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Initial weight loss after restrictive bariatric procedures may predict mid-term weight maintenance: the results from 12-month pilot trial

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The results of this study have been presented at Asian Pacific Digestive Week 2013, Shangai, and were published in an abstract form in the Journal of Gastroenterology and Hepatology, vol.28, 2013, suppl. 3.

Abstract

Background: Bariatric procedures are effective options for weight loss in the morbidly obese. However, some patients fail to lose any weight after bariatric surgery and mid-term weight maintenance is variable. The aim of this study was to investigate whether initial weight loss could predict mid-term weight maintenance.

Methods: We enrolled 80 patients; 44 patients were treated with the Bioenterics Intragastric Ballon (BIB), 21 with laparoscopic adjustable gastric lap-banding (LAGB) and 15 with laparoscopic sleeve gastrectomy (LSG). Percentage of body weight loss (WL) and percentage of excess weight loss (EWL) were calculated at baseline and after 1,3,6 and 12 months. Successful weight loss was defined as EWL>20% for patients treated with BIB and >50% for patients treated with LAGB and SG.

Results: Success in 6th and 12th month was achieved in 80% and 58% of patients in BIB group; 33% and 40% in LAGB group and 60% and 73% in LSG group. In the BIB group, WL in the 1st month correlated positively with WL at the 6th and 12th month, and an initial WL>6.5% best predicted success (sensitivity 50%, specificity 80%). A similar association was observed in the LAGB group at the 6th and 12th month and an initial WL>9,4 best predicted success (sensitivity 90,0%, specificity 81,2%). In patients treated with LSG, WL in the 3rd month correlated positively with EWL at the 6th and 12th month, with a cut-off value of 17% (sensitivity 66.7%, specificity 100%).

Conclusions: WL in the 1st month in patients treated with BIB and LAGB and WL in the 3rd month in patients treated with LSG could be used as a prognostic factor to predict mid-term weight maintenance.

Introduction

With the obesity epidemic on the rise, bariatric procedures are increasingly being performed worldwide. Bariatric surgery is an overall effective method in obesity treatment, with a mean percentage of excess weight loss (EWL) after two years of 47,5% for laparoscopic gastric banding (LAGB) and 68.2% for laparoscopic sleeve gastrectomy (LSG) [1]. The Bioenterics intragastric balloon (BIB) is less effective with EWL ranging from 27,0 to 48,3 % after six months of treatment [2,3]. In addition, only a quarter of patients treated with BIB achieve long-term weight maintenance [4]. Despite the overall success of bariatric surgery, approximately 15-20 % of patients fail to lose any weight after the procedure [5]. To our knowledge, no study to this date has managed to explain the exact cause for these differences in outcome. Few studies have aimed to detect prognostic factors that could influence the outcome of bariatric surgery. Established predictors of weight loss after bariatric surgery include age, preoperative weight loss, initial body mass index (BMI), depression score, eating behavior and level of physical activity after surgery [6-14]. Only one study analyzed the influence of initial weight loss on long-term weight maintenance in patients treated with BIB. The authors concluded that a 5% weight loss after the first month predicted long-term outcome [15]. These findings are of great interest because 50 -75% of patients fail to maintain weight loss after BIB removal [16] and it is crucial to detect those patients early in order to initiate other treatment modalities. To our knowledge, not one study has analyzed the effect of initial weight loss after bariatric surgery on later weight loss maintenance. Therefore, our aim was to investigate whether initial weight loss in the first three months following treatment with BIB, LAGB and LSG could predict weight loss after one year of treatment.

Patients and methods

We have conducted a prospective non-randomized study in a tertiary-care referral hospital in Croatia. Eighty patients were enrolled; 44 patients (37 female and 7 male, age range 20-60) were treated with the BIB, 21 (5 male and 16 female, age range 36-61) with LAGB and 15 patients (4 male and 11 female, age range 25-60) were treated with LSG. Decision on the treatment modality was made during multidisciplinary rounds after detailed endocrinological, gastroenterological, psychological evaluation. The patient's preference was also taken into consideration. The protocol was approved by the institutional review board in our university hospital center and all patients gave informed consent.

The BIB by INAMED Corporation Santa Barbara, CA, USA was used in our study. It was positioned under endoscopic control and filled with 600 ml saline and methylene blue. It was removed after 6 months.

A single experienced surgeon performed the surgeries (M.BB.). LAGB was performed using a Swedish Adjustable Gastric Band, Ethicom EndoSurgery, Cincinnati, CH, USA. The surgeon made the choice regarding the size of the gastric band system used. The standardized pars flaccida technique was used [17]. The band reservoir was gradually filled with 6.5 ml of normal saline. The band reservoir was additionally filled with 2 ml of normal saline in the 4^{th} and 8^{th} week after the procedure. If the patient did not loose more than 0.5 kg per week, the band reservoir was filled with an additional 2–2.5 ml in the 12^{th} week.

For the LSG procedure, the greater curvature of the stomach was dissected from the antrum to the level of the left crus of the diaphragm. A 36 Fr calibration probe was inserted into the stomach and placed next to the lesser curvature. Longitudinal gastric resection was then peformed

parallel to this probe using a 60 mm cartridge stapler (green or black). The resection line extended from the antrum (5 cm proximal to pylorus) to the angle of Hiss. Caution was undertaken in order to avoid placing the resection line too close to the esophagus.

Patients were followed over a one-year period. They were encouraged to change their eating habits, participate in regular physical activity and to comply with their follow-up visits. Follow-up visits were scheduled at the end of the 1^{st}, 3^{rd}, 6^{th} and 12^{th} month. Pre- and post-operative workup included physical examination, anthropometric measurements, detailed laboratory and endocrine evaluation, transabdominal ultrasonography and psychological evaluation. The main outcome measures were percentage weight loss (WL) and EWL. EWL was calculated as weight loss divided by excess weight at baseline, with the quotient multiplied by 100: EWL = (body mass at baseline − body mass at follow-up) / (body mass at baseline − ideal body mass) × 100, where the ideal body mass was calculated using a BMI of 25 kg/m2. The BMI was calculated using kg/height in m^2.

Mid-term weight loss was calculated after the 6th and 12th month. Successful mid-term weight loss was defined as EWL >20% for patients treated with BIB and EWL >50% for patients treated with LAGB and SG.

Statistical analyses

Patient characteristics were assessed using descriptive statistics presented as a median with interquartile range values. Independent variables were compared using the Mann-Whitney test and dependent variables (treatment outcomes) were compared using the Wilcoxon's test. Linear regression was used to evaluate the association between initial WL and EWL after 6 and 12

months (data was expressed with R^2 and P value). Receiver operating characteristic (ROC) analysis was performed for significant associations in order to establish cut-off values of initial WL. Only anthropometric characteristics were compared between patients treated with different procedures. No other statistical analysis was performed between different treatment groups. P values <0.05 were considered significant. The statistical analysis was done using Medcalc Version 12.7.5.

Results

The baseline BMI was 42,1 kg/m^2 (32,6-60,8 kg/m2) in patients treated with BIB, 41,8 kg/m^2 (36,2-50,0) in patients treated with LAGB and 46,8 kg/m^2 (40,8-58,8) in patients treated with LSG (p<0,001). Seven patients in the BIB group, 6 patients in the LAGB group and 1 patient in the LSG group were lost to follow-up on the 12th month. Data was gathered from all patients on the 6th month follow-up visit. BMI and EWL decreased significantly in all groups after the 6 and 12 month. As expected, a more pronounced decrease was observed in the LAGB and the LSG group (Table 1.)

In the BIB group, success was achieved in 80% and 58% of patients at the 6th and 12th month, respectively. However, 6/44 patients did not respond to the treatment and had a WL of less than 6% at the 6th month. After BIB removal, 56% (21/37) of patients gained weight. In the LAGB group, 33% and 40% of patients achieved success at the 6th and 12th month, respectively. In the LSG group, 60% and 73% of patients achieved success at the 6th and 12th month, respectively. In the LAGB group, moderate WL was observed in 5/15 (<15%) patients. Moderate weight loss

was observed in one patient treated with LSG (<35%). Not one patient in the LSG and LAGB group gained weight during the 6^{th}-12^{th} month period.

Linear regression analysis revealed that WL after the first month of treatment with BIB correlated positively with EWL at the 6^{th} (R^2=0,184, P=0,004) and 12^{th} month (R^2=0,2024, P=0,009) . The same association was observed in the LAGB group at the 6^{th} (R^2=0,4470, P=0,001) and 12^{th} month (R^2=0,3006, P=0,0343). In patients treated with LSG there was no association between WL in the 1^{st} month and EWL at the 6^{th} and 12^{th} month. However, WL in 3^{rd} month correlated positively with EWL at the 6^{th} (R^2=0,357, P=0,019) and 12^{th} month (R^2=0,294, P=0,037).

In order to establish cut-off values for initial WL, we performed ROC analysis. We found that an initial WL of 6,5% or higher best predicted success in the BIB group (sensitivity 50%, specificity 80%) (Figure 1). Successful weight loss at the 6^{th} month was achieved in all patients with an initial WL > 6,8% (specificity 100%, 95% CI 63,1 – 100,0). Successful weight loss at the 12^{th} month was achieved in all patients with an initial WL > 7,3% (specificity 100%, 95% CI 75,3 – 100,0). On the other hand, neither one patient with an initial WL < 3,1% (sensitivity 100%, 95% CI 89,4 – 100,0) met success criteria at the 6^{th} month. Similarly, not one patients with an initial WL < 3,4% (sensitivity 100%, 95% CI 83,2 – 100,0) met success criteria at the 12^{th} month. Initial WL > 9,4% in the LAGB group best predicted successful weight loss (sensitivity 90,0%, specificity 81,2%) (Figure 2). All patients with an initial WL > 13,1% (specificity 100%, 95% CI 76,8 – 100,0) and > 12,5% (specificity 100%, 95% CI 66,4 – 100,0) reached success criteria at the 6^{th} and 12^{th} month, respectively. No patients reached success criteria with an initial WL < 7.8% (sensitivity 100%, 95% CI 59,0 – 100,0) and < 7,5% (sensitivity 100%, 95% CI 54,1 – 100,0) at the 6^{th} and 12^{th} month, respectively. In the LSG group, the 3^{rd} month WL cut-off value

of 17,0% best predicted weight loss (sensitivity 66,7%, specificity 100%) (Figure 3). All patients with initial WL > 18,2% (specificity 100%, 95% CI 59,9 – 100,0) reached success criteria at the 6th and 12th month. No patients reached success criteria with an initial WL < 15,4% (sensitivity 100%, 95% CI 63,1 – 100,0) and < 15,6% (sensitivity 100%, 95% CI 54,1 – 100,0) at the 6th and 12th month, respectively.

Discussion

Our study demonstrated that initial weight loss after restrictive bariatric procedures could predict weight loss maintenance up to one year after the procedure. In patients treated with BIB and LAGB, WL in the first month proved to be a good predictor of mid-term weight maintenance. On the other hand, WL in the third month best correlated with mid-term weight maintenance in patients treated with LSG. In comparison with the meta-analysis by Buchwald H et al, our study was inferior in terms of EWL [1]. This could be explained from the socioeconomic standpoint. Our study was publicly funded and it is know that publicly funded treatment is adversely associated with long-term weight maintenance [19]. This difference cannot be explained by the operator's skill because as proposed by Prevot F et al., an experienced surgeon who performs more than 50 LSG and LAGB procedures per year performed the operations [18]. Despite the overall success of bariatric surgery, approximately 15-20 % of patients fail to lose any weight after LSG and LAGB [5]. Furthermore, 50-75% of patients treated with BIB gain weight once the BIB is removed [16]. The exact cause of these trends is still a matter of debate. Some authors emphasize the importance of eating habits and behavior. Psychological aspects also play a role and patients who fail to loose weight after bariatric surgery are also more likely to crave sweets

and have disordered eating behaviors such as bulimia. [20,21]. Additionally, preoperative binge eating is also associated with poor results after gastric bypass [8]. However, since the exact mechanism of failure is still unknown, several studies aimed to detect additional factors that could predict long-term outcome. Important behavioral and prognostic factors include a will to change eating habits and increase physical activity, depression score and cognitive function [6, 9,13]. Age and BMI correlate negatively with weight loss [6,7] and preoperative weight loss achieved with other treatment modalities correlates positively [11,12]. The results of our study indicate that weight loss in the 1st month after BIB placement and LAGB can be used as a predictor for mid-term and possibly long-term weight loss. Unexpectedly, only weight loss in the 3rd month has emerged as prognostic factor in patients treated with LSG. This could possibly be explained by the fact that LSG is a more radical procedure than LAGB and BIB. Therefore, all patients lose weight rapidly in the 1st month and the weight loss pattern emerges after the third month. These findings can help improve the care of patients undergoing bariatric procedures. It can help identify which patients are at high or low risk for treatment failure. Additional medication or psychotherapy could be initiated in "high risk" patients immediately after the procedure in order to avoid bariatric procedures in future [22].

Our study has some limitations. Despite the prospective design, we analyzed a relatively small number of patients with a moderate drop-out rate, particularly in the LAGB group. Moreover, only patients treated with restrictive bariatric procedures were analyzed.

In conclusion, a WL>6,5% in the 1st month in patients treated with BIB and a WL>9,4% in the 1st month in patients treated with LAGB could be used as a good prognostic factor for mid-term and possibly long-term weight loss. In patients treated with LSG, a WL of >17% in the 3rd month could also be used as a good prognostic factor for mid-term and possibly long-term weight loss.

Further studies with a longer follow-up period should be carried out. Additionally, the role of initial WL in predicting long-term weight maintenance should be analyzed in patients treated with malabsorptive procedures as well.

Conflict of interest: M.N., I.K., L.K., G.M. N.LJ., B.PN., I.B., M.BB. and M.V. have no conflicts of interest or financial ties to disclose.

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Table 1. Anthropometric parameters and weight loss in patients treated with intragastric balloon (BIB), laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG).

	BIB (n = 44)	LAGB (n = 21)	LSG (n = 15)	P value
Age (years)	35 (20-59)	36 (21-61)	45 (25-60)	0,054
Weight (kg)	114 (90-197)	120 (109-165)	135 (112-180)	**0,003**
Body mass index (kg/m^2)	40,3 (32,6-60,8)	41,8 (36,2-50,0)	46,8 (40,8-58,8)	**<0,001**
Waist circumference (cm)	117 (96-180)	120 (103-147)	132 (114-165)	**0,007**
Hip circumference (cm)	129,5 (107-166)	129 (120-153)	142 (114-165)	**0,046**
Excess weight (kg)	42,9 (21,6-116)	50,2 (35,3-77,6)	67,6 (47,2- 103,4)	**<0,001**
Gender				
Male No (%)	8 (18,2)	5 (23,8)	4 (26,7)	0,744
Female No (%)	36 (81,8)	16 (76,2)	11 (73,3)	
Weight loss 1st month (%)	5,71 (4,39-7,23)	9,17 (7,64-12,20)	10,70 (8,83-12,6)	**<0,001**
Weight loss 3rd month (%)	9,63 (8,16-11,5)	14,3 (10,9-18,6)	16,9 (15,4-17,9)	**<0,001**
Weight loss 6th month (%)	11,7 (8,26-15,0)	18,3 (14,2-22,2)	23,3 (19,8-26,0)	**<0,001**
P value (initial vs. 6th)	**<0,001**	**<0,001**	**<0,001**	
BMI decrease 1st (kg/m^2)	2,51 (1,86-3,03)	4,10 (3,04-5,02)	4,84 (4,21-5,75)	**<0,001**
BMI decrease 3rd (kg/m^2)	3,90 (3,21-5,00)	6,55 (4,41-7,42)	7,97 (7,17-8,59)	**<0,001**
BMI decrease 6th (kg/m^2)	4,76 (3,03-5,82)	7,9 (5,65-9,08)	10,9 (9,25-13,18)	**<0,001**
P value (initial vs. 6th)	**<0,001**	**<0,001**	**<0,001**	
EWL 6th month (%)	32,0 (21,7-41,3)	43,1 (33,9-51,5)	50,7 (43,8-55,1)	**<0,001**
Weight loss 12th month (%)	9,26 (4,3-17,4)	20,0 (14,3-25,6)	26,3 (22,6-34,7)	**0,002**
P value (initial vs. 12th)	**<0,001**	**<0,001**	**<0,001**	
BMI decrease 12th (kg/m^2)	3,54 (1,63-7,32)	9,30 (6,08-10,80)	11,80 (9,98-17,55)	**<0,001**
P value (initial vs. 12th)	**<0,001**	**<0,001**	**<0,001**	
EWL 12th month (%)	27,3 (10,9-43,5)	44,6 (38,9-61,1)	58,6 (50,7-68,6)	**0,002**

Figure 1. ROC curve and excess weight loss in patients with first month weight loss (WL1) < 6,5% and >6,5% in 6th and 12th month of treatment with intragastric balloon.

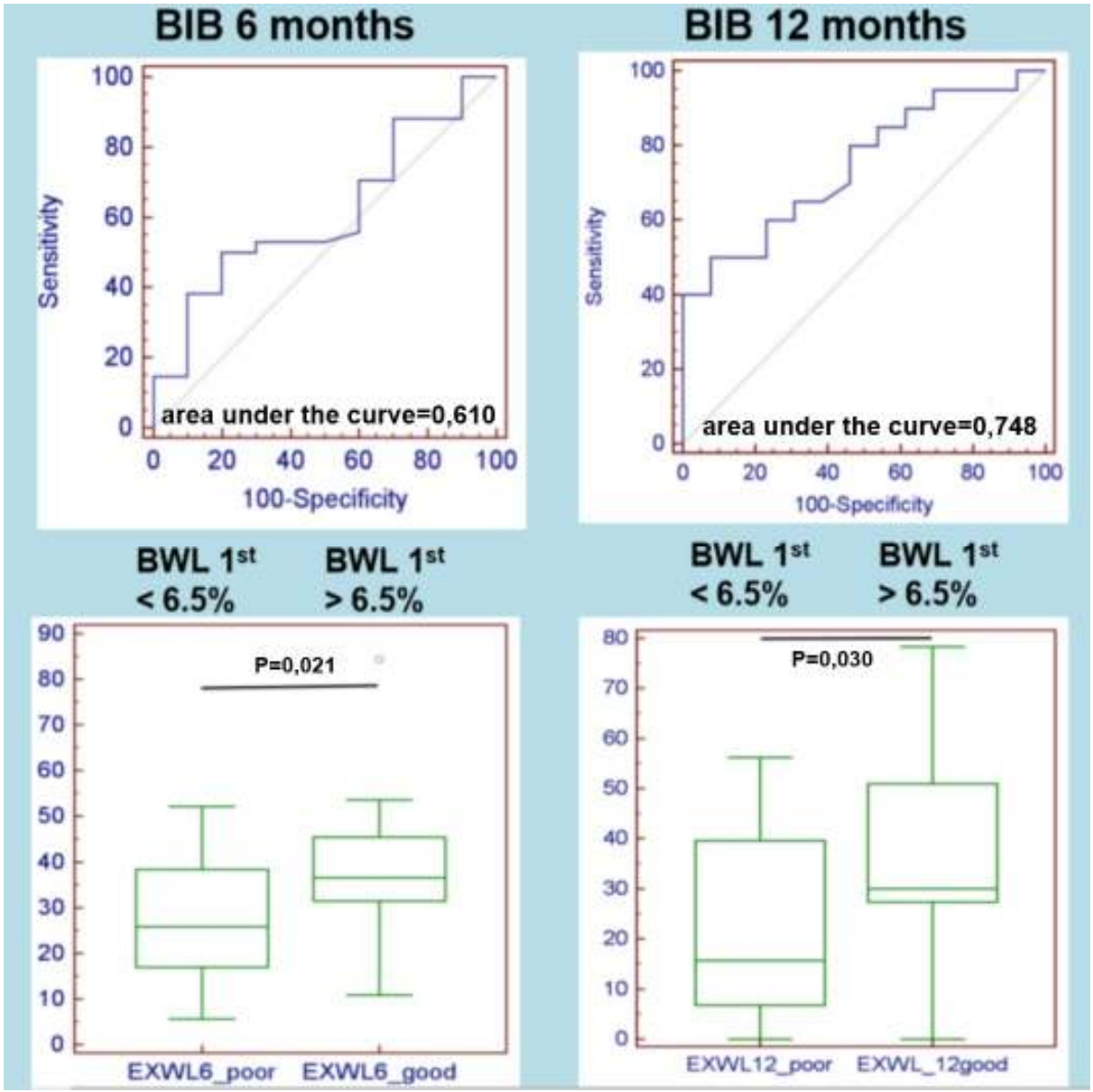

Figure 2. ROC curve and excess weight loss in patients with first month weight loss (WL1) < 9,4% and >9,4% in 6th and 12th month after laparoscopic adjustable gastric banding.

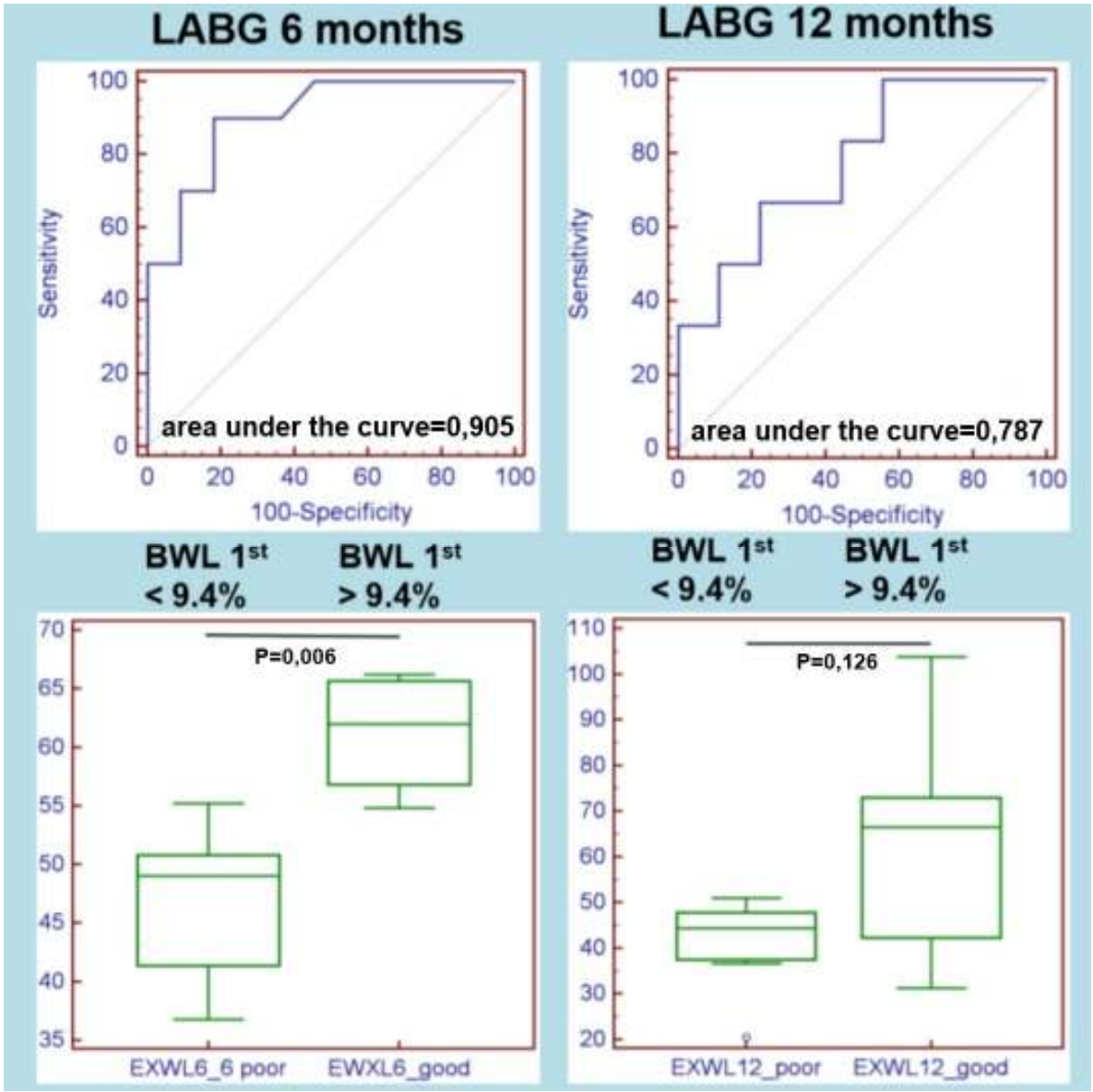

Figure 3. ROC curve and excess weight loss in patients with third month weight loss (WL3) < 17% and > 17% in 6th and 12th month after laparoscopic sleeve gastrectomy.