evidence note

NHS Quality Improvement Scotland

In response to an enquiry from NHS Highland & NHS Orkney | Number 19 September 2007

Surgery for Obesity

Health technology description

Bariatric surgery is a branch of general surgery concerned with enabling obese patients to lose weight. It is usually employed only when other weight reduction methods have failed[1]. Since the first operations in 1954, practice in this area has developed considerably, and various different procedures are available. These can be based upon a restrictive approach, in which the volume of the stomach is reduced, a malabsorptive approach, in which the amount of food absorbed into the body is limited, or by a technique which produces both restriction and altered absorption[2].

Currently the main procedure used in Scotland is laparoscopic adjustable gastric banding. Other procedures in use include laparoscopic Roux en Y gastric bypass, laparoscopic sleeve gastrectomy and bilio-pancreatic diversion. Sleeve gastrectomy can form a precursor to bilio-pancreatic diversion. It is now exceptional for procedures not to be carried out laparoscopically (Mr D Galloway, Personal Communication, July 2007).

Key points

- Criteria for referral for bariatric surgery are commonly based upon a consensus statement developed in the USA in 1991.
- Bariatric surgery can produce greater weight loss than conventional treatment for obese patients, and this effect is sustained at 10 years (one large cohort study).
- Bariatric surgery results in significant reduction in long term mortality and improvement in co-morbid conditions such as diabetes and sleep apnoea.
- No research evidence is available on the effectiveness of pre and post operative support.
- Approximately 13% of bariatric surgery patients experience complications. Thirty day mortality rates of between 0.25 and 1.9% have been reported.
- One UK study suggests that bariatric surgery might be cost-effective.

Epidemiology

Obesity is commonly measured using the Body Mass Index, in which weight (kg) is divided by height squared (m^2). Adults are classified as overweight if their BMI is between 26 and 30, obese if it greater than 30, and morbidly obese if it is greater than 40. Approximately 22.4% of men and 26% of women in Scotland are obese, and 1.6% of men and 3.4% of women are morbidly obese[3].

Obese individuals have an increased risk of developing heart disease, hypertension, diabetes, and various cancers. They are more likely than non obese individuals to experience raised cholesterol levels, impaired glucose tolerance, high blood pressure, osteoarthritis and pregnancy problems[4,5,6]. At all ages, their overall risk of death is higher[7]. Coupled with this increased risk for numerous diseases, obesity can also result in low self esteem, social exclusion, reduced mobility and a lowered quality of life[1].

In 2003 it was estimated that the cost to NHSScotland of obesity and obesity-related illnesses was likely to be approximately £171 million[8].

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Clinical effectiveness

Criteria for referral

There is no strong research evidence available on which patients should receive bariatric surgery. Instead the recently published NICE guideline[1], in common with other HTA reports and guidelines, bases its recommendations on a consensus statement produced by the National Institute of Health in 1991[9].

The NICE guideline states that Bariatric surgery is recommended as a treatment option for adults 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.

In addition, bariatric surgery is recommended as first-line option for adults of BMI>50kg/m^2 in whom surgical treatment is considered appropriate.

Regarding patients with BMI between 35 and 40 kg/m^2, the original consensus statement referred to the presence of 'high risk co-morbid conditions'. This statement is variously interpreted in different reports reflecting uncertainty over which conditions should be included. Whilst bariatric surgery may impact upon many co-morbidities, currently only the most severe are considered appropriate to justify the risks of surgery[6]. Some guidelines[10] specify particular conditions, whereas others are less specific.

A report on bariatric surgery in Scotland for the morbidly obese[2] noted the lack of a referral pathway in Scotland, and proposed a possible pathway. It also suggested adopting the selection criteria for surgery specified by NICE in their 2002 guidance (now superceded by the 2006 guideline[1]), and endorsed in Scotland by the Health Technology Board for Scotland (now NHS Quality Improvement Scotland).

Impact on weight loss

Several randomised controlled trials which compare surgical with non surgical interventions for obesity have been conducted, however these are either old, very small studies, have a short follow up period or are not relevant to the Scottish context. The best evidence therefore comes from a large prospective cohort study, the Swedish Obese Subjects (SOS) Intervention Study[11]. In this study, 2010 subjects electing to receive surgical treatment (gastric banding, vertical banded gastroplasty, gastric bypass – all using open or laparoscopic techniques) were matched to 2037 subjects who received conventional treatment.

At two year follow up, the weight of the control group had increased by 0.1% whereas the weight of the surgical group had decreased by 23.4%. This advantage was maintained at 10 years, with a weight gain of 1.6% in the control group, but loss of 16.1% in the surgical group.

Impact on co-morbid conditions

The clinical effectiveness of bariatric surgery is most obviously measured in terms of weight loss, but of potentially greater significance is the impact of bariatric surgery on risk factors, co-morbid conditions, quality of life and ultimately mortality.

Again in the SOS study, at two year follow up, diabetics in the surgical group had on average an eight times greater chance of recovery than the controls. After 10 years, the chances of recovery were 3.5 times greater. The odds of developing diabetes amongst those in the surgical group were on average 86% lower than the control group at 2 years, and 75% lower at 10 years[12]. The likelihood of the surgical group having sleep apnoea reduced from 23% at baseline to 8% after two years, compared to a reduction of only 22% to 20% in the control group. Improvements in cardiac

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functioning and musculoskeletal pain in the surgical group compared to the control group were also observed[11]. Data collection is ongoing with respect to myocardial infarction, stroke and cancer[12].

Surgical patients had a higher prevalence of clinical depression initially than those opting for conventional treatment, but after surgery, for patients who lost 25% or more of their initial weight, the prevalence of clinical depression at two and ten year follow-up was lower than that of the conventionally treated group. Markedly greater improvements in psychosocial functioning at 4 years were seen in the surgical group compared to the control group, with a linear relationship to the extent of weight lost apparent[11].

The Swedish study is unique in comparing the outcomes for surgical patients with those of conventionally treated patients. Numerous other studies examine the effectiveness of bariatric surgery by comparing a subject's outcomes after surgery, with their baseline values before surgery. In the absence of a comparator group however, their conclusions must be interpreted with caution. A meta-analysis[13] of 18 studies reported the percentage of excess weight loss to vary between 54 and 67% over 10 years of follow up. Another meta-analysis[14] of 136 studies of bariatric procedures found that diabetes completely resolved in 77% of patients, hypertension in 62% of patients, and obstructive sleep apnoea in 86%.

Impact on mortality

Newly available long term mortality data from the Swedish study, showed that the risk of death in the surgical group over 10 years, was reduced by 29% compared to the control group[15]. Two retrospective cohort studies[16,17] also indicate long term reductions in mortality for surgical patients compared to controls.

Pre and post operative support

There is no published research evidence examining the effectiveness of providing pre and post operative assessment and ongoing support to obese patients. Although guidelines, including the NICE guideline 6, commonly recommend that surgery is only performed in conjunction with extensive preoperative assessment and specialist post operative care including long-term nutritional guidance and psychological counselling, this is based upon the NIH statement[9] which was derived by consensus. All refinements of this recommendation have similarly been developed by consensus. The report on Scottish Bariatric services likewise recommends, based upon opinion, pre and post operative support, including availability of plastic surgery[2].

Safety

As with all major surgery, there are peri- and post-operative risks and complications associated with bariatric procedures.

The SOS study reported a 90 day mortality rate among surgical patients of 0.25%[12]. One retrospective cohort study found a peri-operative mortality rate of 0.4%[16], and another[17], a 30 day mortality rate of 1.9%. An association was identified between the surgeon's experience and the mortality rate[17]. In Scotland, the 90 day mortality rate for bariatric surgery is of similar magnitude to that for all elective general surgical procedures (ISD Scotland, Personal communication, 17 August 2007).

Thirteen percent of surgical patients in the SOS study[12] experienced operative complications, of varying degrees of seriousness, with 2.2% requiring re-operation. Shekelle et al.[18] reviewed the adverse events reported in identified trials and case series. They concluded that the proportion of patients experiencing complications following bariatric surgery is likely to lie between 10 and 20%, in line with the Swedish results, and that the occurrence and nature of the adverse effects may vary by procedure.

Comparison between procedures

The effectiveness and safety of all bariatric procedures has been considered as one, but it should be noted that effectiveness and safety vary between different bariatric procedures, as does suitability for different patients[5,6,10]. Surgical learning curves are associated with the different bariatric procedures[1, 2].

Economics

Only one economic evaluation[19] based upon UK costs was identified within the secondary literature. This adequately conducted study evaluated three types of obesity surgery and also non-surgical management. The average net costs of surgical interventions over 20 years were found to be greater than for non surgical intervention. Costs for surgical patients over this time period ranged from £9626 to £10,795, compared to £6964 for those receiving usual care. However the number of Quality Adjusted Life Years (QALYs) gained were also greater. The net cost per QALY gained for the surgical interventions compared to no surgery, were between £6289 and £10,237, values which would generally be considered cost effective. It is reported in the recent NICE guideline[1] however that the assumptions used in this evaluation model may no longer reflect current practice. NICE were unable to gain access to the model to rerun it with updated assumptions, but suggest that the incremental cost per QALY would be lower.

Estimates of Scottish costs[2] for bariatric procedures and the immediate hospital stay, were calculated in 2004 based upon estimates for England and Wales by NICE. It was suggested, using the current assumptions, that these would be £1,360,000 in 2007 for an anticipated 160 procedures, but given improvements in techniques over the forthcoming years, would likely be less.

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