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ORIGINAL CONTRIBUTIONS

Metabolic Surgery: Roux-en-Y Gastric Bypass and Variables Associated with Diabetes Remission in Patients with BMI <35

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Abstract Metabolic results of bariatric surgery have determined an expansion of its traditional indications, being increasingly performed in non-severely obese patients, especially in type 2 diabetes mellitus (T2DM). Our aim is to determine the effectiveness of laparoscopic Roux-en-Y gastric bypass (LRYGB) in T2DM remission in patients with body mass index (BMI) below 35 kg/m^2 and the variables associated with T2DM remission after surgery. Retrospective analysis of diabetic patients with BMI <35 kg/m^2 who underwent LRYGB in our center between 2002 and 2010 was done. We analyzed patient's demographics, comorbidities, BMI, excess weight loss percentage (EWLp), complications, and metabolic results at 3 years. Univariate and multivariate analyses were performed to determine variables associated with T2DM remission. One hundred patients were included. Sixty patients (60 %) were women; median age was 48 years old (interquartile range (IQR) 42–54), and median preoperative BMI was 32.7 kg/m^2 (IQR 31.6–34.1). Median preoperative duration of T2DM was 4 years (IQR 2–7), with 49, 30, 2, and 18 % on treatment with one, two, and three hypoglycemic agents and insulin, respectively. Ninety-four percent achieved 36-month follow-up, and at this time, median EWLp was 93 % (IQR 67–121). A total of 53.2, 9.6, 25.5, and 11.7 % achieved a T2DM complete remission, partial remission, improvement, and no improvement, respectively. T2DM remission only was associated with non-insulin use in multivariate analysis, with an OR=15.1 (2.8–81.2) and p=0.002. LRYGB is a reliable and effective treatment in diabetic patients with a BMI <35 kg/m^2 at 3 years. T2DM remission's best results are observed in non-insulin diabetic patients.

Keywords Metabolic surgery · Gastric bypass · Diabetes mellitus · Obesity

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Introduction

Diabetes is a pandemic and one of the most frequent chronic diseases, with an increasing prevalence worldwide [1]. The relationship between obesity and type 2 diabetes mellitus (T2DM) is a known issue [2], with an important rate of T2DM resolution after bariatric surgery in morbidly obese patients, as reported by previous studies [3–8].

The impact on the resolution of comorbidities like T2DM after bariatric surgery besides weight loss has led to the increasing use of the term "metabolic surgery." The improvement of glucose homeostasis observed before weight loss occurs has drawn attention and has determined an expansion of the traditional indications for bariatric surgery to a lower weight group of patients. Although there is still no definitive

consensus among surgeons regarding its indications, the concept of metabolic surgery has gained acceptance, and the international work group guidelines are beginning to include non-severely obese patients in their recommendations for bariatric and metabolic surgery [9–11]. Nevertheless, little evidence exists on metabolic mid or long-term results in this group of patients [8] and the variables that can influence the remission of diabetes after surgery.

The aim of this retrospective study is to determine the effectiveness of laparoscopic Roux-en-Y gastric bypass (LRYGB) in T2DM remission in patients with a body mass index (BMI) below 35 kg/m^2 and the variables associated with T2DM remission after surgery.

Material and Methods

Retrospective analysis of the electronic database of the Bariatric Surgery Program at the Clinical Hospital of the Pontificia Universidad Católica de Chile between July 2002 and November 2010 was done.

We included all T2DM patients with BMI <35 kg/m^2 who were submitted to LRYGB as a primary bariatric procedure during this period. Database was complemented by electronic medical records, laboratory test results, and a standardized telephone survey regarding medication use during follow-up. Patients who were contacted by telephone were also encouraged to attend to a new medical control where anthropometric measures and laboratory results were updated. No anthropometric measures or laboratory results were asked by telephone. Patients with previous bariatric procedures, type 1 diabetes mellitus, latent autoimmune diabetes of adults, and pregnancy during follow-up were excluded from the analysis. Written informed consent was obtained in all patients.

Metabolic Definitions

Diagnosis and classification of T2DM were performed according to the criteria established by the American Diabetes Association (ADA) [12]. T2DM remission used in this study was based on the 2012 ADA standards of medical care in diabetes recommendations [12]. *T2DM complete remission* was defined as glycated hemoglobin (HbA1c) <6 %, fasting plasma glucose (FPG) <100 mg/dL, and no medication required; *T2DM partial remission* was defined as HbA1c <6.5 %, FPG <126 mg/dL, and no medication required; *TD2M improvement* was defined as HbA1c <7 % and no more medication than the preoperative period; and *TD2M no improvement* was defined as HbA1c >7 % or use of more medication than the preoperative period. Diagnosis of prior comorbidities was according to specific criteria: Fatty liver disease was defined according to the criteria of the American Association for the Study of Liver Diseases (AASLD) [13]. Arterial hypertension was defined by the World Health Organization (WHO) criteria. Dyslipidemia was defined according to ATP III criteria for diabetic patients (LDL-C ≥100, triglycerides ≥150, HDL-C <50). Hypothyroidism was defined according to the American Association of Clinical Endocrinologists. Obstructive sleep apnea was diagnosed by polysomnography, and depression was defined using DSM-IV criteria.

Data Analysis

Data analyzed included patient's demographics, comorbidities, preoperative and postoperative body mass index (BMI), excess weight loss percentage (EWLp), perioperative results, complications, and metabolic results at third postoperative year.

Also, we performed univariate and multivariate analyses in order to determine variables associated with successful T2DM remission (complete or partial remission) at third postoperative year.

Surgical Technique

The patient is placed in a supine position, the abdominal cavity is accessed under direct vision using an optical trocar (ENDOPATH Xcel Bladeless Trocar, Ethicon Endo-Surgery, Cincinnati, OH, USA), and carbon dioxide pneumoperitoneum is maintained at 15 mmHg. LRYGB is performed with a five-trocar technique. A 10- to 15-cc gastric pouch is created with a complete stapled transection of the stomach, leaving a 150-cm antecolic, antegastric alimentary limb and a 50-cm biliary limb. Gastrojejunostomy is performed with a hand-

Table 1 Postoperative complications of diabetic patients with BMI <35 kg/m^2 submitted to LRYGB

	Number of patients *N*=14	Percentage	Clavien-Dindo classification [14]
Early complications			
Upper GI bleeding	1	1	III
Abdominal wall hematoma	2	2	I
G-J anastomosis stenosis	2	2	III
Unrecognized enterotomy	1	1	IIIb
Coronary angina	1	1	II
Total	7	7	
Late complications			
G-J anastomosis stenosis	5	5	III
Small bowel obstruction	1	1	II
Omental torsion	1	1	II
Total	7	7	

LRYGB laparoscopic Roux-en-Y gastric bypass, *BMI* body mass index, *GI* gastrointestinal, *G-J* gastro-jejunal

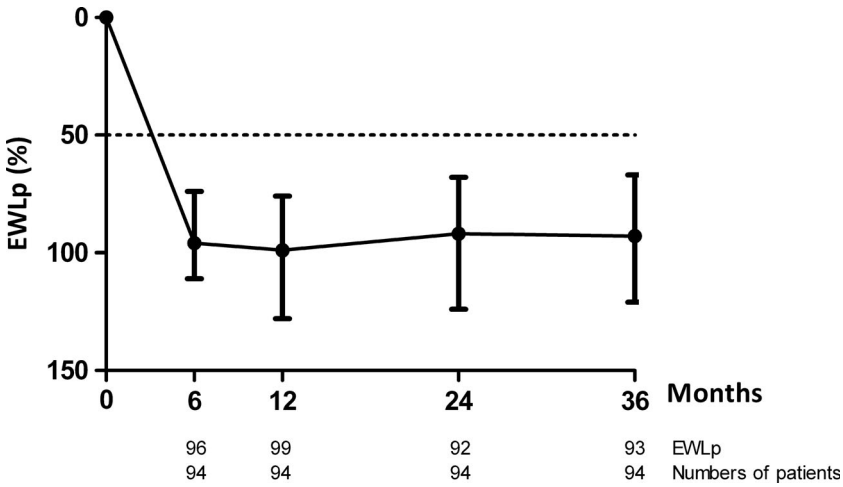

Fig. 1 EWLp progression at 3-year follow-up of diabetic patients with BMI <35 kg/m^2 submitted to LRYGB. *EWLp* excess weight loss percentage, *LRYGB* laparoscopic Roux-en-Y gastric bypass, *BMI* body mass index

sewn double-layer technique and calibrated with a 34-F bougie. Enteroenterostomy is performed with a latero-lateral stapled technique, closing the anterior defect with a hand-sewn single layer using absorbable suture. All mesenteric defects are closed with non-absorbable suture.

Statistical Analysis

Statistical analysis was performed with the Statistical Package for the Social Sciences, version 21.0 (SPSS, Inc., Chicago, IL). Results are reported as median with their ranges or interquartile ranges (IQR).

For univariate analysis of the variables associated with T2DM remission, Student's *t* test was used for numerical parametric variables, Mann-Whitney *U* test for numerical non-parametric variables, and Pearson's chi-square for categorical variables. Later, numerical variables were transformed in new categorical variables for the logistic regression model, setting cutoff values using ROC curves. For multivariate analysis, statistically significant variables previously obtained were included in the model. A p value <0.05 was considered statistically significant.

Results

During this period, 401 patients with BMI <35 were submitted to a LRYGB in our institution. Of these, 100 patients were diabetic and therefore included in this study. Sixty patients (60 %) were women; median age was 48 years old (IQR 42–54), and median preoperative BMI was 32.7 kg/m^2 (IQR 31.6–34.1).

T2DM was diagnosed at a median of 4 years (IQR 2–7) before surgery, with 49 patients (49 %) on treatment with one hypoglycemic agent, 30 patients (30 %) with two hypoglycemic agents, 2 patients (2 %) with three hypoglycemic agents, and 18 patients (18 %) with insulin. In regard to metabolic status, median preoperative HbA1C was 7.3 % (IQR 6.5–8.1), and median preoperative FPG was 125 mg/dL (IQR 105–154).

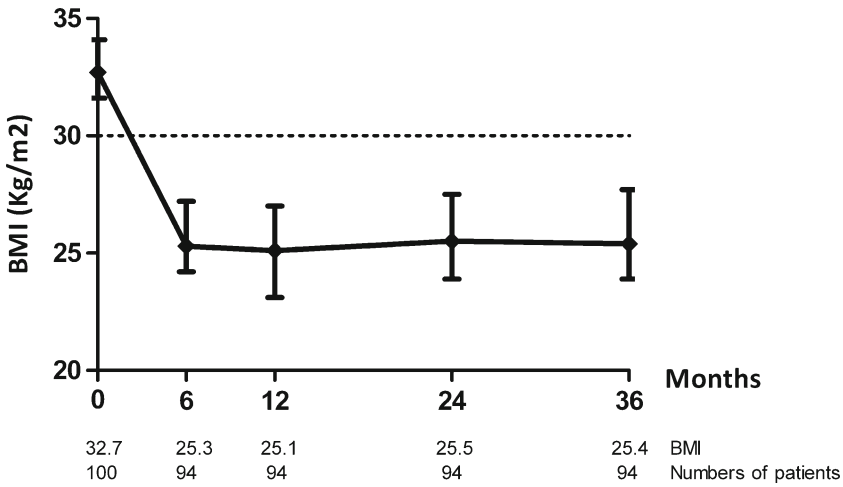

Fig. 2 BMI progression at 3-year follow-up of diabetic patients with BMI <35 kg/m^2 submitted to LRYGB. *BMI* body mass index, *LRYGB* laparoscopic Roux-en-Y gastric bypass

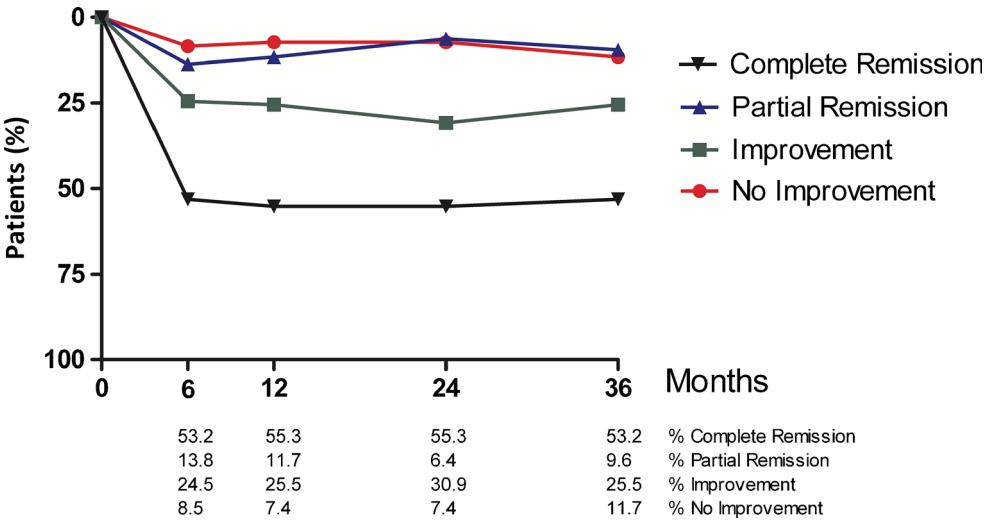

Fig. 3 Diabetes remission at 3-year follow-up of patients with BMI <35 kg/m^2 submitted to LRYGB. *BMI* body mass index, *LRYGB* laparoscopic Roux-en-Y gastric bypass

Regarding preoperative comorbidities, 67 patients (67 %) had fatty liver disease, 60 patients (60 %) had dyslipidemia, 64 patients (64 %) had arterial hypertension, 18 patients (18 %) had hypothyroidism, 15 patients (15 %) had obstructive sleep apnea, and 5 patients (5 %) had depression.

Surgical and Metabolic Results

Median operative time of LRYGB was 110 min (IQR 90–130), and median hospital stay was 3 days (range 2–19).

Fourteen patients (14 %) developed postoperative complications, seven patients (7 %) presented a gastrojejunostomy stenosis that was successfully managed by endoscopic dilatation without complications, one patient (1 %) developed a small bowel obstruction that was successfully managed without surgery, and one patient (1 %) presented an omental torsion. In regard to reoperations, one patient (1 %) had an unrecognized enterotomy and peritonitis that required a reoperation by open surgery on the second postoperative day. No other reoperations or conversions to open surgery were registered, as no mortality was registered in this series. Early and late complications are shown in Table 1.

Ninety-four patients (94 %) completed a 36-month follow-up, 64 patients (64 %) completed a 4-year follow-up, and 31 patients (31 %) completed a 5-year follow-up. All patients were clinically followed, and 64 % of their data of medication use were complemented by telephone survey during follow-up. The highest median EWLp was 99 % (IQR 76–128) and was achieved at 1 year after surgery; afterward, patients experienced some weight regain, reaching a median EWLp of 93 % (IQR 67–121) at 3-year follow-up (Fig. 1). Lowest BMI median achieved after surgery was 25.1 kg/m^2 (IQR 23.1–27.0) and was achieved at 1-year follow-up; afterward, patients experienced some weight regain reaching a median BMI of 25.4 kg/m^2 (IQR 23.9–27.7) at 3-year follow-up (Fig. 2).

In regard to metabolic results, the highest T2DM complete remission percentage was achieved at the first postoperative year (55.3 % of T2DM complete remission). At the third postoperative year, T2DM complete remission was achieved by 53.2 % of patients, 9.6 % achieved a partial remission, 25.5 % presented an improvement in their glycemic control, and 11.7 % had no improvement (Fig. 3). FPG and HbA1C levels during follow-up are presented in Table 2.

Variables Associated with T2DM Remission at 3 Years

Univariate analysis of variables associated with T2DM remission at 3 years is shown in Table 3. Patient's age (p=0.008), T2DM duration (p=0.002), preoperative HbA1C (p<0.001), preoperative FPG (p=0.001), and non-use of insulin prior to surgery (p<0.001) were associated to T2DM remission at the third year after LRYGB. Of note, T2DM remission was not associated to comorbidities or EWLp achieved during follow-up.

In the logistic regression model, univariate analysis of the new categorical variables created showed that T2DM remission at 3-year follow-up was associated to the duration of T2DM <4.5 years (p<0.002), preoperative HbA1C <7.8 %

Table 2 Fasting plasma glucose and glycated hemoglobin levels at 3-year follow-up (median)

	Preoperative (IQR)	1 year (IQR)	2 years (IQR)	3 years (IQR)
Fasting plasma glucose (mg/dL)	125 (105–154)	90 (82–110)	93 (83–109)	95 (85–123)
Glycated hemoglobin (%)	7.3 (6.5–8.1)	5.8 (5.5–6.4)	6.2 (5.7–6.8)	6.2 (5.8–6.9)

Table 3 Univariate analysis of variables associated to T2DM remission at 3-year follow-up

	p value
Female	0.283
Age	0.008*
Preoperative BMI	0.116
Duration of T2DM	0.002*
Preoperative HbA1C	<0.001*
Preoperative FPG	0.001*
T2DM preoperative treatment (non-insulin or insulin)	<0.001*
Preoperative fatty liver disease	0.592
Preoperative dyslipidemia	0.332
Preoperative arterial hypertension	0.77
Preoperative hypothyroidism	0.855
Preoperative obstructive sleep apnea	0.1
Preoperative depression	0.413
EWLp at 3 years	0.279

T2DM type 2 diabetes mellitus, *BMI* body mass index, *HbA1c* glycated hemoglobin, *FPG* fasting plasma glucose, *EWLp* excess weight loss percentage

*$p<0.05$

($p<0.001$), preoperative FPG <126 mg/dL ($p<0.002$), and non-use of insulin prior to surgery ($p<0.001$; Table 4).

In multivariate analysis, non-use of insulin prior to surgery was the only variable associated with T2DM remission at 3-year follow-up, with an OR=15.1 (2.8–81.2) and $p=0.002$ (Table 4).

Discussion

Nowadays, classical criteria for bariatric surgery have been progressively extended to lower values of BMI in response to increasing evidence of good results in patients with BMI <35 kg/m^2. Excellent results in terms of comorbidity resolution after surgery in patients with mild obesity have been recently reported [15], but remission criteria used in these studies are not standardized. Lee et al. [16] reported complete T2DM remission in 55 % and improvement in 90 % of patients at 2-year follow-up. As with other series, best results are achieved in patients with BMI >32.5 kg/m^2, a shorter duration of T2DM, and non-use of insulin in the preoperative period [17–19].

Liang et al. in a randomized controlled trial (RCT) [20] compared LRYGB with medical therapy in mildly obese diabetic patients, with 90 % T2DM remission at 12 months in the surgical group and no remission in the medical group. Another RCT [21] comparing LRYGB versus sleeve gastrectomy in patients with mild obesity showed T2DM remission at 1 year in 93 and 47 %, respectively, concluding that duodenum exclusion plays a role in the glycemic control observed.

To our knowledge, Cohen et al. [22] published the first long-term report of LRYGB in patients with T2DM and mild obesity. At 5-year follow-up, 88 % of patients achieved diabetes remission and 11 % achieved glycemic improvement. Another long-term report [23] with 5-year follow-up showed that complete remission decreased from 73.1 % at 1 year to 57.7 % at 5 years. However, at 5 years, 96.2 % of the patients had an improvement in their metabolic status. Similar to other studies, shorter duration of diabetes and better pancreatic function (according to fasting C-peptide level) were associated with better results. EWLp >75 % also was highly associated with complete diabetes remission [23].

The results obtained in our series showed some differences to those published by other authors, but careful analysis is needed when comparing the results because the T2DM remission criteria used by these studies vary, so the interpretation of the results should be made taking this into consideration. Similar to morbidly obese patients, the best results are achieved in the first postoperative year with a worsening toward the third year; perhaps, weight regain or the appearance of compensatory mechanisms may explain these observations.

Previously reported predictor factors of diabetes remission in morbidly obese patients after bariatric surgery as duration of diabetes and preoperative BMI [24–30] have also been described in patients with lower BMI [31]. Our findings are different, since in the multivariate analysis, only the non-use of insulin was associated to T2DM remission and neither the BMI nor diabetes duration was. It could be explained by the role of the pancreatic function in metabolic outcomes, since

Table 4 Univariate and multivariate analyses of categorical variables associated to T2DM remission at 3-year follow-up

	Univariate		Multivariate	
	p value	Relative risk	*p* value	Odds ratio
Age <50 years	0.061	1.46 (0.95–2.25)	0.207	
Duration T2DM <4.5 years	0.002*	1.95 (1.2–3.18)	0.453	
Preoperative HbA1C <7.8 %	<0.001*	1.91 (1.24–2.92)	0.214	
Preoperative FPG <126 mg/dL	0.002*	2.16 (1.23–3.78)	0.359	
Non-insulin versus insulin	<0.001*	1.69 (1.26–2.26)	0.002*	15.13 (2.82–81.28)

T2DM type 2 diabetes mellitus, *HbA1c* glycated hemoglobin, *FPG* fasting plasma glucose

*$p<0.05$

when a diabetic patient requires insulin treatment prior to surgery, it is due to their disease severity and consequent deterioration of pancreatic beta cells [30, 32]. Perhaps, the use of insulin is a better pancreatic function predictor than other factors previously studied like C-peptide; unfortunately, we cannot affirm this for sure since it was not measured in our study. These findings suggest that surgery should be offered earlier to diabetic patients and not when there is an impaired pancreatic function with little chance for recovery. For example, Schauer et al. [3] achieved 42 % complete T2DM remission with LRYGB after the first postoperative year in contrast to 53.2 % complete T2DM remission at 3 years achieved in our series. This can be explained by the improved preoperative metabolic status of our patients (preoperative HbA1C of 9.2 vs 7.3 % and 44 % use of insulin vs 18 %), affecting the metabolic outcomes achieved after LRYGB. Additional evidence is necessary to confirm the obtained results.

Our group previously reported the initial experience with 31 patients in an earlier publication [33], showing acceptable metabolic results; the present study adds new evidence of an emerging group of patients who are being considered candidates for bariatric surgery. It is important to unify the criteria for remission of diabetes among different studies according to available international guidelines and recommendations to allow proper comparison and interpretation of results across studies.

Our study has few limitations that have to be considered. First, the fact that some medication data were partly collected by a telephone interview (64 %) can be considered a major confounder since patients tend to "not tell the truth" on the phone, altering our metabolic results. Second, it is important to incorporate postoperative variables not included in our study that can modify our metabolic outcomes, as dietary habits, exercise, C-peptide levels, and others, in order to establish the significance of these factors to predict the metabolic response to bariatric surgery. Finally, the results shown in this study are at 3-year follow-up due to a small number of patients followed at long term. We need to evaluate long-term outcomes at 5-year follow-up as other studies do, in order to establish the permanence of metabolic outcomes achieved with bariatric surgery and the real impact in the treatment of T2DM.

Conclusion

In conclusion, in this series, LRYGB is a reliable and effective treatment in diabetic patients with a BMI <35 kg/m^2. T2DM remission rate is achieved in a significant number of patients at 3 years, with best results observed in non-insulin diabetic patients.

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

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