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ORIGINAL CONTRIBUTIONS

Comparison of the Effect of Gastric Bypass and Sleeve Gastrectomy on Metabolic Syndrome and its Components in a Cohort: Tehran Obesity Treatment Study (TOTS)

Maryam Barzin[1] · Mohammad Ali Kalantar Motamedi[1] · Sara Serahati[1] · Alireza Khalaj[2] · Peyman Arian[2] · Majid Valizadeh[1] · Davood Khalili[3] · Fereidoun Azizi[4] · Farhad Hosseinpanah[1,5]

Abstract
Introduction Metabolic syndrome (MetS) is a prevalent counterpart of morbid obesity. With the surgical technique of sleeve gastrectomy (SG) gaining widespread acceptance for weight loss in morbid obese patients, we aimed to undertake a study to compare its effectiveness to gastric bypass (GB) for metabolic control in these patients.
Methods A total of 425 patients from a prospectively collected database of morbid obese subjects between 18 and 65 years of age undergoing a primary bariatric procedure from March 2013 to September 2015 were included. Statistical analysis was performed using general estimation equation and propensity scores, and odds ratios were calculated.
Results Three hundred nineteen patients underwent SG and 106 underwent GB. Mean age of the patients was 37.8 ± 11.7, and mean body mass index (BMI) was 44.3 ± 5.9 kg/m^2. MetS was present in 61.4% of patients and diabetes mellitus in 48.6%. MetS prevalence decreased from 60 and 64% in the SG and GB groups to 16 and 10% at 12 months, respectively. These improvements were consistent throughout the study period in both groups, with no significant difference between the two groups (for all variables: $P_{\text{trend}} < .001$, $P_{\text{interaction}} > .05$). After propensity score-adjusted analysis, neither surgical technique showed superiority over the other regarding metabolic improvement (OR for MetS resolution: 0.81, 95% CI: 0.49–1.34).
Conclusions In this short-term study with 1-year follow-up, SG showed similar results to GB in terms of weight loss, MetS resolution, and glycemic control in a large Middle Eastern cohort. Long-term studies are needed to further investigate the effectiveness of SG in this regard.

Keywords Sleeve gastrectomy · Gastric bypass · Bariatric surgery · Morbid obesity · Metabolic syndrome

✉ Farhad Hosseinpanah
fhospanah@endocrine.ac.ir

1 Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran

2 Faculty of Medicine, Shahed University, Tehran, Iran

3 Prevention of Metabolic Disorders Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran

4 Endocrine Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran

5 Department of Internal Medicine, School of medicine, Shahid Beheshti Medical University (M.C.) Obesity Research Center, Tehran, Iran

Introduction

Metabolic syndrome (MetS) is a constellation of metabolic abnormalities closely linked to obesity and insulin resistance. It is associated with an increased risk of many diseases, including cardiovascular disease (CVD), stroke, type 2 diabetes mellitus (T2DM), liver problems, and all-cause mortality. It is a common feature in morbidly obese patients and entails increased health risks in this population, as well as increasing burden of healthcare costs [1, 2].

Evidence suggests weight loss can effectively improve MetS and its components, and bariatric surgery has proved to be a promising treatment option, if not the best, to achieve this goal [3]. Bariatric surgery induces not only significant

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weight loss not otherwise achieved by conventional non-surgical treatments, but also outstanding results regarding obesity-related comorbidities. T2DM, hypertension (HTN), dyslipidemia, CVD risk, and many other conditions have been reported to resolve or improve significantly following bariatric surgery [4, 5].

A main challenge facing today's clinicians is which type of procedure to choose to provide the most benefit and least harm for the patient. It is generally known that the more malabsorptive procedures like biliopancreatic diversion with duodenal switch provide more weight loss and improvements of comorbidities compared with purely restrictive techniques, while having higher post-operative complications [6, 7]. However, advances in bariatric surgery with new techniques and improving safety profiles have constantly modified the roles of different techniques, necessitating continuous comparison of their effects on patient outcomes. A 2013 meta-analysis concluded that gastric bypass (GB) is more effective for control of MetS and T2DM [8], while a recent 2016 meta-analysis showed similar effectiveness for both GB and sleeve gastrectomy (SG) regarding T2DM resolution [9].

Given this uncertainty, we aimed to study the effects of these most commonly performed bariatric procedures worldwide and in our country, in an ongoing cohort of morbid obese patients at 1 year.

Methods

Study Design and Participants

Tehran Obesity Treatment Study (TOTS) is a prospective study of morbidly obese patients referring to our specialized treatment center to undergo bariatric surgery. Patients aged 18–65 years with a body mass index (BMI) ≥ 40 kg/m^2 or a BMI between 35 and 40 kg/m^2 plus a medical comorbidity, and acceptable surgical risks have been enrolled in this study after providing written informed consent. Details of the study protocol are available elsewhere [10]. For the current study, 425 patients who underwent a primary bariatric procedure from March 2013 to September 2015 and had completed 1-year follow-up data entered the study. Patients were divided into two groups: 319 underwent laparoscopic SG and 106 underwent laparoscopic GB surgery (74 Roux-en-Y gastric bypasses and 32 single anastomosis (mini-) gastric bypasses). Patients were compared in terms of MetS resolution and related metabolic components at 6 and 12-month intervals. Remission of other comorbidities was also assessed.

Definition of Terms

MetS was defined according to the joint interim statement (JIS) definition [1]: the presence of at least three of the following criteria:

- Abdominal obesity (increased waist circumference (WC) ≥ 91 cm in females and ≥89 cm in males) based on national cut-offs [11],
- Triglycerides (TG) ≥ 150 mg/dl or receiving treatment for hypertriglyceridemia,
- High-density lipoprotein (HDL) < 50/40 mg/dl in F/M,
- Systolic blood pressure (SBP) ≥ 130 mmHg or diastolic blood pressure (DBP) ≥ 85 mmHg or receiving treatment for hypertension,
- Fasting plasma glucose (FPG) ≥ 100 mg/dl or previously diagnosed T2DM

Surgical Procedures

All procedures were completed laparoscopically by a single surgical team at three university hospitals. Patients either underwent laparoscopic sleeve gastrectomy or one of two types of gastric bypass procedures, Roux-en-Y or laparoscopic single anastomosis (mini-) gastric bypasses: the technical details of these procedures have been published elsewhere [10].

Follow-Up and Postoperative Care

Following surgery, patients, irrespective of their treatment group, underwent a strict post-op protocol. Each patient underwent comprehensive assessments by our team at 1, 3, 6, and 12 months after surgery, to make sure they are following their schedule. Our post-op care team included an obesity expert, nutritionist, and exercise medicine physician. Patients of both groups received a similar calorie-restricted diet (with 10–35% protein) and were prescribed daily vitamin and mineral supplements up to 6 months, and SG patients continued to do so based on their individual clinical and biochemical assessments. Moreover, all patients followed a physical activity program (at least 30 min/day, combined aerobic-resistive activity) postoperatively.

Statistical Analysis

Continuous variables are reported as the mean ± standard deviation (SD) and categorical variables as frequencies and percentages. Independent student's t test was used to compare groups when variables were normally distributed; otherwise, the Mann–Whitney test was used. The x^2 or Fisher exact tests were used to compare categorical variables.

Table 1 Baseline characteristics of participants by surgery group

Variables	Total $N = 425$	SG $N = 319$ (75%)	GB $N = 106$ (25%)	P value
Sex female, n (%)	360 (84.7)	259 (81.2)	101 (95.3)	<0.001
Age, year, mean ± SD	37.8 ± 11.7	38.0 ± 12.2	37.3 ± 10.1	0.333
Age group, n (%)				
<20	21 (4.9)	19 (6)	2 (1.9)	0.218
20–29	94 (22.1)	69 (21.6)	25 (23.6)	
30–39	135 (31.8)	97 (30.4)	38 (35.8)	
40–49	98 (23.1)	70 (21.9)	28 (26.4)	
50–59	62 (14.6)	51 (16)	11 (10.4)	
≥60	15 (3.5)	13 (4.1)	2 (1.9)	
Anthropometric indices, mean ± SD				
Height (cm)	163.4 ± 8.2	163.6 ± 8.7	162.5 ± 6.8	0.163
Weight (kg)	118.6 ± 20.1	119.5 ± 20.8	116.2 ± 17.7	0.142
WC (cm)	125.4 ± 13.5	125.6 ± 13.7	125.1 ± 13.1	0.754
BMI, kg/m^2	44.3 ± 5.9	44.5 ± 6.2	43.8 ± 5.1	0.332
BMI group, kg/m^2, n (%)				
30–34.9	13 (3.1)	10 (3.1)	3 (2.8)	0.814
35–39.9	83 (19.5)	64 (20.1)	19 (17.9)	
40–44.9	158 (37.2)	116 (36.4)	42 (39.6)	
45–49.9	109 (25.6)	79 (24.8)	30 (28.3)	
50–54.9	41 (9.6)	31 (9.7)	10 (9.4)	
55–59.9	16 (3.8)	14 (4.4)	2 (1.9)	
≥60	5 (1.1)	5 (1.5)	0 (0)	
Metabolic indices, mean ± SD				
SBP (mmHg)	119.5 ± 16.6	119.6 ± 17.2	119.2 ± 15.1	0.811
DBP (mmHg)	75.6 ± 10.9	76.0 ± 11.2	74.7 ± 10.1	0.294
FPG (mg/dl)	108.4 ± 33.6	106.8 ± 29.1	113.4 ± 44.3	0.151
TG (mg/dl)	144 (107.2–190)	144 (109–189)	141 (103.2–195)	0.908
HDL (mg/dl)	48.7 ± 10.9	48.6 ± 10.9	49.0 ± 10.8	0.746
MetS components, n (%)				
Abdominal obesity	425 (100)	319 (100)	106 (100)	0.316
Low HDL	249 (58.6)	183 (57.9)	66 (62.9)	0.219
High TG	229 (53.9)	163 (51.6)	66 (62.9)	0.028
High FPG	209 (49.2)	158(49.7)	51 (48.1)	0.433
High BP	165 (38.8)	124 (38.9)	41 (38.7)	0.272
MetS	261 (61.4)	193 (60.7)	68 (64.2)	0.303
1 MetS criterion	45 (10.6)	36 (11.5)	9 (8.6)	
2 MetS criterion	113 (26.6)	85 (27.2)	28 (26.7)	
3 MetS criterion	104 (24.5)	79 (25.3)	25 (23.8)	0.927
4 MetS criterion	100 (23.6)	74 (23.7)	26 (24.8)	
5 MetS criterion	55 (12.9)	38 (12.2)	17 (16.2)	
Hypertension	122 (27.6)	95 (29.8)	27 (25.5)	0.235
Diabetes mellitus	210 (48.6)	159 (49.8)	51 (48.1)	0.422

Abdominal obesity (WC ≥ 89/91 cm M/F); high TG, triglyceride ≥ 150 mg/dl; low HDL, HDL < 40/50 mg/dl M/F; high BP, blood pressure ≥ 130/85 mmHg; high FPG, fasting blood glucose ≥ 100 mg/dl

SG sleeve gastrectomy, *GB* gastric bypass, *WC* waist circumference, *BMI* body mass index, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *FPG* fasting plasma glucose, *TG* triglyceride, *HDL* high-density lipoprotein, *MetS* metabolic syndrome according to JIS criteria

Considering that the responses were dependent, the generalized estimated equation (GEE) method with autoregressive working correlation structure, through logistic function with binomial errors and linear model with identity link function,

Table 2 Trends of metabolic syndrome and its components at 6 and 12 months follow-up in each surgery group

Variables	Surgery type	Pre op	6 months	12 months	P_{trend}	$P_{between\ groups}$	$P_{interaction}$
BMI (kg/m^2)	SG	44.5 (6.25)	33.1 (5.00)	30.2 (4.46)	<0.001	0.361	0.398
	GB	43.8 (5.04)	32.4 (4.43)	30.0 (5.15)	<0.001		
WC (cm)	SG	125.6 (13.67)	100.8 (12.78)	94.3 (14.55)	<0.001	0.405	0.796
	GB	125.1 (12.97)	99.7 (11.53)	93.0 (14.00)	<0.001		
SBP (mmHg)	SG	119.6 (17.15)	112.4 (15.18)	112.4 (14.17)	<0.001	0.905	0.617
	GB	119.2 (15.03)	113.3 (12.87)	111.7 (11.84)	<0.001		
DBP (mmHg)	SG	75.9 (11.07)	70.4 (10.54)	69.4 (10.89)	<0.001	0.769	0.020
	GB	74.7 (9.99)	70.5 (8.96)	72.3 (9.06)	0.001		
HDL (mg/dl)	SG	48.6 (11.04)	50.1 (12.28)	53.9 (18.34)	<0.001	0.682	0.631
	GB	49.02 (10.71)	49.7 (16.72)	55.9 (18.36)	<0.001		
TG (mg/dl)	SG	157.8 (76.44)	112.8 (54.22)	104.9 (50.31)	<0.001	0.555	0.081
	GB	156.8 (72.71)	116.6 (56.89)	95.1 (45.58)	<0.001		
FPG (mg/dl)	SG	106.8 (29.11)	90.25 (20.36)	88.9 (16.97)	<0.001	0.182	0.180
	GB	113.4 (44.06)	94.4 (24.50)	89.7 (17.71)	<0.001		
HBA_{1C} (%)	SG	5.6 (0.96)	5.3 (0.80)	5.3 (0.80)	<0.001	0.345	0.811
	GB	5.8 (1.32)	5.3 (0.85)	5.4 (1.04)	0.001		
Mets (%)	SG	60.69	21.02	16.39	<0.001	0.964	0.455
	GB	64.15	21.51	10.72	<0.001		

Data is presented as mean (SD) except for Mets, which is presented as percentage

SG sleeve gastrectomy, *GB* gastric bypass, *BMI* body mass index, *WC* waist circumference, *HbA_{1C}* glycated hemoglobin level, *FPG* fasting plasma glucose, *TG* triglyceride, *HDL* HDL-cholesterol, *DBP* diastolic blood pressure, *SBP* systolic blood pressure, *MetS* metabolic syndrome according to JIS criteria

was used to investigate trend of BMI, WC, HDL, TG, FPG, SBP, DBP, glycated hemoglobin (HbA_{1C}), and MetS. GEE is a flexible and robust method for handling longitudinal data and allows the use of all available information, thus dealing better with missing data. Models for examining of time trend were fitted separately for GB and SG groups, and marginal means and P values for trend were reported in each group (P_{trend}). The interaction between surgery groups at each phase of the study was checked in a separate model ($P_{interaction}$). GEE method with autoregressive working correlation structure, through logistic function, was also used to estimate the odds ratios (OR) and 95% CI of responses adjusted for surgery type and propensity score (PS) [12].

For computing PS, we identified characteristics that influence the choice of surgical procedures as well as outcomes of MetS remission after surgery. We assessed the balance of measured confounders through standardized mean difference (SMD) between surgery groups. A large standardized difference of greater than 10%, not necessarily reaching significance, usually exhibits enough imbalance to be adjusted for by PS analysis. [13] PS–based method was used to control confounding factors by balancing the distribution of confounders in the surgical procedures. [14] We fitted a logistic regression model to estimate the probability of treatment (or the PS) with SG vs. GB, adjusted for all the selected covariates including sex, baseline BMI, FPG, HbA_{1C}, and cholesterol. Furthermore, we included nutritional behaviors such as "sweet lover" or endoscopic results such as gastroesophageal reflux disease, based on their relationship with both surgery groups and outcome variables. Inverse probability of treatment weights (IPTW) was calculated as 1/PS for those who underwent GB and 1/ (1 − PS) for those who underwent SG. All the statistical analyses were made using SPSS software. P value < 0.05 was considered statistically significant.

Results

A total of 425 patients (84.7% female) were included in the analysis: 319 patients with a mean age of 38 ± 12.2 years and a mean BMI of 44.5 ± 6.2 kg/m^2 undergoing SG were compared with 106 patients with a mean age of 37.3 ± 10.1 years and a mean BMI of 43.8 ± 5.1 kg/m^2 undergoing GB. Two groups were similar regarding their baseline characteristics (Table 1).

Prior to surgery, MetS was diagnosed in 61.4% of our study population (60.7% in SG group and 64.2% in GB group, P = NS), with 3 (24.5%), 4 (23.6%), or 5 components (12.9%) of MetS. The most prevalent criteria for MetS were abdominal obesity (100%), low HDL (58.6%), hypertriglyceridemia (53.9%), elevated fasting plasma glucose (49.2%), and elevated blood pressure

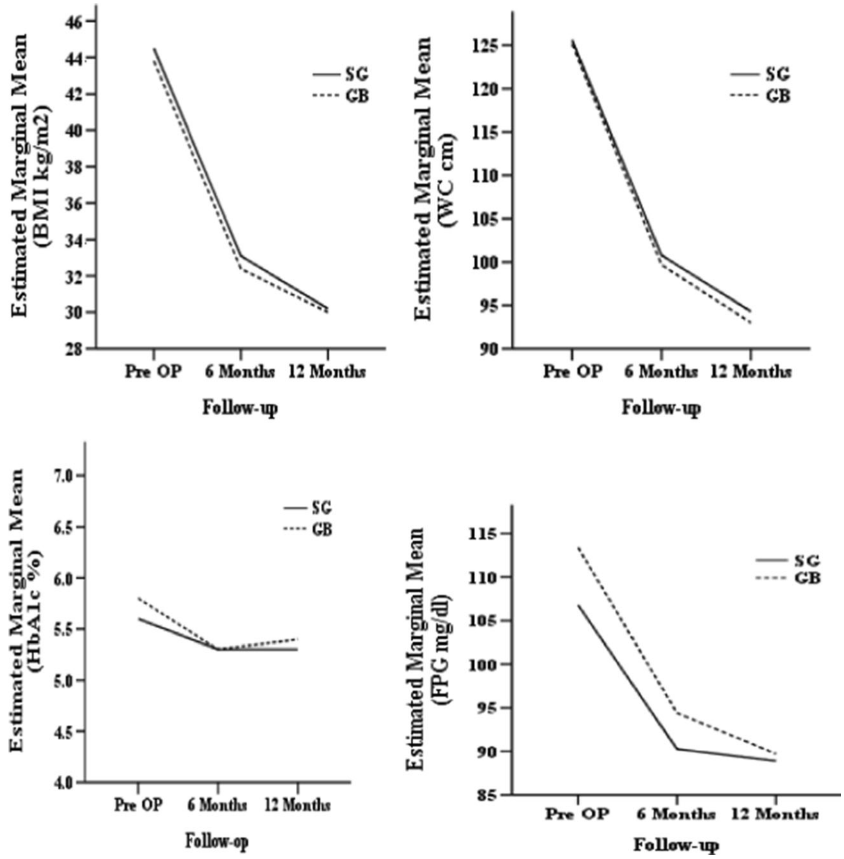

Fig. 1 Estimated marginal mean of MetS and its components at 6 and 12 months after SG (sleeve gastrectomy) and GB (gastric bypass). *WC* waist circumference, *FPG* fasting plasma glucose, *TG* triglyceride, *DBP* diastolic blood pressure, *SBP* systolic blood pressure, *MetS* metabolic syndrome according to JIS criteria

levels (38.8%). Two groups were comparable with respect to all variables except for hypertriglyceridemia, which was higher in the GB group (P = 0.028). Moreover, there were 210 patients (48.6%) with T2DM (159 patients in SG and 51 in GB group) and 122 (27.6%) with HTN (95 patients in SG and 27 in GB group) in our cohort (Table 1).

Follow-up rates at 6 and 12 months were 84% (342/407) and 72% (236/327), respectively, and were similar in the two surgery groups. Average excess weight loss (EWL%) at 6 and 12 months postoperatively was 59.7 ± 16.6 and 75 ± 20.1% for the SG group and 61.9 ± 19.4 and 75.2 ± 23.4% for the GB group, respectively.

Both at 6 and 12 months, MetS prevalence and all of its components improved significantly (Table 2 and Fig. 1). Both procedures resulted in a considerable and comparable improvement of MetS: 67.6% (100/148) and 74% (71/96) in the SG group and 69.1% (38/55) and 83.9% (26/31) in the GB group at 6 and 12 months, respectively. Mean BMI, WC, SBP, DBP, TG, FPG, and HbA1c decreased, and HDL increased significantly in both groups at 6 and 12 months (P_{trend} for all indices < 0.001). Between-group difference was not significant regarding various components except DBP at 12 months, which showed a better improvement in the GB group ($P_{\text{interaction}}$ = 0.02).

After propensity score-adjusted multivariable analysis, neither surgical technique showed superiority over the other regarding improvement of the metabolic components, as well as the resolution of the MetS itself (OR for MetS resolution: 0.81, 95%CI: 0.49–1.34, P = 0.493, Table 3).

Discussion

MetS constitutes a major health concern especially in morbid obese patients, and bariatric surgery has proven to be the best option to address this risk. Our findings show that SG and GB can both result in significant resolution of MetS, T2DM, and hypertension in the short-term follow-up, supporting the idea that SG can also be considered a viable option for “metabolic surgery”.

Although there is now a consensus that bariatric surgery is the mainstay of treatment for MetS in morbid obesity, decision on the procedure of choice is still under debate. Biliopancreatic diversion with duodenal switch has been reported to provide the highest EWL and resolution of T2DM,

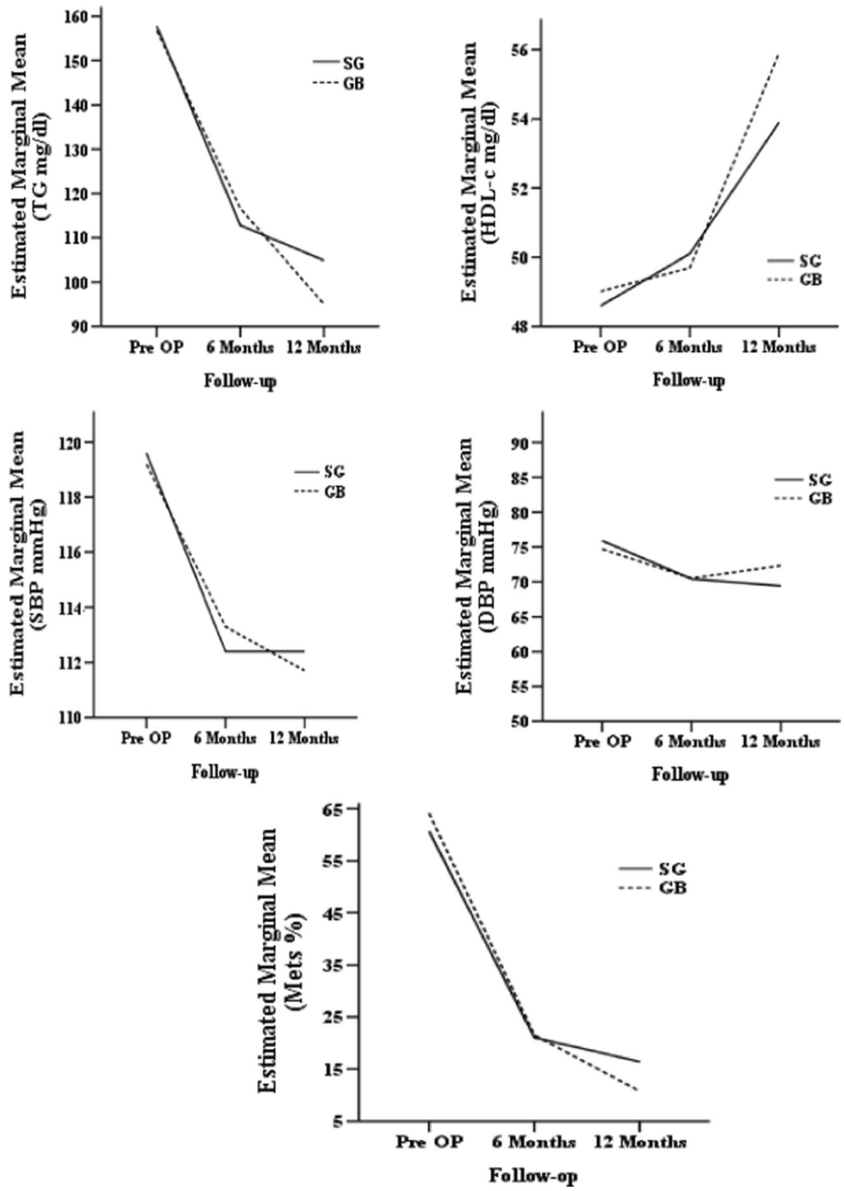

Fig. 1 (continued)

Table 3 Odds ratios (OR) for remission of MetS and its components at 1 year follow-up

MetS criteria	Propensity score-adjusted OR	95% CI	*P* value
Abdominal obesity	1.01	0.65–1.55	0.98
Low HDL	0.82	0.55–1.22	0.32
High TG	0.79	0.54–1.17	0.24
High FPG	1.42	0.90–2.25	0.13
High BP	1.16	0.76–1.78	0.49
MetS	0.81	0.94–1.34	0.49

Abdominal obesity (WC ≥ 89/91 cm M/F); high TG, triglyceride ≥ 150 mg/dl; low HDL, HDL < 40/50 mg/dl M/F; high BP, blood pressure ≥ 130/85 mmHg; high FPG, fasting plasma glucose ≥ 100 mg/dl, MetS, metabolic syndrome according to JIS criteria

with rates as high as 95.1%. [4, 7] However, it is not generally a popular choice owing to its high morbidity rate, and thus is usually reserved for super-obese patients. [6] GB, on the other hand, being the most commonly performed operation worldwide, [15] has been the gold standard for metabolic surgery for years now, with remission rates of up to 80%. [7] Yet, the growing amount of evidence on SG shows an increasing interest for this technique, considering its lower complication rates, [16] shorter duration of operation, [17] and easier technique, as well as other benefits such as preserving endoscopic access to the biliopancreatic system and retaining the possibility for a second surgical procedure. Other restrictive procedures such as laparoscopic adjustable gastric banding (LAGB) have had the least success in terms of metabolic improvements but are still more effective than medical therapy alone. [18]

The definitive role of SG in metabolic surgery remains to be determined. Single-center experiences with this technique reported promising results [19–21], and some comparative studies showed better results for SG compared to LAGB, and similar or near-similar results compared to GB. [3, 22–24] Although a previous 2013 meta-analysis of 5 randomized clinical trials (RCTs) with 1-year follow-up consisting of 396 patients undergoing either GB or SG showed superior results for GB in terms of diabetes resolution and dyslipidemia, [8] a more recent meta-analysis of 18,455 patients showed similar T2DM resolution rates between the two procedures, although GB achieved higher EWL%, HTN, and dyslipidemia improvements. [9]. This rapidly evolving picture reflects on the fact that this field is undergoing continuous advancements. As suggested in a study by Coleman et al., less anticipated factors such as ethnicity [25], as well as diet and behavior [26] might also play a role in achieving favorable results. Moreover, as SG is surpassing GB in numbers at many centers worldwide, [15] more is being learned about the different aspects of its mechanisms and effects.

Our results provide an insight on the effectiveness of this procedure in a Middle Eastern population with a distinct genetic composition and dietary habits. SG achieved a MetS remission rate of 74% in our study, not significantly lower than that of GB, as well as significant and comparable improvements of MetS individual components.

A more detailed investigation of individual components of MetS following bariatric surgery suggests a universal improvement of most items, with malabsorptive procedures shown to be more successful in this regard. [8, 27] Similar to our findings however, regarding glycemic indices, the 1-year results of two RCTs [3, 28] and a recent meta-analysis by Li et al. [9] show that both RYGB and SG induce a comparable glycemic control. Likewise, when breaking down dyslipidemia to its components, reported results do not follow a universal pattern. Vix et al. demonstrated a comparable decrease in TG levels in both SG and GB groups in an RCT of 100 patients at 1 year. [28] On the other hand, the meta-analysis by Li et al. showed that RYGB resulted in a better resolution of hypertension and dyslipidemia compared to SG. [9] This discrepancy may be explained by the fact that not all studies consider each element of dyslipidemia separately, rather they treat dyslipidemia as a composite outcome. This may obscure the different effect of each procedure on individual components, as some studies have shown better improvement of total cholesterol and LDL after RYGB but not TG and HDL, which are components of metabolic syndrome. [29] Secondly, different operating teams may not necessarily achieve the same results, as learning curves play a major role.

Regarding limitations of our study, we should mention the short follow-up period, which necessitates a more definite and longer-term comparison of SG and GB in further studies. The two groups were unequal in size, reflecting on the fact that patients were not randomized since they had a say in their final treatment decision. We attempted to correct this bias in our multivariable analyses through the generation of propensity scores for each patient. Moreover, our follow-up rate of 72% was not entirely favorable. Nevertheless, this is the first large cohort in a Middle Eastern population, comparing two commonly performed bariatric procedures in terms of metabolic control.

In conclusion, this study shows that SG is as effective as GB in metabolic terms, with no significant difference during the first postoperative year. Considering several advantages of SG over GB, such as ease of technique, shorter operative times, lower risk of nutritional deficiency postoperatively, and preserving endoscopic access, SG may be considered as an acceptable surgical option for controlling obesity-related comorbidities. With continuous follow-up and maintenance of our prospective database, long-term results will further enlighten this relatively new field in our region, helping experts to achieve the best results for their patients.

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Compliance with Ethical Standards

Grant Information There are no grants associated with this study.

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

Informed Consent Informed consent was obtained from all individual participants included in the study.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for this study was obtained from the Human Research Review Committee of the Endocrine Research Center, Shahid Beheshti University of Medical Sciences (No. 2ECRIES 93/03/13).

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