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MIDDLE TERM IMPACT OF SLEEVE GASTRECTOMY ON MAJOR CARDIOVASCULAR RISK FACTORS IN A GROUP OF ROMANIAN OBESE PATIENTS

D. Timofte[1,*], I. Hristov[2], F. Zugun-Eloae[3], M.C. Ungureanu[4], C. Galesanu[4], V. Mocanu[2]

"Gr. T. Popa" University of Medicine and Pharmacy, [1]Dept. of Surgery, [2]Dept. of Pathophysiology, [3]Dept. of Morphofunctional Sciences, [4]Dept. of Endocrinology, Iasi, Romania

Abstract

Background and aim. The goals of bariatric surgery are to improve the quality of life by lowering body mass index (BMI) but also to treat obesity comorbidities. The aim of our study was to evaluate the impact of laparoscopic sleeve gastrectomy (LSG) on metabolic parameters.

Methods. 85 obese patients treated by bariatric surgery LSG procedure were included in the study. Basal, 6 and 12 months after surgery serum glucose levels and lipid fractions were measured. Metabolic syndrome criteria according to IDF 2006 were evaluated at baseline and after bariatric surgery.

Results. Our group included 61.2 % female patients, the mean age was 40.2 ±10.2 years and the metabolic syndrome criteria at baseline were confirmed in 69.4% of the study group. At twelve months after the intervention, the mean excess weight loss (%EWL) was 72%, with age and BMI subgroups variations. We found significant improvements of serum concentrations for triglycerides (P-value = 0.001, decreased by 30%), HDL-cholesterol (P-value = 0.017, increased by 26%), total cholesterol (P-value = 0.043, decreased by 12%) and glucose (P-value = 0.007, decreased by 12%).

Conclusions. The positive effect of bariatric surgery was confirmed for lipid fractions and fasting glucose levels, also the metabolic syndrome prevalence was significantly reduced, all these changes contribute to lower cardiovascular risk together with significant weight loss.

Key words: Obesity, dyslipidemia, metabolic syndrome, bariatric surgery.

INTRODUCTION

Obesity, defined by a body mass index (BMI) ≥ 30 kg/m^2, often coexists with the metabolic syndrome, which is associated with increased risk for cardiovascular diseases (CVD). The risk of serious health consequences is associated with an increase in BMI (1) but it is an excess of body fat in the abdomen, measured simply by waist circumference, that is more indicative of the metabolic syndrome profile than BMI. Excess lipid accumulation in several organs, including adipose tissue, liver, muscle, heart, and blood vessels, results in insulin resistance and triggers metabolic inflammation, a low-grade and chronic inflammatory response (2, 3).

Obesity is associated with hypertension, diabetes, elevated triglyceride (TG), and decreased HDL-cholesterol (HDL-C) levels, all acknowledged as independent CVD risk factors by the American Heart Association (AHA)(4). Most patients with obesity present with lipid abnormalities; however, only 20% of the obese patients population are not showing classical metabolic lipid changes (5). Hyperlipidemia is widely recognized as one of the main co-morbidities in severe obesity. It is therefore not surprising that research and treatment are increasingly focused on lipid profiles in the drive to potentially reduce cardiovascular related-diseases (6).

As the metabolic syndrome correlation with CVD risk and overall mortality was demonstrated for both lean and obese subjects (7, 8), the accurate evaluation of the metabolic syndrome parameters is a more valuable follow-up parameter for bariatric patients than BMI and weight loss (9).

Bariatric surgery, designed to achieve and sustain substantial weight loss, was demonstrated by numerous studies to improve obesity-related comorbidities with still few long term follow-up data to confirm the stable effect. The control mechanisms of metabolic surgery are unclear, but it is likely that the surgery resets metabolic parameters in a balanced way, such that energy intake and expenditure are optimized. Among the various surgical procedures laparoscopic sleeve gastrectomy (LSG) was proven to obtain significant reduction in glucose, triglyceride levels, triglycerides/HDL ratio and increased HDL levels and

*Correspondence to: Ioana Hristov MD, "Gr. T. Popa" University of Medicine and Pharmacy, Dept. of Pathophysiology, Independentei Blvd., Iasi, 700115, Romania, E-mail: ioanahristov@yahoo.com

these changes were maintained under normal ranges for at least two years after surgery (10).

The aim of our study was to evaluate the impact of bariatric surgery procedure (LSG) on the main metabolic parameters including: Total Cholesterol, Cholesterol fractions, Triglycerides and Fasting Plasma Glucose levels in a lot of 85 Romanian obese patients with a follow-up at 3 months, 6 months and 12 months.

PATIENTS AND METHODS

Patients selection

This prospective study was conducted between June 2012 and January 2016 on obese patients hospitalized for bariatric surgery in the Surgery Service, "Sf. Spiridon" Clinical Emergency Hospital in Iasi (Romania). The study included 85 obese patients, proposed for bariatric surgery according to the recommendations of the National Institutes of Health (NIH) consensus on gastrointestinal surgery for severe obesity (11): BMI≥ 40 kg/m^2 or BMI≥ 35 kg/m^2 with obesity-related morbidities including: type 2 diabetes mellitus, arterial hypertension, sleep apnea or dyslipidemia. The study was approved the Ethics Committee of "Grigore T. Popa" University of Medicine and Pharmacy, Iasi (Romania) and all patients signed an informed consent.

Characteristics of the study group

The study group included 85 patients, 33 males (38.8%) and 52 females (61.2 %), with a mean age of 40.2±10.2 years. The mean BMI for the males subgroup was: 44.5±5.3 kg/m^2 as for the females subgroup was 43.4 ± 8.0 kg/m^2 and 37.6% (32 patients of 85) were morbidly obese (BMI>45 kg/m^2). (Table 1, Table 2).

The bariatric surgery procedure was Laparoscopic Sleeve Gastrectomy (LSG).

From the initial study group of 85 patients, we recorded 32 patients with complete lipid profile and serum glucose follow-up at 12 months in order to evaluate the paired statistical significance of the post-bariatric surgery impact.

Anthropometric measurements

Anthropometric data were collected at three different points: preoperatively, at 6 months and at

Table 1. Demographic features and co-morbidities of the patients submitted to LSG (N=85)

Parameter	Men (N=33)	Women (N=52)	Total (N=85)
Age, years (mean±SD)	41.8±8.4	39.2±11.1	40.2±10.2
BMI>45 kg/m^2, N (%)	14 (39.4%)	19 (36.5%)	32 (37.6%)
Arterial hypertension, N (%)	16 (38.5%)	15(28.8%)	31 (36.5%)
T2DM, N (%)	17 (51.5%)	15(28.8%)	32 (37.6%)
Any dyslipidemia, N (%)	29 (87.8%)	45 (86.5%)	74 (87.1%)
Liver steatosis, N (%)	29 (87.8%)	19 (36.5%)	48 (56.5%)
MS, N (%)	29 (87.8%)	30 (57.7%)	59 (69.4%)

[1]Mean values ± standard deviation. 2P-values were assessed between parameters at baseline and at 12 months after bariatric surgery by paired Student's t-test. Abbreviations: BMI: body mass index, T2DM: Type 2 Diabetes mellitus, MS: Metabolic syndrome.

Table 2. Changes in BMI and metabolic parameters[1] after bariatric surgery (LSG intervention) in obese patients

Parameter		Before surgery (N= 85) (M=33, F=52)	At 6 months (N=40) (M=12, F=28)	At 12 months (N=32) (M=10, F=22)	Change at 12 months (%)	P-value[2]
BMI (kg/m^2)	M	44.5 ± 5.3	33.9±3.7	30.2 ±2.2	-28.5	<0.001
	F	43.4 ± 8.0	32.3±5.3	30.4 ±4.9	-30.3	<0.001
TC (mg/dl)	M	208.4±38.3	194.1±34.0	190.6±34.9	-18.9	0.004
	F	217.7±40.4	205.9±39.8	197.3±35.8	-2.8	0.004
LDL-C (mg/dL)	M	127.9±34.9	118.3±24.4	113.7±9.8	-16.5	0.253
	F	138.5±36.5	123.3±30.4	120.7±16.7	+0.8	0.929
HDL-C (mg/dL)	M	36.8±10.5	41.3±11.9	46.9±8.6	+26.2	0.006
	F	46.1±7.5	48.3±1.6	58.4±13.0	+29.0	0.004
TG (mg/dL)	M	231.9±78.1	133.7±50.6	130.0±10.6	-40.6	0.001
	F	132.9±54.2	109.8±31.9	78.7±8.7	-29.9	0.001
GLU (mg/dL)	M	113.5±31.8	87.8±4.8	88.3±3.3	-9.2±0.1	0.009
	F	107.1±41.0	86.9±3.5	92±0.9	-16.7±0.4	<0.001

[1]Mean values ± standard deviation. 2P-values were assessed between parameters at baseline and at 12 months after bariatric surgery by paired Student's t-test. Abbreviations: BMI: body mass index, TG: serum triglycerides, TC: serum total cholesterol, LDL = serum low density lipoprotein cholesterol, HDL= serum high density lipoprotein cholesterol, GLU= serum glucose).

12 months after surgery. Anthropometric evaluation was based on the determination of weight (kg), height and BMI (kg/m^2). The weight change was reported as the percentage of excess weight loss (%EWL). This widely used equation was estimated as the percent excess weight loss (using the initial excess weight) or %EBWL = (preoperative body mass index – current BMI) x100)/(preoperative BMI – 25kg/m^2) (10).

Lipid profile and serum glucose measurements

The blood samples were collected after a 12 hour fast. We evaluated the serum lipid profile and glucose in obese patients before bariatric surgery (baseline levels) and at 6 and 12 months post-operative follow-up. Serum levels of triglycerides (TG), total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C) were measured.

The hexokinase method was used to measure serum glucose, and photometric method (Abbott Architect c16000 analyzer) was used to measure serum concentrations of total cholesterol, triglyceride (TG), high-density lipoprotein cholesterol (HDL-cholesterol), and low-density lipoprotein cholesterol (LDL-cholesterol).

We evaluated the metabolic syndrome parameters using the reference values of the IDF definition of the metabolic syndrome criteria (2006), including the lipid profile with the following cut-offs for dyslipidemia: TG> 150 mg/dL, HDL-C < 40 mg/dL (male patients)/ HDL-C<50 mg/dL (female patients), blood pressure measurement (systolic value ≥130 mmHg or diastolic value ≥85 mmHg) or arterial hypertension previous diagnosis criteria, and high fasting plasma glucose ≥ 100 mg/dL or previous diabetes mellitus diagnosis criteria. For obese patients BMI ≥ 30 kg/m^2, IDF criteria do not include waist circumference criteria. Additional data included the prevalence of hepatic steatosis evaluated by abdominal ultrasound as a serious metabolic consequence of obesity (Table 1).

Statistical analysis

The statistical analysis was performed using Windows 19.0 version of SPSS software (SPSS Inc., Chicago, IL, USA). Numerical data are reported as means ± SD. Categorical data are reported as number (%) and compared by the Pearson chi-square test. Changes in lipid profiles between the baseline and the six-months and twelve months evaluations were assessed using Student's t-test for paired samples. Statistical significance was set at $P < 0.05$.

RESULTS

The baseline lipid profile for our study group before bariatric surgery was characterized by atherogenic dyslipidemia (high serum concentrations of LDL-cholesterol/non-HDL-cholesterol and low levels of cardio-vascular protective fraction HDL-cholesterol), high triglycerides and hyperglycemia (Table 2).

The bariatric surgery outcomes followed the BMI reduction at 1 month, 3 months, 6 months and 12 months after bariatric surgery, when a mean BMI of 29 kg/m^2 was obtained for the study group (Fig. 1).

The mean excess weight loss (EWL%) was 58% at 6 months and 72 % at 12 months after the intervention, the overall success rate for LSG defined by EWL% is > 50% (Fig. 2). When we analyzed EWL% according to age and BMI categories we obtained higher EWL% rates for the subgroup of patients younger than 40 years old, and also in terms of BMI the subgroup of patients < 45 kg/m^2 obtained better weight loss results (Figs 3, 4).

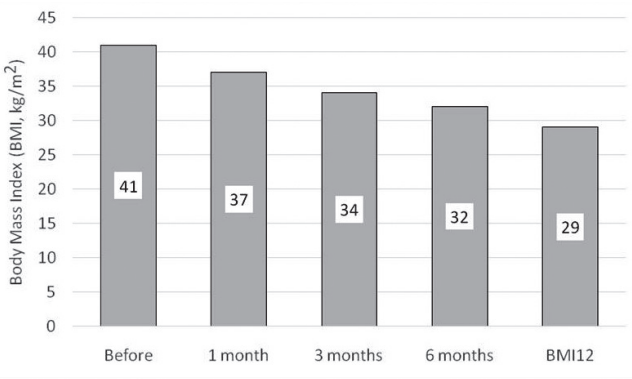

Figure 1. Mean BMI dynamics at 1 month, 3 months, 6 months and 12 months in post-bariatric surgery obese patients.

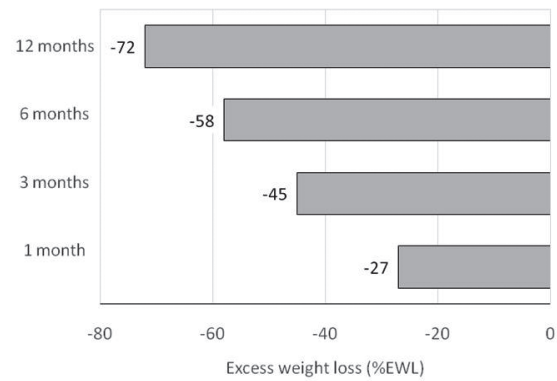

Figure 2. Excess weight loss percentage (%EWL) after bariatric surgery procedure (LSG)-follow-up at 3 months, 6 months and 12 months.

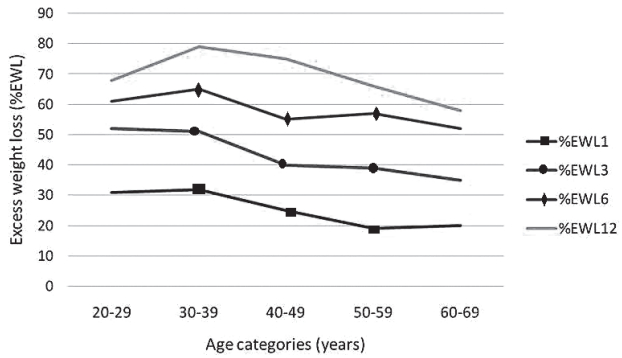

Figure 3. Excess weight loss percentage (%EWL) according to patients age category.

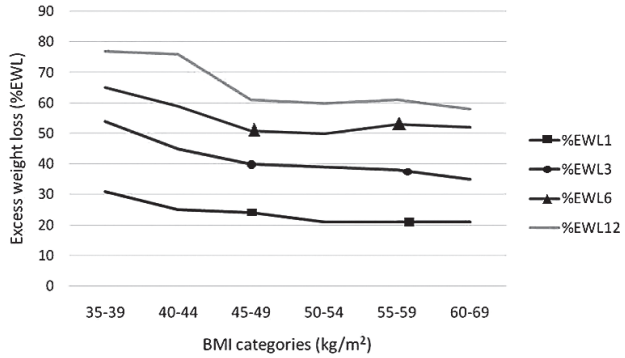

Figure 4. Excess weight loss percentage (%EWL) according to pre-operative BMI category.

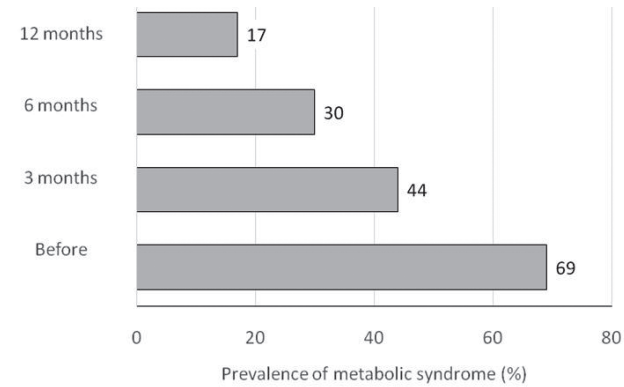

Figure 5. Metabolic syndrome (IDF 2006 definition) prevalence at baseline and after bariatric surgery procedure (LSG) at 3 months, 6 months and 12 months follow-up.

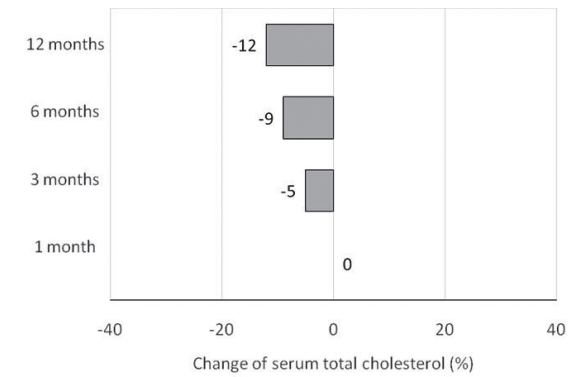

Figure 6. Total cholesterol reduction percentage after bariatric surgery procedure (LSG) follow-up at 3 months, 6 months and 12 months.

At twelve months after the intervention, we found statistically significant improvements in triglycerides, HDL-cholesterol, total cholesterol and glucose in both female and male subgroups after bariatric surgery. The evidence showed a more important decrease in triglycerides level and total cholesterol for males (-40.6% and -18.9%) compared to females (-29.9% respectively - 2.8%). We could not find a statistically significant reduction of LDL-cholesterol (Table 2).

The metabolic syndrome prevalence was reduced progressively from 69% before the bariatric surgery intervention to 30% at 6 months after surgery and at 12 months after the intervention only 17% of our study group had persistent metabolic syndrome criteria. (Fig. 5). The evolution in post-bariatric surgery period for the metabolic syndrome parameters was subject for a detailed data analysis regarding glucose and lipid metabolism changes in post-bariatric patients.

Lipid fraction follow-up at 3 months, 6 months and 12 months after bariatric surgery shows a significant reduction for serum triglycerides (-30% at 12 months) and total cholesterol (-12% at 12 months) together with an augmentation of HDL fraction of cholesterol by 26% which contributes to an optimized, non-atherogenic lipid profile (Figs 6-8).

Another metabolic syndrome parameter according to IDF definition we evaluated is fasting glucose that was also improved after the bariatric surgery procedure (mean decrease of 12% towards pre-operative values) (Fig. 9).

The metabolic syndrome criteria in obese patients seem to have an influence also on weight loss velocity, as we obtained different descending curves for BMI after bariatric surgery, with a more flat descending curve in patients with associated metabolic syndrome criteria, translated as a tendency for weight loss resistance, compared to "metabolic healthy" obese subgroup (Fig. 10).

DISCUSSION

In this study, we reported significant improvement in serum glucose, TC, HDL-cholesterol and TG one year after LSG intervention in Romanian patients. This suggests that LSG surgery associated

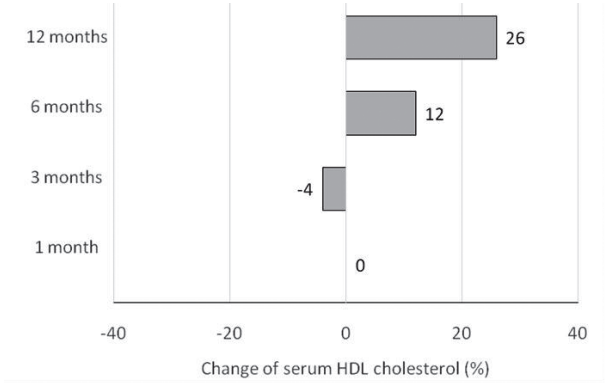

Figure 7. Changes in High density lipoprotein serum levels after bariatric surgery.

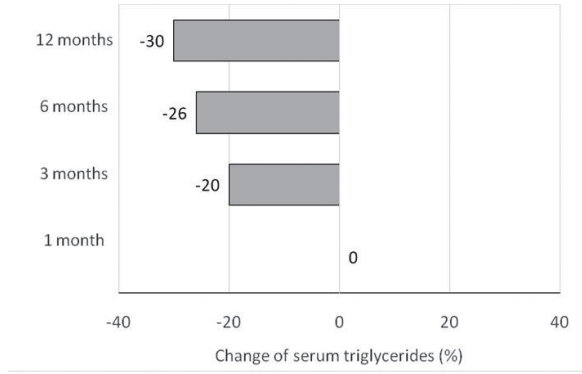

Figure 8. Serum triglycerides reduction percentage after bariatric surgery.

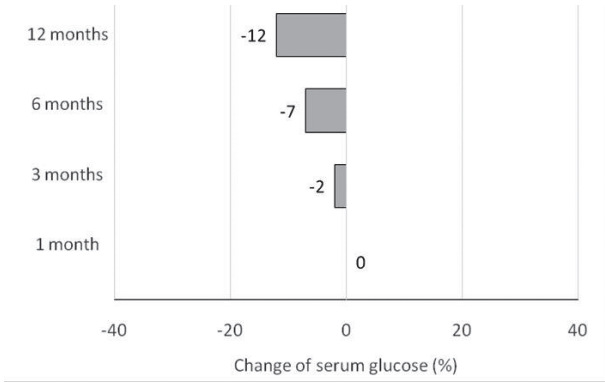

Figure 9. Changes in fasting glucose levels after LSG (% from pre-operative values).

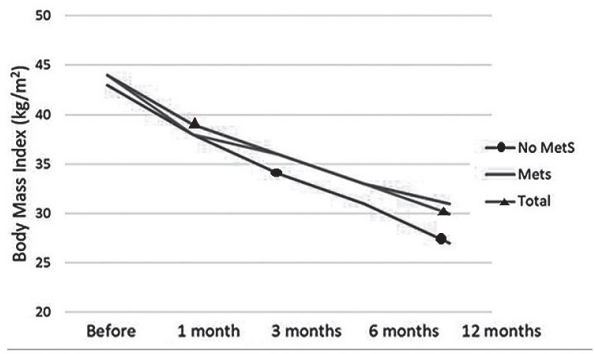

Figure 10. Body mass index (kg/m^2) descendent curve after LSG according to the metabolic syndrome status.

with appropriate weight loss has a positive effect on obesity comorbidities like atherogenic dyslipidemia and serum glucose levels. These positive results of LSG on metabolic parameters are obtained during the first 6 months after surgery and maintained at 12 months follow-up.

Similar studies following LSG effects on a Romanian group of patients also demonstrated a significant improvement on lipid fractions, including a decrease in total cholesterol, LDL cholesterol and TG levels as well as an increase in HDL levels (12) and also a major effect on type 2 diabetes remission, with normal fasting glucose levels in all diabetic patients at one year follow-up (13).

Bariatric surgery has been shown to resolve or improve cardiovascular risk factors such as diabetes, hypertension and dyslipidemia . The meta-analysis by Buchwald *et al.* (14) followed the bariatric surgery effect on type 2 diabetes, including 621 studies with 135,246 184 patients (all types of bariatric surgery) and reported that 78% of diabetic patients had complete resolution (HbA1C <6.5% and no anti-diabetic drugs) and 86.6% had diabetes improvement. Also the Stampede Trial, a reference study evaluating long term bariatric surgery effects, showed that not only there was a significant reduction in overall oral hypoglycemic use, but at 1 year follow-up only 8% of Sleeve Gastrectomy patients required insulin (15).

Although the effect of bariatric surgery on the glucose metabolism is widely demonstrated, with significant improvement of overall glycemic control in diabetic patients, correlated with the duration of type 2 diabetes mellitus (16), there are data that show a tendency for increased fasting plasma glucose in patients suffering gastrectomy intervention for malignancy (17). Our data regarding the fasting glucose levels follow-up at 12 months after LSG showed a significant decrease (12%) for serum glucose compared to pre-operative values.

Literature evidence are even less conclusive concerning the lipid metabolism with heterogeneous data regarding the effect on lipid fractions.

Weight loss surgery promotes substantial decreases in triglycerides levels as well as improvements in cholesterol profiles. Buchwald *et al.* (18) showed a 41% reduction in serum triglycerides one year after

RYGB, an elevation in HDL cholesterol by 23%, and lowering of LDL cholesterol by 19%, with sustained beneficial effects on cholesterol profiles up to 2 years follow-up. A long-term follow-up study of morbidly obese patients with T2DM (n=219) reported a 40% decrease in triglyceride levels and 20% increase in HDL-C levels. These improvements were maintained 2 to 4 years after surgery (19).

Valezi *et al.* (20) reported normalization of serum TC concentrations in 51.7% of the patients, an improvement in 44.8%, and no changes in 3.5% Courcoulas *et al.* (21) observed remission of all types of dyslipidemia in 61.9% of their patients after RYGB and in 27.1% after another surgical technique: laparoscopic adjustable gastric banding (LAGB).

Comparing LSG to the reference metabolic surgery procedure-RYGB, Vidal *et al.* (22) found significant improvements in high-density lipoprotein cholesterol (HDL) and triglycerides (TRG) after LSG and the results, similar to those seen after gastric bypass but no change in low-density lipoprotein cholesterol (LDL) and total cholesterol (TC). Also Perathoner *et al.* (23) demonstrates the positive effect of LSG at 12 months follow-up with the resolution of diabetes in 85% of patients and dyslipidemia remission in 50%.

Omana *et al.* (24) found a greater resolution or improvement of hyperlipidemia with LSG in comparison with laparoscopic adjustable gastric banding. Hyperlipidemia improved in 87% of patients after LSG and in 50% of patients after gastric banding after a 15-month follow-up period. Long term follow-up (6-8 years) data published in 2012 by Eid *et al.* (25) showed a 77% improvement or remission of diabetes, lesser medications for diabetes, hypertension and hyperlipidaemia in patients after sleeve gastrectomy. A systematic review of the literature, published by Khalifa in 2013 (26), concludes that LSG has a significant effect on hyperlipidemia, producing resolution or improvement in most of the cases. Therefore, LSG is an effective surgical option for weight loss and reduction in co-morbidities such as hyperlipidemia.

CONCLUSION

Our data are conclusive in terms of weight loss consecutive to LSG, comparable to other clinical trials that have reported similar 60-64 % for EWL% (27, 28) This study confirms the existing data on the benefits of the laparoscopic sleeve gastrectrectomy (LSG) procedures on atherogenic dyslipidemia, but additional data are needed for the evaluation of the long term effect on cardiovascular mortality, morbidity and risk factors in obese patients. The main drawback of the study was the small lot of patients. A larger study and a longer follow-up is necessary for establishing the metabolic impact for this bariatric surgery procedure.

Conflict of interest

The authors declare no conflict of interest.

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