

Improved Obesity Reduction and Co-morbidity Resolution in Patients Treated with 40-French Bougie Versus 50-French Bougie Four Years after Laparoscopic Sleeve Gastrectomy. Analysis of 294 Patients

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Abstract

Background We compared percent excess body mass index loss (%EBMIL) and resolution of dyslipidaemia, hypertension, and type 2 diabetes mellitus in the 4 years following laparoscopic sleeve gastrectomy (LSG) between patients calibrated with a 40-French (40F) or a 50-French (50F) bougie. **Methods** We conducted a longitudinal retrospective descriptive study of routinely collected pre- and post-surgical data from 294 patients who underwent LSG at a single surgical centre (50F— $n=106$, 40F— $n=185$). Obesity measurements were taken prior to surgery and at regular intervals until 48 months post-surgery. Co-morbidity resolution was also assessed across the 48-month observation period. Multivariate regression modelling was used to control analyses for baseline obesity and sociodemographic variables.

Results At 48 months post-surgery mean (\pm SD) %EBMIL was $60.2\pm 27.6\%$ and $45.4\pm 38.4\%$ for those treated with the 40F and 50F bougie, respectively. After controlling for sociodemographic variables and baseline excess weight, mean %EBMIL was 15.5% greater with a 40F bougie

compared with a 50F bougie at the end of follow-up. The likelihood of dyslipidaemia resolution within 48 months post-LSG was 19.0 times greater ($p=0.006$), hypertension resolution 3.6 times greater ($p=0.005$) and type 2 diabetes mellitus resolution 5.2 times greater ($p=0.034$) by 4 years post-surgery in patients treated with the 40F bougie compared with a 50F bougie.

Conclusion Improved obesity reduction and resolution of dyslipidaemia, hypertension and type 2 diabetes mellitus is experienced during the 4 years following surgery by patients treated with a 40F bougie compared with the 50F. These findings remain when controlling for potential confounding clinical and sociodemographic factors.

Keywords Bariatric surgery · Laparoscopic surgery · Gastrectomy · Obesity · Multivariate regression · Dyslipidaemia · Hypertension · Type 2 diabetes mellitus

Introduction

Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that is being increasingly performed despite a comparative shortage of long-term empirical data [1, 2]. Weight loss and co-morbidity resolution have been well described during the first 12–18 months following LSG surgery, but there is limited information available on longer-term outcomes [1, 3–16]. This information is vital in determining the sustained effectiveness of this relatively new bariatric surgery as a stand-alone procedure.

A recent article by Himpens and co-workers found a mean 77.5% excess weight loss (%EWL) at 3 years post-LSG and 53.3%EWL at 6 years post-LSG for a small series of 30 patients [17]. This finding suggests that many patients

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undergoing LSG may experience weight regain in the long term. If weight loss and associated improvements in comorbidity are not maintained in the longer term, the effectiveness of LSG is debateable, and given the invasive and irreversible nature of this procedure the appropriateness of the surgery may also be uncertain. Furthermore, there is a paucity of investigation regarding whether the extent of gastric restriction created during LSG (determined by the diameter of the surgical bougie used) has implications for more sustained weight reduction and greater co-morbidity resolution. In addition, most previous LSG-focussed research has only used small study samples (often $n < 30$), and there is a complete lack of research in this area which has controlled for potential confounding factors such as patient sociodemographic characteristics and pre-surgery obesity level [1, 3, 6–10, 13, 14, 17–19].

Therefore, we aimed to compare the influence of bougie size (40F vs. 50F) on obesity reduction and resolution of dyslipidaemia, hypertension and type 2 diabetes mellitus in patients during the 4 years post-surgery in a sample of almost 300 patients, with analyses controlled for other possible influencing factors.

Materials and Methods

Study Design

This investigation comprised a longitudinal descriptive study of routinely collected pre- and post-surgical obesity and comorbidity data from 2003 to 2010 at a single bariatric surgical practice, for patients undergoing primary LSG.

Study Sample

Participants were patients who underwent LSG prior to 1 June 2007 at Mercy Bariatrics Obesity Surgical Centre (MBOSC). Patients were already scheduled for surgery independent of this study. MBOSC is a private obesity surgery clinic located in Mercy Medical Centre in Perth, Western Australia [20]. To be eligible to be scheduled to undergo LSG, patients were required to have a body mass index (BMI) ≥ 40 kg/m² (i.e. classified as morbidly obese [5]) or ≥ 35 kg/m² with co-morbidity, as per the clinical guidelines published by the American Bariatric Surgery Society and the Obesity Surgery Society of Australia and New Zealand [21, 22].

Surgery

All surgeries were performed by a single surgeon with >4 years' experience with this specific type of surgery, therefore diminishing the possibility that the results were an artefact of

physician competence or inter-surgeon differences. All procedures were performed laparoscopically using a five-port technique. Sleeves were calibrated against a 40F or 50F rubber bougie and transection began as close to the pylorus as possible. The first 106 patients in this series had been calibrated against a 50F bougie. After June 2006, all patients were calibrated against a 40F bougie. In all other respects, the technique of resection did not vary between patients. There was complete mobilisation of the greater curve side of the stomach from antrum to hiatus. Hiatal hernia repaired by anterior plication suture when encountered. The stapling device was placed 'snugly' against the bougie but deviated by 1 cm from the oesophagus at the fundus to ensure the staple line was wholly on gastric wall. Typically six to eight firings were required with the first two to three firings of green load and the subsequent firings of blue load. A drain was placed alongside staple line. The staple lines were not routinely oversewn in either study group. All patients were administered a standard fluid-based diet for the first 2 weeks following surgery and transitioned to solids by 4–6 weeks post-surgery. No patients were excluded based on any sociodemographic or clinical factor, and consequently the study investigated all patients undergoing LSG surgery at this medical facility during the observation period.

Variables Collected

Baseline body mass and height were recorded prior to surgery and BMI [23], excess BMI and excess weight calculated [24]. These variables were also evaluated at 1.5, 3, 6, 12, 18, 24, 36 and 48 months post-surgery.

Co-morbidity was clinically assessed at baseline with assessment of resolution at each routine post-operative consultation during the 4-year follow-up period. As part of standard pre-surgery consultation at MBOSC, all patients are screened for a number of clinical diagnoses that are commonly associated with obesity. Dyslipidaemia, hypertension and type 2 diabetes mellitus were selected for investigation in this study as they reflect those most commonly reported in the LSG literature [2, 12, 16, 25].

Patient sociodemographic characteristics including age, gender, location of residence and possession of private health insurance were collected prior to surgery for all patients. The surgical bougie size (40F or 50F), and any surgery-related complications, for all LSG procedures was also recorded.

All variables studied were routinely recorded in LapBase, a specifically designed bariatric surgical database [26], which provided the primary data source used in this investigation.

More than half of the patients (60.5%) had not been in contact with MBOSC for routine post-surgical follow-up since the 24 months' post-surgery visit. Consequently, in order to increase data completeness and reduce longitudinal

loss-to-follow-up during the 4-year post-surgery observation period desired for this investigation, these patients were contacted in order to obtain information relating to current weight and co-morbidity status. This was achieved through a telephone contact, mail-out or email. Preliminary statistical analyses were performed to determine the appropriateness of including the self-reported data; these revealed no significant differences between the dataset with self-reported measures and the dataset without self-reported measures for baseline demographic variables, baseline obesity measures and obesity reduction.

Statistical Methods

All analyses were performed using PASW (version 17.0; SPSS Inc., Chicago, IL, USA) with significance set at $p < 0.05$. Descriptive statistics were calculated for all obesity and co-morbidity variables at baseline and during the 4-year follow-up period. All analyses were performed for the entire patient sample as well as separately by operative bougie size (i.e. 40F and 50F bougie groups).

Repeated measures analysis of variance (ANOVA) was conducted for %EBMIL to determine changes across the 4-year observation period. Significant findings were further investigated using Tukey's post hoc analyses. Chi-square tests were conducted to determine differences in proportions of patients with each co-morbidity and resolution of co-morbidity, between the 40F and 50F bougie groups at each time point. Independent samples *t* tests were conducted to determine differences in the time from surgery to co-morbidity resolution between the 40F and 50F bougie groups.

Linear and logistic regression modelling were performed to determine the association between bougie size and %EBMIL and co-morbidity resolution at 4 years post-surgery, respectively. All regression models were adjusted for age, gender, insurance status, baseline obesity level and bougie size.

Ethics

Ethics approval for this research was obtained from The University of Western Australia's Human Research Ethics Committee.

Results

Baseline Patient Characteristics

Table 1 presents the baseline characteristics of the study sample overall and by operative bougie size. Participants were 294 patients who underwent LSG of which 106 (36%) patients were operated on using a 50F bougie and 185

(63%) with a 40F bougie. Three patients did not have bougie size recorded in the LapBase data and were excluded from comparative analyses of bougie size. The mean (\pm SD) age of patients was 45.8 ± 10.9 years, and the majority of participants ($n=226$, 76.9%) were female. Most patients ($n=216$, 75.8%) resided in metropolitan Perth. No significant differences existed in these factors between the two bougie groups. Most patients (92.8%) possessed private health insurance, with a significantly greater proportion in the 40F group (95.6%) than in 50F patients (87.7%) ($p < 0.05$).

Obesity Reduction

For all patients combined, mean %EBMIL was significantly different to baseline at each post-LSG time point (range 21.1–68.4%). Mean %EBMIL continued to increase significantly from previous measurement time points until 18 months post-surgery, with a peak of $68.4 \pm 28.0\%$ %EBMIL at 24 months post-LSG. By 48 months post-surgery, the study sample as a whole had a mean (\pm SD) %EBMIL of $53.1 \pm 33.6\%$.

Figure 1 shows the results for %EBMIL across the observation period between patients treated with a 40F and 50F bougie. Patients who underwent LSG with the 40F bougie experienced significantly greater mean %EBMIL at 6, 12, 18, 24, 36 and 48 months post-surgery compared with those patients with the 50F bougie, ranging from 9.8% greater %EBMIL at 6 months to 22.7% at 36 months. Mean %EBMIL peaked at 73.7% (at 24 months) and 60.4% (at 18 months) for the 40F and 50F groups, respectively ($p < 0.05$). Mean (\pm SD) %EBMIL at the end of observation (i.e. 48 months post-surgery) was $60.2 \pm 27.6\%$ and $45.4 \pm 38.4\%$ for 40F and 50F patient groups, respectively. A reduction of 13.5% from peak %EBMIL at 24 months to 48 months post-surgery in the 40F group was statistically significant ($p < 0.05$), similar was seen from the peak %EBMIL in those treated with the 50F (15.0% reduction, $p = 0.05$). Loss to follow-up data are presented in Table 2. Analysis of variance was performed comparing the %EWL and %EBMIL for the first, second, third and fourth quartiles of patients to each other within the 50F and 40F bougie groups. This showed no statistically significant difference between the quartiles.

Multivariate linear regression modelling revealed a statistically significant association between baseline excess weight and %EBMIL across the 4-year observation period, such that a 10-kg increase in excess weight reduces %EBMIL by 2.7%. After controlling for age, sex, private health insurance and baseline excess weight, mean %EBMIL was estimated to be 15.47% greater (95% CI = 7.80, 23.14; $p < 0.001$) for patients treated with a 40F bougie compared with a 50F bougie.

Table 1 Baseline characteristics of patients who underwent LSG with 40F or 50F bougie

Baseline characteristics	40F (n=185)	50F (n=106)	All patients (n=294) ^a
Demographics			
Age (years), mean (SD)	46.1 (11.2)	45.2 (10.5)	45.8 (10.9)
Female, n (%)	146 (78.9)	79 (74.5)	226 (76.9)
Height (cm), mean (SD)	167.6 (8.8)	168.5 (9.9)	167.9 (9.2)
Metropolitan residence, n (%)	135 (76.3)	79 (75.2)	216 (75.8)
Private health insurance, n (%)	175 (95.6)	93 (87.7)*	271 (92.8)
Obesity measures			
Weight (kg), mean (SD)	117.5 (19.5)	122.2 (25.8)	119.2 (22.0)
BMI (kg/m ²), mean (SD)	41.8 (5.6)	42.9 (7.0)	42.2 (6.2)
Excess weight (kg), mean (SD)	54.4 (17.0)	58.4 (22.7)	55.8 (19.3)
Excess BMI (kg/m ²), mean (SD)	16.8 (5.7)	17.9 (7.0)	17.2 (6.2)

**p*<0.05, 50F significantly different to 40F at baseline

^aThree patients were missing bougie size records and were excluded from comparisons involving bougie size

Co-morbidity

Of the entire study sample, dyslipidaemia affected 17.0% (*n*=50) of patients at baseline. One third (*n*=98) of patients had clinically diagnosed hypertension at time of surgery, making it the most ‘prevalent’ co-morbidity in this study sample. Type 2 diabetes mellitus affected 18.7% (*n*=55) of all patients prior to LSG.

When evaluated according to bougie size, 41.5% (*n*=44) of patients treated with 50F bougie had hypertension at baseline compared with 28.6% (*n*=53) of patients treated

with the 40F bougie, making the proportion of patients with hypertension at baseline 4.2 times greater in those treated with the 50F bougie (*p*<0.05). Dyslipidaemia affected 13.5% (*n*=25) of patients treated with the 40F bougie and 22.6% (*n*=24) of those treated with the 50F bougie. Type 2 diabetes mellitus affected 16.2% (*n*=30) of those treated with the 40F bougie and 23.6% (*n*=25) of those treated with the 50F bougie.

Results relating to the crude analysis of resolution of the three co-morbidities investigated in this study are shown in Table 3. No statistically significant differences in the

Fig. 1 Mean (±SD) percentage excess BMI loss from baseline to 4 years post-surgery for patients treated with the 40F and 50F bougie. *a* %EBMIL significantly different (*p*<0.05) from baseline within the same bougie group, *b* %EBMIL significantly different (*p*<0.05) from the previous time point within the same bougie group, *c* %EBMIL for 40F is significantly different (*p*<0.05) to 50F at the same time point

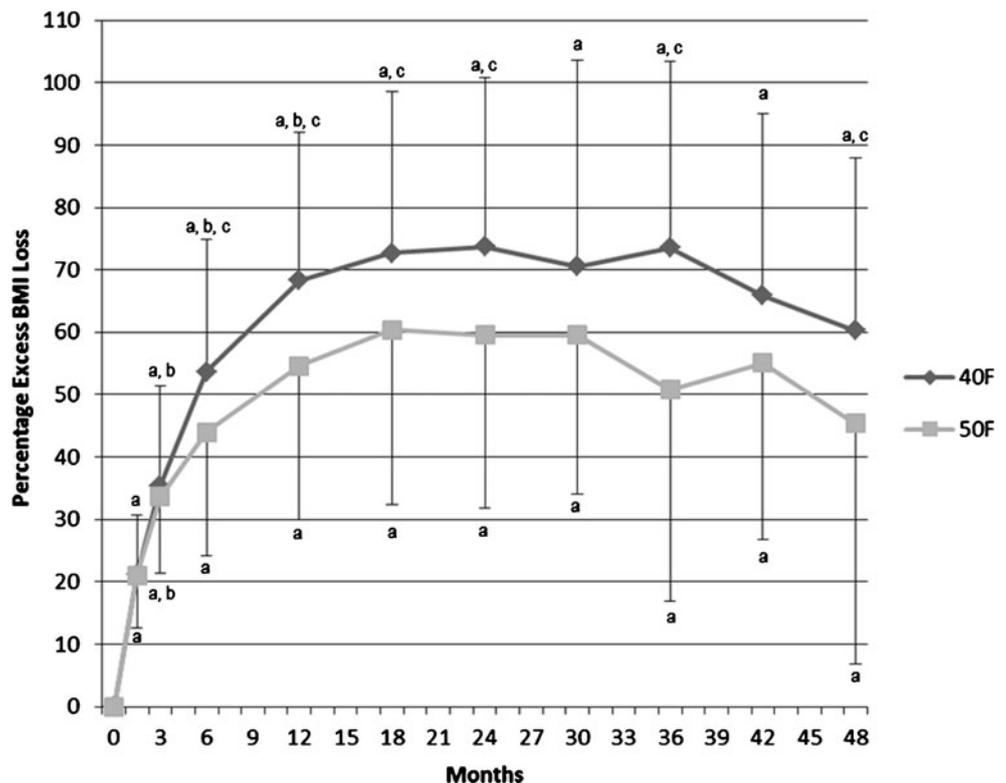


Table 2 Number (and percentage) of patients who underwent LSG with 40F or 50F bougie with obesity reduction data recorded at each follow-up time point

Months post-LSG	40F n (%) ^a	50F n (%)	All patients n (%)
0	185 (100%)	106 (100%)	291 (100%)
6	122 (65.9%)	73 (68.9%)	195 (67.0%)
12	138 (74.6%)	89 (84.0%)	227 (78.0%)
18	87 (47.0%)	66 (62.3%)	153 (52.6%)
24	85 (45.9%)	49 (46.2%)	134 (46.0%)
30	82 (44.3%)	33 (31.1%)	115 (39.5%)
36	67 (36.2%)	29 (27.4%)	96 (33.0%)
42	85 (45.9%)	31 (29.2%)	116 (39.9%)
48	43 (23.2%)	39 (36.8%)	82 (28.2%)

^a Percent of patients from baseline with obesity reduction data at each time point

proportion of patients experiencing co-morbidity resolution by the end of the 48-month observation period were observed between patients treated with the 40F or 50F bougie. However, although not reaching a statistical level, the proportion of patients who experienced resolution of dyslipidaemia, hypertension and type 2 diabetes was respectively 3.4, 2.0 and 1.6 times greater in the 40F group than for their 50F patient counterparts.

The results from the multivariate logistic regression modelling of co-morbidity resolution, controlling for the effects of age, gender, baseline BMI, insurance status and bougie size, are shown in Table 4. Age was significantly associated with dyslipidaemia resolution and approached statistical significance ($p=0.063$) with type 2 diabetes mellitus resolution. After adjusting for all factors, the likelihood of dyslipidaemia resolution by 4 years post-LSG were 19.0 times greater (95% CI=2.36, 152.20; $p=0.006$) in patients treated with the 40F bougie compared with the 50F bougie. The likelihood of hypertension and type 2 diabetes mellitus resolution by 4 years post-surgery were 3.6 times greater (95% CI=1.47, 8.63; $p=0.005$) and

Table 3 Post-surgical co-morbidity resolution of patients who underwent LSG with 40F or 50F bougie prior to 1 June 2007

Co-morbidities	Resolved		
	40F n (%) ^a	50F n (%)	All patients n (%)
Dyslipidaemia	10 (40.0)	3 (12.5)	13 (26.5)
Hypertension	34 (64.2)	14 (31.8)	48 (49.5)
Type 2 diabetes mellitus	27 (90.0)	14 (56.0)	41 (74.5)

^a Percent of patients with co-morbid condition at baseline

Table 4 Adjusted logistic regression of resolution of dyslipidaemia, hypertension and type 2 diabetes mellitus in the 4 years post-LSG surgery

Variable	OR	95% CI	<i>p</i> value
Dyslipidaemia			
Age	0.88	0.79, 0.99	0.038
Sex ^a	0.14	0.02, 1.17	0.070
Baseline BMI	0.93	0.76, 1.13	0.466
Private health insurance ^b	0.44	0.01, 17.7	0.664
Bougie ^c	18.96	2.36, 152.20	0.006
Hypertension			
Age	1.05	0.99, 1.11	0.104
Sex ^a	1.53	0.58, 4.01	0.388
Baseline BMI	1.04	0.98, 1.12	0.220
Private health insurance ^b	0.25	0.02, 2.60	0.248
Bougie ^c	3.56	1.47, 8.63	0.005
Type 2 diabetes mellitus			
Age	1.07	0.99, 1.16	0.063
Sex ^a	1.26	0.22, 7.28	0.800
Baseline BMI	1.10	0.97, 1.25	0.121
Bougie ^c	5.25	1.13, 24.31	0.034

^a Males compared with females as the reference category

^b Uninsured patients compared with insured patients (note—all three uninsured patients with diabetes experienced resolution)

^c 40F bougie compared with 50F bougie as the reference category

5.2 times greater (95% CI=1.13, 24.31; $p=0.034$) in patients treated with the 40F compared with a 50F bougie after controlling for other factors.

Complications

Table 5 presents the complications data. There were 24 patients (8.2%) who experienced a complication. One death (0.3%) was recorded which followed an attempt at laparotomy and drainage complicated by liver necrosis, due to hepatic artery injury, and multiple organ failure. The

Table 5 Number (and percentage) of complications experienced by patients who underwent LSG with 40F or 50F bougie

Selected complications	40F n (%)	50F n (%)	All patients ^a n (%)
Leak/gastric fistula	5 (2.7)	2 (1.9)	8 (2.7)
Infected perigastric haematoma	4 (2.2)	2 (1.9)	6 (2.0)
Intra-abdominal bleeding	6 (3.2)	3 (2.8)	10 (3.4)
Total	15 (8.1)	7 (6.7)	24 (8.2)

No significant differences between 40F and 50F bougie patients were seen for any type of surgical complication

^a Two patients without bougie size recorded experienced complications

most common complications were intra-abdominal bleeding ($n=10$, 3.4%), leak/gastric fistula ($n=8$, 2.7%) and infected perigastric haematoma ($n=6$, 2.0%). Of those treated with the 40F bougie, there were 15 complications (8.1% of 40F patients) compared with seven complications (6.6%) in the 50F bougie group. No significant differences were seen for any type of surgical complication. Two patients with a complication recorded did not have a bougie size recorded.

Discussion

This study is the first to directly compare obesity reduction and co-morbidity resolution between the 40F and the 50F bougie. Furthermore, this study has advantages over previous investigation of LSG due to its comparatively large sample size, 4-year follow-up period and control of the effects of sociodemographic variables and baseline obesity level on obesity reduction and co-morbidity resolution.

Obesity Reduction

Reduction in obesity level in the first 24 months post-LSG (68%EBMIL) in our study was comparable with previous investigation which reported %EBMIL of 65% and 71% by this time [13, 27]. One study which incorporated a 3-year follow-up of 53 patients reported %EBMIL to be 89% with a more restrictive 34F bougie [17]. In comparison, the 40F patients in our study ($n=185$) experienced 73%EBMIL by 3 years post-surgery, possibly indicating that further restriction will lead to a greater degree of obesity reduction.

Some weight regain was evident from 30 to 48 months post-LSG in our study, regardless of bougie size. It is possible that after the relative ease of losing weight in the first 18 months following surgery, patients fail to make the significant lifestyle changes required to sustain this lower weight [17]. There may also be a degree of gastric dilation which may contribute to reduced satiety and increased meal volumes in the years following LSG [2, 16, 17]. The period in which a weight loss plateau occurs provides a window in which a review of lifestyle, dietary, physical activity and other first-line therapies can be targeted to continue weight loss before significant regain occurs. Furthermore, this may represent a time where surgical revision may be considered as a viable option for patients with attenuating weight loss who still have not achieved their ideal weight [2, 14, 16, 28, 29].

Our study clearly demonstrates that superior obesity reduction is experienced by those patients treated with a 40F bougie compared with a 50F bougie. On average, a 14% greater EBMIL was achieved across the observation period by the more restrictive bougie. Additionally, after controlling for sociodemographic factors and baseline

obesity, which have been suggested to influence post-surgical obesity reduction [30, 31], the more restrictive 40F bougie was still significantly associated with greater %EBMIL, with a 15.5% difference in this measurement between the two groups. No previously published study investigating LSG has accounted for the possible modifying influences of these factors, and consequently this represents the most robust evaluation of obesity reduction following LSG undertaken to date. As such, these findings provide justification for the use of the more restrictive 40F bougie, compared with less restrictive procedures, as this does not increase surgical and post-operative complications. Anecdotal evidence from MBOSC suggests that a more restrictive 36-French bougie is also well tolerated. This study did not see any differences in the complications between groups, and the combined complications was 8.5% which compares favourably with the 12.1% complication fraction reported in a recent review of LSG [32]. However, this evaluation was affected by small event rates and future research employing a much larger sample size could address this issue definitively.

Co-morbidity

The crude results indicated large, but not significant, differences in co-morbidity resolution between the 40F and 50F bougie groups; however, once controlled for sociodemographic factors and baseline obesity level, the differences increase in magnitude and become statistically significant. It may be these factors which resulted in the initial non-significant findings, and as previously published studies have not controlled for these factors the benefits of LSG may have been underestimated.

Our findings clearly indicate that treatment with the more restrictive 40F bougie is associated with considerable increases in the likelihood of resolution for all three co-morbidities investigated after controlling for age, sex, baseline obesity and private health insurance. In fact, the likelihood of dyslipidaemia, hypertension and type 2 diabetes mellitus resolution were 19.0, 3.6 and 5.3 times greater, respectively, in those treated with the 40F bougie compared to those treated with the 50F. Furthermore, the statistically significant association between age and dyslipidaemia resolution suggests that younger patients benefit more from LSG in terms of blood lipids returning to a normal range, such that for every 10 years of age younger a patient is, the likelihood of resolution is increased by 22%.

Dyslipidaemia resolution in those treated with the 40F bougie here (42%) was much lower than the largest published sample ($n=126$ patients) investigating co-morbidity to date which reported a 73% resolution [12], but higher than the second largest study (6%) [2]. Hypertension resolution in the current investigation (65%)

was consistent with other published results (range 15–78%) [1, 2, 6, 8, 12, 16], while type 2 diabetes mellitus resolution in those patients treated with the 40F bougie here (90%) was greater than that reported in other studies with more than 10 patients affected by the condition (range 48–82%) [1, 2, 6, 9, 12, 16, 25]. Such variability in the proportion of patients experiencing co-morbidity resolution in the literature makes it difficult to compare these results with current evidence. However, as outlined above, previous investigation in this area has not controlled the modifying effects of potential confounding factors of the relationship with co-morbidity resolution which may explain the different findings given that such sociodemographic characteristics often vary widely between different populations.

One unexpected finding was that the proportion of patients with private health insurance was significantly lower in those treated with the 50F bougie compared with those treated with the 40F bougie. Further exploration determined this was not due to differences in socioeconomic status or systematic bias, suggesting there is another unknown factor involved which may warrant further investigation.

While representing one of the most robust evaluations of LSG due to the large sample size, length of post-surgical observation, comparison of bougie size and use of regression modelling to control for possible confounders, some limitations do exist with this study.

Arguably the largest limitation of this research is the use of some self-reported data. The last weight measure recorded was self-reported for 38.8% of the study sample. For those patients with a weight recorded at 48 months follow-up, 55.4% had self-reported this measure. It has been reported that self-reported weight is often underestimated [33]. An Australian study of mid-aged women (which describes the majority of patients in this study) found significant but small differences between self-reported and measured height and weight (0.65 cm and 0.96 kg) [34]. Furthermore, there was 84% agreement between BMI calculated from self-reported and measured height and weight which suggests it may be suitable in instances where direct measurement is not feasible [34]. To determine the suitability of the self-reported data, preliminary comparative analyses comparing self-report and LapBase data for all sociodemographic, obesity reduction and co-morbidity measures were conducted, and no significant differences were found between the two groups. In addition, all analyses presented in this paper were initially undertaken with and without the self-reported data, and inclusion of the additional data did not change the significance of any parameter estimate, and therefore it was considered appropriate to include the additional data in this study.

Another limitation of this paper is the degree of loss to follow-up; with only 82 (28.2%) of patients reaching 48 months follow-up, the results may be biased such that

those who are less successful are lost to follow-up as they may stop attending review appointments or decline study participation.

Finally, patients were not randomised to their treatment group. As a retrospective analysis of a clinical database, it was not possible to randomise treatment; however, the patient characteristics did not determine bougie size—this was determined by the timing of surgery. In June 2006, MBOSC switched from using the 50F to the 40F.

Recommendations

While the findings of the current study are encouraging in terms of %EBMIL and co-morbidity resolution in the longer term, given the attenuation in weight loss in the last year of observation, future research should attempt to study a larger sample over a longer period, without any reliance on self-report. In addition to this, research should attempt to determine the causes behind weight regain and establish whether a targeted first-line weight loss intervention at 24 months is effective at reducing regain by 48 months.

Conclusions

The results of this research demonstrate that patients treated with the more restrictive 40F bougie experienced a significantly greater reduction in obesity level (as determined by % EBMIL) and increased likelihood of resolution for dyslipidaemia, hypertension and type 2 diabetes mellitus in the 4 years following LSG than those treated with a 50F bougie. Although a trend to late weight regain is apparent by 4 years, the results for 40F LSG remain excellent, and none of the study patients has required resleeve. These results remain when controlling for factors that have previously been reported to influence weight loss over time.

Conflict of interest Catherine Jarman and Dr Leon Cohen received payment for the original treatment of these patients. All other authors report no conflict of interest.

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