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LONG-TERM IMPROVEMENT OF GLUCOSE HOMEOSTASIS AND BODY COMPOSITION IN PATIENTS UNDERGOING LAPAROSCOPIC SLEEVE GASTRECTOMY

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Abstract

Context. Laparoscopic sleeve gastrectomy (SG) has gained popularity as a metabolic procedure, but its long-term effectiveness for Romanian patients remains unclear.

Objectives. To assess the long-term efficacy of SG for Romanian patients and to evaluate the differences between 5 years and 1 year follow-up.

Design. A longitudinal, prospective analysis of collected data from 68 patients undergoing SG between 2009 and 2014 was performed. Long-term outcomes at 5 years were analyzed in terms of total weight loss (%TWL), excess weight loss (%EWL), body composition and glucose homeostasis.

Subjects and Methods. All patients meeting the standard criteria for SG before inclusion were prospectively enrolled in the study. Of the 68 patients, eight were lost to follow-up, therefore, 60 patients (41.7±12.5 years, baseline body mass index [BMI] 44.6±9.9Kg/m^2) were analyzed.

Results. The BMI decreased at 12 months with 30.7% from the preoperative BMI ($p<0.001$) and subsequently stabilized at 5 years.

TWL and EWL were 30.6% and 83.1%, respectively at 1 year, with a slightly increase at 5 years.

Therapeutic success rate (%EWL≥50) and diabetes remission rate (Buchwald criteria) were 93.3% and respectively 63.6% at 5 years. Insulin sensitivity index and metabolic clearance rate of glucose increased with 92.5% and 60.1% respectively, in the third month from baseline ($p<0.001$), while estimated second phase of insulin secretion decreased with 7.9% in the first month postoperatively ($p=0.04$), remaining stable afterwards.

Conclusions. SG was effective in terms of %EWL, body composition and glucose homeostasis improvement for Romanian patients, the outcomes stabilizing after 1 year follow-up.

Key words: Sleeve gastrectomy, Percentage excess body mass index loss, Body composition, Glucose homeostasis.

INTRODUCTION

Obesity is a preventable disease and a recognized major health problem, but however its prevalence is continuously increasing reaching 32.4% in the US (1) and 16.7% in Europe (2). Recent findings from the national epidemiological study PREDATORR showed that 31.9% of the adult Romanian population has obesity (3) and another study indicated that 17.5% of the population from a rural community from the North-East region of Romania has obesity (4). Obesity is an important risk factor for cardiometabolic diseases, cancer, chronic kidney disease (3-5).

Lifestyle optimization can lead to 5-10% weight loss, but most of the patients regain part of the weight within 3-6 months suggesting that in general obesity is refractory to lifestyle optimization (6). Anti-obesity medication can induce 2-8 kg weight loss (7) with poor long-term maintenance.

Studies showed that the only effective and durable treatment for mid- and long-term weight control is bariatric surgery, procedure that leads to 20-30% weight loss that can be maintained for at least 15-20 years (8). Laparoscopic sleeve gastrectomy (SG) is a restrictive technique consisting in the removal of approximately 70-80% of the stomach.

SG is thought of as "metabolic procedures" due to the effects it has on metabolic syndrome and type 2 diabetes mellitus (T2DM), beyond weight loss bariatric surgery can lead to improvement or resolution of T2DM, reducing insulin resistance and improving beta cell function (9-11). The reports about efficacy of SG in Romanian patients and the data regarding the long-term effects of bariatric surgery are still scarce (12).

The primary aim of this study was to assess the medium and long-term clinical outcomes of

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SG in terms of ponderal status, body composition, insulin resistance, insulin secretion, T2DM remission in patients with obesity undergoing SG as a stand-alone procedure, with a follow-up of 60 months. The secondary aim was to evaluate whether there are any significant differences between 5 years and 1 year follow-up in anthropometric and glucose homeostasis parameters in the analyzed patients.

MATERIALS AND METHODS

Study design and data collection

A longitudinal, prospective, cohort study evaluating the effectiveness of SG was carried out in the “N.C. Paulescu” National Institute of Diabetes, Nutrition and Metabolic Diseases Bucharest and in the Clinical Hospital “Euroclinic - Regina Maria” Bucharest between 2009 and 2014. All patients meeting the standard criteria for SG before inclusion were prospectively enrolled in the study.

The exclusion criteria were: inability to give informed consent, previous gastrointestinal surgery, medical conditions that change body weight, pharmacological therapy (except anti-diabetic drugs) that interferes with carbohydrate metabolism or changes body weight.

Informed consent was obtained from all participants included in the study. All procedures performed in this study involving human participants were approved by the Ethics Committee of “Carol Davila” University of Medicine and Pharmacy Bucharest and were in accordance with the Helsinki declaration on clinical experimentation.

Patient data were collected preoperatively and 1, 3, 12 and 60 months afterward. Weight, height and waist were measured using standard procedures. BMI was calculated.

Postoperative weight loss was expressed as change in BMI, percentage excess body weight loss (%EWL) and percentage total body weight loss (%TWL). %EWL was calculated as follows: [(preoperative weight – postoperative weight)/(preoperative weight - ideal weight)]*100, where ideal body weight is that equivalent to BMI of 25 kg/m^2 (13). A EWL≥50% was defined as therapeutic success. %TWL was calculated using the formula: [(preoperative weight - postoperative weight)/preoperative weight]*100 (11,13).

Body composition analysis was performed using a bioelectrical impedance method (OMRON brand, model 508– Body Composition Monitors), which provides estimated total fat mass, visceral fat mass and muscle mass as percentages of body weight.

Fasting plasma glucose (FPG) was determined using enzymatic methods. HbA1c was determined using the immunoturbidimetric method and serum insulin was assessed with a chemiluminescent immunoassay.

Oral glucose tolerance test (OGTT) with 75 g anhydrous glucose was performed in all patients. Plasma glucose concentrations were measured at 0, 30, 60 and 120 minutes and serum insulin concentrations were assessed at 0 and 30 minutes. In patients with impaired glucose regulation the anti-diabetic therapy was discontinued 24 hours before the test.

Diabetes was diagnosed according to the 2014 American Diabetes Association guidelines (14) or self-reported diagnosis.

Complete remission of T2DM was defined, according to Buchwald criteria, as a FPG <5.6mmol/L or HbA1c <6%, in the absence of antidiabetic therapy (15).

OGTT-derived Stumvoll indexes such as the insulin sensitivity index (ISI), metabolic clearance rate (MCR) of glucose and first-phase and second-phase insulin secretion were calculated (16).

Surgical technique

SG surgery was performed by one experienced team. The gastric transection started from the distal antrum (4-6 cm proximal to the pylorus) to the angle of His, the gastric fundus being completely dissect. Endoscopic staples were fired to transect the excess stomach. A gastric remnant of 100 mL volume was obtained.

Statistical analysis

Of the 68 participants enrolled in the study, 60 participants had complete data in all the follow-up time points. Cochran’s test was used to test the differences of categorical variables. Spearman’s test was used to quantify cross-sectional association between variables of interest and EWL.

Longitudinal analysis was performed using general linear model analysis for repeated measures (ANOVA), followed by pairwise comparisons with Bonferroni correction in order to test for significant differences in longitudinal changes of variables at each postoperative time point from baseline and from the previous one. Statistical significance was set at $p<0.05$. Statistical analysis was performed using SPSS software v19.0.

RESULTS

The study comprised 68 patients, out of which 8 participants were lost to follow-up. Overall, 60 patients (41.7±12.5 years, 83.3% females) that underwent SG were included in the analysis.

Weight loss

At baseline, the average BMI was 44.6±9.9 Kg/m^2, most of the patients (60%) having a BMI above 45kg/m^2, and 16.7% having extreme obesity (BMI≥55 kg/m^2).

BMI decreased early in the first month postoperatively (p<0.001), and then significantly decreased during the first year, with a 19.4% and respectively 30.7% decrease from the preoperatively BMI at 3 months and 12 months. The BMI subsequently stabilized, at 5 years postoperatively patients having lost only 0.7 BMI points compared to 1 year follow-up (Table 1).

Waist decreased in parallel with BMI, with a 24.9% reduction at 5 years compared to baseline (Table 1).

%EWL and %TWL significantly increased from months 1 to 12 after surgery (p<0.001), reaching 83.1% and 30.6%, respectively at 1 year follow-up, with a slightly increase of 3.3 only for %EWL at 5 years postoperative (Table 1, Fig. 1).

Defined as % EWL ≥50, the therapeutic success rate increased significantly from the first postoperative month, reaching 89.8% at 12 months (p <0.001), and remaining stable thereafter (Fig. 1).

Body composition

SG induced weight loss was associated with a significant change in body composition early in the first month postoperative, characterized by marked decrease in visceral fat (p<0.001) and fat mass (p<0.001) and increase in muscle mass (p=0.001) (Table 1, Fig. 2).

Visceral fat showed a slightly reduction in the next 2 months, followed by a significant decrease at 1 year (p=0.014 compared to 3 months), stabilizing thereafter (Table 1).

Glucose homeostasis

Preoperatively, 22 (36.7%) patients presented T2DM (48.6±10.6 years, diabetes duration 5.8±4.0

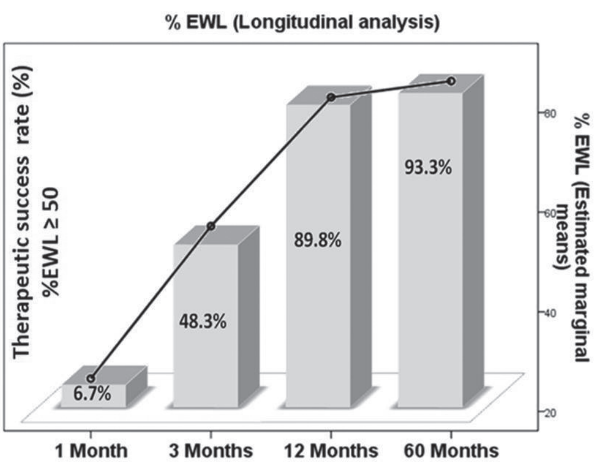

Figure 1. Time variation in %EWL (full line) and frequency of therapeutic success (EWL≥50%) in each time points (bars).

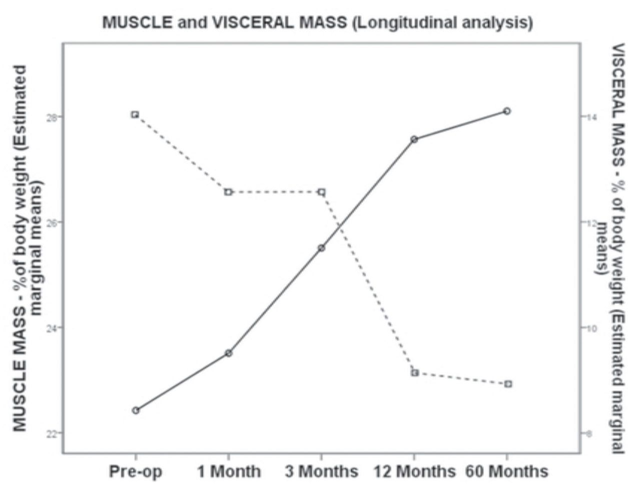

Figure 2. Time trend in muscle mass (full line) and visceral mass (dashed line).

Table 1. Longitudinal repeated measures ANOVA for anthropometric parameters, body composition indices and %EWL, %TWL

Anthropometric parameters	Pre-op	1 month Post-op	3 months Post-op	12 months Post-op	60 months Post-op
Weight (Kg)	126.8(118.5-135.3)	115.8(107.7-123.8)[a,b]	100.7(93.8-107.5)[a,b]	87.5(81.9-93.1)[a,b]	85.8(80.4-91.1)[a]
BMI (Kg/m^2)	44.7(42.1-47.4)	40.8(38.2-43.4)[a,b]	36.0(33.4-38.6)[a,b]	31.0(29.0-33.0)[a,b]	30.3(28.5-32.1)[a]
Waist (cm)	128.0(122.7-133.3)	118.7(113.6-123.8)[a,b]	107.2(102.2-112.3)[a,b]	97.8(93.4-102.2)[a,b]	96.2(91.9-100.4)[a]
Muscle Mass (%BW)	22.4(21.6-23.2)	23.5(22.8-24.2)[a,b]	25.5(24.8-26.2)[a,b]	27.6(26.6-28.5)[a,b]	28.1(27.1-29.2)[a]
Fat Mass (%BW)	47.1(45.5-48.7)	45.1(43.5-46.7)[a,b]	40.5(38.1-42.9)[a,b]	39.3(37.6-40.9)[a]	38.4(36.5-40.3)[a]
Visceral Fat (%BW)	14.0(13.1-15.0)	12.6(11.6-13.5)[a,b]	12.5(10.5-14.7)	9.1(8.3-9.9)[a,b]	8.9(8.1-9.7)[a]
%EWL	-	26.6(20.3-32.9)	57.2(48.0-66.4)[b]	83.1(72.2-94.0)[b]	86.3(75.2-97.5)[b]
%TWL	-	9.0(7.9-10.0)	20.3(17.7-22.8)[b]	30.6(28.7-32.5)[b]	32.0(30.1-33.8)

[a]Compared to baseline; bCompared to previous. The values between parentheses represent 95%CI.

years, 45.5% of patients having T2DM duration >5 years).

The complete remission rate of T2DM was noticed in 13.6% of the patients at 1 month postoperative, the percentage increasing to 35% at 3 months, the difference not reaching statistical significance. T2DM remission rate increased at 12 months after surgery to 50% ($p<0.05$ compared to first month follow-up), reaching a maximum of 63.6% after 60 months ($p<0.05$ compared to first and third months follow-up). There were no significant differences between T2DM remission rate at 1 year and 5 years postoperative.

SG induced a significant increase in ISI and MCR of glucose at first month postoperative ($p<0.001$) and 3 months after surgery ($p<0.001$ compared to baseline and first month) (Table 2). At 5 years, ISI and MCR of glucose had a drop of 0.003, respectively 0.2 compared to their values at 1 year follow-up (Table 2, Fig. 3).

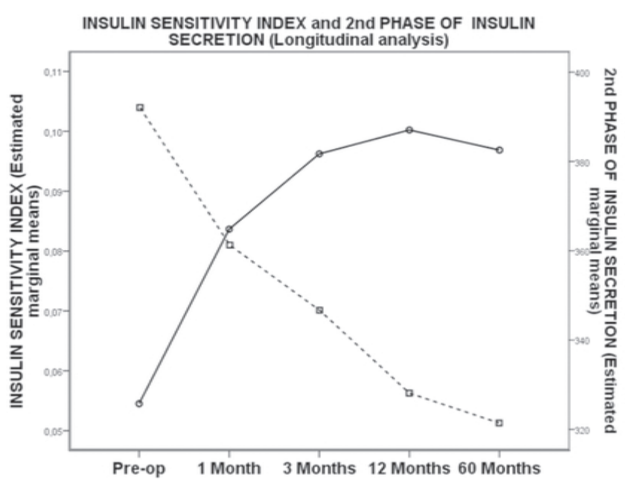

Figure 3. Time trend in insulin sensitivity index (full line) and insulin secretion 2nd phase (dashed line).

The estimated second phase of insulin secretion markedly decreased during the first month post-operative ($p=0.04$), afterwards showing a statistically non-significant descendant trend throughout the 5 years follow-up (Table 2, Fig. 3).

We found significant association of ISI ($p=0.005$) and MCR ($p=0.004$) at 3 months and %EWL at the same assessment point, as well as between estimated first and second phase of insulin secretion ($p=0.006$ for both) at 5 years postoperative and %EWL at the same time point. All the insulin sensitivity and insulin secretion indices evaluated at 1 year postoperative were significant associated with %EWL assessed at 1 year follow-up ($p<0.001$ for all). There were no associations between %EWL at 1 month and estimates of insulin sensitivity and β-cell function. HbA1c markedly decreased during the first year ($p<0.001$ for all), HbA1c level subsequently stabilized at 5.3% (Table 2).

DISCUSSION

SG is a stand-alone technique recently approved, therefore the long-term outcomes from large series are scarce. The most significant SG efficacy parameters are %EWL, %EWL≥50 and %TWL, which in our study reached at 5 years follow-up values of 86.3%, 93.3% and 32.0% respectively. The therapeutic success rate found in our study was considerably higher than that reported by Diamantis *et al.* (62.3%) (17) and Sieber *et al.* (57.4%) (18), but comparable to that reported by Casella *et al.* (87.1%) (11) at the same follow-up time point.

The trend of %EWL at 5 years follow-up indicated that SG efficacy is maintained over time, results that are consistent with previous findings (11). Opposed to other studies (11), which detected

Table 2. Longitudinal repeated measures ANOVA for glucose homeostasis parameters

Glucose homeostasis parameters	Pre-op	1 month Post-op	3 months Post-op	12 months Post-op	60 months Post-op
Fasting glycemia (mmol/l)	5.7(5.3-6.2)	4.(4.5-5.1)[a,b]	4.5(4.2-4.7)[a,b]	4.4(4.2-4.6)[a]	4.5(4.2-4.7)[a]
Fasting insulinemia (pmol/l)	101.7(86.7-116.8)	74.3(65.5-83.1)[a,b]	59.9(53.9-66.0)[a,b]	54.5(48.3-60.6)[a]	59.2(40.4-78.0)[a]
HbA1c (%)	6.1(5.9-6.4)	5.8(5.6-6.0)[a,b]	5.6(5.4-5.7)[a,b]	5.3(5.2-5.4)[a,b]	5.3(5.2-5.4)[a]
Insulin Sensitivity Index (μmolxKg-1xmin-1xpmol/L)	0.055(0.04-0.07)	0.084(0.08-0.09)[a,b]	0.096(0.09-0.10)[a,b]	0.100(0.10-0.11)[a]	0.097(0.09-0.11)[a]
Metabolic Clearance Rate (ml x Kg-1 x min-1)	5.1(4.2-6.1)	7.2(6.6-7.9)[a,b]	8.2(7.7-8.6) [a,b]	8.5(8.1-8.8)[a]	8.2(7.5-8.9)[a]
Insulin secretion 1st phase (pmol/L)	1445.3(1288.6-1602.0)	1362.4(1201.0-1523.7)	1331.3(1201.6-1461.0)	1265.8(1129.4-1402.3)	1235.5(1081.5-1389.5)
Insulin secretion 2nd phase (pmol/L)	392.1(356.6-427.5)	361.3(325.2-397.3)[a,b]	346.7(317.2-376.1)[a]	328.1(297.0-359.2)[a]	321.4(286.4-356.5)[a]

[a]Compared to baseline; bCompared to previous. The values between parentheses represent 95%CI.

a tendency towards a slight weight increase from the third year after SG, none of the subjects included in our study regained weight throughout the entire follow-up period.

Data regarding changes in body composition after SG are scarce and inconsistent due to various methods of evaluation. Similar to our findings, Schneider *et al.* showed that after SG the total fat mass decreased significantly compared with baseline and the percentage of muscle mass per kilogram of weight increased postoperatively (19).

The remission rate of T2DM after SG is variable. In the current study the diabetes remission rate increased significantly from the first postoperative year, reaching a maximum value of 63.6% of the patients at 5 years. This remission rate is similar to that reported by Pujante *et al.* (20), but considerably lower than that reported by other several studies (11, 121). Gill *et al.* reported in a systematic review including 27 studies, a mean rate of T2DM remission of 66.2% (range 14% to 100%) (22). The different criteria used to define diabetes remission, as well as the long duration of diabetes in our patients could be potential explanations (21, 23).

Similar to other studies (12, 20, 24-26), we observed an early improvement of glucose homeostasis, followed by a stabilization of glycemic parameters.

Few studies have evaluated insulin secretion after SG. Our study indicated an early increase of ISI and MCR associated with decrease of estimated second phase of insulin secretion. Consistent with our findings, Casella *et al.* demonstrated that SG improved insulin sensitivity (euglycemic hyperinsulinemic clamp technique) and reduced insulin secretion (OGTT) within 12 months after surgery. The significant changes in insulin sensitivity and insulin secretion indices found in our study were not related to weight loss in the first month follow-up, which might be explained by the early postoperative hormonal changes induced by SG (10, 27).

We noticed no significant differences in all anthropometric, body composition indices and glucose homeostasis parameters between 1 year and 5 years follow-up. These results might help establishing the usefulness of long term clinical results assessment.

To our knowledge, our study is the first national prospective study to assess the long-term outcomes of SG in Romanian patients. Furthermore, this is one of the few studies which evaluated over a long-term follow-up period the impact of SG on body composition and also on the estimates of insulin sensitivity and β-cell function using OGTT.

Concerning limitations, our study was performed on a small number of patients due to the enrollment only of the patients with complete data in all the follow-up time points.

In conclusion, SG proved to be an effective long-lasting procedure in Romanian patients, showing favorable outcomes in terms of %EWL, adipose tissue redistribution and glucose homeostasis improvement. Although these improvements were marked in the first year post-operative, there were no significant differences between 5 years and 1 year follow-up. Further studies with larger sample size are needed to confirm our findings.

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Romanian National Ethics Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

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