Title: Body-contouring surgery and the maintenance of weight-loss following Roux-en-Y gastric bypass: A retrospective study

Abstract

Background: Bariatric surgery leads to significant weight-loss with reduced morbidity and mortality. However, excess skin as a consequence of weight-loss represents a major problem, impacting upon patient's functionality with potential negative effects on weight-loss.

Objectives: We evaluated the effect of body-contouring-surgery on weight-loss maintenance following bariatric surgery.

Methods: We undertook a retrospective analysis of patients undergoing Roux-en-Y gastric bypass (RYGB) +/- Body-contouring surgery (BC). The control group (n=61) received RYGB, the test group (n=30) received RYGB+BC 12-18 months after bariatric surgery. Each RYGB+BC patient was matched to two control patients for age, sex, glycaemic status and weight on day of surgery. Percent weight-loss (%WL) was calculated at 3, 6, 12, 24, 36, 48 and 60 months post-RYGB for both groups.

Results: %WL was similar at 3, 6 and 12 months post-RYGB. At 24 months %WL was 35.6% in the RYGB+BC group and 30.0% in the RYGB group (p<0.05). At 36 months the RYGB+BC group maintained their weight-loss (%WL 33.0%), in contrast the RYGB gained weight (%WL = 27.3%, p<0.05). This trend continued (RYGB+BC v RYGB) at 48 months (%WL 30.8% v 27.0%) and at 60 months (%WL 32.2% v 22.7%, p<0.05).

Conclusions: Our results suggest patients who undergo body-contouring after bariatric surgery are able to lose significantly more weight and maintain weight-loss at five years of follow-up compared to those undergoing bariatric surgery alone.

Text

Introduction

Obesity is a significant health crisis which costs the United Kingdom National Health Service (NHS) £5.3 billion per year (1) with this figure estimated to rise a further £2billion by 2030 (2). The global burden of disease study 2013 (3) found the UK to have one of the highest obesity rates in Western Europe with approximately 28% of the population classed as obese. The effectiveness of bariatric surgery, and in particular RYGB, as a method of weight loss in obese individuals is well known (4-6). It also has a considerable effect on patient's co-morbidities; particularly improvement and sometimes resolution of type-2 diabetes and improvement in hypertension (4). Given the increasing proportion of the population who are severely obese it is no surprise that the number of bariatric procedures performed per year is greatly increasing (7). However, despite the proven benefits of bariatric surgery, there are potential limitations.

A significant number of patients suffer with excess skin following marked weight-loss after bariatric surgery (8). This can reduce exercise capacity, functionality, emotional wellbeing, quality of life, cause poor body image and result in sequelae such as skin rashes and ulceration (9-12). Up to 95.6% of marked weight -loss patients report ongoing body image dissatisfaction (13) and more than two-thirds of patients view excess skin as a negative consequence of their surgery (14). A considerable number of studies have shown that body-contouring surgery (BCS) for these patients can significantly improve their quality of life, functional capacity and body image (15-25).

Studies have indicated that the majority of patients lose the greatest amount of weight in the first 1-2 years after bariatric surgery and following this they gradually and continuously regain weight up to and beyond 10 years (5,26). The reasons for this are complex and there is currently no clear beneficial management strategy identified to combat this. However, two studies have indicated a potential benefit of BCS in maintaining weight-loss following bariatric surgery (27,28). In the larger of these studies Balague et al (2013) found that patients who undergo BCS following a RYGB maintain a significantly lower average weight regain up to 7 years follow-up than those who have no BCS (28). Friedman et al (2014) also found that patients undergoing BCS following laparoscopic adjustable gastric banding have significantly improved long term body mass index (BMI) control (27).

However, despite the evidence that BCS benefits quality of life in weight-loss patients, the surgery is rarely available in the UK due to lack of funding and a clear referral pathway (29). There is good evidence to suggest BCS improves patient quality of life following bariatric surgery and therefore this was not assessed in this study. However, current literature on the effect of BCS on weight-loss maintenance is extremely limited. Therefore the aim of our study was to evaluate whether BCS has a significant effect on weight-loss maintenance following post-surgical marked weight -loss in the UK setting.

Methods

All patients undergoing bariatric surgery at the University College London Hospital (UCLH) Bariatric Centre for Weight Management and Metabolic Surgery London between October 2007 and April 2013 were prospectively entered into a database. Demographic data were collected pre-operatively and patients were followed up at 6 weeks and then 3, 6, 12, 24, 36, 48, and 60 months post-operatively. Follow-up time was recorded from the date of the initial bariatric surgery. All patients were entered into a standard multidisciplinary follow-up programme at UCLH. As the study was retrospective and reviewed previously conducted procedures that were given written consent at the time then IRB/Ethical approval was not required for the study. Patients provided written consent at the time of surgery for their followup data to be retrospectively reviewed in any future studiesPatients provided written consent at the time of surgery for their followup data to be retrospectively reviewed in any future studies, and the study was conducted in accordance with the Declaration of Helsinki. For this study a retrospective analysis of the prospectively collected data of two RYGB patient groups was undertaken. All patients underwent multidisciplinary assessment prior to bariatric surgery. A standard laparoscopic RYGB procedure was undertaken for all patients (30). No patients were self-funded with all patients being treated on the NHS.

The study group consisted of 30 patients who underwent RYGB followed by body contouring surgery (RYGB+BC). In order to be accepted for BCS, patients must have achieved a BMI<35 kg/m², have maintained a 'stable weight' for the past six months, be a non-smoker and have significant psychological or physical impact resulting from the excess skin. All patients meeting these criteria had their case for BCS assessed by a cosmetic surgery tribunal and those receiving a positive tribunal outcome were granted full NHS funding for the procedure. All 30 study patients received full NHS funding through the cosmetic surgery tribunal. Patients were not consecutive and were judged on a case by case basis in line with the inclusion criteria outlined above.

All patients underwent BCS at the Department of Plastic and Reconstructive Surgery, Royal Free Hospital, London. Twenty-six patients underwent an abdominoplasty (excision of excess abdominal skin plus rectus plication where indicated in 11 patients), with one patient receiving simultaneous brachioplasty and three patients undergoing thigh or arm lifts. Three abdominoplasty patients later underwent further body-contouring procedures, and the excised weight at these procedures was adjusted for when measuring percentage weight loss. The procedures carried out are summarised in **Table 1**.

Each RYGB-BCS patient was matched to two RYGB patients for age, female sex, pre-operative HbA1c and BMI. These measurements were taking prospectively on the day of surgery and the patients were then retrospectively matched. Demographic data for all patients included in the study is summarised in **Table 2.** Data for other pre-operative comorbidities including hypertension, throm-boembolism and nutritional deficiencies was unfortunately inadequate to allow matching for these factors. Data were extracted from the database for each patient for: weight at 6 weeks, 3 months, 6 months, 12 months, 24 months, 36 months, 48 months and 60 months. Follow up weight was then

recorded as a percentage weight loss (%WL) compared to the patient's weight on the day of surgery. Percentage weight loss at each follow-up interval was recorded as mean ± SD.

Percentage weight loss was used as the primary outcome measure as several studies have shown that it is the parameter least influenced by pre-operative BMI (31-33). Pre-operative BMI strongly influences the effect of Roux-en-Y bypass on weight loss (34) and by eliminating this confounder through the use of percentage weight loss as a primary outcome measure we are more accurately illustrating the true effect of the procedures on weight loss. Percentage excess weight loss and change in BMI have been shown to be inaccurate parameters for evaluating weight loss in Roux-en-Y bypass patients as they are strongly influenced by pre-operative BMI and therefore they were not used as outcome measures in this study (32).

Statistical analysis was performed using SPSS Version 22 (IBM, USA). Data was found to be nonparametric, therefore a Mann-Whitney U Test was used to compare the difference in percentage weight loss between groups at each follow-up interval. Statistical significance was p<0.05.

Results

Patients were followed up and weighed at 6 weeks, 3 months, 6 months, 12 months, 24 months, 36 months, 48 months and 60 months. The number of patients who had followup data recorded at each time point is summarised in Table 3. Mean followup for the study group was 45 months (range 3-60 months). Mean followup for the control group was 46 months (range 24-60 months).

Impact of BCS upon %WL

Median excised skin weight in the RYGB+BC group was 1796g and this weight was subtracted from the average degree of weight loss measurement to show the true value of average weight loss. The differences in %WL at 6 weeks and 3, 6, 12, 24, 36, 48 and 60 months between the test and control groups are summarised in **Table 4**. Over the first 12 months of follow-up there was no significant difference in %WL between the groups. However following BCS, undertaken between

12 and 18 months in the study group, there was a significant difference in %WL at 24 (p<0.05), 36 months (p<0.05) and 60 months (p<0.05). At 48 months the difference in %WL was not found to be significant although the amount of weight lost in the test group was still greater. The differences in %WL between the two groups are illustrated in **Figure 1**.

Maintenance of Weight Loss

In the study group there was a significant increase in the average amount of weight lost between 6 weeks and 12 months (p<0.05) and between 12 months and 24 months (p<0.05). Between 24 and 60 months there was no difference in the average amount of weight lost (p>0.05) suggesting this group sustained and maintained weight loss throughout follow-up and following BCS.

In the control group there was a significant increase in the average amount of weight lost between 6 weeks and 12 months (p<0.05). Between 12 months and 24 months there was no significant change in amount of weight lost (p>0.05) suggesting maintenance of, but not continued, weight loss. Between 24 and 60 months there was a regain of weight with a decrease in average percentage weight loss from 30.0% to 22.8%; this difference was significant (p<0.05) suggesting the control group did not sustain or maintain weight loss throughout follow-up.

Average postoperative hospital stay following bariatric surgery was 4.1 days (range 1-10 days) in the BCS+RYGB group and 3.1 days (range 1-10 days) in the control group, there was no significant difference (p>0.05) between the two. Postoperative bariatric complications in the study group were: 2 anastomotic leaks, 2 wound infections, 2 bowel obstructions and 1 anastomotic bleed. Complications in the control group were: 3 anastomotic leaks, 2 wound infections, 2 anastomotic bleeds and 1 incisional hernia. Average postoperative hospital stay for BCS patients was 4.5 days (range 1-15 days). Eight (27%) of BCS patients suffered postoperative complications. These included 4 wound infections (13%), 3 seromas (10%), 2 haematomas (7%) and 2 wound dehiscences (7%). Three patients (10%) required an emergency return to theatre and 2 patients (7%) required readmission to hospital following discharge. All patients made a full recovery with no significant long term sequelae.

Discussion

The vast majority of patients who have marked weight-loss following bariatric surgery suffer with excess skin. This can have a significant effect on their quality of life leaving them feeling socially isolated with poor self-esteem (35). Patients are often still highly dissatisfied with their body image following bariatric procedures (36-38). Up to 77% of patients have mobility issues due to excess skin, with 45% avoiding physical activity altogether (9). Several studies have shown that BCS for these patients can cause a significant improvement in patients' body image, physical activity and quality of life (15-25). 92% patients who have undergone BCS would recommend it to a friend (20) and 96% would have procedure again (22).

However, despite this, the provision of plastic surgery for weight loss patients is extremely limited. This is despite 92% of surveyed UK based bariatric surgeons feeling that excess skin causes functional problems and that the majority view plastic surgery as a useful adjunct. In the UK there is no standardised provision of BCS for these patients and plastic surgeons are not routinely involved in their multidisciplinary management. Only 22% of UK patients are able to gain access to a plastic surgeon following significant weight loss (29). Many regions do not have referral guidelines for plastic surgery and several exclude post-bariatric patients altogether (39). There is also a significant postcode lottery in terms of who is accepted for BCS, with a recent study indicating that many of the patients approved in Scotland would not be accepted in some areas in England (36). The term postcode lottery refers to the fact that living in a certain area may make you more or less likely to be accepted for NHS funding for BCS. All patients must have their case heard at a cosmetic surgery tribunal in order to have funding approved by the NHS and a significant majority of cases are rejected.

In the USA only 7% of bariatric surgeons routinely refer patients to a plastic surgeon (40) and less than 25% of patients undergo BCS after bariatric surgery (13,36-38,41). The main reasons behind the lack of uptake of BCS in these patients is expense and lack of awareness regarding treatment options (42). Medical insurance often does not grant funding for these patients and a significant

number of patients eligible for BCS are in the lowest income bracket and so are unable to afford the costs themselves (38, 43). This is despite up to 95% of marked weight loss patients desiring BCS (44). This can lead to a significant selection bias for patients undergoing BCS as they tend to be wealthier and therefore able to pay for post-weight loss procedures. This is not the case in this study given that no patients were self funded, and all patients undergoing a body-contouring procedure received full NHS funding via a cosmetic surgery tribunal.

Our results indicate that, when comparing two demographically matched groups, patients who undergo BCS following post-surgical weight loss maintain a significantly greater percentage weight loss (32.2% vs. 22.8%) at 5-years follow-up and this remains significant even when the weight of excess skin excised was included. The patients undergoing BCS are able to show sustained weight loss over five years whereas those who do not have BCS show an average weight regain of 7.2% between 24 and 60 months. These patients also have relatively low complication rates with no significant postoperative morbidity found in this study.

The reasons for this are unclear, and only two previous studies have shown similar results (27,28). One explanation could be that, as reported in several studies (9,10,20), BCS patients have an increased level of physical activity. Stuerz et al (18) anecdotally reported that BCS increases selfesteem which in turn could improve patients activity levels. However, there will clearly be an element of selection bias in patients undergoing BCS. Firstly, they are self selecting and therefore likely to be more motivated to maintain weight loss and improve their body image. Secondly, they must show ability to maintain a stable body weight in ordered to be considered for the surgery in the first place. However in our study, the two groups showed very similar weight loss up to 12 months after their bariatric surgery, suggesting they were similarly motivated prior to BCS.

Our findings add further evidence to the benefits of BCS in this patient population and back up the findings of the only two previous studies to evaluate effect on weight loss maintenance. A key question is whether this is cost effective, helps reduce hospital stays and whether helping maintain

the weight loss allows patients to put back in to society i.e. return to work and this needs to be answered in further studies. There is evidence that BCS following bariatric surgery increases the risk of complications compared to non-BCS patients (45) and although this may not necessarily influence patients satisfaction (21) the additional financial implications of this must be recognised. Formal reporting of complication rates would add to the body of evidence required to influence funding authorities to support BCS. To further illustrate the beneficial effects of BCS for patients the resolution of significant comorbidities needs to be investigated e.g. HbA1C (diabetes) and hypertension. This was unfortunately beyond the scope of this article due to insufficient follow-up data, however retrospective collection of postoperative HbA1C is currently underway and the authors hope to use the findings from this subsequent study to produce further evidence for the benefits of BCS.

Limitations of this study include the relatively small sample size that, although demographically matched, allows for sampling error and may reduce the importance of the conclusions. This was further limited by the loss to followup of some patients at each time interval, although statistical tests still illustrated significant differences despite this. Another limitation is the relatively short follow-up of both groups, although this may be less important given that there is strong evidence that the greatest weight loss is always in the first 2 years which our findings confirmed (5). Another limitation is selection bias given that all patients in the study were potentially eligible for BCS. We do not have the data for why individual patients were referred for BCS nor why they passed the cosmetic surgery tribunal however there is likely to be a significant element of self-selection amongst patients who underwent BCS. We also do not have the data as to whether the control patients suffered with problems related to excess skin or whether they were interested in undergoing BCS. In order to confirm our findings a randomised controlled trial is required to determine if weight loss maintenance can be attributed to BCS alone.

Conclusions

As bariatric surgery increases in prevalence there will be a greater number of patients seeking BCS following marked weight loss. Our study has shown that BCS may help these patients maintain weight loss in addition to the proven benefits in quality of life and functionality. Whether this improved weight loss maintenance is cost effective needs to be investigated further. However, it is clear that the provision of plastic surgery for weight loss patients must improve if these patients are to benefit from it.

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Tables

Procedure	Frequency
Single procedure	
Abdominoplasty	26
Bilateral thigh lift	2
Bilateral brachioplasty	1
Combined procedure	
Abdominoplasty + brachioplasty	1

Table 1: Summary of body contouring procedures undertaken in the study group

	Study (±SD)	Control (±SD)
Gender	Female	Female
Age (±SD) : Range	41.5 (±9.6) : 21.6 - 58.9	41.5 (±8.6) : 22.1 - 56.9
Type of Bariatric Surgery	Gastric Bypass Only	Gastric Bypass Only
Pre-op HbA1C (mmol/mol) (±SD) : Range	6.5 (±1.4) : 5.4 - 11.6	6.5 (±1.0) : 5.5 - 10.4
T2DM	30% +ve	30% +ve
Booking Weight on day of surgery (Kg) (±SD) : Range	124.2 (±16.7) : 91 - 145	124.1 (±18.9) : 88 - 174
Booking BMI (±SD) : Range	46.7 (±5.6) : 36.8 - 61.7	46.7 (±6.7) : 36 - 61.7

 Table 2: Summary of demographic data for all patients

Followup time	No of patients with data study group	No of patients with data control group
6 weeks	23	58

3 months	24	50
6 months	20	51
12 months	28	60
24 months	21	57
36 months	20	41
48 months	18	35
60 months	12	26
Mean (months)	44.9	46.1
Range (months)	3-60	24-60

Table 3: Summary of followup data for all patients

% Weight loss: Mean (±SD)	Study group	Control group	p value
6 weeks	9.0 (2.1)	10.2 (3.1)	0.078
3 months	18.2 (3.3)	18.5 (4.1)	0.9
6 months	25.1 (5.4)	26.9 (11.1)	0.83
12 months	32.1 (7.4)	29.5 (7.2)	0.09
24 months	35.6 (9.8)	30.0 (9.1)	0.015*
36 months	33.1 (10.1)	27.3 (10.6)	0.043*
48 months	30.8 (9.0)	27.0 (9.3)	0.27
60 months	32.2 (8.8)	22.8 (10.2)	0.017

 Table 4: Differences in percentage weight loss between the two groups

Figure Legend

1. The differences in %WL between the two groups