Chapter 1

Indications for Bariatric Surgery and Selecting the Appropriate Procedure

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Indications for Bariatric Surgery

When is surgery an option for a patient? When should it be recommended as best care?

In 1991, the National Institutes of Health (NIH) criteria for patient selection for gastrointestinal surgery for severe obesity were developed at a consensus conference involving expert surgeons, gastroenterologists, endocrinologists, psychiatrists, nutritionists and other health care professionals as well as the public. After weighing the evidence the panel recommended that:

1. patients seeking therapy for severe obesity for the first time should be considered for treatment in a non-surgical programme with integrated components of a dietary regimen, appropriate exercise and behavioural modification and support;
2. gastric restrictive or bypass procedures could be considered for well-informed and motivated patients with acceptable operative risks;
3. patients who are candidates for surgical procedures should be selected carefully after evaluation by a multidisciplinary team with medical, surgical, psychiatric and nutritional expertise;
4. the operation should be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical

setting with adequate support for all aspects of management and assessment;
5. lifelong medical surveillance after surgical therapy is a necessity to monitor for complications and lifestyle adjustments.[1]

The patient selection criteria recommendations were that surgery is an option for well-informed and motivated patients who have 'clinically severe obesity' Body Mass Index (BMI) 40, or a BMI 35 and serious co-morbid conditions.

There were many weaknesses with the NIH approach at the time. Recommendations came from an expert panel and were not necessarily evidence-based at the time. The cut-off values of BMI 35 and 40 were arbitrarily chosen although 'patient risk' is clearly a continuous concept which is based on much more than weight corrected for height and the presence of a co-morbid condition. Patient selection involves a clinical assessment of risk versus benefit for the individual patient and while BMI is one consideration, others include age, ethnicity, weight distribution, a wide range of obesity related medical and psychological co-morbidities, and risk factors for future obesity-related morbidity and mortality

An additional concern is the concept of option. The NIH describes a group of patient characteristics and conditions that are required before surgery can be considered. This is a far cry from the description of a recommendation. A recommendation would imply that a caring physician, after identifying a patient's specific conditions, recommends that the patient seek a surgical opinion regarding surgical treatment as best therapy or standard of care. A male aged 25 with BMI 55, severe obstructive sleep apnoea, type-2 diabetes and steatohepatitis may provide an example where recommendation for a surgical opinion is appropriate. To withhold such a recommendation may now be seen as negligent. While it may have been inappropriate in 1991, current evidence regarding the outcomes of surgical versus non-surgical therapy indicates a category of patient where recommendation is now appropriate.

Since 1991 there have also been major advances in our understanding of the benefits of substantial sustained weight loss which include resolution or improvement in obesity related co-morbidity,[2] improved quality of life[3] and psychological conditions, reductions in disease risk factors, and

evidence that therapy is cost effective[4] and saves lives.[5,6] We now have considerably more information to use when making a risk–benefit assessment of a patient.

Thus the NIH term 'clinically severe obesity' needs to have plasticity with an ability to mould to a range of important considerations. It also needs to be graded to indicate subjects where surgery should be considered an option and those where a surgical referral and assessment is recommended as best care.

Why have I focused on the NIH criteria? This is simply because they are the most quoted and used. Many surgical societies, health service providers and third party payers around the world have adopted very similar, or at times more restrictive, eligibility criteria for bariatric surgery.

Let us consider some of the factors associated with a patient that should be considered when selecting a patient for a surgical option or consideration.

Age

Age is an important factor in the risk–benefit analysis. Obesity-related excess mortality declines with age at all levels of obesity.[7,8] In a German cohort, older men and women aged 50–74 with a BMI range of 25 to less than 32 had no excess mortality.[7] A US analysis of life table and large health surveys also estimated that years of life lost are significantly greater in younger subjects.[8] The Seven Countries Study found a BMI of up to 30 kg/m^2 was not associated with increased mortality when middle aged men became older.[9] The American Cancer Society's Cancer Prevention Study I also found that the relative risk associated with greater body weight is higher among younger subjects.[10] However, obesity at the age of 40 years is a predictor of a significantly shortened life and has an effect similar to smoking.[11] A Finnish study demonstrated that years of disability and poor health related to obesity were likely to be greater in younger subjects.[12] Elderly patients presenting for bariatric surgery may therefore have limited benefit in both years of life and in years of healthy life gained. Improving shorter term quality of life may be the primary benefit in operating on elderly subjects, but on the other hand older patients

have a higher mortality associated with bariatric surgery.[13,14] These findings have important implications when assessing benefit versus risk in older obese subjects presenting for treatment, and emphasizes the importance of treating clinically severe obesity in younger adults. One may use the information concerning age when considering bariatric surgery for adolescents where arguably we may achieve greatest benefit from treating the clinically severely obese. It is in this age group that static BMI cut-off levels have limited value as there is a moving target. Normally with growth and development, BMI rises throughout adolescence in both boys and girls.[15,16] Using age adjusted BMI z-scores and obesity related co-morbidity we may, with further careful evaluation, be able to set guidelines for bariatric surgery in adolescents. Several attempts have been made to define criteria for the use of bariatric surgery in adolescents,[17] but these are flawed by the same lack of sufficient evidence that confronted the NIH in 1991. Fortunately many carefully designed studies are currently in progress and in the near future we should have a better understanding of the relative benefits and risks of intervening early in adolescents. In the meantime adolescent bariatric surgery should only be performed by experienced multidisciplinary teams with experience in managing the issues and nuances of severely obese adolescents, with data collected to evaluate long term clinical outcomes.[17]

Ethnicity

Body Mass Index is used as a surrogate for adiposity and as a marker for risk associated with increasing body weight. However there are major ethnic differences in both the degree of adiposity and risk of obesity related diseases at any given body mass index. The World Health Organization (WHO) consultation has recommended that for those with Asian ethnicity public health BMI action points may be reduced by 2.0–2.5 kg/m^2 to 23.0, 27.5, 32.5 and 37.5 kg/m^2. Recognizing the increased adiposity and co-morbidity risk, the WHO and International Obesity Task Force have also recognized an increased risk of type-2 diabetes at lower BMI levels in Asian populations[18] and the International Diabetes Federation has used ethnic specific waist circumferences for men and women when defining the metabolic syndrome.[19,20] Ethnic differences in adiposity and disease

risk should be considered in determining indications for bariatric surgery. It is not acceptable to use cut-off values based on the white population for those of higher risk ethnicity.

Co-morbidity

As already stated there should be graded levels of indications for bariatric surgery: a level where a patient is eligible for surgery and another where it is recommended as best care for the patient's condition (Fig. 1).

On what basis can we assess co-morbidity as an indication or a recommendation for surgery? It would seem logical that a number of criteria could be examined for any particular co-morbidity:

- What is the strength of the relationship between the co-morbidity and obesity?
- How serious is the co-morbidity?
- What is the effectiveness of weight loss for this co-morbidity?
- How effective is current therapy for the patient's condition?

Co-morbidities cluster, and patients often present with a range which all relate to the inflammatory and metabolic consequences of central obesity such as type-2 diabetes, hypertension, obstructive sleep apnoea, non-alcoholic steatohepatitis (NASH) and polycystic ovary syndrome. We

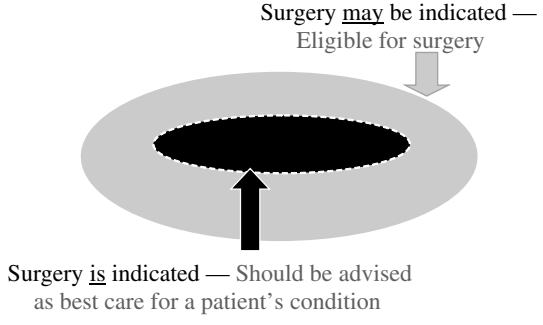

Figure 1. Indications for surgery.

Table 1. Some conditions associated with obesity.

Relative risk > 5	Relative risk 2–5	Relative risk 1–2
Type-2 diabetes	All-cause mortality	Cancer mortality
Dyslipidemia	Hypertension	Breast cancer
Obstructive sleep apnoea	Myocardial infarction and stroke	Prostate and colon cancer in men
Breathlessness	Endometrial carcinoma in women and hepatoma in men	Impaired fertility
Excessive daytime sleepiness	Gallstones and complications, including cancer	Obstetric complications, including fetal abnormalities
Obesity hypoventilation syndrome	Polycystic ovary syndrome	Asthma
Idiopathic intracranial hypertension	Osteoarthritis (knees)	Gastro-oesophageal reflux
Nonalcoholic steatohepatitis	Gout	Anaesthetic risk

need to recognize that we have far less knowledge about the importance and severity of psychological co-morbidities and these are rarely seen as important and pressing indications for bariatric surgery.

Some of the conditions associated with obesity are demonstrated in Table 1. Those with a relative risk greater than 5 are all strongly related to obesity. Of these, type-2 diabetes, obstructive sleep apnoea, obesity hypoventilation syndrome, idiopathic intracranial hypertension and more advanced forms of NASH may be seen as serious. In the context of obesity, these have been shown to respond well to substantial sustained weight loss, but do not respond as well to other therapy.

Bariatric surgery recommended or indicated as 'best care'

Using the NIH notion that BMI is an important marker of adiposity we could argue that those with a BMI > 50 or those with a BMI > 40 with one or more of the serious but responsive co-morbidities should, as best care, be referred for a bariatric surgical assessment (Table 2). Currently we have no indications or guidelines that physicians could use for the obligatory

Table 2. The author's proposed criteria for the two categories.

Surgery an option for therapy*	Surgery is indicated
BMI > 40	BMI > 50
BMI > 35 with a broad range of problems related to obesity	BMI > 40 with serious weight loss — responsive co-morbidity**
BMI > 30 with serious weight loss — responsive co-morbidity	

*For 'at risk' ethnicity the criteria should be dropped by a BMI of 2–3.

**Serious weight loss responsive co-morbidity could include: type-2 diabetes, obesity hypoventilation syndrome, severe obstructive sleep apnoea, obesity related raised intracranial pressure and non-alcoholic steatohepatitis with substantial fibrosis.

referral for bariatric surgical assessment as best practice, and health care providers can use their discretion in providing bariatric surgical services. Further carefully conducted longitudinal studies of long term outcomes of patients in these categories are recommended. There would be ethical concerns about randomized controlled trials for patients with these conditions because it could be seen as negligent not to provide appropriate or 'best care'. There must be equipoise, a balance of risk and benefit, when designing and conducting randomized controlled trials.[21]

Bariatric surgery as an option for therapy

As knowledge about the safety and efficacy of bariatric surgery increases, there has been a growing interest in its utilization in those with a BMI < 35. Our Melbourne group has recently reported two randomized controlled trials including subjects in the BMI 30–35 range.[22,23] The first showed better weight loss, health and quality of life outcomes in participants in the BMI 30–35 range for those randomized to laparoscopic adjustable gastric banding (LAGB) surgery when compared to those randomized to an intensive medical weight loss programme. The second study included participants with type-2 diabetes in the BMI range 30–40. Subjects were randomized to LAGB surgery with conventional diabetes therapy or to a best care lifestyle programme with conventional diabetes therapy. Those randomized to surgery achieved 73 per cent remission of type-2 diabetes compared to

only 13 per cent for those on the conventional lifestyle programme when using an intention to treat analysis. The likelihood of remission was directly related to the extent of weight loss. Clearly, evidence such as this provides strong evidence that bariatric surgery is beneficial and may be indicated in those with a BMI < 35. Further randomized controlled trials are needed to strengthen this evidence base. Table 2 shows the hypothetical two-tiered approach to bariatric surgical indications.

Selection of the procedure

Bariatric surgery has evolved as an inexact science. It has advanced through many dedicated surgeons communicating with one another to progress an art, and there have been some wonderful achievements.[24] Experimental designs have almost all been small series on human subjects, with surgeons modifying and changing their procedures to provide greater efficacy and safety, an approach perhaps not unlike the development of many other surgical therapies.

This must change! Bariatric surgery is now considered a 'standard of care'. There are now good data on the efficacy, safety and durability of specific surgical procedures. Deviation from standard techniques should be tested, after appropriate ethical approval, in properly designed clinical trials. If the proposed surgery or technique is a major departure from a standard of care, animal models should be used.

The current most commonly used procedures are shown below in Table 3. The proportion of each procedure used varies enormously from region to region so I have estimated current use based on the 33 international societies and countries surveyed in 2002–3.[25] Since that survey there will have been a marked increase in the number of laparoscopic procedures, a reduction in the proportion of vertical banded and other gastroplasties, and an increase in the proportion of laparoscopic adjustable gastric banding (LAGB) procedures.

While these figures above are hypothetical estimates there is no doubt the RYGB (Roux-en-Y gastric banding) and LAGB dominate the current world scene and there are sufficient data regarding safety, efficacy and durability to justify this trend.

While there are quality data regarding BPD and BPD-DS, the weight loss efficacy and durability have not been a concern, but safety

Table 3. Commonly used surgical procedures.

Procedure	Global estimate
Roux-en-Y gastric bypass (RYGB) — laparoscopic and open (including variants of long limb gastric bypass and banded bypass)	40–55%
Laparoscopic adjustable gastric banding (LAGB)	30–45%
Vertical banded gastroplasty (VBG)	< 5% and falling
Bilio-pancreatic diversion (BPD). (including the duodenal switch variant (BPD-DS)	< 5% and steady
Sleeve gastrectomy (SG)	Unknown, but gaining popularity

is problematic as short and long term nutritional concerns abound.[26,27] Few surgeons have followed the path of performing these procedures as primary bariatric surgical procedures. For sleeve gastrectomy (SG) the efficacy, safety and durability of weight loss remain untested against the RYGB and LAGB standards as a primary bariatric procedure. It was initially utilized as a first stage procedure for those at high risk having BPB-DS, or more recently RYGB, as the definitive procedure.[28,29] This procedure needs further ethical study of a wide range of outcome measures. The American Society for Metabolic and Bariatric Surgery issued a statement of caution regarding the use of SG in 2007. The standard of care provided by RYGB and LAGB means they are the logical choice for primary bariatric procedures today. I will not address failed or revisional surgery. The choice of a primary procedure today is between RYGB and LAGB. There have been a large number of attempts to match the right patient to the right procedure to ensure great results, but to date these attempts have largely failed and lack of hard data means they are not credible.[30] The preoperative unpredictability and variability of weight loss following surgery is problematic. Preoperative BMI, age, co-morbidity, food choices, eating behaviours, personality testing, quality of life testing, motivation and many other variables have been tested, and found to predict a small proportion of weight loss variance.[31–33] These preoperative variables have largely had a common effect on the two candidate procedures and have not really separated them. Perhaps more relevant is that postoperative follow-up and adopted behaviours following surgery are highly

predictive of outcome variance.[34,35] Our difficulties with preoperative predictability are perhaps largely driven by our lack of knowledge regarding the actual mechanism of action of bariatric surgery. Just how does surgery have such a profound effect on energy balance and why is any other current therapy so poor in comparison?

One caveat to the comparison of RYGB and LAGB is the very different pattern of weight loss. There is rapid weight loss following RYGB and usually a much steadier loss following LAGB. The difference in mean weight loss between the procedures is quite substantial with better weight loss in those treated with RYGB, but at three years and beyond the percentage of excess weight loss outcomes are comparable.[36] One can argue that more rapid weight loss increases the risk of cholelithiasis, loss of lean body mass and nutritional deficiencies.

The decision as to which procedure a patient should have comes down to a range of issues. Clearly the local experience of the surgeon(s) and multidisciplinary team and their knowledge of the procedures involved are crucial. Most critical is the availability of excellent long term follow-up care.

In addition to this peri-operative mortality, the severity of morbidity and nutritional risk associated with the procedures are important, and clearly LAGB carries a significant advantage in all of these categories.[37] The LAGB procedure is also adjustable and easily reversible providing a more logical choice of adolescents and those considering a pregnancy in the future.[38,39] It also provides a logical choice for patients at high risk of mortality with RYGB.[14,40] On the other hand while weight loss achieved with LAGB surgery has a profound effect on the improvement or resolution of type-2 diabetes, there is growing evidence that in subjects with diabetes, the diversionary aspects of RYGB have benefit in addition to that of weight loss.[23,41] It may be that this benefit is important to those with type-2 diabetes who already have significant beta cell dysfunction. However, the nature and durability of the beta cell stimulatory effects are yet to be fully determined.

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