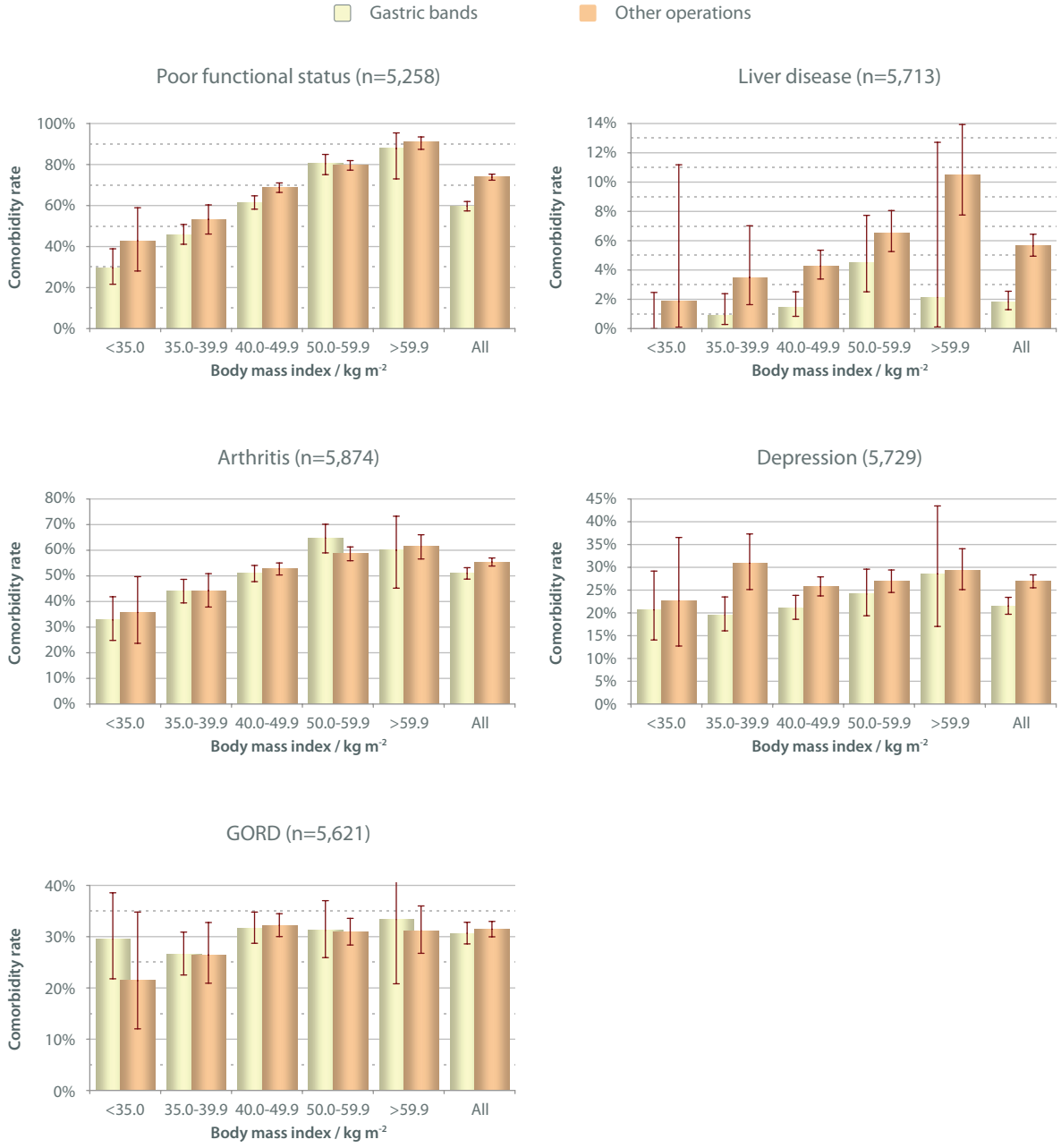
The prevalence of asthma in the patients in this registry is very interesting as it is not generally recognised that this is a condition associated with obesity, nor that it can be improved by bariatric surgery .

Primary operations: Distributions of the various comorbid conditions for patients undergoing gastric banding *versus* all other patients according to initial body mass index



These data serve to demonstrate that the relationships between BMI and coexisting comorbid disease are not as simple and predictable as one might expect.

Primary operations: Distributions of the various comorbid conditions for patients undergoing gastric banding *versus* all other patients according to initial body mass index



Technical aspects of gastric banding

Gastro-gastric tunnelling sutures

There are no data on the technique of gastric banding on the scale of a national registry, and these data from the NBSR may inform the discussion for benchmarking or standardizing procedures.

Despite controversy about this technique, almost 95% of gastric band operations used sutures to fix the band in front of the stomach. The intention of this suturing is to prevent slippage of the band lower down the stomach.

Gastric banding procedures: the use of gastro-gastric tunnelling sutures

		Gastro-gastric tunnelling sutures			
		No	Yes	Unspecified	Rate (95% CI)
Operation	Gastric band	100	1,831	201	94.8% (93.7-95.7%)
	Revisional gastric band	3	56	80	94.9% (84.9-98.7%)
	All	**103**	**1,887**	**281**	94.8% (93.7-95.7%)

Dissection

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 recommended to reduce the risk of band erosion into the stomach.

Gastric banding procedures: dissection

		Dissection			
		Pars flaccida	Peri-gastric	Unspecified	Pars flaccida rate (95% CI)
Operation	Gastric band	1,945	21	166	98.9% (98.3-99.3%)
	Revisional gastric band	57	1	81	98.3% (89.5-99.9%)
	All	**2,002**	**22**	**247**	98.9% (98.3-99.3%)

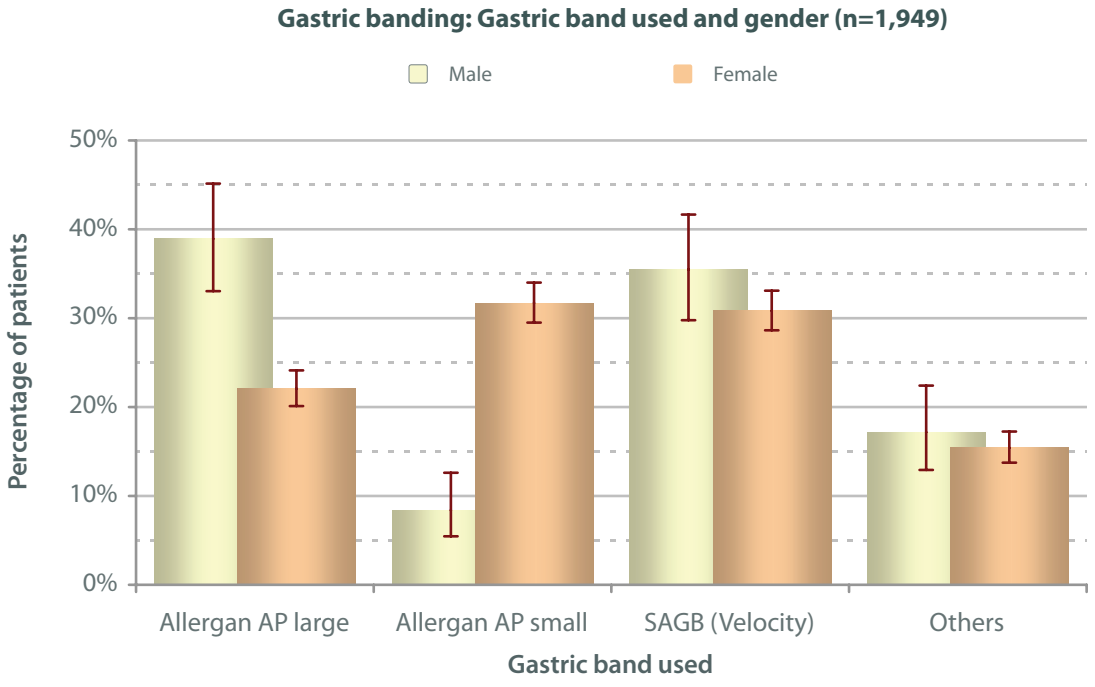
Type of band used

There are a variety of bands available to use. As there are no data in the literature to suggest that weight-loss is any better with one brand of gastric band over another; there is no question in the NBSR to collect data on the reasons for the selection of a brand of gastric band for an individual patient.

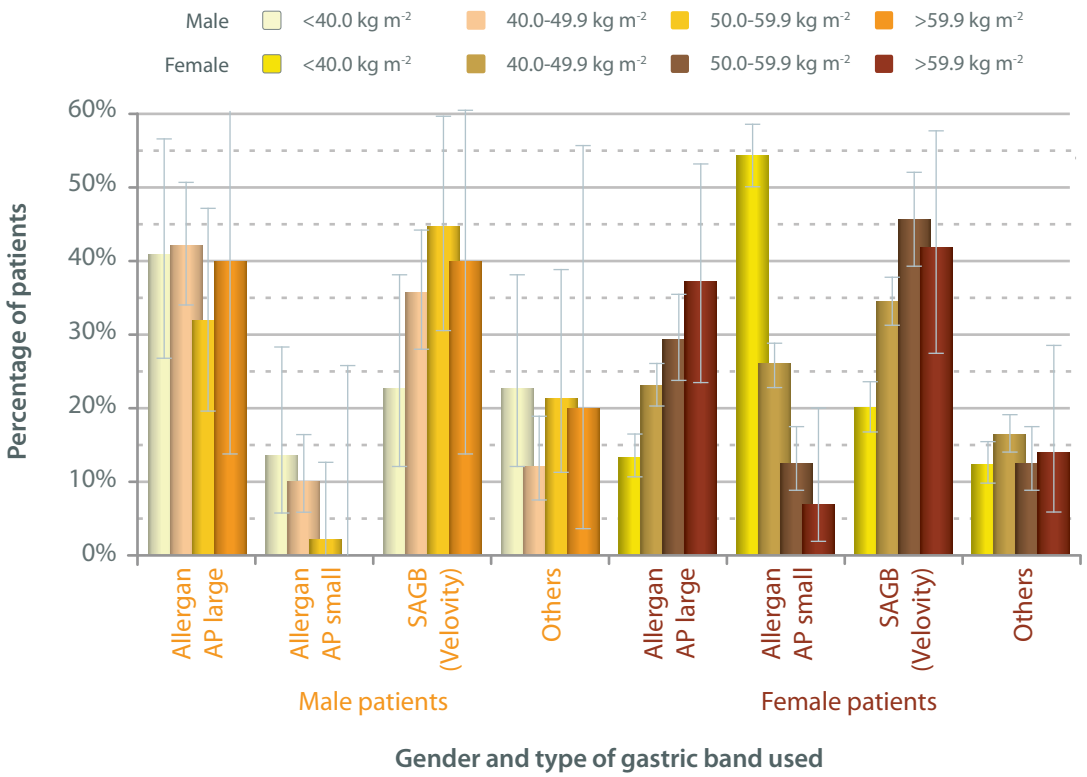
Primary gastric banding: gastric band used

		Gender					
		Male		Female		All	
		Count	Proportion	Count	Proportion	Count	Proportion
Gastric band used[i]	Allergan AP large	102	38.9%	372	22.1%	**474**	**24.3%**
	Allergan AP small	22	8.4%	535	31.7%	**557**	**28.6%**
	AMI	14	5.3%	101	6.0%	**115**	**5.9%**
	BioEnterics LAP-BAND	0	0.0%	1	0.1%	**1**	**0.1%**
	Bioring (Cousin)	6	2.3%	43	2.5%	**49**	**2.5%**
	MID	8	3.1%	35	2.1%	**43**	**2.2%**
	SAGB (Quickclose)	12	4.6%	65	3.9%	**77**	**4.0%**
	SAGB (Velocity)	93	35.5%	520	30.8%	**613**	**31.5%**
	Other	5	1.9%	15	0.9%	**20**	**1.0%**
	Unspecified	32		150		**182**	
	All	**294**		**1,837**		**2,131**	

i. This analysis is not intended to be representative of market share as the registry is not currently capturing 100% procedures performed in the United Kingdom.



Primary gastric banding: ASA grade and initial body mass index (n=1,847)



Additional procedures

It is interesting to note that hiatus hernia repair was performed in only 2.3% of patients at the time of their gastric banding procedure, despite the 30.7% prevalence of reflux symptoms in this group of patients. Further reports will be able to examine any trends in the repair of hiatal defects.

All gastric banding procedures: additional procedures

		Operation			
		Gastric band		Revisional gastric band	
		Count	Percentage	Count	Percentage
Additional procedures[i]	No additional procedures	1,858	96.3%	99	92.5%
	Cholecystectomy	12	0.6%	0	0.0%
	Hernia repair	45	2.3%	3	2.8%
	Apronectomy	0	0.0%	0	0.0%
	Other	16	0.8%	5	4.7%
	Unspecified	203		32	
	Number of operations	**2,132**		**139**	

i. More than one additional procedure may be recorded for each operation recorded in the NBSR, so the total number of additional procedures may exceed the number of operations performed.

Post-procedure outcomes

30-day complications

On an intention-to-treat basis, gastric banding appears to be a very safe technique. However, the apparent surgical complication rate of 0.9% is so low as to suggest significantly under-reporting, possibly due to a structural problem with the database or procedural issues related to data collection.

All gastric banding procedures: 30-day operative complications including re-operations

		Operation			
		Gastric band		Revisional gastric band	
		Count	Rate	Count	Rate
Number of Complications	0	2,113	99.1%	136	97.8%
	1	18	0.8%	3	2.2%
	2	1	0.1%	0	0.0%
	3	0	0.0%	0	0.0%

All gastric banding procedures: specified operative complications within 30 days

		Operation							
		Gastric band				Revisional gastric band			
		None recorded	Yes	Not recorded	Rate	None recorded	Yes	Not recorded	Rate
Complications	Any complication	2,113	17	2	0.80%	136	3	0	2.2%
	Slippage	2,129	1	2	0.05%	139	0	0	0.0%
	Perforation	2,129	1	2	0.05%	138	1	0	0.7%
	Infection	2,129	1	2	0.09%	137	2	0	1.4%
	Bleeding	2,128	2	2	0.09%	139	0	0	0.0%
	Other	2,117	13	2	0.61%	139	0	0	0.0%

All gastric banding procedures: type of re-operation within 30 days

		Operation							
		Gastric band				Revisional gastric band			
		No	Yes	Not recorded	Rate	No	Yes	Not recorded	Rate
Type of re-operation	Any re-operation	2,113	6	13	0.28%	136	2	1	1.5%
	Band slippage	2,116	3	13	0.14%	138	0	1	0.0%
	Band removed	2,118	1	13	0.05%	136	2	1	1.5%
	Attention to port / tubing	2,117	2	13	0.09%	138	0	1	0.0%

Comorbid disease after surgery

There is a reduction in the rate of each comorbidity 12 months after gastric banding. Two comorbid conditions show a statistically significant improvement in the same period: dyslipidaemia (p=0.037) and functional status (p<0.001).

For the patients with follow-up data dated at 12 months after their procedure, 15.9% have dyslipidaemia initially, reducing to a rate of 11.2% one year later. As far as functional status is concerned, the reported rate falls from 64.4% of patients unable to climb 3 flights of stairs to only 46.7% at 12 months after surgery. This is an important measure as many of these patients who attain increased mobility will be able to have to fuller lives, including returning to work, exercise, reducing the fiscal burden on the healthcare and welfare sectors, and contributing to the public purse by becoming tax-payers.

Although the data show improvements for all the other named conditions as well, these results should be interpreted with some caution as this sub-population was relatively fit prior to surgery and there is some uncertainty around the reported rates (note that the 95% confidence intervals substantially overlap). As the NBSR accumulates data on more operations and more follow-up data, the confidence in the observed rates of disease both before and after surgery will increase, which should allow us to make more definite statements about the changes in patients' comorbid conditions over time.

Primary gastric bands: comorbid conditions pre-operatively and 12 months after surgery [i]

Source of data				Comorbidity [ii]							
				Type 2 diabetes	Hypertension	Dyslipidaemia	Sleep apnoea	Functional status [iii]	Arthritis	GORD [iv]	PCOS [v]
All patients	Pre-operative data		No	1,693	1,480	1,693	1,815	721	968	1,303	1,536
			Yes	315	540	269	167	1,068	1,006	576	127
			Unspecified	123	111	169	149	342	157	252	174
			Rate	15.7%	26.7%	13.7%	8.4%	59.7%	51.0%	30.7%	7.6%
Patients with follow-up data	Pre-operative data		No	429	372	419	469	171	226	337	392
			Yes	74	132	79	32	310	265	132	33
			Unspecified	2	1	4	2	11	4	14	9
			Rate	14.7%	26.2%	15.9%	6.4%	64.4%	54.0%	28.1%	7.8%
	12-month follow-up data [i]		No	449	400	446	483	262	256	370	405
			Yes	56	105	56	20	230	239	113	29
			Unspecified	0	0	0	0	0	0	0	0
			Rate	11.1%	20.8%	11.2%	4.0%	46.7%	48.3%	23.4%	6.7%
Significance [vi] (χ^2 probability)				0.105	0.051	0.037	0.114	<0.001	0.085	0.109	0.651

i. The data used to determine the incidence of the risk factor fall in the defined time-period 365 ± 91 days. The follow-up entry used in the analysis is that row of data that is nearest in time to the 365-day point.

ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovarian syndrome.

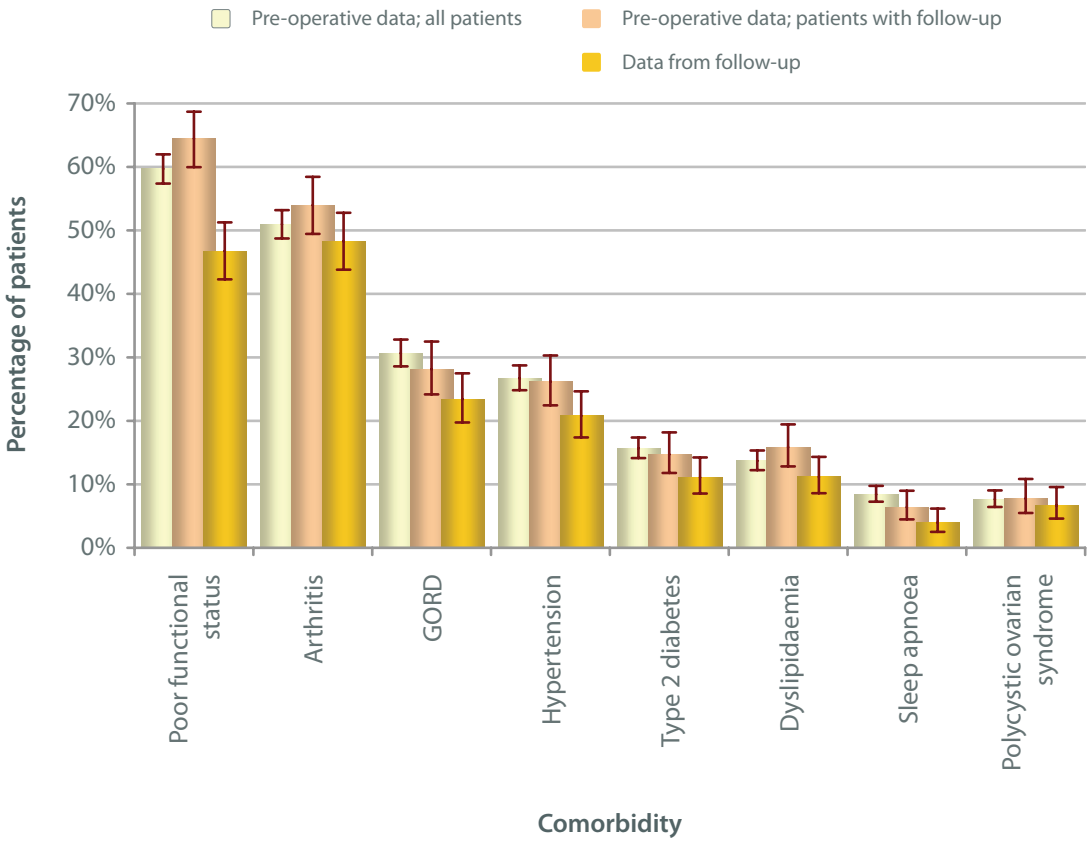
iii. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

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

v. Polycystic ovarian syndrome.

vi. Comparing the pre-operative incidence to the 12-month follow-up incidence in the patients with follow-up data.

**Primary gastric banding procedures:
Comorbid conditions before and after surgery**

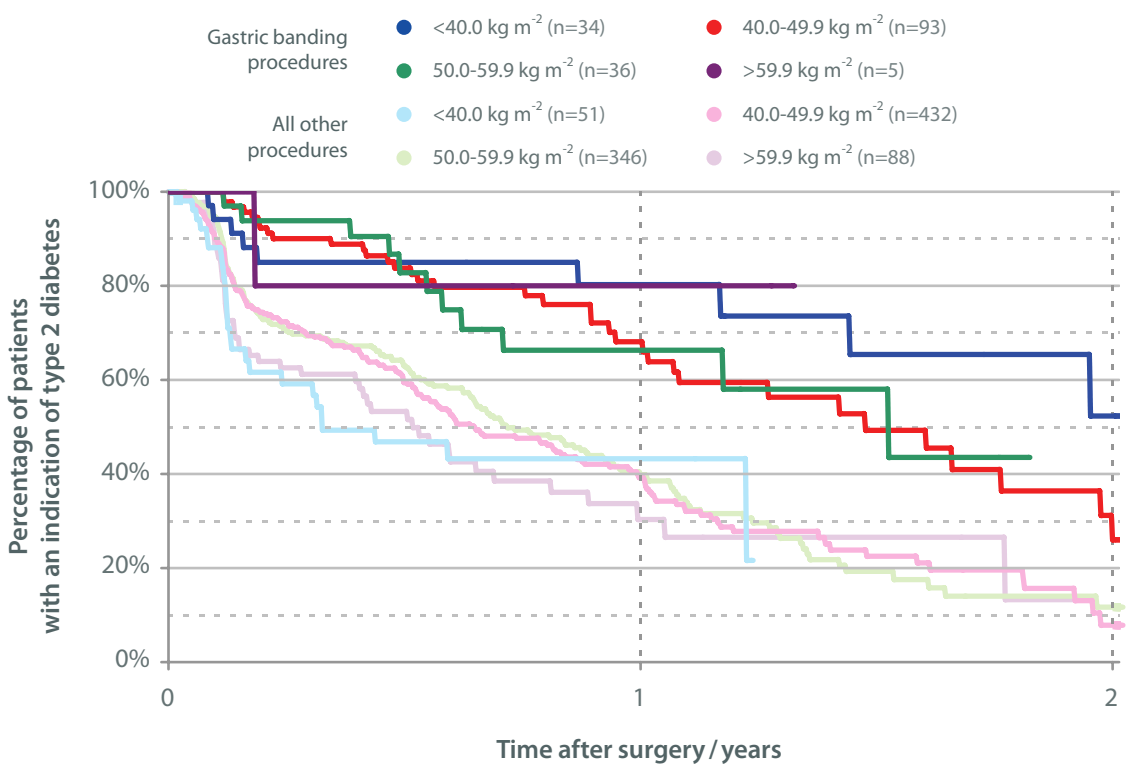


Improvement in diabetes

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

The data seem to show that the rate of change after gastric banding is 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).

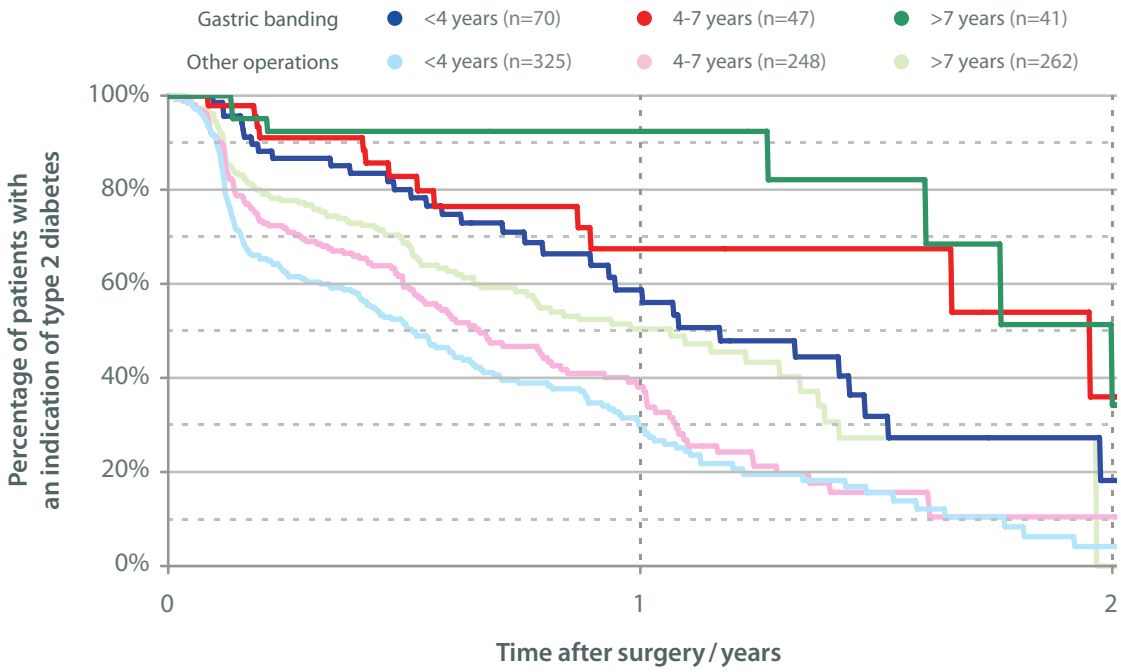
Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and BMI



Even with the *caveats* noted previously, it is clear that the duration of diabetes has an effect on the reported rate of clinical indications of diabetes. This reinforces the argument for early intervention for obese patients with or at risk of diabetes.

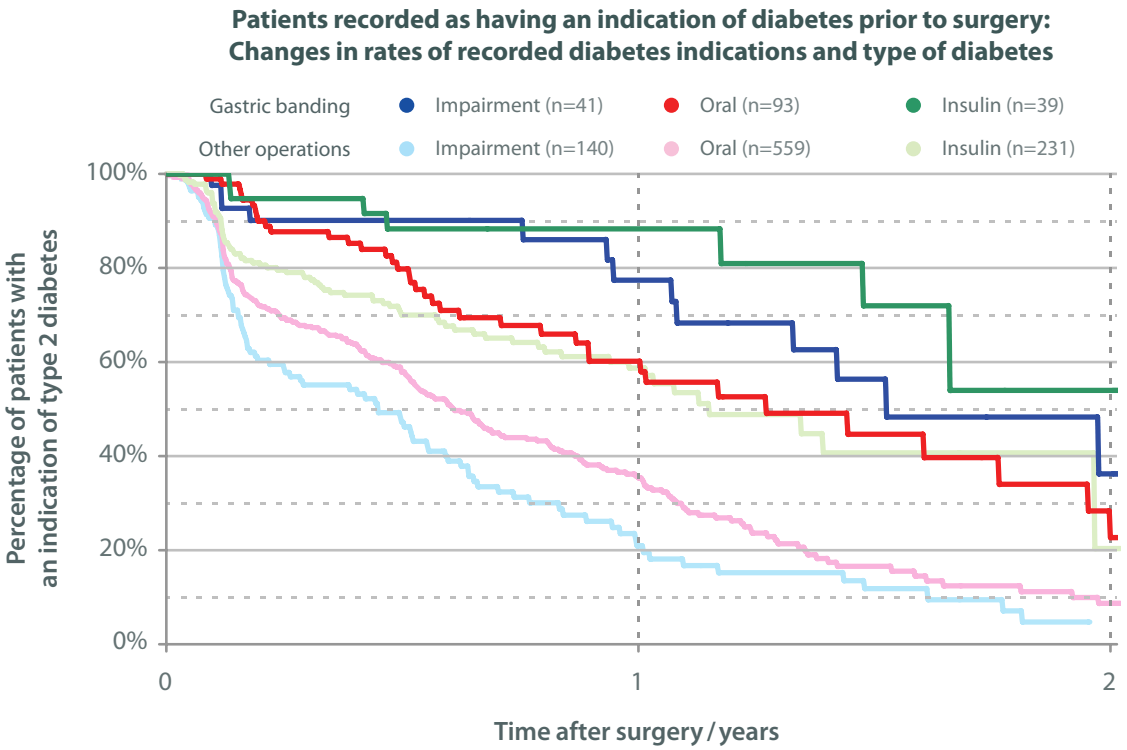
In this analysis there are relatively few patients, but, as might be expected, those with a shorter duration of diabetes were more likely to revert to a state of *No indication of diabetes*. Looking in a little more detail at the curves for the gastric banding patients, further analysis shows that the curve for patients who have had diabetes for <4 years is significantly different to that for patients whose diabetes spanned >7 years (p=0.004); comparing the curves for <4 years and 4-7 years duration also reveals a significant difference (p=0.043); whereas, the differences between the curves for diabetes of 4-7 and >7 years duration did not attain statistical significance (p=0.443).

Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and duration of diabetes



This graph show the patients returning to a state of *No indication of diabetes* according to the type of diabetes. The only statistically significance difference detected when comparing the curves for the gastric banding patients is between the patients whose diabetes was originally treated with oral medication *versus* patients treated with insulin (p=0.011).

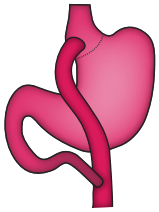
These are the first results from the NBSR, and it will be interesting to see how the picture evolves over the coming years as the database accumulates more data.



Roux en Y gastric bypass

Roux-en-Y gastric bypass

Number of entries in the context of the registry



In this procedure the stomach is divided and stitched (by very small staples) to produce a small pouch (about 30 ml, similar to that in gastric banding). The rest of the stomach remains in the body. The intestine is rearranged so that food enters it directly, bypassing both the rest of the stomach and an initial length of intestine. These are reconnected to the remaining intestine lower down (*Roux-en-Y*). Cesar Roux was the name of the Swiss surgeon who popularized the Y technique of re-joining the small bowel after gastric surgery.

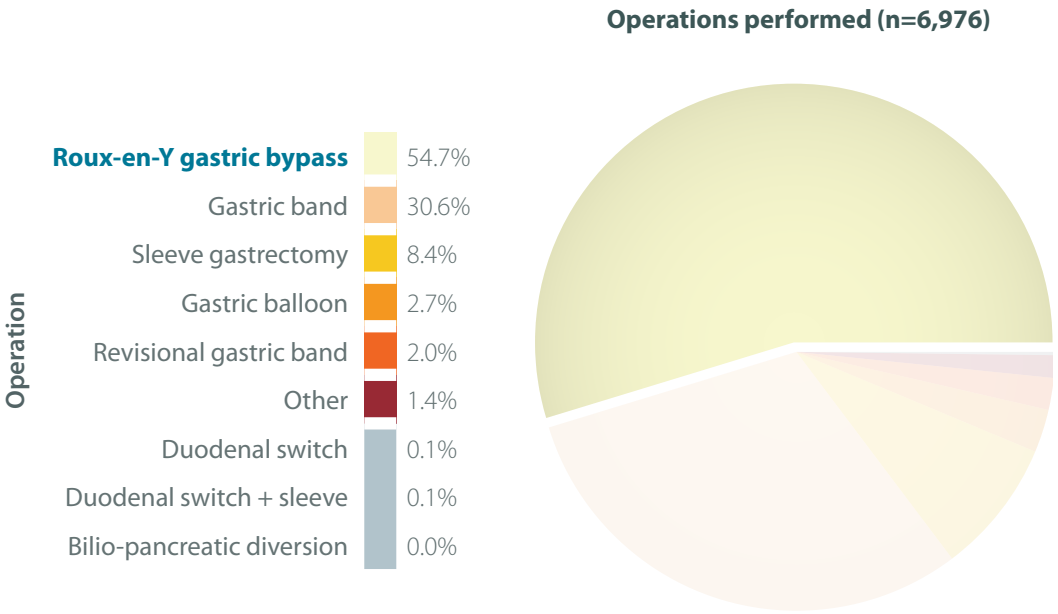
The operation greatly reduces the amount of food that can be eaten. It mildly reduces the amount of fat that can be absorbed from the food that is eaten. It has a direct effect in that it reduces appetite and also improves type 2 diabetes.

Type of operation performed

		Type of surgery					
		Primary	Revision	Revision as a primary	Planned 2nd stage	Unspecified	All
Operation	Gastric band	2,131	0	0	0	1	2,132
	Roux-en-Y gastric bypass	3,626	33	136	22	0	3,817
	Sleeve gastrectomy	543	5	25	14	1	588
	Duodenal switch	0	0	0	9	0	9
	Duodenal switch + sleeve	2	0	2	0	0	4
	Bilio-pancreatic diversion	1	0	0	0	0	1
	Revisional gastric band	0	54	83	2	0	139
	Gastric balloon	112	8	5	63	0	188
	Other	24	24	37	12	0	98
	Unspecified	43	1	0	0	25	69
	All	6,483	125	288	122	27	7,045

Gastric bypass constituted 54.7% of all operations in the NBSR. Over 95% of these were performed as a primary procedure, that is, the patients had had no previous bariatric surgery. For less than 1% of patients the operation was a revision (that is the unit had already done a previous bariatric operation and then converted to a bypass). In future reports it should be possible to examine this group of patients in more detail. The same also applies to bypasses done as a planned second stage procedure.

It is worth noting that 3.6% of recorded gastric bypass procedures were carried out as a revision procedure where the primary surgery had been performed in another unit by another surgeon (the *Revision as a primary* category).



Patient profiles

Age and gender

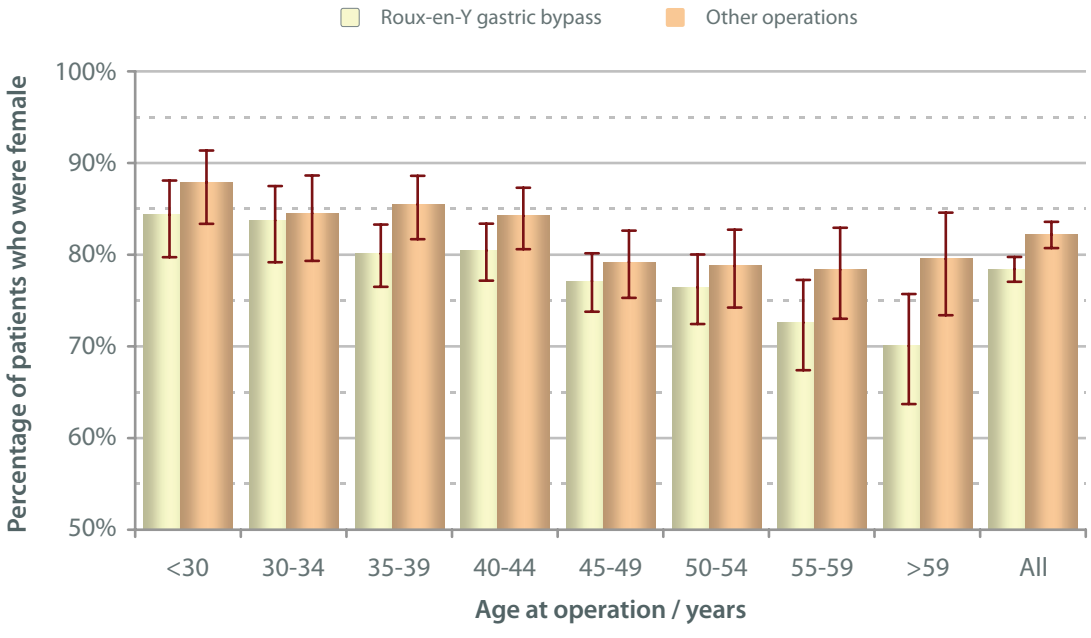
The average age for a female patient undergoing primary Roux-en-Y gastric bypass was 43.5 years (n=2,840; SE=0.19 years), and for a male patient 45.7 years (n=781; SE=0.36 years).

Women have proportionally fewer gastric bypasses than other bariatric procedures (p<0.001), and yet women still dominate the numbers of patients undergoing Roux-en-Y gastric bypass. As already demonstrated in analyses for the database as a whole and for procedures other than gastric bypass, there is a reduction in the proportion of female patients with increasing age. This means that men come to bariatric surgery later in life than women irrespective of the kind of surgery that they undergo.

Roux-en-Y gastric bypass: age and gender distributions

		Gender			
		Male	Female	Unspecified	All
Age at operation / years	<30	49	264	0	**313**
	30-34	53	273	0	**326**
	35-39	111	447	0	**558**
	40-44	128	527	0	**655**
	45-49	159	536	0	**695**
	50-54	119	386	0	**505**
	55-59	91	241	0	**332**
	60-64	57	129	0	**186**
	>64	14	37	0	**51**
	Unspecified	1	4	0	**5**
	All	**782**	**2,844**	**0**	**3,626**

Primary operations: Age and gender distributions (n=6,440)



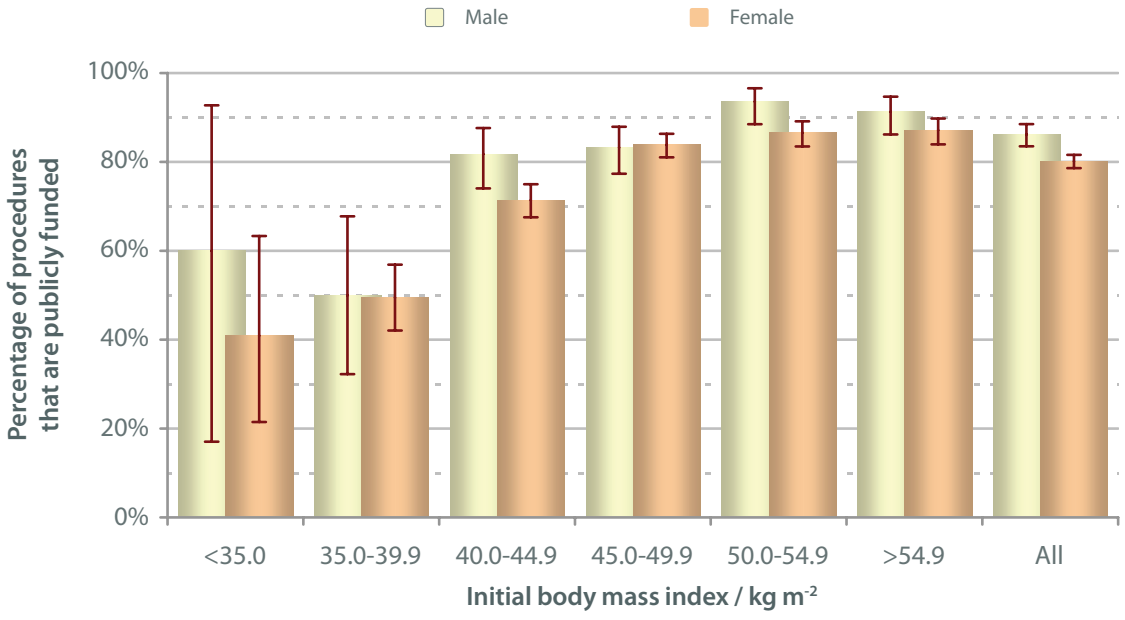
Source of funding

Gastric bypass is a predominantly publicly-funded operation. The chart below shows that women are more likely to fund their own surgery ($p<0.001$), as with the other procedures recorded in the NBSR. This seems to be the case across all BMI groups, even though there is a marked reduction in privately-funded surgery for patients with a BMI in excess of 40.0 kg m^{-2}. Again, this may suggest that access to publicly-funded surgery is being restricted to patients with significant and severe obesity.

Primary Roux-en-Y gastric bypass: source of funding according to initial BMI and gender

Initial body mass index / kg m^{-2}	Gender and funding					
	Male			Female		
	Funding known	Funding unspecified	Publicly funded rate	Funding known	Funding unspecified	Publicly funded rate
<35.0	5	0	60.0%	22	0	40.0%
35.0-39.9	32	0	50.0%	184	1	49.5%
40.0-44.9	137	1	81.8%	591	10	71.4%
45.0-49.9	209	1	83.3%	780	5	83.8%
50.0-54.9	171	1	93.6%	595	4	86.6%
>54.9	195	3	91.3%	544	1	87.1%
Unspecified	26	1	96.2%	99	8	91.9%
All	**775**	**7**	**86.2%**	**2,815**	**29**	**80.1%**

Primary Roux-en-Y gastric bypass:
Source of funding, initial body mass index and gender (n=3,590)



Comorbid conditions at presentation

Number of comorbid conditions

As we can see here, men have more comorbid conditions than women (p=0.002), in common with the results presented for gastric banding.

Patients undergoing gastric bypass, both male and female, had more obesity-related comorbid disease than for other procedures (male gastric bypass patients *versus* men undergoing other bariatric procedures: p=0.001; female gastric bypass patients *versus* women undergoing other bariatric procedures p<0.001). The reasons patients have one operation *versus* another procedure are not explored in the registry.

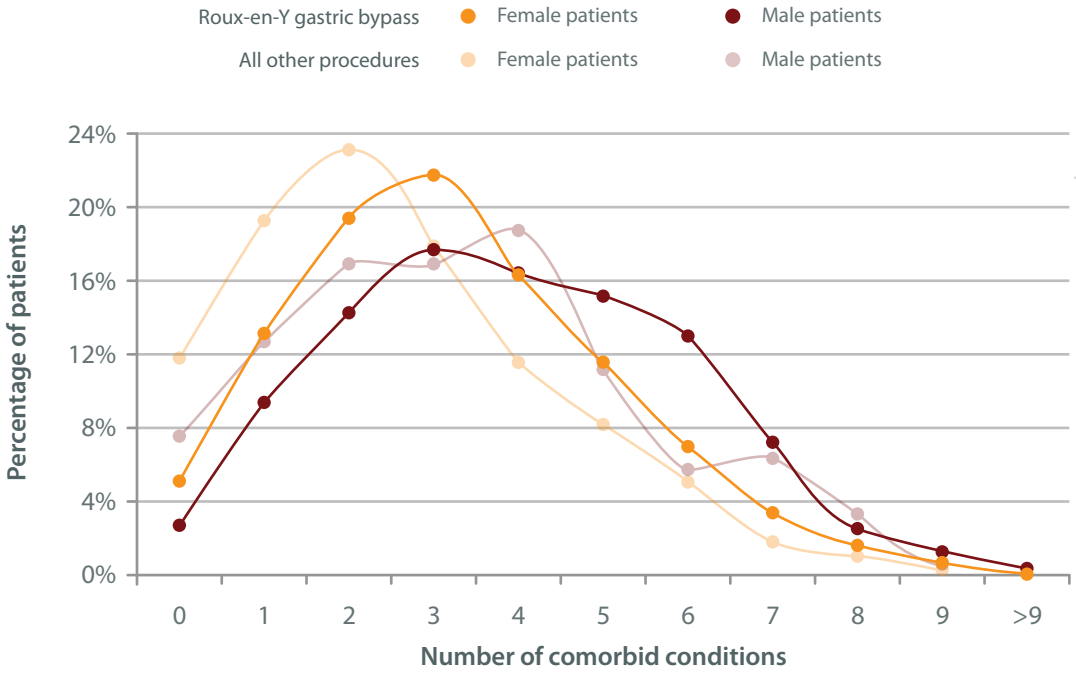
The second chart opposite clearly show that gastric bypass patients with a BMI of less than 55.0 kg m^{-2} have substantially more comorbidities than patients having other kinds of bariatric procedures. For patients with a BMI ≥55.0 kg m^{-2}, the numbers of comorbid conditions are comparable across the different kinds of primary bariatric surgery. This tends to suggest that patients with significant disease are more likely to have gastric bypass operations, possibly in the belief that this procedure will more quickly produce improvements in their condition.

Primary Roux-en-Y gastric bypass: operations where all comorbidity questions are completed: number of comorbid conditions

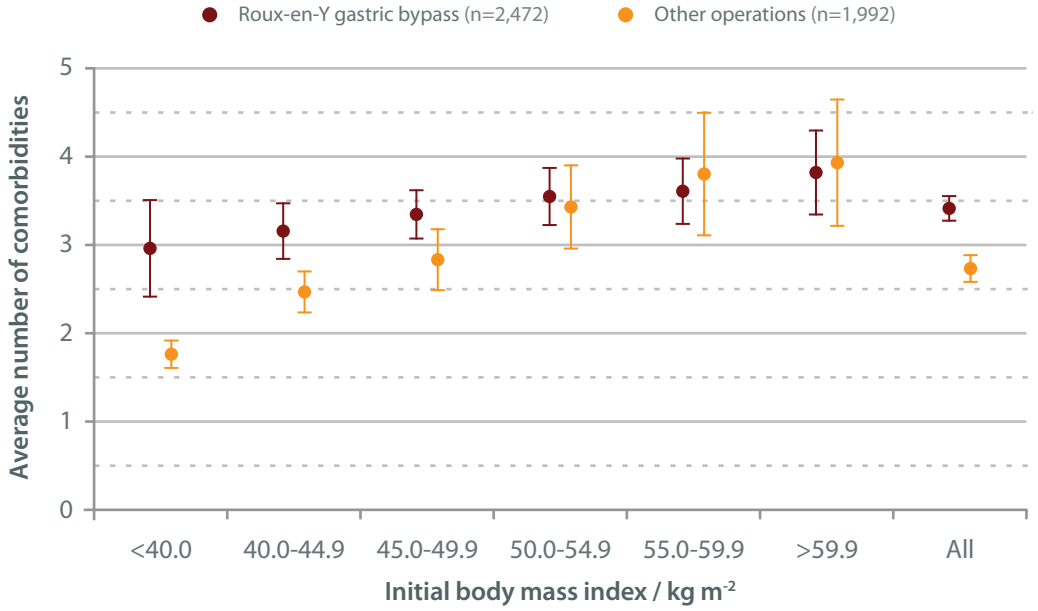
		Gender			
		Male		Female	
		Count	Percentage	Count	Percentage
Number of comorbidities[i]	0	15	2.7%	98	5.1%
	1	52	9.4%	252	13.1%
	2	79	14.3%	372	19.4%
	3	98	17.7%	417	21.7%
	4	91	16.4%	313	16.3%
	5	84	15.2%	222	11.6%
	6	72	13.0%	134	7.0%
	7	40	7.2%	65	3.4%
	8	14	2.5%	31	1.6%
	9	7	1.3%	13	0.7%
	10	1	0.2%	1	0.1%
	11	1	0.2%	0	0.0%
	All	**554**		**1,918**	

i. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome. Therefore, the maximum number of missing comorbidity data-items for male patients is 11, whereas the maximum number of missing data-items for female patients is 12.

Primary Roux-en-Y gastric bypass operations with complete comorbidity data: Number of comorbidities and gender (n=2,472)



Primary Roux-en-Y gastric bypass operations with complete comorbidity data: Number of comorbidities and body mass index



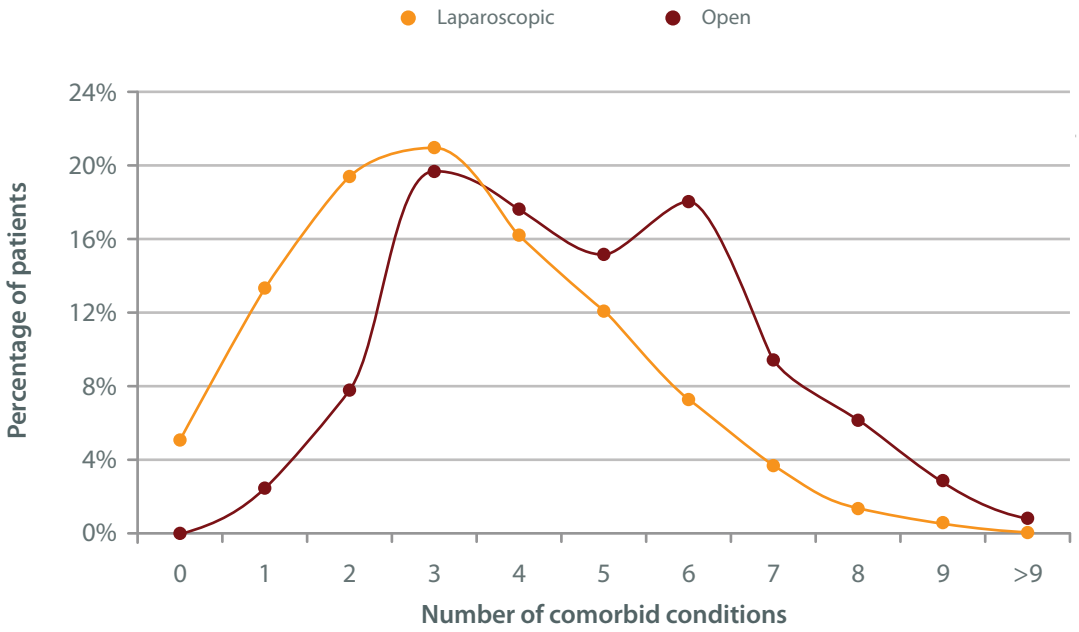
Number of comorbid conditions and approach

Although only 8.3% (301 open *versus* 3,319 laparoscopic; 6 unspecified) of gastric bypass operations were performed by open surgery, analysis shows that this group of patients had significantly more comorbid conditions than the corresponding group of patients treated laparoscopically ($p<0.001$). The NBSR does not record the reason that the patient and surgeon decided to opt for a particular operative approach, however one possible explanation for adopting the open approach is that surgeons find it preferable for high-risk patients.

Primary Roux-en-Y gastric bypass procedures: number of risk factors and operative approach for entries with complete risk factor data

		Number of risk factors										
		0	1	2	3	4	5	6	7	8	9	>9
Approach	Laparoscopic	113	297	432	467	361	269	162	82	30	13	1
	Open [i]	0	6	19	48	43	37	44	23	15	7	2
	Unspecified	0	1	0	0	0	0	0	0	0	0	0
	All	**113**	**304**	**451**	**515**	**404**	**306**	**206**	**105**	**45**	**20**	**3**

Primary Roux-en-Y gastric bypass operations with complete comorbidity data: Number of comorbidities and approach (n=2,471)



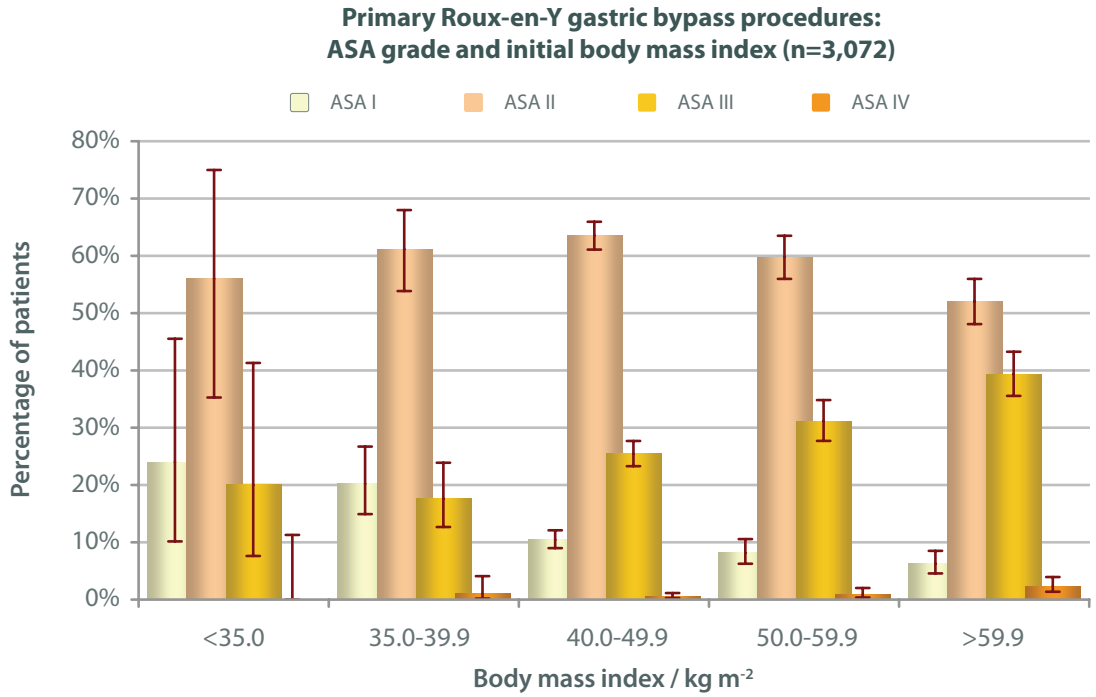
i. The operations reported as *Open* include 12 procedures that started off as laparoscopic procedures, but were later converted to an open approach..

ASA grade

This chart shows that the proportion of patients with an ASA grade of III increases with increasing BMI. At least a quarter of patients with BMI ≥40.0 kg m^{-2} were ASA III. Given the relatively high operative risk traditionally associated with this group of patients, the rate of complications amongst this group of patients was remarkably low, confirming that gastric bypass surgery is a safe procedure in the United Kingdom & Ireland.

Primary Roux-en-Y gastric bypass procedures: ASA grade and initial body mass index

Initial body mass index / kg m^{-2}	ASA grade				
	ASA I	ASA II	ASA III	ASA IV	Unspecified
<35.0	6	14	5	0	2
35.0-39.9	39	118	34	2	24
40.0-49.9	161	980	392	9	192
50.0-59.9	55	403	210	6	97
>59.9	40	332	251	15	105
Unspecified	4	44	24	1	61
All	**305**	**1,891**	**916**	**33**	**481**



Comorbidity rates

The prevalence of each obesity-related comorbid disease is significantly greater in the patients undergoing gastric bypass surgery when compared to all the other patients in the registry, with the exception of gastro-oesophageal reflux disease for which the rates are almost identical in the two groups.

It is worth noting that:

- one-third of the patients having gastric bypass surgery have diabetes.
- almost two-fifths of these patients have hypertension.
- one-fifth have dyslipidaemia.
- one-fifth of gastric bypass patients also have sleep apnoea.
- almost three-quarters could not manage to climb three flights of stairs.
- about 6% have liver disease.

These rates are clearly much higher than those reported for other patients in the NBSR. The group of patients having a gastric bypass procedure are clearly more systemically unwell and theoretically at higher risk of adverse outcomes following surgery, but they also have the more to gain in terms of improved wellbeing associated with successful weight loss after surgery.

Primary operations: details on comorbid conditions

		Operation								
		Roux-en-Y gastric bypass				Other procedures				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	Significance [i]
Comorbidities [ii]	Type 2 diabetes	2,206	1,126	294	33.8%	2,123	513	178	19.5%	<0.001
	Hypertension	2,063	1,291	272	38.5%	1,832	822	160	31.0%	<0.001
	Dyslipidaemia	2,605	658	363	20.2%	2,179	409	226	15.8%	<0.001
	Atherosclerosis	3,007	195	424	6.1%	2,456	114	244	4.4%	0.007
	Sleep apnoea	2,648	647	331	19.6%	2,283	326	205	12.5%	<0.001
	Asthma	2,621	670	335	20.4%	2,185	437	192	16.7%	<0.001
	Functional status [iii]	794	2,109	723	72.6%	834	1,521	459	64.6%	<0.001
	Arthritis	1,445	1,828	353	55.9%	1,262	1,339	213	51.5%	<0.001
	GORD [iv]	2,150	992	484	31.6%	1,718	761	335	30.7%	0.501
	Liver disease	2,994	186	446	5.8%	2,470	63	281	2.5%	<0.001
	Depression	2,335	857	434	26.8%	1,957	580	277	22.9%	<0.001
	PCOS [v]	2,237	235	372	9.5%	1,927	155	231	7.4%	0.015

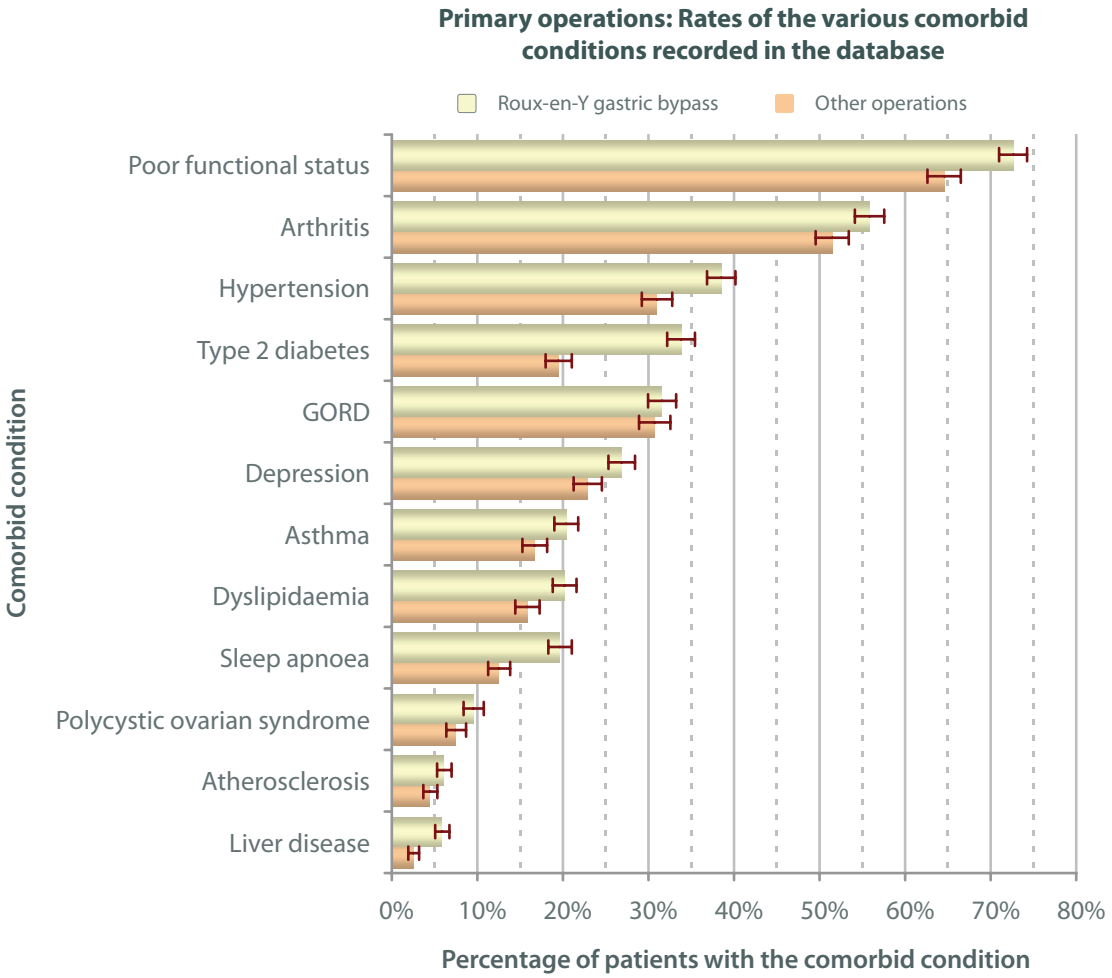
i. χ^2 probability; comparing the incidence amongst the Roux-en-Y gastric bypass patients with the patients undergoing other primary procedures.

ii. One of the comorbidity questions in the database is only collected for 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 ovarian syndrome.


Primary operations: Rates of the various comorbid conditions recorded in the database
Roux-en-Y gastric bypass
Other operations
Comorbid condition
Poor functional status
Arthritis
Hypertension
Type 2 diabetes
GORD
Depression
Asthma
Dyslipidaemia
Sleep apnoea
Polycystic ovarian syndrome
Atherosclerosis
Liver disease
0%
10%
20%
30%
40%
50%
60%
70%
80%
Percentage of patients with the comorbid condition

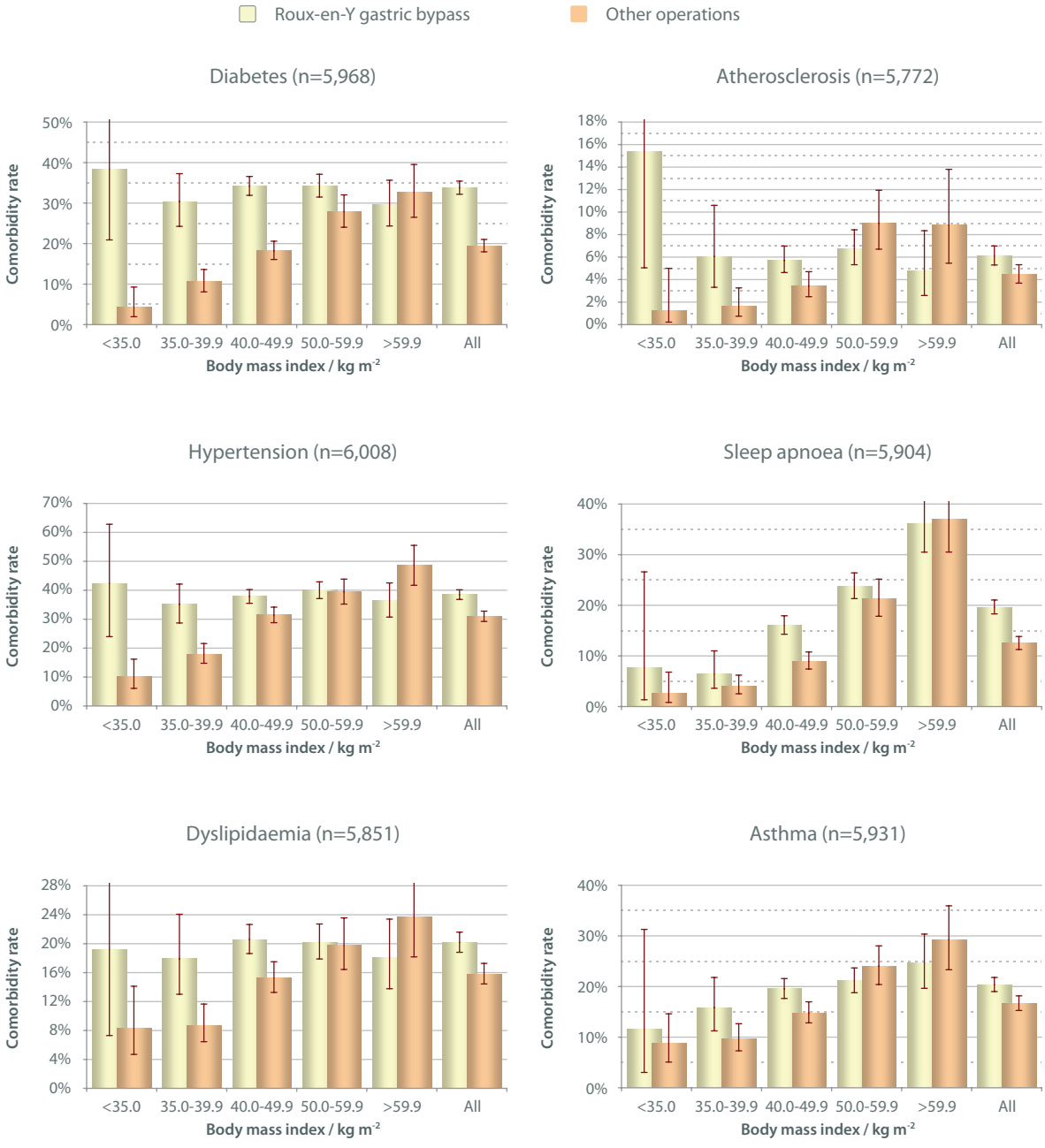
Rates of comorbid conditions, gender and body mass index

As previously demonstrated for gastric banding patients, on the whole the incidence of each obesity-related comorbid condition rises with increasing BMI.

For some of these conditions this is also generally true for the patients undergoing Roux-en-Y gastric bypass:

- sleep apnoea.
- asthma.
- poor functional status.
- liver disease.
- arthritis.

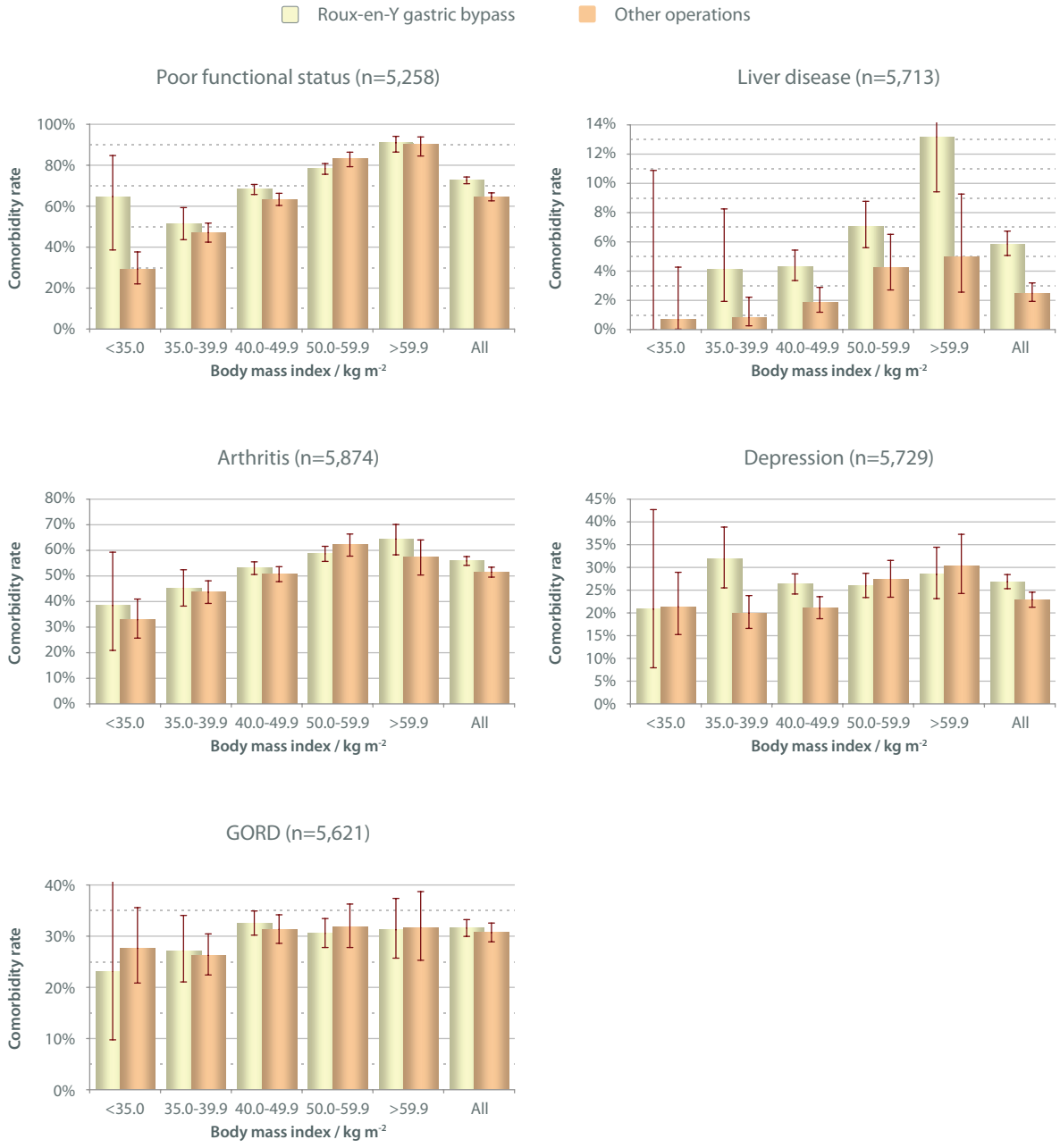
Primary operations: Distributions of the various comorbid conditions for patients undergoing Roux-en-Y gastric bypass *versus* all other patients according to initial body mass index



The relationships between BMI and the other comorbid conditions are not so clear-cut. For example, the rate of diabetes in patients undergoing gastric bypass surgery seems to be independent of the patient's initial BMI. Likewise, the rate of atherosclerosis is very high in the lowest BMI group (which may just be an artefact of the relatively low number of patients in this group, indicated by the wide 95% confidence intervals; another possible explanation could be that patients with established cardiovascular disease in the lower BMI range are being referred for surgery) and thereafter is relatively stable at round 6%. The prevalence of asthma is very interesting in all the patients in the NBSR as it is not generally recognised that this is a condition associated with obesity, nor that it can be improved by bariatric surgery.

This all serves to demonstrate that the relationships between BMI and coexisting comorbid disease are not as simple and predictable as one might expect.

Primary operations: Distributions of the various comorbid conditions for patients undergoing Roux-en-Y gastric bypass *versus* all other patients according to initial body mass index



Obesity Surgery Mortality Risk Score

The Obesity Surgery Mortality Risk Score [1] (OSMRS) is a simple additive system designed to assessing the risk of operative mortality following Roux-en-Y gastric bypass surgery. It is calculated from the following factors, each one of which scores one point:

- male gender.
- age as 45 years or older.
- BMI >50.0 kg m^{-2}.
- hypertension (or on treatment).
- known risk of pulmonary embolus / deep vein thrombosis.

The possibles scores ranges between 0 and 5. 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).

Primary Roux-en-Y gastric bypass procedures: Obesity Surgery Mortality Risk Score (OSMRS)

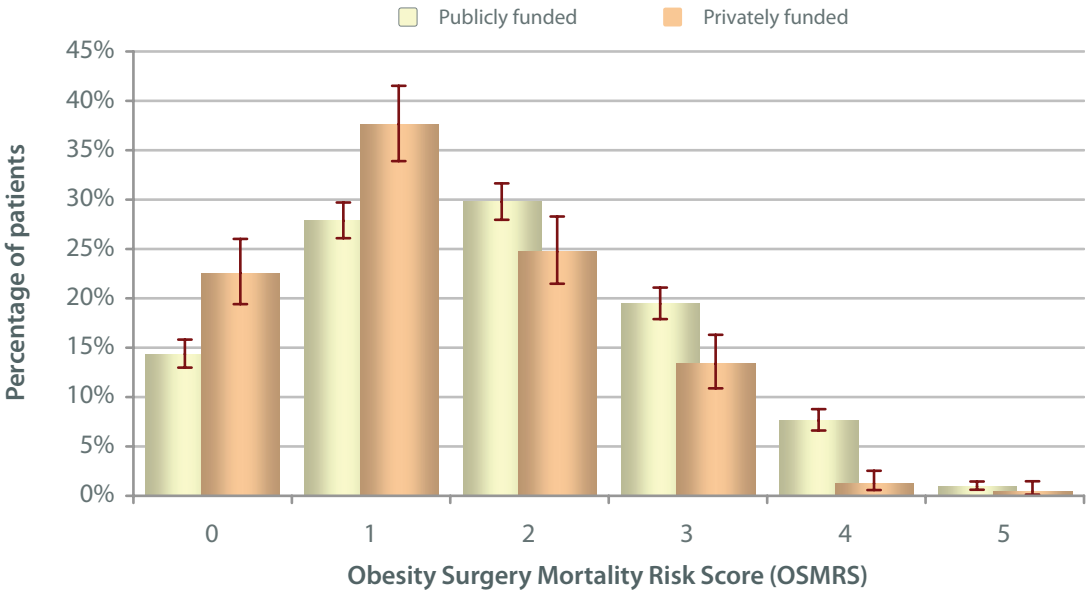
			Funding			
			Publicly funded	Privately funded	Unspecified	All
OSMRS	Group A	0	346 (14.3%)	145 (22.6%)	0	**491**
		1	672 (27.9%)	242 (37.6%)	1	**915**
		Group A	**1,018** (42.2%)	**387** (60.2%)	1	**1,406**
	Group B	2	718 (29.8%)	159 (24.7%)	0	**877**
		3	469 (19.4%)	86 (13.4%)	1	**556**
		Group B	**1,187** (49.2%)	**245** (38.1%)	1	**1,433**
	Group C	4	184 (7.6%)	8 (1.2%)	0	**192**
		5	23 (1.0%)	3 (0.5%)	0	**26**
		Group C	**207** (8.6%)	**11** (1.7%)	0	**218**
		Unspecified	512	23	34	**569**
		All	**2,924**	**666**	**36**	**3,626**

It is highly noteworthy that 8.6% of publicly funded patients are in Group C, indicating that surgeons in the United Kingdom & Ireland are undertaking gastric bypass on high-risk patients, with very low reported complication and mortality rates.

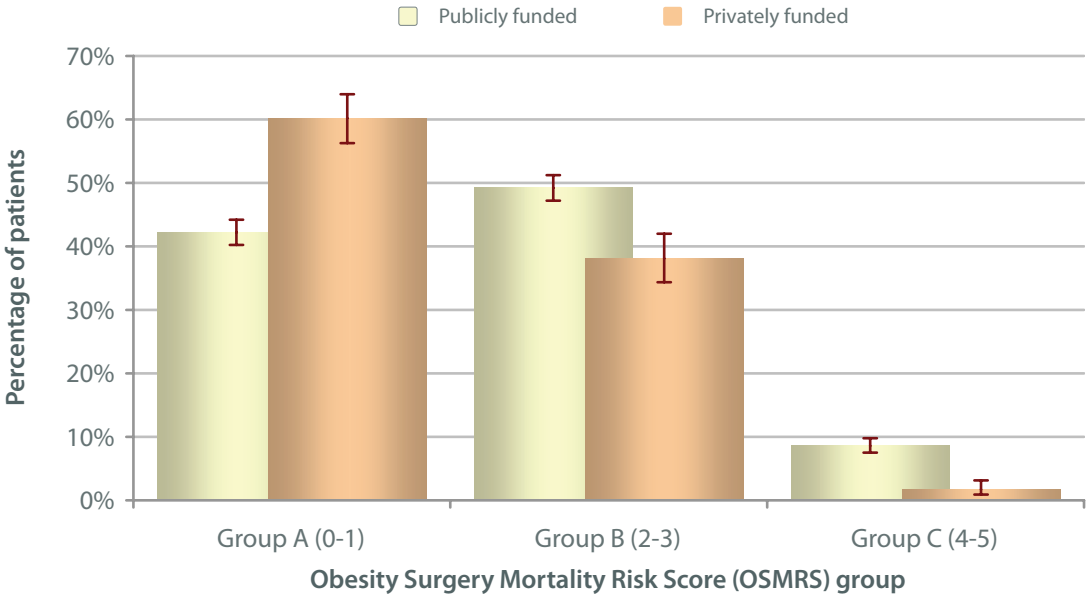
These are the first data from a national registry to report on OSMRS for gastric bypass.

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 and Related Diseases.* 2007; **3(2):** 134-40.

Primary Roux-en-Y gastric bypass: OSMRS and source of funding (n=3,055)



Primary Roux-en-Y gastric bypass: OSMRS group & source of funding (n=3,055)



Technical aspects of Roux-en-Y gastric bypass

Gastric pouch

Several hundred-thousand gastric bypass procedures are probably performed worldwide each year. For a procedure that is so common it is surprising that there is, as yet, no consensus on what constitutes a *standard* gastric bypass procedure. It may be that each technique delivers similar results for the patient, but data collected in the NBSR on technical aspects of Roux-en-Y gastric bypass will serve to inform the debate on this issue.

These data are the first published from a national database on the specifics of operative technique.

The NBSR recorded rate of 94.2% of patients who had a vertical lesser curve-based gastric pouch is consistent with the technique as published by MacLean in Montreal [1].

Roux-en-Y gastric bypass: gastric pouch and type of operation

		Gastric pouch			
		Vertical lesser curve pouch	Horizontal pouch including fundus	Unspecified	**All**
Type of surgery	Primary	3,178	194	254	**3,626**
	Revision	24	0	9	**33**
	Revision as a primary	122	9	5	**136**
	Planned 2nd stage	22	0	0	**22**
	Unspecified	0	0	0	**0**
	All	**3,346**	**203**	**268**	**3,817**

1. MacLean LD, , Rhode BM, and Nohr CW. Late Outcome of Isolated Gastric Bypass. *Annals of Surgery.* 2000; **231(4):** 524–528

Linear stapler for gastric pouch

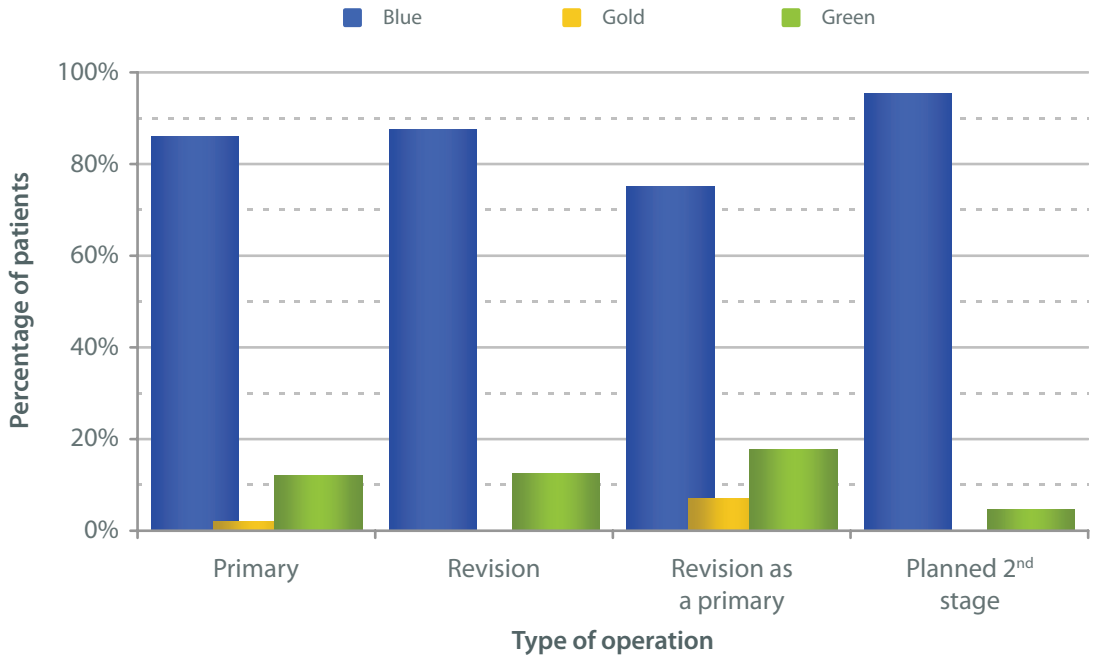
87.7% of gastric pouches were formed with surgical stapling instruments called linear staplers, which fire several rows of staples then cut and divide the tissue in between. Staplers can be used to separate bowel; conversely they can also be used join two adjacent loops of the bowel.

The different colours indicate different staple heights. In *revision as a primary* procedures green (larger) staples were used more often than the standard blue cartridge (p=0.049). This is probably because surgeons preferred to use larger staples on scarred tissue.

Roux-en-Y gastric bypass: linear stapler used in gastric pouch formation and type of operation

		Linear stapler				
		Blue	Gold	Green	Unspecified	**All**
Type of surgery	Primary	2,727	61	383	455	**3,626**
	Revision	21	0	3	9	**33**
	Revision as a primary	97	9	23	7	**136**
	Planned 2nd stage	21	0	1	0	**22**
	Unspecified	0	0	0	0	**0**
	All	**2,866**	**70**	**410**	**471**	**3,817**

Roux-en-Y gastric bypass: Linear stapler used for gastric pouch formation (n=3,346)

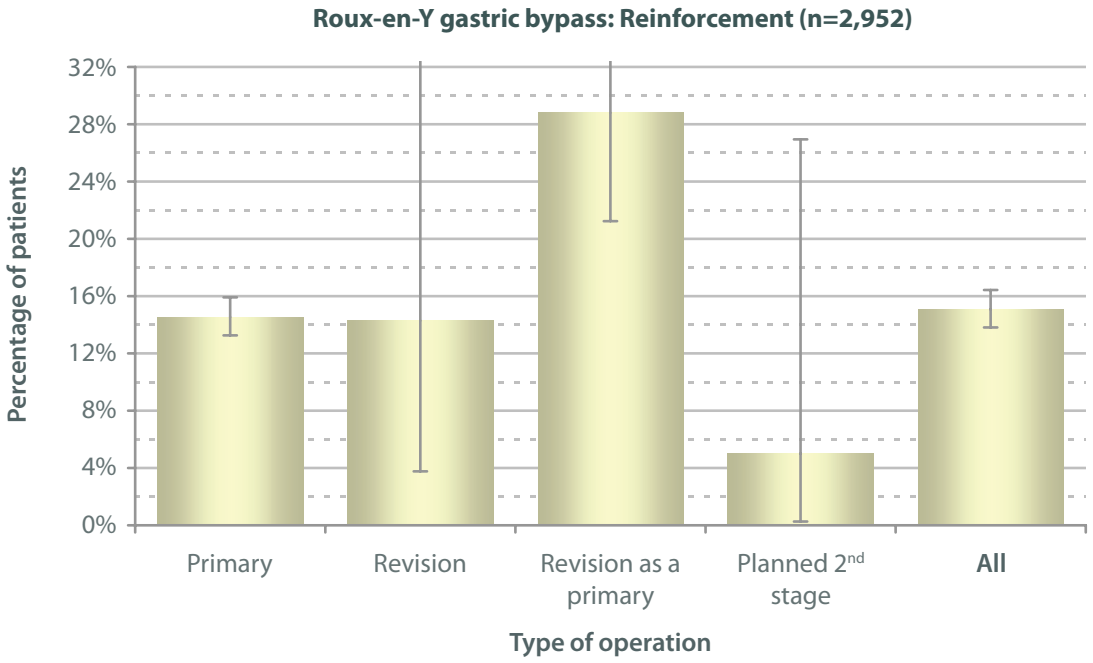


Reinforcement

The two most-feared surgical complications after gastric bypass are leakage and bleeding. Future reports should be able to investigate the relative risk of adverse outcomes following revisional gastric bypass surgery (as opposed to primary surgery), to determine whether or not there is any elevated risk, as is generally reported in the international literature.

Roux-en-Y gastric bypass: staple line reinforcement of gastric pouch

		Linear stapler			
		No	Yes	Unspecified	**All**
Type of surgery	Primary	2,381	405	840	**3,626**
	Revision	18	3	12	**33**
	Revision as a primary	89	36	11	**136**
	Planned 2nd stage	19	1	2	**22**
	Unspecified	0	0	0	**0**
	All	**2,507**	**445**	**865**	**3,817**



Gastric pouch jejunostomy

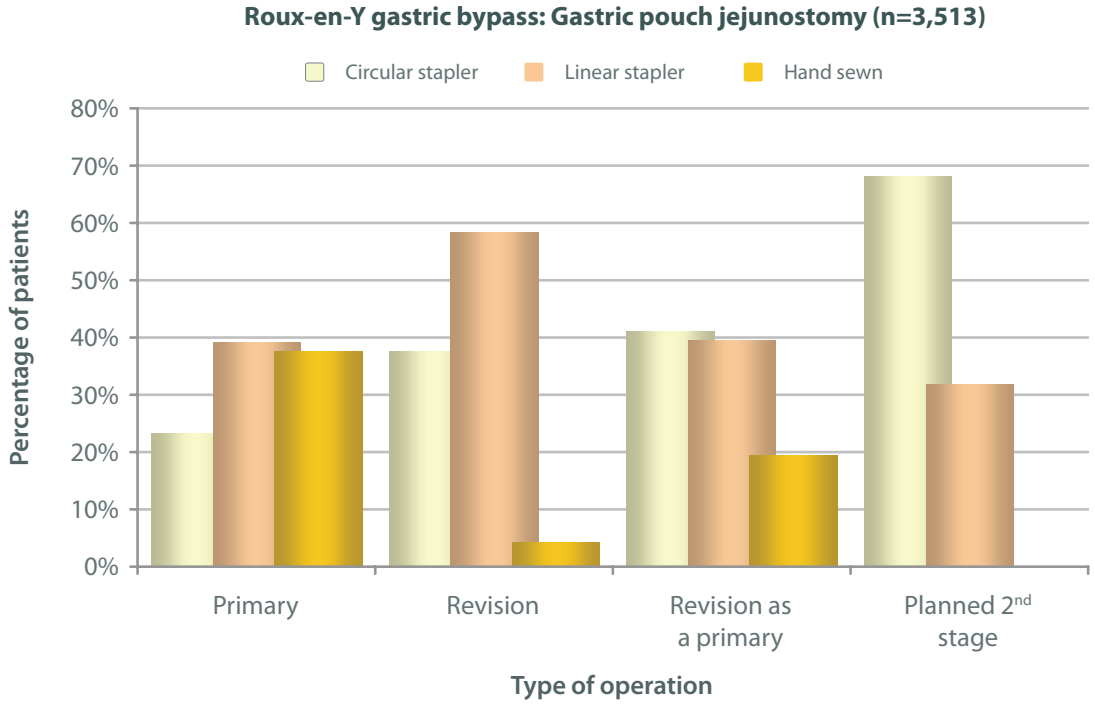
There are 3 different ways to join the *Roux limb* to the new gastric pouch:

- circular stapling.
- linear stapler (and suture closure of the stapler entry hole).
- entirely hand sewn.

These are the first published data from a national registry to show which techniques are used. The majority of surgeons used a linear stapler. Future reports from the registry may be able to explore whether the techniques lead to different complication rates; for instance leakage in the post-operative period, or, later, stenosis (narrowing) of the anastomosis (join).

Roux-en-Y gastric bypass: gastric pouch jejunostomy

		Gastric pouch jejunostomy				
		Circular stapler	Linear stapler	Hand sewn	Unspecified	**All**
Type of surgery	Primary	778	1,309	1,251	288	**3,626**
	Revision	9	14	1	9	**33**
	Revision as a primary	53	51	25	7	**136**
	Planned 2nd stage	15	7	0	0	**22**
	Unspecified	0	0	0	0	**0**
	All	**855**	**1,381**	**1,277**	**304**	**3,817**

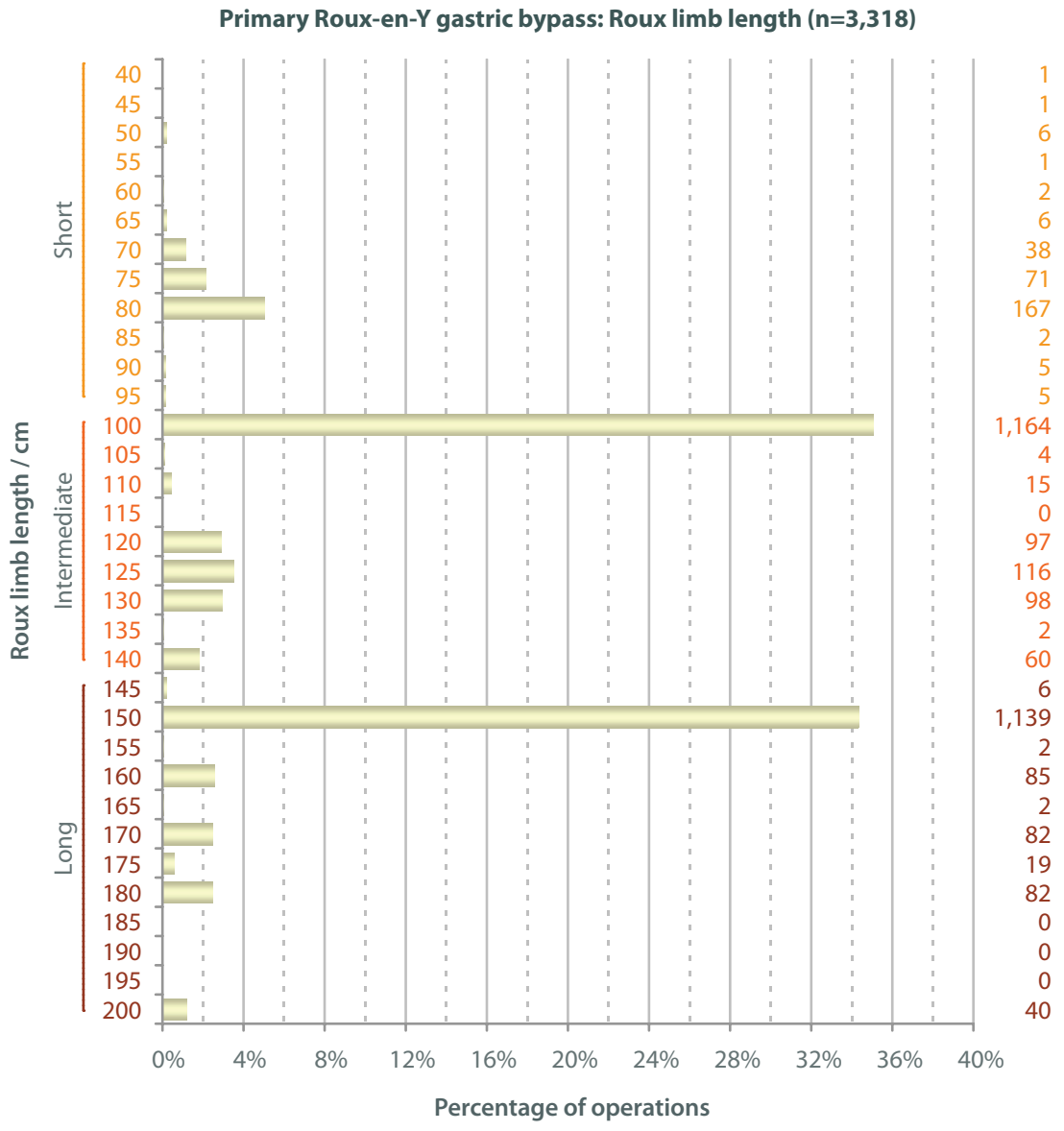


Roux limb

Roux limb length

It is very difficult to measure the length of the small bowel accurately, as it can stretch significantly, and, partly for this reason alone, there is wide variation in the amount of small bowel that surgeons choose to bypass from the flow of bile and digestive enzymes from the pancreas as part of the gastric bypass procedure [1,2].

By far the majority of operations used either a 100 cm or 150 cm Roux limb-length; a very small minority of surgeons used a length of 200 cm.



1. Christou NV, Look D, and MacLean LD. Weight Gain After Short- and Long-Limb Gastric Bypass in Patients Followed for Longer Than 10 Years. *Annals of Surgery.* 2006; **244(5):** 734–740.

2. Brolin RE, Kenler HA, Gorman JH, *et al*. Long-limb gastric bypass in the super-obese: A prospective randomized study. *Annals of Surgery.* 1992; **215:** 387-395

Roux limb length and BMI

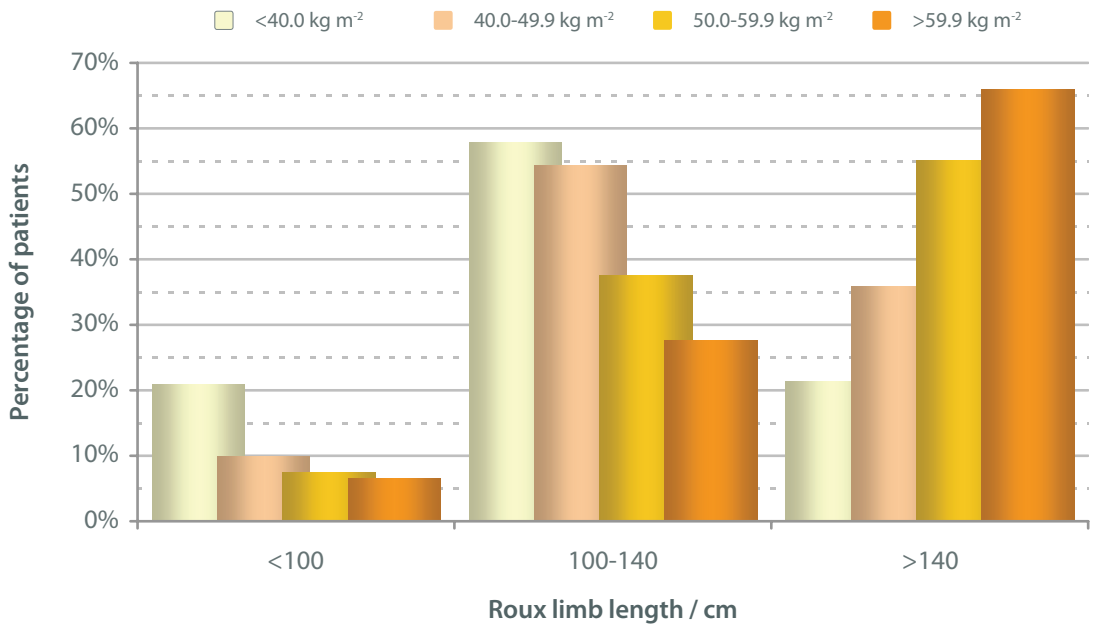
As BMI increases, there is a tendency to favour increasing Roux limb-length. For patients in the lowest BMI group (<40.0 kg m^{-2}) a Roux limb length of <100 cm is used in around 20% of operations; as BMI increases, this same limb-length is used in 10% or fewer procedures. The proportion of operations employing a Roux limb-length of 100-140 cm falls with increasing BMI from 57.8% for the smallest (<40.0 kg m^{-2}) patients to 27.8% in the largest (>59.9 kg m^{-2}) patients; there is a concomitant rise in the use of >140 cm Roux limb-lengths with increasing BMI.

Although most international reports seem to agree that small variations in limb-lengths do not affect long-term weight loss, the registry will be able to record any developing consensus in the United Kingdom & Ireland in due course.

Primary Roux-en-Y gastric bypass: Roux limb length and initial body mass index

		Initial body mass index / kg m^{-2}					
		<40.0	40.0-49.9	50.0-59.9	>59.9	Unspecified	**All**
Roux limb length / cm	<100	48	157	81	18	1	**305**
	100-140	133	862	413	77	71	**1,556**
	>140	49	569	605	184	50	**1,457**
	Unspecified	14	146	108	28	12	**308**
	All	**244**	**1,734**	**1,207**	**307**	**134**	**3,626**

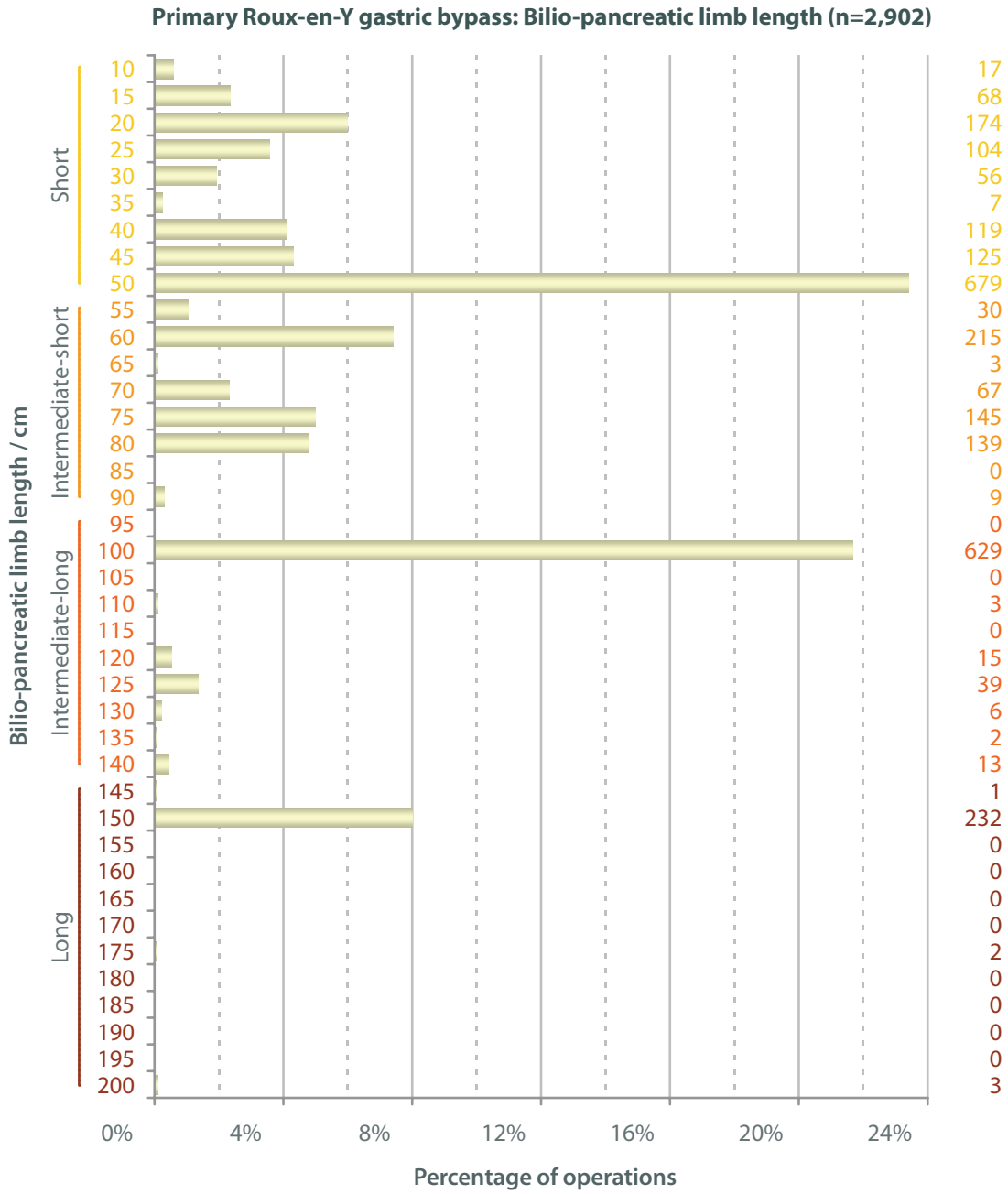
Primary Roux-en-Y gastric bypass: Roux limb length and initial body mass index (n=3,196)



Bilio-pancreatic limb

Bilio-pancreatic limb length

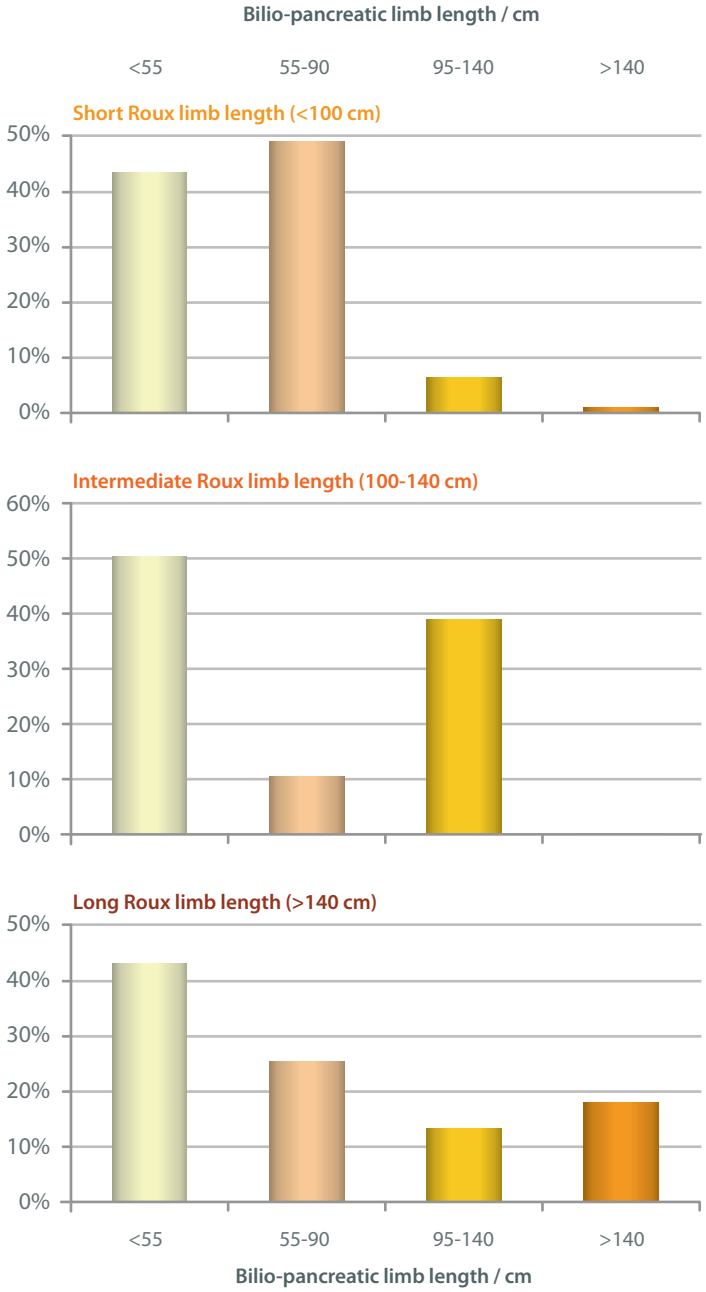
In line with the results from the analysis of Roux limb-lengths, there is also a wide variation in the biliary limb-length chosen by surgeons. Although the commonest choice is 50 cm or less, a substantial number of biliary limbs were 100 cm, and as many as 10% were 150 cm long, indicating that the surgeons were probably aiming to induce a significant element of malabsorption to the gastric bypass.



The graphs show that usually biliary limb lengths were kept at 90 cm or less when the Roux limb was <100 cm. For longer Roux limbs of 100-140 cm nearly 40% of biliary limbs were >95 cm, probably indicating an intentional to create a degree of malabsorption. Thus patients (n=229) who had biliary limbs in excess of 140 cm also had Roux limbs in excess of 140 cm.

In due course, follow-up data from the NBSR may indicate whether or not patients develop clinically significant malnutrition as a result of long-limb bypass.

Primary Roux-en-Y gastric bypass: Roux and bilio-pancreatic limb length inter-relationship (n=2,890)



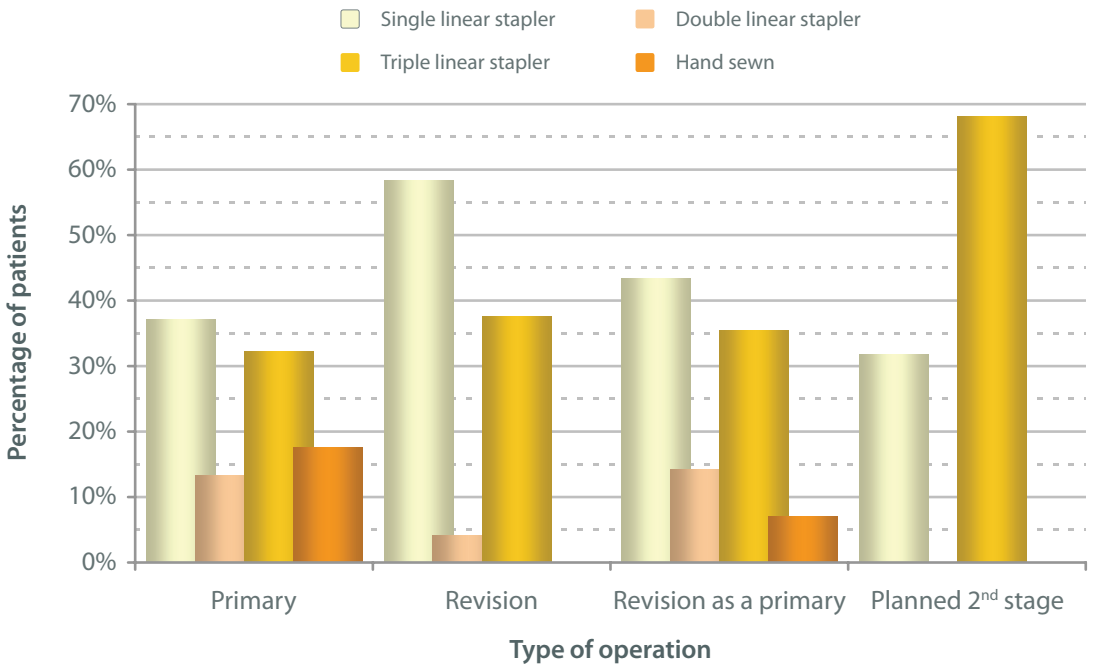
Jejuno-jejunostomy

Like the gastric-pouch-to-Roux-limb join, there are different techniques for the small bowel anastomosis (Y-connection). Surgeons have different preferences, all of which appear equally safe and with similar, low complication rates.

Roux-en-Y gastric bypass: jejuno-jejunostomy

		Jejuno-jejunostomy				
		Single linear stapler	Double linear stapler	Triple linear stapler	Hand sewn	Unspecified
Type of surgery	Primary	1,234	440	1,071	586	295
	Revision	14	1	9	0	9
	Revision as a primary	55	18	45	9	9
	Planned 2nd stage	7	0	15	0	0
	Unspecified	0	0	0	0	0
	All	**1,310**	**459**	**1,140**	**595**	**313**

Roux-en-Y gastric bypass: Jejuno-jejunostomy and type of operation (n=3,504)



Stapler used

The white stapler cartridge was most often used (94.1% of all operations), which has the lowest staple heights of the available staplers. A small number of surgeons, mainly those performing open surgery, favour a totally hand sewn technique (primary operations: 47.2% of procedures hand sewn for open operations *versus* 0.7% for laparoscopic procedures; p<0.001).

Roux-en-Y gastric bypass: linear stapler used and type of operation for procedures where a stapler was used

		Linear stapler			
		White	Blue	Unspecified	**All**
Type of surgery	Primary	2,253	128	364	**2,745**
	Revision	22	0	2	**24**
	Revision as a primary	84	21	13	**118**
	Planned 2nd stage	20	1	1	**22**
	Unspecified	0	0	0	**0**
	All	**2,379**	**150**	**380**	**2,909**

Route of Roux limb

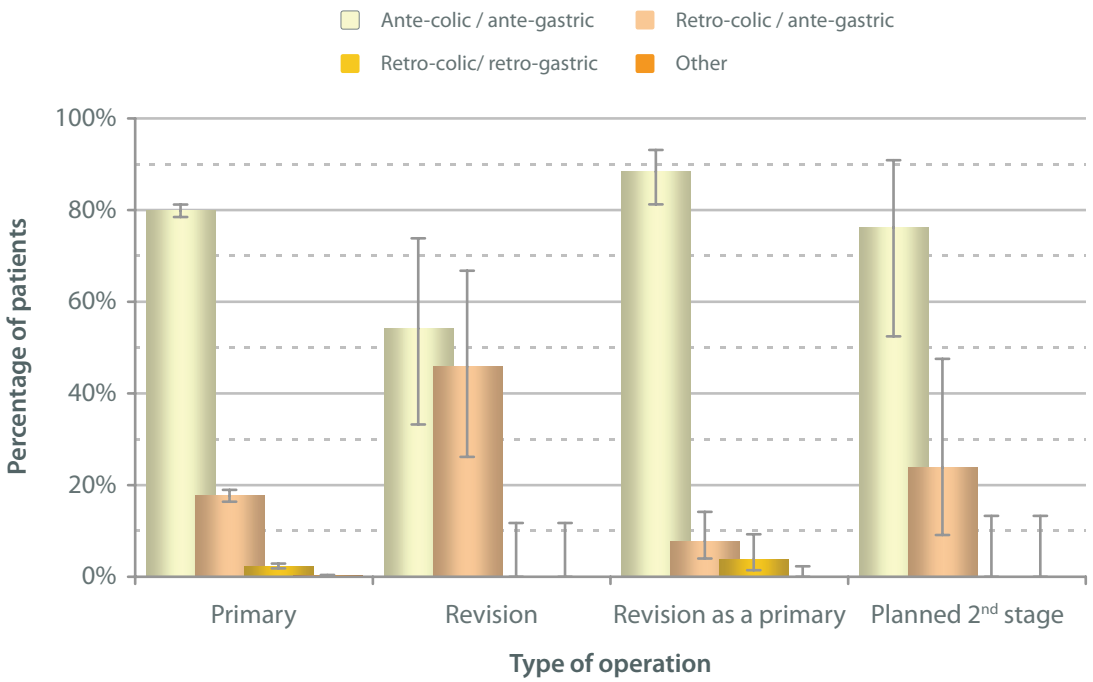
The Roux limb can be routed in front of the colon (antecolic) or behind the colon (retrocolic). Both techniques have potential advantages and disadvantages. However, these are the first data from a national registry to explore which route is actually chosen.

By far the most common technique is the antecolic route, with the Roux limb passing in front of the stomach. Future reports may be able to analyse differences in complication rates between the techniques.

Roux-en-Y gastric bypass: route of Roux limb and type of operation

		Route of Roux limb				
		Ante-colic / ante-gastric	Retro-colic / ante-gastric	Retro-colic / retro-gastric	Other	Unspecified
Type of surgery	Primary	2,705	597	78	6	240
	Revision	13	11	0	0	9
	Revision as a primary	114	10	5	0	7
	Planned 2nd stage	16	5	0	0	1
	Unspecified	0	0	0	0	0
	All	**2,848**	**623**	**83**	**6**	**257**

Roux-en-Y gastric bypass: Route of Roux limb and type of operation (n=3,560)



Closure of hernia defect

After gastric bypass potential hernia defects in the abdomen widen as the patient loses weight. These have the potential to become spaces for internal hernias, and many advocate routine closure of the spaces in an attempt to prevent future hernias, which may present as life-threatening small-bowel obstruction or strangulation.

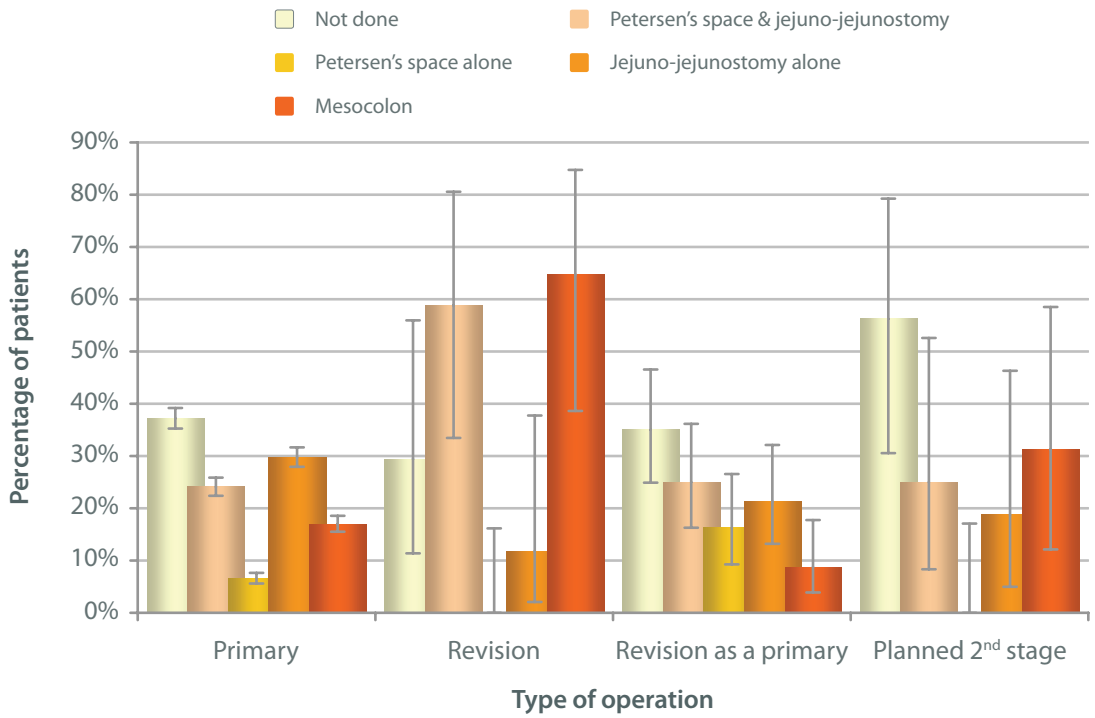
Depending on the route of the Roux limb there are 2 (antecolic) or 3 (retrocolic) hernia spaces. Current practice is that only 30% or fewer hernia spaces are closed for the majority of bypasses.

The registry does not attempt to collect long-term data on patients presenting acutely as an emergency with an obstructed or strangulated internal hernia. Many or most of these will present to hospitals other than those where the original gastric bypass surgery was carried out, and to non-bariatric surgeons. This means that collecting data on reoperations for complications in future years is inherently problematic. Internal hernia is probably the most significant long-term, surgical complication after gastric bypass.

Roux-en-Y gastric bypass: closure of hernia defect and type of operation

		Type of surgery					
		Primary	Revision	Revision as a primary	Planned 2nd stage	Unspecified	All
Hernia repair	No hernial space closure	885	5	28	9	0	**927**
	Petersen's space & Jejuno-jejunostomy	573	10	20	4	0	**607**
	Petersen's space alone	156	0	13	0	0	**169**
	Jejuno-jejunostomy alone	708	2	17	3	0	**730**
	Mesocolon	404	11	7	5	0	**427**
	Unspecified	1,247	16	56	6	0	**1,325**
	Patient denominator	**3,626**	**33**	**136**	**22**	**0**	**3,817**

Roux-en-Y gastric bypass: Closure of hernia defect & type of operation (n=2,492)



Additional procedures

Obesity is associated with gallstones, and it is interesting that 4.8% of bypasses also included cholecystectomy. There is no consensus on whether this procedure should be performed at the same time as the bypass surgery. Rapid weight loss also increases the risk of gallstones, and there is a high rate of cholecystectomy after bariatric surgery; these data may inform the debate on concurrent cholecystectomy.

Roux-en-Y gastric bypass: additional procedures

		Additional procedures [i]						
		None	Cholecystectomy	Hernia repair	Apronectomy	Other	Unspecified	**Patient count**
Type of surgery	Primary	2,034	111	48	3	67	1,370	**3,626**
	Revision	15	0	0	0	2	16	**33**
	Revision as a primary	55	1	3	1	18	58	**136**
	Planned 2nd stage	10	1	0	0	7	4	**22**
	Unspecified	0	0	0	0	0	0	**0**
	All	**2,114**	**113**	**51**	**4**	**94**	**1,448**	**3,817**
	Primary	90.2%	4.9%	2.1%	0.1%	3.0%		
	Revision	88.2%	0.0%	0.0%	0.0%	11.8%		
	Revision as a primary	70.5%	1.3%	3.8%	1.3%	23.1%		
	Planned 2nd stage	55.6%	5.6%	0.0%	0.0%	38.9%		
	Unspecified	NA	NA	NA	NA	NA		
	All	**89.2%**	**4.8%**	**2.2%**	**0.2%**	**4.0%**		

i More than one additional procedure may be recorded for each operation recorded in the NBSR, so the total number of additional procedures may exceed the number of operations performed.

Other additional procedures		
Primary	6	Adhesiolysis
	1	Bleed from Petersen's defect closure
	16	Division of adhesions
	1	Excision GIST & division of adhesion
	1	Hiatus hernia repair
	30	Liver biopsy
	2	Removal gastric balloon
	1	Removal incidental small bowel tumour
	1	Repair torn oesophagus
	1	Small bowel resection
	1	Splenectomy
	1	Take down of anti-reflux wrap
	1	Umbilical hernia repair
	4	Unspecified
Revision	2	Removal gastric band
Revision as a primary	2	Adhesiolysis
	14	Gastric band removal
	1	Partial gastrectomy
	1	Take down gastric tunnel
	1	Take down Nissen fundoplication
Planned 2nd stage	7	Balloon removal

Post procedure outcomes

30-day complications

The table shows that the overall operative complication rate for gastric bypass is remarkably low at 3.4%. The most-feared complication, leakage of one of the small bowel joins, occurred in only 0.6% of cases. These data are an important indicator of the safety of gastric bypass surgery in the United Kingdom and Ireland.

Roux-en-Y gastric bypass: 30-day operative complications including re-operations

		Operation			
		Primary		Any revision	
		Count	Rate	Count	Rate
Number of complications	0	3,503	96.6%	181	94.8%
	1	113	3.1%	9	4.7%
	2	9	0.2%	0	0.0%
	3	1	0.03%	1	0.5%

Roux-en-Y gastric bypass: specified operative complications within 30 days

		Operation							
		Primary				Any revision			
		None recorded	Yes	Not recorded	Rate	None recorded	Yes	Not recorded	Rate
Complication	Any reason	3,503	123	0	3.4%	181	10	0	5.2%
	Leak	3,605	21	0	0.6%	187	4	0	2.1%
	Bleeding	3,583	43	0	1.2%	189	2	0	1.0%
	Obstruction	3,605	21	0	0.6%	190	1	0	0.5%
	Other	3,583	43	0	1.2%	188	3	0	1.6%

The 30-day re-operation rate recorded for primary operations is remarkably low at 1.9%. We cannot dismiss the possibility that there could be a degree of under-reporting of the data. However, the mortality data elsewhere in the registry are not dissimilar to those collected externally from a different source: the Hospital Episode Statistics (HES) data [1].

Roux-en-Y gastric bypass: type of re-operation within 30 days

		Operation							
		Primary				Any revision			
		No	Yes	Not recorded	Rate	No	Yes	Not recorded	Rate
Type of re-operation	Any re-operation	3,505	67	56	1.9%	181	7	3	3.7%
	Re-fashioning anastomosis	3,555	13	56	0.4%	186	2	3	1.1%
	Attention to bleeding area	3,556	12	56	0.3%	187	1	3	0.5%
	Hernia repair	3,563	5	56	0.1%	187	1	3	0.5%
	Drain replacement	3,561	7	56	0.2%	187	1	3	0.5%
	Gastrostomy	3,564	4	56	0.1%	186	2	3	1.1%
	Enteral feeding	3,567	1	56	0.0%	188	0	3	0.0%
	Laparoscopy only	3,557	13	56	0.4%	188	0	3	0.0%
	Other	3,544	25	56	0.7%	187	1	3	0.5%

1. Burns EM, Naseem H, Bottle A, Lazarino AI, Aylin P, Darzi A, Morrthy K and Faiz O. Introduction of laparoscopic bariatric surgery in England: observational population cohort study. *British Medical Journal.* 2010; **341:** 546.

Cardiovascular complications

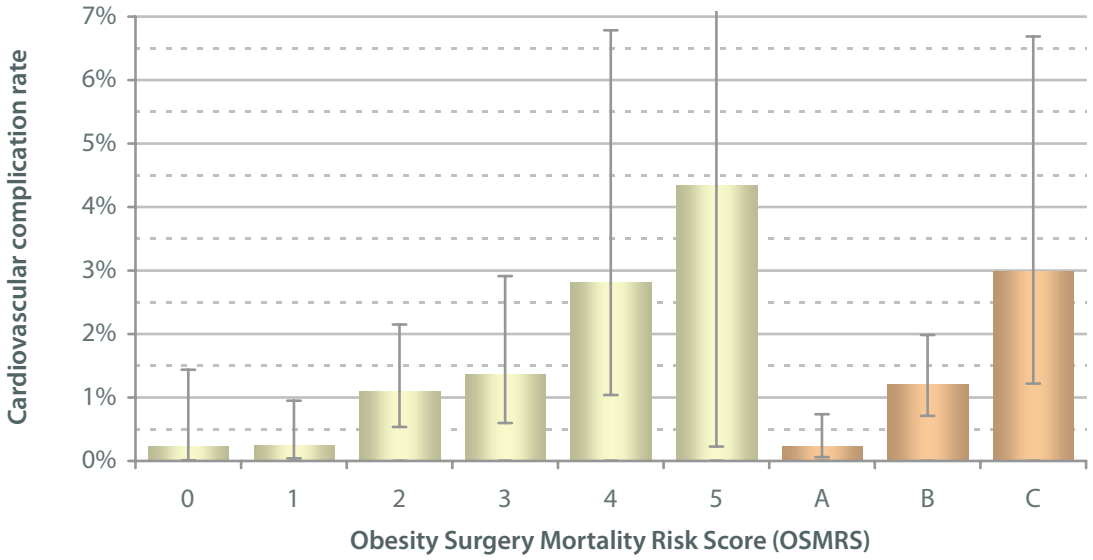
The rate of cardiovascular complications recorded was, again, very low, but, as expected, a greater Obesity Surgery Mortality Risk Score (OSMRS) was associated with increased complication rates (Group A *versus* Group B: p=0.003; Group A *versus* Group C: p<0.001; Group B *versus* Group C: p=0.047).

These are the first data from a national registry to report cardiovascular complication rates according to OSMRS groups for gastric bypass.

Primary Roux-en-Y gastric bypass: cardiovascular complications and OSMRS

			Cardiovascular complications			
			No	Yes	Unspecified	Rate (95% CI)
OSMRS	Group A	0	447	1	43	0.2% (0.0-1.4%)
		1	843	2	70	0.2% (0.0-0.9%)
		Group A	**1,290**	**3**	**113**	**0.2%** (0.1-0.7%)
	Group B	2	812	9	56	1.1% (0.5-2.1%)
		3	507	7	42	1.4% (0.6-2.9%)
		Group B	**1,319**	**16**	**98**	**1.2%** (0.7-2.0%)
	Group C	4	173	5	14	2.8% (1.0-6.8%)
		5	22	1	3	4.3% (0.2-24.0%)
		Group C	**195**	**6**	**17**	**3.0%** (1.2-6.7%)
		Unspecified	336	2	231	0.6% (0.1-2.4%)
		All	**3,140**	**27**	**459**	**0.9% (0.6-1.3%)**

Primary Roux-en-Y gastric bypass: Post-operative cardiovascular complications and OSMRS (n=2,829)



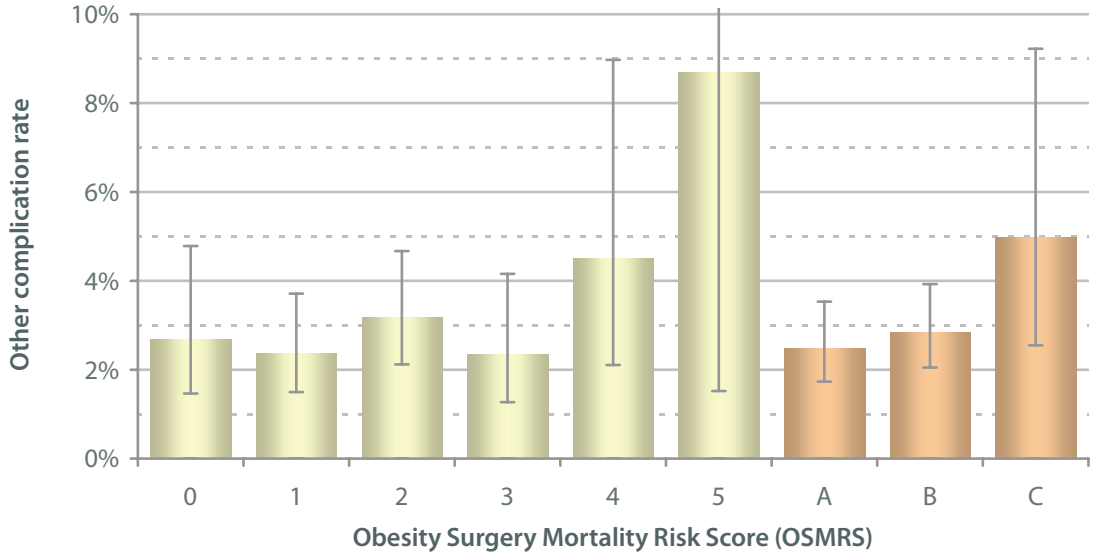
Other complications

The rate of *other* complications was also very low, and although there was a suggestion of greater complications rates for Group C this did not reach statistical significance (Group A *versus* Group B: p=0.650; Group A *versus* Group C: p=0.079; Group B *versus* Group C: p=0.162).

Primary Roux-en-Y gastric bypass: cardiovascular complications and OSMRS

			Other complications			
			No	Yes	Unspecified	Rate (95% CI)
OSMRS	Group A	0	434	12	45	2.7% (1.5-4.8%)
		1	822	20	73	2.4% (1.5-3.7%)
		Group A	**1,256**	**32**	**118**	**2.5%** (1.7-3.5%)
	Group B	2	795	26	56	3.2% (2.1-4.7%)
		3	502	12	42	2.3% (1.3-4.2%)
		Group B	**1,297**	**38**	**98**	**2.8%** (2.0-3.9%)
	Group C	4	170	8	14	4.5% (2.1-9.0%)
		5	21	2	3	8.7% (1.5-29.5%)
		Group C	**191**	**10**	**17**	**5.0%** (2.5-9.2%)
		Unspecified	329	8	232	2.4% (1.1-4.8%)
		All	**3,073**	**88**	**465**	**2.8% (2.3-3.4%)**

Primary Roux-en-Y gastric bypass: Other complications post-operatively and OSMRS (n=2,824)



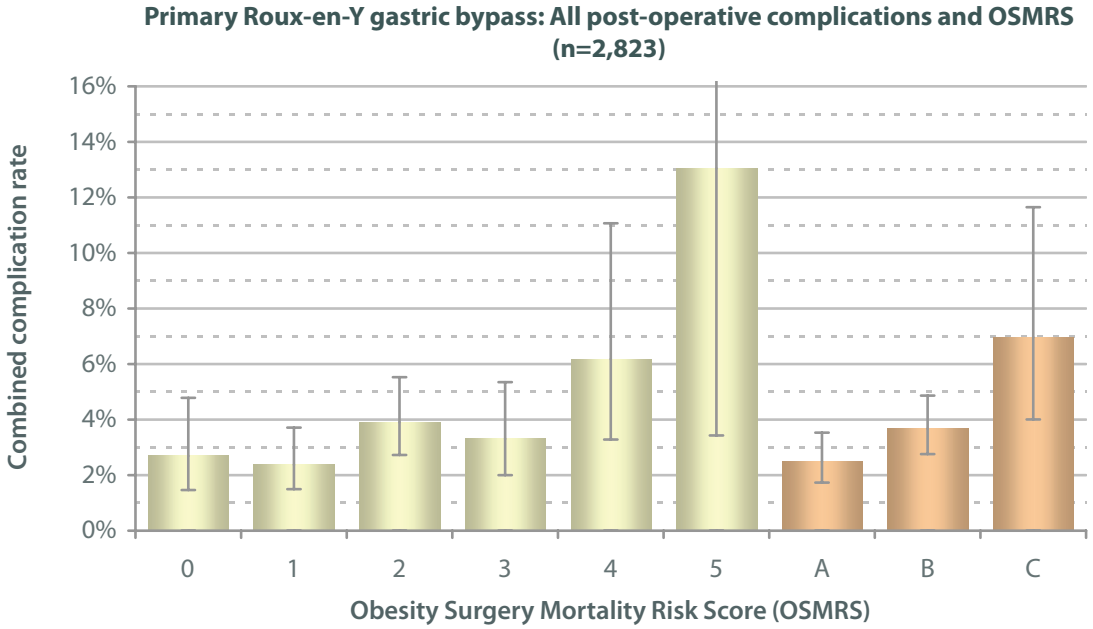
Combined post-operative complications

The derived, combined complication rate (cardiovascular ± other complications) was relatively low, and increased OSMRS was associated with increased combined complication rates, significantly elevated in Group C (Group A *versus* Group B: p=0.100; Group A *versus* Group C: p=0.001; Group B *versus* Group C: p=0.045).

Primary Roux-en-Y gastric bypass: post-operative complications (cardiovascular & other) and OSMRS

			Combined complications [i]			
			No	Yes	Unspecified	Rate (95% CI)
OSMRS	Group A	0	434	12	45	2.7% (1.5-4.8%)
		1	822	20	73	2.4% (1.5-3.7%)
		Group A	**1,256**	**32**	**118**	**2.5%** (1.7-3.5%)
	Group B	2	788	32	57	3.9% (2.7-5.5%)
		3	497	17	42	3.3% (2.0-5.4%)
		Group B	**1,285**	**49**	**99**	**3.7%** (2.8-4.9%)
	Group C	4	167	11	14	6.2% (3.3-11.1%)
		5	20	3	3	13.0% (3.4-34.7%)
		Group C	**187**	**14**	**17**	**7.0%** (4.0-11.6%)
		Unspecified	327	9	233	2.7% (1.3-5.2%)
		All	**3,055**	**104**	**467**	**3.3% (2.7-4.0%)**

i Cardiovascular complications ± other complications



Mortality

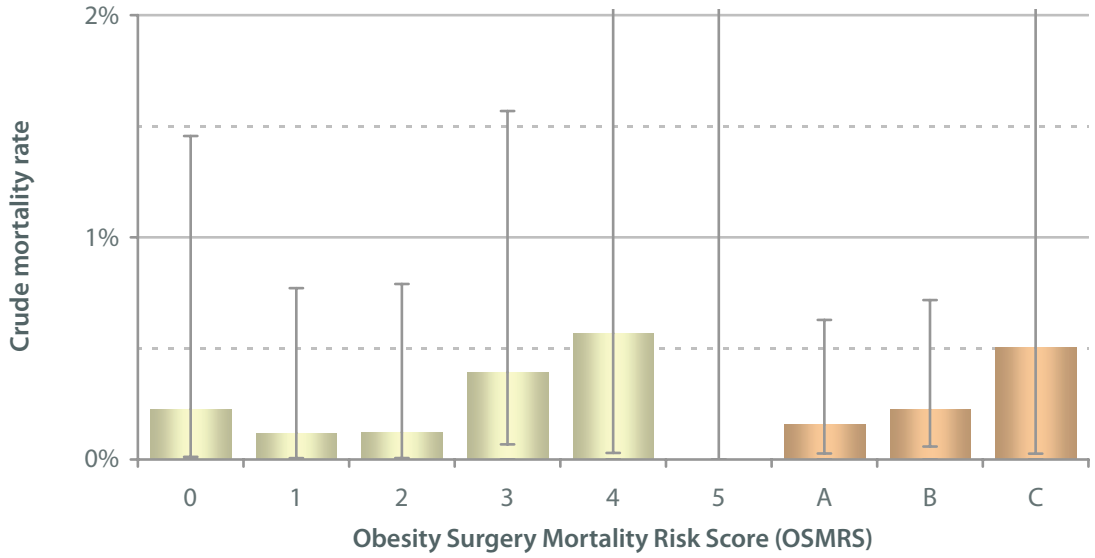
The overall mortality rate for gastric bypass surgery was 0.22%, which compares favourably to best international data [1]. Due to the small number of deaths comparisons of mortality rates across OSMRS groups did not reach statistical significance.

Causes: cardiac ×2; Leak ×1; Other ×2; PE ×1; pneumonia ×1.

Primary Roux-en-Y gastric bypass: post-operative mortality and OSMRS

			Post-operative mortality			
			No	Yes	Unspecified	Rate (95% CI)
OSMRS	Group A	0	441	1	49	0.23% (0.01-1.46%)
		1	837	1	77	0.12% (0.01-0.77%)
		Group A	**1,278**	**2**	**126**	**0.16%** (0.03-0.63%)
	Group B	2	817	1	59	0.12% (0.01-0.79%)
		3	508	2	46	0.39% (0.07-1.57%)
		Group B	**1,325**	**3**	**105**	**0.23%** (0.06-0.72%)
	Group C	4	175	1	16	0.57% (0.03-3.61%)
		5	23	0	3	0.0% (0.00-12.21%)
		Group C	**198**	**1**	**19**	**0.50%** (0.03-3.20%)
		Unspecified	331	1	237	0.30% (0.02-1.93%)
		All	**3,132**	**7**	**487**	**0.22% (0.10-0.48%)**

Primary Roux-en-Y gastric bypass: Post-operative mortality and OSMRS (n=2,807)



1. Flum D *et al.* Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery. The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. *New England Journal of Medicine.* 2009; **361:** 445-54.

2. Belle SH *et al.* The Relationship of BMI with Demographic and Clinical Characteristics in the Longitudinal Assessment of Bariatric Surgery (LABS). *Surgery for Obesity and Related Diseases.* 2008; **4(4):** 474–480.

Post-operative stay

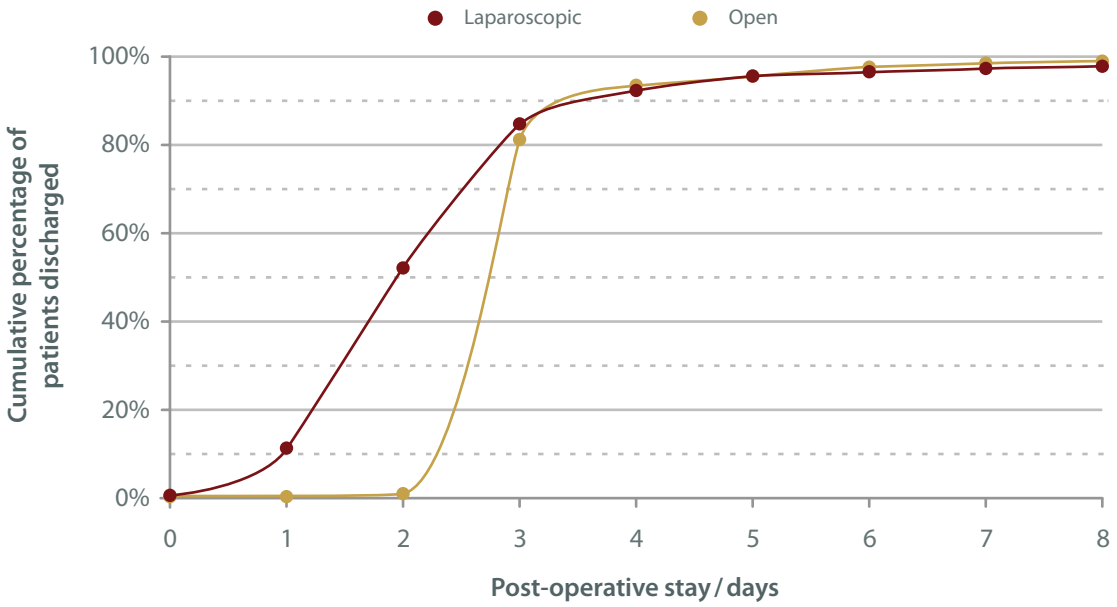
Remarkably, over 80% of all bypass patients were discharged by day 3 (see page 91). In addition, over 50% patients having laparoscopic surgery were able to go home by day 2, reflecting the quick recovery after minimally invasive surgery.

Future reports should be able to examine the data on the reasons that patients fail to leave hospital by day 30, and the frequency of re-admission and re-operation with 30 days.

Primary Roux-en-Y gastric bypass: post-operative length-of-stay and approach

		Approach			
		Laparoscopic	Open	Unspecified	All
Post-operative stay / days	0	18	1	0	**19**
	1	300	0	1	**301**
	2	1,144	2	4	**1,150**
	3	915	235	0	**1,150**
	4	212	36	1	**249**
	5	92	6	0	**98**
	6	27	6	0	**33**
	7	21	4	0	**25**
	8	14	0	0	**14**
	>8	61	3	0	**64**
	Unspecified	515	8	0	**523**
	All	**3,319**	**301**	**6**	**3,626**
	>30-day stay rate	0.8%	0.3%	0.0%	**0.7%**

Primary Roux-en-Y gastric bypass: Post-operative stay and operative approach (n=3,097)



Comorbid disease after surgery

There is a reduction in the rate of each comorbidity 12 months after Roux-en-Y gastric bypass surgery. All the improvements are statistically significant.

For the patients with follow-up data dated 12 months after their procedure, there are some extraordinary and significant (in all senses of the word) changes in morbidity rates:

- sleep apnoea rates fall by over 63%.
- dyslipidaemia rates fall by over 61%.
- the proportion of patients able to climb 3 flights of stairs improves dramatically, from 26.9% to 70.4%.
- type 2 diabetes and GORD fall by a little over 56%.

For the remaining conditions analysed, the fall in the prevalence is in the range 30-42%.

As the NBSR accumulates data on more operations and more follow-up data, the confidence in the observed rates of disease both before and after surgery will increase, which will allow us to make more definite statements about the changes in patients' comorbid conditions over time.

Primary Roux-en-Y gastric bypass: comorbid conditions pre-operatively and 12 months after surgery [i]

Source of data				Comorbidity [ii]							
				Type 2 diabetes	Hypertension	Dyslipidaemia	Sleep apnoea	Functional status [iii]	Arthritis	GORD [iv]	PCOS [v]
	All patients	Pre-operative data	No	2,206	2,063	2,605	2,648	794	1,445	2,150	2,237
			Yes	1,126	1,291	658	647	2,109	1,828	992	235
			Unspecified	294	272	363	331	723	353	484	372
			Rate	33.8%	38.5%	20.2%	19.6%	72.6%	55.9%	31.6%	9.5%
	Patients with follow-up data	Pre-operative data	No	542	539	673	672	201	368	562	536
			Yes	281	283	144	151	545	445	219	67
			Unspecified	3	3	5	3	30	5	26	23
			Rate	34.1%	34.4%	17.6%	18.3%	73.1%	54.7%	28.0%	11.1%
		12-month follow-up data [i]	No	703	660	766	770	546	508	709	585
			Yes	123	165	56	56	230	310	98	41
			Unspecified	0	0	0	0	0	0	0	0
			Rate	14.9%	20.0%	6.8%	6.8%	29.6%	37.9%	12.1%	6.5%
Significance [vi] (χ^2 probability)				<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.006

i. The data used to determine the incidence of the risk factor fall in the defined time-period 365 ± 91 days. The follow-up entry used in the analysis is that row of data that is nearest in time to the 365-day point.

ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovarian syndrome.

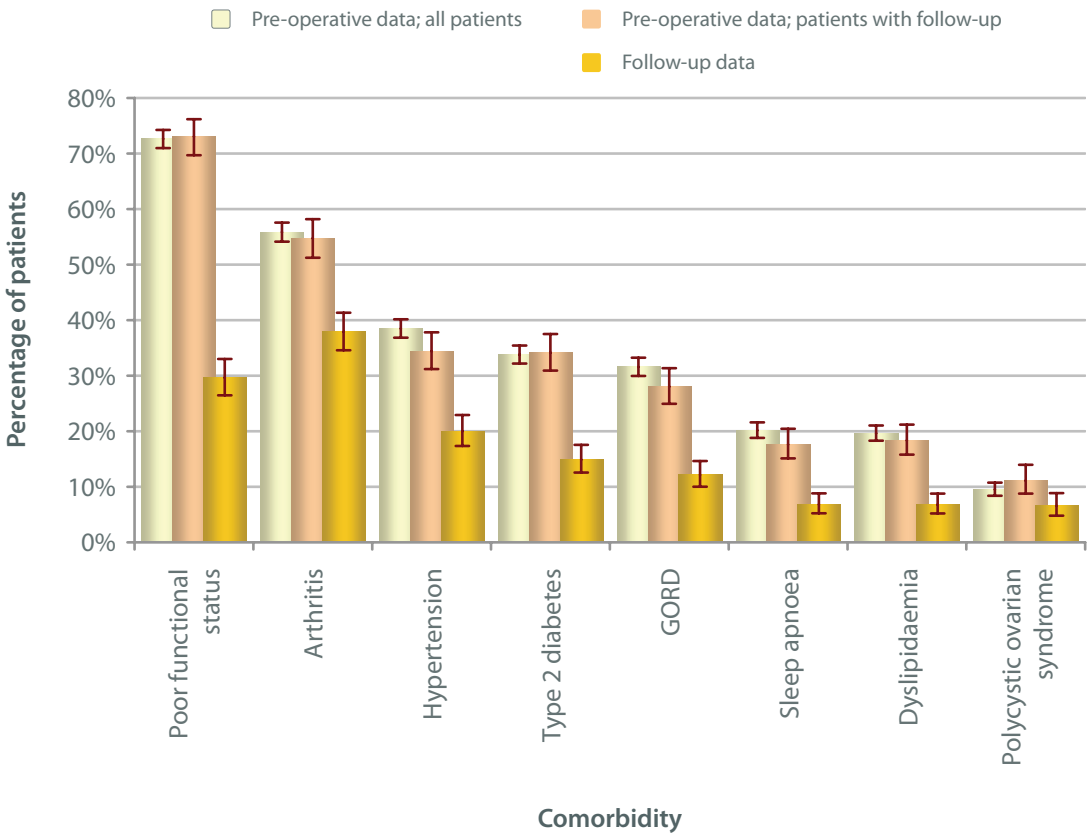
iii. Presence of the *functional status* comorbidity is defined as unable to climb 3 flights of stairs without resting.

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

v. Polycystic ovarian syndrome.

vi. Comparing the pre-operative incidence to the 12-month follow-up incidence in the patients with follow-up data.

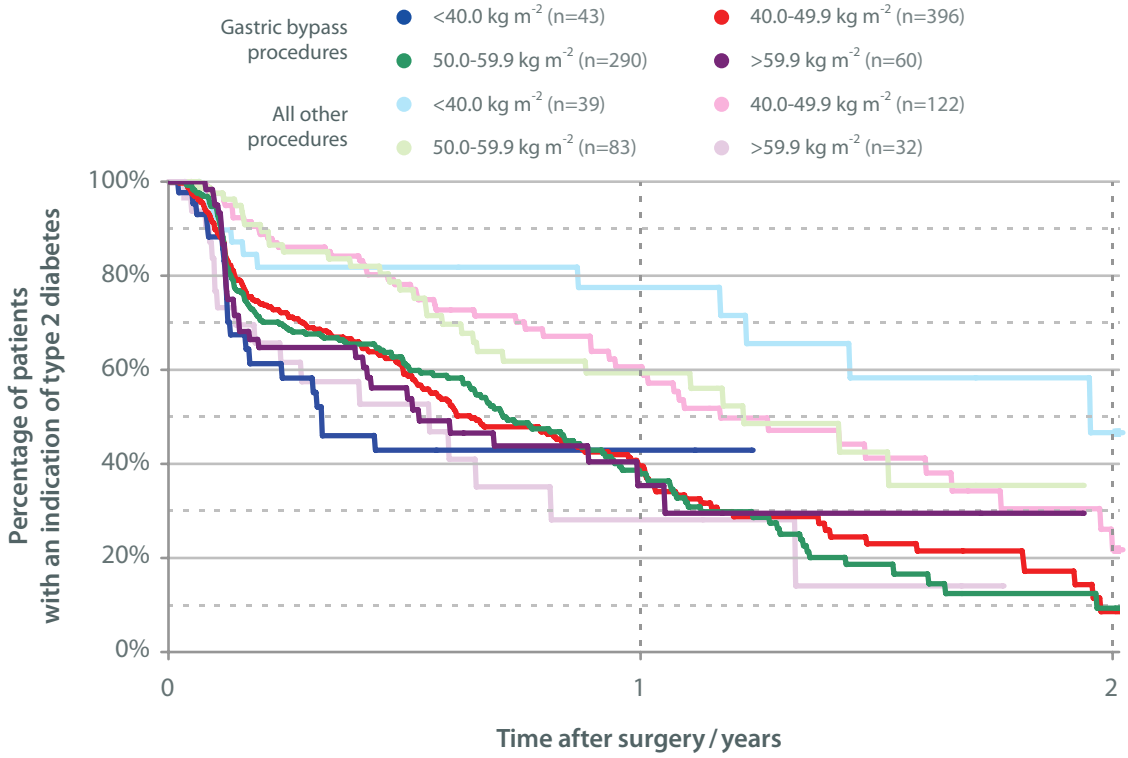
**Primary Roux-en-Y gastric bypass procedures:
Comorbid conditions before and after surgery**



Improvement in diabetes

The gastric bypass operation has a dramatic effect on the reported rates of diabetes, with the majority of patients returning to a state where they exhibit *no indication of diabetes*. The data need to be interpreted with some caution, but thus far suggest that bypass has a profound effect on diabetes compared to other bariatric procedures.

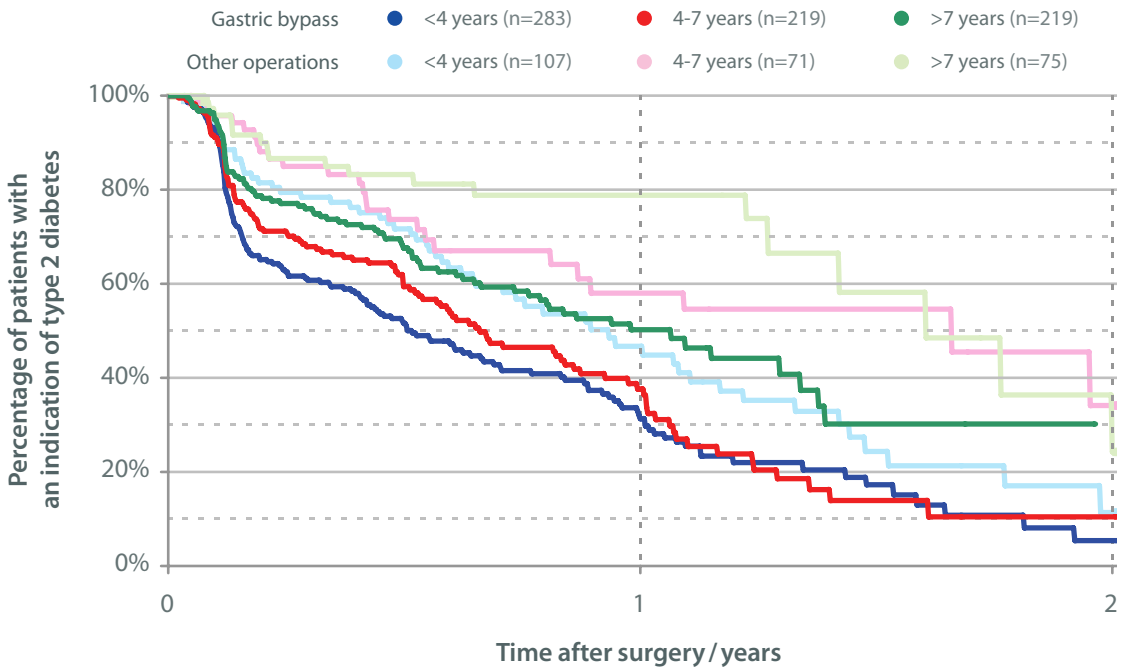
Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and BMI



As expected from the overall data already reported (see page 104), improvement in clinical indications of diabetes was greatest for those patients with a shorter duration of diabetes. The level of improvement far exceeds that seen after other types of bariatric surgery. Identifying the reasons for the rate and extent of this improvement after Roux-en-Y gastric bypass surgery will be a subject revisited when the registry has accumulated a little more data.

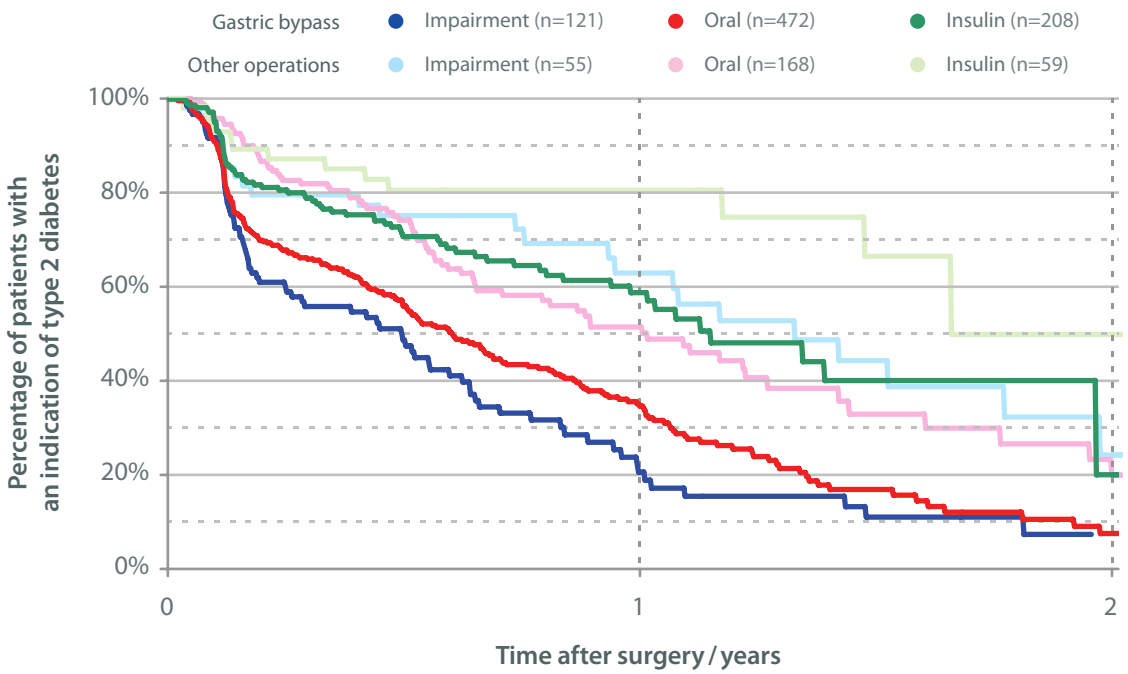
Again, these results may have profound implications for the treatment of type 2 diabetes within the Health Service.

Patients recorded as having an indication of diabetes prior to surgery: Changes in rates of recorded diabetes indications and duration of diabetes



The data in this chart are inextricably linked to the analysis on the previous page, which looked at improvement in diabetes according to the reported period that the patient had had clinical indications of diabetes. Patients who have lived with diabetes for a long period of time are more likely to be treated with insulin, and are correspondingly less likely to show a return to a state of *No indication of diabetes*.

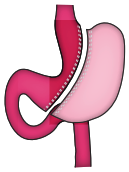
Patients diabetic prior to surgery undergoing a primary Roux-en-Y gastric bypass: Changes in diabetes rates over time and type of diabetes



Sleeve gastrectomy

Sleeve gastrectomy

Number of entries in the context of the database

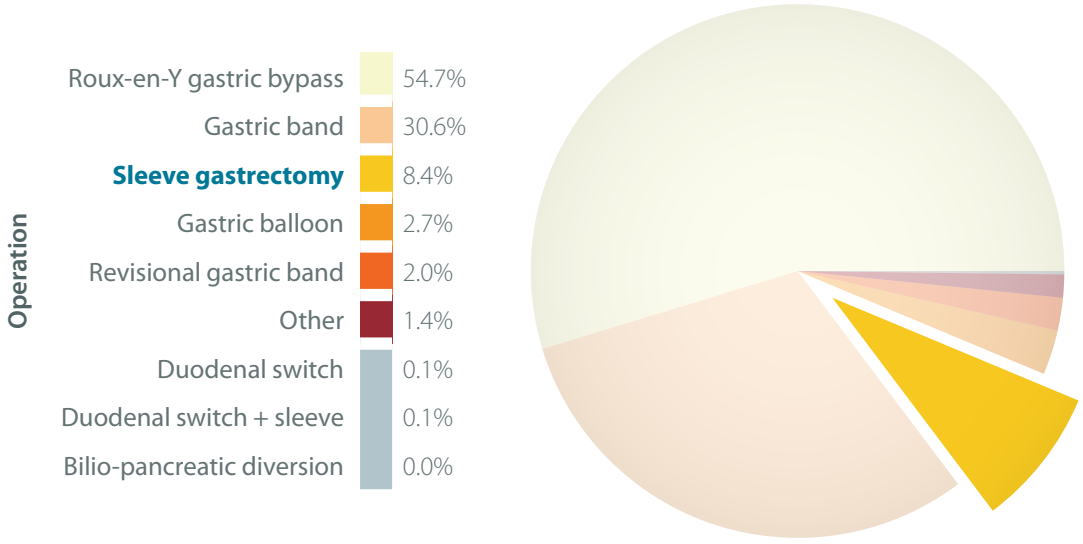


Sleeve gastrectomy comprised 8.4% of the operations recorded in the National Bariatric Surgery Registry. This operation is gaining in popularity as a (possibly) less risky procedure than gastric bypass surgery when gastric banding is not the preferred choice. Even so, the 588 patients recorded constitute a large series of patients with a low complication rate that compares favourably to international data [1].

Type of operation performed

Operation	Type of surgery: Primary	Revision	Revision as a primary	Planned 2nd stage	Unspecified	All
Gastric band	2,131	0	0	0	1	**2,132**
Roux-en-Y gastric bypass	3,626	33	136	22	0	**3,817**
Sleeve gastrectomy	543	5	25	14	1	**588**
Duodenal switch	0	0	0	9	0	**9**
Duodenal switch + sleeve	2	0	2	0	0	**4**
Bilio-pancreatic diversion	1	0	0	0	0	**1**
Revisional gastric band	0	54	83	2	0	**139**
Gastric balloon	112	8	5	63	0	**188**
Other	24	24	37	12	0	**98**
Unspecified	43	1	0	0	25	**69**
All	**6,483**	**125**	**288**	**122**	**27**	**7,045**

Operations performed (n=6,976)



1. Sanchez-Santos R. Short- and Mid-term Outcomes of Sleeve Gastrectomy for Morbid Obesity: The Experience of the Spanish National Registry. *Obesity Surgery.* 2009; **19:** 1203-1210.

Patient profiles

Age and gender

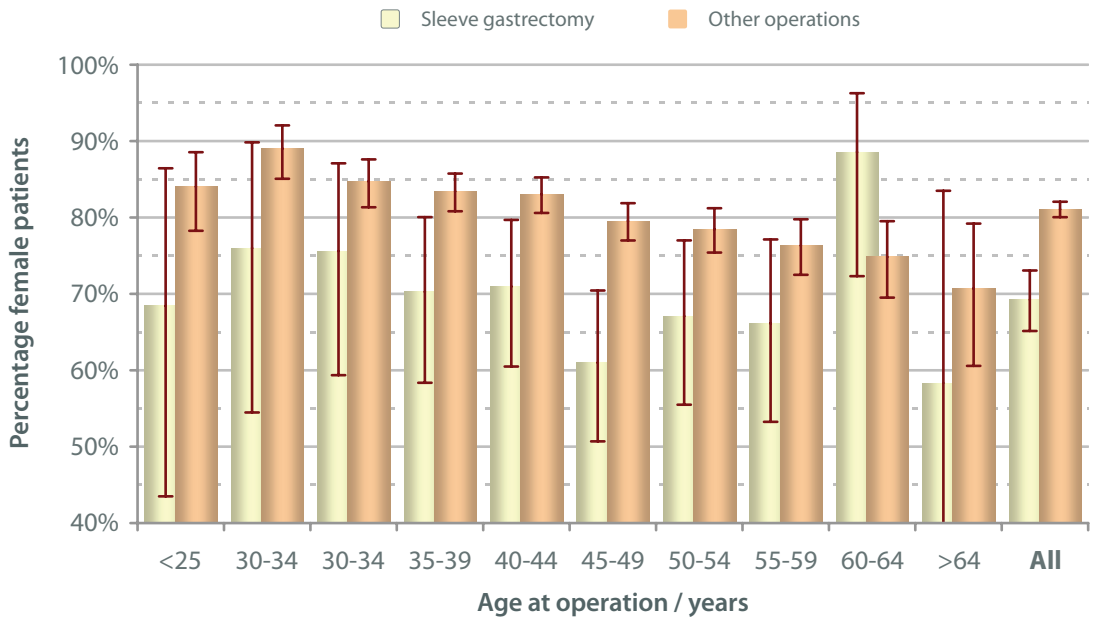
The average age for a female patient undergoing a sleeve gastrectomy procedure was 45.0 years (n=376; SE=0.56 years), and for a male patient 45.3 years (n=167; SE=0.77 years). Sleeve gastrectomy is clearly being performed much more frequently for male publicly funded patients, probably because of the perceived high risk in patients with much comorbidity. There is as yet little strong evidence favouring one procedure over another.

As the number of sleeve gastrectomy procedures is smaller than the other, major procedure groups (gastric banding and Roux-en-Y gastric bypass surgery) it is inevitable that the confidence intervals around the proportions of female patients in each age-group will be much wider, which means there is less confidence in the reported rates, but as the database matures and more sleeve gastrectomy data are added these kinds of analyses will firm up and the *real* picture will gradually emerge.

Primary sleeve gastrectomy procedures: age and gender distributions

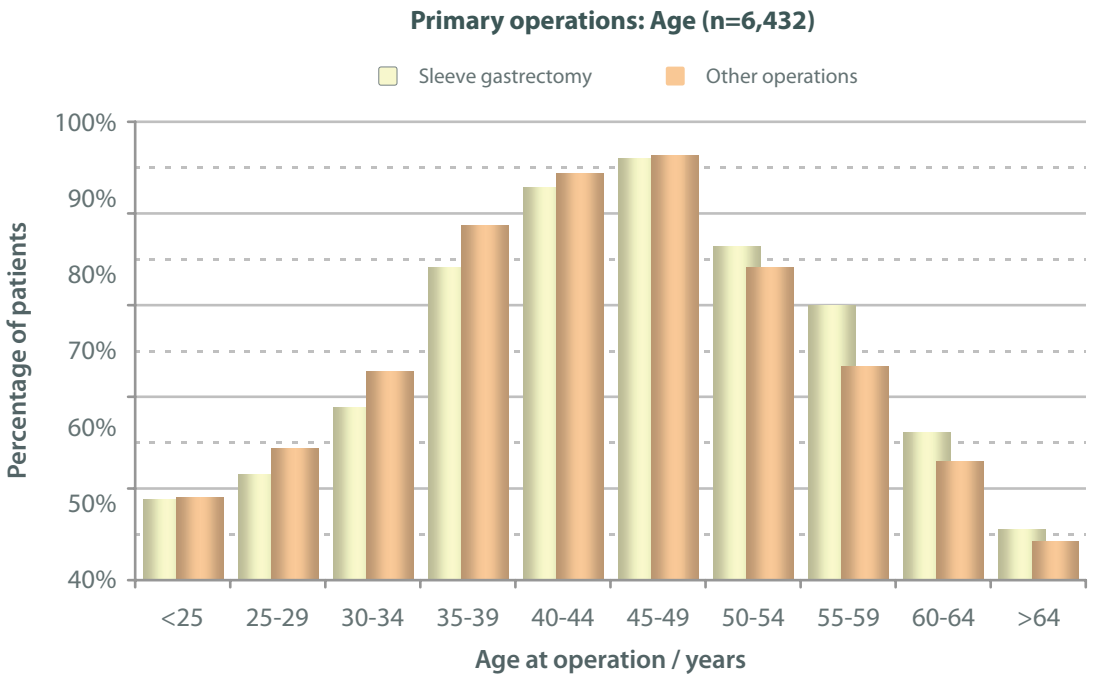
		Gender			
		Male	Female	Unspecified	All
Age at operation / years	<25	6	13	0	**19**
	25-29	6	19	0	**25**
	30-34	10	31	0	**41**
	35-39	22	52	0	**74**
	40-44	27	66	0	**93**
	45-49	39	61	0	**100**
	50-54	26	53	0	**79**
	55-59	22	43	0	**65**
	60-64	4	31	0	**35**
	>64	4	7	0	**11**
	Unspecified	1	0	0	**1**
	All	**167**	**376**	**0**	**543**

Primary operations: Age and gender distributions (n=6,440)



The following chart shows that a greater proportion of the sleeve gastrectomy patients fall in the 50-54, 54-59, 60-64 and >64 year-old age groups than do patients undergoing other bariatric procedures. These differences between the age profiles for sleeve gastrectomy patients and *other* patients are not (yet) statistically significant (analysis of the categoric data: male patients $\chi^2 \Rightarrow p=0.776$ and female patients $\chi^2 \Rightarrow p=0.097$), but the differences may (yet) attain significance as the registry continues to accumulate data. The average age for a male patient having a primary sleeve gastrectomy procedure is 45.3 years compare to 45.8 years for all other primary bariatric procedures, and the average female patients are 45.0 years old and 43.3 years old respectively. This shows that the differences in the chart are largely a consequence of having a female population treated by sleeve gastrectomy who are older.

The increased age of those (female) patients undergoing a sleeve gastrectomy procedure means that there is potentially added risk of adverse events after the operation, simply because of the patients' relatively greater age, but the data recorded in the NBSR show that they are at no greater risk of having an operative complication (p=0.851), nor of having a 30-day re-operation (p=0.461) than the patients undergoing gastric bypass surgery (see pages 160 and 188); the observed post-operative complication rates are also comparable (cardiovascular complication are almost identical at around 1%, p=0.937; *other* complications are 2.8% for both procedures, p=0.916), suggesting that this is a safe bariatric procedure in the hands of surgeons across the united Kingdom & Ireland.



Source of funding

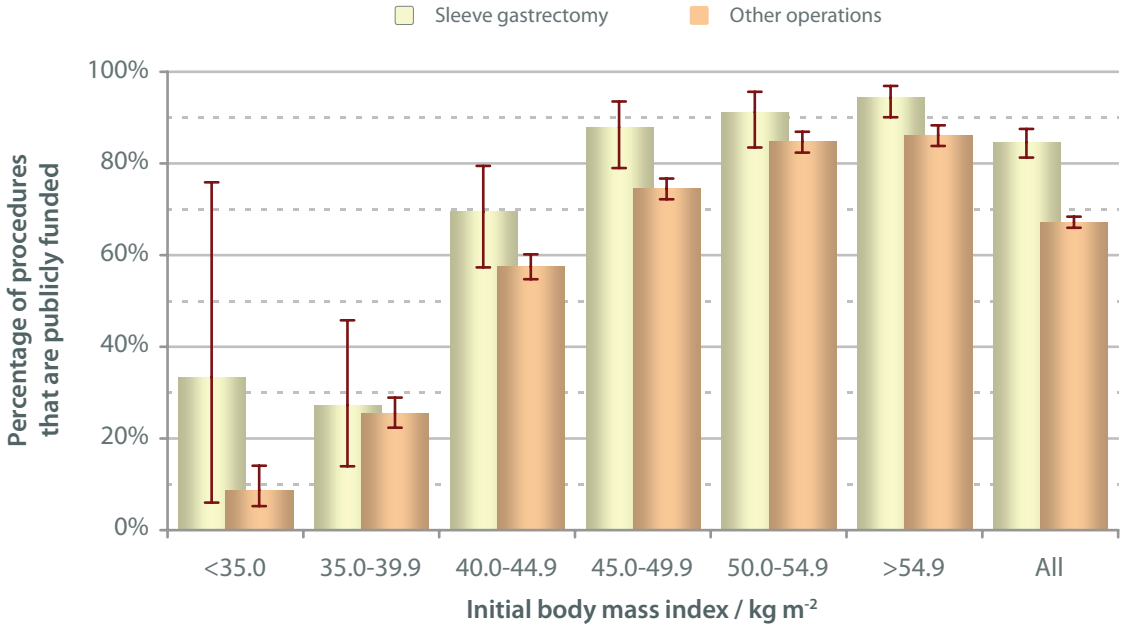
By far the majority of sleeve gastrectomy operations are publicly funded, with similar rates compared to gastric bypass (see page 135) and in comparison with gastric banding where many more are privately funded (see page 110).

The difference in funding rates between sleeve gastrectomy procedures and *other* procedures is largely driven by the high rates of privately-funded gastric banding operations.

Primary procedures: source of funding according to initial BMI and operation

Initial body mass index / kg m^{-2}	Gender and funding					
	Sleeve gastrectomy			Other operations		
	Funding known	Funding unspecified	Publicly funded rate	Funding known	Funding unspecified	Publicly funded rate
<35.0	6	0	33.3%	183	1	8.7%
35.0-39.9	33	0	27.3%	702	1	25.5%
40.0-44.9	72	0	69.4%	1,303	12	57.5%
45.0-49.9	91	0	87.9%	1,471	6	74.5%
50.0-54.9	102	1	91.2%	999	6	84.8%
>54.9	212	0	94.3%	943	5	86.2%
Unspecified	25	1	96.0%	252	13	92.5%
All	**541**	**2**	**84.7%**	**5,853**	**44**	**67.2%**

Primary sleeve gastrectomy procedures:
Source of funding, initial body mass index and gender (n=6,394)



Comorbid conditions at presentation

Number of comorbid conditions

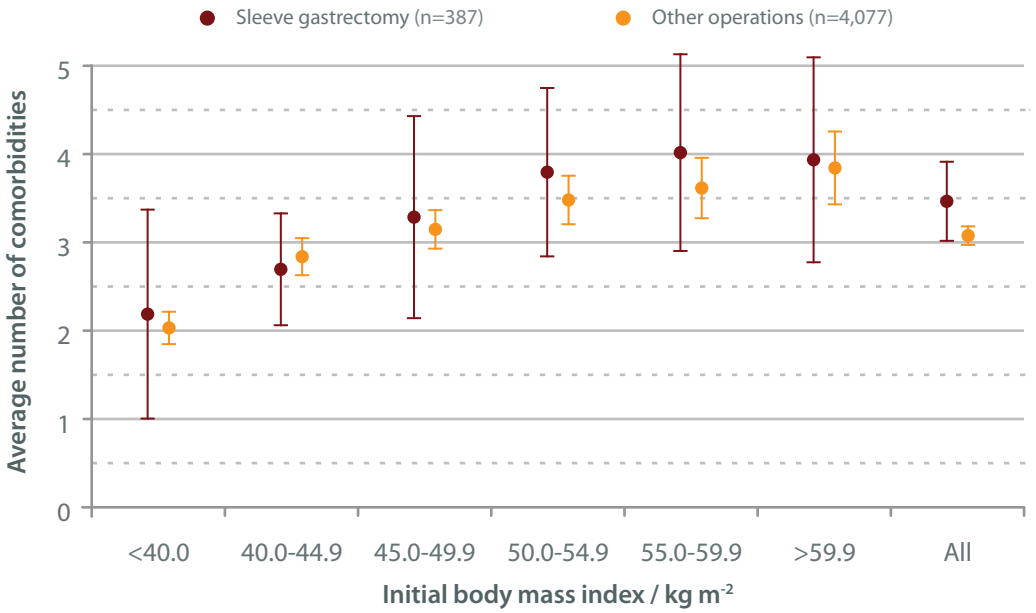
Fitting in with the analyses that demonstrated sleeve gastrectomy surgery is mainly performed on older (see page 178), publicly-funded (see page 179) patients, the frequency of obesity-related disease was also higher, suggesting that the patients undergoing this kind of bariatric procedure are a generally sicker population.

These patients have relatively more coexisting disease at higher (>44.9 kg m^{-2}) BMIs, which suggests that there is something more complex underlying the increased comorbidity than simply increased BMI. This observation holds even when comparing those patients having a primary sleeve gastrectomy procedure with the patients undergoing primary gastric bypass surgery (excepting the >59.9 kg m^{-2} group, where there is convergence across all procedure types, irrespective of gender), and the same general pattern is there in both the male and female patient groups.

As indicated previously, the number of operation records in the NBSR for this procedure are much lower than recorded for gastric banding and Roux-en-Y gastric bypass procedures, but over time the numbers will increase, making any apparent differences clearer.

In the context of the relatively higher rates of comorbid disease across the range of BMIs reported here, it is even more encouraging that the immediate outcomes are so good after this procedure.

Sleeve gastrectomy operations with complete comorbidity data: Number of comorbidities and body mass index



ASA grade

As one might expect from looking at the analyses in the preceding sections on sleeve gastrectomy surgery, the vast majority of these were graded ASA II or ASA III, and therefore at elevated operative risk.

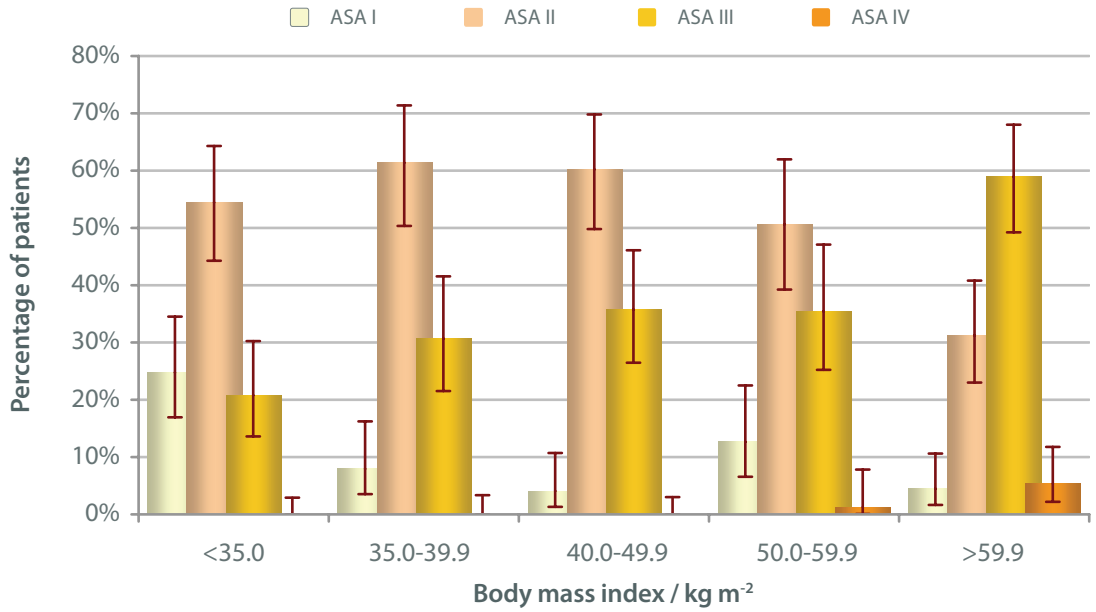
Taking into account the data for patients of all BMIs, the proportion of patients in the ASA I and ASA IV groups for those undergoing sleeve gastrectomy surgery (ASA I: 9.7%; ASA IV 1.0%) are directly comparable to the patients having Roux-en-Y gastric bypass surgery (ASA I: 10.4%; ASA IV 1.4%); however, there are significantly more patients graded as ASA III in the sleeve gastrectomy group (36.7% *versus* 29.1% for gastric bypass surgery; p=0.001).

The difference in ASA grade between sleeve gastrectomy and gastric bypass patients is statistically significant for the most obese patients (BMI >59.9 kg m^{-2}) where more sleeve patients are ASA III (58.9% *versus* 42.5% for gastric bypass p=0.005). There is an obvious increase in proportion of ASA III with increasing BMI.

Primary sleeve gastrectomy procedures: ASA grade and initial body mass index

		ASA grade				
		ASA I	ASA II	ASA III	ASA IV	Unspecified
initial body mass index / kg m^{-2}	<45.0	25	55	21	0	10
	45.0-49.9	7	54	27	0	3
	50.0-54.9	4	59	35	0	5
	55.0-59.9	10	40	28	1	8
	>59.9	5	35	66	6	13
	Unspecified	0	9	3	0	14
	All	**51**	**252**	**180**	**7**	**53**

Primary sleeve gastrectomy procedures:
ASA grade and initial body mass index (n=478)



Comorbidity rates

This table shows the prevalence of each recorded obesity-related disease for sleeve gastrectomy compared to the overall population.

The reported prevalence of three conditions is lower amongst patients undergoing a the sleeve gastrectomy procedure, although none of these differences is statistically significant:

- arthritis.
- GORD.
- polycystic ovarian syndrome.

The rates of the remaining comorbid conditions are higher for sleeve gastrectomy patients. For 6 of the named conditions, the observed prevalence for the patients undergoing a sleeve gastrectomy is significantly higher:

- type 2 diabetes.
- hypertension.
- dyslipidaemia.
- sleep apnoea.
- asthma.
- poor functional status.

Primary operations: details on comorbid conditions

		Operation								
		Sleeve gastrectomy				Other procedures				
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate	Significance [i]
Comorbidities [ii]	Type 2 diabetes	347	160	36	31.6%	3,982	1,479	436	27.1%	0.035
	Hypertension	276	237	30	46.2%	3,619	1,876	402	34.1%	<0.001
	Dyslipidaemia	395	113	35	22.2%	4,389	954	554	17.9%	0.017
	Atherosclerosis	470	36	37	7.1%	4,993	273	631	5.2%	0.082
	Sleep apnoea	382	126	35	24.8%	4,549	847	501	15.7%	<0.001
	Asthma	395	114	34	22.4%	4,411	993	493	18.4%	0.030
	Functional status [iii]	80	378	85	82.5%	1,548	3,252	1,097	67.8%	<0.001
	Arthritis	244	265	34	52.1%	2,463	2,902	532	54.1%	0.406
	GORD [iv]	342	144	57	29.6%	3,526	1,609	762	31.3%	0.469
	Liver disease	473	24	46	4.8%	4,991	225	681	4.3%	0.673
	Depression	367	130	46	26.2%	3,925	1,307	665	25.0%	0.600
	PCOS [v]	317	21	38	6.2%	3,847	369	565	8.8%	0.133

i. χ^2 probability; comparing the incidence amongst the Sleeve gastrectomy patients with the patients undergoing other primary procedures.

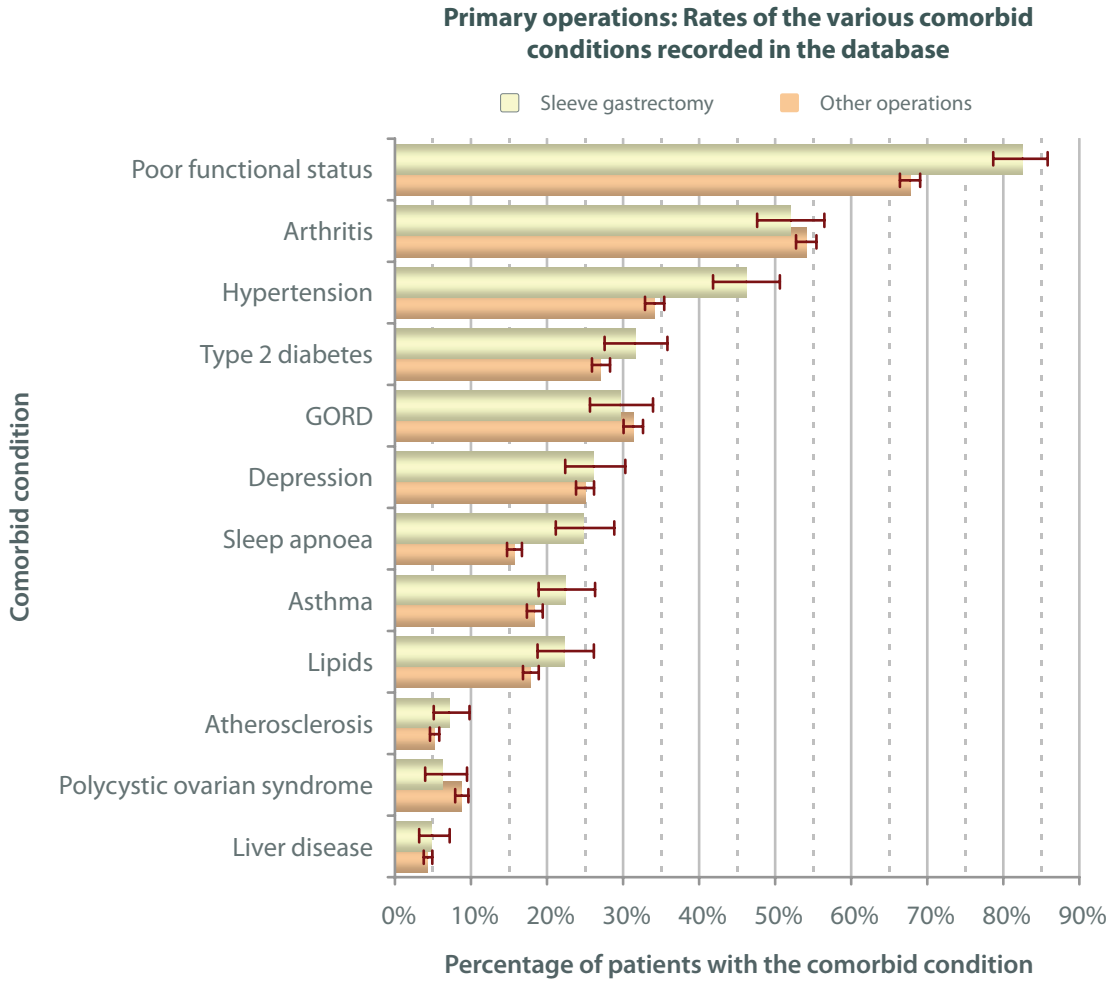
ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovary syndrome.

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 ovarian syndrome.

Comparing the patients going for a sleeve gastrectomy procedure with the patients treated by gastric bypass surgery shows that there are no significant differences in the rates of comorbid conditions across the two groups on the whole, but the former have much higher rates of hypertension (p=0.001), sleep apnoea (p=0.008) and poor functional status (p<0.001). There is therefore a very high degree of comorbidity in these patients.



Technical aspects of sleeve gastrectomy procedures

Linear stapler

Similar to the prevailing lack of consensus on the finer technical aspects of gastric bypass surgery, there is as yet no international agreement on what constitutes a *standard* sleeve gastrectomy. The data from the NBSR show that the stapler size used most frequently to form the gastric staple line is a blue stapler.

Sleeve gastrectomy: linear stapler used in gastric pouch formation and type of operation

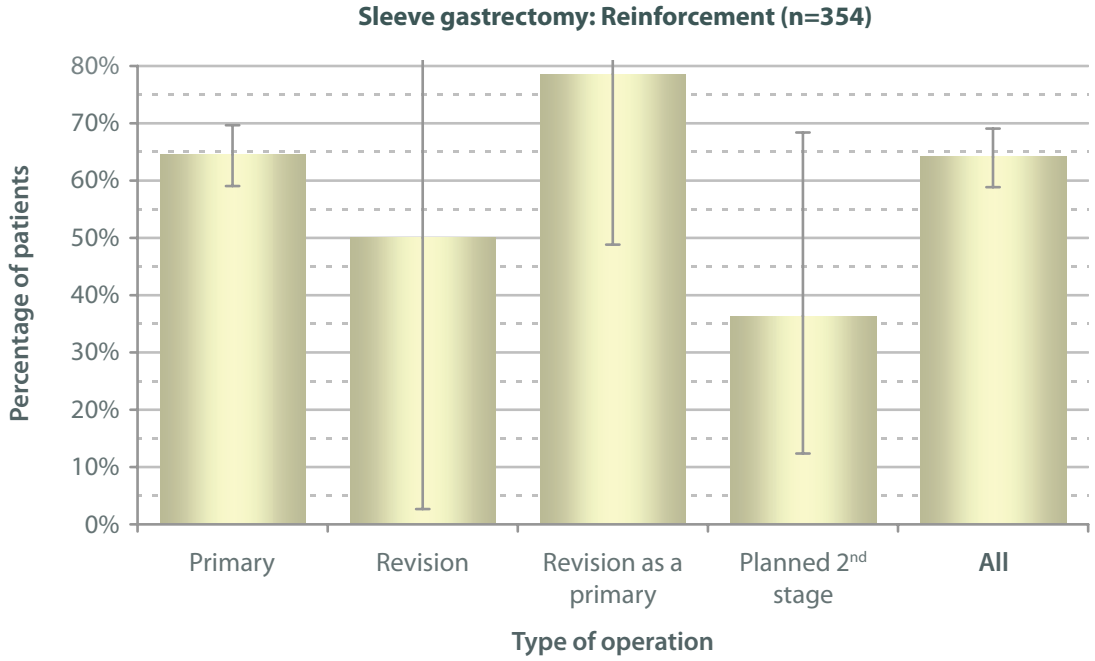
		Linear stapler				
		Blue	Gold	Green	Unspecified	**All**
Type of surgery	Primary	223	39	91	190	**543**
	Revision	2	0	0	3	**5**
	Revision as a primary	7	0	10	8	**25**
	Planned 2nd stage	7	0	4	3	**14**
	Unspecified	0	0	0	1	**1**
	All	**239**	**39**	**105**	**205**	**588**
	Primary	63.2%	11.0%	25.8%		
	Revision	100.0%	0.0%	0.0%		
	Revision as a primary	41.2%	0.0%	58.8%		
	Planned 2nd stage	63.6%	0.0%	36.4%		
	Unspecified	NA	NA	NA		
	All	**62.4%**	**10.2%**	**27.4%**		

Reinforcement

As for gastric bypass, the feared complications after a sleeve gastrectomy are leak or bleeding from the staple line; 64.1% of operations had some form of staple line reinforcement, indicating that most surgeons considered this an essential safety element.

Sleeve gastrectomy: staple line reinforcement of gastric pouch

		Reinforcement			
		No	Yes	Unspecified	**All**
Type of surgery	Primary	116	211	216	**543**
	Revision	1	1	3	**5**
	Revision as a primary	3	11	11	**25**
	Planned 2nd stage	7	4	3	**14**
	Unspecified	0	0	1	**1**
	All	**127**	**227**	**234**	**588**

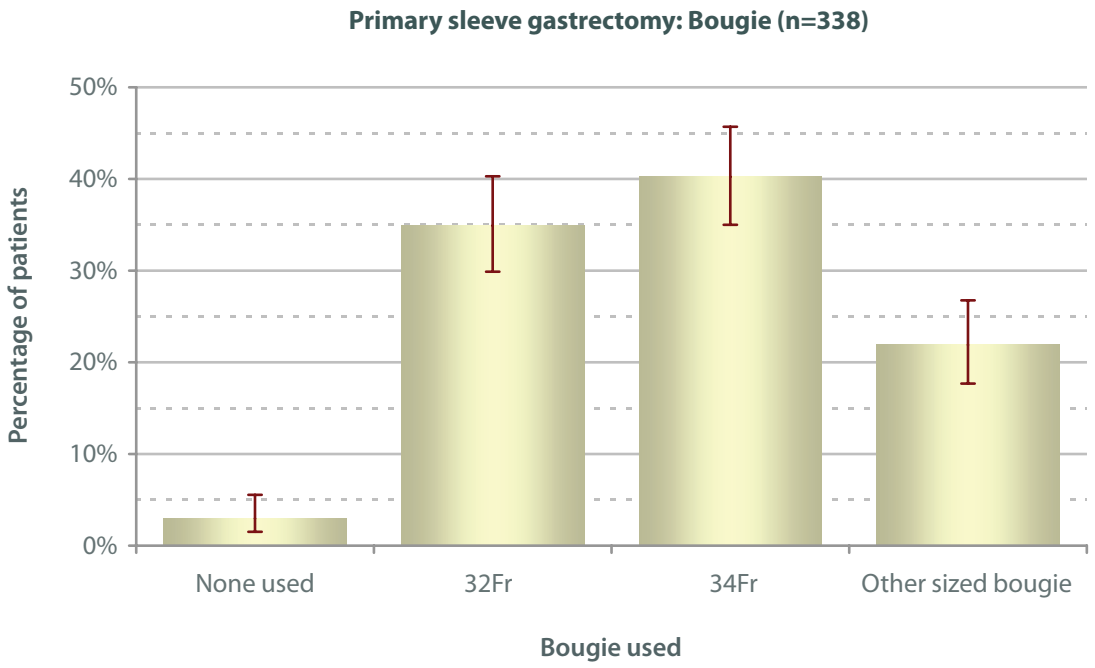


Bougie

Furthermore, there is no consensus on the appropriate width of the gastric tube formed for the sleeve. These data from the NBSR indicate that the majority of surgeons used a bougie to gauge this, but some prefer not to.

Sleeve gastrectomy: bougie used

		Bougie					
		None used	32 Fr	34 Fr	Other	Unspecified	All
Type of surgery	Primary	10	109	126	68	230	**543**
	Revision	0	0	1	1	3	**5**
	Revision as a primary	0	7	3	2	13	**25**
	Planned 2nd stage	0	2	6	3	3	**14**
	Unspecified	0	0	0	0	1	**1**
	All	**10**	**118**	**136**	**74**	**250**	**588**



Additional procedures

As for gastric banding and Roux-en-Y gastric bypass procedures, the data suggest that another additional procedure was only rarely done at the same time as the primary operation.

Sleeve gastrectomy: additional procedures

		Additional procedures[i]						
		None	Cholecystectomy	Hernia repair	Apronectomy	Other	Unspecified	Patient count
Type of surgery	Primary	323	2	8	0	13	197	**543**
	Revision	1	0	0	0	0	4	**5**
	Revision as a primary	13	0	0	0	3	9	**25**
	Planned 2nd stage	7	0	0	0	3	4	**14**
	Unspecified	0	0	0	0	0	1	**1**
	All	**344**	**2**	**8**	**0**	**19**	**215**	**588**
	Primary	93.4%	0.6%	2.3%	0.0%	3.8%		
	Revision	100.0%	0.0%	0.0%	0.0%	0.0%		
	Revision as a primary	81.3%	0.0%	0.0%	0.0%	18.8%		
	Planned 2nd stage	70.0%	0.0%	0.0%	0.0%	30.0%		
	Unspecified	NA	NA	NA	NA	NA		
	All	**92.2%**	**0.5%**	**2.1%**	**0.0%**	**5.1%**		

i More than one additional procedure may be recorded for each operation recorded in the NBSR, so the total number of additional procedures may exceed the number of operations performed.

We are delighted that 4 cases of single incision laparoscopic sleeve gastrectomy were recorded in the registry. This is a potentially exciting new technique for performing sleeve gastrectomy, and future reports should be able to assess its progress.

Details on *other* additional procedures

Primary	4	Division of adhesions
	1	Gastroscopy
	1	Liver biopsy
	1	Release of adhesions & repair of small bowel
	1	Removal gastric band & division of adhesions
	1	Removal of gastric balloon
	4	**Single incision laparoscopic surgery**
Revision as a primary	1	OGD
	2	Removal of gastric band
Planned 2nd stage	3	Removal of intragastric balloon

Post procedure outcomes

30-day complications

The 30-day re-operation rate was 2.9%, which is low for an operation performed predominantly for high-risk patients with substantial comorbidity.

The risk of a re-operation within 30 days is significantly higher after revisional surgery (3.1% *versus* 11.4%; p=0.019), which is consistent with operating on patients who have had prior surgery in the same area.

Sleeve gastrectomy procedures: 30-day post-operative events

		Type of operation			
		Primary		Revisions	
		Count	Rate	Count	Rate
Number of events	0	526	96.9%	39	88.6%
	1	15	2.8%	5	11.4%
	2	2	0.4%	0	0.0%
	3	0	0.0%	0	0.0%

Sleeve gastrectomy procedures: reason for re-operation within 30 days

		Operation							
		Primary				Revisions			
		No	Yes	Not recorded	Rate	No	Yes	Not recorded	Rate
Reason for re-operation	Any complication	526	17	0	3.1%	39	5	0	11.4%
	Leak	540	3	0	0.6%	43	1	0	2.6%
	Bleeding	536	7	0	1.3%	41	3	0	6.8%
	Obstruction	543	0	0	0.0%	44	0	0	0.0%
	Other	535	8	0	1.3%	43	1	0	2.3%

Although as yet the number of sleeve gastrectomies performed as a revisional bariatric procedure are relatively low, there is a statistically significant increased risk of any complication developing and also for re-operations within 30 days.

Future reports should be able to examine the difference in complication and re-operations rates between sleeve and bypass operations.

Sleeve gastrectomy procedures: type of re-operation within 30 days

		Operation							
		Primary				Any revision			
		No	Yes	Not recorded	Rate	No	Yes	Not recorded	Rate
Type of re-operation	Any re-operation	526	7	10	1.3%	39	3	2	7.1%
	Refashioning anastomosis	530	3	10	0.6%	40	2	2	4.8%
	Attention to bleeding area	532	1	10	0.2%	42	0	2	0.0%
	Hernia repair	533	0	10	0.0%	42	0	2	0.0%
	Drain replacement	531	2	10	0.4%	42	0	2	0.0%
	Gastrostomy	533	0	10	0.0%	42	0	2	0.0%
	Enteral feeding	533	0	10	0.0%	42	0	2	0.0%
	Laparoscopy only	531	2	10	0.4%	42	0	2	0.0%
	Other	530	3	10	0.6%	41	1	2	2.4%

Comorbid disease after surgery

There are reductions in all rates of comorbidity for this group of patients, and for five of the conditions the fall is already statistically significant 12 months after surgery:

- type 2 diabetes.
- hypertension.
- dyslipidaemia.
- sleep apnoea.
- functional status.

Primary sleeve gastrectomy: comorbid conditions pre-operatively and 12 months after surgery [i]

			Comorbidity [ii]							
			Type 2 diabetes	Hypertension	Dyslipidaemia	Sleep apnoea	Functional status [iii]	Arthritis	GORD [iv]	PCOS [v]
Source of data	All patients	No	347	276	470	382	80	244	342	317
		Yes	160	237	36	126	378	265	144	21
		Unspecified	36	30	37	35	85	34	57	38
		Rate	31.6%	46.2%	7.1%	24.8%	82.5%	52.1%	29.6%	6.2%
	Patients with follow-up data: Pre-operative data	No	57	50	66	60	11	43	59	45
		Yes	22	30	12	20	62	36	17	2
		Unspecified	1	0	1	0	1	0	3	2
		Rate	27.8%	37.5%	15.4%	25.0%	84.9%	45.6%	22.4%	4.3%
	Patients with follow-up data: 12-month [i] follow-up data	No	72	63	76	71	51	53	68	48
		Yes	8	17	3	9	23	26	11	1
		Unspecified	0	0	0	0	0	0	0	0
		Rate	10.0%	21.3%	3.8%	11.3%	31.1%	32.9%	13.9%	2.0%
Significance [vi] (χ^2 probability)			0.008	0.037	0.028	0.040	<0.001	0.143	0.247	0.971

i. The data used to determine the incidence of the risk factor fall in the defined time-period 365 ± 91 days. The follow-up entry used in the analysis is that row of data that is nearest in time to the 365-day point.

ii. One of the comorbidity questions in the database is only collected for female patients: Polycystic ovarian syndrome.

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

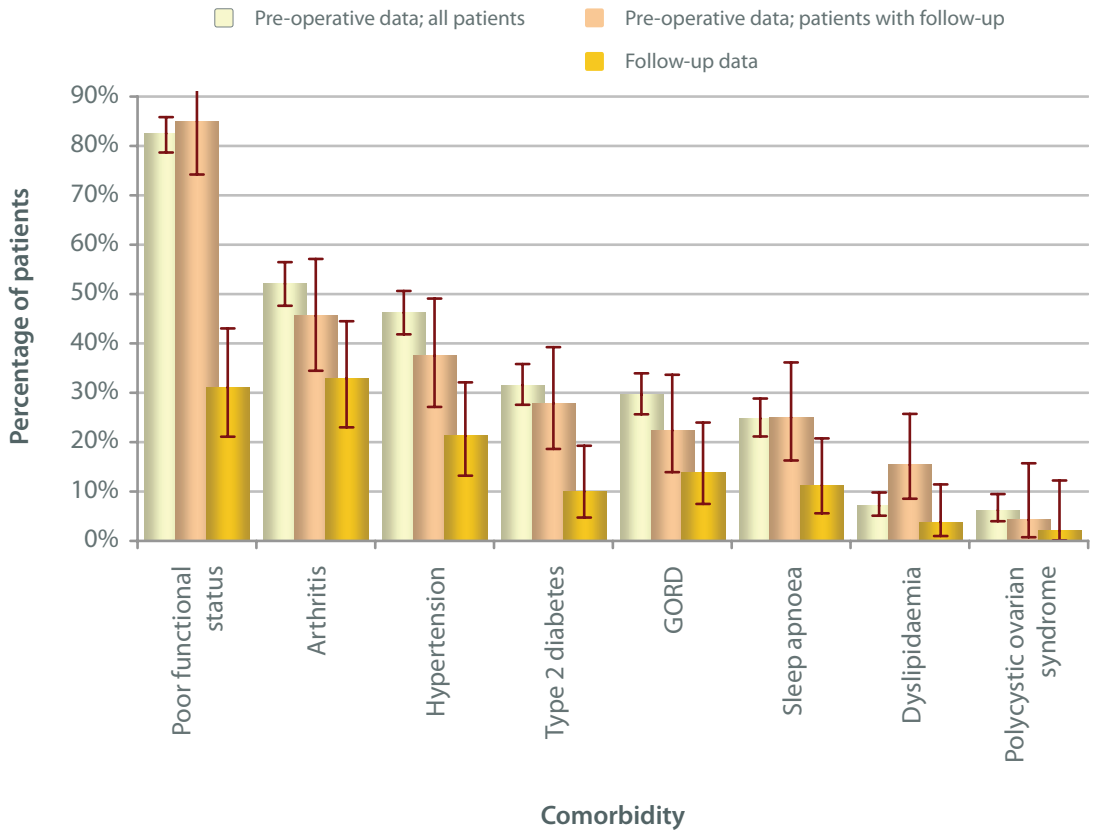
iv. Gastro-oesophageal acid reflux, heartburn or hiatus hernia.

v. Polycystic ovarian syndrome.

vi. Comparing the pre-operative incidence to the 12-month follow-up incidence in the patients with follow-up data.

The most striking reduction in comorbidity is the vast improvement in functional status. Before surgery only 15.1% could climb 3 flights of stairs without resting; one year later 68.9% could do this: a remarkable change. Only bariatric surgery can produce such an improvement in functional status in these patients.

**Primary sleeve gastrectomy procedures:
Comorbid conditions before and after surgery**



Appendices

Appendices

The NBSR database form

Form A

UK National Bariatric Surgery Registry
Initial data
Page 1; Version 2.1 (01/01/2009)

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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)

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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
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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
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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
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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)

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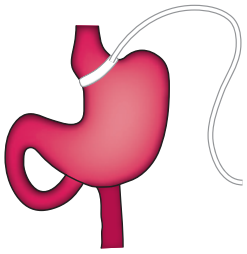
Unique patient-identifier

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)

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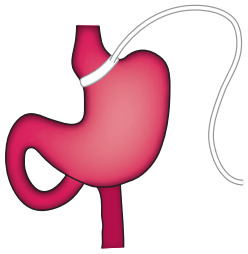
Unique patient-identifier

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
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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
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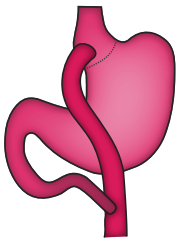
Unique patient-identifier

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
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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)

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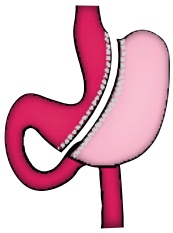
Unique patient-identifier		
Date of operation		dd / mm / yyyy

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)

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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)

ALS GBI
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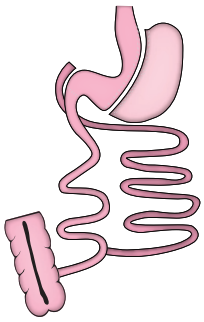
Unique patient-identifier

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)

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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)

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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)

ALS GBI
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Unique patient-identifier	
Date of operation	dd / mm / yyyy

Bilio-pancreatic diversion 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 J

UK National Bariatric Surgery Registry
Balloon placement / retrieval
Page 1; Version 2.1 (01/01/2009)

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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)

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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)

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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)

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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.

Form L

UK National Bariatric Surgery Registry
Follow up
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Dataset definitions

These entries appear as hover prompts in the live database.

Lipids

• Dyslipidaemia	Only for high lipids / cholesterol; does not include routine statin therapy

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

Database tooltips

Throughout the on-line database, hover prompts provide definitions where it may not be entirely intuitive as to which response-option should be selected:

Question	Option	Tooltip
ASA [1] 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
Depression	Depression on medication	Clinically significant depression as an indication for bariatric surgery
Liver disease	No indication of liver disease	LFTs returned to normal
	Suspected NAFLD	Non-alcoholic fatty liver disease suspected by abnormal LFTs or abnormal US 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
Sleep apnoea	No diagnosis or indication	No witnessed apnoea and no daytime sleepiness
	Diagnosis; on CPAP / BIPAP	Continuous positive airway pressure / Bi-level positive airway pressure
	Sleep apnoea + complications	Pulmonary hypertension and / or right heart failure secondary to lung disease
Weight loss drugs	VLCD	Very low calorie diet
Balloon as sole treatment	No	Balloon placed for weight-loss before planned bariatric operation
	Yes	Usually lower BMI patients with no plan for subsequent bariatric operation
Closure of hernia defects	Gastro-ileostomy defect	Petersen's space, defined as small bowel hernia posterior to ante- or retro-colic alimentary limb
	Petersen's space	Small bowel hernia posterior to Roux limb
	Mesocolon	Jejuno-jejunostomy or gastro-ileostomy defect
Type of reinforcement	Biodesign SLR	Biodesign Surgisis Staple Line Reinforcement
Other complications	Acute renal failure	Oliguria / anuria
	Pneumonia / atelectasis	Significant CXR changes + fever
	Rhabdomyolysis	CPK >5,000
	Wound infection / breakdown	Cellulitis + fever

1. American Society of Anesthesiologists

Notes

The First National Bariatric Surgery Registry Report to March 2010

This report is a tribute to British surgery. It … demonstrates a professional commitment to hard-nosed analysis of results.

Sir Bruce Keogh, Medical Director of the National Health Service in England

This report represents the coming of age of bariatric surgery in the United Kingdom...the most powerful and accurate dataset with which to represent United Kingdom bariatric surgery.

Michael Rhodes, President, Association of Laparoscopic Surgeons of Great Britain & Ireland

Every surgeon who performs a bariatric / metabolic procedure should consider participation mandatory.

Kelvin Higa, Past President, American Society for Metabolic and Bariatric Surgery

For the bariatric surgery community to have produced this registry is timely and impressive …

Graeme Poston, President, Association of Upper GI Surgeons of Great Britain & Ireland

This volume contains the first ever compilation of pooled national outcome data for bariatric & metabolic surgery in the United Kingdom. Eighty-four surgeons and their teams, working at 86 hospitals, contributed data on some 8,700 patients treated up to March 31st 2010. The data are analysed in detail for the 7,000 patients operated on in the fiscal years ending 2009 and 2010.

Bariatric and metabolic surgery has increased in volume dramatically throughout the developed world over the past decade. It comprises operations to treat the condition of Severe and Complex Obesity or to ameliorate the associated Metabolic Syndrome (including diabetes, raised cholesterol, high blood pressure and sleep apnoea).

In these pages the reader will find introductory information about these conditions and their surgical treatment as well as the number and types of operation performed. The data go on to demonstrate a level of safety for this surgery comparable to that for many of the standard planned and routine operations widely accepted throughout modern healthcare. This is quite contrary to widely held beliefs. The effectiveness of this surgery is also demonstrated. Lasting major weight loss has its own consequences for return to normal social and economic activity. The data also document, prospectively and in the context of United Kingdom practice, the striking ability of this surgery to induce profound improvement of type-2 diabetes, abolish sleep apnoea, improve circulatory disease and restore functional capacity. Previous international publications have documented major health-economic saving against otherwise rapidly rising future treatment costs: This is the first substantial body of United Kingdom patient outcome data to support such dramatic cost-effectiveness as well as personal benefit in our national context. Future editions of the present project will provide progressively long-term information.

To our knowledge this publication is unique internationally as a detailed body of audit data and is offered as a benchmark for the care of the tens of thousands of patients undergoing bariatric / metabolic surgery world-wide.

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