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Clinical Characterization and Evolution at 12 Months in Patients with Obesity and Type 2 Diabetes Undergoing Bariatric Surgery Using One Anastomosis Gastric Bypass Technique.

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Abstract:

Introduction: Obesity is an epidemic disease that has tripled since 1975, it represents an important problem for public health as the increase of the morbidity and mortality of various diseases, including cardiovascular diseases. In cases where conventional treatment fails, the metabolic-objective bariatric surgery has shown positive results in weight reduction, glycosylated hemoglobin, and risk factors, recently, the gastric bypass technique of an anastomosis (GBTA) has shown adequate results in the metabolic control of patients. (GBTA)

Objective: the description of GBTA clinical effects in obese patients with diabetes.

Materials and Methods: A prospective descriptive observational study was conducted in patients submitted to GBTA between April 2017 and September 2017. Patients diagnosed with obesity, type 2 diabetes (based on the American Diabetes Association criteria) and who were submitted to a pharmacological treatment for diabetes prior to surgery and who complied with a one year-follow-up.

Results: Out of 150 candidates, 40 patients were included, fulfilling the inclusion criteria or none of exclusion. It was found that 97.5% of the patients had remission of diabetes, 100% indicated suspension of hypoglycemic drugs, and an overall decrease of the level obesity was observed in all patients.

Discussion: The GBTA technique has shown success in the metabolic control of obese patients with diabetes, where the conservative treatment has failed with adequate safety, the percentage of weight lost is associated with the size of the ASA, the success of the remission of diabetes is associated with the deterioration of the pancreatic beta cell function.

Conclusion: The intervention by GBTA in patients with obesity and type 2 diabetes is a safe therapeutic alternative in patients who do not achieve control of the disease with conventional treatment.

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Introduction

The World Health Organization (WHO) defines overweight and obesity as an abnormal or excessive accumulation of fat that can affect health, where global obesity has almost tripled since 1975. By 2016, about 1900 million adults were overweight and 650 million were obese. Overweight and obesity are significant in regard to public health, as they are a risk factor and they increase the morbidity and mortality of cardiovascular diseases, diabetes, musculoskeletal disorders, and some neoplasms (1,2).

The (WHO) reports that in 1980, about 108 million people were diagnosed with Diabetes Mellitus type 2 (DM2), this disease has had a steady growth and, by 2014 the number of people with diabetes was about 422 million. DM2 is an important cause of preventable death, blindness, renal failure, acute myocardial infarction, and cerebrovascular accident, among others (3,4).

We found a strong association between weight loss and improvement of blood glucose in patients with DM2, the findings suggest that a weight loss between 2 and 5% observed an improvement in fasting blood glucose, and with a loss greater than 5% it has beneficial metabolic effects on HbA1c (5,6). In cases where lifestyle interventions and pharmacological management fail and the metabolic goals are not achieved (HbA1C <7%), the surgical option is considered as an alternative, which has shown DM2 resolution rates of 73% (7).

It has been reported that in obese patients with DM2 Bariatric surgery procedures have shown a remission of DM2 with rates of 80-95% in various studies, even some authors suggest that bariatric surgery has more powerful long-term benefits than hypoglycemic treatment most used in diabetology, so the notion of metabolic surgery as a possible surgical management of diabetes is being considered within the options of management with greater force (8,9).

Bariatric surgery can be defined as the set of surgical techniques which goal is to reduce excess weight and as a side effect reduce the consequences of comorbidities; while the definition of metabolic surgery has a constant discussion since its definition differs according to the interpretation of the term "metabolic" (9). Metabolic surgery can be defined as the set of surgical techniques that improve glycemic values with little effect on weight, and which objective is to manage uncontrolled DM2, despite the maximum hypoglycemic treatment tolerated in obese or overweight patients, being the loss of weight a side effect (9).

A 2016 meta-analysis reports that remission rates of DMT2 and patients with obesity with a BMI <35 kg / m2 are between 55 and 93% after a one-year follow-up, which is why the European recommendations in patients with uncontrolled DM2 with BMI between 30-35 kg / m2 can be considered for bariatric surgery with a metabolic objective (9,10).

The Gastric Bypass with an Anastomosis (One Gastric Bypass Anastomosis), GBTA is among the most used techniques for metabolic surgery is, it was introduced by Rutledge in 1997 (11). Since then, this bariatric procedure has found favor with a large number of surgeons, becoming the fourth most performed surgery in Europe and in Asia, and, according to the fourth report of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO, for its acronym in English) represents the third most performed procedure in the world (12,13).

In recent years several studies have reported the benefits of GBTA in patients with DM2 , showing weight control and the resolution of DM2, but, despite these results, there is still controversy about its use due to the lack of more evidence to assess its safety, efficiency and possible postoperative challenges of this technique (12,14); despite this controversy a 2019 systematic review with 12800 patients, found that the overall mortality was 0.10% and the leakage rate was 0.96% with a DM2 resolution of 83.7% after 6 and 12 months, which suggests, that there is evidence that supports their safety so that this procedure is taken into account within the main bariatric options (15).

The GBTA presents technical and conceptual proposals which are different from those of other procedures, one of them, is the complete measurement of the entire small intestine to determine the extension of the annulled biliopancreatic ASA and the common ASA; the lengths of these segments are not fixed, but they are assigned according to the body mass index, the length of the intestinal ASA and other metabolic variables, which lead to GBTA having a more malabsorptive profile (16). This allows us to consider it as an effective technique, since it allows the reduction % of excess weight which is greater than or equal to 50% (14,15).

The goal of this study is to describe the metabolic effects in patients with obesity and diabetes after undergoing surgery with the GBTA technique.

Material and method

An observational, descriptive, prospective study was performed at the Malvinas Argentina's Obesity and Metabolic Disease Center "Dr. Alberto Cormillot ". We selected 150 patients with criteria for bariatric (CB) and metabolic surgery (CM), submitted to GBTA between April 1, 2017 and September 31, 2017, where the surgeon acting in all procedures, was the same with the goal of decreasing variations of the surgical technique, the GBTA technique is

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chosen in our institution due to its fast learning curve, shorter operative time, and fewer complications.

Patients who accepted to participate in the study by signing a written informed consent and, who met the following criteria were included: they presented some degree of obesity (Criteria of the SEEDO-WHO); a diagnosis of type 2 diabetes (based on the criteria of the American Diabetes Association, ADA) and, those who were under pharmacological treatment for diabetes prior to CB or CM; who have completed a minimum of 12 months after being submitted to CB or CM; a partial or complete remission of DM2 according to the ADA (complete remission:

HbA1C <6.0% and baseline glucose <100 mg / dL, a partial remission HbA1C <6.5% and basal glucose between 100 mg / dL and 124 mg / d;

As exclusion criteria of the sample, those patients who had incomplete data such as: age, height, weight, glycosylated hemoglobin after CB or CM, surgical technique, and percentage of weight loss (defined as the 50% reduction of excess weight) were not included.

The technique performed in our center is governed by the technical parameters established by Dr. Miguel Carbajo, which consists of performing a long gastric pouch calibrated with a probe of 36 Fr, the total count of the small intestine from the fixed handle to the ileocecal valve, and the determination of biliopancreatic ASA length and the common ASA (60% biliopancreatic and 40% common when the target is bariatric with a length of less than 2.5 m for the common ASA, 40% biliopancreatic and 60% common when the target is the metabolic with a length greater than 2.5 m for the common ASA); also the performance of a latero-lateral gastrojejunal anastomosis that ranges from 30 to 50 mm. (16-18)

Description of the technique: 6 ports are positioned; the right and left flank (12 mm), the supraumbilical (11 mm), the right and left hypochondrium and, the right iliac fossa (5 mm). The gastric pouch is made between 18-20 cm long after calibration with a 36 Fr probe, and a lateral-lateral gastrojejunal anastomosis is performed with a linear stapler (I-Drive with Tri-staple cartridges, Medtronic). It is finished by closing with continuous barbada suture (V-Loc 3/0 Medtronic) (16-18). Intraoperatively, a hydro pneumatic test was performed with blue methylene to evaluate the anastomosis.

A serial esophagogastroduodenal serial imaging study, was performed by request the following day, to assess the indemnity of the gastrojejunostomy anastomosis and the contrast passage, and to rule out anastomotic leaks. Subsequently, a liquid diet starts. The patient was discharged according to tolerance and clinical evolution in the first 24 postoperative hours.

Medical controls were performed at 1, 3, 6, 12 months after surgery, endoscopy of upper digestive tract at 12 months, a one a- day sucralfate was prescribed for a year, omeprazole 40 mg day, multivitamin supplement (vitamins: A, B1, B2, B6, B12, C, D3, E, minerals and trace elements: Folic Acid, nicotinamide, Calcium Pantothenate, Biotin , Calcium, Phosphorus, Magnesium, Iron, Manganese, Copper, Zinc, Chromium)

For the statistical analysis, Epiinfo 7.2 was used to determine the descriptive values of the studied population Confronting variables in the analysis; age, gender and BMI, size of the common ASA and remission of diabetes defined for the study as normal values of glycosylated hemoglobin without the need to restart the pharmacological treatment.

Results

Out of 150 patients with some degree of obesity, submitted to GBTA, 40 of them met the selection criteria; 32 (80%) of the patients were submitted to GBTA for bariatric purposes, and 8 (20%) for metabolic purposes. (Table 1).

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Table 1 – Features of the patients submitted to bariatric surgery with metabolic or bariatric purposes

Characteristics	GBTA -OAGB n= 40		
		Val min.	*Val max.*
Oral antidiabetics / Those who required Insulin	29/11		
Evolution average time of DM 2 in years	4.5 ± 4.3	*1*	*20*
Average age, years	40 ± 8.00	*17*	*63*
Gender M/F	12/28		
Bariatric/ Metabolic Goal	32/8		
Weight before surgery	134.65 ± 24.76	*96*	*196*
IMC before surgery	48.52 ± 8.00	*36*	*66.5*
Glycemia before surgery	109.97 ± 17.83	*78*	*142*
HbA1c before surgery	7.39 ± 0.85	*5.8*	*8.9*
Surgery time in minutes	113.1 ± 24.37	*69*	*179*
Complications, *n* (%)	3/40 (7.5%)		
DM Remission after 6 months *n* (%)	38/40 (95%)		
DM partial remission after 6 months, *n* (%)	2/40 (5%)		
DM total remission after 6 months *n* (%)	36/40 (90%)		
DM remission after 12 months, *n* (%)	39/40 (97.5%)		
DM partial remission after 12 months *n* (%)	1/40 (2.5%)		
DM total remission after 12 months, *n* (%)	38/40 (95%)		
Suspension of medication after 6 months	40/40 (100%)		
Suspension of medication after 12 months	40/40 (100%)		
Weight control after 6 months, *n* (%)	18/40 (45%)		
Weight control after 12 months, *n* (%)	40/40 (100%)		
		Val min.	*Val max.*
Weight after the surgery after 6 months (kg)	97.17 ± 19.96	*60*	*138*
Weight after the surgery after12 months (kg) (kg)	80.77 ± 11.43	*58.1*	*112*
Loss weight after 6 months (kg)	37.57 ± 13.10	*16*	*64*
Loss weight after 12 months (kg)	51.97 ± 17.19	*24.9*	*84*
% Loss weight after 6 months	50.43 ± 13.99	*20.4*	*82.3*
% Loss weight after12 months	72.27 ± 9.41	*54.47*	*92.54*
Glycemia (mg/dL)	89.55 ± 8.27	*76*	*102*
Glycemia after 6 months (mg/dL)	79.42 ± 4.9	*71*	*90*
HbA1c after 6 months of surgery (%)	5.51 ± 0.96	*4*	*7.5*
HbA1c after 12 months of surgery (%)	5.29 ± 0.73	*4*	*7*
IMC after 6 months of surgery (%)	35.02 ± 5.99	*24.7*	*46.6*
IMC after 12 months of surgery (%)	29.09 ± 3.08	*22.13*	*37.17*

Gastric bypass with anastomosis GBTA, Mellitus diabetes type (DM2), Corporal Mass Index (CMI)

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In the first 6 months and 12 months of follow-up, 95% and 97.5% of patients achieved remission of DM2, and, a 100% obtained criteria for discontinuation of hypoglycemic drugs from the first 6 months of follow-up, 5% (2 patients) who did not achieve remission of diabetes had indications of dietary management and lifestyle changes, and there was a significant decrease in patients' weight and better control of HbA1c (Figure 1).

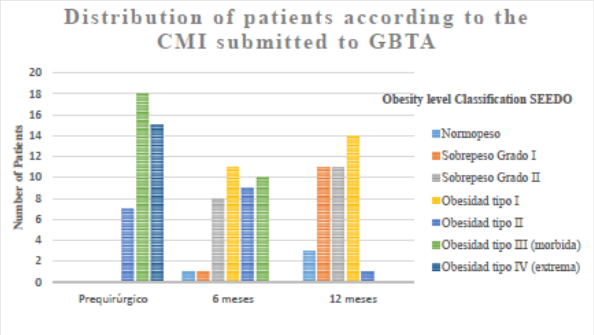

Figure 1. Distribution of patients submitted to GBTA according to the pre-surgery CMI, after 6 and 12 months. Obesity type
(On the right) Normal weight – Overweight Grade I - Overweight Grade II – Obesity type I - Obesity type II - Obesity type III (morbid) - Obesity type IV (extreme).
(In the bottom) Pre—surgery – 6 months – 12 months

There was a decrease in BMI of all patients, changing the distribution of the IMC-SEEDO classification after 6 months and 12 months, at the beginning of the study the population was distributed between the classification of type II to type IV obesity; after 12 months of the study there were no patients in category III and IV, there was one patient in category II, 14 patients in the category of obesity type I, and the rest of patients were located between normal weight, and overweight (figure 1).

According to the purpose of the surgery (bariatric or metabolic), it is observed that, when it is performed for bariatric purposes, the weight reduction is greater than when it is performed for metabolic purposes (Figure 2). A correlation analysis was made between the length of the common ASA and the weight loss, and the resolution of the DM2, but it was not statistically significant, so the data are not included.

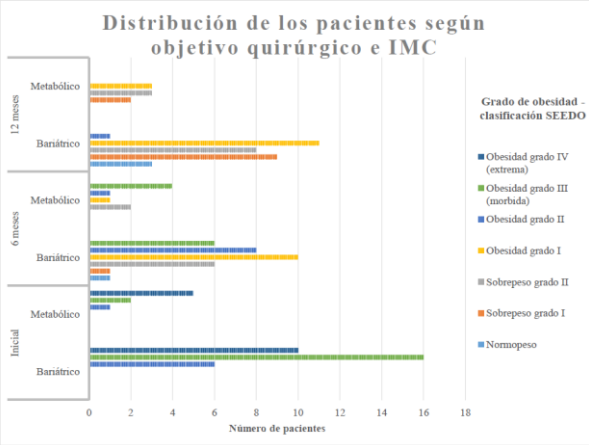

Figura 2. Distribución de los pacientes según objetivo quirúrgico y grado de obesidad inicial, a los 6 meses y 12 meses.
(On the left side) 12 months – Metabolic / Bariatric – 6 months Metabolic / Bariatric – Initial Metabolic / Bariatric
(On the bottom) Number of patients.

It was observed that after 6 months, 42.5% (17 patients) lost between 50-75% of excess weight and 52.5% (21 patients) lost between 25-50% of excess weight; and after 12 months, 42.5% (17 patients) lost between 75-100% of excess weight and 57.5% (23 patients) lost between 50-75% of excess weight (figure 3).

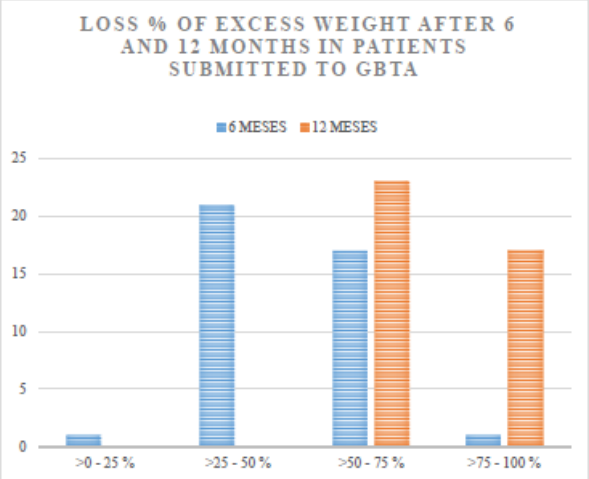

Figure 3. Percentage of excess weight loss after 6 and 12 months
6 months – 12 months

When comparing the weight loss percentage according to the size of the ASA, it is observed that, when the target is metabolic after 6 months, patients have lost between 25-75% of excess weight, and after 12 months they have lost between 50-50%. 100% of excess weight; when the goal is bariatric after 6 months, most patients (30 patients) lost between 25-75% of excess weight, and after 12 months, all

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patients had lost between 50-100% of excess weight (figure 4).

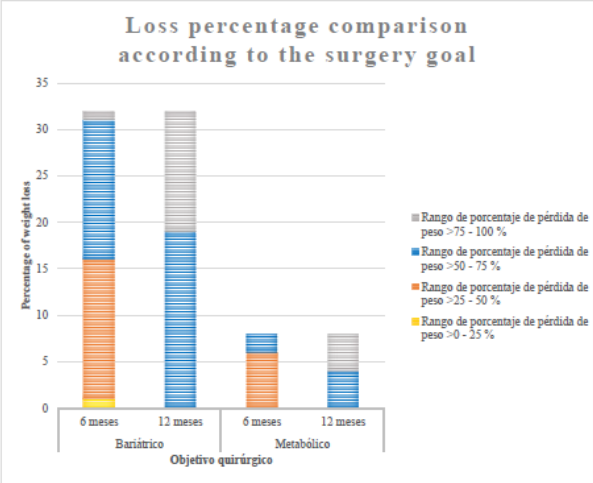

Figure 4. Comparison of weight loss percentage according to the size of ASA (Bariatric of metabolic goal) (Right) Weight Loss percentage range > 75-100% - Weight Loss percentage range >50-75% - Weight Loss percentage range >25-50% - Weight Loss percentage range >0-25% (Bottom) Surgery goal: 6 and 12 months – Bariatric -6 and 12 months Metabolic

After 12 months, patients undergoing CB for metabolic purposes, achieved DM2 control in 100% of cases, while patients undergoing CB for bariatric purposes, achieved DM2 control in 93.75% of the cases. (figure 5). In addition, there was a significant decrease in fasting blood glucose and Hb1AC both after 6 months and 12 months of follow-up (Figure 6).

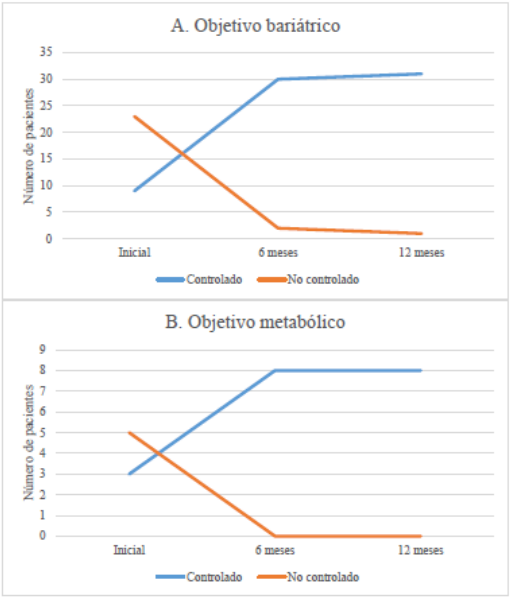

Figure 5. Control of diabetes in patients undergoing GBTA according to the surgical goal after 6 and 12 months, bariatric goal (A), metabolic goal (B).

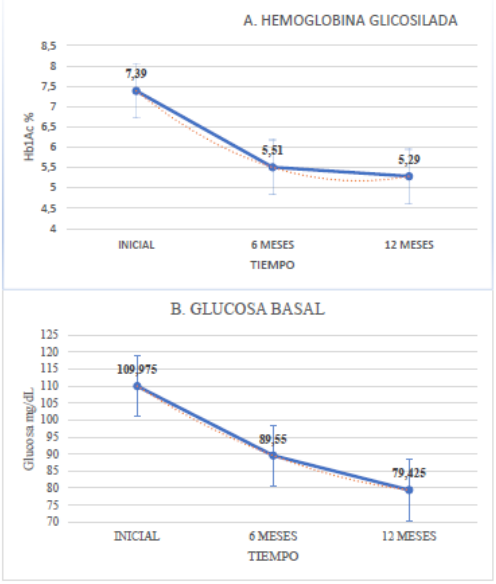

Figure 6: Glycosylated hemoglobin values after 6 and 12 months (A). Basal glucose values after 6 and 12 months (B). A percentage of complications of 7.5% (3 patients) of the entire sample was observed, out of which, 5% had to be submitted to surgery again and, 2.5% required dilation of the anastomosis via endoscopy (Table 2). After 12 months of follow-up, no patient presented malnutrition or the presence of bile reflux.

Table 2. Type of complications in patients submitted to GBTA.

Type of complications	Cases	Percentage	Treatment
Bleeding	1	2,50%	Reoperation
Stenosis	1	2,50%	Endoscopic
Perforation	1	2,50%	Reoperation
Gastro esophageal reflux	0	0%	N/A
Malnutrition	0	0%	N/A
None	37	92,50%	N/A
Total	40	100,00%	

Discussion

Bariatric surgery makes changes in the secretion of intestinal hormones with remarkable effects on metabolism, appetite and food intake; One of the first effects that have been observed after CB, is the change in the liver resistance to insulin that can be observed during the first week after the procedure, with insulin resistance values similar to subjects tolerant to insulin, on the other hand, the clearance of insulin presents an increase which influences the concentration of peripheral insulin.

Probably these improvements are due to the decrease in liver fat secondary to the caloric restriction, which is

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associated with what has been reported in previous studies, where hepatic fat association with impaired insulin clearance and liver resistance have been found. The hepatic sensitivity to insulin is associated with the hepatic fat content independently from the clearance of insulin. (19,20).

Another mechanism that could explain the improvement of glucose values correlates with the insular whole axis, with a high production of incretins, together with a decrease in the production of antiintintins (generating a greater effect in incretins) (21) ; In addition, current evidence suggests that GLP 1 mediates some of the glycemic benefits subsequent to CB, however, it is likely that other factors derived from the intestine intervene in the protection or increase in mass of pancreatic beta cells in the long term. Studies are needed to determine the association of these benefits in relation to CB and LPG 1. (22).

Among the factors that contributed to the failure in remission of DM2, we can highlight the reserve of pancreatic beta cells, so the long-term illness, the use of insulin and low levels of C-peptide are factors that are associated with probable irreversible death of these cells and, therefore, they can be used as indicators of failure to remission of the disease (22,23).

The DM2 remission results of this study are correlated to the results provided in a systematic review of 2018, that included patients undergoing CB with the GBTA technique; with a total of 12,807 patients, who obtained an average resolution of the T2D of the 83.7% (15). The highest remission found in our study, can probably be explained by a greater reserve of pancreatic beta cells, and that our sample is discrete compared to the final population of the systematic review, which may overestimate the remission value.

The loss of excess weight in our study acted in a similar way to that reported in the readings, finding between 60.68 and 78.2%; in relation to the recovery of weight or remission of DM2, according to the size of the ASA, no studies with statistically significant results; have been conducted with long-term follow-up, so it would be convenient to perform the studies in association with the size of the ASA for the purpose of standardizing its length (15).

In two recent studies, the YOLIMA randomized clinical trial in which they compared the Roux-en-Y technique (RYGB), and a prospective 5-year cohort, where they compared the gastric sleeve, RYGB, and GBTA techniques; in both studies they found that the resolution of DM2 and weight loss was greater with the GBTA after 2 and 5 years of follow-up as well, which suggests that this technique has a higher performance in relation to the performance related to reach the metabolic goal in DM2. These results are similar to those found in our study (18,24).

The results of the higher % of weight loss with the GBTA technique have results similar to more complex malabsorptive techniques, so it can be deemed as a malabsorptive technique, and it is widely known that malabsorptive procedures have a higher risk of developing nutritional deficiencies than restrictive or mixed procedures. In our study, no patients with malnutrition or nutritional deficiencies were found after one year of control. In the YOLIMA trial, the authors did not find significant differences between RYGB and GBTA, they conclude that there is a higher incidence of malnutrition if the biliopancreatic ASA is longer and they suggest that it does not exceed 150 cm in length; These results are similar to the Tovar et al. cohort, in which there was no significant difference in the need for nutritional supplements between the RYGB and GBTA, versus the gastric sleeve, with the need for iron and folic acid to be higher. RYGB and GBTA, these needs were observed after the second year of follow-up, while in the first year there were no significant differences in the needs for specific supplementation in the 3 groups. In addition, the authors suggest that personalized measures to determine the length of the ASA could be associated with a lower malnutrition rate (18,24).

Biliary reflux in the YOLIMA clinical trial, occurred in 16% of the patients, and none in the RYGB group; while, in the cohort of Tovar et al., after 5 years, only 2 patients presented biliary reflux with the GBTA technique that required conversion to RYGB and, 3 for the gastric sleeve group (18,24). In our study, no case of bile reflux was present after 12 months of follow-up, this can be explained by the small sample size and a follow-up of only 12 months. Complications in patients undergoing GBTA were low with 7.5%, which correlates with that reported in the readings, which shows minor complications in the first postoperative 30 days from 1.96 to 10.0% and major complications between 0 and 5.5 % (fifteen).

The mortality of CB with the GBTA technique is low, in our study there was no case of mortality; while in what is reported by the readings, it is close to a mortality of around 0.1%, showing safety in the CB in general (15,18,24).

Conclusions

The intervention with the GBTA technique in patients with DM2 with, either a metabolic or bariatric goal can be recommended as a conventional bariatric procedure, with an important weight control, a high remission rate or better control of DM2 observed at the same time after 6 and 12 months. The current readings suggest the maintenance after 24 months, but further studies are needed to define the behavior of the remission of diabetes with the GBTA technique.

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