International Journal of Surgery 74 (2020) 5–10

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.elsevier.com/locate/ijsu

Before and After Study

Metabolic syndrome after Roux-en-Y gastric bypass in patients with morbid obesity: Five years of follow-up, a before and after study

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ARTICLE INFO

Keywords:
Laparoscopic gastric bypass
Bariatric surgery
Metabolic syndrome
Morbid obesity
Before-after study

ABSTRACT

Background: Metabolic syndrome (MetS) is common among morbidly obese patients undergoing bariatric surgery. The aim of this study is to analyse prevalence and evolution of MetS in patients suffering from morbid obesity, before and after bariatric surgery, during a follow-up period of 5 years.

Methods: A before-after study was carried out including 156 patients with MetS. The definition of metabolic syndrome according to the Joint Interim Statement (JIS) definition was used. Demographic, as well as anthropometric, biochemical, and clinical analyses were assessed before, as well as 2 and 5 years after performing laparoscopic Roux-en-Y gastric bypass (RYGB).

Results: High BMI (100%), elevated blood pressure (78%) and low levels of high density lipoprotein (70%) were the most prevalent criteria for MetS. The percentage of people with MetS decreased significantly to 48.9% at 2 years and 24.1% at 5 years. The weight was also significantly reduced at 2 years, although at 5 years a rebound effect is already observed. Percentage of total weight loss (%TWL) and excess BMI loss (%EBMIL) were.

49.7 ± 19.4% and 68.2 ± 18.9%, respectively, at 2 years and 29.3 ± 11.6% and 62.0 ± 24.9 at 5 years, both presenting significant differences ($p < 0.001$).

Conclusion: RYGB in obese patients is associated with a significant improvement of MetS and its comorbidities. Insufficient weight loss is the main factor related to the prevalence of MetS.

1. Introduction

Obesity is one of the most serious and prevalent non-communicable diseases of the 21st century. It is a chronic multifactorial process where a combination of dietetic treatment, lifestyle changes, exercise and behavioural therapy, as well as adjunctive medication treatment achieve weight loss, improving some of obesity related comorbidities [1,2]. However, these treatments do not provide the expected results in individuals suffering from morbid obesity.

Morbid obesity is defined as an organic disproportion between body weight and size, quantitatively measured by a Body Mass Index (BMI) ≥ 40 kg/m^2 [3]. Various authors have indicated that bariatric surgery is the most efficient procedure to control obesity and its comorbidities over lifestyle changes (diet and physical activity) and pharmacological intervention [4–8]. A beneficial effect has been widely proven on excess body weight, cardiovascular risk, dyslipidemia, non-alcoholic fatty liver disease orglucose homeostasis, among other obesity-related metabolic diseases [6,7,9–11].

Metabolic syndrome (MetS) includes a group of interrelated risk factors which contribute to the development of cardiovascular diseases and type 2 diabetes mellitus [12–16]. A high percentage of patients suffering from morbid obesity present MetS and bariatric surgery is the treatment of choice in these cases, which helps improve comorbidities [6,17–19]. Bariatric surgery is an effective treatment for patients suffering from severe or moderate obesity. However, various authors indicate that some of the patients regain weight on the long term [7,20,21]. The aim of this study is to analyse the prevalence and evolution of MetS and its comorbidities in patients suffering from morbid obesity, before and after bariatric surgery, during a follow-up period of 5 years, as well as analysing the differences in comorbidities between patients who maintained MetS at the end of the follow-up period and those who did not.

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https://doi.org/10.1016/j.ijsu.2019.12.019
Received 3 October 2019; Accepted 19 December 2019
Available online 23 December 2019

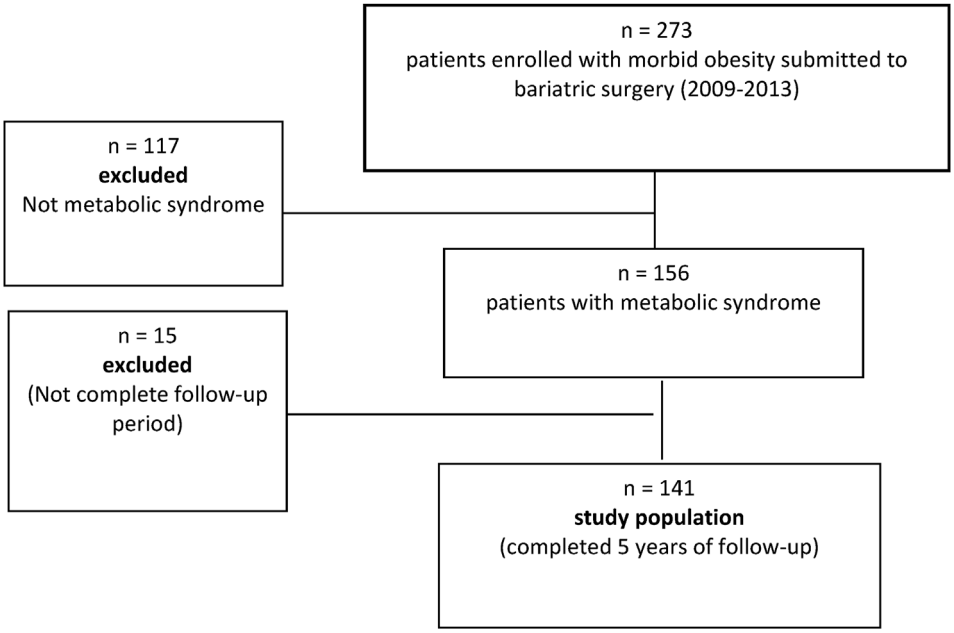

Fig. 1. Patient selection.

2. Methods

2.1. Design of the study

We conducted a before-after study on a consecutive, nonrandomized sample, including all patients suffering from morbid obesity submitted to bariatric surgery in the Surgery Service of the Public Reference Hospital, between January 2009 and December 2013. The number of patients submitted to surgery was 273 (69 men and 204 women) aged 20 to 61 and 19 to 64, respectively. Exclusión criteria were patients with incomplete or missing data at any time point during follow-up. (Fig. 1).

The surgical technique used was laparoscopic Roux-en-Y gastric bypass (RYGBP). RYGBP is a mixed technique that combines restrictive and malabsorptive procedures. Its main features are the creation of a gastric "pouch" (25 ± 5 ml), an alimentary loop of 100 cm, a biliopancreatic loop of 60 cm and a common channel. Surgeries were performed by the same group with standardization of the processes and technique.

According to the study protocol, all patients were evaluated in their pre and post operative phases for a period of 5 years after surgery.

MetS was defined according to the joint interim statement (JIS) definition [16] using body mass index (BMI) greater or equal to 30 kg/m^2 as a substitute for waist circumference. Three or more of the following criteria had thus to be met to be defined as MetS: plasma triglycerides (≥150 mg dl or specific treatment), HDL cholesterol (< 40 mg dl in men, < 50 mg dl in women or specific treatment), elevation of blood pressure (systolic ≥130 mm Hg, or diastolic ≥ 85 mm Hg or antihypertensive treatment), elevation of fasting plasma glucose (≥100 mg dl or previous diagnose of type 1 or 2 mellitus diabetes) and (BMI) > 30 kg/m2 as surrogate for waist circumference of ≥102 cm (male) and ≥88 cm (female).

BP was taken using an Omron M6 AC automatic digital monitor (Omron Healthcare, Kyoto, Japan). Three BP readings were taken at 1 min intervals and the mean value of the second and third readings was used for study analysis. BP was measured in the seated position for ≥5 min in a quiet room, bladder empty, and arm at heart level.

A post surgery follow-up of 5 years was performed to patients identified as suffering from MetS. MetS improvement was considered when the criteria applied were not met. The list of medication used during follow-up and date of medication withdrawal were also collected to complete the definition of improvement. Patients who did not complete the follow-up period (due to moving house, death or other causes) were excluded from the study.

The improvement of MetS and its components was assessed at 5 years (with a check point at 2 years). Demographic as well as anthropometric, biochemical and clinical analyses were included. Weight loss during the study period was evaluated calculating percentage of total weight loss (% TWL) and percentage of excess BMI loss (%EBMIL), as described by Sabench [22].

Finally, an analysis of the variables weight, % TWL, BMI and % EBMIL was carried out comparing the patients who presented MetS at 5 years with those who did not. This information was collected from the patients 1 month, 6 months, 2 years, 4 years and 5 years after surgery.

This study was reported according with the STROCSS criteria [23]. The study protocol was approved by the local Ethics Committee and respects the Declaration of Helsinki.According to the regulations of the Hospital Ethical Committee, no approval was required for this before-after study. It is registered in the Research Registry Platform.

2.2. Statistical analysis

Continuous variables were summarized with the mean ± standard deviation and categorical and discrete variables with frequency and percentage. Comparisons between two periods were carried out with paired *t*-test and McNemar chi-square test, respectively. A repeated measure analysis of variances (RM-ANOVA) was applied to study the evolution of % TWL and % EBMIL between patients who maintained MetS at 5 years and those who did not. Firstly, it was applied in periods of 1 month, 6 months and 2 years, and then in periods of 2, 4 and 5 years. Analyses were performed using SPSS 25 (IBM SPSS, Armonk, NY) and differences with a p-value < 0.05 were considered statistically significant.

3. Results

Throughout the study period, a total of 273 patients underwent bariatric surgery. Initially, 156 patients presented MetS (57.1%). For the final analysis, 141 patients completed the 5- year follow-up (90.4%).

Table 1
Evolucion of anthropometric, clinical and biochemical parameters.

	Initial (n = 141)	Two years (n = 141)	Five years (n = 141)	P[a]	P[b]
Weight (kg)	133.1 (24.2)	89.5 (15.2)	93.2 (18.6)	< 0.001	0.002
Body mass index (kg/m^2)	48.8 (7.6)	32.9 (5.3)	34.3 (6.7)	< 0.001	0.001
Blood pressure					
Systolic (mmHg)	143.0 (19.0)	134.8 (14.0)	135.2 (18.7)	< 0.001	0.774
Diastolic (mmHg)	90.3 (11.7)	85.4 (10.4)	83.1 (11.0)	< 0.001	0.038
Glucose (mg/dl)	129.8 (49.0)	94.3 (21.2)	88.7 (15.6)	< 0.001	0.001
HDL (mg/dl)	44.2 (9.0)	51.3 (11.5)	60.1 (14.5)	< 0.001	< 0.001
Triglycerides (mg/dl)	160.5 (83.5)	108.6 (42.7)	94.0 (42.9)	< 0.001	< 0.001
Total Cholesterol (mg/dl)	197.6 (40.1)	189.9 (42.0)	193.1 (40.3)	0.024	0.243
LDL (mg/dl)	123.5 (32.9)	123.8 (33.1)	118.1 (31.3)	0.871	0.007
HbA1C (%)	7.4 (1.0)	6.0 (1.0)	5.4 (0.8)	< 0.001	< 0.001
TWL (%)	–	49.7 (19.4)	29.2 (11.6)	–	< 0.001
EBMIL (%)	–	68.2 (18.9)	62.0 (24.9)	–	0.001

The values show mean (standard deviation).
[a] p-value between initial and 2 years.
[b] p-value between 2 years and 5 years.
HDL (high density cholesterol), LDL (low density lipoprotein), HbA1C (glycated hemoglobin), TWL (total weight loss); EBMIL (excess body mass index loss).

The average age of the patients prior to surgery was 41.1 ± 9.7 and 105 (74.4%) of them were women. Initial weight was 133.1 ± 24.2 kg and BMI was 48.8 ± 7.6 kg/m^2. The evolution of antropometric, clinical and biochemical parameters throughout the study period is shown in Table 1.

As to patients presenting type 2 diabetes, there were 77 (54.6%) initially, 45 (31.9%) at 2 years, and 18 (12.8%) at 5 years. This implies a reduction rate of −41.6% at 2 years and −76.6% at 5 years.

Most clinical and biochemical parameters improved within 2 and 5 years (at a slower pace than from the beginning to the second year). It should be emphasized that a rebound effect is observed at 5 years, regarding variables related to antropometric parameters, as weight and BMI have increased considerably from the second to the fifth year. Weight loss general analysis showed 49.7 ± 19.4% TWL at 2 years and 29.32 ± 11.6 at 5 years ($p < 0.001$). At 2 years, 74 patients (52.5%) presented % TWL below 50%, whereas 138 (97.9%) presented it at 5 years. Regarding % EBMIL, it was 68.2 ± 18.9 at 2 years and 62.0 ± 24.9 at 5 years ($p < 0.001$).

Table 2 shows the number and percentage of patients presenting the different components of MetS, as well as their evolution.

The percentage of reduction in the number of patients presenting risk values according to Mets definition at 2 and 5 years over initial values were the following: 29.1% and 24.1% for BMI, 65.2% and 81.8% for triglycerides, 48.5% and 77.8% for HDL cholesterol, regarding hypertension there was 3.6% increase in the first period and a 12.7% reduction at 5 years, and as to blood glucose plus type 2 diabetes mellitus there was 43.5% and 76.1% reduction at 2 and 5 years, respectively.

As to the number of MetS'components, 55.3% of patients presented 3 components in the initial period, 29.1% presented 4 and 15.6% presented 5; observing a significant decrease in comorbidities during the study periods. MetS prevalence decreased in the second year in 48.9% of patients and in 24.1% at 5 years, with remarkable differences between the two periods (Table 3).

Table 3
Evolution of the number of comorbidities and metabolic syndrome.

Nº of Comorbidities	Initial (n = 141)	Two years (n = 141)	Five years (n = 141)	P[a]	P[b]
0	0	2 (1.4)	9 (6.4)	0.877	0.065
1	0	27 (19.1)	45 (31.9)	< 0.001	0.013
2	0	43 (30.5)	53 (37.6)	< 0.001	0.268
3	78 (55.3)	54 (38.3)	30 (21.3)	0.013	0.002
4	41 (29.1)	10 (7.1)	2 (1.4)	< 0.001	0.039
5	22 (15.6)	5 (3.5)	2 (1.4)	< 0.001	0.453
Total with MetS	141 (100)	69 (48.9)	34 (24.1)	< 0.001	< 0.001

The values show frequency (%).
[a] p-value between initial and 2 years.
[b] p-value between 2 years and 5 years.

When comparing patients who maintained MetS at 5 years with those who did not, it was obtained that, initially, type 2 diabetes rates were 61.8% vs 52.3% ($p = 0.44$), at 2 years they were 44.1% vs 28.0% ($p = 0.12$), and at 5 years, 47.1% vs. 1.9% ($p < 0.001$). Thus, reduction rates at 2 years were −28.6% vs - 46.4%, and −23.8 vs −96.4% at 5 years.

Within the group of patients that continued presenting MetS at 5 years it was obtained that 4 (12%) and 18 (53%) presented %TWL < 25% at 2 and 5 years, respectively, whereas those values in the group of patients that no longer presented MetS were 5 (5%) and 31 (19%), respectively (Table 4).

Fig. 2 shows weight, % TWL, BMI and % EBMIL evolution in the different periods recorded, drawing a distinction between patients

Table 2
Evolution of component of metabolic síndrome.

	Initial (n = 141)	Two years (n = 141)	Five years (n = 141)	P[a]	P[b]
BMI > 30 kg/m^2	141 (100)	100 (70.9)	107 (75.9)	< 0.001	< 0.001
TGs ≥ 150 mg/dl	66 (46.8)	23 (16.3)	12 (8.5)	< 0.001	0.035
HDL < 40/ < 50 mg/dl	99 (70.2)	51 (36.2)	22 (15.6)	< 0.001	< 0.001
Total (T2DM + FPG)	92 (65.2)	52 (36.9)	22 (15.6)	< 0.001	< 0.001
Hypertension > 130/85 (mmHg)	110 (78.0)	114 (80.9)	96 (68.1)	0.597	0.006

The values show frequency (%).
[a] p-value between initial and 2 years.
[b] p-value between 2 years and 5 years.
BMI (Body mass index), TGs (triglycerides), HDL (high density cholesterol), T2DM (Type 2 diabetes mellitus), FPG (fasting plasma glucose).

Table 4
Comparison of percentage of total weight loss (TWL), between patients without metabolic syndrome at five years and those who continue to present it.

		Two years		Five years	
		With MetS at 5 years	Without MetS	With MetS at 5 years	Without MetS
Total weight loss (% TWL)	< 25	4 (12%)	5 (5%)	18 (53%)	31 (29%)
	[25–50)	15 (44%)	50 (47%)	15 (44%)	74 (69%)
	[50–75)	12 (35%)	43 (40%)	1 (3%)	2 (2%)
	≥75	3 (9%)	9 (8%)	–	–
p-value		0.525		0.031	

presenting MetS at 5 years and those who did not. Patients still presenting MetS at 5 years had 48.7% EBMIL, considerably lower than the 66.2% presented by patients who no longer had MetS ($p < 0.001$). Significant differences were also observed between these two groups at 2 and 5 years ($p = 0.002$ and 0.001, respectively), which was not the case at 1 and 6 months ($p = 0.3$ and 0.236, respectively). Maximum % EBMIL (with MetS 60.6% and without MetS 70.6%) were reached in both groups at 2 years. As to % TWL, marked differences between both groups were only observed at 5 years (with MetS 24.3% and without MetS 30.4%, $p = 0.016$). Regarding weight and BMI, considerable differences were observed in all periods between the group that presented MetS at 5 years and those who did not, always higher in the group with MetS. The study of %EBMIL evolution between those two groups showed a considerable linear increase ($p = 0.001$) in the 2–5 year period, without significant differences regarding the increase pattern of those two groups of patients ($p = 0.354$), although having considerably lower values than the group presenting MetS at 5 years compared to the one who did not ($p = 0.009$).

4. Discussion

In this study we present outcome data of metabolic syndrome, weight loss and comorbidities in patients following bariatric surgery by RYGB with a follow-up period of 5 years and we have analized the differences regarding comorbilities between patients who maintained MetS and those who did not, at the end of the follow-up period.

Before surgery, MetS prevalence of all patients who attended the bariatric surgery unit throughout the study period was 57.9%, similar to various published studies [17,19,24], but lower than the study by Nassour et al. [18] who indicated a prevalence of 88.7% and Barzin et al. [25] who noted 61.4%. Lower values have been described by Rodríguez-Ortiz et al. [26] and Martini et al. [27].

MetS patients presented an average age of 41.1 (± 9.7) and 74.4% of all case samples were women (105). These demographic features are similar in most studies consulted [16,18,24–26].

Regarding the number of comorbidities, 55.3% of the sample presented 3 criteria of MetS, 29.1% presented 4 and 15.6% presented 5. Rossi et al. [17] observed that 54.2% presented 3 factors, 17.5% presented 4 and 8.5% presented 5. Guilbert et al. [19] indicated 3

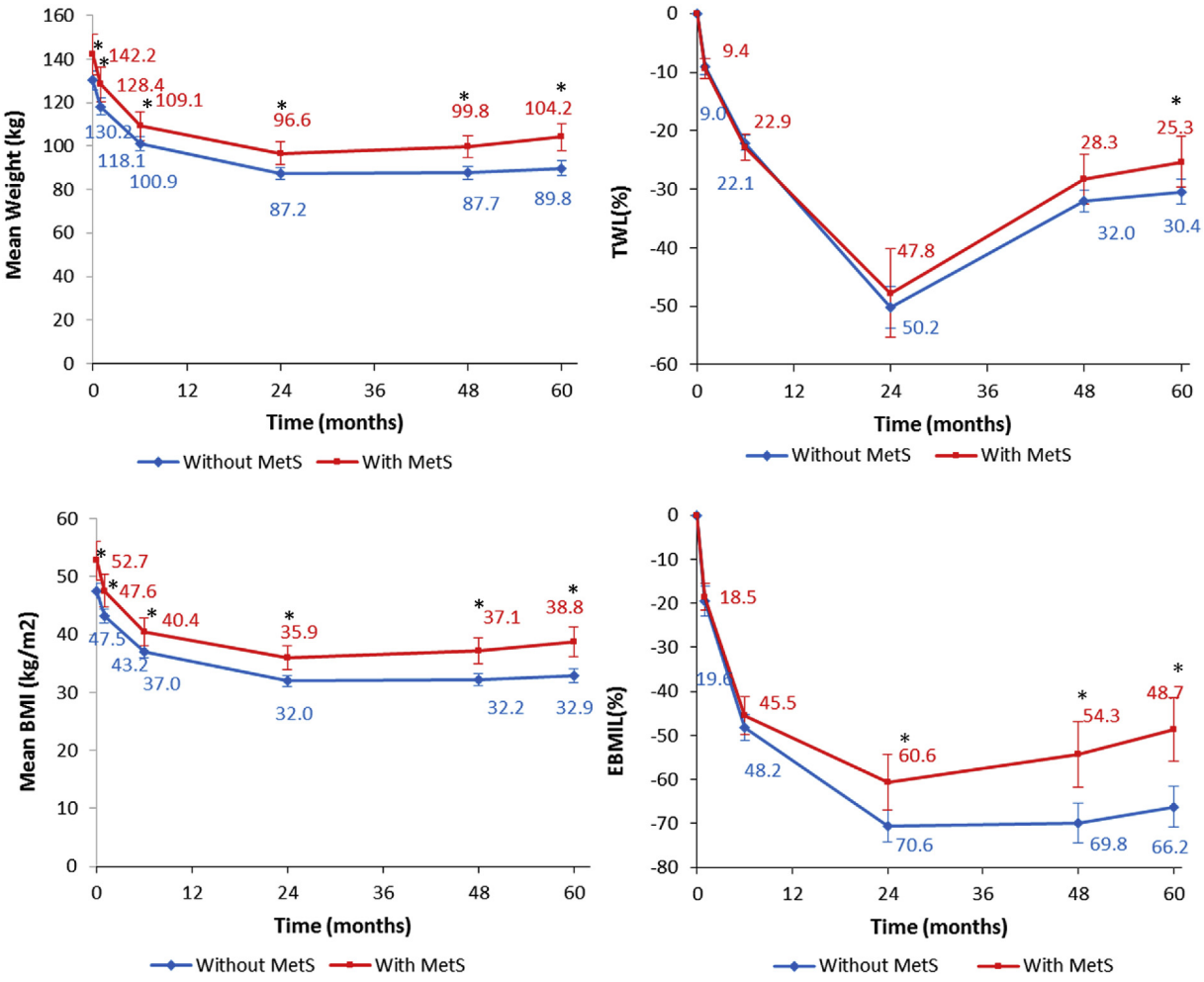

Fig. 2. Comparison of mean weight, percentage of total weight loss (TWL), mean BMI and percentage of excess BMI loss (EBMIL) between patients without metabolic syndrome at five years and those who continue to present it. (Bars represent the 95% confidence intervals and * significant differences in that period).

comorbidities in 52.3% of patients, 4 in 39.7% and 5 in 7.9%. In our study, we found a higher percentage of patients meeting 5 criteria than in the studies mentioned. The most prevalent criteria for MetS were BMI (100%), elevated blood pressure (78.0%) and low HDL (70.2%). Unlike the studies by Barzin et al. [24], who found the more frequent factors to be low HDL (58.6%) and hypertriglyceridemia (53.95), finding less hypertensive patients (38.8%) than us. Guilbert et al. [19] indicate as prevalence factors reduced HDL (98.4%) and raised glucose or T2DM (60.9%) and an initial percentage of hypertensive patients of 54%.

In our study, we observed that patients submitted to bariatric surgery experienced improvement in MetS at 2 years, which continued until the fifth year, and this change was significant in both periods studied, percentage of change being of - 51.1% at 2 years and −75.9% at 5 years. It should be highlighted that at 5 years, only 1.4% of the patients presented 4 or 5 risk factors. Most studies show a remission rate of MetS higher than ours [17,19]. It is difficult to compare the results as there are differences regarding MetS criteria, follow-up periods and surgical techniques used.

Our cohort initially presented a high percentage of patients with 5 components of MetS (15.6%) and the follow-up period has been longer than most studies consulted. We have set this follow-up period based on the fact that various studies show the existence of a rebound effect of weight and, thus, comorbidities and MetS throughout the years [7,20,21]. In our case, we had 48.9% of patients with MetS at 2 years and 24.1% at 5. Shah et al. [24] found that, after a long follow-up period of 6–9 years, 24.8% remained with MetS, a value similar to ours, and Nassour et al. [18], with a follow-up period of 4 years, found that MetS prevalence was reduced to 37.6% in patients who underwent RYGB.

Sabench et al. [22] indicate that full weight normalisation is not an indispensable condition to obtain a significant improvement, but what matters most is the improvement of comorbidities. In our study, the number of comorbidities significantly decreased in both periods compared, showing a high remission of MetS components at 2 and 5 years, excepting BMI and blood pressure. As to blood pressure, it increased slightly at 2 years but diminished considerably at 5 years, although remission rate was 31.9%, lower than most studies consulted [17–19,28]. We consider this must be due to the fact that we started with a cohort having an average BMI and a higher percentage of hypertension [17–19]). The GATEWAY randomized trial by Schiavon et al. [29] indicated that, a year after bariatric surgery, 51% of the patients submitted to gastric bypass showed remission of hypertension, a value equal to that previously obtained by Shah et al. [24], with a follow-up of 5 years. A recent cohort study published by Jakobsen et al. [30] comparing patients after bariatric surgery (92% of gastric bypass) to those who underwent medical treatment with a median follow-up of 6.5 years found that remission of hypertension was 31.9% in the surgery group and 12.4% in the medical treatment group. This remission rate of high blood pressure in patients following surgery is equal to that which we found at 5 years.

Various studies indicate that it is important to know different indicators of weight loss in order to assess the quality and efficacy of bariatric surgery [19,22]. We used percentage of total weight loss (%TWL) and percentage of excess of body mass index loss (%EBMIL).

Bariatric Outcomes Longitudinal Database (BOLD) pointed at percentage of total weight loss (%TWL) as the most homogeneous and less variable value to assess the efficacity of bariatric surgery [31]. Sabench et al. [22] indicated that % TWL allows to compare improvement results, as it avoids initial BMI bias which would give better results to patients with lower BMI. In our study, general weight loss analysis showed a %TWL of 49.7 (± 19.4) at 2 years and 29.3 (± 11.6) at 5. Nassour et al. [18] indicated that percentage of weight loss was 26.5% 4 years after RYGB and the greatest percentage of weight change (28.7%) occurred 1 year after, showing a weight gain when increasing the follow-up period.

As to % EBMIL, we obtained values of 68.2 ± 18.9 at 2 years and 62.0 ± 24.9 at 5 years, presenting significant differences ($p < 0.001$). Larrad et al. [32] propose to arrange this parameter's results in order of importance, as excellent if above 65%, good if between 50% and 65% and failure if under 50%. Following this criterion, our results would be excellent at 2 years and good at 5 years. For this parameter, Guilbert et al. [19] indicate values of 84.8 ± 19.5 at 1 year and 79.6 ± 22.6 at 2 years, with a higher improvement than ours.

In our study, patients who still showed MetS at 2 and 5 years presented higher weight and BMI, and lower %TWL and % EBMIL, which could indicate, as other authors point out, that there was a direct relationship between percentage of weight loss or percentage of excess BMI loss and improvement of the syndrome [19,24].

Although weight loss reduction was significant in our cohort considering both parameters studied, it should be noted that we departed from a high mean BMI, which could explain that most patients still presented BMI > 30 kg/m^2 after surgery and during the follow-up period. On the other hand, weight gain detected coincides with that referred to by studies assessing patients' evolution on the long term [7,20,21]. There is a variety of factors contributing to this weight gain, such as biological, environmental, social and phycological; which calls for an increased periodic control of these patients following surgery, focused mainly on lifestyle-related factors [1,7]. Implementation of comprehensive nutrition counseling, as well as advice on behavioural changes before and after surgery will help obtain optimal weight results [20,21].

4.1. Limitations of the study

In this type of studies, with a long follow-up period, the accuracy of the measurement of comorbilities can be affected by measurement variability. We used BMI as a substitute for waist circumference, as this value is not collected routinely, and this substitution could affect the prevalence of MetS, but not the comparison between pre and post operative periods. However, considering the duration of the follow-up period and the fact that it was carried out with a very high percentage of the initial cohort, the percentage of loss being 9.5%, we believe our study is of high interest to assess the improvement of MetS and its comorbidities in this population.

5. Conclusion

RYGB in obese patients is associated with a significant improvement of MetS and its comorbidities. Insufficient weight loss is the main factor related to the prevalence of MetS in the population studied. Considering the weight regain detected in our cohort at 5 five years, we believe the study should be extended with an increased follow-up period.

Ethical approval

All patients signed the informed consent forms to be included in the study. According to the regulations of the Hospital Ethical Committee, no approval was required for this before-after study. The principles stated in the Declaration of Helsinky have been respected.

Sources of funding

There is no source of funding.

Author contribution

Cristobalina Rodríguez-Álvarez, Angeles Arias, Alfonso Acosta Torrecilla y Enrique González -Dávila conceived the research idea and conducted literature review. Alfonso Acosta Torreccilla collected the data. Enrique González Dávila conducted the statistical analyses. All authors were involved in critically reviewing the manuscript draft and

approving the final version for submission.

Trial registry number

Name of the registry: Research Registry.
Unique Identifying number or registration ID: researchregistry5157.
Hyperlink to the registration: https://www.researchregistry.com/browse-the-registry#home/

Guarantor

Cristobalina Rodríguez-Álvarez, Angeles Arias.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Data statement

Authors can confirm that all relevant data are included in the article and/or its supplementary information files.

Declaration of competing interest

The authors declare that they have no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.12.019.

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