

## Conference on ‘Malnutrition matters’

# Symposium 7: Downsize me Bariatric surgery: a cost-effective intervention for morbid obesity; functional and nutritional outcomes

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Obesity has been described as the health crisis of the 21st century. It is a chronic lifelong medical condition, whose pattern often starts in childhood, and is demographically worsening in every developed country. The cost of treating the many medical conditions associated with obesity threatens to overwhelm healthcare resources. Medical treatments produce at most no more than 10% weight loss in the severely obese, with high failure rates. In this article, we review the available evidence regarding long-term reduction in weight, reduced mortality and improvement in most, if not all, obesity-related comorbidities. There is a need for daily multi-vitamins and extra minerals, especially with gastric bypass, and nutritional deficiencies of vitamins D and B<sub>12</sub>, Ca, Fe and folate need monitoring and prevention. Currently there is no medical therapy on the near horizon that will match the effect of surgery, which, if done safely, remains the only effective therapy. Bariatric surgery is cost effective, and health providers should embrace the development and rapid expansion of services.

### Outcomes: Cost effectiveness: Safety: Nutrition

In 2008 for the first time there were reported to be more obese individuals in the world than malnourished, with 1 billion obese compared to 800 million malnourished. It is accepted that the average lifespan for an obese individual is about 9 years less than for normal-weight individuals, and that those who are obese have only a one in seven chance of reaching a normal lifespan<sup>(1)</sup>. In developed countries, obese individuals are stigmatised and disenfranchised, and have higher rates of unemployment and higher rates of benefit claims<sup>(2)</sup>.

The causes of the so-called obesogenic environment are complex<sup>(3)</sup>. In the UK, the 2007 Foresight report accepted that humans are predisposed to putting on weight (‘passive obesity’) and recognised that in the current obesogenic environment with freely available energy-dense foods, motorised transport and reduced need for physical activity, weight gain is inevitable<sup>(4)</sup>. The report estimates that within 40 years, by 2050, 60% of adult men and 50% of adult women will be obese. Worryingly, by then a quarter of all children under 16 may also be obese. Clearly the primary

goal must be to change social policy drastically and to quickly stop this.

A systematic review of 24 studies of individuals born between 1927 and 1994 suggested that the relative risk (RR) for adult obesity was between 1.35 and 9.38 if the individual was above the 85th centile as a child<sup>(5)</sup>. More recent data suggest that a ‘tipping point’ for overweight and obesity is reached early, with half of those overweight up to the age of 20 becoming overweight before 2 years and 90% before 5 years<sup>(6)</sup>. These data indicate that the adult obesity epidemic is likely to worsen before it can improve. One report even suggests that obesity may be a socially communicable disease<sup>(7)</sup>. In a study of the Framingham population of 12 000 individuals from 1971 to 2003, the likelihood of obesity occurring within social networks increased by 57% if a friend became obese, by 40% if a sibling became obese and by 37% if a spouse became obese<sup>(7)</sup>.

Considerable resource is devoted to treating obesity-related comorbidities such as type 2 diabetes, sleep apnoea

**Abbreviations:** HR, hazard ratio; RR, relative risk.

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and arthritis. The cost burden of this to health services is inexorable, as increasing BMI is an independent predictor of development of obesity-related disease<sup>(8)</sup>. Thus by 2050, the cost to the National Health Service in the UK is estimated to double to £10 × 10<sup>9</sup> per year and the indirect cost to society is estimated to rise to nearly £50 × 10<sup>9</sup> at today's prices<sup>(4)</sup>.

In addition, increasing evidence suggests that the epidemic of obesity, led by the USA, but closely followed by the UK and many other countries in Europe, is likely to get much worse before any attempts at prevention are effective. No medical therapy produces effective long-term weight loss. The withdrawals of rimonabant in 2009 and sibutramine in 2010 from the market have done nothing to encourage enthusiasm for a magic tablet<sup>(9)</sup>. Orlistat is the only drug still available, but it leads to unpleasant defecation of fat and produces only modest weight loss<sup>(9)</sup>.

In contrast, surgical treatment for the severely obese can produce durable effective weight loss<sup>(10)</sup>. Thus, bariatric surgery, derived from the Greek word 'baros' for weight and the suffix '-iatic' from the word 'iatrike' meaning 'medicine or surgery', is now established as a mainstream surgical specialty in the USA, South America, Australasia and many European countries. Indeed, in the USA, bariatric surgery may already exceed cholecystectomy as the commonest elective abdominal operation<sup>(11)</sup>. According to the 1991 National Institutes of Health guidelines, a patient qualifies for surgery if the BMI is >40, or if the BMI is >35 in the presence of an obesity-related comorbidity that may improve with surgery. The 2006 National Institute of Clinical Excellence Guidance uses the same BMI range and suggests referral for surgery if 'all appropriate non-surgical measures have failed to achieve or maintain adequate clinically beneficial weight loss for at least 6 months', patients have specialist management and are committed to long-term follow-up<sup>(12)</sup>.

### Common bariatric operations

#### *Gastric bypass and gastric banding*

These are the commonest operations worldwide and in the UK<sup>(13,14)</sup>. Other operations such as biliopancreatic diversion (the Scopinaro operation), its variant the duodenal switch, sleeve gastrectomy, and sleeve gastrectomy combined with intestinal transposition constitute only a small percentage of operations performed. Despite many hundreds of thousands of bypasses and bandings performed over the last two decades, there have been only two randomised trials between the two published<sup>(15,16)</sup>. Many authors consider that randomisation is not feasible since strong patient, surgeon and cultural preferences drive patient choice<sup>(17)</sup>. In a matched-pair analysis, Weber and colleagues found better weight loss at every time point up to 2 years favouring bypass<sup>(18)</sup>.

Although O'Brien and co-workers maintain that weight loss for band patients catches up with bypass after this point, it is not clear whether a similar weight loss for up to 5 and 10 years can be achieved on an intention-to-treat basis outside centres of excellence<sup>(18)</sup>. It is also not known whether the more rapid weight loss, and therefore quicker

improvement in comorbidity, that bypass causes is beneficial in the long term. Ideally, lean mass should be preserved during weight loss. Some evidence suggests that gastric banding is better at this than gastric bypass<sup>(19)</sup>. Intuitively, however, barring the dangers of too rapid weight loss, very large patients need resolution of their comorbidity quickly. Certainly this is what the pharmaceutical companies would seek to achieve if bariatric surgery was a tablet.

Typically a band patient loses 40% excess weight by 1 year, rising to 50–60%, provided there is no complication, by 2–3 years. A bypass patient loses 60–70% excess weight by 1 year, settling at 55–65% thereafter. Given the above, long-term comparative data (and randomised trials) are still needed to determine best long-term treatment (5–15 years) on an intention-to-treat basis.

What determines the choice of operation? Patient preference, peer pressure, surgeon and cultural preferences seem to be the greatest influences<sup>(17)</sup>. Whatever the choice, it is clear that surgeons should ensure that patients are fully educated about the process of surgery and the likely outcomes. Multidisciplinary input from physicians (to diagnose comorbidity and improve it pre-operatively), dietitians and specialist nurses is essential. Busy units also need a full-time administrator to cope with the demands made on office time. Patients need to understand how band adjustments work, and the team needs to have sufficient infrastructure in place to provide support. More than six visits in the first year and the necessary infrastructure to achieve this are requirements for good weight loss<sup>(20)</sup>. Group education sessions have a vital role to ensure 'buy-in' of patients and families/friends into the process.

#### *How do gastric bypass and banding work?*

Almost universally, gastric-bypass patients lose their appetite and have much earlier satiety immediately after surgery. These findings are accompanied by reproducible marked rises in the levels of peptide YY and glucagon-like peptide 1<sup>(21,22)</sup>. These gut hormones are thought to be central to the mechanism by which the brain perceives satiety signals from the gut. In a randomised trial, it was found that when patients were given somatostatin, which blocked peptide YY and glucagon-like peptide 1, they ate more when presented with a standard buffet meal, returning to their pre-bypass state<sup>(21)</sup>. In addition, dumping syndrome (abdominal pain and sweating associated with sugary foods) is said to be common and perhaps puts patients off sugary foods. Some evidence also suggests that taste and food preferences also change (C. le Roux, personal communication, 2009). A small gastric pouch, usually with no more than a 20 ml volume, probably ensures that food empties quickly into the small bowel. Emptying will be limited by the rate at which the jejunum beyond the gastric pouch can peristalsis food distally. A standard short-limb bypass does not cause weight loss by malabsorption; in fact, constipation due to the reduced intake is normal and malnutrition is rare.

Gastric-band patients also feel early satiety, and when the band opening is adjusted to the so-called 'sweet spot' of optimal restriction they characteristically feel satisfied

with small volumes and are not looking for food between meals. There is good evidence that banding is also a physiological operation. A randomised trial by Dixon and co-workers showed differences in satiety scores depending on fill volume<sup>(23)</sup>, and another study by the same group showed that high 'Readiness to Change' scores made no difference to weight loss after 2 years<sup>(24)</sup>. Taken together, these mechanistic findings on bypass and banding suggest that the obese state is amenable to physiological manipulation (i.e. surgery) via mechanisms other than promoting malnutrition.

### Obesity-related comorbidity

#### *What happens in the non-operated patient*

Why does motivational weight loss not work? Many studies, in particular those on very low energy diets, have shown that yo-yo dieting is associated with rebound weight regain. One of the factors that could account for this is the extreme hunger that follows intense dieting. Ghrelin, produced in the gastric fundus, has been identified as a hunger hormone and may be involved in this mechanism<sup>(25)</sup>. Thus many individuals, once they have become obese, suffer a lifetime of repeated dieting and weight regain. Exhortations to eat less and exercise more are ineffective if a patient has missed the boat of prevention and is already in the state of chronic obesity<sup>(10)</sup>. Indeed, if the BMI is >50, National Institute of Clinical Excellence guidance suggests referral for surgery as a first-line option<sup>(12)</sup>.

The association between obesity and components of the metabolic syndrome such as type 2 diabetes, hypertension, sleep apnoea and also arthritis is well established<sup>(26)</sup>. Less well recognised is the association with cancer. Obesity is now considered probably the second commonest cause, after smoking. In data from the Cancer Prevention Study II in the USA from 1982 to 1998, the RR of death from cancer increased above a BMI of 30 for both men and women<sup>(27)</sup>. In 900 000 individuals the risk of most, if not all, cancers was increased in non-smokers<sup>(28)</sup>. For women with BMI >40, there was an RR of 6.25 for uterine cancer, and the overall RR was 2.51 for other cancers, in particular kidney, cervix and pancreas. For men with BMI >35, there was an RR of 4.52 for liver cancer, and for BMI >30 the RR was 1.68 for all other cancers. Thus the impact of obesity appears to be important for most, if not all, organs.

#### *Effect of bariatric surgery on comorbidity and mortality*

Many reports in the surgical literature document the amelioration of obesity-related comorbidity after bariatric surgery<sup>(29)</sup>. Some of these studies have been criticised for having only short follow-up, limited to 1–2 years, and less than rigorous methodology for assessing progression of comorbidities over time. For instance, assessment of diabetes by medication usage is open to misinterpretation<sup>(29)</sup>. Thus a patient may remain on metformin because she has polycystic ovarian syndrome, although she is in diabetic remission. Conversely, a patient taken off medication inappropriately in the expectation that diabetes will reverse could still be diabetic. There need to be standard definitions of remission, and better agreement on how to

document changes in other comorbidities over time<sup>(30)</sup>. Studies using more rigorous methodology are now emerging on the positive effects of bariatric surgery<sup>(30)</sup>.

A large study from Montreal demonstrated the effect of gastric bypass on 1035 patients, who were matched from the Quebec provincial health insurance database to 5746 controls<sup>(31)</sup>. The surgery patients had an average BMI of 50, and over the 5-year study, had a risk of dying of 0.68% v. 6.17% in the controls<sup>(31)</sup>. The surgery patients had fewer new diagnoses of cancer (2% v. 8%), fewer heart problems (5% v. 27%), a smaller risk of developing diabetes (9% v. 27%), fewer significant infections (9% v. 37%), less arthritis (5% v. 12%), fewer respiratory problems (3% v. 11%) and less overall time in hospital (21 d v. 36 d), all  $P < 0.01$ <sup>(31)</sup>. The morbidity and case mix of these patients were probably comparable to the average patient seen in the National Health Service in the UK.

In a meta-analysis of 3201 operated patients followed for 2 years, there were differences observed in 'resolution' of diabetes between the two commonest operations, Roux-en-Y gastric bypass and adjustable gastric banding<sup>(29)</sup>. For diabetes, 83.8% of bypass patients were in remission compared to 47.8% for banding. When the term 'improved' was included, the figures rose to 90.6% for bypass and 80.2% for banding. A recent cohort comparison study used much stricter criteria for diabetes remission<sup>(30)</sup>. In this study, it was defined as fasting plasma glucose <7 mmol/l off all medication, 2 h fasting glucose <11.1 mmol/l OGTT (WHO definition) and HbA1c <6% after 3 months of the last hypoglycaemic agent usage<sup>(30)</sup>. Although the study was not randomised, the groups were well matched. At the latest follow-up, 72% of gastric bypass patients were in remission compared to 17% of banding patients ( $P < 0.01$ )<sup>(30)</sup>. Bypass patients achieved fasting plasma glucose <7 mmol/l off all medication quicker than banding patients (hazard ratio (HR) 8.2, 95% CI 1.8, 36.7;  $P = 0.001$ )<sup>(30)</sup>.

Other reports have shown that banding can also be effective in causing diabetes remission. In the only published randomised trial of banding v. best medical therapy for BMI 30–40, Dixon and co-workers found a 73% remission rate for the banded group v. 13% for the medical treatment group (RR 5.5, 95% CI 2.2, 14.0)<sup>(32)</sup>. The differences in these findings can be explained by different severities of diabetes between the studies. Leaving this aside, it is clear that bariatric surgery has much to offer as best medical therapy controls diabetes but never puts it into remission.

In another large study in the USA, 11 903 surgery patients were matched to 11 901 controls selected from 190 448 Medicare patients matched for age, sex and comorbidity<sup>(33)</sup>. Recorded ICD-9 codes were used to document comorbidity prevalence. Over the 2 years of the study, the incidence of diabetes fell by 21%, sleep apnoea by 10%, hypertension by 21%, hyperlipidaemia by 30% and coronary artery disease by 32%, all statistically highly significant findings<sup>(33)</sup>.

In Sweden, a long-term non-randomised cohort study of the effect of bariatric surgery v. medical therapy was initiated in the 1980s<sup>(34)</sup>. At the time, in the era of open surgery, bariatric surgery was considered too dangerous to

allow ethical randomisation between this and best medical therapy. Thus in the Swedish Obese Subjects study, 2037 patients choosing not to have surgery were compared to 2010 surgical patients. Over a mean follow-up of 10.9 years (range 4.9–18.2), there was no significant weight loss in the medical group. By contrast, weight loss in the surgical groups, consisting of adjustable gastric banding, Roux-en-Y gastric bypass and vertical banded gastroplasty (an operation now replaced by banding), was between 13.2 and 25%. More importantly, there was a significant difference in mortality, with 129 control patients dying compared to 101 in the surgical group, HR 0.76 (95% CI 0.59, 0.99), with a time to reach significance ( $P < 0.05$ ) of 13 years<sup>(35)</sup>. This was the first prospective study to show that bariatric surgery confers survival benefit, even after the 90-d mortality rate from surgery of 0.25%<sup>(35)</sup>. It is of interest that many of the gastric banding and vertical-banded-gastroplasty patients were converted to bypass during the study period, so the results cannot be taken as evidence of the long-term effect of these individual operations on an intention-to-treat basis.

Another report also found survival benefit in a retrospective analysis of prospectively collected data<sup>(36)</sup>. Using self-reported BMI data collected from driving licences in Utah, Adams and co-workers were able to match for age, sex and BMI 7925 patients who had undergone gastric bypass with 7925 controls<sup>(36)</sup>. The study period was 1984–2002 and the mean follow-up was 7.1 years. Expressing mortality as deaths/10 000 patient years, 37.6 patients died in the years after surgery compared to 57.1 controls (40% reduction,  $P < 0.001$ )<sup>(36)</sup>. Disease-specific reductions in mortality were also seen for coronary artery disease (56% reduction, 2.6 v. 5.9,  $P = 0.006$ ), diabetes (92% reduction, 0.4 v. 3.4,  $P = 0.005$ ) and cancer (60% reduction, 5.5 v. 13.3,  $P = 0.001$ ). The post-surgical mortality at 1 year was 0.53%, which compared to 0.52% of controls dying in the same period<sup>(36)</sup>.

The reports described confirmed survival benefit after mainly gastric bypass surgery. O'Brien and Dixon's group in Melbourne has also reported survival benefit after gastric banding<sup>(37)</sup>. In a series of 966 operated patients followed up for 4 years, the HR for death was 0.28 (95% CI 0.10, 0.85) compared to a matched cohort of 2119 community controls followed up for 12 years<sup>(37)</sup>.

### Bariatric surgery is cost effective

#### *Hospital and drug prescription costs*

There is accumulating evidence that bariatric surgery is cost effective. The Montreal group reviewed the healthcare costs of 1035 bariatric surgery patients operated from 1986 with a 5-year follow-up to 2002 and compared them to 5746 age- and sex-matched controls<sup>(38)</sup>. All-cause hospitalisations were costed in 1996 CAD\$ after and including the initial operation. After the outlay for the initial surgery, costs continued to rise, but by comparison the costs for the control patients, initially nearly zero, rose much more rapidly and in fact overtook those for surgery at 3.5 years<sup>(38)</sup>. With laparoscopic techniques, the equivalent cost would now almost certainly be less.

Another study from Alabama assessed drug prescription costs after gastric bypass, comparing them to the initial cost of surgery<sup>(39)</sup>. Thirty percent of those on obesity-related medication had stopped them by 1 year, and the average number of medications per patient fell by 66%<sup>(39)</sup>. Taking the surgery as a one-off cost, the crossover point for cost effectiveness was 2.5 years, with surgery favoured thereafter up to the 4-year follow-up point<sup>(39)</sup>.

The Health Technology Assessment report that informed the earlier, 2002 National Institute of Clinical Excellence Guidelines for bariatric surgery estimated that the incremental cost effectiveness ratios per quality-adjusted life year were £8527 for gastric banding and £6289 for gastric bypass<sup>(40)</sup>. Both of these are well below the threshold of £30 000 considered by the National Institute of Clinical Excellence to be cost effective, and they are therefore among the cheapest of interventions. The Health Technology Assessment report has recently updated its costing of the incremental cost effectiveness ratios to £2000–4000 per quality-adjusted life year gained<sup>(41)</sup>. More recent data on cost effectiveness show clear benefits for diabetes<sup>(42)</sup>.

#### *Effect on paid work*

Studies of cost effectiveness do not routinely consider the effect of bariatric surgery on subsequent employment potential or claims for state benefits. In a study in south-west England, fifty-nine patients were assessed a mean 14 months after surgery<sup>(2)</sup>. The proportion in paid work after surgery rose from 58% to 76%, which was the same as the population average. Individuals worked 30.1 h per week on average before surgery and 35.8 h per week afterwards. The total time worked per week rose from 1023 to 1611 h, a 57% increase<sup>(2)</sup>.

The study also examined self-reported benefit claims (Disability Living Allowance, Incapacity Benefit and Carer's Allowance). Thirty-two percent claimed benefit before surgery and this fell to 10% afterwards, similar to the average level of claims of 8.6% for the population. Similarly, the total number of benefits claimed fell by 75%<sup>(2)</sup>. In an earlier Dutch study of 62 patients after bariatric surgery, unemployment improved from 53% pre-surgery to 80% afterwards, similar to the levels of employment in the UK study<sup>(43)</sup>. The data therefore suggest economic benefit to the wider community from surgery.

### Complications of surgery in the short and long term

Proponents of gastric banding cite very low mortality (1–2 per 1000 operations) as its principal benefit<sup>(44)</sup>. Mortality from gastric bypass in high-volume centres should be no more than 0.5%, depending on peri-operative risk factors. Even with this mortality, gastric bypass is perceived as having a 10-fold higher risk of death than banding. However, in many reported studies, band patients have lower BMI and are therefore lower risk (with little or no comorbidity) compared to bypass series where the average BMI may be 7 or 8 points higher. Heavier patients therefore have more comorbidity and may do badly if there is a complication. As larger patients stand to gain much more from weight loss, higher mortality may be an acceptable

trade-off. However, when the Swedish Obese Subjects study operative mortality was experimentally modelled at 6%, it became mathematically impossible for there to be survival benefit from surgery (L. Sjostrom, personal communication, 2008). Similarly, the Utah study above shows the importance of low operative mortality.

Therefore, to avoid comparing apples and oranges, data are needed on the risk of surgery on a like-for-like basis. The Obesity Surgery–Mortality Risk Score of de Maria has been proposed as just such a method to stratify risk for gastric bypass<sup>(45)</sup>. In this prospectively validated score, higher operative mortality is associated with age >45, BMI >50, male gender, hypertension (these two because of their association with central obesity and therefore more difficult surgery) and risk of deep vein thrombosis or pulmonary embolism.

Every bariatric operation has a complication, revision and failure rate. For banding, reoperation rates are often quoted at 10–20% over 5–10 years due to band slippage, band infection (usually in port site), tubing or device fractures (usually due to needling injury during fill adjustment), and erosion (where the band erodes into the stomach)<sup>(46)</sup>. Fortunately band erosion, the most serious of these complications, is the least common. Although these complication rates may be at variance with the often excellent published data, it is also clear that a substantial proportion of patients in many series are lost to follow-up. National registries are needed to collect data on the fate of bands on an intention-to-treat basis.

Adjustable gastric banding was introduced in 1986, and in Europe the enthusiasm for placing bands that prevailed in the 1990s has waned due to the perception that there is a high risk of long-term complications or failure to lose weight, with high removal rates. In many studies, the proportion of patients who fail to lose the first quartile of their excess weight is up to 15–20%<sup>(47)</sup>. Thus many patients have conversions to gastric bypass due to 'band intolerance'. By contrast there is now huge enthusiasm for gastric banding in the US, where FDA approval for the procedure was achieved only in 2001.

The main short-term risk of gastric bypass is the operation itself. Provided the patient leaves hospital without a complication (which after the learning curve carries a risk of a few percent only), then the later reoperation rate is low. The proportion of patients failing to lose the first quarter of their excess weight is <5%<sup>(15,47)</sup>. In the vast majority, it seems that weight loss is achieved irrespective of outpatient attendance and team infrastructure (although this has not been subjected to randomised study compared to banding). There is some weight regain after the nadir that is reached at about 12–18 months. The Montreal group has shown durable weight loss to at least 15 years after this<sup>(48)</sup>. However, for a procedure that was introduced in 1967 it is a shortcoming in the literature that there are so few long-term follow-up studies.

The biggest challenge for gastric bypass is getting through the learning curve<sup>(49–51)</sup>. Excess mortality during this time defeats the point of the surgery. Start-up units and surgeons should therefore be mentored. The learning curve is challenging because techniques to join bowel laparoscopically are not common in the surgical repertoire.

Therefore surgeons are learning these techniques in a situation where even a small leak can have catastrophic consequences.

In addition, opening up of internal hernias caused by the anatomic rearrangement (Petersen's defect, jejuno-jejunosomy defect +/-trans-mesocolic defect) as the patient loses weight predisposes to small bowel obstruction. Many view sewing up the defects preventively as a standard part of the operation in order to avoid the potentially disastrous consequences of obstruction with gangrene of the bowel years after bypass.

### Centres of Excellence: improving outcomes of surgery

Increasing specialisation has been shown to reduce complications and mortality in every area of major surgery, and bariatric surgery is no different<sup>(52,53)</sup>. Although the data on hospital volume and specialisation all refer to gastric bypass, it seems likely that high-volume gastric band centres will also have better outcomes because of better infrastructure for intensive follow-up. Data from the Longitudinal Assessment of Bariatric Surgery study in the USA confirm better outcomes for gastric bypass for higher-volume surgeons<sup>(54)</sup>.

In a drive to improve standards after well-reported high cost claims for complications after surgery, the American Society for Metabolic and Bariatric Surgery established criteria and an infrastructure to create Centres of Excellence<sup>(55)</sup>. Since 2007, more than 700 surgeons and 400 hospitals in the USA have been awarded Centre of Excellence status. The rigorous application process was designed to ensure the highest achievable standards of care. Each hospital must have a minimum annual volume of 125 cases, at least two surgeons on the on-call rota, and a designated lead, full-time bariatric surgeon. The priority of the approval process is a site visit and a 10% random notes review. Standards for follow-up are also specified so that at least 75% of patients should be seen annually.

In June 2009, the results of 57 918 patients entered into the Centre of Excellence database were published on-line: the commonest operations were gastric bypass (54.8%) followed by gastric banding (39.8%)<sup>(54)</sup>. Overall, 10.77% of patients had an adverse event after surgery, mainly minor, with nausea/vomiting being the commonest. The overall mortality rate was 0.135%. Presently, no further procedure-specific data are available.

In Europe, a similar Centre of Excellence process is being initiated<sup>(56)</sup>. In the UK, the National Bariatric Surgery Registry ([www.nbsr.org.uk](http://www.nbsr.org.uk)) was created in 2009, and in its first year had already accumulated more than 6000 operated patients. It is hoped that all surgeons performing surgery in the UK will contribute their patient data so that national outcomes can be known.

### Long-term nutritional consequences of bariatric surgery

The first bariatric operation, jejuno-ileal bypass, which originated nearly 50 years ago, is rightly obsolete due to its many side effects. These were due to the small bowel blind-loop created, which led to liver damage, osteomalacia

and osteoporosis<sup>(57)</sup>. Procedures with a malabsorptive element such as biliopancreatic diversion and duodenal switch and DS are associated with a higher risk for nutritional complications compared to gastric banding, gastric bypass and sleeve gastrectomy where significant protein and energy malabsorption is rare.

#### *Gastric bypass and banding*

Fe, Ca, Mg and Zn are normally absorbed in the duodenum and proximal jejunum, and their absorption is decreased in gastric bypass. With a normal small bowel length of perhaps 9 m, protein and energy malnutrition is rarely seen after standard gastric bypass where the biliopancreatic limb is kept short, often 20–30 cm, and usually no longer than 75 cm. Similarly, the Roux limb, routed to the new gastric pouch and joined downstream to the end of the biliopancreatic limb in a 'Y', is usually kept between 75 and 150 cm. 'Long-limb' bypass (limbs 200 cm each) carries a much higher risk of malnutrition but is rarely performed (biliopancreatic diversion duodenal switch would be preferred if the intention was to create protein and energy malabsorption).

It is considered mandatory that all gastric bypass patients take lifelong dietary supplementation of minerals. The daily percentages of the RDA that should be taken are Fe (50%), Ca (100%), Zn (33%), Cu (50%) and Se (33%)<sup>(58)</sup>. In addition, bypass patients should take multivitamins that include vitamins A, D, E (all 100%), K (25%), B group (all 150–300%), B<sub>12</sub> (300%) and C (200%) and folate. About one in three patients need added vitamin B<sub>12</sub> injections, and some clinicians prefer to prescribe this to all patients. Specific deficiencies of vitamins A, E and K are rare<sup>(59,60)</sup>.

Bypass patients should have blood tests regularly to search for deficiencies. According to the European Association for Endoscopic Surgery guidelines, patients should be seen between three and eight times in the first year after surgery, one to four times in the second year and once or twice annually thereafter<sup>(61)</sup>. Blood count, urea and electrolytes, liver function tests, parathormone, iron indices, B<sub>12</sub> and folate should be measured at each follow-up. Dosages of regular medication should also be reviewed, as alternatives may be needed for drugs that are absorbed in an acid environment. For instance with phenytoin, under-dosage may result<sup>(62)</sup>. Recommendations for banding are similar to bypass, as vitamin deficiency, though infrequent, may occur with the decreased food intake. However, vitamin levels probably do not need long-term monitoring.

Vitamin D deficiency is increasingly recognised as being associated with obesity. Ca supplements alone are insufficient to protect from osteoporosis. In a study of bypass patients from Nebraska it was found that 61% were vitamin D deficient compared to 12% of non-obese controls, and as many as 49% had secondary hyperparathyroidism compared to 2% of controls<sup>(63)</sup>. The findings were not explained by a difference in vitamin D or Ca levels, Ca intake or sunlight exposure. Long-term data (>10 years) on bone mineral deficiency are lacking after gastric bypass, but reassuringly there are no reports of increased fracture rates<sup>(35)</sup>.

#### **Future areas for surgery and research**

Fundamental questions that need answering include why obesity leads to insulin resistance, diabetes, cancer and infertility. Surgery for adolescents is increasing and needs careful study<sup>(64)</sup>. Surgery for diabetes is also likely to increase. The current BMI level for surgery (1991 National Institutes of Health guidelines) uses an arbitrary cut-off of 35. The Diabetes Surgery Consensus Summit (Rome 2007) suggested that 'surgery should be considered for the treatment of diabetes' in patients with a BMI of 35 or more 'who are inadequately controlled by lifestyle and medical therapy'. Further, surgery may also be appropriate for the treatment of people with type 2 diabetes and BMI 30–35<sup>(65)</sup>. If clinicians believe in and adopt these guidelines, the floodgates could open for surgery.

To put the effect of bariatric surgery into the context of cancer, the recent Swedish Obese Subjects study data showed a 33% fall in the incidence of cancer over 18 years after surgery ( $P = 0.0009$ ). Compare this to statin therapy, universally accepted as a mainstay of treatment for prevention of CVD, which gives at maximum a 20% RR reduction in fatal or non-fatal heart attacks<sup>(66,67)</sup>.

#### **Conclusions and summary**

Despite the accumulating evidence in favour of bariatric surgery, there is still reticence among many clinicians to refer patients. How should this be challenged? Dr Henry Buchwald in his presidential address to the American Society for Bariatric Surgery in 2004 said that 'there are no surgical or medical diseases: there are just conditions and treatments'. At the Diabetes Surgery Summit Dr Ricardo Cohen, a Brazilian surgeon, went further when he said, 'if there would be one pill that keeps weight down and resolves type 2 diabetes mellitus (and other comorbidities) for at least 15–20 years, with low morbidity and mortality and impressive decrease in long-term mortality, its inventor would probably deserve a Nobel prize'. That view is just as true now, and all who are involved in the delivery of healthcare to our increasingly obese population should embrace and propagate it.

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#### **References**

1. Humadi S & Welbourn R (2008) Bariatric surgery: rationale, development and current status. In *Recent Advances in Surgery* 31, pp. 59–70. [C Johnson and I Taylor, editors], London: Royal Society of Medicine Press.
2. Hawkins SC, Osborne A, Finlay IG *et al.* (2007) Paid work increases and state benefit claims decrease after bariatric surgery. *Obes Surg* 17, 434–437.

3. Sørensen TI (2009) Conference on “Multidisciplinary approaches to nutritional problems”. Symposium on “Diabetes and health”. Challenges in the study of causation of obesity. *Proc Nutr Soc* **68**, 43–54.
4. Foresight report (2007) Tackling Obesities. Future Choices Project. <http://www.foresight.gov.uk/OurWork/ActiveProjects/Obesity/Obesity.asp>
5. Baird J, Fisher D, Lucas P *et al.* (2005) Being big or growing fast: systematic review of size and growth in infancy and later obesity. *BMJ* **331**, 929.
6. Harrington JW, Nguyen VQ, Paulson JF *et al.* (2010) Identifying the “Tipping Point” age for overweight pediatric patients. *Clin Pediatr (Phila)* (In the Press).
7. Christakis NA & Fowler JH (2007) The spread of obesity in a large social network over 32 years. *N Engl J Med* **357**, 370–379.
8. LABS Writing Group for the LABS Consortium, Belle SH, Chapman W *et al.* (2008) Relationship of body mass index with demographic and clinical characteristics in the longitudinal assessment of bariatric surgery (LABS). *Surg Obes Relat Dis* **4**, 474–480.
9. Williams G (2010) Withdrawal of sibutramine in Europe. *BMJ* **340**, 377–378.
10. Leff DR & Heath D (2009) Surgery for obesity in adulthood. *BMJ* **339**, b3402.
11. Belle SH, Berk PD, Courcoulas AP *et al.* (2007) Safety and efficacy of bariatric surgery: longitudinal assessment of bariatric surgery. *Surg Obes Relat Dis* **3**, 116–126.
12. National Institute for Health and Clinical Excellence (2006). <http://www.nice.org.uk/nicemedia/pdf/CG43quickrefguide2.pdf>
13. Buchwald H & Oien DM (2009) Metabolic/bariatric surgery worldwide 2008. *Obes Surg* **19**, 1605–1611.
14. Longitudinal Assessment of Bariatric Surgery (LABS) Consortium, Flum DR, Belle SH, *et al.* (2009) Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med* **361**, 445–454.
15. Nguyen NT, Slone JA, Nguyen XM *et al.* (2010) A prospective randomized trial of laparoscopic gastric bypass versus laparoscopic adjustable gastric banding for the treatment of morbid obesity: outcomes, quality of life, and costs. *Ann Surg* (In the Press).
16. Angrisani L, Lorenzo M & Borrelli V (2007) Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial. *Surg Obes Relat Dis* **3**, 127–132.
17. Weber M, Müller MK, Bucher T *et al.* (2004) Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. *Ann Surg* **240**, 975–982.
18. O’Brien PE, McPhail T, Chaston TB *et al.* (2006) Systematic review of medium-term weight loss after bariatric operations. *Obes Surg* **16**, 1032–1040.
19. Dixon JB, Strauss BJ, Laurie C *et al.* (2007) Changes in body composition with weight loss: obese subjects randomized to surgical and medical programs. *Obesity (Silver Spring)* **15**, 1187–1198.
20. Shen R, Dugay G, Rajaram K *et al.* (2004) Impact of patient follow-up on weight loss after bariatric surgery. *Obes Surg* **14**, 514–519.
21. le Roux CW, Welbourn R, Werling M *et al.* (2007) Gut hormones as mediators of appetite and weight loss after Roux-en-Y gastric bypass. *Ann Surg* **246**, 780–785.
22. Pournaras DJ, Osborne A, Hawkins SC *et al.* (2010) The gut hormone response following Roux-en-Y gastric bypass: cross-sectional and prospective study. *Obes Surg* **20**, 56–60.
23. Dixon AF, Dixon JB & O’Brien PE (2005) Laparoscopic adjustable gastric banding induces prolonged satiety: a randomized blind crossover study. *J Clin Endocrinol Metab* **90**, 813–819.
24. Dixon JB, Laurie CP, Anderson ML *et al.* (2009) Motivation, readiness to change, and weight loss following adjustable gastric band surgery. *Obesity (Silver Spring)* **17**, 698–705.
25. Bueter M & le Roux CW (2009) Sir David Cuthbertson Medal Lecture. Bariatric surgery as a model to study appetite control. *Proc Nutr Soc* **68**, 227–233.
26. Dixon JB, Pories WJ, O’Brien PE *et al.* (2005) Surgery as an effective early intervention for diabetes: why the reluctance? *Diabetes Care* **28**, 472–474.
27. Adami HO & Trichopoulos D (2003) Obesity and mortality from cancer. *N Engl J Med* **348**, 1623–1624.
28. Calle EE, Rodriguez C, Walker-Thurmond K *et al.* (2003) Overweight, obesity, and mortality from cancer in a prospectively studied cohort of U.S. adults. *N Engl J Med* **348**, 1625–1638.
29. Buchwald H, Avidor Y, Braunwald E *et al.* (2004) Bariatric surgery: a systematic review and meta-analysis. *JAMA* **292**, 1724–1737.
30. Pournaras DJ, Osborne A, Hawkins SC *et al.* (2010) Remission of type 2 diabetes after gastric bypass and banding: mechanisms and two year outcomes. *Ann Surg* (In the Press).
31. Christou NV, Sampalis JS, Liberman M *et al.* (2004) Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg* **240**, 416–423.
32. Dixon JB, O’Brien PE, Playfair J *et al.* (2008) Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. *JAMA* **299**, 316–323.
33. Perry CD, Hutter MM, Smith DB *et al.* (2008) Survival and changes in comorbidities after bariatric surgery. *Ann Surg* **247**, 21–27.
34. Sjöström L, Lindroos AK, Peltonen M *et al.* (2004) Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med* **351**, 2683–2693.
35. Sjöström L, Narbro K, Sjöström CD *et al.* (2007) Swedish obese subjects study. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med* **357**, 741–752.
36. Adams TD, Gress RE, Smith SC *et al.* (2007) Long-term mortality after gastric bypass surgery. *N Engl J Med* **357**, 753–761.
37. Peeters A, O’Brien PE, Laurie C *et al.* (2007) Substantial intentional weight loss and mortality in the severely obese. *Ann Surg* **246**, 1028–1033.
38. Sampalis JS, Liberman M, Auger S *et al.* (2004) The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg* **14**, 939–947.
39. Snow LL, Weinstein LS, Hannon JK *et al.* (2004) The effect of Roux-en-Y gastric bypass on prescription drug costs. *Obes Surg* **14**, 1031–1035.
40. Clegg AJ, Colquitt J, Sidhu MK *et al.* (2002) The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technol Assess* **6**, 1–153.
41. Picot J, Jones J, Colquitt JL *et al.* (2009) The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technol Assess* **13**(41), 1–190, 215–357, iii–iv.
42. Keating CL, Dixon JB, Moodie ML *et al.* (2009) Cost-efficacy of surgically induced weight loss for the management of type 2 diabetes: a randomized controlled trial. *Diabetes Care* **32**, 580–584.
43. van Gemert WG, Adang EM, Greve JW *et al.* (1998) Quality of life assessment of morbidly obese patients: effect of weight-reducing surgery. *Am J Clin Nutr* **67**, 197–201.

44. O'Brien PE, Dixon JB, Laurie C *et al.* (2005) A prospective randomized trial of placement of the laparoscopic adjustable gastric band: comparison of the perigastric and pars flaccida pathways. *Obes Surg* **15**, 820–826.
45. DeMaria EJ, Murr M, Byrne TK *et al.* (2007) Validation of the obesity surgery mortality risk score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. *Ann Surg* **246**, 578–582.
46. Suter M, Calmes JM, Paroz A *et al.* (2006) A 10-year experience with laparoscopic gastric banding for morbid obesity: high long-term complication and failure rates. *Obes Surg* **16**, 829–835.
47. Puzziferri N, Nakonezny PA, Livingston EH *et al.* (2008) Variations of weight loss following gastric bypass and gastric band. *Ann Surg* **248**, 233–242.
48. Christou NV, Look D & Maclean LD (2006) Weight gain after short- and long-limb gastric bypass in patients followed for longer than 10 years. *Ann Surg* **244**(5), 734–740.
49. Shikora SA, Kim JJ, Tarnoff ME *et al.* (2005) Laparoscopic Roux-en-Y gastric bypass: results and learning curve of a high-volume academic program. *Arch Surg* **140**, 362–367.
50. Schauer P, Ikramuddin S, Hamad G *et al.* (2003) The learning curve for laparoscopic Roux-en-Y gastric bypass is 100 cases. *Surg Endosc* **17**, 212–215.
51. Pournaras DJ, Jafferbhoy S, Titcomb DR *et al.* (2010) Three hundred laparoscopic Roux-en-Y gastric bypasses: managing the learning curve in higher risk patients. *Obes Surg* **20**, 290–294.
52. Courcoulas A, Schuchert M, Gatti G *et al.* (2003) The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. *Surgery* **134**, 613–623.
53. Flum DR & Dellinger EP (2004) Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg* **199**, 543–551.
54. Smith MD, Patterson E, Wahed AS *et al.* (2010) Relationship between surgeon volume and adverse outcomes after RYGB in longitudinal assessment of bariatric surgery (LABS) study. *Surg Obes Relat Dis* **6**, 118–125.
55. Surgical Review Corporation (2009) [http://www.surgicalreview.org/NewsReleasesPage.aspx?item=BOLDASMBMS\\_2009\\_News\\_Release](http://www.surgicalreview.org/NewsReleasesPage.aspx?item=BOLDASMBMS_2009_News_Release).
56. Melissas J (2008) IFSO guidelines for safety, quality, and excellence in bariatric surgery. *Obes Surg* **18**, 497–500.
57. Jørgensen S, Olesen M & Gudman-Høyer E (1997) A review of 20 years of jejunioileal bypass. *Scand J Gastroenterol* **32**, 334–339.
58. Pournaras DJ & le Roux CW (2009) After bariatric surgery, what vitamins should be measured and what supplements should be given? *Clin Endocrinol* **71**(3), 322–325.
59. Davies DJ, Baxter JM & Baxter JN (2007) Nutritional deficiencies after bariatric surgery. *Obes Surg* **17**, 1150–1158.
60. Bloomberg RD, Fleishman A, Nalle JE, Herron DM & Kini S (2005) Nutritional deficiencies following bariatric surgery: what have we learned? *Obes Surg* **15**(2), 145–154.
61. Sauerland S, Angrisani L, Belachew M *et al.* (2005) Obesity surgery: evidence-based guidelines of the European Association for Endoscopic Surgery (EAES). *Surg Endosc* **19**, 200–221.
62. Pournaras DJ, Footitt D, Mahon D & Welbourn R (2010) Reduced phenytoin levels in an epileptic patient following Roux-En-Y gastric bypass for obesity. *Obes Surg* (In the Press).
63. Goldner WS, Stoner JA, Thompson J, Taylor K, Larson L, Erickson J & McBride C (2008) Prevalence of vitamin D insufficiency and deficiency in morbidly obese patients: a comparison with non-obese controls. *Obes Surg* **18**(2), 145–150.
64. O'Brien PE, Sawyer SM, Laurie C *et al.* (2010) Laparoscopic adjustable gastric banding in severely obese adolescents. A randomized trial. *JAMA* **303**, 519–526.
65. Rubino F, Kaplan LM, Schauer PR *et al.* (2010) The diabetes surgery summit consensus conference: recommendations for the evaluation and use of gastrointestinal surgery to treat type 2 diabetes mellitus. *Ann Surg* **251**, 399–405.
66. Sjöström L, Gummesson A, Sjöström CD *et al.* (2009) Effects of bariatric surgery on cancer incidence in obese patients in Sweden (Swedish Obese Subjects Study): a prospective, controlled intervention trial. *Lancet Oncol* **10**, 653–662.
67. Preiss D & Sattar N (2009) Lipids, lipid modifying agents and cardiovascular risk: a review of the evidence. *Clin Endocrinol* **70**, 815–828.