INTRODUCTION

Overweight and obesity have reached epidemic proportions globally along with an adoption of a westernized lifestyle characterized by a combination of excessive food intake and inadequate physical activity (1). According to data published by the International Obesity Task Force, at least 1.1 billion adults are overweight and 312 million of them are obese (2). In the United States, the prevalence of obesity (body mass index BMI=30) doubled during the past two decades, and currently 30% of the US adult population is classified as obese (1). Prevalence of obesity in Europe is reported in the range of 10-20% in men and 15-25% in women (3). In Romania obesity is increasing at an alarming rate. It is estimated that the prevalence of overweight and obesity together are over 50% (4).

SUMMARY:

Obesity is increasing worldwide at an alarming rate. Morbid obesity (body mass index BMI=40 kg/m²) is associated with high risk of morbidity and mortality. Conservative treatment leads to insufficient weight loss in morbidly obese patients and bariatric surgery has proved to be the most effective mode of treatment in these cases. Among the different operations, silastic ring vertical gastroplasty (SRVG) is a safe and simple restrictive operation. The aim of the present study was to evaluate the effects of SRVG on body weight, BMI, excess body loss (EBL), and on obesity associated diseases during the first postoperative year. The study was carried out on eighty morbidly obese patients with the mean age of 38.43±10.60 and a mean BMI of 48±8.20 kg/m² before the operation. Weight and height were determined by the currently used means, BMI and excess body loss EBL were calculated, and systolic and diastolic blood pressure were measured according to routine methods. Blood samples were collected for blood glucose, total cholesterol (chol), triglycerides (TG), HDL cholesterol (HDL), and LDL cholesterol (LDL). All parameters were assessed before and 3. 6 and 12 months postoperatively. At baseline BMI was 48.48±8.20 kg/m² and decreased to 31.33±5.82 kg/m² (p<0.0001) by the end of the first year. EBL was 75.97±21.60% 12 mnths after SRVG. The prevalence of co-morbidities in morbidly obese patients at baseline was high: 43.75% had diabetes, 12.5% had hypertrygliceridemia, 23.75% had hypercholesterolemia, 35% had hyperlipidemia and 40% had hypertension. One year after surgery prevalence of diabetes decreased to 1.25%, hypertrygliceridemia to 1.25% and hyperlipidemia to 7.5%. However, hypercholesterolemia increased at 30%. Hypertension was found in only 7.5% of the patients by the end of the first year after the surgical intervention. Our study demonstrated that SRVG results in very significant weight loss, improvement in metabolic profile and reduction in associated diseases. Furthermore, this study suggests that the first three months are very important in improvement of biological abnormalities.

Key Words: morbid obesity, silastic ring vertical gastroplasty, co-morbidities

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Obesity is associated with serious medical illness such as: type 2 diabetes mellitus, hypertension, cardiovascular disease, dyslipidemia, osteoarthritis, nonalcoholic steatohepatitis, gallbladder disease, sleep apnea syndrome as well as various forms of malignancies. Increasing body weight impairs quality of life and reduces life expectancy. Mortality attributable to excess weight loss is a serious public health problem in Europe, where about 7.7% of all deaths are related to excess weight (2).

A US epidemiological study found that the most serious forms of obesity, morbid obesity (BMI =40kg/m²), is increasing at a faster rate than other categories of obesity (5). It is associated not only with a high risk of morbidity and mortality, but also with psychosocial consequences and a high socioeconomic burden. In morbidly obese patients, conservative treatment (i.e. diet, lifestyle changes, and drugs) leads to insufficient weight loss with reduction of comorbidities in <4% (6). Bariatric surgery has proved to be the most effective mode of treatment for morbidly obese patients (2). Among the different operations, silastic ring vertical gastroplasty (SRVG) is a safe and simple restrictive operation. Weight loss is not the only goal of obesity surgery. Improvement or resolution of obesity-related co-morbidities should also be considered a primary target (7). Long term studies show that there is a substantial reduction in mortality after bariatric surgery, as well as decreased risk of developing new health-related co-morbidities, decreased health-care utilization and decreased direct health-care costs (8,9).

The aim of the present study was to evaluate the effects of SRVG on body weight, BMI, excess body loss (EBL), and on obesity associated diseases during the first postoperative year.

**MATERIAL AND METHOD**

**Patients**

The study was carried out on eighty morbidly obese patients with the mean age of 38.43±10.60 (range 19-58) and with a mean BMI of 48±8.20 kg/m² (range 37.45 to 80.1 kg/m²) before the operation. They were all submitted to SRVG. Inclusion criteria were BMI=40 kg/m² or 35-40 kg/m² with at least one co-morbidity, history of obesity for at least several years and unsuccessful attempts to lose weight at medical therapy for at least 2 years. Exclusion criteria were: patients who did not follow up the medical management of obesity, with diseases threatening life in short term, psychiatric pathology, alcohol abuse and/or drug dependencies, patients unable to participate to prolonged medical follow up or to care for themselves (2).

**Anthropometric measurements**

Weight and height were determined by the currently used means. BMI was calculated by the formula weight/height². EBL was calculated using the formula [(initial BMI- final BMI) / (initial BMI-25)]*100 (10). Success was defined as EBL>50%. The anthropometric parameters were determined at baseline and at 3. 6 and 12 months after SRVG.

**Biological parameters**

Blood samples were collected in the morning after overnight fast. Blood glucose, total cholesterol (chol), triglycerides (TG), HDL cholesterol (HDL) were determined and systolic and diastolic blood pressure were measured according to routine methods. LDL cholesterol (LDL) was calculated using the Friedewald formula LDL=chol-HDL-TG/5. All parameters were assessed before and 3. 6 and 12 months postoperatively. However only 62.5% patients returned for all follow up visits. Patients with diabetes were defined as having a fasting glucose level=126 mg/dl in at least two determinations or previous diagnosis of diabetes on specific treatment. Hypertensive subjects were defined as having blood pressure=140/90 mmHg confirmed by two subsequent measurements or previous diagnosis of hypertension on pharmacological treatment. Dyslipemias were defined as hypertrigliceridemia if TG were=150 mg/dl and LDL<130 mg/dl; hypercholesterolemia if LDL=130 mg/dl and TG<150 mg/dl, and hyperlipidemia if TG were=150 mg/dl and LDL=130 mg/dl. This corresponds to the normal values according to the European Guidelines on Cardiovascular Disease Prevention (11). The normal value for total cholesterol was defined as <190/dl and HDL should be=40 mg/dl in males and =46 mg/dl in females (12).

Reduction in co-morbidity in the follow-up was scaled to the preoperative co-morbidity level as:

1. cured (symptoms disappeared, no medication, normal blood pressure levels)
2. improved (less symptoms, reduction of dosage or change of medication type)
3. unchanged
4. worsened or newly developed co-morbidity

**Surgical intervention**

All patients were submitted to SRVG. Surgery was performed at the Second Surgical Clinic from “Iuliu Hatieganu” University of Medicine and Pharmacy,
Cluj-Napoca, by the same surgeon, between 2004-2006. The first SRVG in Romania were performed in Cluj-Napoca, in the same clinic, by the same surgeon in 1997 (13). SRVG is a restrictive procedure, consisting in reduction of gastric capacity without gastric resection. The stomach is vertically divided into compartments parallel to the small curvature, by mechanical suture with titanium clips, from the Hiss angle over a 9 cm distance. At the base of this suture, a 5.3 cm silicon ring is fixed. Two compartments are formed, the upper one of 70 ml and the lower one of 1230 ml, which are separated by a 12 mm opening (14).

**Statistical analysis**

Statistic evaluation was performed using the SPSS 13.0 software. The analysis included descriptive statistical indices: mean, median, standard deviation, minimum, maximum values. We used Q-Q plots to verify the normal distribution of the data. There was a gaussian distribution of the values which permitted us to use parametric statistical tests to analyse the data. We used paired sample T test to compare the evolution of the mean values in time for measured and calculated parameters. We considered the difference to be statistical significant when P-value was equal or less than 0.05.

**RESULTS**

**Anthropometric parameters**

At baseline BMI was $48.48\pm8.20$ kg/m² and decreased significantly to the mean value of $39.73\pm7.18$ kg/m² ($p<0.0001$) at 3 months, $35.29\pm6.43$kg/m²($p<0.0001$) at 6 months and by the end of the first year to $31.33\pm5.82$ kg/m² ($p<0.0001$). EBL was $75.97\pm21.60\%$ by the end of the first year after SRVG (figure 1,2).

![Figure 1. Evolution of BMI](image)

![Figure 2. Evolution of EBL](image)
**Metabolic parameters**

As expected, the prevalence of co-morbidities in morbidly obese patients at baseline was high: 43.75% had diabetes, 12.5% had hypertriglyceridemia, 23.75% had hypercholesterolemia, 35% had hyperlipidemia and 40% had hypertension. One year after surgery prevalence of diabetes decreased to 1.25%, hypertriglyceridemia to 1.25% and hyperlipidemia to 7.5%. Interestingly, hypercholesterolemia increased at 30%. Hypertension was found in only 7.5% of the patients by the end of the first year after the surgical intervention. Changes in co-morbidities after 12 months are shown in table I.

The evolution of biochemical parameters and blood pressure over 12 months is shown in table II as well as in figure 3. There was a significant statistical and clinical (p<0.0001) improvement in blood glucose and TG at each moment evaluated after SRVG. Total cholesterol, LDL cholesterol and HDL cholesterol also improved significantly after surgery. Blood pressure improved significantly by the third month (p<0.0001) after the intervention and remained in normal range during the first year after SRVG.

**DISCUSSION**

Morbidly obese individuals have a higher prevalence of many medical problems than the general population and a diminished quality of life as well as life expectancy as a result. Bariatric surgery is the only effective method of treatment in morbidly patients who have failed repeated attempts with diet, exercise and behavioural modifications.

SRVG is a safe, simple and effective operation. There were no deaths after the surgical intervention. Weight loss ranged between 5-10 kg/month. In the present study, 80 patients who underwent SRVG achieved rapidly a maximum EBL of 75.97±21.60% and a decrease in BMI from 48.48±8.20 kg/m² to 31.33±5.82 kg/m² within first year after the operation. One important observation of our study was the rapid weight loss achieved. Six months after SRVG, EBL was 59.07±19.51% and BMI decreased

### Table I. Co-morbidities changes 12 months after surgery

<table>
<thead>
<tr>
<th>1 YEAR AFTER SURGICAL INTERVENTION</th>
<th>DIABETES MELITUS</th>
<th>HYPERTRIGLYCERIDEMIA</th>
<th>HYPERCHOLESTEROLEMIA</th>
<th>HYPERTENSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>cured</td>
<td>97.14%</td>
<td>85.20%</td>
<td>51.01%</td>
<td>81.25%</td>
</tr>
<tr>
<td>improved</td>
<td>2.85%</td>
<td>13.15%</td>
<td>27.65%</td>
<td>18.75%</td>
</tr>
<tr>
<td>unchanged</td>
<td>0%</td>
<td>1.25%</td>
<td>6.36%</td>
<td>0%</td>
</tr>
<tr>
<td>worsened</td>
<td>0%</td>
<td>0%</td>
<td>14.89%</td>
<td>0%</td>
</tr>
</tbody>
</table>

### Table II. Modifications of biochemical parameters and blood pressure during 12 months after silastic ring vertical gastroplasty

<table>
<thead>
<tr>
<th></th>
<th>baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycemia</td>
<td>134.05±59.36</td>
<td>100.57±16.50***</td>
<td>96.95±12.79***</td>
<td>95.17±13.01***</td>
</tr>
<tr>
<td>Tryglicerides</td>
<td>180.48±104.95</td>
<td>127.61±55.59***</td>
<td>120.14±51.42***</td>
<td>96.87±35.57***</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>219.05±54.24</td>
<td>205.05±51.93**</td>
<td>199.86±55.32***</td>
<td>196.04±45.12*</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>142.85±41.83</td>
<td>136.96±44.46</td>
<td>132.81±48.62*</td>
<td>128.08±41.12</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>45.99±12.37</td>
<td>46.15±10.46</td>
<td>46.29±12.18</td>
<td>51.66±11.66*</td>
</tr>
<tr>
<td>Sistolic blood pressure</td>
<td>142.81±23.51</td>
<td>121.41±8.36***</td>
<td>119.74±8.46***</td>
<td>118.98±8.63***</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>85.19±13.07</td>
<td>71.81±6.96***</td>
<td>70.82±6.95***</td>
<td>70.15±7.11***</td>
</tr>
</tbody>
</table>

*p<0.05; **p<0.001; ***p<0.0001 when compared to baseline
to 35.29 ± 6.43 kg/m². Our results are similar to those reported by Closset and colleagues (15). Paran and colleagues (16) recently reported a weight loss from a BMI of 48 kg/m² (range 34 to 69 kg/m²) to 29 kg/m² and an EBL of 67% by the end of the first year after SRVG. Other authors, using laparoscopic adjustable gastric banding, a similar restrictive technique, reported a decrease of BMI from an average of 48.5 kg/m² to 34 kg/m² (range 22.2-56.2 kg/m²) at latest follow up, corresponding to a mean EBL of 61.9% (17). Using the same technique, Ahroni and colleagues (18) reported a weight loss from 45 kg/m² at baseline to 32.3 kg/m² and an excess weight loss (EWL) of 45.7% by the end of the first year. Ma Y and colleagues (19) reported results of weight reduction, using a different technique, laparoscopic gastric by pass, from BMI of 51.5 kg/m² to 33 kg/m² at one year after the intervention and a mean EWL of 65% at the same moment.

Obesity plays an important role in the pathogenesis of insulin resistance and type 2 diabetes mellitus. In our study 43.75% of the patients had diabetes before the surgical intervention. At three months after SRVG blood glucose decreased to normal range. By the end of the first year after SRVG diabetes was cured (97.14%), with just one patient on oral medication who initially was on insulin. Many other authors reported improvement or cure of diabetes shortly after bariatric surgery. Even small changes in weight can have a major impact on diabetes control and symptoms. Ahroni and colleagues (18) demonstrated that diabetes was much better or somewhat better but these improvements were not statistically correlated to excess weight loss. Closset and colleagues (15) reported cured diabetes in 78% of the cases, improvement in 11% and no change in 11% of the cases. Paran and colleagues (16) reported cure in 53% and improvement in 47%. However, these improvements are not correlated to the magnitude of weight loss. This can be explained by the fact that a moderate weight loss of only 5-10% of body weight or diet itself reduces diabetes very efficiently (20). Ballanthyne and colleagues (21) proposed that rapid short term improvement in insulin resistance following weight loss is mediated by changes in levels of incretin hormones and that long term changes are modulated by alterations in levels of adipocytokines generated by decrease in the fat mass. Also, the immediate improvement/cure in glycemic control may be encountered by diminished caloric intake and decreased carbohydrate load (22).

The effect of weight loss was not equal in all tested metabolic parameters. Tryglicerides decreased significantly, with only one patient having unchanged values by the end of the first year after SRVG. However, total cholesterol cured in 51.01%, but worsened in 14.89% cases. On the other hand, in 8.75% cases, patients with preoperatively normal total cholesterol levels developed increased levels during the first year. Our results on lipid metabolism are partly concordant with other series with a certain improvement, but also persistence of high levels of lipids. Frigg and colleagues (20) reported increased levels of lipids one year after gastric banding in 15% of patients who had normal values at baseline. Gasteyger and colleagues (23) reported a mean value of total cholesterol of 216 mg/dl at baseline and of 202 mg/dl after 12 months after gastric banding. A previous study already noted the same trend, with a reduction in total cholesterol 12-24 months after gastric

![Figure 3. Evolution of metabolic parameters over 12 months after SRVG](image-url)
banding of only 4% (24). Wolf and colleagues (12) reported resolution of all metabolic co-morbidities with excess weight loss, except for LDL values which increased in all but in male morbidly obese patients. The LDL levels indicate the fact that during excess weight loss the percentage of hypercholesterolemia increased in all groups. The reason of this change in the metabolic profile might be due to the higher insulin sensitivity after weight loss and thereby induced lipoprotein lipase activity. It is important to mention, however, that the increase of LDL is compensated by HDL increase (12).

However, unlike other parameters, total cholesterol is not directly related only to obesity, but also to other factors, like genetic determinants (23).

In conclusion, our study demonstrated that the first three months after the surgical intervention are very important in improvement of biological abnormalities.

REFERENCES
REFERENCES (continued)