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Long-term follow-up after sleeve gastrectomy versus Roux-en-Y gastric bypass versus one-anastomosis gastric bypass: a prospective randomized comparative study of weight loss and remission of comorbidities

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Abstract

Background One-Anastomosis Gastric Bypass (OAGB) has exponentially increased in the last decade, as it is associated with very low complications, mortality, readmissions and reoperations rates, and shows excellent short- and long-term benefits of weight loss and resolution of comorbidities. The aim of this study was to compare the effect of SG, RYGB, and OAGB, on short- and long-term weight loss and comorbidities resolution.

Methods A prospective randomized clinical study of all morbidly obese patients undergoing SG, RYGB, and OAGB, as primary bariatric procedures, was performed. Patients were randomly assigned into 3 groups: those patients undergoing SG, those ones undergoing RYGB and those ones undergoing OAGB. BMI, excess BMI loss (EBMIL) and remission of type 2 diabetes (T2DM), hypertension (HT), and dyslipidemia (DL) were assessed.

Results 600 patients were included in the study, 200 in each group. Follow-up rate at 5 years postoperatively was 91% in SG group, 92% in RYGB, and 90% in OAGB. OAGB achieves significantly greater EBMIL than RYGB and SG at 1, 2, and 5 years ($p<0.001$, respectively). At 5 years, OAGB achieves significantly greater remission of T2DM ($p=0.027$), HT ($p=0.006$), and DL ($p<0.001$) than RYGB and SG. RYGB did not show significant superiority than SG in short- and long-term remission of T2DM and HT, but achieves greater remission of DL ($p<0.001$).

Conclusion OAGB achieves superior mid- and long-term weight loss than RYGB and SG. There are no significant differences in weight loss between SG and RYGB at 1, 2, and 5 years. OAGB achieves better short- and long-term resolution rates of DM, HT, and DL than SG and RYGB. RYGB and SG obtain similar T2DM and HT remissions, but RYGB reaches significantly greater rates of DL remission. ClinicalTrials.gov Identifier: NCT03467646.

Keywords Sleeve gastrectomy · Roux-en-Y gastric bypass · One-anastomosis gastric bypass · Type 2 diabetes mellitus · Hypertension · Dyslipidemia

Obesity is a global health problem, mainly in developed countries. In the last 2 years, about 6 million people have been diagnosed with morbid obesity [1]. Moreover, the prevalence of this disease in adolescents has increased [2], resulting in an early onset of comorbidities such as arterial hypertension (HT), dyslipidemia (DL), type 2 diabetes mellitus (T2DM), and sleep apnea hypopnea syndrome (SAHS) with an increase of cardiovascular risk. Bariatric surgery is the most efficient treatment option for patients with moderate to severe obesity, in whom conservative measures have failed, to obtain a significant and maintained weight loss and improvement of obesity-related comorbidities. Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) are the most frequently performed bariatric procedures worldwide [3]. However, One-Anastomosis Gastric Bypass has exponentially increased in the last decade, as it is associated with very low complications, mortality, readmissions, and

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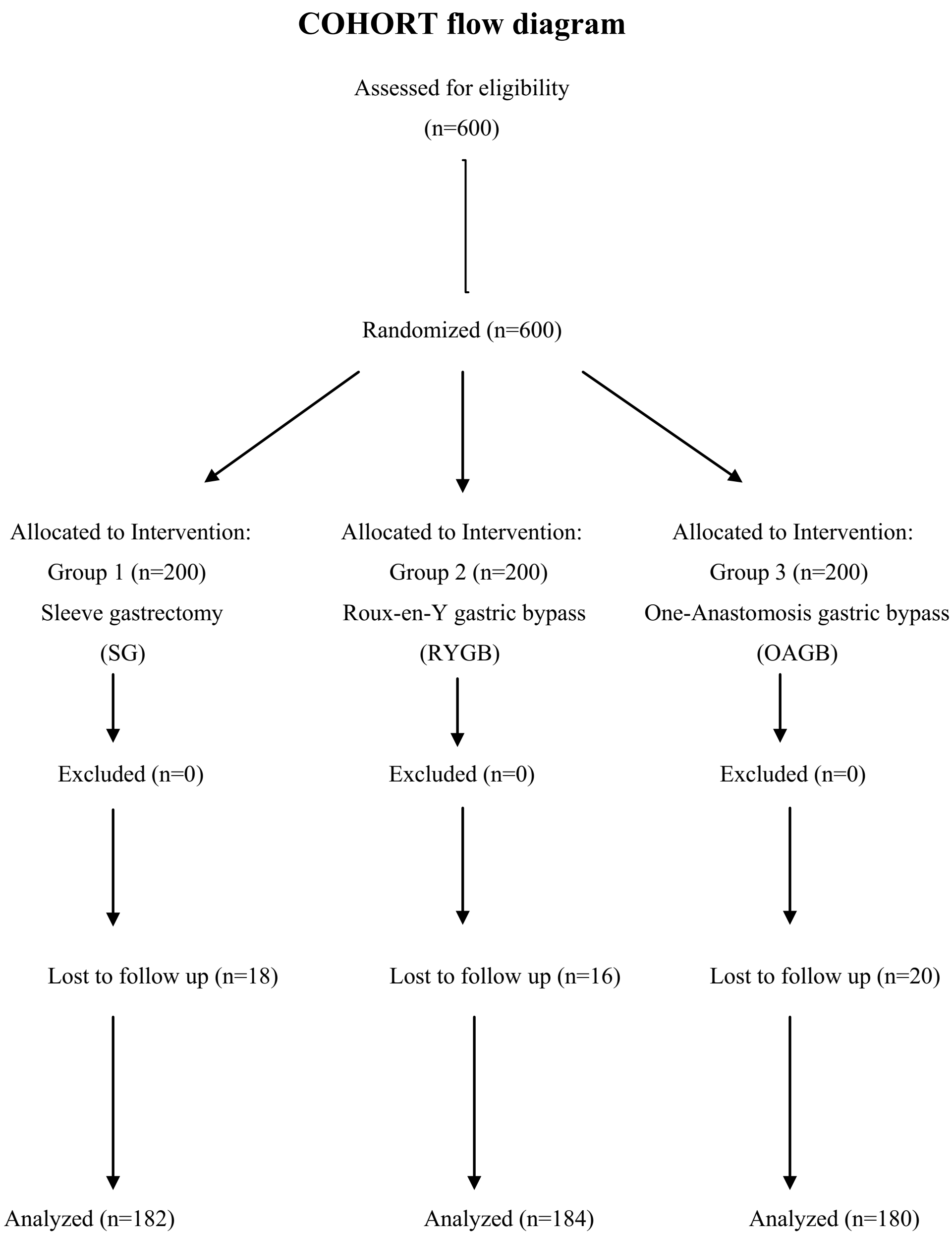
reoperations rates and shows excellent short- and long-term benefits of weight loss and resolution of comorbidities [4].

The aim of this study was to compare the effect of SG, RYGB, and OAGB, on short- and long-term weight loss and comorbidities resolution.



Patients and methods

A prospective randomized clinical study of all morbidly obese patients undergoing SG, RYGB, and OAGB, as primary bariatric procedures, was performed between June 2010 and December 2012.

Inclusion criteria were body mass index (BMI) > 40 or BMI > 35 Kg/m^2 with the presence of comorbidities associated to obesity, age older than 18 years and willing to participate in the study and giving their written consent. Exclusion criteria were patients undergoing other bariatric techniques than SG, RYGB, and OAGB, patients undergoing any other surgical procedure added to the bariatric surgery, inability to understand the nature and purpose of the study and/or to accept written participation in the study, and impossibility to comply with pre-established clinical follow-up.

The sample size calculation was based on historic data of our center of excess BMI loss (EBMIL) 5 years after SG of 72.5% (Control Group) and an expected increase up to 85% EBMIL 5 years after RYGB and OAGB. At 80% power and a significance level of $p = 0.05$, it was calculated that 200 patients were required in each arm of the study. The sample size was calculated to obtain adequate statistical power for the multiple comparison procedures performed. The number of patients was calculated, anticipating a 15% of loss at follow-up.

Patients were randomly assigned using a random-number table into 3 groups: those patients undergoing SG, those ones undergoing RYGB, and those ones undergoing OAGB. The patients were randomized in their initial visit to the Outpatient Clinic.

Preoperative evaluation

A multidisciplinary team, including surgeons, endocrinologists, dieticians, endoscopists, radiologists, anaesthesiologists, psychologists, and specialized nurse staff, performed a combined medical, nutritional, and endocrinological work-up to evaluate potential surgical candidates. Preoperative assessment included abdominal ultrasound, upper gastrointestinal endoscopy ,and analytical evaluation of the nutritional status. Psychologists assessed additional interviews to evaluate the implication of the patient in following a strict diet in the postoperative course. A dietician established a diet consisting in a total daily energy intake of 1200 Kcal. A weight loss of at least 10% of the patient's weight was considered an indispensable condition to undergo the selected bariatric technique (SG, RYGB, or OAGB).

Patients received information about possible perioperative complications, and necessary postoperative nutritional supplementation.

Surgical techniques

All procedures were performed laparoscopically.

SG: Five ports were used; two 12-mm ports located in right and left hypochondria, two 11-mm ports located in epigastrium and subxiphoideal region, and one 5-mm port in left flank. A longitudinal resection from the angle of His to approximately 3–5 cm orally to the pylorus was performed using linear stapler (I-Drive with Tri-staple cartridges, Medtronic, USA). A 40-Fr bougie was used as calibration method, inserted along the lesser curvature. A staple line inversion was performed with a continuous oversewing absorbable barbed suture (V-loc 2/0, Covidien, USA) before extracting the bougie. The section with the stapler was not performed very tight to the dilator and the inversion was used to adjust the suture to the tube size. Anastomosis integrity was verified with a pneumatic test.

RYGB: 5 ports were placed in right hypochondrium (12 mm), left hypochondrium (12 mm), epigastrium (11 mm), subxiphoideal (11 mm), and left flank (5 mm). A 6-cm-long gastric pouch was performed, calibrating it with a 36-Fr bougie, with a linear stapler (I-Drive with Tri-staple cartridges, Medtronic, USA). A 100-cm biliary limb and a 150-cm alimentary limb were performed. Both anastomoses were performed with linear stapler (I-Drive with Tri-staple cartridges, Medtronic, USA), calibrating the gastrojejunal anastomosis at 2 cm. The enterotomies and gastrotomies were sutured with continuous barbed suture V-Loc 2/0 (Medtronic, USA). Mesenteric defects were not closed in any of the cases. Anastomosis integrity was verified with a pneumatic test.

OAGB: 6 ports were placed; right and left flank (12 mm), supraumbilical (11 mm), right and left hypochondrium and right iliac fossa (5 mm). A 20-cm-long gastric pouch, calibrated with a 36 Fr bougie, was constructed. Termino-lateral gastrojejunal anastomosis with linear stapler (I-Drive with Tri-staple cartridges, Medtronic, USA) was performed. The enterotomies and gastrotomies were sutured with continuous barbed suture V-Loc 2/0 (Medtronic, USA). The total bowel length was determined; the biliopancreatic limb length ranged between was 200 and 350 cm long and the common limb between 180 and 250 cm. After the assessment of the total bowel length, the appropriate length of the limbs was determined following the ratio Biliopancreatic limb 60%/Common limb 40%.

Before hospital discharge, the 3 groups of patients received identical postoperative counseling, support, diet and exercise instructions. Multivitamin and mineral supplements (Elevit®, Bayer®, Germany) were uniformly prescribed in the three groups (2 tablets/day).

Follow-up

All the patients were followed up by the surgeon and endocrinologist 1, 2, and 5 years after surgery. Follow-up rate at 5 years postoperatively was 91% in SG group, 92% in RYGB and 90% in OAGB. During the follow-up, anthropometric parameters and comorbidities resolution were evaluated.

Medical treatment, such as antidiabetic, anti-hypertensive and hypolipemiant drugs, was adjusted according to the current needs of the patient. The nutritional status of the patients was evaluated by the endocrinologist with analytical blood tests. Deficiencies were supplemented, according to the results obtained.

Remission of comorbidities

Remission of type 2 diabetes mellitus (T2DM) was defined as plasma glucose below 110 mg/dL and glycated hemoglobin (HbA1c) below 6.5% in the absence of hypoglycemic treatment. Remission of hypertension (HT) was defined as blood pressure below 135/85 mmHg in the absence of anti-hypertensive treatment; remission of dyslipidemia (DL) was defined as fasting plasma triglycerides below 200 mg/dL, total cholesterol below 200 mg/dL, and high-density lipoprotein cholesterol over 40 mg/dL in the absence of pharmacological therapy.

Variables

All the variables were analyzed at baseline (preoperative values) and 1, 2, and 5 years after surgery. Anthropometric variables included BMI and EBMIL. Remission of comorbidities (T2DM, HT, and DL) was monitored. Specific vitamin and mineral supplementation needs were recorded, according to the deficiencies observed in the laboratory data.

Statistical analysis

Statistical analysis was performed with SPSS 22.0 for Windows. Quantitative variables that followed a normal distribution were summarized by means and standard deviations. For non-Gaussian variables, median and range were used. Qualitative variables were summarized by number and percentage of cases. Comparison of quantitative variables between the 3 groups was done using analysis of variance (ANOVA).Comparison of qualitative variables was performed with the Chi-square test; in cases with fewer than 5 observations in the cell, the Fisher exact probability method was used. Pairwise comparisons of groups used a Bonferroni corrected p value. Values of $p < 0.05$ were considered significant.

Results

A total of 600 patients were included in the study, 200 in each group. There were no significant differences in age, gender, preoperative weight and BMI, and distribution of comorbidities between groups (Table 1). The patients, lost to follow up at 5 years postoperatively, were excluded from the analysis of weight loss and remission of comorbidities. Finally, 182 patients were analyzed in group SG, 184 in RYGB and 180 in OAGB.

Postoperative complications included 4 staple line leaks (all of them conservatively managed with an endoscopic stent placement) and 1 hemoperitoneum, (requiring reintervention) in the SG group. In the RYGB group, there were 1 hemoperitoneum, 1 gastrojejunal anastomotic leak, and 2 jejuno-jejunal anastomotic leaks, all of them requiring reintervention. In the OAGB group, there was 1 hemoperitoneum and 1 intestinal obstruction, both requiring reintervention. There was no mortality in any of the groups.

Table 1 Distribution of age, gender, preoperative anthropometric measures, and distribution of comorbidities between groups

	SG	RYGB	OAGB	p
N	200	200	200	
Age (years)	43.9 ± 10.9	45 ± 11.3	43.8 ± 11.5	0.220
Females/males	150 /50	150 /50	150 / 50	1
Weight (Kg)	124.5 ± 11.3	121.9 ± 10.9	121.1 ± 11.1	0.794
BMI (Kg/m^2)	46.5 ± 3.4 (Range 35–58.1)	45.3 ± 3.2 (Range 35–56.6)	45 ± 4.1 (Range 35–61.3)	0.250
T2DM (%)	30.5	29.5	35	0.452
HT (%)	41.5	41.5	43	0.940
DL (%)	32.5	34.5	37	0.638

Postoperative anthropometric measurements

One year after surgery, BMI after SG was 28.9 ± 2.1 Kg/m^2, after RYGB 28.7 ± 2 Kg/m^2 and after OAGB 25 ± 1.6 Kg/m^2 ($p < 0.001$), with EBMIL of 81.7 ± 6.3, 81.2 ± 5.9 and $100.4 \pm 6.7\%$, respectively ($p < 0.001$). Pairwise analysis revealed that BMI after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), while there were no significant differences between RYGB and SG ($p = 0.864$). Similarly, EBMIL after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), but without reaching statistical significance between RYGB and SG ($p = 0.789$).

2 years after surgery, BMI after SG was 28.7 ± 2 Kg/m^2, after RYGB 27.8 ± 1.9 Kg/m^2 and after OAGB 24.8 ± 1.7 Kg/m^2 ($p < 0.001$), with EBMIL of 87 ± 7.1, 87.2 ± 6.7 and $104.3 \pm 7\%$, respectively ($p < 0.001$). Pairwise analysis revealed that BMI after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), while there were no significant differences between RYGB and SG ($p = 0.884$). In the same way, EBMIL after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), but without reaching statistical significance between RYGB and SG ($p = 0.811$).

5 years after surgery, BMI after SG was 30.8 ± 2.2 Kg/m^2, after RYGB 29.9 ± 2.3 Kg/m^2 and after OAGB 25.1 ± 1.8 Kg/m^2 ($p < 0.001$), with EWL of 76.3 ± 6, 77.1 ± 6.1 and $97.9 \pm 7\%$, respectively ($p < 0.001$). Pairwise analysis revealed that BMI after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), while there were no significant differences between RYGB and SG ($p = 0.763$). Similarly, EBMIL after OAGB was significantly lower than after RYGB and SG ($p < 0.001$, respectively), but without reaching statistical significance between RYGB and SG ($p = 0.746$) (Figs. 1, 2).

Fig. 1 Evolution of BMI after the different techniques

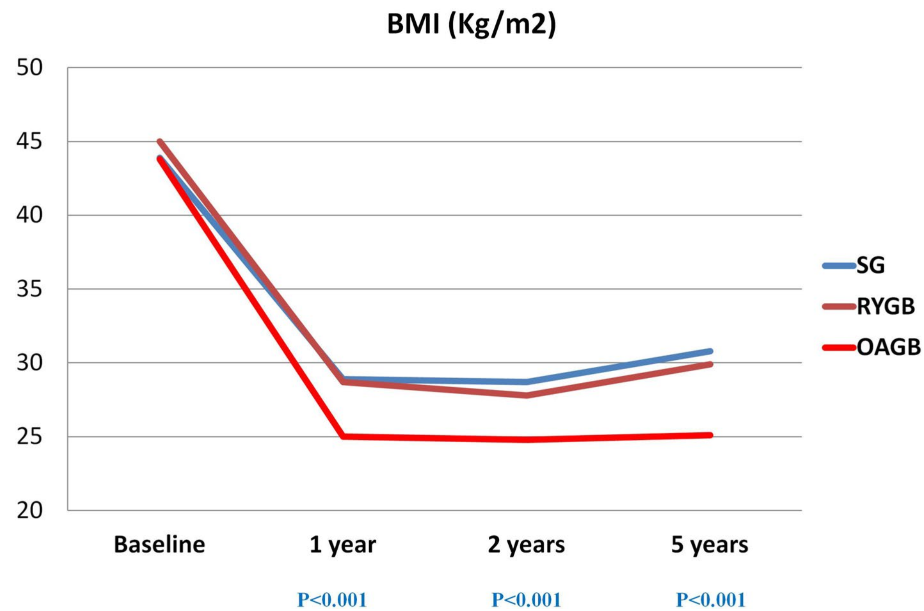
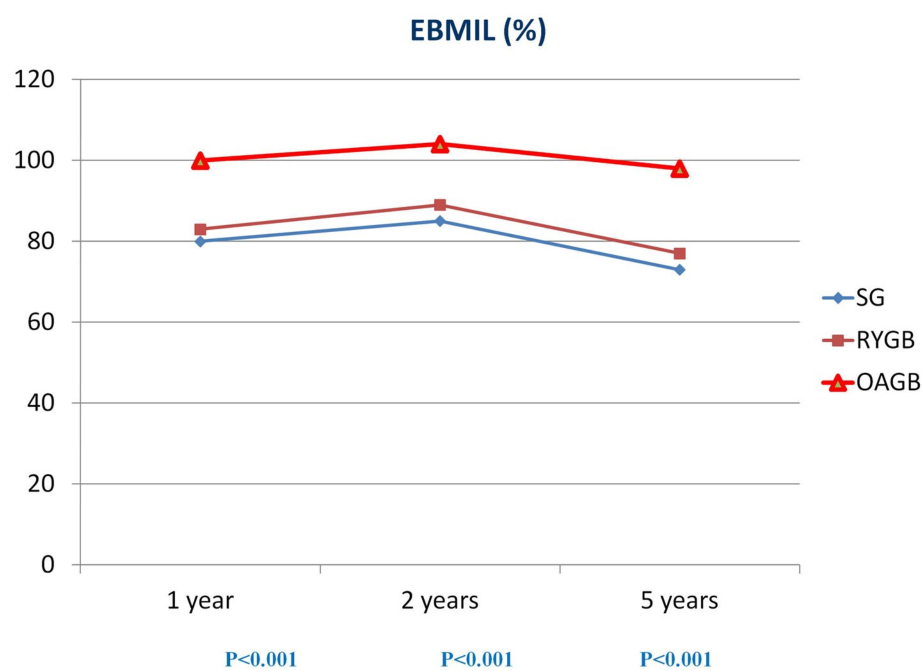


Fig. 2 Evolution of excess BMI loss after the different techniques



Remission of comorbidities

One year after surgery, the remission rate of T2DM after SG was 86.9%, after RYGB 89.8% and after OAGB 94.2% ($p=0.305$). 2 years after surgery, the remission rate of DM after SG was 85.2%, after RYGB 91.5% and after OAGB 95.7% ($p=0.046$). 5 years after surgery, the remission rate of DM after SG was 82%, after RYGB 86.4% and after OAGB 95.7% ($p=0.027$) (Fig. 3).

One year after surgery, remission rate of HT after SG was 78.3%, after RYGB 84.3% and after OAGB 89.5% ($p=0.17$). Two years after surgery, remission rate of HT after SG was 75.9%, after RYGB 84.3% and after OAGB 86% ($p=0.100$). Five years after surgery, remission rate of HT after SG was 63.8%, after RYGB 73.5% and after OAGB 83.7% ($p=0.006$) (Fig. 4).

One year after surgery, remission rate of DL after SG was 41.4%, after RYGB 79.7% and after OAGB 100% ($p<0.001$). Two years after surgery, remission rate of DL after SG was 38.6%, after RYGB 78.3% and after OAGB 100% ($p<0.001$). Five years after surgery, remission rate

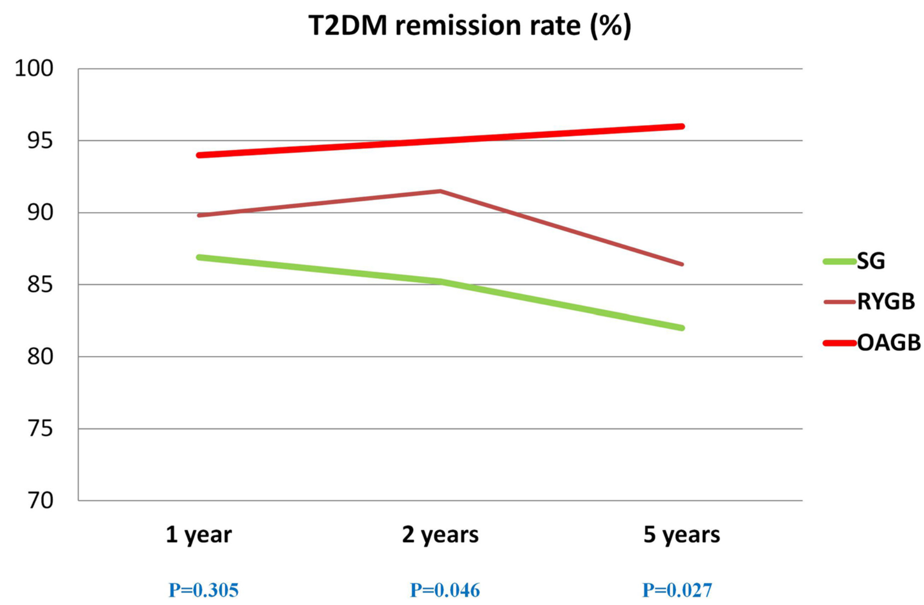


Fig. 3 Remission of type 2 diabetes mellitus after 1, 2, and 5 years follow-up

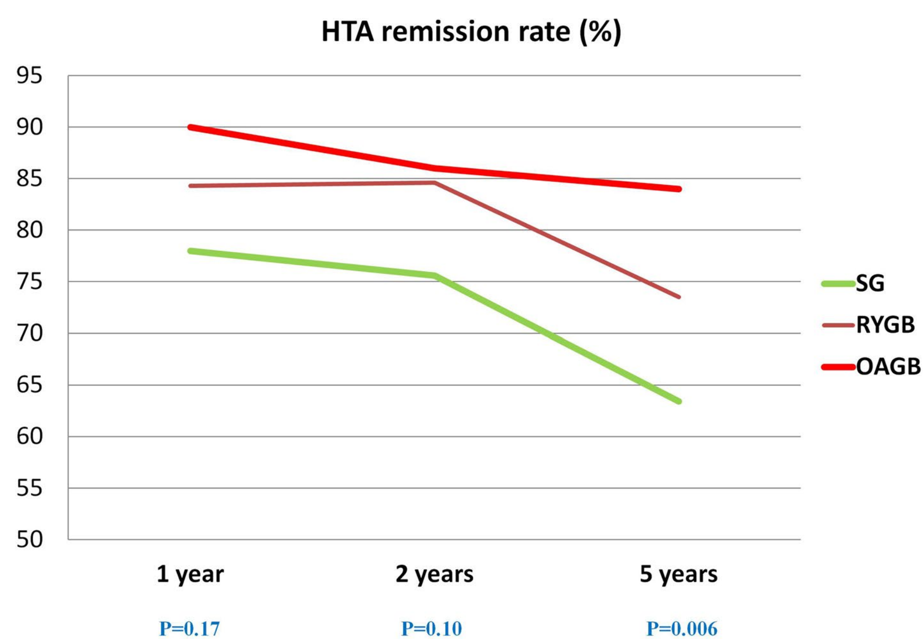


Fig. 4 Remission of hypertension after 1, 2, and 5 years follow-up

of DL after SG was 28.6%, after RYGB 71% and after OAGB 100% ($p < 0.001$) (Fig. 5).

Pairwise analysis of all the comorbidities is described in Table 2. OAGB has shown to achieve greater 5-years remission rates of all comorbidities, compared with both RYGB and SG. At 2-year follow-up, a greater remission of comorbidities is observed when compared OAGB with SG. The remission of dyslipidemia is greater after OAGB than after SG or RYGB from the first postoperative year onwards.

Despite in the OAGB the length of the limbs varied, according to the previously mentioned ratio 60/40%, there were no intragroup significant differences in weight loss or remission of comorbidities.

Specific vitamins and minerals supplementation needs

One year after surgery, there were no significant differences in the specific supplementation needs between groups. 2 years postoperatively, iron deficiencies were significantly greater in RYGB and OAGB when compared with SG. 5 years after surgery, iron and folic acid needs were significantly lower in SG. There were no significant differences

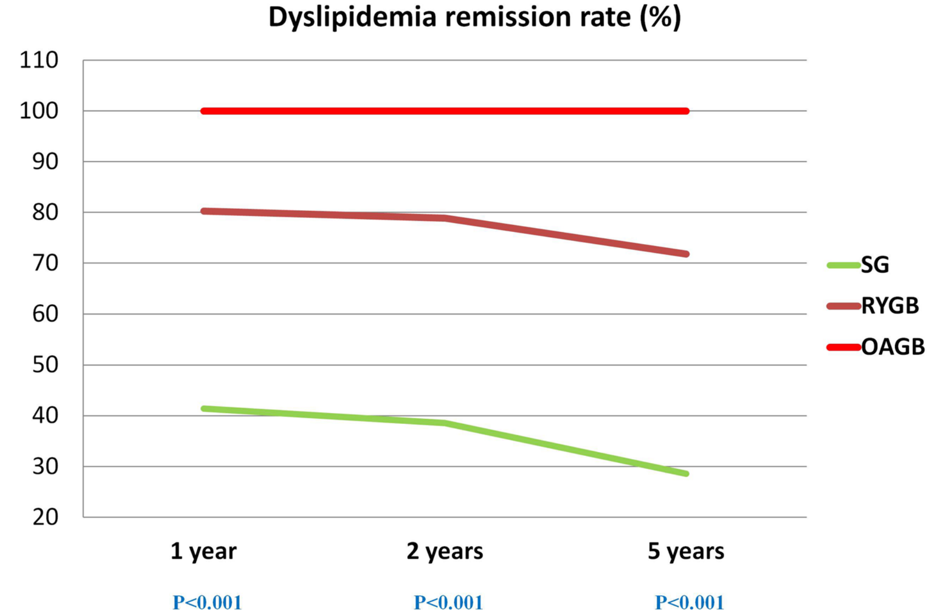


Fig. 5 Remission of dyslipidemia after 1, 2, and 5 years follow-up

Table 2 Pairwise analysis of remission of comorbidities between groups

Comorbidities	SG (%)	RYGB (%)	*P* (SG vs. RYGB)	OAGB (%)	*P* (SG vs. OAGB)	*P* (RYGB vs. OAGB)
T2DM						
1 year	86.9	89.8	0.615	94.2	0.143	0.345
2 years	85.2	91.5	0.284	95.7	0.038	0.325
5 years	82	86.4	0.502	95.7	0.011	0.061
HT						
1 year	78.3	84.3	0.319	89.5	0.046	0.315
2 years	75.9	84.3	0.173	86	0.09	0.092
5 years	63.8	73.5	0.180	83.7	0.003	0.003
DL						
1 year	41.4	79.7	0.000	100	0.000	0.000
2 years	38.6	78.3	0.000	100	0.000	0.000
5 years	28.6	71	0.000	100	0.000	0.000

in any of the specific needs between OAGB and RYGB (Table 3).

Late complications and revisions

During the 5-year follow-up, in the SG there were 3 patients with uncontrollable gastroesophageal reflux disease, requiring conversion to RYGB, and 3 patients with weight regain, also converted to RYGB. In the RYGB, 4 patients presented internal hernias and were reoperated for closure of the mesenteric space. Three patients presented weight regain; in 2 cases the gastric pouch was recalibrated and in the third one the biliopancreatic limb was elongated. Three patients presented anastomotic ulcer; 2 of them were medically treated and the latter required surgical treatment with resection of the anastomosis and new reconstruction. In the OAGB group, 2 patients presented uncontrollable biliary reflux and required conversion to RYGB. There were no cases of weight regain. There were 2 anastomotic ulcers, both medically treated. Three patients presented punctual cases of hypoproteinemia, coinciding with period of illness, and were satisfactorily managed with temporal oral intake of hyperproteic supplements.

Discussion

There are advantages and disadvantages in every bariatric operation; in general, weight loss and remission of comorbidities are inversely related to a potential risk of nutritional deficiencies. While restrictive procedures are less effective in achieving substantial long-term EWL and metabolic

Table 3 Specific vitamins and minerals supplementation needs at 1, 2, and 5 years postoperatively

	SG (%)	RYGB (%)	OAGB (%)	*P*
1 year postoperatively				
Calcium	4	6	4.5	NS
Vitamin D	24	32	29.5	NS
Iron	14.5	23	19	NS
Vitamin B12	4	4.5	5.5	NS
Folic acid	8	8.5	8	NS
Vitamin A	0.5	1	0.5	NS
2 years postoperatively				
Calcium	6.5	7	6.5	NS
Vitamin D	27	28.5	37.5	NS
Iron	14.5	24	23	0.05
Vitamin B12	8.5	9.5	10.5	NS
Folic acid	8	11	11	NS
Vitamin A	1	2.5	3	NS
5 years postoperatively				
Calcium	5	8	8	NS
Vitamin D	22	28	33	NS
Iron	11	25	24	0.042
Vitamin B12	7	10	10	NS
Folic acid	5	12	13	0.048
Vitamin A	0	2	2.5	NS

NS Non-significant

benefits, malabsorptive techniques have shown excellent weight loss and improvement of comorbidities, but at the cost of long more immediate and long-term complications [5–7]. SG is a mostly restrictive procedure, achieving acceptable results in terms of weight loss during the first postoperative years [5]. However, there is increasing evidence that after 3–5 years there is a tendence to weight regain and consequently to recurrence of the obesity-related comorbidities [8]. This fact can be also demonstrated in our study, with an increase in the mean BMI 5 years after surgery, up to an obesity range again. However, it is remarkable that in our SG patients the EBMIL after 5 years is significantly greater than the one reported by most groups. The IFSO European database 2017 shows a mean EBMIL 5 years after SG of 23.65% [9], in contrast to the 76.3% reported in this paper. In our opinion, the main reasons for obtaining these differences in EBMIL are the correct preoperative selection of patients undergoing any type of bariatric surgery and the close postoperative follow-up [10].

Many surgeons still consider RYGB the gold standard bariatric technique [11]. Laparoscopic RYGB, however, is a technically more demanding procedure than SG, requiring a learning curve, and therefore it is expected to reach significantly better results than SG and maintained for long-term. It is true that many groups report significantly greater weight loss than SG; the IFSO European database reports an EBMIL of 76.11% at 1 year and 71.88% at 5 years [9]. Our ponderal results are slightly better than that reported, with 1-year EBMIL of 81.2% and 5-year EBMIL of 77.1%. However, in our series, there are no significant differences in EBMIL between RYGB and SG at short-term or long-term follow-up. This demonstrates that with careful preoperative selection of bariatric candidates and close postoperative follow-up, there are no significant differences between both techniques. In contrast to SG, many authors defend that after RYGB there is no weight regain, but it has also been found in series 10 years follow-up [12].

Mini-gastric bypass, and its variant OAGB, as described by Carbajo [4], have increased in the last decade and represent actually the third most frequently performed technique world-wide. Actually, there are several comparative studies and randomized clinical trials, comparing OAGB with RYGB and SG, concluding all of them that OAGB is a safe technique with lower morbidity and mortality rates than the other techniques, and associating greater weight loss without long-term weight regain [13–16]. These results are also confirmed in the present study, presenting the patients undergoing OAGB a EBMIL of 97.9% and remaining in a BMI of 25 Kg/m^2 5 years after surgery. In terms of weight loss, OAGB has demonstrated a significantly greater EBMIL than RYGB and SG. It has been reported that OAGB reaches similar results to those obtained with more complex malabsorptive techniques [6, 17].

Referring to the remission of comorbidities, OAGB also obtains significantly greater long-term resolution of T2DM, HT, and DL, than RYGB and SG. On the other hand, RYGB and SG do not show significant differences in T2DM and HT remission, though the rates tend to be slightly better after RYGB. This confirms the actual evidence of non-superiority of RYGB over SG in T2DM and HT remission [18, 19], but a clear superiority of OAGB over the other 2 techniques [13–16]. OAGB comprise characteristics which are common in metabolic surgery. These include some form of restriction, and a long biliopancreatic limb which bypasses the proximal gut and places food in the distal SB [20].

Remission of DL was reached in 100% of the patients at 1 year after OAGB and maintained at 2 and 5 years postoperatively. These results were significantly better than the 79.7% at 1 year and 71% at 5 years of RYGB. Even so, RYGB has been shown to be superior than SG in DL remission rates. The poor results achieved by SG are based on the scarce postoperative reduction of LDL-cholesterol. However, recent evidence defends that despite this lack of LDL-cholesterol improvement, SG is also associated with a reduction in the cardiovascular risk. A great increase of HDL-cholesterol and a significant reduction of Triglycerides are achieved after SG. Given that HDL-cholesterol is in the denominator of most cardiovascular risk assessment formulas, SG is also associated with a reduction cardiovascular risk, despite a decrease in the LDL-cholesterol levels are not obtained [21].

Referring to nutritional deficiencies, it is widely known that malabsorptive procedures are associated with the highest risk of developing them, in comparison with restrictive or mixed procedures, such as RYGB. International guidelines recommend postoperative supplementation with multivitamin and mineral tablets and periodical laboratory controls, in order to detect early deficiencies, that can be specifically supplemented [22]. Surprisingly, in our series there were no significant differences in the specific supplementation needs during the first postoperative year between groups. At 2 years after surgery, iron needs were higher in patients undergoing RYGB and OAGB and at 5 years, iron and folic acid needs were higher in the RYGB and OAGB groups. As a mostly malabsorptive procedure, it could be expected that specific supplementation needs should be greater in patients undergoing OAGB, than in those ones undergoing RYGB, especially when considering that in some subjects the biliopancreatic limb was up to 350 cm long. In our opinion, the main reason for such low deficiency rates is the assessment of the total bowel length, allowing a customize measure for obtaining optimal weight loss without associating nutritional deficiencies. A recent report of our group demonstrated that with the customized lengths of the limbs, based on the total bowel measure, the malnutrition rate was 1.1%, requiring surgical treatment for common limb elongation in less than 0.1% of the cases [4].

Conclusion

OAGB achieves superior mid- and long-term weight loss than RYGB and SG. There are no significant differences in weight loss between SG and RYGB at 1, 2, and 5 years. Five years after surgery, the patients who underwent SG and RYGB present again mean BMI in range of obesity, while after OAGB, anthropometric parameters remain in normal weight range.

OAGB achieves better short and long-term resolution rates of DM, HT, and DL than SG and RYGB. RYGB and SG obtain similar T2DM and HT remissions, but RYGB reaches significantly greater rates of DL remission.

Compliance with ethical standards

Disclosures Jaime Ruiz-Tovar, Miguel Angel Carbajo, Jose Maria Jimenez, Maria Jose Castro, Gilberto Gonzalez, Javier Ortiz-de-Solorzano, Lorea Zubiaga have no conflicts of interest or financial ties to disclose.

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