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ORIGINAL CONTRIBUTIONS

Laparoscopic Silastic Ring Mini-Gastric Bypass (SR-MGBP): Up to 11-Year Results from a Single Centre

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Abstract
Background Bariatric surgery is well established as an effective method for treating obesity and its related comorbidities. The laparoscopic mini-gastric bypass (MGBP) represents a simpler alternative to a Roux-en-Y gastric bypass (RYGBP). The placement of a silastic ring (SR) may enhance excess weight loss and minimize weight regain. This study reports long-term results from a cohort of patients undergoing a SR-MGBP in a single centre.
Methods Long-term outcomes (up to 11 years) in a cohort of 156 patients undergoing surgery between August 2005 and January 2008 were analysed. A combination of follow-up questionnaires and electronic hospital records were used to assess weight loss, comorbidity resolution and complications.
Results A total of 156 patients (mean body mass index 46 kg/m^2) underwent surgery. Ninety-two patients responded to the follow-up questionnaires. Computer-based hospital information was available on a total of 139 patients. Mean percent excess weight loss (%EWL) at 11 years was 84.3%. Comorbidity resolution, determined by medication use, showed a reduction in diabetes (21.8% to 7.1%), hypertension (37.2% to 21.4%) and hypercholesterolaemia (40.4% to 13.4%). Five of 139 patients (3.6%) had SR problems needing removal. Two other patients had the SR changed to a bigger size and a further two had endoscopic removal of the SR for erosion. Of the 139 patients, 9.4% required conversion to a Roux-en-Y gastric bypass (RYGBP). The number of patients on anti-reflux medications increased from 5.1% to 44.6% at 11 years. There were two deaths unrelated to surgery.
Conclusions SR-MGBP appears to be a safe and effective operation for the morbidly obese. It is durable, with good weight loss at up to 11 years post-surgery. The SR can easily be removed or exchanged for another size and is reasonable to consider when performing a MGBP. Concerns about bile reflux appear to be well founded, and some patients who are poorly controlled medically will require revision.

Keywords Mini-gastric bypass · Gastric bypass · Excess weight loss · Silastic ring · Bariatric surgery

Introduction

Bariatric surgery is well established as an effective means of treating obesity and its associated comorbidities [1]. The field has evolved over time and continues to change. There are many different operations with different risk/benefit profiles. Choice of operation is dependent both on patient comorbidities and surgeon's experience and preference. The Roux-en-Y gastric bypass (RYGBP) is the most commonly performed bypass procedure for bariatric surgery and is well recognized for its efficacy.

The mini-gastric bypass (MGBP) was performed by Rutledge in 1997. It represents a simpler alternative with only a single anastomosis, no closure of mesenteric defects and shorter operative times. Initial concerns were raised about the potential for bile reflux and marginal ulceration. However, Rutledge reported positive results from the first cohort of patients that underwent this operation in 2001 with mean percentage excess weight loss (EWL) of 77% at 2 years

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and a marginal ulcer incidence of less than 2%. He also reported a reduction in the incidence of reflux post-operatively [2]. Since then, its short-term and medium-term efficacy for both weight loss and comorbidity resolution has been well established [3–6]. However, long-term data (greater than 2–5 years after surgery) is not well documented. Furthermore, concerns about bile reflux and marginal ulceration still exist with mixed results in the literature [7–9]. In a retrospective study, Johnson et al. [9] raised concerns about the potential under-reporting of complications following the MGBP and highlighted the need for further research. However, other studies have demonstrated low rates of revisional surgery following this procedure [10].

Weight regain remains a problem following bypass surgery. Addition of a silastic ring (SR) to the gastric pouch has been proposed as a method for reducing weight regain [11]. The SR may also act as an anti-bile reflux device. Results from a recent meta-analysis on patients undergoing RYGBP with a SR show a reduction in weight regain in the long term when compared to non-banded RYGBP. They also showed no increase in complication rates with the addition of a SR [12]. There have been no long-term studies to date on the addition of a SR to the MGBP. Recently, we published medium-term results from our cohort of patients that underwent a SR-MGBP [13].

This study aimed to report long-term outcomes following SR-MGBP on a cohort of patients from a single centre.

Methods

Between August 2005 and January 2008, 156 patients underwent a laparoscopic SR-MGBP at a single centre. A specialist bariatric surgeon, bariatric nurse specialist, dietician and anaesthetist evaluated patients pre-operatively. Main exclusion criteria included patients under the age of 18, smokers, major psychiatric illness, coagulopathy and inflammatory bowel disease. Patient demographics, BMI, weight and comorbidity data were recorded prospectively.

All patients were started on a low calorie diet using Optifast 2 weeks prior to surgery. A standard five-port laparoscopic technique was used. A shortened afferent limb (150 cm) was created. A 6.5-7 cm silastic ring was placed around the distal third of the gastric pouch, at least 2 cm above the gastrojejunostomy, and secured using non-absorbable sutures (Fig. 1). Post-operatively, patients were evaluated at 1 week, 6 weeks and every 3 months in the first year, every 6 months for the second year and annually thereafter for 5 years. Where patients had moved, attempts were made for follow-up via phone or email.

In September 2015, all patients were posted a questionnaire to assess long-term outcomes. This included questions about current weight, food intolerances, reflux, current medications and supplements, further operations and/or hospital admissions and overall patient satisfaction. This was followed-up with phone calls and emails. Overall response rate was 59%. To elucidate further data, ethics approval was obtained to access electronic hospital records (Concerto) in the Auckland region for these patients. Two researchers accessed Concerto records for all patients. Current medications, bloods including iron studies and glycated haemoglobin (HbA1c), subsequent operations or hospital admissions, investigations related to their previous surgery and any more recent documented weight were recorded.

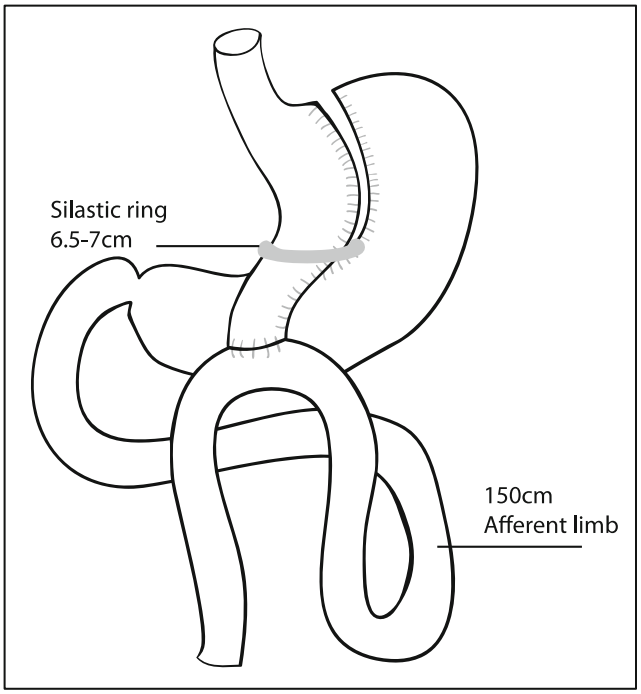

Fig. 1 The MGBP operation schematic

Results

Patient Data

Patient demographics are reported in Table 1. Eighty-seven percent of patients had obesity-related comorbidities with 49% being on medications.

Ninety-two patients (59%) responded to the follow-up questionnaire. Further information from computerized hospital-based records in the Auckland area was available on a total of 139 patients. The 17 missing patients were due to missing patient identification numbers or patients moving outside the Auckland area.

Weight Loss

Weight loss data up to 11 years was available on a total of 102 (65%) patients (Fig. 2). Mean percentage total weight loss

Table 1 Patient demographics (original patient cohort)

Demographic		Value
Age	Mean (range)	44 (18–63) years
Sex	Male/female	22%:78%
Pre-operative weight	Mean (range)	129 (83–197) kg
Pre-operative BMI	Mean (range)	46 (35–64) kg/m^2
Pre-operative comorbidities	Hypertension	58 (37%)
	Type 2 diabetes	34 (22%)
	Hypercholesterolaemia	63 (40%)
	Obstructive sleep apnoea	45 (29%)
	Gastro-oesophageal reflux	61 (39%)
Pre-operative medications	*N* (%)	76 (49%)

(%TWL) at 11 years was 37.1%. Mean percentage EWL at 11 years (%EWL) was 84.3% with a mean BMI of 28.1 (range 21–43). Mean length of follow-up was 9.1 years (range 6–11 years).

Comorbidities

Comorbidity resolution at 11 years was deduced from patient medication profiles from computer pharmacy dispensing records (Table 2). Medication information was available on 112 patients (71.3%). Only 4 of the 34 initial diabetic patients had a HbA1C level greater than 49. There was one new diagnosis of diabetes.

Of the 112 patients, 58.2% remained on iron supplements (oral or infusions), 19.8% on vitamin B_{12} supplements and 4% on folate at 11 years. Twenty-four patients (of 94 who had blood results available) had ongoing iron deficiency and three were vitamin B_{12} deficient.

Complications

Early post-operative complications have been published previously [13]. Two patients died at 8 and 9 years post-operatively from conditions unrelated to their surgery—metastatic lung and neuroendocrine cancers, respectively.

- Silastic Ring

Five patients (3.6%) had the SR removed for food intolerance (4 within the first 5 years, 1 at 6 years). One of these had had a conversion to a RYGBP prior to removal. One patient suffered extreme weight loss and required nasojejunal feeding prior to removal of the SR. Two patients had the SR replaced with a larger diameter ring for food intolerance at 2 and 8 years post-operatively, with improvement in their symptoms. A further two patients had erosion of the SR needing endoscopic removal using a dual channel endoscope.

- Conversion to RYGBP

Thirteen patients (9.4%) had a revision to RYGBP. The reasons for revision are outlined in Table 3. Four of these were done over 5 years after their initial operation. One patient developed an internal hernia following conversion to RYGBP with one other needing a revision bypass for a chronic gastrojejunal ulcer and a gastro-gastric fistula.

- Ulcers

Seven patients had marginal ulcers post-operatively (4.5%). Three of these were perforated ulcers needing

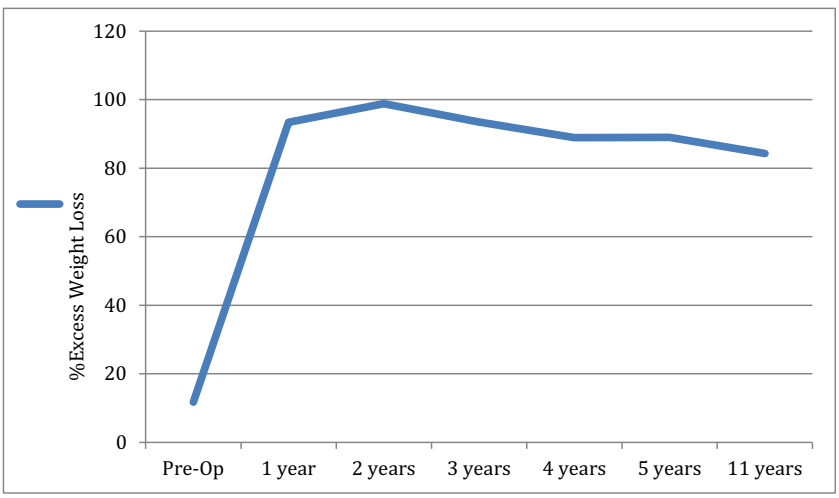

Fig. 2 Percent excess weight loss at 11 years

Table 2 Medication use at 11 years (numbers and percentages)

Medication	Pre-operative (original cohort)	10 years (112 patients)
Anti-hypertensive	58 (37.2%)	24 (21.4%)
Hypoglycaemics	34 (21.8%)	8 (7.1%)
Lipid-lowering therapy	63 (40.4%)	15 (13.4%)
Proton pump inhibitors	8 (5.1%)	50 (44.6%)

operative management. They presented at 2, 3 and 7 years post-operatively.

- Reflux

Sixty-one patients (38.9%) complained of reflux pre-operatively. Eight of these were on regular proton pump inhibitors. Post-operatively, 50 patients (44.6%) were on regular proton pump inhibitors. VISICK reflux scores were recorded on the 92 patients that responded to the questionnaire. Of the 92, 69.5% of patients complained of reflux, with 17.4% complaining of severe reflux not controlled with medications or worsening symptoms (score 3 or 4). All of the patients that had revisional surgery for reflux had no subsequent reflux or minimal symptoms (score 1 or 2).

Discussion

This study has demonstrated that the laparoscopic SR-MGBP can achieve excellent weight loss that can be maintained in the long term. There is concomitant reduction in comorbidities that appears to be maintained in the long term. While reflux remains problematic, many cases can be managed effectively with pharmacological intervention. However, approximately 10% of patients did require surgical intervention for this and a number of patients still complain of significant symptomatic reflux.

The mean percentage EWL at 11 years of 84.3% in this study is higher than that reported in the literature. As discussed previously, long-term weight loss data on the MGBP is limited. In a large study with over 1000 patients, Lee et al. demonstrated %EWL of 72.9% at 5 years, with follow-up ranging up to 10 years [3]. Other studies have also demonstrated similar weight loss (approximately 70% EWL) at 5 years [14, 15]. The consistent weight loss in this study may be due to the addition of the SR to reduce weight regain. However, in the absence of a non-banded control group, the contribution of the SR is speculative. We await, with interest, similar long-term results of other MGBP series. To date, our study has the best weight loss despite a shorter afferent limb of 150 cm compared to the 200+cm afferent limbs of other series [4]. It would appear from this that the SR does have an effect on long-term weight loss when compared to non-banded groups. The weight loss results in this study also appear superior to that of the RYGBP reported in the literature. Lee et al. compared results of the MGBP and RYGBP at 5 years [3]. They found improved weight loss in the MGBP group, with %EWL at 5 years in the RYGBP of 60.1%, although the length of the afferent limb differed between the two groups. Overall, 5-year %EWL for RYGBP ranges from 63% to 70% [16–18]. In a longer term study on RYGBP, Higa et al. reported 10-year %EWL of 57% in their cohort [19]. However, their 10-year follow-up rates were lower at 35%.

To date, there are no other studies on the addition of the SR to the MGBP. A recent meta-analysis on banded RYGBP showed a reduction in weight regain compared to non-banded RYGBP over time. Their cumulative %EWL at 10 years was 70% [12]. Two more recent studies also showed better weight loss in the banded RYGBP group compared with a non-banded bypass group. Two-year %EWL in both these studies was 70% [20, 21]. The SR is associated with complications. Buchwald et al. reported an overall band-related complication rate of 6.1% [12]. Other studies have also reported increased gastrointestinal complications such as vomiting and food intolerance in banded groups [22]. Our results show 6.5% of patients had complications associated with the SR. One patient suffered severe nutritional deficiency requiring nasojejunal feeding. This resolved following removal of the SR. The benefits of excess weight loss must be weighed against the risks. Currently, there is limited data on the use of a SR in the MGBP and further research directly comparing the two would be helpful to determine its role in gastric bypass surgery. Our results would suggest that it does.

Resolution or improvement of obesity-related comorbidities after bariatric surgery is well documented. A systematic review on the MGBP reported over 80% resolution of comorbidities at 12 months in most studies, particularly for type 2 diabetes mellitus [5]. However, assessment of comorbidity resolution was either poorly documented or varied between studies. In this study, long-term comorbidity resolution was difficult to assess. We used patients' medications as an indication of the presence of comorbidities. This may have

Table 3 Reason for conversion to RYGBP

Reason for conversion	Numbers
Reflux	8
Bleeding marginal ulcer	1
Bleeding from jejunal loop	1
Ongoing pain	1
Intractable vomiting (normal gastroscopy and contrast swallow)	1
Small bowel obstruction	1

underestimated presence of comorbidities at 10 years. Furthermore, medication use was based on pharmacy dispensing records on the computer-based hospital system. Overall, only 23.5% of patients initially on hypoglycaemic medications, 23.8% of patients on cholesterol lowering therapy and 41.3% of patients on anti-hypertensives remained on medication at 10 years.

Overall mortality at 11 years was 1.4%. Both deaths were unrelated to their SR-MGBP. Of the 139 patients, 9.4% required conversion to a RYGBP, predominantly for reflux. None of the revisions to another procedure in our series were for malnutrition or inadequate weight loss. Increased bile reflux is one of the concerns about the MGBP operation. Measures of post-operative reflux in the literature have been variable. Lee et al. reported an overall revision rate of 2.8% with only 12% of these due to reflux [3]. They also noted equivalent quality of life scores between MGBP and RYGBP patients. Rutledge et al. reported an improvement in reflux symptoms at 5-year follow-up [23]. Long term data comparing Billroth II and Roux-en-Y anastomosis also found no difference in long-term reflux scores between groups [24]. In our study, the overall incidence of reflux was increased post-operatively as evidence by the VISICK score and the increased number of patients on proton pump inhibitors. While many cases were well controlled with medications, 17% of patients still complained of symptoms not controlled despite medications. This appears to be higher than other series and may be related to the longer follow-up in this group of patients, as many appeared to develop reflux subsequent to previous clinical follow-up.

The rate of marginal ulcers following the MGBP ranges from 5% to 8% in the literature [23, 25]. Our rate of 4.5% is similar. However, concerns have been raised in the literature that these estimates may not be accurate [7]. Three of the seven patients with marginal ulcers in our cohort presented with perforations requiring operative management. All three had a history of recent non-steroidal anti-inflammatory use and had not been on any proton pump inhibitors. The true incidence of marginal ulcers may be underdiagnosed given many asymptomatic ones may not be diagnosed. The clinical relevance of these remains questionable. However, given the risk of perforation with marginal ulcers, perhaps further studies to determine risk factors to then enable better prophylactic management may be indicated.

Some surgeons may regard the reflux-related complications as acceptable given the excellent weight loss. Also, RYGBP hasits own unique post-operative problems uncommonly seen after MGBP, such as internal hernia formation, which can be serious if not managed appropriately. MGBP is certainly an easier operation to revise than RYGBP. Given the high incidence of reflux, our practice has reverted to performing RYGBP. Occasionally, we still perform a MGBP if patient characteristics such as a hostile abdomen or the requirement of minimal time on the operating table indicate this approach.

Conclusion

SR-MGBP appears to be a safe and effective operation for the morbidly obese. It is durable, with good weight loss extending out to 11 years post-surgery. The SR can easily be removed or exchanged for another size and is reasonable to consider when performing a MGBP. However, data is still lacking with respect to how much of a contribution it makes to long-term weight loss. Concerns about bile reflux appear to be well founded and some patients who are poorly controlled medically will require revision. On the other hand, no revisions were required for poor weight loss, malnutrition or weight regain.

Compliance of Ethical Standards

Conflict of Interest Dr. Sheikh has nothing to disclose.
L. Pearless MN (Hons) has nothing to disclose.
Dr. Booth has nothing to disclose.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Statement of Human and Animal Rights The study has been approved by the national ethics committee and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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