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ORIGINAL CONTRIBUTIONS

Predictors of Short-Term Diabetes Remission After Laparoscopic Roux-en-Y Gastric Bypass

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Abstract
Purpose A remission of type 2 diabetes mellitus (T2DM) is one of the major goals of the contemporary bariatric surgery. The goal of our study is to identify predictors of short-term postoperative diabetes remission in order to facilitate preoperative patient selection.
Materials and Methods Two hundred forty-five obese (body mass index (BMI) ≥35 kg/m2) T2DM subjects who underwent laparoscopic Roux-en-Y gastric bypass (RYGB) were followed up to 1 year after bariatric surgery. Diabetes remission was defined as hemoglobin A1c (HbA1c) ≤6 % and fasting blood glucose (FBG) <100 mg/dl in absence of all diabetic medications.
Results Twenty-six percent of the patients seen in f/u achieved complete remission at 1 year. Average Hba1c decreased from 8 to 6.7 % and 6.4 % after 6 and 12 months, respectively. Regression analysis showed that age (p=0.01), number of diabetes complications (p=0.03), family history of diabetes (p=0.04), preoperative use of insulin (p=0.04), and peri- and postoperative weight loss (p=0.05, for both) were the best preoperative predictors of diabetes remission at 6 and 12 months (R^2=0.3).
Conclusion Younger patients, with fewer diabetic complications, no family history of diabetes, not using insulin, and with greater peri- and postoperative weight loss were the best candidates to achieve a rapid diabetes remission after RYGB.

Keywords RYGB · Type 2 diabetes mellitus · Obesity · Diabetes remission

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Introduction

The high failure rate of medical treatment, along with the rising prevalence and life-threatening complications from both obesity and diabetes [1–5], has led to the wide use of bariatric surgery [6]. The therapeutic superiority of bariatric surgery over medical therapy has been demonstrated in multiple randomized control trials [7–9] and clinical studies [10]. Data from a meta-analysis of 621 studies showed that 78 % of diabetic patients had complete resolution and 62 % remained in remission more than 2 years after operation [11]. From these observations, the International Federation of Diabetes announced support for the surgical treatment of diabetes in obese patients [12].

However, not every patient has remission of diabetes after surgery, and some patients show recurrence at a later date that may or may not correlate with weight regain [13–15]. Several factors have been previously reported to be associated with treatment failure, and other factors have been indicated as good predictors of diabetes remission [16–22]. There are certain limitations in many of these studies, particularly inadequate sample size and short follow-up.

The main objective of this study is to identify simple and clinical presurgical predictors of diabetes remission after laparoscopic Roux-en-Y gastric bypass (RYGB) in a cohort of 245 patients with 12-month follow-up.

Methods

Study Design

We performed a prospective study in 245 obese patients with type 2 diabetes mellitus (T2DM) and body mass index (BMI) ≥35 kg/m^2 who underwent RYGB from 2010 to 2013. The diagnosis of T2DM was established by the primary care physician, the endocrinologist, or the staff at the University Bariatric Center during the preoperative process using the current American Diabetes Association (ADA) guidelines. Surgical procedures and perioperative management were performed according to the protocols and guidelines of the American Association of Metabolic and Bariatric Surgery (ASMBS) and Society American Gastrointestinal Endoscopic Surgeons (SAGES) [23, 24]. All patients had met the National Institutes of Health criteria for bariatric surgery. All surgical procedures were performed at the University Hospital Center of Excellence for Bariatric Surgery, by the same bariatric surgeon (NFDLCM). Data was collected from medical records from 2010 to 2013. Patients were followed up after bariatric surgery through scheduled postoperative follow-up visits with the bariatric surgeon (NFDLCM) and/or with the endocrinologist (GI). Each patient signed an informed consent form. The institutional review board of the university approved the study (IRB No.: MOD00000856).

Data Collection

At baseline, we collected preoperative information from the electronic medical records including patient's gender, age, initial body weight, initial BMI, duration of T2DM, presence of family history of DM, daily insulin amount, fasting blood glucose, and hemoglobin A1c levels. Diabetes complications were evaluated and defined as macrovascular complications (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy). Perioperatively, we collected their body weight value during the timeframe from 1 week prior to surgery until 3 weeks after surgery (whichever value was available and lowest.) We then calculated their perioperative weight loss by subtracting perioperative weight from baseline weight in kilograms. Postoperatively, we obtained data of hemoglobin A1c (HbA1c), fasting blood glucose (FBG), body weight, BMI, and diabetic medication status during their follow-up office visit at approximately 6 and 12 months after surgery.

Definition for Diabetes Remission

Diabetes remission was defined HbA1c ≤6 % and FBG <100 mg/dl in absence of all diabetic medications, as per ADA [25].

Preoperative Meal Replacement

During the 14 day preoperative period, all patients were placed on Optifast, which is a liquid diet with very low calorie count ranging from 800 to 1200 cal per day. Previous studies have reported an average weight loss of approximately 11 kg (1.5–2.0 % of body weight/week) over 12 weeks of presurgical treatment with the Optifast diet [26]. The benefits of weight loss before surgery include a reduced risk of complications during surgery, shorter hospital stays, and increased weight loss during the first year following surgery [27].

In- and Outpatient Diabetes Care

During their hospital stay after surgery, patients' finger stick glucose was monitored every 6 h and treated, as needed, with subcutaneous fast acting insulin either by standard or individualized sliding scale protocols. Upon discharge, patients were instructed to monitor home finger stick glucose regularly and to follow up with their primary care physician or endocrinologist to make further adjustments of their discharge diabetes regimen.

Statistical Analysis

Univariate regression analysis between baseline Hba1c and study parameters was performed in overall patients.

ANOVA tests were used to compare the changes in study parameters postoperatively. Independent variables showing $p<0.1$ in the simple regression analysis were included in models of multiple regression analysis to evaluate the best predictor(s) of HbA1c ≤6 % after bariatric surgery. Only patients who followed up at 1 year (n=206) were included in the ANOVA and multiple regression analyses. $p<0.05$ was considered statistically significant. All clinical data were analyzed using SalSTAT2.

Results

Preoperative Patient Characteristics

Patients' baseline characteristics are summarized in Table 1. The average preoperative HbA1c was around 8.0 %. Eighty-one (33 %) out of the enrolled 245 patients were on insulin prior to undergo surgery. The majority (90 %) of the enrolled patients was taking at least one antidiabetic medication, 60 % of them were taking two antidiabetic medications, and 40 % were on three antidiabetic drugs.

Table 1 Postoperative changes

	Pre-op	Post-op 6 month	Post-op 12 month	*p*
Age	51±12			
Male (%)	35 %			
Weight (−kg)	125±29	102±24	92±22	<0.01
BMI (kg/m^2)	45.2±8.9	37.5±8	33.5±6	<0.01
Duration DM (years)	11.5±8			
Daily insulin (units)	30±47	6.8±16	4±10	<0.001
FH of DM (%)	50 %			
HbA1c (%)	8.0±1.8	6.7±1.6	6.4±1.2	<0.01
FBG (mg/dl)	159±63	122±43	109±21	<0.01

BMI body mass index, *DM* diabetes mellitus, *FH* family history of diabetes, *HbA1c* hemoglobin A1c, *FBG* fasting blood glucose

Postoperative Follow-up

Two hundred six patients completed the 1-year follow-up, whereas 16 % of the patients were lost in follow-up and did not return at either 6-month or 1-year follow-up visit.

Postoperative Changes

Twenty-six percent of the patients seen in follow-up achieved complete diabetes remission at 1 year. Main postoperative changes are summarized in Table 2. Average Hba1c decreased to 6.7 and 6.4 % after 6 and 12 months, respectively (Fig. 1). Patients' daily insulin requirement reduced drastically ($p<0.001$) just 6 months after the surgery, as shown in Fig. 2. The average weight loss during the perioperative period was around 8 kg (range from 2.2 to 14 kg). Postoperative weight loss at 6 months and 1 year was 24±4 and 34±3.2 kg, respectively.

Predictors of Diabetes Remission

Independent variables showing $p<0.1$ in the univariate regression analysis were included in a model of multiple regression analysis to evaluate the best predictor(s) of HbA1c ≤6 % at 12 months, chosen as dependent variable (Table 2). Age, diabetes complications, family history of diabetes, presurgical insulin requirement, and perioperative and postoperative weight loss were the best preoperative predictors of HbA1c ≤6 % at 12 months. Basically, similar results were obtained when HbA1c ≤6 % at 6 months was considered as dependent variable.

Table 2 Univariate and multivariate correlates of HbA1c ≤6 % 1 year after RYGB

Univariate		Multivariate R^2=0.3	
		β coeff	*p*
Age	r=0.54, p<0.01	2.2	0.02
BMI	r=0.20, p=0.08	0.2	0.21
Complications	r=0.51, p<0.01	2.1	0.03
Family history	r=0.49, p<0.01	1.8	0.04
Duration of diabetes	r=0.31, p=0.05	0.6	0.09
Peri-op weight loss	r=0.37, p<0.05	0.6	0.05
Post-op weight loss	r=0.36, p<0.05	0.6	0.05
Pre-op insulin	r=0.40, p<0.05	1.1	0.04

HbA1c hemoglobin A1c, *Peri-op* perioperative weight loss, *Post-op weight loss* postoperative weight loss at 1 year, *Pre-op insulin* preoperative daily insulin requirement, *Coeff* coefficient

Discussion

A remission of T2DM is one of the major goals of the contemporary bariatric surgery. Our study provides helpful and novel information to identify the best candidates to achieve this goal.

In this large study, we found that age, number of diabetes complications, family history of diabetes, preoperative insulin treatment, and peri- and postoperative weight loss were the best preoperative predictors of short-term diabetes remission. Interestingly, a rapid reduction in Hba1c, such as 6 months after the surgery, was also well predicted by these preoperative factors. The relatively low rate (26 %) of diabetes resolution in

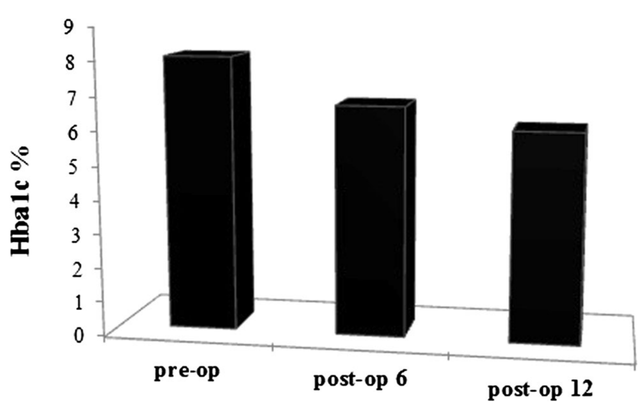

Fig. 1 Six and 12 months post-operatively HbA1c trend. Hemoglobin A1c (*HbA1c*), laparoscopic Roux-en-Y gastric bypass (RYGB), preoperatively (*pre-op*), 6 months postoperatively (*post-op 6*), 12 months postoperatively (*post-op 12*)

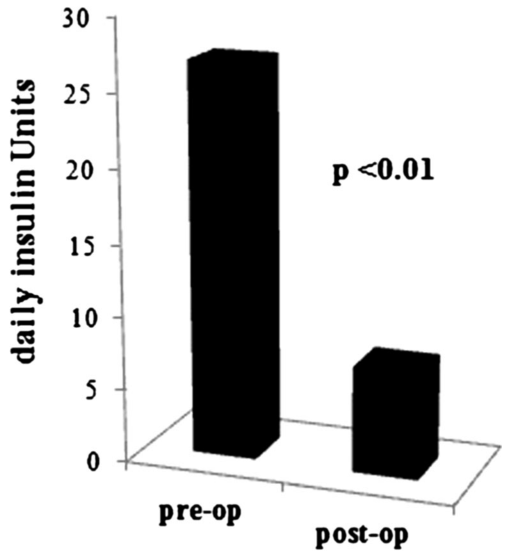

Fig. 2 Insulin requirement changes 6 months after RYGB. Patients' daily insulin requirement reduced drastically (p<0.001) 6 months after the surgery

our study could be explained by the strict criteria to define the remission.

Younger age has been consistently recognized as an independent predictor of postoperative DM remission. Dixon and O'Brien found older age to be a predictor of inferior weight loss after LAGB [28]. Sugerman et al. observed that younger patients had better glycemic control after RYGB [29]. Hamza et al. reported each additional 12 years of age reduced the chance of T2DM remission by 20 % in both LAGB and RYGB [19]. Our study results are consistent with these previous observations, supporting the fact that age is the most significant preoperative predictor of diabetes remission.

Other surrogate factors estimating the severity of preoperative T2DM, including disease duration, number of diabetes complications, and requirement for insulin treatment have been previously identified as significant predictors of T2DM remission after bariatric surgery in some, but not all, studies. Blackstone et al. reported that the remission rates were greater for patients not taking insulin preoperatively [53.8 versus 13.5 %, p<0.001] and for patients with a more recent preoperative T2DM diagnosis [8.9 versus 3.7 years, p<0.001] after RYGB [30]. Dixon et al. found two of three important independent predictors with clinical useful cutoffs which are associated with T2DM severity: DM duration <4 years and fasting C-peptide concentration >2.9 ng/ml [31]. Robert M et al. reported that a short duration of diabetes and good preoperative glycemic control increase the rate of T2DM remission 1 year after surgery [20]. Jurowich et al. in his study concluded that age, preoperative insulin, and oral antidiabetic medication can be regarded as independent, significant predictors for metabolic outcome after bariatric surgery [21]. However, there are no univocal data in the literature. In fact, Hamza's group found that neither the T2DM duration nor the type of preoperative diabetic therapy had significant influence on T2DM remission after surgery [19].

Our study suggests that the occurrence and number of diabetes complications is crucial in predicting a postoperative diabetes remission. Although the role of the diabetes complication was previously suggested, this is the first time that objective data are provided in a large sample size.

Of great interest, we showed that family history of T2DM can play an important role in predicting a diabetes resolution. To our knowledge, no or few studies attributed this role to the family history of diabetes. Genetic, metabolic, and environmental factors can explain why a negative family history of T2DM increases the chances of post-bariatric surgery diabetes resolution.

Our results showed and confirmed a correlation between perioperative weight loss and DM remission. Previous studies have shown that %EWL (percentage of estimated weight loss) is associated with major increase in insulin sensitivity and improvement in pancreatic b cell functions [16, 32, 33]. Perioperative weight loss was also predictive of DM remission although not until several years after the bariatric procedure [7, 16, 19, 29, 34, 35]. The effect of perioperative weight loss in favoring a resolution of diabetes is very likely due to the combination of the perioperative meal replacement therapy and an overall improved diabetes care. The Optifast diet has been shown to cause weight loss prior to surgery, reduce insulin requirement, and improve the surgical outcomes [27, 28]. Moreover, the beneficial role of the perioperative weight loss can be attributed to the effect of the Optifast diet on the intra-organ fat accumulation, such as on the intra-hepatic fat accumulation. The influence and importance of preoperative changes in body fat compartment and visceral fat loss in achieving diabetes resolution will warrant future studies.

Interestingly, we also found that weight loss 1 year after surgery was a good predictor of diabetes remission at 1 year.

Remarkably and consistently with Still et al. [22], we found presurgical insulin treatment as a predictor of diabetes remission at 1 year. This finding suggests that those patients who were not using insulin or were on a low daily insulin requirement were the best candidates for a diabetes remission at 1 year.

Differently by most of the previous studies, we did not find that duration of diabetes had a major impact on the likelihood of remission, although it was significantly related to the Hba1c in the univariate regression analysis. It is plausible that the lack of statistical significance in predicting diabetes remission at 1 year could be due to the skewed distribution of this parameter. However, we do recognize the importance of an earlier intervention to increase the likelihood of diabetes remission, as previously reported [20–31, 36].

There are strength and limitations in our study. We have relative larger sample size compared to other published studies. We looked at short-term postoperative changes. Also, the fact that it is a single-center study with all bariatric procedures performed by one same surgeon may potentially avoid bias induced from different surgical protocols adopted by multiple centers and variable operational experience in bariatric surgery performed by different surgeons.

On the other hand, our study has important limitations. The durability and long-term safety profile of our results remain uncertain. However, our protocol supports continued recruitment and follow-up of eligible patients in the prospective part of the study with expanded data collection including C-peptide, fasting insulin levels, and waist and hip circumference. Such effort should allow additional assessment of long-term efficacy and safety results as well as identification of novel clinical important predictors such as C-peptide, which was recently reported as a potential preoperative predictor of diabetes outcome after gastric bypass surgery [37]. We did not compare outcomes among different types of bariatric procedures. The ultimate goal of our study was to facilitate preoperative patient selection in order to achieve a short-term diabetes remission after RYGB, recognized as the most effective metabolic bariatric surgery procedure [38–40].

Conclusion

In conclusion, our study showed that younger patients, with lower presence of complications, not using insulin, with no family history of T2DM and greater peri- and postoperative weight loss were the best candidates to achieve a HbA1c <6 % after RYGB.

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Conflict of Interest The authors declare that there are no conflicts of interest.

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

Statement of Human and Animal Rights This study has been approved by the Institutional Review Board (IRB) of the University of the Miami (IRB No.: MOD00000856) 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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