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# **Who wants weight loss? What do they need?**

## **Time to re-think non-surgical approaches in obesity management**

### **Invited Editorial Review**

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### **Word Count = 1963 (excluding references)**

Mahawar and Small (1) have argued that access and provision of bariatric surgery (BS) is being restricted in the UK because of obstructive national clinical guidelines, which currently require prior engagement (and failure) with local medical weight management services (MWMS). Their view is that weight loss outcomes with MWMS are minimal, poorly sustained, and lack cost effectiveness, that the pathway promoted by NICE and NIH is not evidence-based, and that surgical intervention is being rationed for reasons other than clinical effectiveness. It is true that the current model for obesity management is not evidence-based, but lack of evidence does not automatically imply that the pathway is inappropriate. It may be wrong, but possibly not for the reasons set out by Mahawar and Small.

Many share their frustration that services are not offering people the best possible chance to overcome their obesity. Health Services are poorly directed, poorly coordinated and ill-equipped to deal with an epidemic that is overwhelming our healthcare system. Compared to the colossal budgets which have been, and continue to be, applied to tackling the chronic-disease consequences of obesity (T2DM, CVD, cancers, depression, etc), mainly with drugs, the investment into treatment and prevention of obesity has been minimal. Lack of opportunity for financial profit by commercial companies has relegated, into near-oblivion, investment to develop diet and lifestyle interventions which could tackle the causes of the 21<sup>st</sup> century's most expensive

and debilitating disease. The one exception, where large commercial profits can currently be made is BS.

It is very curious, indeed an anomaly among disease treatments, that Health Services and guidelines have promoted a surgical treatment with so little research attention to non-surgical interventions. The normal approach to any disease is first to establish the optimal non-surgical management, in terms of safety and efficacy, and only then to consider whether surgery offers better results, with its certainty of immediate hazard (however rare), frequent complications and high costs. There are examples, such as coronary artery bypass grafting for angina, or gastric surgery for peptic ulceration, where effective medical interventions were lacking, but improved non-surgical interventions have gradually replaced previously dominant surgery, to the great benefit of patients. Massive investment, and experience over a long period, was needed to establish those non-surgical treatments. There is no doubt that BS can 'work', as did gastric surgery for peptic ulcers, but the investment into non-surgical alternative approaches to obesity has been minimal and very mixed values have been applied. Effective anti-obesity drugs have been developed, but most have been drummed out of the market because of rare side-effects – orders of magnitude less frequent than the complications of BS.

Mahawar and Small suggest a cost of £5,000 for BS in the UK. Others have estimated the cost to be almost double that (2). In addition to the cost of the procedure, there are very substantial added costs from consultations and preparation for surgery, post-operative follow-up, and management of complications. The argument that BS essentially 'pays for itself' within a few years does not stand up to scrutiny. There seems little doubt that BS reduces T2DM, CVD events, depression and improves mobility, and it is 'cost-effective' if one accepts the notion that a Quality-Adjusted Life Year is worth £30,000, but this should not be mistaken for it being 'cost-saving'. Patients use more inpatient and outpatient care in the years following BS, although drug costs are reduced (4). Reduced obesity-related disease and consequent increase in life expectancy means that life-time healthcare costs may actually rise (2). It would be more accurate to say that it provides improved health at a cost which some, but not all, consider acceptable.

There is no good reference for the costs attributable to complications of BS. Through surgical complications, inadequate weight loss, or significant weight regain, a further surgical procedure, including reversal, is needed in 10-25% of cases (3). After the initial surgical and media frenzy, gastric bands proved to have very high failure rates, up to 50% (4,5). Sleeve gastrectomy and Roux-en-Y gastric bypass, have rapidly become the more fashionable approaches but reoperation is still required in 10-20% of bypass patients (6,7) and chronic micro-nutrient deficiencies will emerge in about 50% (8), sometimes with devastating and irreversible neurological consequences (9). There is a glaring disparity between the levels of scientific research and patient safety required to license a new drug, compared to surgery. A drug which caused one in every 1000 patients to die immediately, or landed a quarter in hospital for a surgical operation to correct complications, or which resulted in half of all patients requiring life-long treatment for micronutrient deficiencies, would be unlikely to get a license, or to be recommended by NICE. Not so for BS. In addition, attention has recently been drawn to the considerable and unexplained problem of patients developing alcoholism and mental health problems, including suicides, after BS. These are more serious than the 'suicidal ideation' which led to the withdrawal of rimonabant as an effective anti-obesity drug (10). Diversion of addictive personality away from eating is one theory, but this could also result from alteration of the normal gut-hormone and hedonic responses to eating. Given that similar risks were described in large studies after gastric surgery for peptic ulcer disease, there is concern about possible late effects after sleeve gastrectomy.

Mahawar and Small criticise the usual requirement that patients must demonstrate an ability to adhere to a diet, and lose 5% of weight before being accepted for surgery. Losing weight preoperatively makes BS an easier and safer operation by reducing intra-abdominal fat (11) and liver volume (12). It may also predict better weight-loss outcomes (11). Most agree that this practice should continue to be recommended (13). Valuably, it represents an important adjustment period for the patient, both physically and mentally, as they begin the transition from 'unrestricted'

eating to a severely reduced intake after surgery. It is the best time to begin the education and lifestyle-change processes fundamental to an optimal long-term outcome.

There has been an assumption that the treatment which offers the greatest weight loss must be best. Somewhere along the line, we have forgotten to ask our patients what they want, or assess what they actually need: what amount of weight loss is necessary for the required health improvement, and how might we achieve that? The amount needed to generate valuable clinical and biochemical improvement at a population-level is as little as 5-10%, but this is not what severely obese patients or their doctors seek (15). Real improvements in clinically important consequences of obesity, such as sleep apnea and remission of T2DM require 15-20% weight loss (16,17), an amount more acceptable as a goal for patients. Recent guidelines are in line with this, and targets of 5-20% loss have been suggested for treatment of obesity related complications (18). Greater weight losses may appear necessary to improve mobility for patients with very extreme obesity (e.g. BMI>50). but greater weight loss also substantially reduces lean mass and is rarely justified by measurable improvement in mobility because arthritis has set in.

What should we do for patients who require help, but do not want surgery? Among Canadian patients attending a weight management service, less than a quarter of those eligible were interested in having BS (19). Many know that weight loss can be achieved with less invasive methods, and over half are concerned to avoid the known complications of BS. With better, and more readily accessed non-surgical treatments, it is likely that even fewer obese patients would favour BS. The lure of BS for some is the perception that patients who fail to restrict their food intakes with dietary interventions will lose huge amounts of weight, and keep it off indefinitely. The actual weight losses with BS have been of the order of 20-32% body weight (20,21), and although this comfortably beats other interventions, some weight regain is usual (22).

It is true that there is currently no established non-surgical intervention offered routinely in primary or secondary care which can reliably produce a sustained weight loss, or rival the weight-loss effects of BS (23, 24). However, this literature has been evaluating generally under-studied, under-resourced, poorly structured and ineffective medical weight management interventions,

which could be substantially improved. Part of the problem is that dietetic services continue to promote using modest energy-deficit diets (eg. 500-600 kcal/day below maintenance requirements, aiming for weight losses of 0.5kg per week) (25), in the belief that less restrictive diets promote better adherence and better long term maintenance. However, this approach de-motivates patients with morbid obesity, who require to lose at least 15-20kg, so many patients disengage. The increasing numbers of patients with BMI >40, or >50, require more aggressive approaches than conventional dietary methods. Growing evidence finds that the best long-term outcomes are achieved by those who lose weight most rapidly (26-28).

It is clear that there is no “one size fits all” approach, suitable and effective for all patients. Many people are unwilling to put themselves through the deprivations of weight loss, regardless of the intervention. But recent evidence has emerged that a programme using a micronutrient-replete liquid formula diet (~800 kcal/day), in parallel with individually tailored food reintroduction plans and long term support, is achieving and maintaining weight losses >15kg for one third of patients at 12 months (29). This is delivered by routine NHS staff in primary care settings, and at a reasonable cost of £861 per patient. Importantly, weight losses achieved with formula diet programmes can be now be better maintained in the long term, with published data documenting mean weight loss outcomes >10% four years out (30). T2DM is the biggest concern with regards to the increasing prevalence of obesity and 15kg weight loss reliably normalises beta cell function and hepatic insulin sensitivity by reducing liver and pancreatic fat, thus correcting the metabolic abnormalities underlying pre-diabetes and type 2 diabetes (31,32). New trials are underway to further examine the benefits of formula diet led programmes, with promising results recently reported from the early stages of the PREVIEW study (33) aimed at preventing T2DM. Results from the Diabetes UK funded DiRECT trial, using the Counterweight formula-diet and long-term weight-maintenance programme (34) are anticipated in 2017. It is time to start adequately funding such programmes, which offer an evidence-based alternative and more scalable intervention to BS, within routine primary care services.

We also, urgently, need to discover whether the patients who do well with BS are in fact those who would do well with an optimal non-surgical programme. Mahawar and Small have focused on the illogicality of asking patients to do badly with second-rate non-surgical treatments, and played down the high rate of complications after BS. We know that patients usually do badly after a second operation for 'failed BS': the problem was usually not the surgery, or the surgeon, but the patient. Patients who have poor outcomes with one treatment are rather likely to have problems with another treatment. The converse is probably also true: patients who do well with BS may actually do well with an optimal non-surgical treatment. But the randomised trials have not compared BS with optimal non-surgical alternatives (23).

We believe that all patients before being considered for BS should be offered an evidence-based, adequately resourced programme which aims for and can achieve 15-20kg weight loss, maintained at least 1-2 years. The 30-40% who succeed rarely then require BS on medical grounds. In principle, funds could be diverted to expand BS above current levels, but non-surgical approaches need first to be funded appropriately, and the real need is to invest more in obesity/weight-management overall. There is as yet no model of effectiveness for the prevention of obesity, but it is truly this area that requires accelerated funding and thinking, if we are to get to grips with this colossal public health problem.

### **Competing interests**

ML and GT have received funding from Cambridge Weight Plan and Counterweight Ltd for conference attendance and other departmental research, outside the submitted work. ML also acts as a consultant to Counterweight Ltd.

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