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Resolution of type 2 diabetes and prediabetes following laparoscopic sleeve gastrectomy: medium term results

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Abstract

Purpose: **To determine the impact of Laparoscopic Sleeve Gastrectomy (LSG) on the resolution of type 2 diabetes (T2DM) and Prediabetes (PDM) in obese patients, as well as potential improvements in other comorbidities.**

Material and Methods: **Observational retrospective study. We studied all patients with T2DM (n= 36) or PDM (n= 44) who underwent LSG in our hospital between years 2009 and 2012. PDM was defined as having at least 2 values of HbA1c between 5.7 and 6.4%. Follow-up period was 1-4 years (mean 17.5 months). T2DM remission criteria were fasting plasma glucose (FPG)<100 mg/dl and HbA1c<6% without using hypoglycemic agents. PDM remission criteria were HbA1c< 5.7% plus FPG< 100 mg/dL.**

Results: **Quantitative variables are defined as mean ± standard deviation. T2DM group: Description at baseline: 66% women, age 49.5±9.9 years, weight 132.2±18.8 Kg, Body Mass Index (BMI) 50.4±5.2 Kg/m^2, HbA1c 7.8±1.9%. After LSG, weight was 94.2±20.5 Kg, BMI 35.8±6.4 and HbA1c 6.1±1.2 % (p<0.0001). T2DM improved in 97.6% patients, with a remission rate of 58.3% (n=21). Improvement or resolution of comorbidities was as follows: dyslipidemia 64%, Hypertension 39.3%, Obstructive Sleep Apnea 26.3%. PDM group: Baseline: 59% women, age 42.7 ± 8.2 years, weight: 144.2±26.2 Kg, BMI 50.6±5.5 Kg/m^2. Post-LSG: weight 92.7±16.5 Kg, BMI 32.8±4.8 Kg/m^2 (p<0.0001). HbA1c decreased from 6.04±0.3 % to 5.31±0.27 % (p<0.0001) after LSG. 95.5% of patients that initially met PDM criteria achieved FPG<100 mg/dl and HbA1c<5.7% (resolution of PDM).**

Conclusion: **LSG effectively achieves improvement or remission of T2DM or PDM in obese patients meeting surgical treatment criteria.**

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Key Words: *Bariatric surgery. Sleeve gastrectomy. Type 2 diabetes. Prediabetes.*

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EFECTIVIDAD DE LA GASTROPLASTIA TUBULAR LAPAROSCÓPICA EN LA RESOLUCIÓN DE LA DIABETES MELLITUS TIPO 2 Y PREDIABETES: RESULTADOS A MEDIO PLAZO

Resumen

Objetivos: **Evaluar la efectividad de la gastroplastia tubular laparoscópica (GTL) en la resolución de la diabetes tipo 2 (DM2), de la prediabetes (PDM) y de otras comorbilidades en pacientes obesos.**

Material y métodos: **Estudio observacional retrospectivo. Se incluyeron a los pacientes con DM2 (n= 36) o PDM (n= 44) que fueron sometidos a GTL en nuestro hospital entre 2009 y 2012. Se consideró criterio de PDM presentar HbA1c entre 5.7-6.4% en al menos dos ocasiones. Periodo de seguimiento entre 1-4 años (media 17.5 meses). Como criterio de resolución de la DM2 se consideró presentar HbA1c<6% con glucemia basal (GB)<100 mg/dL sin hipoglucemiantes. Se definió resolución de PDM como HbA1c<5.7% y GB<100 mg/dL.**

Resultados: **Variables cuantitativas expresadas como media±DS. Grupo de pacientes con DM2: 66% mujeres, 49.5±9.9 años, 132.2±18.8 Kg, Índice de Masa Corporal (IMC) 50.4±5.2 Kg/m^2, HbA1c 7.8±1.9%. Tras GTL el peso fue 94.2±20.5 Kg, el IMC 35.8±6.4 y la HbA1c 6.1±1.2% (p<0.0001). La DM2 mejoró en el 97.6% de los pacientes, con una tasa de resolución del 58.3%(n=21). La resolución o mejoría de las comorbilidades fue la siguiente: dislipemia 64%, hipertensión 39.3%, SAOS 26.3%. Grupo de pacientes con PDM: 59% mujeres, 42.7±8.2 años, 144.2±26.2 Kg, IMC 50.6±5.5 Kg/m^2. Tras GTL: Peso 92.7±16.5 Kg, IMC 32.8±4.8 Kg/m^2 (p<0.0001). La HbA1c se redujo de 6.04±0.3% a 5.31±0.27% tras GTL(p<0.0001). El 95.5% de los pacientes con PDM obtuvo criterios de curación de la PDM (GB<100 mg/dl y HbA1c<5.7%).**

Conclusiones: **La GTL es eficaz en la resolución de la DM2 y PDM en pacientes obesos con criterios de cirugía bariátrica.**

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Palabras clave: Cirugía bariátrica. Gastroplastia tubular laparoscópica. Diabetes tipo 2. Prediabetes.

Abbreviations

AACE: American Association of Clinical Endocrinologists.
ASMBS: American Society for Metabolic & Bariatric Surgery.
ADA: American Diabetes Association.
BMI: Body Mass Index.
BP: Blood Pressure.
FPG: Fasting Plasma Glucose.
GB: Gastric Bypass.
HbA1c: Glycosilated Hemoglobin.
HT: Hypertension.
IU: International Units.
LSG: Laparoscopic Sleeve Gastrectomy.
OHA: Oral Hypoglycemic Agents.
OSAS: Obstructive Sleep Apnea Syndrome.
T2DM: Type 2 Diabetes Mellitus.
%EWL: Percentage of Excess Weight Loss.

Introduction

Type 2 Diabetes Mellitus (T2DM) is a global pandemic with an approximate worldwide prevalence of 8.3%, and is predicted to rise to 10% in 2030[1]. However, in some countries this prevalence is notably higher; in Spain the estimated prevalence is 13.8%, and up to 30% of the general population has any degree of glucose metabolism impairment[2]. The relationship between overweight and obesity with T2DM is clearly established; these two risk factors are steadily increasing among general population, possibly as a consequence of changes in lifestyle[3]. Given the magnitude of this problem, the chronicity and progressiveness of the disease, and the costs derived from T2DM treatment and complications, it is imperative not only proper treatment of hyperglycemia, but also to prevent the development of the disease in patients at high risk. Following this philosophy, bariatric surgery has proven to be an effective an well-validated method to improve T2DM in patients with Body Mass Index (BMI) ≥ 35 Kg/m^2, obtaining better results than standard treatment and even disease remission in the medium-term[4-6]. However, not all surgical procedures for obesity treatment achieve the same results. The best results have been reported with mixed techniques (malabsortive plus restrictive), as biliopancreatic diversion (presently fallen into disuse due to the high rates of complications and secondary effects) and gastric bypass (GB), the current Gold Standard in obese diabetic patients[4,7-9]. Purely restrictive techniques (Gastric band and mainly Lapaparoscopic Sleeve Gastrectomy, LSG) are an alternative choice on the rise due to their simplicity, low rates of complications and promising results, sometimes comparable to GB[4,10-12].

Remission rates of T2DM after bariatric surgery are significantly different according to the surgical technique, the criteria used to determine remission of T2DM and follow-up time[6]. Presently, there are several reports of long-term (5 or more years) diabetes remission after GB, ranging from 24 to 88%[13-19]. In comparison, and to the best of our knowledge, there are few studies reporting long-term remission rates in LSG-treated patients, partly because of the novelty of the technique. Also, these studies (with follow-up time over 5 years) are not focused on T2DM, with few patients with diabetes included and inhomogeneous (and sometimes too permissive) remission criteria; thus, it is not surprising to find highly variable T2DM remission rates (9-85%)[14, 20-23].

Potential predictive factors of T2DM remission failure or recurrence after bariatric surgery are higher glycosilated hemoglobin (HbA1c) at baseline, longer duration of T2DM and treatment with insulin before surgery[16,19,24]. Furthermore, improvement of the pancreatic β-cell after GB surgery depends on presurgery β-cell function and it has been proven than β-cell impairment may persist after GB even in patients in clinical DM remission[25]. As these factors seem to point, an early surgical indication in obese patients with T2DM, or even in prediabetic patients (impaired glucose tolerance or impaired fasting glucose) is crucial to achieve better results in terms of remission or even effectively prevent the development of the disease. In 2012, *Carlsson et al* reported that obese patients on conventional medical therapy had higher T2DM incidence than those who underwent bariatric surgery[26]. Also, the prevalence of T2DM is lower after GB and gastric banding[27], but to the best of our knowledge there are no studies with LSG regarding this matter.

To broaden our clinical knowledge about this novel technique, we studied the mid-term effectiveness of LSG in T2DM and prediabetes remission in obese patients (at least one year after surgery).

Materials and methods

Patient selection

We designed an observational retrospective study, including all patients admitted to our center to undergo LSG between February 2009 and April 2012. Inclusion criteria were pre-surgical diagnosis of T2DM or prediabetes, following the ADA (American Diabetes Association) definitions from the 2012 consensus statement[28]. So, T2DM patients were considered as those on oral hypoglycemic agents (OHA) or insulin, as well as fasting plasma glucose (FPG) ≥ 126 mg/dL and/or HbA1c ≥ 6.5% at least in two determinations; prediabetes patients were considered as those with HbA1c levels between 5.70-6.49% at least in two measurements and not on hypoglycemic treatment. All patients included underwent surgery

at Virgen del Rocío University Hospital (Seville, Spain) by a single surgical team, and afterwards were systematically revised by the same multidisciplinary team.

Pre-surgical evaluation

All patients completed an exhaustive pre-surgical evaluation (by endocrinologists, surgeons and mental health practitioners) to ensure the absence of contraindications for surgery, and that all of them met surgical criteria (BMI ≥ 40 Kg/m^2 or ≥ 35 Kg/m^2 with comorbidities: Hypertension –HT-, dyslipidemia, severe arthropathy, or Obstructive Sleep Apnea Syndrome –OSAS-). LSG was proposed based on medical criteria and with the full consensus of the pre-surgical evaluation committee.

Surgical technique

All patients underwent LSG performed by a single team of surgeons with broad experience in bariatric surgery at our hospital, using a standard technique: transection of the stomach was performed 4-5 cm from the pylorus using a 40 French bougie.

Post-surgical follow-up

Postoperative care was performed by endocrinologists, surgeons and nurses specialized in nutrition, with clinical follow-up at 1, 3, 6, 12 and 18 months, and yearly afterwards. All patients started with a progressive dietetic plan to ensure tolerance and a multivitaminic compound once daily indefinitely. In each follow-up visit, all patients were tested for metabolic complications improvement with an analytic control (glucose, urea, ions, creatinina, hepatic profile, lipid fractions, lipophilic vitamins, B12 vitamin, folic acid, HbA1c, iron metabolism markers and complete blood count); anthropometric measures, as well as blood pressure (BP), were measured and registered. Antihypertensive, lipid-lowering or hypoglycemic treatment withdrawal was progressively achieved when possible according to the clinical situation of each patient.

Definitions

The efficacy of LSG was assessed using the percentage of excess weight loss (%EWL), calculated as 100 × [preoperative weight-postoperative weight] /excess preoperative weight, for a BMI of 25 Kg/m^2.

The criteria used to define remission or improvement of comorbidities are shown in table I.

Statistical analysis

Demographic, anthropometric and analytical variables, as well as comorbidities and treatment, were collected pre-LSG and postoperatively in the T2DM group. In the group of prediabetic patients only anthropometric data and relative to glucose metabolism were collected before and after surgery. All data were processed using IBM SPSS V.21.0 statistical suite. Qualitative variables were expressed as frequencies and percentages, and quantitative variables as mean and standard deviation. To detect differences between pre and postoperative findings, a T-Student test was performed (after ascertaining normality using Kolmogorov-Smirnov and/or Shapiro-Wilks tests when indicated), considering as statistically significant a p value <0.05. To compare proportions McNemar test was used.

Table I
Criteria for remission or improvement of comorbidities

	Remission/ resolution criteria	*Improvement criteria*
Type 2 DM	– FPG < 100 mg/dL and HbA1c < 6% without requiring hypoglycemic agents	– Withdrawal or reduction of insulin/OHA daily dose or – HbA1c reduction in comparison with pre-surgical values (without significant treatment modifications).
Prediabetes	– HbA1c < 5.7% plus FPG < 100 mg/dL	
Hypertension	– BP < 140/90 mmHg without antihypertensive treatment.	– Reduction of the number of drugs used or – Reduction of the dose of antihypertensive treatment.
Dyslipidemia	– Normalization of total plasma cholesterol and triglycerides without treatment.	– Reduction of the dose and/or potency of lipid-lowering treatment or – Improvement in overall control without need of treatment change (in previously uncontrolled patients).
Artropathy		– Subjective criteria (improvement reported by patients).

DM, Diabetes Mellitus; *FPG*, Fasting Plasma Glucose; *HbA1c*, Glicated Hemoglobin; *BP*, Blood Pressure.

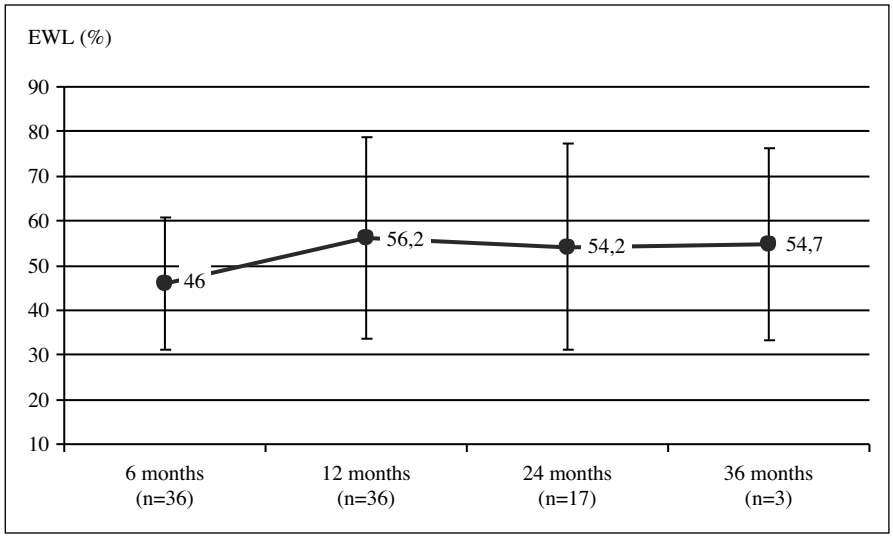

Fig. 1.—Evolution of percentage of Excess Weight loss (%EWL) after surgery in diabetic patients (mean ± SD).

Results

Type 2 Diabetes Mellitus Group

N=36 T2DM patients were included (66% females). Mean age was 49.5±9.9 years (range 19-68 years). Main presurgical comorbidities were HT (77.8%), dyslipidemia (69.4 %) and OSAS (52.8%), with a prevalence of arthropathy of 30.6%. Mean pre-surgical weight was 132.2±18.8 Kg, with BMI of 50.4±5.2 Kg/m^2.

In T2DM patients, metabolic control was suboptimal, with a presurgical HbA1c of 7.8±1.9% (range 5.5-14.2%); 61.1% (n=22) of them required one or more OHA, while 27.8% (n=10) were on insulin (basal insulin only or multiple doses with or without OHA), and 11.1 % (n=4) were on diet and exercise only.

Mean follow-up after LSG was 18.2±8.1 months (range 12-44 months; 58.4% of patients with a follow-up period of ≥ 24 months). 6 months after surgery, mean %EWL was 46.0±14.9, reaching 56.2±22.5 % 1 year post LSG, with a tendency afterwards to stability (see figure 1). Post-surgical weight and BMI loss changes were statistically significant at 6, 12 and 24 months, but not at 36 months (see figure 2 and table II). As can be seen, the reduction of weight and BMI was substantially greater at 6-12 months, with a later stabilization. At the global last follow-up cutoff, mean weight was 94.2±20.5 Kg, and mean BMI 35.8±6.4 Kg/m^2 (p<0.0001 in comparison with pre-surgical values in both cases).

The vast majority of our T2DM patients (97.6%, n=35) met remission or improvement criteria of T2DM. Total remission rate at the last follow-up cutoff for each patient was 58.3% (n=21), and interestingly most of them achieved this result in the first 6 months (remission rate 52.7% at 6 and 12 months, 55.5% at 24 months). HbA1c also improved notably, from 7.8±1.9 to 6.1±1.2 % (p<0.0001, see table II). A comparative between pre and postoperative hypoglycemic treatment is shown in table III; in the 10 patients previously on insulin, we achieved a withdrawal rate of 60% (complete transition to OHA or diet and exercise only). Daily insulin dose could be reduced from a mean of 75.5±54.3 International Units (IU) to 59.5±25.3 IU

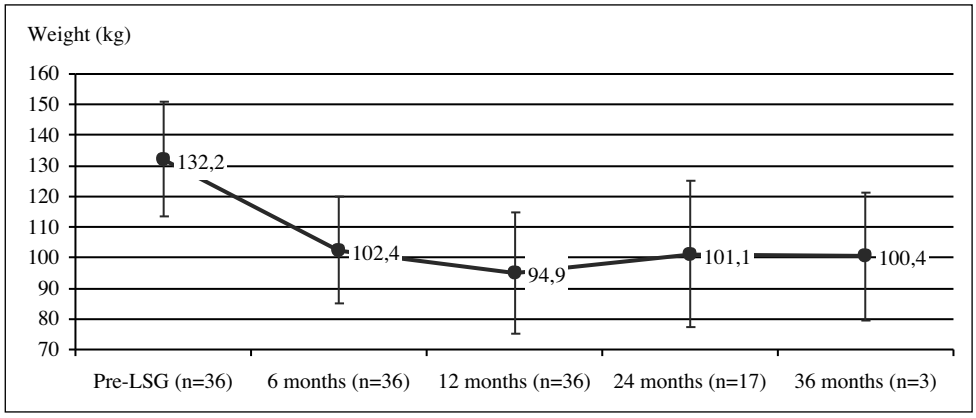

Fig. 2.—Weight changes after surgery in diabetic patients (mean±SD). LSG, *Laparoscopic Sleeve Gastrectomy; p< 0.0001 at 6, 12 and 24 months, p= 0.051 at 36 months vs presurgery.*

Table II
Evolution of weight and BMI after LSG in T2DM patients

	Pre LSG	*6 months*	*12 months*	*24 months*	*36 months*	*Last follow-up cutoff*
N	36	36	36	17	3	36
Weight (Kg)	132.2±18.8	102.4±17.5 *	94.9±19.9 *	101.1±23.9 *	100.4±20.9 p=0.051	94.2±20.5 *
BMI (Kg/m^2)	50.4±5.2	39.0±5.1 *	36.2±6.3 *	36.1±6.1 *	36.0±4.5 p= 0.63	35.8±6.4 *
HbA1c (%)	7.76±1.91	6.36±1.10 *	6.06±1.07 *	6.09±1.32 *	5.97±0.67 p=0.12	6.14±1.19 *

BMI, Body Mass Index; *LSG*, Laparoscopic Sleeve Gastectomy; *T2DM*, Type 2 Diabetes Mellitus. Mean ± SD.
* p<0.0001 in each point in comparison with presurgery.

Table III
Hypoglycemic treatment before and after LSG

	Pre LSG	*Post LSG*	p
OHA (1 or more)	22 (61.1%)	9 (25%)	0.007
OHA (1 or more) + insulin	9 (25%)	4 (11.1%)	*ns*
Insulin	1 (2.8%)	0	*ns*
Diet and exercise only	4 (11.1%)	23 (63.9%)	<0.0001

Number of patients (percentage). *LSG*, Laparoscopic Sleeve Gastectomy; *OHA*, Oral Hypoglycemic Agents; *ns*, no significant; Post LSG, in the last follow-up cutoff for each patient.

after the procedure (p=0.52). Only one patient on insulin treatment achieved diabetes remission. The rates of remission or improvement in the rest of comorbidities are shown in table IV; as we report, although all comorbidities improved, the best results in our series were achieved in arthropathy and dyslipidemia, followed by HT and in last position OSAS. HDL cholesterol significantly increased from 44.7±13.8 mg/dL to 61.9±19.1 mg/dL (p=0.01), and triglycerides markedly fell from 231.9±122.2 to 125.5±58.7 mg/dL (p<0.0001). No substantial changes in total cholesterol and LDL cholesterol were observed (see table V for detailed data).

All patients were tested for vitamin and micronutrient deficiencies during the postoperative follow-up; unfortunately, in many cases we could not do a proper comparison with pre-surgical values due to the absence of analytical determinations before LSG. We detected the following deficiencies (in descendent order): vitamin D 52.8% (n=19), iron 33.3% (n=12), vitamin A 22.2% (n=8), folic acid 19.4% (n=7), vitamin B12 13.9% (n=5) and vitamin E 8.3% (n=3).

Prediabetes Group

The final sample was composed of n=44 patients (59%, n=26, females); mean age was 42.7±8.2 years (range 20-60). Presurgical weight was 144.2±6.2 Kg (range 87.7-200.0), and BMI 50.6±5.5 Kg/m^2 (range 40.6-69.3).

After a mean follow-up of 16.9±8.4 months (maximum 33 months), weight significantly fell to 92.7±16.5 Kg, as BMI did to 32.8±4.8 Kg/m^2 (p<0.0001 in both cases). All patients obtained a %EWL > 50% at the end off follow-up, with a mean %EWL of 70.2±16.6. Pre-

Table IV
Remission or improvement of comorbidities in T2DM group at the end of follow-up for each patient

	Remission	*Remission or improvement*
HT	5 (17.9%)	11 (39.3%)
Dyslipidemia	4 (16%)	16 (64%)
OSAS	3 (15.8%)	5 (26.3%)
Artropathy	0	11 (100%)

Number of patients (percentage). *T2DM*, Type 2 Diabetes Mellitus; *HT*, Hypertension; *OSAS*, Obstructive Sleep Apnea Syndrome.

Table V
Lipid profile changes after bariatric surgery in T2DM patients at the end of follow-up

	Pre LSG	*Post LSG*	p
Total Cholesterol (mg/dL)	222.7 ± 47.5	221 ± 42.9	0.78
LDL cholesterol (mg/dL)	137.9 ± 46.8	144.2 ± 41.1	0.97
HDL cholesterol (mg/dL)	44.7 ± 13.8	61.9 ± 19.1	0.01
Triglycerides (mg/dL)	231.9 ± 122.2	125.5 ± 58.7	< 0.0001

T2DM, Type 2 Diabetes Mellitus; *LSG*, Laparoscopic Sleeve Gastectomy; *LDL*, Low density lipoprotein; *HDL*, High density lipoprotein. Mean ± SD.

diabetes remission rate was 95.5% (n=42), and HbA1c improved from 6.04±0.3 % to 5.31±0.27% (p<0.0001).

Discussion

Our study shows the mid-term efficacy of LSG as a way to improve or induce stable remission of T2DM in obese patients meeting bariatric surgery criteria; and perhaps more encouraging, even better results in prediabetic obese patients, with glycemic normalization in more than 95% at 17 months of follow-up. Regarding the good results in our series, there are some possible causes[16, 19, 24]:

- Firstly, most of our T2DM patients were on OHA and/or diet only without using insulin. This is frequently seen in patients with early and mid-onset diabetes, and as it has been already concluded in previous studies, it could explain the near 100% of remission/improvement of T2DM achieved.
- Secondly, baseline HbA1c was 7.8±1.9 %. Although it is far from optimum control considering the ADA guidelines, it is not high enough to be deemed as poor control, and could be another factor behind our findings.

In our study, major weight losses were registered between 6-12 months after LSG, and afterwards followed a trend towards stability, as other authors have previously reported[20-22]. Interestingly, T2DM remission rates through the study are not uniform or stable; instead, the improvement of T2DM is mainly seen at 6-12 months after surgery, with a subtle increase at 24 months, in contrast with previous studies (in which remission rates are rather stable through the follow-up period)[16,24,29]. Recently, a prospective study focused on long-term T2DM remission rates after bariatric surgery (median follow-up of 17 years) has been published that support our observations[29]. The authors report a T2DM remission rate in the intervention group (surgery) at 2 years of 72.3% that decreases to 30.4% after 15 years of follow-up, but still clearly higher than those achieved by the control group (conventional non-surgical approach). And more importantly, they found less T2DM-related complications (micro and macrovascular disease) in the surgery group over the follow-up period than those on conventional T2DM therapy. Unfortunately, surgical patients subjected to LSG were not included in this study as this technique was not yet available at the recruitment phase[29].

Regarding other comorbidities, the best results in our series were achieved in dyslipidemia (64%). Despite the lack of response in terms of total cholesterol and/or LDL cholesterol, overall lipid risk profile improved as HDL cholesterol (a protective factor currently not modifiable by pharmacological methods) increased and plasmatic triglycerides significantly fell. This fact in association with our T2DM remission data could point to a potential reversibility of metabolic syndrome in these patients, although further investigations are needed[30].

Current bariatric surgery criteria from AACE (American Association of Clinical Endocrinologists), the Obesity Society and the ASMBS (American Society for Metabolic & Bariatric Surgery) recommend surgery for patients with BMI ≥ 40 Kg/m^2 without comorbidities or BMI ≥ 35 Kg/m^2 with any severe comorbidity associated (grade A recommendation)[31]. Prediabetes is still not considered in these guidelines as a comorbidity of enough specific weight to grant surgery by itself, and therefore a prediabetic patient without other comorbidities could only be considered eligible for surgery in the first scenario (BMI ≥ 40 Kg/m^2); consequently, all our prediabetic patients met this prerequisite. In our series, LSG achieved mid-term prediabetes remission in 95.5% of cases. These results are indeed encouraging, and perhaps this technique should be evaluated in terms of profitability in prediabetic patients: it is a relatively safe and easy to perform surgery in expert hands, with a low rate of complications, and in the long-term it could be cost effective, as it could prevent or delay the onset of T2DM (and at the same time, the onset of diabetes-related complications)[30].

As a retrospective study, our results are limited in several ways, mainly due to the loss of data concerning biochemical markers (vitamins, trace elements…) that hinders the comparison between pre-surgical and post-surgical values, but also diabetes evolution time and other variables.

In conclusion, LSG is an effective technique to be considered in the treatment of obese diabetic patients meeting bariatric surgery criteria, achieving mid-term remission or improvement of T2DM in most cases in our series, as well as in the case of other major comorbidities. Also, in our experience LSG is highly effective in the remission of prediabetes, with a success rate of nearly 100%.

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