ORIGINAL CONTRIBUTIONS



# **Outcomes of One Anastomosis Gastric Bypass in 472 Diabetic Patients**

Osama Taha $^{1,2}\cdot$  Mahmoud Abdelaal $^1$ <br/> $\bigcirc$   $\cdot$  Mohamed Abozeid $^3\cdot$  Awny Askalany $^1\cdot$  Mohamed Alaa $^2$ 

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#### Abstract

*Background* The positive impact of Roux-en-Y gastric bypass (RYGB) on metabolic syndrome and glycemic control has been proven in obese patients. One anastomosis gastric bypass (OAGB) is a simple, effective and easy to learn procedure. OAGB provides encouraging results for the treatment of diabetes obese patients, but does it have the ability to be an alternative procedure to RYGB in the treatment of these patients? The aim of this study is to evaluate the outcomes of OAGB on diabetic obese patients at the bariatric centre of our university hospital. By extension, we evaluated the possibility of BMI and the preoperative antidiabetic medication usage to be predictive factors for postoperative diabetes resolution.

*Methods* This is a retrospective single-centre study of 472 diabetic patients who underwent OAGB from November

Mahmoud Abdelaal Mahmoud.abdel-aal@ucdconnect.ie; mahmoudplastic84@gmail.com

> Osama Taha dr.osamataha@overweightegypt.com

Mohamed Abozeid abouzeid2000@hotmail.com

Awny Askalany awnyplastic@yahoo.com

Mohamed Alaa info@overweightegypt.com

- <sup>1</sup> Plastic and Obesity Surgery Department, Assiut University Hospital, Assiut, Egypt
- <sup>2</sup> Overweight Clinics, Cairo, Egypt
- <sup>3</sup> General Surgery Department, Ain Shams University hospital, Cairo, Egypt

2009 to December 2015. All patients were followed-up for at least 1 year, and up to 3 years, where available. Weight, HbA1c, and anti-diabetic medications were recorded at baseline, 3, 6, 12, 24 and 36 months.

*Results* A total of 472 patients have been followed-up for 1 year and 361 for 3 years. The mean BMI decreased from  $46.8 \pm 7.2$  to  $29.5 \pm 2.8$  kg/m<sup>2</sup> and HbA1c from  $9.6 \pm 1.3$  to  $5.7 \pm 1.5\%$  at the 12-month follow-up. At the 3-year follow-up, the mean BMI was  $32.1 \pm 3.3$  and HbA1c mean was  $5.8 \pm 0.9\%$ . Diabetes remission was achieved by 84.1% of patients.

*Conclusions* OAGB can be an excellent alternative to RYGB for the treatment of diabetes and obesity. Pre-operative medications may be used to predict postoperative diabetes remission, but not BMI.

**Keywords** Diabetes mellitus · One anastomosis gastric bypass · And obesity

## Introduction

Morbid obesity and its associated comorbidities including type 2 diabetes mellitus (T2DM) are increasing at alarming rates [1]. T2DM affects more than 312 million people worldwide and about 80% of the diagnosed cases are obese [2]. The term 'diabesity' describes the overlap between T2DM and obesity [3]. The risk of developing T2DM increases progressively with increased body mass index (BMI). In fact, in people with BMI >27 kg/m<sup>2</sup>, the risk of developing T2DM increases by 20% for every 1 kg/m<sup>2</sup> increase in the BMI [4].

Despite the marked advances in the treatment interventions of T2DM, less than 50% of patients achieve the therapeutic goal of a glycated haemoglobin (HbA1c) <7% [5]. Patients with uncontrolled diabetes are at higher risk of developing

microvascular and macrovascular complications such as myocardial infarction, ischemic stroke, blindness, neuropathy, and end-stage renal disease [6, 7]. Although approximately 80% of patients diagnosed with diabetes are obese, only 20–30% of them seek metabolic surgery [8, 9].

Metabolic surgery is the most effective treatment for clinically severe obesity (BMI > 35 kg/m<sup>2</sup>) and its associated comorbidities such as T2DM [10, 11]. Metabolic surgery differs conceptually from bariatric surgery as the latter aims to improve body weight as the primary objective and improvement in comorbidities as the secondary objective. On the other hand, metabolic surgery aims to improve glycaemic control in obese patients with weight loss being a helpful 'side effect'. Thus metabolic surgery is now considered a new treatment modality for T2DM in patients with BMI <35 kg/m<sup>2</sup> [12, 13]. Several randomised trials have previously demonstrated that metabolic surgery is superior to non-surgical interventions for the control of hyperglycaemia in T2DM patients [14, 15].

The postoperative improvement of the metabolic milieu such as remission of diabetes is attributed to weight lossdependent and independent mechanisms. Gastric bypass results in greater remission rates of diabetes when compared to adjustable gastric banding (AGB) or vertical sleeve gastrectomy (VSG), even if similar postoperative weight loss is achieved [16].

Although Roux-en-Y gastric bypass (RYGB) is accepted as the gold standard procedure of metabolic surgery, it is associated with high complication rates particularly with unexperienced surgeons [2, 17]. One anastomosis gastric bypass (OAGB) is a simple, easy, and reversible procedure with fewer complication rate and equal or even potentially better efficacy for the treatment of obesity and T2DM than RYGB [18–21]. The short- and long-term follow-up outcomes of the OAGB showed impressive diabetic remission rates even in patients with lower BMI [22, 23]. Therefore, the aim of this study is to evaluate the outcome of OAGB on diabetic obese patients at the bariatric centre of our university hospital. By extension, we evaluate the possibility of BMI and the preoperative antidiabetic medication usage to be predictive factors for postoperative diabetes resolution.

## Material and Methods

Between November 2009 and December 2015, a total of 1520 obese patients underwent OAGB in our bariatric unit; 683 of those patients were diabetic. Out of those patients, 472 (349 women) patients were applicable for this study and had at least 1-year follow-up (465 patients were T2DM and 7 patients were T1DM). All patients were preoperatively evaluated by a multidisciplinary and integrated medical team. Pre- and postsurgical management were conducted by the bariatric

surgery team. The inclusion criteria were based on the recommendations of the National Institutes of Health Consensus Development Panel, created in 1991 [24]. Patients with Barrett's oesophagus and severe gastroesophageal reflux disease (GERD) were a contraindication to OAGB and thus shifted to receive an RYGB instead.

**Data Collection and Management** Clinical evaluation forms were used for the collection of demographic and clinic data. The data sources included office and hospital charts, interviews with patients, physicians' reports, follow-up notes and telephone contacts. All data were entred into a computer database that was maintained prospectively.

Preoperative Evaluation Patients were evaluated by history and physical examination. The surgical details, risks, benefits and consequences of the OAGB procedure and its effect on DM were discussed in details during the initial meeting of the patient with the surgeon, dietician and diabetologist. Laboratory assessments included complete blood count, prothrombin concentration, random blood sugar, liver function test, renal function test, thyroid function, glycated haemoglobin (HbA1c) and serology for viral hepatitis or HIV. Patients with HbA1c >6.5% were referred to the diabetology department for a medical management of DM and to assess any associated secondary complications. These patients were followed-up until a preoperative satisfactory level of HbA1c was achieved. Written informed consents were obtained from all patients before being scheduled for the surgery.

Operative Technique The five-port technique which was previously described by Rutledge was used [25]. A long and narrow gastric tube calibrated with a 36-French bougie was created, starting by one horizontal gastrointestinal anastomosing (GIA) stapler loaded with cartridges (4.8 mm staples) at the level of the crow's foot, then three to four vertical 60-mm GIA upward to the angle of His. There was no need for reinforcement of the staple lines with continuous sutures in the majority of patients. Then, antecolic end to side anastomosis between the gastric pouch and jejunum using a posterior 30mm roticulator endo-GIA stapler and an anterior hand suture at a distance 150-300 cm distal to the ligament of Treitz based on the BMI of the patient was performed. Intraoperative methylene blue test for leak was performed in all patients. In the majority of cases, abdominal drain was inserted and no nasogastric tube was needed.

**Postoperative Care** Only water was allowed on the evening of the surgery and patients were informed about the importance of early (2–4 h) postoperative ambulation. Patients had to follow a clear fluid diet for 10 days postoperatively followed by a slow introduction of semi-solid food. By the

Table 1Preoperative demographics presented by mean  $\pm$  SD

Variable	OAGB $(n = 472)$
Age (years)	42 ± 16.6
Gender (female/male)	349/123
Weight (kg)	$125.8\pm24.8$
BMI (kg/m <sup>2</sup> )	$46.8\pm7.2$
HbA1c (%)	$9.6\pm1.3$
Duration of surgery (minutes)	$38 \pm 12.1$
Hospital stay (days)	1.1 ± 1.9

postoperative week 4, solid food was allowed. At discharge, all patients received detailed dietary instruction sheets and were instructed to take daily multivitamins, supplemental minerals and proton pump inhibitor (PPI) prophylaxis for at least 6 months. Follow-up appointments were scheduled at 2 weeks postoperatively then monthly for the first year, increasing every 3 months thereafter.

**Diagnosing Criteria of DM and Definition of Diabetes Remission** The preoperative diagnosis of type 2 diabetes mellitus (T2DM) in the current series was based on the criteria of the American Diabetes Association [26] after adding the HbA1c by the International Expert Committee [26, 27]. The preoperative T1DM defined as the inability to achieve glycaemic control with non-insulin therapies and random C-peptide level <0.6 nmol/l or fasting C-peptide level <0.25 nmol/l [28]. Complete remission of DM was defined as HbA1c <6.0% without anti-diabetic medication for 1 year. Partial remission was defined as HbA1c <6.5% for at least 1 year without antidiabetes medications. Improved disease was defined as HbA1c <7.0% for at least 1 year. These definitions were based on the ADA criteria for DM remissions [29].

## **Statistical Analysis**

Data are presented as mean  $\pm$  SD or as percentages when appropriate. The continuous data through the first year follow-up were compared to the baseline data by paired *t* test and compared to the 3-year follow-up data by unpaired *t* test after using Levene's test to assess the equality of variance. Statistical significance was set at *p* values <0.05. All data were analysed using SPSS version 15.0 for Windows (SPSS Inc., Chicago, IL, USA).

# Results

Preoperative demographics and patient characteristics are shown in Table 1. The mean age of the study subjects was  $42.5 \pm 16.6$  years. The mean preoperative weight was  $125.8 \pm 24.8$  kg, BMI was  $46.8 \pm 7.2$  kg/m<sup>2</sup> and the preoperative HbA1c was  $9.6 \pm 1.3\%$  (Table 1).

Regarding the preoperative diabetes medications, 43 (9.1%) patients had a stable HbA1c (around 6.5%) without receiving any treatment, 154 (32.6%) received one oral hypoglycemic drug, 146 (30.9%) received two, 29 (6.1%) received three different types of oral drugs and 100 (21.9%) required insulin to stabilise their HbA1c in the normal range. All patients were followed up for 1 year, but only 361 of them were applicable for 3 years of follow-up.

Complications All patients underwent laparoscopic OAGB with no mortality and the overall complication rate was 6.8%. Six (1.3%) patients presented with abdominal bleeding requiring blood transfusions. In five of these patients, the bleeding was related to the trocar insertion site, and all cases were managed conservatively. One patient developed gastrointestinal bleeding; this patient was managed by a secondary surgical intervention to control the source of bleeding, which was the short gastric vessel near the His angle. Jejunal perforation occurred in one patient (0.2%), and this was discovered and sutured intraoperatively. A late revision was required in one patient who presented with >100% excess weight loss (EWL). Interactable reflux was presented by five (1.1%) patients, four of them were treated by PPI, but surgical interference in the form of Braun anastomosis (jejunojejunostomy at 80 cm distal to the gastrojejunostomy) was needed for the fifth patient. The most common complication was iron deficiency anaemia, presented by 18 (3.8%) patients. Symptomatic anastomotic ulcers unrelated to the administration of antiinflammatory drugs also occurred in one patient (0.2%), who was treated with PPI.

Weight Loss At 3 months postoperative, weight decreased from  $125.8 \pm 24.8$  to  $106 \pm 14.7$  kg,  $91 \pm 10.9$  kg at 6 months,

Table 2Weight, BMI andHbA1c pre- and post-OAGBpresented by mean  $\pm$  SD

	Preoperative	3 months	6 months	12 months	24 months	36 months
Weight (Kg)	$125.8\pm24.8$	$106\pm14.7^{a}$	$91\pm10.9^{a}$	$79.3\pm9.1$	$82.6\pm9.7$	$84\pm9.8$
BMI(Kg/m <sup>2</sup> )	$46.8\pm7.2$	$40\pm 6.1^{a}$	$34.7\pm5.2$	$29.5\pm2.8$	$31.7\pm3.1$	$32.1\pm3.3$
HbA1c (%)	$9.6\pm1.3$	$6.8\pm1.2^{a}$	$6.7\pm1.4$	$5.7\pm1.5$	$5.6\pm1.1$	$5.8\pm0.9$

Each p value was calculated by paired t test. We compared each value with just before follow-up values <sup>a</sup> Statistical significance after surgery

Fig. 1 Reduction in BMI after surgery over 3 years (mean  $\pm$  SD)



 $79.3 \pm 9.1$  kg at 1 year and  $84 \pm 9.8$  kg in patients who followed up for 3 years. Also, the BMI mean was  $40 \pm 6.1$ ,  $34.7 \pm 5.2$ ,  $29.5 \pm 2.8$  and  $32.1 \pm 3.3$  kg/m<sup>2</sup> at 3, 6, 12 and 36 months, respectively (Table 2) (Fig. 1).

In the current study, at the 1-year follow-up, weight and BMI decreased on average by 36.9% (p < 0.01). There was a mild elevation of weight and BMI at the 3-year follow-up when compared to the 1-year follow-up data. However, comparing the 3-year follow-up data to the baseline data showed a significant reduction by average 33.3% (p < 0.01) (Fig. 1 and Table 2).

**Diabetes Remission** Up to 1 year, a total of 472 patients have been followed-up. Out of those patients, only 361 were followed-up up to 3 years. HbA1c decreased to  $5.7 \pm 1.5\%$ after 1 year and to  $5.8 \pm 0.9\%$  after 3 years (Table 2 and Fig. 2). Complete diabetes remission was achieved by 397/ 472 (84.1%) patients. Thirty-seven (7.8%) patients achieved partial remission, and 33 (7%) patients had moderate improvements (Fig. 3). No improvement was encountered in five patients (Fig. 3). At the 3-year follow-up, diabetes remission was achieved by 328/361 (90.9%) patients (Table 3).

Remission of diabetes achievement at 1-year follow-up in the current series was significantly higher in patients who were receiving oral hypoglycaemic drugs before surgery than in those who were receiving an injection treatment (p < 0.01). Remission was 92.2% (142/154) in patients who were receiving a single oral hypoglycaemic drug preoperatively. In patients treated with a bi-therapy, the remission rate was 95.2% (139/146) and 72.4% (21/29) in patients who were on three oral hypoglycaemic drugs. Diabetic patients who were discovered accidentally during the preoperative assessments showed 100% (43/43) complete diabetic remission. Patients who received preoperative insulin injection to control DM showed 52% (52/100) remission rate (Table 4).

The 472 patients were divided into 3 groups according to BMI: group 1 BMI < 35 kg/m<sup>2</sup> (n = 68), group 2 BMI 35–45 kg/m<sup>2</sup> (n = 284) and group 3 BMI > 45 kg/m<sup>2</sup>. The diabetes remission rates were 76.5, 91.5 and 94.2% for patients of groups 1, 2 and 3, respectively. The mean postoperative









□ Complete Remission □ Partial Remission □ Improved disease ■ No Improvement

changes in HbA1c were  $-3.7 \pm 2.1\%$  for group 1,  $-3.6 \pm 1.2\%$ for group 2 and  $-3.5 \pm 1.9\%$  for group 3. No significant difference was detected in comparing the HbA1c changes between groups (p = 0.94) (Fig. 4). Patients of all groups showed a rapid reduction in HbA1c, which was apparent at the 3month follow-up (Fig. 2). Although there was less prediction of diabetic remission in patients with lower BMI, no significant difference in the percentage of remission between patients with BMI <35 kg/m<sup>2</sup>(76.5%) vs patients with BMI >35 kg/m<sup>2</sup> (92.3%) (p = 0.06).

In the current study, seven patients were presented preoperatively with type 1 DM. Although all hypotheses have reported no beneficial role of metabolic surgeries in type 1 diabetes mellitus (T1DM) [30–32]; in the current study, two out of these seven patients achieved diabetic remission at 1-year follow-up. One of them was 32 years old, BMI was 39.7 kg/ m<sup>2</sup> and his preoperative HbA1c was 11.6% on insulin. Six months after the surgery, his HbA1c was 7.1%, his insulin dosage was decreased and complete remission was noted at 1-year postoperatively when his HbA1c was 5.8%. The HbA1c of the other patient decreased continuously; the values were 10.3, 7.9, and 6%, at preoperative, 6 months, and 1 year after the surgery, respectively.

Table 3 Effect of OAGB on diabetes mellitus

	Number of patients	Percent
Complete remission	397/472	84.1
Partial remission	37/472	7.8
Improved disease	33/472	7
No improvement	5/472	1.1
Three-year remission	328/361	90.9

#### Discussion

The positive impact of metabolic surgery such as RYGB or biliopancreatic diversion (BPD) on metabolic syndrome and glycaemic control has been reported in obese patients [33, 34]. The mechanism of this glycemic control was thought to be weight loss independent because it occurs immediately even before any weight loss occurs [35-37]. T2DM remission after gastric bypass surgery can be a result of several possible mechanisms: increased secretion of glucagon-like peptide 1 (GLP-1) and PYY hormones, decreased ghrelin hormone production and decrease in insulin resistance through weight loss are among the strongest hypotheses [38, 39]. Early exposure to nutrients in the ileum stimulates L-cells to secrete GLP-1, which has anti-diabetogenic and strong insulinotropic effect. During hyperglycaemia, GLP-1 improves insulin sensitivity, decreases glucagon secretion, increases insulin secretion, delays gastric emptying and reduces appetite [40, 41].

Although RYGB is approved as a gold standard treatment for T2DM in obese and non-obese patients, approaching it laparoscopically still remains a challenge and still requires a long learning period with high complication rates particularly when performed by less experienced surgeons [10, 42–46]. Since Rutledge presented the OAGB procedure in the USA in 1997, ten thousands of OAGB have been performed with highly promising results [47]. Lee et al.'s studies demonstrated that OAGB is as effective as RYGB in reducing weight, if not more effective. Also, it is associated with less operative duration, shorter learning curve and fewer major complications [2, 19, 23, 48, 49]. At the presentation of OAGB, it was received with scepticism because of possible complications such as biliary reflux, which is associated with the 'old Mason's loop gastric bypass' [50]. The published data over the last 16 years demonstrated a significantly low incidence of bile reflux being associated with OAGB [51].

**Table 4** Diabetes remission ratesaccording to the preoperativemanagement of DM

Preoperative treatment of DM	No. of DM remission	Percentage of DM remission	
No drugs	43/43	100%	
Single oral drug	142/154	92.2%	
Two oral drugs	139/146	95.2%	
Three oral drugs	21/29	72.4%	
Injection	52/100	52%	

A large number of studies reported the beneficial impact of RYGB on diabetes remission. In a study by Cohen et al. 2012, the T2DM resolution was 88% for patients who underwent RYGB at 3 years of follow-up [52]. Similarly, the diabetic remission rate was 93% in patients who underwent RYGB in Navarrete et al.'s study [53]. VSG appears less effective than gastric bypass in glycaemic control but still shows good results in terms of diabetes remission. This is apparent in multiple studies; in a study by Gill et al., diabetes remission was 66.2% [54]. Therefore, in our current series, diabetes remission of 90.9% at 3 years of follow-up (328/361) appears to be an encouraging result.

The overall results of our current study revealed a diabetic remission rate of 84.1%, a decrease in HbA1c mean from 9.6 to 5.7% in the 1-year follow-up, no mortality and acceptable complication rates (overall morbidity rate was 6.8%). These results are complementary to the results of the largest OAGB published studies as shown in Table 5 [2, 55–58]. Although OAGB had a better glycaemic control than RYGB and VSG, we need to be careful about micronutrient malnutrition such as iron deficiency as a long-term disadvantage. In our study, iron deficiency anaemia was presented by 18 (3.8%) patients, which is comparable to that seen in other OAGB series reports [2, 19, 23], but a little higher than VSG [59] or RYGB series [60].

Some authors postulate that diabetes is a single disease, rather than two distinct entities, type 1 and type 2 diabetes. They argue that the two types of diabetes are distinguished only by the rate of  $\beta$ -cell loss. Proponents of the previous hypothesis claim that the rise in childhood obesity parallels the rise in both types of diabetes in childhood and that the decreasing age of onset of type 1 diabetes in heavier children lends further support to their argument [61–63]. On the other hand, there is a significant inconsistency regarding the effect of bariatric surgery on HbA1C in T1DM patients. Most authors have reported a non-significant improvement or even worsening of HbA1C, claiming that poor preoperative glycaemic control may have accounted for the apparent improvement demonstrated by others [31, 64–66]. Brethauer et al. and Middelbeek et al. found a significant reduction in HbA1C after surgery [67, 68].

There were two forms of T1DM are identified; type 1A results from a cell-mediated autoimmune attack on  $\beta$ -cells [69, 70], whereas type 1B has no known cause and associated with variable degrees of insulin deficiency between sporadic episodes of ketoacidosis [71, 72]. Pathogenesis of T1DM characterised by continuous damage of  $\beta$ -cells which leads to progressive loss of insulin secretion capacity with, in order, loss of first-phase insulin secretion in response to an intravenous glucose tolerance test, then to clinical diabetes when insulin secretion falls below a critical amount and finally, in most but not all T1DM patients, to a state of absolute insulin deficiency [72, 73].

Although talking about the relationship between OAGB and T1DM remission may initiate a lot of criticism, we had two T1DM patients have achieved





### Table 5 Data presented in mean

Study	Number	Mortality %	Initial BMI	Final BMI	% DM remission
Current study	472	0	46.8	32.1	84.1
Lee et al. [2]	1163	0.2	41.4	27.7	93
Darabi et al. [56]	20	0	49.5	33.4	50
Musella et al. [55]	974	0.2	48	28	86
Kular et al. [57]	1054	0.2	43.2	25.9	93
Guenzi et al. [58]	81	0	47	30.3	87.6

BMI body mass index, DM diabetes mellitus

remission at 1-year follow-up after surgery. We have no clear explanation, but the previous hypothesis which demonstrated that not all T1DM patients have an absolute absent of insulin secretion may explain the remission in these two patients in our study. Nevertheless, the misdiagnoses of those two cases of T1DM is still highly possible. Moreover, both patients underwent the surgery in 2015 and they were applicable only for the 1-year follow-up; further investigation, and continuation of the follow-up of these patients will be performed. Future prospective and large subjective trials about the impact of bariatric surgery on type 1 DM should be performed.

Preoperative weight, BMI, sex, age, DM duration and hypoglycaemic drugs act as predictive factors for the postbariatric DM remission [16, 43, 74-76]. The complete DM remission is remarkable after OAGB, which is comparable or even superior to RYGB but is still less than BPD [10, 20, 77-79]. Maintenance of weight loss over time after OAGB could lead to better long-term DM remission than that obtained with RYGB [10, 75, 80-82]. Some studies showed a link between the preoperative BMI and postoperative DM resolution with better remission rates at higher BMI [10, 74]. Although increased remission rates in patients with higher BMI were observed in this study, we could not confirm it as a predictive factor since there was no significant difference in DM remission rates between different BMI groups (76.5% in patients with BMI < 35 kg/m<sup>2</sup>, 91.5% for 35–45 kg/m<sup>2</sup> group and 94.2% in patients with BMI > 45 kg/m<sup>2</sup>). These results support the results of the previously published studies that demonstrate a link between BMI and DM remission remains controversial [58, 83].

In our study, remission of diabetes at 1-year follow-up was significantly higher in patients that were receiving oral hypoglycaemic drugs before surgery than in those who were receiving an injection treatment (p < 0.01) (Table 4). These results were comparable with the published data reporting that insulin usage is a poor predictor for resolution of DM, and easy preoperative glycaemic control (diet and monotherapy) is associated with high remission rates [23, 43, 75, 76, 84].

The main limitations of our study were the dropout of patients at follow-up assessment and a predictable loss of some data. A significant effort was put in place to reduce the follow-up loss; however, it was proved difficult as many patients were travelling from different cities and overseas.

## Conclusion

OAGB is a simple, safe, effective, easy to learn and easy to reverse procedure. It has acceptable complications and mortality rates. Therefore, OAGB has the ability to be an excellent alternative to RYGB in the treatment of diabetic obese patients. BMI could not be used for the prediction of postoperative diabetic remission, but preoperative medication is a good predictive factor. Longer follow-up for diabetic remission is needed. Future prospective and large subjective trials about the impact of bariatric surgery on type 1 DM should be performed.

#### **Compliance with Ethical Standards**

**Conflict of Interest** The authors declare that they have no conflicts of interest.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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

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