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ORIGINAL CONTRIBUTIONS

Long-Term Outcomes of Three Types of Bariatric Surgery on Obesity and Type 2 Diabetes Control and Remission

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Abstract
Background Different bariatric surgeries have demonstrated different effectiveness for weight loss and glucose control in obese persons with diabetes, over a short follow-up time. The aim of this study was to compare weight loss, glucose control, and diabetes remission in individuals with type 2 diabetes, after three types of bariatric surgery: gastric banding (GB), sleeve gastrectomy (SG), and Roux-en-Y gastric bypass (RYGB), with 5 years follow-up.
Methods A retrospective study was conducted on bariatric surgeries performed during 2002–2011 in a large nationwide healthcare organization.
Results Of 2190 patients, 64.8 % were women. The operations performed were 1027 GB, 1023 SG, and 140 RYGB. Mean BMI ± SD at baseline, 1 year postoperatively, and 5 years postoperatively were 43.5 ± 6.18, 37.1 ± 6.35, and 35.5 ± 6.48 for GB; 43.6 ± 6.42, 34.4 ± 6.08, and 35.3 ± 6.7 for SG; and 42.8 ± 5.81, 32.8 ± 4.9, and 34.1 ± 5.09 for RYGB. Mean HbA1c ± SD at baseline, 1 year postoperatively, and 5 years postoperatively were 7.6 + 1.58, 6.5 + 1.22, and 6.8 + 1.48 for GB; 7.7 + 1.63, 6.4 + 1.18, and 6.7 + 1.57 for SG; and 8.0 + 1.78, 6.3 + 0.98, and 7.04 + 1.42 for RYGB. At 1 year follow-up, 53.2 % had achieved remission; at 5 years, 54.4 %. Remission rates at 5 years were similar for the three surgeries. Five-year remission was inversely associated with baseline HbA1c and with treatment with insulin at baseline and positively associated with BMI.
Conclusions For all three surgeries, diabetes remission was higher than the baseline after 5 years; mean BMI and HbA1c decreased considerably during the first year postoperatively and remained lower than basal values throughout follow-up. Early improvements were greatest for RYGB, though the advantage over the other operations diminished with time.

Keywords Bariatric surgery · Weight loss · Diabetes remission · Long-term follow-up

Introduction

About one in every seven persons in the world is obese, summing to over one half billion people [1]. About 347 million persons were estimated to have diabetes in the year 2008, which is more than double the number three decades before [2]. Despite the increases in obesity and diabetes, "diabetes remission" has emerged as a possibility, specifically in conjunction with bariatric surgery. The most recently issued guidelines of the American Diabetes Association include bariatric surgery as a treatment for adults with BMI >35 kg/m^2 and with type 2 diabetes, "especially if diabetes or associated comorbidities are difficult to control with lifestyle and pharmacological therapy" [3]. Two recently published meta-analyses, with more than 1 year [4] and more than 2 years follow-up [5], concluded that bariatric surgery is more effective than conventional medical therapy for weight loss and glucose control in obese persons with diabetes. A retrospective review of medical records in the USA and the Swedish Obese Subjects prospective study showed such benefit to persist at

The work was performed in Clalit Health Services in Israel.

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a median of 6 years and 17.6 years, respectively [6, 7]. However, outcomes by type of surgery were not analyzed in these studies.

Gastric banding (GB), Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy (SG) are the three main bariatric procedures that are currently performed in Israel. RYGB has shown substantial weight loss and improvement in glucose control in a number of observational studies of diabetic patients [8, 9] and better outcomes than lifestyle modification and/or medical therapy alone in randomized trials [10, 11]. Most studies that have compared types of bariatric surgery in obese individuals with diabetes have investigated outcomes between only two types of procedures.

We conducted an observational study based on electronic medical records from a large nationwide healthcare organization, to compare weight loss and improvement in glucose control in individuals with type 2 diabetes, after RYGB, GB, and SG, with 5 years follow-up.

Methods

This is a retrospective study based on the electronic medical records of Clalit Health Services (CHS), the largest healthcare organization in Israel, insuring and providing care to over four million Israeli citizens (53 % of the total population). Members of CHS with diabetes who underwent bariatric surgery during the years 1999–2011 were included in this study. Follow-up data were accessed until December 2014. Data from the electronic database of CHS included demographic characteristics: sex, age, marital status, and socioeconomic status (low, medium, high), according to affiliation to local CHS clinics, and baseline and follow-up values of clinical parameters, including weight, height, calculated BMI, fasting glucose, HbA1c, creatinine, systolic and diastolic blood pressure, total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides.

The criteria for the performance of bariatric surgery in CHS are BMI >40, or >35 kg/m^2 and at least one obesity-related risk factor. These are the same criteria issued by the US Department of Health and Human Services, National Institutes of Health, for bariatric surgery for severe obesity (http://www.niddk.nih.gov/health-information/health-topics/weight-control/bariatric-surgery-severe-obesity/Pages/bariatric-surgery-for-severe-obesity.aspx#a [accessed July 17, 2015]).

The main outcomes of this study were changes in BMI and in HbA1c and the achievement of diabetes remission, defined as HbA1c <6 %, without the use of a diabetes medication except metformin. This definition was used since at CHS we treat some prediabetic patients (HbA1c 5.7–6.4 %) with metformin, in line with the current ADA guidelines for Prevention or Delay of Type 2 Diabetes [12]. Outcomes were assessed at 1, 2, and 5 years postoperatively.

Rabin Medical Center Ethics Committee approved the study.

Statistical Analysis

A comparison between three groups of patients according to procedure (GB, SG, and RYGB) regarding demographic (age, gender, etc.) and clinical (lab results, BMI) parameters was performed using one-way analysis of variance (ANOVA) and chi-square test, as applicable. Whenever the ANOVA test was significant, pair-wise comparisons were performed using the Gabriel post hoc test.

Multivariate logistic regression models were applied to the data to study simultaneously the independent relationship between clinical factors and diabetes remission at 1, 2, and

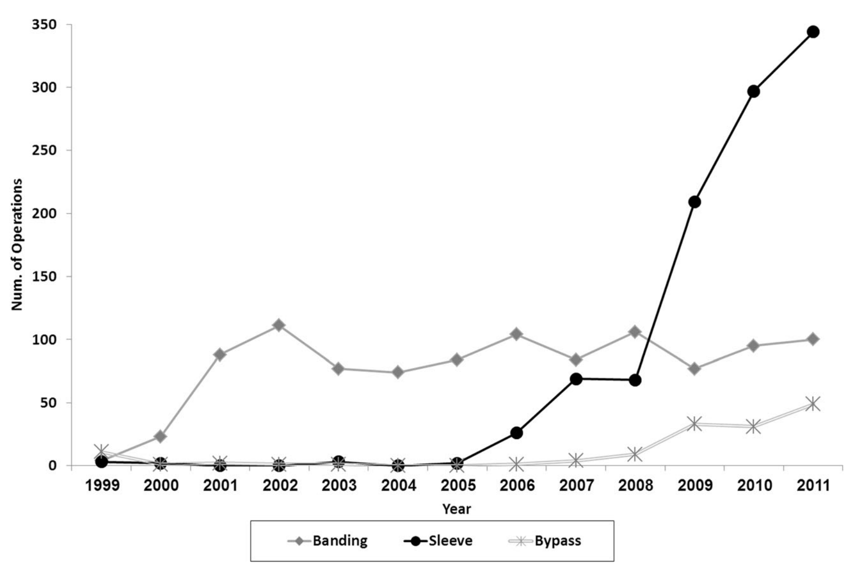


Fig. 1 Types of bariatric surgery performed during the study period. The numbers of banding, sleeve, and bypass operations performed during 1999–2011

5 years after surgery. These models predict the probability of remission as a function of the explanatory variables. The statistical significance level was set to 0.05 and the power analysis was set to 90 %. Statistical analysis was done by SPSS for Windows software, version 20.0 (Chicago, IL).

Results

A total of 13,425 members of CHS underwent bariatric surgery during the study period. Of them, 2190 (16 %) were with diabetes: 64.8 % women and 35.2 % men. The operations performed were 1027 GB, 1023 SG, and 140 RYGB (Fig. 1). Table 1 presents demographic and clinical characteristics of the patients at baseline according to type of surgery. A higher proportion of the men underwent SG and a higher proportion of the women underwent RYGB. Mean baseline HbA1c was higher for the RYGB group, and a higher proportion of these patients used insulin. For the three groups, 9 % of the patients were at remission from diabetes at baseline, indicating that they had been diagnosed with diabetes, but already met our study criteria for remission when they underwent

Table 1 Demographic and baseline clinical characteristics of individuals undergoing bariatric surgery, according to type of operation

Characteristic	All	Banding	Sleeve	Bypass	*p* value
N	2190	1027	1023	140	
Age (years)	47.1 ± 10.9	46.5 ± 10.8	47.7 ± 10.8	47.4 ± 9.5	0.030[a]
Gender (female)	64.8 %	67.9 %	61.0 %	70.7 %	0.002[a, c]
Married (yes)	71.1 %	70.6 %	71.7 %	70.7 %	0.841
Socioeconomic status					
Low	37.9 %	36.2 %	39.3 %	40.6 %	0.307
Medium	42.9 %	43.2 %	43.2 %	39.1 %	
High	19.1 %	20.6 %	17.5 %	20.3 %	
Body weight (kg)	119.7 ± 20.3	118.3 ± 20.2	121.0 ± 20.2	117.9 ± 20.3	0.015[a]
BMI	43.5 ± 6.3	43.5 ± 6.2	43.6 ± 6.4	42.4 ± 5.6	0.513
Blood pressure (systolic)	132.1 ± 15.1	133.0 ± 15.6	131.6 ± 14.8	132.1 ± 15.1	0.181
Blood pressure (diastolic)	79.2 ± 9.7	79.6 ± 10.4	79.0 ± 7.6	78.7 ± 7.6	0.331
Glucose (mg%)	154.1 ± 56.4	156.6 ± 56.2	150.8 ± 56.1	158.9 ± 59.9	0.221
HbA1c (%)	7.7 ± 1.6	7.6 ± 1.3	7.6 ± 1.6	8.0 ± 1.8	0.03[b, c]
Diabetes "in remission"	8.9 %	8.6 %	9.2 %	8.7 %	0.911
Creatinine (mg/dl)	0.77 ± 0.40	0.76 ± 0.33	0.78 ± 0.47	0.73 ± 0.20	0.210
Cholesterol—total (mg/dl)	186.1 ± 39.3	190.8 ± 39.2	182.6 ± 39.0	183.2 ± 39.7	<0.001[a, b]
Triglycerides (mg/dl)	203.9 ± 144.8	202.0 ± 139.4	206.9 ± 152.9	192.8 ± 108.3	0.467[a]
Cholesterol—LDL (mg/dl)	104.6 ± 32.8	107.1 ± 32.6	102.7 ± 33.2	102.9 ± 30.1	0.021
Cholesterol—HDL (mg/dl)	43.1 ± 10.7	43.9 ± 11.0	42.4 ± 10.5	43.5 ± 10.2	0.012[a]
Smoking (past or current)	34.6 %	27.5 %	42.3 %	30.0 %	<0.001[a, c]
Hypertension	59.4 %	54.1 %	64.0 %	64.3 %	<0.001[a, b]
Ischemic heart disease	6.7 %	4.6 %	8.1 %	11.4 %	0.002[a, b]
CVA	3.2 %	2.3 %	4.4 %	1.4 %	<0.001[a, b]
Peripheral vascular disease	3.2 %	3.1 %	3.1 %	3.6 %	0.333
Insulin treatment	21.0 %	16.0 %	24.9 %	29.4 %	<0.001[a, b]
Other anti-diabetes medications	69.6 %	68.2 %	70.6 %	72.7 %	0.345

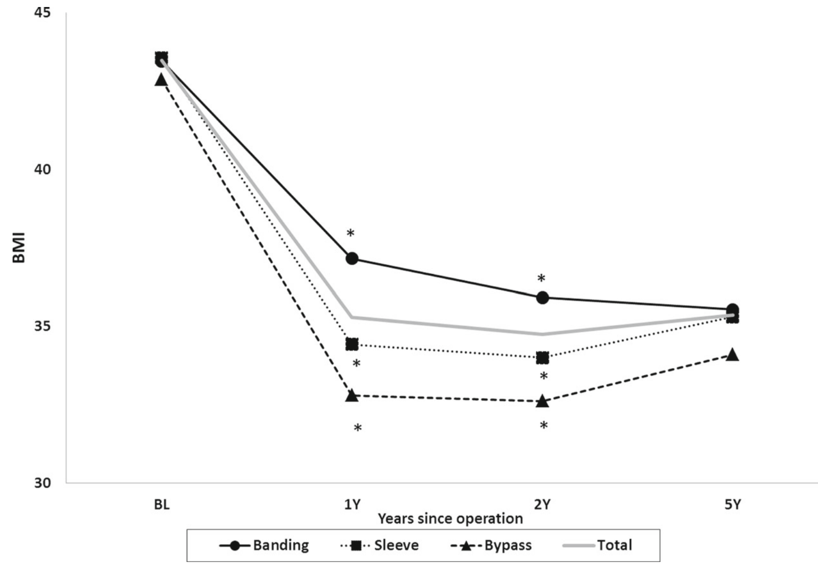
p values represent relationships among all three groups. Superscript letters designate statistically significant differences between group pairs

[a] Banding and sleeve

[b] Banding and bypass

[c] Sleeve and bypass

Fig. 2 Trends in BMI over time, according to procedure. BMI values at baseline (*BL*) and at 1, 2, and 5 years postoperatively (*1Y, 2Y, 5Y*). *At 1 year and at 2 years follow-up, all couples (banding vs. sleeve, banding vs. bypass, and sleeve vs. banding) are different at the level of $p < 0.001$



bariatric surgery. No secondary revisions or conversions were performed in 87.5 % of the patients who underwent GB and in 94 % of those who underwent SG.

Weight Reduction

During the first year postoperatively, mean BMI + SD at baseline, 1 year postoperatively, and 5 years postoperatively were 43.5 ± 6.18, 37.1 ± 6.35 (14.5 % weight loss from baseline weight [WL]), and 35.5 ± 6.48 (18.2 % WL) for GB; 43.6 ± 6.42, 34.4 ± 6.08 (21.0 % WL), and 35.3 ± 6.7 (19.0 % WL) for SG; and 42.8 ± 5.81, 32.8 ± 4.91 (23.5 % WL), and 34.1 ± 5.09 (20.5 % WL) for RYGB (Fig. 2). During the first year of follow-up, mean BMI decreased by 10.1, 9.2, and 6.3 units, for RYGB, SG, and GB, respectively. At 5 years follow-up, the mean decreases in BMI, from baseline, were more similar among the procedures: 8.8, 8.3, and 8.0, respectively.

Glucose Control

For the three procedures, a mean reduction of HbA1c of 1.0 % or more was maintained at all three time points. Mean HbA1c decreased by 2.0 % in the first year following RYGB, substantially and significantly more than following SG and GB ($p < 0.001$), and at 5 years was 1.4 % lower than the baseline mean (Fig. 3). The mean HbA1c decreased slightly more

Fig. 3 HbA1c change over time, according to procedure. Changes in HbA1c between baseline (*BL*) and 1 year (*1Y*) postoperatively, *BL* and *2Y*, and *BL* and *5Y* for banding, sleeve, and bypass surgeries. *Bypass is significantly different from banding and sleeve ($p < 0.001$)

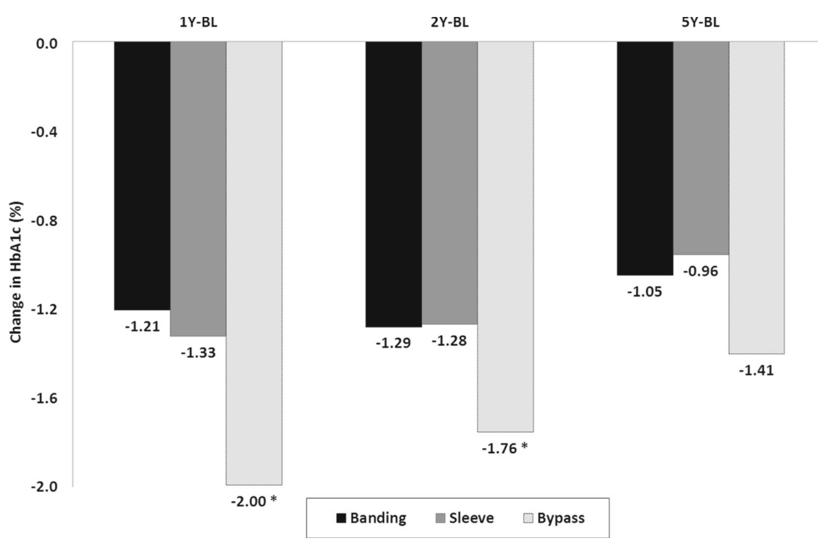


Table 2 Percentage of patients in diabetes remission (HbA1c < 6.0 %, with no diabetes medications or treated by metformin only)

Time	Total	Banding	Sleeve	Bypass	*p* value
BL	8.9 %	8.6 %	9.2 %	8.7 %	0.911
1Y	53.2 %	46.1 %	58.5 %	58.6 %	0.001[a]
2Y	60.6 %	57.5 %	63.0 %	64.4 %	0.05
5Y	54.4 %	55.6 %	53.6 %	51.1 %	0.60
Number of observations					
BL	1890	821	943	126	
1Y	1685	724	845	116	
2Y	1815	817	880	118	
5Y	1587	801	694	92	

p values represent relationships among all three groups. Statistically significant differences between group pairs are designated by a superscript letter

[a] Statistically significant differences between the banding and sleeve groups and between the banding and bypass groups

following SG than following GB (1.3 vs. 1.2 %) during the first year postoperatively; the difference in mean HbA1c reduction between SG and GB lessened during the subsequent 4 years. No statistically significant difference was observed among the procedures in HbA1c reduction after 5 years ($p = 0.098$).

Diabetes Remission

Considering all patients together, more than half were in diabetes remission at 1, 2, and 5 years follow-up (Table 2). At 1 year follow-up, remission rates were significantly higher for patients who underwent RYGB or SG, compared to GB. During the subsequent 4 years, rates of remission decreased for patients who underwent both RYGB and SG, and were equal for those who underwent GB, reaching similar rates for all the procedures.

Remission Prediction

In a multiple regression model (Table 3), SG and RYGB were associated with increased likelihood of diabetes remission at the three follow-up points, though the advantage over GB was not statistically significant at 5 years. Older age, higher baseline HbA1c, and treatment with insulin or with other diabetes medications at baseline were associated with decreased likelihood of diabetes remission at all follow-up points. Female gender was associated with lower likelihood of remission, which was only statistically significant in the first year. Higher baseline BMI was associated with diabetes remission.

Conclusions

The main findings of this large observational study of diabetic patients are the following: (1) the greatest reductions in BMI and HbA1c occurred during the first year following bariatric surgery; at 5 years post-operatively, improvements were attenuated, though still significantly below baseline. (2) Compared to SG and GB, RYGB showed a greater reduction in BMI during the first and second years, but this difference was diminished by 5 years follow-up. (3) Compared to SG and GB, RYGB showed a greater reduction in HbA1c, which lessened but persisted during the 5 years follow-up. (4) Diabetes remission was greater following RYGB and SG at the first year of follow-up but equal to that of GB at 5 years follow-up. (5) Older age, higher baseline HbA1c, and baseline insulin use predicted lower diabetes remission rates.

Over the long duration of this observational study, the distribution of operations changed greatly. Altogether, rates of RYGB, SG, and GB were 6, 47, and 47 %, respectively. During the same period, the distribution of operations among individuals without diabetes was 4, 32, and 64 %, respectively. The low rate of RYGB reflects the fact that it has been performed in Israel in considerable

Table 3 Logistic regression model for patients in diabetes remission (HbA1c < 6.0 %, with no diabetes medications or metformin only). Each follow-up point (1, 2, and 5 years) was calculated separately, with remission following band surgery considered as the reference value

	1 year	2 years	5 years
Banding	1	1	1
Sleeve	2.41 (1.80–3.22)	1.82 (1.38–2.40)	1.26 (0.95–1.68)
Bypass	4.41 (2.38–8.18)	3.17 (1.77–5.67)	1.75 (0.95–3.21)
Treated with insulin at baseline	0.34 (0.23–0.49)	0.52 (0.37–0.73)	0.66 (0.46–0.93)
Treated with other diabetes medications at baseline	0.12 (0.08–0.17)	0.14 (0.10–0.19)	0.17 (0.12–0.24)
Age (for each year)	0.95 (0.94–0.96)	0.96 (0.95–0.97)	0.97 (0.96–0.98)
Gender (female vs. male)	0.73 (0.55–0.97)	0.80 (0.60–1.05)	0.84 (0.63–1.12)
Baseline HbA_1c (for each 1 %)	0.60 (0.54–0.67)	0.66 (0.60–0.72)	0.70 (0.63–0.77)
Baseline BMI (for each 1 unit)	1.01 (0.99–1.04)	1.03 (1.01–1.06)	1.04 (1.02–1.06)

numbers only from 2009. Thus, the proportion of operations available for long-term analysis was even lower. Rates of GB remained constant throughout the study period and rates of SG increased dramatically since 2006. Similarly, an email questionnaire distributed in 2011 by the International Federation for the Surgery of Obesity and Metabolic Disorders revealed a substantial rise in the prevalence of SG during 2003–2013, making it the most frequently performed procedure in the USA, Canada, and Asia and second to RYGB in Europe and South America [13].

We showed that reduction in BMI was greater following RYGB than SG or GB during the first and second years postoperatively. A large meta-analysis [14], as well as more recent observational studies [6, 15], showed greater weight loss to be associated with more improved glucose control.

RYGB showed a greater mean reduction in HbA1c than did the other surgeries, which may be partially explained by the higher mean baseline HbA1c level of the RYGB group. This finding is in line with the prospective STAMPEDE study that showed RYGB to be more effective than SG in achieving HbA1c goals at 3 years postoperatively [16], and with small single-center observational studies that reported greater improvement in glucose control in obese patients with diabetes, following bypass and SG, compared to banding surgery, with up to 3 years follow-up [17, 18]. In contrast, a Spanish observational study showed similar rates of remission for the two procedures [15].

Nevertheless, the large magnitude of reduction in HbA1c levels following RYGB supports the notion that RYGB may have a role other than weight loss in improving glucose control. Examples of such effects include increases in peptide YY (PYY) and glucagon-like peptide-1 (GLP-1) [19–21], reduction in the hunger-stimulating hormone ghrelin [22], increased insulin sensitivity and enhanced β-cell function [23, 24], the enhancement of an alternative insulin-independent pathway for glucose transport [25], and increases in the regulation of glucose transporter-1, in basolateral glucose uptake, and in aerobic glycolysis, due to the exposure of the Roux limb to undigested nutrients [26]. In addition, the notion of microbiota alteration after RYGB has become an important explanation for these effects [27].

A multiple regression analysis that controlled for several demographic and clinical characteristics showed RYGB and SG to predict diabetes remission, compared to GB, though the advantage was not statistically significant at 5 years. Similarly, two large meta-analyses showed greater diabetes resolution following bypass than banding procedures [14, 28]. One of these analyses showed that diabetes resolution was also greater following bypass procedures than following sleeve gastrectomy [28]. The long-term positive results for GB in the current study, compared to other reports, may be due, at least in part, to the regular follow-up regime at some of our centers. The band was first adjusted 4–6 weeks after surgery and then five more times every 3 weeks, with the aim of reducing weight by 0.5–1 kg a week. Subsequent visits were scheduled at 6-month intervals.

Older age, higher baseline HbA1c, and insulin use were associated with lower rates of diabetes remission. Others have reported higher baseline HbA1c and insulin treatment at baseline to be associated with lower rates of diabetes remission [15, 29, 30]. We also found female gender to be negatively associated with remission during the first year postoperatively. Considering the poorer profile of our RYGB patients, characterized by a higher mean baseline HbA1c and a higher proportion of women and of insulin users at baseline, the achievement of a similar rate of remission suggests that RYGB may be more beneficial than other procedures for patients with diabetes. Hence, our study highlights the importance of considering patient characteristics in any study of bariatric surgery. The association of older age, higher baseline HbA1c, and the use of insulin and other diabetic medications with lower rates of diabetes remission stresses the importance of earlier bariatric surgery and suggests that a staging system and prediction models may contribute to decision-making about bariatric surgery procedures in diabetic patients.

Strengths of the current study are the large number of diabetes patients, the comparison of three rather than two procedures, and the 5 years follow-up including data for more than 70 % of the patients. Most studies that compared outcomes of types of bariatric surgery did not relate to the diabetes state of their patients. Differences that have been reported between those with and without diabetes support the separate analysis of outcomes on diabetes.

As an observational study, this research has a number of limitations. We did not assess and compare complications of the different bariatric procedures. We assessed BMI but not waist circumference, though the latter is considered a more relevant measure of adiposity for glucose control.

In conclusion, our study demonstrated weight loss and improvement in glucose control and diabetes remission following three types of bariatric surgeries, attenuated but still substantial after 5 years. A recent report that diabetes remission after RYGB and SG may be associated with distinct glycemic profiles suggests that different procedures may be more suited to different patients [31]. The present study showed greater weight reduction and improved glucose control following RYGB than SG or GB, and a higher likelihood of diabetes remission following RYGB or SG than GB. However, the attenuation of the advantage of RYGB during 5 years follow-up highlights the importance of long-term studies for comparing outcomes of bariatric procedures on diabetes disease and its complications.

Compliance with Ethical Standards Since all data were obtained from medical records and no identifying information was included in any of the study documentations, informed consent from patients was not required.

All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of Interest The authors declare that they have no competing interests.

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