What is the most effective operation for adults with severe and complex obesity?

Jane M Blazeby,1,2 James Byrne,3 Richard Welbourn4

Accessing, undergoing, and achieving a successful outcome from surgery for “severe and complex obesity” is difficult and requires determination and effort. Here, we consider “severe and complex obesity” to mean that an individual’s health is compromised by his or her weight to the extent that surgery can be considered to be an appropriate option. Surgery may be offered to adults with a body mass index (BMI) of ≥40, or a BMI of ≥35 with an obesity related disease, and it can be very successful. An average 50% of excess weight may be lost in the first few years after surgery, and if this is sustained it is associated with long term reduction in overall mortality and decreased incidences of diabetes, myocardial infarction, stroke and cancer. This treatment, however, requires careful consideration and serious commitment, with the need to demonstrate full engagement in a structured weight loss programme, to have tried all appropriate non-invasive measures of weight loss, and persevered for referral to a specialist surgical team. Once surgery is approved it is necessary to choose which operation to undergo.

Worldwide, three operations predominate: laparoscopic adjustable gastric band surgery (gastric band), laparoscopic Roux-en-Y gastric bypass (gastric bypass), and laparoscopic sleeve gastrectomy. In gastric band surgery an adjustable band is placed around the top of the stomach (fig 1). Gastric bypass, which takes longer to perform than a band and requires more operative skill, involves creation of a small gastric pouch that is attached to a limb of intestine so ingested food bypasses the duodenum and proximal small intestine (fig 2). In sleeve gastrectomy, which is technically less complex than a bypass, the greater curvature of the stomach is resected (fig 3).

All the procedures reduce eating capacity and influence appetite and satiety by changing the hormonal milieu and by possible vagal nerve feedback. The surgery itself also necessitates changes in eating and lifestyle behaviours, critical factors which maintain sustained weight loss and which require appropriate support in follow-up. Band surgery requires follow-up “band consultations” to regulate the gastric capacity by adjusting the volume of fluid in the band (a band fill or defill). After gastric bypass, long term vitamin supplementation and monitoring is needed—particularly of the fat soluble vitamins, folic acid, and zinc—to ensure a good outcome and to avoid potentially dangerous nutritional sequelae (such as bone demineralisation due to vitamin D deficiency). After all types of surgery, provision of dietary and lifestyle advice is important. Most patients are anatomically suitable for the three types of bariatric surgery.

Increasing numbers of procedures are being undertaken in many countries, although the prevalence of

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1Centre for Surgical Research, School of Social and Community Medicine, University of Bristol, Bristol BS8 2PR, UK
2Division of Surgery, Head and Neck, University Hospitals Bristol NHS Foundation Trust, Bristol
3Department of Upper Gastrointestinal Surgery, University Hospital Southampton NHS Trust, Southampton, UK
4Department of Upper Gastrointestinal and Bariatric Surgery, Musgrove Park Hospital, Taunton, UK

Correspondence to: J M Blazeby j.m.blazeby@bhs.nhs.uk

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This is one of a series of occasional articles that highlight areas of practice where management lacks convincing supporting evidence. The series adviser is David Tovey, editor in chief, the Cochrane Library. This paper is based on a research priority identified and commissioned by the National Institute for Health Research’s Health Technology Assessment programme on an important clinical uncertainty. To suggest a topic, please email us at practice@bmj.com.

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Fig 1 | Gastric band surgery showing (a) a small “virtual” pouch of stomach below the gastro-oesophageal junction and (b) gastro-gastro tunnelling sutures. (Reproduced from SM Griffin, SA Raimes, J Shenfine. Oesophagogastric Surgery. 5th ed. Saunders Elsevier, 2013)

Fig 2 | Gastric bypass showing short vertical lesser curve-based gastric pouch with Roux-en-Y jejunoojejunostomy reconstruction. (Reproduced from SM Griffin, SA Raimes, J Shenfine. Oesophagogastric Surgery. 5th ed. Saunders Elsevier, 2013)
each is changing. In 2009-10, gastric band, gastric bypass, and sleeve gastrectomy accounted for 21%, 67%, and 10% of procedures in the UK National Health Service respectively, but more recent data for individual UK surgeons and worldwide surveys show that fewer gastric bands are being inserted and there is a dramatic increase in sleeve gastrectomy, with rates of the three procedures in the UK now being approximately 10%, 60%, and 25% respectively.

What is the evidence of uncertainty?

Randomised controlled trials

A systematic review in 2009 included 20 randomised controlled trials examining the clinical and cost effectiveness of bariatric surgery. We updated this and identified five additional trials with searches in Medline and the Cochrane Libraries using search terms for bariatric surgery combined with terms for obesity and a validated filter for randomised controlled trials, restricted to studies in humans. Of the 25 trials, two compared gastric band and bypass, and three evaluated sleeve gastrectomy. The remainder focused on rare specialist interventions or historic procedures.

The trials of gastric band and bypass, while being landmark studies, included just 301 patients, were at a single centre, and were at high risk of bias. Allocation concealment was inadequate, subjects were excluded after randomisation, and there was no blinding of outcome assessors. One study assessed quality of life (QoL), but details of questionnaire response rates were missing. Although both trials showed a weight loss benefit for gastric bypass, their methodological weaknesses mean that results lack rigour and generalisability.

The three trials comparing types of sleeve gastrectomy with gastric band or bypass had similar methodological flaws. Those reporting outcomes at 12 and 36 months showed that, although surgery results in significant weight loss, there were no differences between procedural types. The systematic review concluded that well designed, long term trials comparing different operative techniques are required that include an assessment of quality of life and that a comparison of procedures such as gastric bypass with the restrictive procedures (particularly gastric band) is desirable. The review stated, however, that because of strong preferences held by surgeons and patients, such a trial would be impossible to do.

Registries and national audits

Evidence from national registries and large cohort studies including patients undergoing bariatric surgery is useful to consider rates of rare events such as in hospital death. The UK National Bariatric Surgery Registry (NBSR), the US Bariatric Outcomes Longitudinal Database (BOLD), and other registries show the safety of surgery (NBSR and BOLD reporting outcomes on 8710 and 57 918 operations respectively). In hospital mortality is about 0.1%. Gastric band and sleeve gastrectomy have consistently lower in hospital mortality than gastric bypass.

Long term outcome data in the registries are incomplete, however, meaning that rates of re-operation or weight regain for each type of surgery are unknown. Gastric bands may require minor “servicing,” major revision, or removal for slippage or erosion. After gastric bypass, surgery to treat internal hernia (where the bowel protrudes within a restricted space in the abdominal cavity and is at risk of incarceration) is occasionally required, and a small number of patients will experience life threatening problems associated with intestinal failure (inadequate digestion and absorption of nutrients to maintain energy, fluids, and micronutrient balance). A serious complication of sleeve gastrectomy is leakage from the gastric staple line, which may take months to heal.

Which operation is optimal for patients with diabetes and other obesity related disease?

All operations can induce improvement or remission of type 2 diabetes. Although a widespread perception holds that gastric bypass is better than other types of bariatric surgery at improving diabetes remission and limiting progression of end organ damage, the lack of well designed clinical trials comparing different operations makes this difficult to ascertain. It is not known which operation most improves other obesity related disease, although it is widely assumed that sustained weight loss is the key to benefit.

What is the impact of bariatric surgery on quality of life?

In general studies show that quality of life improves after surgery. It is difficult, however, to draw conclusions about differences between types of surgery in improved quality of life because of the confusing number of instruments used to measure quality of life and the lack of well designed comparative studies.

Is ongoing research likely to provide relevant evidence?

The By-Band study is a large (724 patient), pragmatic, randomised controlled trial comparing the effects of gastric bypass versus gastric band on weight loss and quality of life at three years. The trialists and funding body will consider whether sleeve gastrectomy can also be evaluated as it expands into more centres. Searches in the WHO...
International Clinical Trials Registry identified ongoing trials comparing gastric bypass with sleeve gastrectomy, measuring weight loss, remission of obesity related disease, and quality of life, though some are small and single centred.21-24 The SurgiCal Obesity Treatment Study (SCOTS) is a longitudinal cohort study of 2000 patients having bariatric surgery in Scotland, who will be followed up for 10 years to determine outcomes including diabetic control, cardiovascular events, cancer incidence, quality of life, and cost.23

What should we do in light of the uncertainty?

There are some situations where one operation may legitimately be favoured. For example, severe gastrooesophageal reflux would be regarded by many as a contraindication to sleeve gastrectomy, and if previous major bowel or abdominal wall surgery has been done or there is concurrent inflammatory bowel disease a gastric bypass may be precluded. Another consideration is the practicality of optimal follow-up of gastric band. Geographical difficulties may prohibit attendance, or the service may not be funded within the health system.

Aside from these concerns, it is critical for surgical teams and decision makers to understand what patients wish to achieve and expect from surgery. Although weight loss is easily measurable and a reasonable marker of outcome for the clinician, it is not necessarily the most important measure of success for the patient compared with improvement in obesity related disease or behaviour change. In most bariatric centres patients are given the choice of operation to have, and provided with information. Information should highlight that no one operation will guarantee successful sustained weight loss and that behaviour change and a concerted effort from patients themselves are required. Ideally, all suitable patients should be encouraged to participate in well designed, multicentre, randomised controlled trials designed to answer questions about which surgery is best and most cost effective.

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18. By-Band. Gastric bypass or adjustable gastric banding surgery to treat morbid obesity: a multi-centre randomised controlled trial. www.hta. ac.uk/project/2575.asp.
Silence is golden? No, lonely
Michel A Ibrahim

“Who’s for dinner?” I asked my wife—who, by the way, frequently mumbles when she addresses me—as I entered the house and saw her working in the kitchen. I suspected she had a hearing problem, and so I moved closer and repeated, “Who’s for dinner?” Having again received no response, I was almost certain it was because of her hearing loss. I then stood inches behind her and barked, “Who’s for dinner?” She turned around to face me and barked right back, “For the third time: chicken!”

When I was about 55 years old, while watching the evening news one night, I realized that I was not able to comprehend some of it, which I attributed to the newsreader not speaking clearly. I also noticed my inability to hear and understand conversations in other situations, and the problem was brought into focus when I started not being able to hear (or understand) questions raised by students after I had given a talk in a large room. I began to have difficulty following conversations in small groups—initially in noisy places, but later in quiet environments as well.

When I could not follow a conversation, my mind would start to wander, and that essentially created an “attention deficit disorder” that exacerbated the hearing loss. In a small group setting, I was thought to be aloof. When lecturing in an auditorium, I would move closer to the person asking the question in order to hear better, and so I was characterized as being a “warm” person (little did they know that “warm” was a cover-up for “deaf”). The fear of not hearing and, therefore, not being able to respond intelligently led me to avoid social gatherings and to decline many speaking engagements. I was worried about becoming socially isolated and about the serious consequences of this.

I would often ask my wife to repeat what she was saying or I would just nod and pretend I understood, but that was transparent to her. After a group gathering, I would ask her: what did I miss? It was horrifying to learn that I had missed most of the conversation. I would ask myself: was I really present at that gathering? I could afford to miss information at social occasions but work meetings were a different story. In spite of making an intense effort to listen and concentrate, I would still miss most of the conversation carried on by my colleagues. The emotional burden of pretending otherwise was getting to be too much.

The embarrassment of these situations finally forced me to seek advice from audiologists. Protracted encounters with numerous audiologists and bumpy experiences with hearing aid devices followed. The initial devices were of an analog type that simply amplified sound, including background noise, making it louder but not necessarily clearer. Later, digital hearing aids became available. These devices were better but certainly not a panacea. I tried several types—completely in the canal, half-shell, and behind the ear—and each device had more or less to offer. A balance between benefit and cosmetics. Initially, vanity and cosmetics won—I would select a smaller invisible device at the expense of maximizing the improvement in hearing.

But even with the advanced digital devices, following a conversation continued to be a challenge. Hearing aids did not restore normal hearing; they only boosted whatever hearing remained. With moderate to severe hearing loss, I was able to hear better using the advanced digital types of devices, but my hearing was still not good enough for me to fully grasp the conversation in a group setting. The killer, of course, was trying to follow a conversation while dining in a crowded, noisy restaurant, especially one with bare wooden floors and tables, in which diners are packed a foot or two apart. I suffered from excruciatingly loud background noise on top of drastically impaired hearing. I resigned myself to living with a disability that could be only partially resolved.
Then I heard an interview on National Public Radio and read several newspaper articles about the potential benefits of cochlear implants, which have been gaining in popularity among older adults. An examination by a cochlear implant audiologist indicated that my right ear was definitely a candidate. The device consists of a surgically implanted “cochlea” and a sound processor worn around the ear; this transmits sound to the cochlea, which in turn transmits it to the brain for virtual recognition as speech.

I was told that the surgery would take one to two hours, there would be a healing process of one month, and then the device would be activated, which would be followed by periodic testing until the full benefit is realized—a process that can take about a year. This sounded like a serious undertaking, so I had to make a decision: Should I do this?

I reasoned, what was there to lose? I had virtually no hearing in that ear anyway, meaning that whatever hearing was realized by the surgery would represent a net gain. After a bit of soul searching and consultations with friends, I decided to proceed with the surgery.

One month later, the long process of activating and calibrating the device began. I had to adjust to the “computer-like” sound of the device until it was eventually transformed to “regular” sound. Although I’ve had to work hard to learn how to listen again and to concentrate on what is being said in a small group setting, I am generally able to follow conversations and actually participate in them. I still have trouble when several side conversations are going on at the same time or when there are loud background noises.

The classroom, being naturally quiet, has offered the best and most welcome test of the hearing improvement. I can actually hear the questions, and more importantly, I am not afraid of inviting questions. The classrooms that are specially wired (looped) for the hearing impaired offer the best environment for optimal hearing. I simply switch the hearing device to the proper position using the remote control and the conversation and questions become even clearer.

Finally, going to a symphony is a real pleasure. In the past, music occasionally sounded like “noise,” and I had trouble appreciating it. With the implant device, music sounds like music again. I had forgotten how beautiful it can be.

I would not want to oversell the cochlear implant because it is not perfect and does not necessarily work for everyone. But in my case, it offered substantially better hearing than hearing aids, albeit at a considerable cost. The operation and the device cost more than $30 000 (£17 901; €21 614; $4000), compared with a hearing aid that runs to about $3000.

My wife does not mumble as much anymore, and I know—after asking once or twice—that I will be having chicken for dinner tonight.

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EDUCATIONAL RESOURCES
Bouton K. Shouting won’t help: why I—and 50 million other Americans—can’t hear you. Farrar Strauss and Giroux, 2013
Niparko J, ed. Cochlear implants: principles and practices. 2d ed. Lippincott Williams & Wilkins, 2009

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PRACTICE

STATISTICAL QUESTION
Clinical significance versus statistical significance
Statements a and b are true, whereas c is false.

PICTURE QUIZ
Chest pain and neck discomfort in a young man
1 The chest radiograph shows paratracheal free air.
2 The diagnosis is spontaneous pneumomediastinum (Hamman’s syndrome).
3 The differential diagnoses should include mediastinitis, tissue dissection after pneumothorax, chest wall trauma, and oesophageal perforation (Boerhaave’s syndrome).
4 The presence of crepitus synchronised with the heart sounds on auscultation of the precordium is known as Hamman’s sign.
5 Spontaneous pneumomediastinum is a benign condition that can be managed conservatively with oxygen therapy, analgesia, and rest.

ANATOMY QUIZ
Sagittal computed tomogram of the abdomen and pelvis
A: Left atrium  B: Oesophagus  C: Aorta  D: Coeliac trunk  E: Superior mesenteric artery  F: Left renal vein

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