The role of bariatric surgery in the management of type 2 diabetes

Jane Diggle

Whilst the causes of type 2 diabetes are multifactorial, there is a strong association with obesity and the term "diabesity" has been coined. Diabesity is on the increase in the UK and management will involve a combination of lifestyle changes and drug therapy in order to normalise hyperglycaemia and reduce cardiovascular risk factors. Weight reduction has also been identified as an important contributing factor in the management of type 2 diabetes, with studies showing that improvement in glycaemic control is directly related to the degree of weight loss. With the increase in diabesity and escalating healthcare costs, bariatric surgery has been suggested as a cost-effective method of tackling this problem. This article outlines the shortfalls of conventional management approaches such as lifestyle changes and drug therapy and provides an overview of the evidence base for the use of bariatric surgery in improving glycaemic control and reducing weight in people with type 2 diabetes.

lmost two-thirds of all adults in the UK are overweight or obese (Diabetes UK, 2010). If current trends continue, it is estimated that 60% of men and 50% of women will be obese by 2050 (Foresight, 2007), which is undoubtedly fuelled by sedentary lifestyles and the abundance of cheap calorie-laden food (Dixon et al, 2011). The prevalence of type 2 diabetes is also increasing, with estimates that the 2.5 million people currently diagnosed in the UK could rise to over 4 million by 2025 (Diabetes UK, 2010). Whilst the causes of type 2 diabetes are multifactorial, there is a strong association with being overweight or obese. Wolf and Colditz (1998) suggest obesity is the primary contributor in around 80% of cases and it is a key factor in people developing the condition at a young age (Nathan et al, 2009).

The link between type 2 diabetes and obesity has led to increasing popularity of the term "diabesity". Both type 2 diabetes and obesity are important risk factors for cardiovascular disease (UKPDS Group, 1998; Kopelman, 2007) and are associated with shortened life expectancy (Roper et al, 2001; Peeters et al, 2003; Adams et al, 2006). The financial implications for the NHS are projected to reach £9.7 billion by 2050 (Rajeswaran, 2012).

Management of type 2 diabetes

The treatment goal for diabetes is to halt the progression of the condition and prevent complications by normalising hyperglycaemia and reducing other cardiovascular risk factors such as hypertension and dyslipidaemia (Nathan et al, 2009). Weight reduction has also been identified as an important contributing factor in the management of type 2 diabetes (Williamson et al, 2000) with improvement in glycaemic control directly related to the degree of weight loss (Norris et al, 2004). Haslam (2012) argues that treating the condition without addressing weight loss is futile and that the two conditions should be managed in unison.

The current management of diabetes is influenced by evidence-based guidelines such as those published by NICE (2009). These guidelines offer a logical and stepwise approach but do they adequately address the problem of type 2 diabetes and obesity simultaneously? **Citation:** Diggle J (2013) The role of bariatric surgery in the management of diabesity *Diabesity in Practice* **2**: 7–14

Article points

- Diabesity is on the increase in the UK and weight reduction is an essential part of diabetes management.
- 2. Conventional management approaches for type 2 diabetes such as lifestyle changes and drug therapies do have shortcomings and cannot always effectively manage type 2 diabetes in people who are obese.
- There is a strong evidence base to suggest that bariatric surgery is an effective management approach in people with type 2 diabetes.

Key words

- Bariatric surgery
- DiabesityType 2 diabetes
- Weight loss

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- Whilst lifestyle measures are an essential part of diabetes management, robust evidence to support any particular dietary intervention is lacking.
- 2. Many drugs used to lower glucose are associated with weight gain.
- Fear of weight gain has been identified as having a negative effect on medication adherence.

Lifestyle measures

Lifestyle measures are an essential part of diabetes management (NICE, 2009) and although there is some evidence that dietary interventions have a small but significant effect on weight loss (Aucott et al, 2004), robust evidence to support any particular dietary intervention is lacking (Nield et al, 2007). Body weight is defended by powerful physiological mechanisms. Dieting causes changes to circulating levels of hormones such as leptin, peptide YY, incretins and ghrelin, which are all involved in the homeostatic regulation of body weight. This might explain why most obese people cannot maintain weight loss (Sumithran et al, 2011). There are also psychological barriers to weight loss, such as the distorted hunger perceptions (Kennedy and Alberti, 2010).

There is evidence that achieving sustained weight loss is more difficult for those with diabetes (Wing et al, 1987; Khan et al, 2000; Zimmet et al, 2003; Eeg-Olofsson et al, 2009). Additionally, research has not definitively proven a benefit of exercise on patient-orientated outcomes such as diabetes-related morbidity and mortality (Thomas et al, 2006).

Drug therapy

It is inevitable that drug therapy will be required to maintain glycaemic control given the progressive nature of type 2 diabetes. The coexistence of type 2 diabetes with obesity presents a therapeutic challenge because many of the drugs used to lower blood glucose are associated with weight gain, as illustrated in *Table 1*. Drugs such as the sulphonylureas, pioglitazone and insulin often lead to a weight gain of around 5 kg (Bolen et al, 2007; Holman et al, 2007).

The pathophysiology of type 2 diabetes is hugely complex and a greater understanding of the processes involved has led to the development of new therapies, including those that target the diminished "incretin effect" described by Nauck et al (1986). The incretinbased therapy class dipeptidyl peptidase-4 (DPP-4) inhibitors offer the advantage of being weight-neutral and glucagon-like peptide 1 (GLP-1) therapies achieve weight losses of 2-3 kg over 2 years (Mitri and Hamdy, 2009). In addition, dapagliflozin has been recently launched as the first agent in the sodium-glucose co-transporter 2 (SGLT2) inhibitor class. In shorter-term trials, dapagliflozin 10 mg as an add-on to metformin, glimepiride or insulin resulted in statistically significant body weight reduction at 24 weeks. In longer-term trials, when added to metformin, these effects were sustained at 52 weeks (4.65 kg reduction versus glipizide) and 102 weeks (3.07 kg reduction versus placebo; Electronic Medicines Compendium, 2012).

However, these therapies are costly and prescribers face increasing pressure to demonstrate cost-efficient prescribing (DH, 2011). Additionally, further evidence is awaited to show the long-term safety and sustained efficacy.

Intensification of pharmacotherapy is required to maintain blood glucose control and this often involves therapies that cause weight gain (Nathan et al, 2009).

Table 1. The benefits of drug therapy for type 2 diabetes (adapted from Piya, 2010).*

	Metformin	Sulphonylureas	TZDs	Acarbose	Insulin	DPP-4 inhibitors	Incretin mimetics
Efficacy	++	++	++	+	+++	++(+)	++
Influence on disease progression	No	No	(?)	No	No	(?)	(?)
Cardiovascular outcome studies with reported data	Yes	Yes	Yes	No	Yes	No	No
Tolerability	Moderate	Moderate	Moderate	Poor	Moderate	Very good	Moderate
Weight gain	No	Yes	Yes	No	Yes	No	Weight loss
Hypoglycaemia in monotherapy use	No	Yes	No	No	Yes	No (Yes with sulphonylurea or insulin)	No (Yes with sulphonylurea or insulin)

DPP-4=dipeptidyl peptidase-4; TZDs=thiazolidinediones. *This article was written before the sodium–glucose co-transporter 2 (SGLT2) inhibitor class was added to the treatment armamentarium. Weight loss is a secondary benefit of treatment with this class (Electronic Medicines Compendium, 2012).

This further contributes to the obesity problem in people with type 2 diabetes. Polypharmacy is a feature of diabetes management yet medication adherence is notoriously poor in this population (Donnan et al, 2002). Fear of weight gain has been identified as having a negative effect on medication adherence (Wing, 2010), further highlighting the limitations of a pharmacological approach to diabesity.

Several drugs have been introduced to treat obesity but with the withdrawal of rimonabant and sibutramine amidst safety concerns, the only drug licensed in the UK is orlistat. Whilst this drug has been shown to reduce HbA_{1c} by 5.5 mmol/mol (0.5%) alongside weight reductions of 2–4 kg (Day and Bailey, 2006; Henness and Perry, 2006), I have found that it is not easily tolerated, has a fairly modest effect in clinical practice and adds to the daily "pill burden" for a group of people known to have poor medication concordance. According to Taheri et al (2009), pharmacotherapy achieves modest weight loss, with weight gain when therapy is discontinued.

Evidence base for bariatric surgery

The focus of this article is to review the evidence base for bariatric surgery, with emphasis on its impact on weight loss and diabetes as well as safety, longevity and cost-effectiveness.

The primary goal of bariatric surgery is to achieve weight loss and weight loss of 30–50 kg can be achieved (Bult et al, 2008). In a metaanalysis of 22 094 patients, Buchwald et al (2004) reported mean excess weight loss of 61% across all procedures (72% with malabsorptive procedures and 48–68% with restrictive). Furthermore, a Cochrane review concluded that bariatric surgery resulted in greater weight loss than conventional treatment in people with a BMI >30 kg/m², with or without diabetes, and led to improvements in comorbidities such as type 2 diabetes and hypertension and improvements in health-related quality of life (Colquitt et al, 2009).

Diabetes resolution and improvement through bariatric surgery is the subject of huge interest, partly fuelled by media claims that bariatric surgery cures diabetes (Burne, 2008). In their review of studies published since the mid-60s, Vetter et al (2009) reported that in patients with type 2 diabetes the condition resolved in 84–98% of those undergoing bypass procedures and 48–68% of those undergoing restrictive procedure. Buchwald et al (2004) showed an improvement in diabetes in 86.4% and resolution in 76.8% across all bariatric procedures. A subsequent analysis suggested that post-operative diabetes resolution was related to the degree of weight loss achieved and was also greater for procedures that were not purely restrictive (Buchwald et al, 2009). Two years after surgery, 62% of patients remained in remission. Admittedly, these studies have been the subject of some criticism because objective biochemical outcome measures were often not observed (Dixon et al, 2011).

The Swedish Obese Subjects (SOS) study conducted by Sjöström et al (2004), a prospective non-randomised trial involving over 2000 subjects, demonstrated diabetes resolution in 72% of patients 2 years after surgery but this fell to 36% at the 10-year follow-up. Dixon et al (2008) carried out a trial comparing medical therapy with gastric banding in 60 patients with moderate-to-severe obesity. Gastric banding was shown to be superior in achieving HbA_{1c} levels \leq 44 mmol/mol (\leq 6.2%; 73% versus 13%) and this study is upheld as a well-designed prospective randomised controlled trial investigating bariatric surgery specifically as a treatment for type 2 diabetes (Dixon et al, 2011). Mingrone et al (2012) published data showing diabetes remission after 2 years in 75% of those undergoing gastric bypass and 95% of those having bilio-pancreatic diversion.

The STAMPEDE trial (Schauer et al, 2012) compared intensive medical therapy with gastric bypass or sleeve gastrectomy. After 1 year, an HbA_{1c} level of less than 42 mmol/mol (6%) was achieved in 42% of those in the gastric bypass group and 37% of those in the sleevegastrectomy group, compared with only 12% in the medical therapy group. The surgically treated group lost weight and reduced their need for medication for diabetes, hyperlipidaemia and hypertension. The medically treated group gained weight and required increased antidiabetes medication. Recently published results from the ongoing SOS study (Sjöström et al, 2012) have demonstrated reduced cardiovascular events and reduced cardiovascular mortality in those undergoing bariatric surgery. This further supports "Bariatric surgery will not suit everyone and as with every therapeutic intervention, the approach needs to be tailored to each individual."

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- 1. The risks and potential longterm problems of bariatric surgery need to be considered.
- Studies have shown that bariatric surgery has led to a reduction in the need for drug therapy and is associated with lower healthcare costs.

the contention that there may be benefits beyond weight loss and improved glycaemic control.

Factors affecting the likelihood of remission include: the extent of weight loss and weight regain; pre-operative hypoglycaemic drug therapy requirements and glycaemic control; duration of diabetes; the bariatric procedure itself; as well as the patient's commitment to dietary and lifestyle modification after surgery (Schauer et al, 2003; Sugerman et al, 2003; Vetter et al, 2009; Taheri et al, 2009; Dixon et al, 2011).

The STAMPEDE trial (Schauer et al, 2012) involved people with relatively advanced diabetes and complications but because of its short duration and open-label design it is subject to bias. The results of a 4-year follow-up are awaited although the conclusion so far is that bariatric surgery offers a useful strategy for managing obese patients with poorly controlled type 2 diabetes.

Risks associated with bariatric surgery

Decreased overall mortality has been observed in those achieving long-term weight loss after bariatric surgery (Adams et al, 2007). However, surgery of any kind carries risk and this has to be balanced against the potential benefits already discussed. Taheri et al (2009) highlight potential hazards including deep vein thrombosis, pulmonary embolism and pneumonia, as well as the more specific complications of bariatric procedures including gastric band slippage and erosion, oesophageal dilatation, gastric pouch development, anastomotic leakage, bleeding and infection. Most procedures are performed laparoscopically and, as more procedures are undertaken, expertise and skill has grown and surgery has become increasingly safer (Buchwald et al, 2007). Mortality ranges from almost nil for laparoscopic adjustable gastric banding to about 1% for Roux-en-Y gastric bypass undertaken at centres of excellence (Taheri et al, 2009).

There are potential long-term problems such as failure to absorb certain nutrients and the need for life-long supplements with malabsorptive procedures (Shah et al, 2006; Dixon et al, 2011) and with such profound weight loss patients may find the resulting excess skin aesthetically unacceptable (Kennedy and Alberti, 2010).

Some people are not able to cope psychologically following bariatric surgery (Zimmet and Alberti

2012), with one study even showing an increased suicide risk (Tindle et al, 2010). Appropriate patient selection is key with a comprehensive programme of psychological support before, during and on an ongoing basis after surgery (NICE, 2006; Dixon et al, 2011). Patients need to be adequately prepared for the life-changing effect that bariatric surgery can bring and need to fully appreciate the risks as well as the potential benefits. It is also crucial for patients to modify their lifestyle and eating habits for life post-operatively.

Bariatric surgery will not suit everyone and as with every therapeutic intervention, the approach needs to be tailored to each individual. As Zimmet and Alberti (2012) point out it is not yet the "universal panacea". Most of the studies have involved relatively small numbers with fairly short duration and were conducted at centres of excellence by highly skilled clinicians so the results may not translate so favourably into routine clinical practice.

Nevertheless, bariatric surgery can be an effective, comparatively safe and cost-effective therapy for obese people with type 2 diabetes and should be considered an appropriate treatment for those not achieving recommended treatment targets with medical therapies, especially in the presence of other major comorbidities (Dixon et al, 2011).

Cost-effectiveness of bariatric surgery

In terms of cost-effectiveness, a retrospective time series review by Makary et al (2010) explored the impact of bariatric surgery on medication utilisation and related healthcare costs. According to Pignone (2011) some of the studies were subject to bias and had the potential influence of confounding factors such as lifestyle modification, yet his conclusion was that surgery can lead to a decreased use of glucose-lowering medication (98% reduction) and can be associated with lower healthcare costs.

Hoerger et al (2010) conducted a rigorous cost-effective analysis of bariatric surgery for severely obese adults with diabetes in the US. They found the cost per quality-adjusted life-year (QALY) to be less than \$15000 (approximately $\pounds 10000$), making it relatively good value for money. Klein et al (2009) would argue that it takes 26–29 months to fully recoup the cost of surgery. Studies

in Europe (Anselmino et al, 2009) have found both adjustable gastric banding (AGB) and gastric bypass to be cost-saving compared to conventional medical therapy.

A UK review by Picot et al (2009) found that in people with moderate-to-severe obesity (BMI \geq 30 kg/m² and <40 kg/m²) and type 2 diabetes treated with AGB, the cost per QALY was £18 930 at 2 years, £4580 at 5 years and just £1367 at 20 years. This is substantially lower than the £20 000–30 000 per QALY threshold usually used

Box 1. NICE guidance (2006) on the use of bariatric surgery in people with obesity.

NICE recommends bariatric surgery as a treatment option for people with obesity providing:

- They are ≥ 18 years of age.
- They have a BMI of 40 kg/m² or more or they have a BMI of 35–40 kg/m² and other significant conditions (for example, type 2 diabetes) that could be improved if they lost weight.
- They will receive intensive management in a specialist obesity clinic at a hospital.
- They have tried all other non-surgical treatments but have not been able to maintain weight loss.
- They have no medical or psychological reasons why they should not have surgery.
- They are generally fit enough to have an anaesthetic and surgery.
- They understand that they will need long-term follow-up.

for determining cost-effectiveness by NICE (2012).

With the huge increase in diabesity and escalating healthcare costs, bariatric surgery has been proposed as a cost-effective method for tackling this problem. The Office of Health Economics (2010) has proposed that:

"... if 25% of eligible patients were offered surgery the potential savings, direct and indirect, could be between £382 million and £1295 million within three years."

Clearly, this must be balanced against the fact that were every eligible person granted surgery this would consume 70% of the entire NHS budget (Seymour et al, 2010). In an effort to make the best possible use of resources, guidelines have been developed, including guidance from NICE (2006), outlined in *Box 1*.

On the basis of strong clinical evidence the International Diabetes Federation Taskforce called for national guidelines for bariatric surgery in people with type 2 diabetes and a BMI of 35 kg/m² or more (Dixon et al, 2011). Villamizar and Pryor (2011) advocate a relaxing of referral criteria to include patients with a BMI of 30 kg/m² or above but it remains to be seen whether UK guidelines change. The difficulty will be persuading policy makers to invest money in the short-term in order to achieve long-term gain. On a personal level, type 2 diabetes is a selfmanaged condition (Graffy et al, 2009) and current health policy encourages clinicians to engage patients in the decision-making process (DH, 2010). There is evidence that the health of obese people with type 2 diabetes benefits substantially from bariatric surgery (Sjöström et al, 2007; Buchwald et al, 2009), as well as improving other cardiovascular risks including hypertension, dyslipidaemia and sleep apnoea and other quality of life measures (Buchwald et al, 2004). These are powerful arguments for the use of bariatric surgery in the management of obese people with type 2 diabetes.

Bariatric surgery does not remove the need for people with type 2 diabetes to make lifestyle changes; indeed this is vital to the ultimate success of surgery. Strict selection criteria are required but I would argue that many more people with type 2 diabetes would benefit from this treatment.

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