

## ONE YEAR FOLLOW-UP RESULTS AFTER SLEEVE GASTRECTOMY IN TYPE 2 DIABETES MELLITUS PATIENTS WITH MORBID OBESITY

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### Abstract

**Background and aims:** Bariatric surgery has been shown to be superior to nonsurgical approaches in terms of weight loss and remission of type 2 diabetes (T2DM) and metabolic syndrome. This prospective, single-center, follow-up study assessed percentage of excessive weight loss (%EWL), glycosylated hemoglobin (HbA1c) levels, prescribed antidiabetes drugs and diabetes remission rates in obese T2DM patients who underwent laparoscopic sleeve gastrectomy. **Materials and methods:** 81 patients were selected and data recorded preoperatively, 3, 6 and 12 months postoperatively. **Results:** We recorded -69.3% EWL at 12 months ( $p < 0.0001$  compared to baseline) and a fall of HbA1c from  $8.1 \pm 2.6\%$  to  $6.7 \pm 2.8\%$  at 12 months postoperatively ( $p < 0.0001$ ). The percentage of patients with HbA1c  $< 6.5\%$  showed an increase to 40.7% ( $p = 0.0004$ ) and the one year T2DM remission rate was 20.9% ( $p = 0.0012$ ). **Conclusions:** Laparoscopic sleeve gastrectomy can significantly reduce the BMI, with near 70% EWL and near 21% T2DM remission rate in 1 year.

**key words:** laparoscopic sleeve gastrectomy, morbid obesity, type 2 diabetes mellitus, excessive weight loss

### Background and aims

Obesity is a global problem. It induces health risks, diminishes quality of life, associates psychosocial problems and increases public costs. When patients become morbidly obese, health risks increase rapidly [1]. Morbid obesity is defined as having a body mass index (BMI)  $\geq 40$  or BMI  $> 35$  kg/m<sup>2</sup> combined with at least one comorbid condition, such as type 2 diabetes (T2DM), hypertension, dyslipidemia, or sleep apnea.

Many treatment options exist for the management of obesity, including both nonsurgical and surgical treatments. Dietary therapy, physical activity, behavior therapy, pharmacotherapy, or combinations of these strategies are considered effective nonsurgical weight loss interventions [2]. However, in patients with morbid obesity for whom these strategies have failed to produce the desired weight loss, a surgical approach is suggested [2]. Moreover, bariatric (metabolic) surgery has been shown to be superior to nonsurgical approaches in terms of weight loss and remission of T2DM

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and metabolic syndrome over both the short term and long term [3,4]. Indeed, bariatric surgery is considered an appealing treatment for severe obesity worldwide. In the last decade, the number of bariatric surgeries performed worldwide has increased substantially, doubling between 2003 and 2008 from 143,301 to 344,221 procedures per year [5].

The potential role of bariatric surgery in the prevention [6,7] and treatment [8] of diabetes in individuals with severe obesity is increasingly recognized [9]. A systematic review found that use of bariatric surgery in obese patients with T2DM was associated with remission of diabetes in approximately 70 % of patients over the first 2 years following surgery [10]. Weight loss is an important therapeutic goal in obese patients with T2DM, because even moderate weight loss (5%) improves insulin sensitivity [11,12].

Laparoscopic Roux-en-Y gastric bypass (RYGB) is considered the gold standard in bariatric surgery, providing significant and sustained weight loss and resulting in resolution or improvement of obesity-related comorbidities at long-term follow-up [13,4]. However, during the last few years, laparoscopic sleeve gastrectomy (SG) has increasingly been performed as a primary procedure. SG was first described in the 1990s by Marceau et al. [14] and Hess et al. [15] as part of the duodenal switch operation, and then introduced as a first step of a two-stage operation for high-risk super obese patients [16]. The promising short-term results of SG have somewhat altered the paradigm for SG from a two-stage procedure to a stand-alone definitive bariatric procedure [17-19]. SG achieves clearly better results than other restrictive techniques and is comparable in some aspects to the Roux-en-Y gastric bypass, the current gold standard in bariatric surgery. These benefits have been associated with different pathophysiologic mechanisms unrelated to weight loss such as increased gastric

emptying and intestinal transit, and activation of hormonal mechanisms such as increased glucagon-like peptide-1 (GLP-1) hormone and decreased ghrelin [20]. Weight-loss surgery by laparoscopic sleeve gastrectomy (SG) leads to a 40–65% reduction in excess weight and, amazingly, 56% of patients achieve remission of T2DM and 37% see improvement in their T2DM symptoms [13]. The mechanism by which stomach rerouting leads to weight loss and the improvement or resolution of diabetes is multifactorial.

In metabolomics, an individual's metabolic state is profiled by multiplexed measurement of many low-molecular weight metabolites [21]. Over 4,000 such metabolites have been identified in human serum [22]. Two complementary approaches, targeted and non-targeted analyses, have evolved [23]. In targeted analysis, discrete groups of chemically related metabolites (e.g., amino acids) are quantified in a biological sample. In contrast, non-targeted analysis is a more qualitative approach that surveys as many different metabolites as possible [20]. Using primarily targeted approaches, multiple studies have identified higher levels of branched-chain and aromatic amino acids in insulin-resistant, obese, and T2DM individuals [24]. More recent studies demonstrated that higher levels of these amino acids are predictive of progression to T2DM as well as future insulin resistance and hyperglycemia [25-27]. Recently, Gall and colleagues [28] used non-targeted approach to identify plasma metabolites associated with development of insulin resistance and/or glucose intolerance. Two top-ranked metabolites were an organic acid,  $\beta$ -hydroxybutyrate ( $\beta$ -HB), and a lipid, 1-linoleoyl-glycerophosphocholine (L-GPC). Ferrannini et al. proposed fasting  $\beta$ -HB and L-GPC levels as new biomarkers to help predict dysglycemia and T2DM [29]. This non-targeted global metabolomic profiling represents

new tool that allows the comprehensive survey of metabolism and metabolic networks to gain insight into phenotype and identify biomarker candidates. So far this approach was used to find a way to predict the progression to T2DM as well as future insulin resistance and impaired glucose tolerance by serum analysis of insulin-resistant, obese individuals who progressed to T2DM [20].

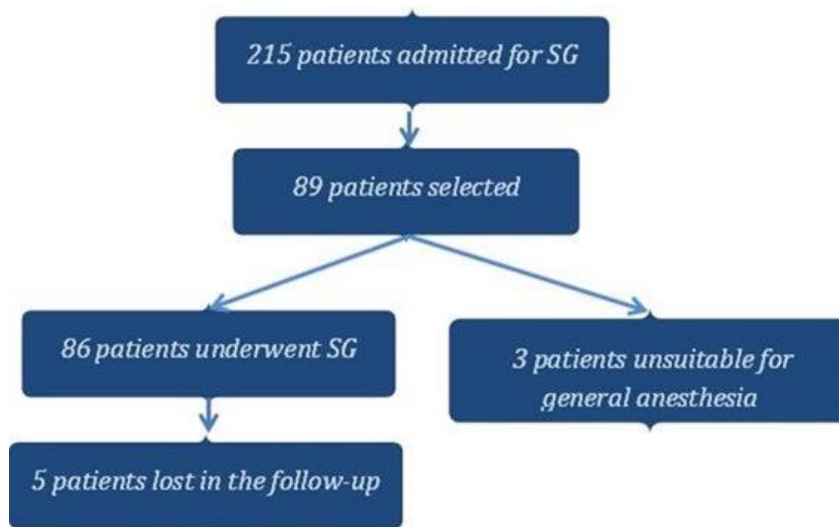
This prospective, single-center, follow-up study was designed to assess the effectiveness of sleeve gastrectomy for weight loss and its effect on glycosylated hemoglobin (HbA1c) levels, prescribed antidiabetes drugs and diabetes remission rates in obese T2DM patients who underwent this type of weight-loss surgery. All data were collected at baseline and at 3, 6, and 12 months postoperatively. The comparison of these results will give an overview about the long-term effects of SG in T2DM obese patients.

## Material and methods

The present study was conducted by a surgical team from January 2011 to December 2015. The cases were selected from the patients admitted in the 1st Surgery Clinic of Bihor County Emergency Clinical Hospital, Oradea, Romania and Medlife-Genesys Clinic, Arad, Romania for sleeve gastrectomy in the period January 2011-December 2014.

Only patients with known T2DM were included, if their medical records contained documentation of past history of T2DM or past laboratory results compatible with the diagnosis of T2DM, according to the American Diabetes Association (ADA) 2010 Revised Clinical Practice Guidelines for diabetes diagnosis [30]. Other inclusion criterion was BMI > 35 kg/m<sup>2</sup>.

The patient selection flowchart for this study is presented in [Figure 1](#).



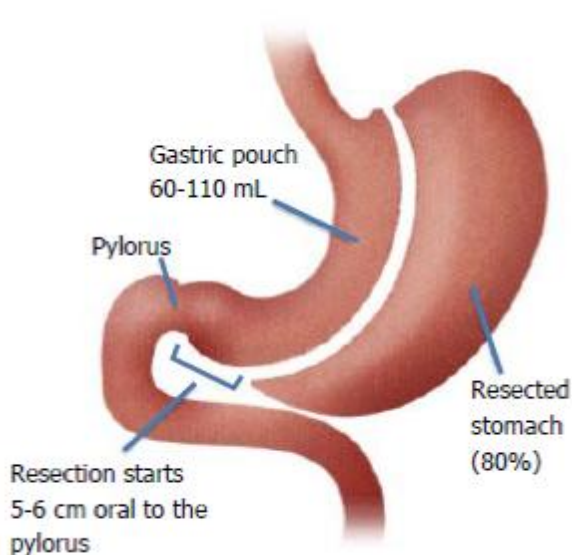
**Figure 1.** Patient selection flowchart.

Patients were excluded from the bariatric program based on the American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines exclusion criteria [31], which are the following: current drug or alcohol abuse; reversible endocrine or other disorder that can cause obesity; uncontrolled/severe psychiatric

illness; and lack of comprehension of the risks/benefits/expected outcomes/lifestyle changes associated with bariatric surgery.

Sleeve gastrectomy is a bariatric technique consisting of subtotal vertical gastrectomy with preservation of the pylorus, including longitudinal resection of the fundus, corpus and

antrum, to create a tubular duct along the lesser curvature. Resection comprises approximately 80% of the stomach and the remnant gastric pouch has a capacity of ~100 mL. It is considered an easier technique than other procedures such as RYGB that requires multiple anastomoses (Figure 2) [32]. Variants of SG have been described, and although no comparative studies have been conducted, none seems to offer advantages. Furthermore, SG has been performed with different degrees of intestinal bypass, including variants with 2 exits from the stomach such as SG transit with bipartition [33] and SG with loop bipartition [34]. In an attempt to achieve a surgery with more metabolic effects, SG has also been linked with ileal transposition [35]; finally, short-term studies on SG with a gastric band have been reported [36]. In our study the classic form of laparoscopic sleeve gastrectomy was performed for all the attendants.



**Figure 2.** Sleeve gastrectomy.

The following information was recorded from patient medical records: sociodemographics, including age and sex; anthropometric data, including weight and height, body mass index (BMI), HbA1c plasma

level (using a turbidimetric inhibition immunoassay method) and use of any antidiabetes drug. These parameters were assessed preoperatively and at 3, 6 and 12 months after surgery.

Percentage of excess weight loss (% EWL) was calculated by dividing the amount of weight loss after surgery by the amount of preoperative excess body weight (calculated as that excess to yield a BMI of 25 kg/m<sup>2</sup>) and multiplied by 100 [37]. Remission of T2DM was established if the HbA1c level was < 6.5% with no prescription of any antidiabetes drug in the last month.

*Statistical analysis:* We used MedCalc version 12.5.0.0 (MedCalc Software, Mariakerke, Belgium) for statistical analysis. The Kolmogorov-Smirnov test was applied to examine normal distribution. Continuous variables with normal distribution are presented as mean and standard deviation – SD (in brackets); those with skewed distribution as median and interquartile range (in brackets). Categorical variables were presented as number of patients and percentage. Because this is a follow-up study we used the paired sample t-test, respectively the Wilcoxon test to study the evolution of the objectives comparing pairwise results. A  $p < 0.05$  was considered statistically significant.

## Results

According to the patient selection flowchart we were able to analyze 81 T2DM patients who underwent sleeve gastrectomy and attended all the follow-up evaluations.

There were no fatalities at 12 months. There was two patients (2.4%) presented major complications following SG (recurrent aspirational pneumonia and intra-abdominal infection caused by a fistula of the esogastric junction) and 5 patients had minor complications

(6.2%) like reflux esophagitis, pneumonia, persistent difficulties in eating. The readmission rate was 4.9%.

The baseline demographic and clinical data are shown in [Table 1](#).

**Table 1.** Baseline characteristics of the study group.

Characteristics	SG patients (n=81)
Age (years) – mean (SD)	48.6 (11.2)
Gender (M/F) – number (ratio)	28/53 (1:1.9)
BMI (kg/m <sup>2</sup> ) – mean (SD)	47.2 (7.1)
HbA1c level (%) – mean (SD)	8.1 (2.6)
Diabetes duration (years) – median (IQR)	5 (2.5-9)

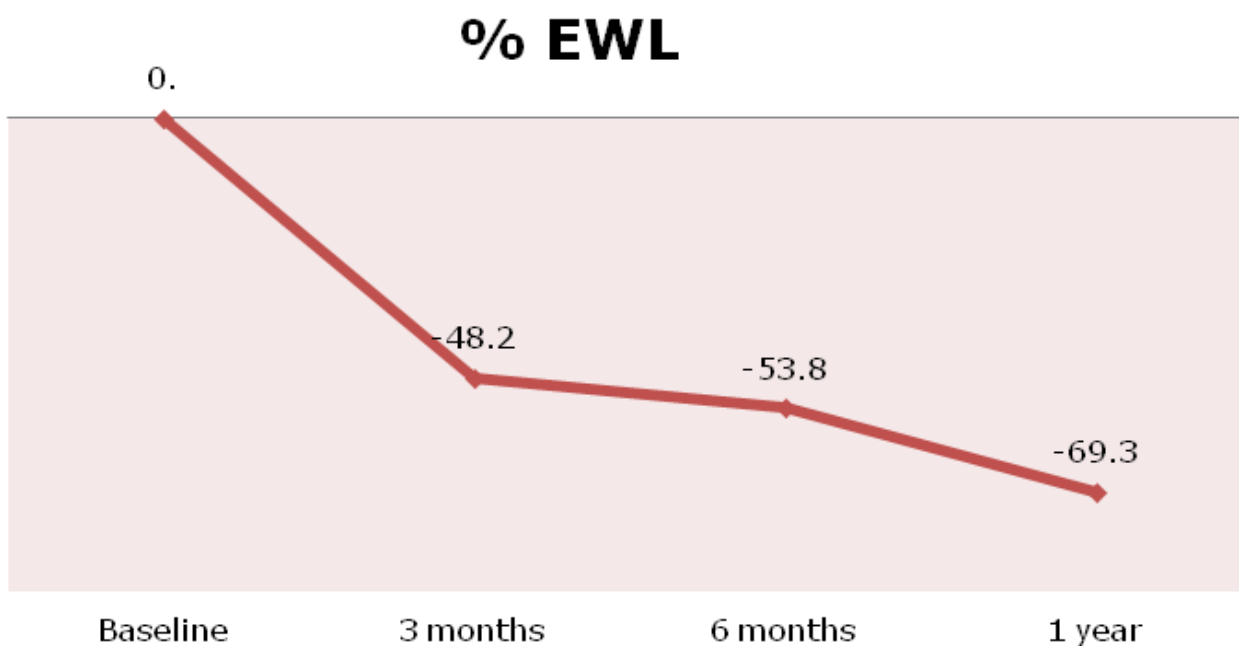
Antihypertensive therapy – no. (%)	61 (75.3)
Statin therapy – no. (%)	55 (67.9)
Current smokers – no. (%)	16 (19.7)

M/F – Male/Female; BMI – body mass index; IQR – interquartile range

The BMI fall in the first year after sleeve gastrectomy is represented in [Table 2](#), together with the number of patients analyzed in each follow-up session and the statistical significance of the difference from the anterior value.

**Table 2.** The evolution of BMI at one year after SG in T2DM patients.

	Before SG	3 months	6 months	12 months
No. of patients assessed	86	85	84	81
BMI (kg/m <sup>2</sup> ) – mean (SD)	47.2 (7.1)	41.8 (5.6)	37.8 (5.5)	31.7 (5.9)
p		< 0.0001	< 0.0001	< 0.0001

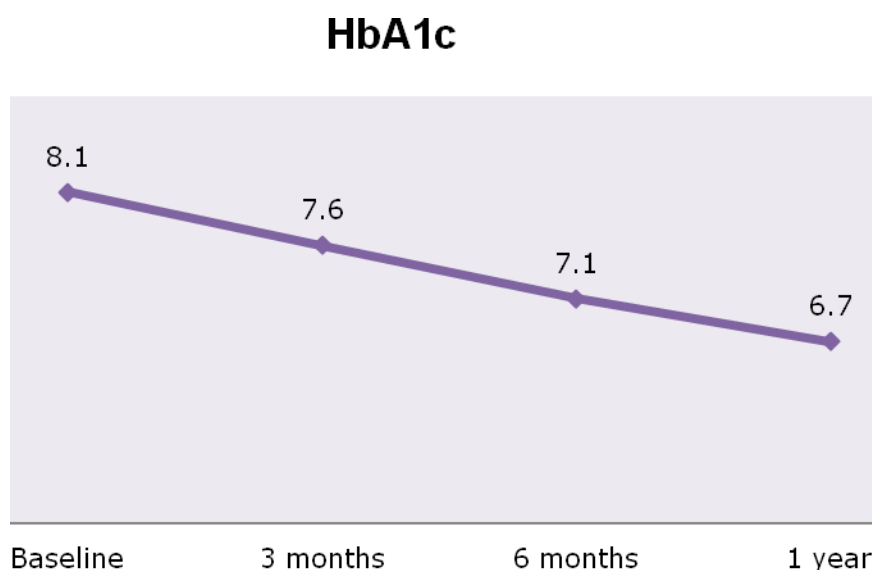


**Figure 3.** Percentage of excessive weight loss in 1 year after sleeve gastrectomy in T2DM patients.

The corresponding percentage of excessive weight loss (% EWL) is shown in [Figure 3](#).

The mean values of HbA1c plasma levels presented a constant decrease during the follow-

up period (p=0.001 baseline value compared to the one year level) as shown in [Figure 4](#).



**Figure 4.** HbA1c plasma levels (mean and SD) in the follow-up period after SG in T2DM patients.

The percentages of patients with HbA1c<6.5% and with diabetes remission (no

antidiabetes drug prescription in the last month) in each follow-up sessions are shown in [Table 3](#).

**Table 3.** Diabetes remission rates at one year after SG in T2DM patients.

	Before SG	3 months	6 months	12 months
No. of patients assessed	86	85	84	81
HbA1c <6.5% - no. (%)	13 (15.1)	17 (20.0)	22 (26.2)	33 (40.7)
p <sup>a</sup>		0.5232	0.1106	0.0004
T2DM remission – no. (%)	3 (3.5)	6 (7.1)	10 (11.9)	17 (20.9)
p <sup>a</sup>		0.4821	0.0758	0.0012

<sup>a</sup> – each value compared to baseline

For each criterion the difference between the baseline value and the 1 year data reached the statistical significance limit.

### Discussions

The baseline characteristics for our study group were comparable with the results published in other centers [38-40], with slight

longer duration of diabetes (explained probably by the later introduction of these surgical procedures in our country). However, the 69.3% EWL found here was higher than the average % EWL reported by the latter review (61.56%, n=4,204) for the RYGB procedure [40]. This might be due to their inclusion of both short-term (< 2 years) and long-term (> 2 years)

outcomes, whereas our study reports results covering a maximum of 12 months. Looking at similar short term follow-up studies, our results fell within the wide range observed. Thus, percentage EWLs between 64.3% (n=111) [41] and 86% (n=75) [42] were reported after laparoscopic sleeve gastrectomy.

Change in mean HbA1c in our study was similar to those reported in previous studies [43] while the rate of diabetes remission after surgery in the present study was significantly lower than those reported in published reviews [3,13,44] and by the UK National Bariatric Surgery Registry (NBSR) data, which reported 80% of patients to be in remission 3 years post-surgery [45]. A retrospective cohort study by Arterburn et al. [46] found partial diabetes remission rates of 47, 73 and 77% at 1, 3 and 5 years after gastric bypass surgery. The reasons for the differences in observed remission rates are not clear, although patients in our study had a slightly longer history of diabetes, which Arterburn et al. found to reduce likelihood of remission. The proportion of patients in remission declined over time following surgery and there was biochemical evidence that individual patients showed relapse of diabetes after a period of remission. A recent paper using UK Clinical Practice Research Datalink (CPRD)

data found overall 28% diabetes remission, based on 'remission' recorded by family physicians [39].

*Study limitations.* This study was a non-randomized, cohort study; to prove the effectiveness of the surgical approach in weight-loss for patients with T2DM, the case-control study design would have been the best. Apart from that, the study population was relatively small. This might result in inadequate power to detect a slight difference in clinical outcomes in time. Therefore, it will be more informative if a larger sample size is studied. In addition, there are some confounding risk factors that were not evaluated related to the diabetes remission because the lack of data: lipid profile, dietary changes. These can constitute limitations for the present study.

## Conclusion

Laparoscopic sleeve gastrectomy is a low risk procedure that can significantly reduce the BMI, with near 70% EWL and near 21% T2DM remission rate in 1 year.

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**Duality of interest** – no conflicts of interest.

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