What is The Effect of Sleeve Gastrectomy in Patients with a BMI ≥ 50 kg/m2?

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Abstract

Background: To investigate the effect of Sleeve Gastrectomy (SG) in patient with a Body Mass Index (BMI)≥50 kg/m² groups on weight loss and comorbidities as the first and alone option.

Methods: The prospectively maintained data obtained from patients with a BMI ≥ 50 who underwent SG between February, 2016 - February, 2020 were evaluated.

Results: 138 patient with a BMI≥50 kg/m² underwent surgery. Average BMI: 56.36±7.661, age 37.41±12.33. Forty eight patients underwent cholecystectomy and/or hiatal hernia repair (HHR), as well. The percentage of excess weight loss (%EWL) values of patients in months 3, 6, 12 and 24 were 36.70%, 54.34%, 67.58%, 72.45%, 74.14% and the percentage of total weight loss (TWL%) values were 20.17%, 29.59%, 36.93%, 39.62%, 40.65%, respectively. The mean BMI values in month 0 and in the 3rd, 6th, 12th, 18th, 24th months were 56.36, 45.10, 39.76, 35.48, 33.96 and 33.42 respectively. The values measured in the month 0 and in the 3rd, 6th, 12th, 18th, 24th months were significantly different for EWL%, TWL% and BMI variables ($p<0.001$), but EWL% ($p = 0.527$), TWL% ($p = 0.396$) and BMI ($p=0.657$) were not found significantly different between the 18th and 24th months. When EWL% was accepted as ≥50, the success rate was found to be 93.55% (n=93) and 92%(n=50) in months 12 and 24, respectively.

Conclusion: SG appears to be an effective and safe treatment method as the first option for weight loss and for treatment of concomitant disorders in patient with a BMI ≥ 50 kg/m² groups. Further long-term studies are needed to confirm these results.

Backgraund

Obesity is a major health problem, which underlies may diseases such as diabetes mellitus (DM), hypertension (HT), dyslipidemia, cardiovascular diseases and respiratory system disorders(1). Bariatric surgery is the most effective treatment method in treating obesity in comparison with conventional types of medical treatment (2, 3). It is difficult to perform bariatric surgical procedures in the super obese (SO, BMI ≥ 50 kg/m²) and super-super obese (SSO, BMI ≥ 60 kg/m²) patient groups due to massive hepatomegaly, limited intraabdominal operating space, thick abdominal wall and increased intraabdominal fat tissue(4). In this patient groups, surgery is associated with high mortality, morbidity and increased surgical risk(5, 6). The fact that SG is a procedure which can be applied more easily as a technique in comparison with the Roux and Y Gastric Bypass (RYGB), has a short period of hospital stay and low morbidity makes it more preferable. On the other hand, the fact that not enough weight loss is obtained via sleeve gastrectomy as the first choice in patient with a BMI ≥ 50 kg/m² group may require secondary bariatric surgeries(5, 6, 7). Nevertheless, current studies have shown that sleeve gastrectomy ensures effective weight loss in patient with a BMI ≥ 50 kg/m² group and it eliminates the need for secondary malabsorptive procedures(8, 9, 10). The ideal bariatric surgical type in patient with a BMI ≥ 50 kg/m² group is still subject to controversy. In this study, we aimed to investigate the effect of SG in patient with a BMI ≥ 50 kg/m² group on weight loss and the accompanying comorbidities.

Methods

The prospectively maintained data obtained from patients with a BMI ≥ 50, who underwent SG between February, 2016 - February, 2020, were evaluated. All of the patients were operated on by the same bariatric surgeon. The patients were assessed by a multidisciplinary team consisting of a bariatric surgeon, a dietician, an endocrinologist, a cardiologist, an anesthesiologist and a psychiatrist before surgery. All patients received upper gastrointestinal system endoscopy and abdominal ultrasonography before surgery. The patients were assessed with respect to demographic data (age, sex), anthropometric measurements (weight, height, BMI), accompanying comorbidities, biochemical parameters (lipid profile,

HbA1c, fasting blood sugar), the weight loss in months 3, 6, 12, 18 and 24, the percentages of excess weight they lost and their complications.

BMI was defined as weight (kg)/height (m)^2, ideal body weight as that equivalent to a BMI of 25 kg/m^2 and excess weight (EW) as the difference between initial weight and ideal weight.

The percentage of excess weight loss (%EWL) = [(initial weight − current weight) / (initial weight − ideal weight)] × 100. The percentage of total weight loss (%TWL) = [(initial weight – current weight/initial weight] × 100 (11). The success of bariatric surgery was assessed according to the modified Reinhold criteria (Table 1) and Brion criteria(12,13,14). As per the Brion criteria, success in patients with BMI≥ 50 was defined as post-operative BMI 40.

Diabetes was diagnosed according to the criteria of the American Diabetes Association(15). DM was defined as glycated hemoglobin HbA1c ≥6.5 or fasting blood sugar ≥126 mg/dl. Patients without medication whose HbA1c level dropped 6% were defined as resolved from diabetes and those whose HbA1c level decreased from their preoperative HbA1c level were defined as improved. Hypertension was defined as blood pressure >140/90mm Hg. Remission was defined if the patient had normal blood pressure (≤120/80) without any antihypertensive medications, and improvement was considered if the number of antihypertensive medications or the dose of the antihypertensive medications was lowered. As for the total cholesterol levels, the levels 200 were considered Normal, the range of 200-239 Marginally High and ≥240 High. For the LDL levels, the levels 100 were considered normal, the range of 130-159 Marginally High and ≥160 High. Patients who had gastroesophageal reflux disease (GERD) symptoms or complaints completed a severity symptom questionnaire. Patients with a severity symptom score above 4 or on regular proton pump inhibitor use, who showed hiatal hernia in their endoscopy, also underwent posterior hiatus repair. Remission was defined as the patient being symptom-free without the use of proton pump inhibitor. An improvement was considered if the patient required a decrease in the dose of proton pump inhibitor or decrease in symptoms(16,17).

Surgical Procedure

All of the patients received low molecular weight heparin prophylaxis the night before surgery, which was also maintained in the post-operative period. All surgeries were performed laparoscopically. The first trocar was introduced using visiport (between umbilicus and xiphoid with 1/3 proximity to the umbilicus); 5 trocars were used in total. The greater curvature of the stomach was de-vascularized; The short gastric vessels and gastrosplenic ligaments were divided using a ligasure® device. The stomach was transected by starting 2-4 cm proximally from the pylorus, until the gastroesophageal junction was reached. A 38 Fr bougie were used. The first stapler used was an endo GIA™ 60 mm black tri-stapler. The consequent staplers used were endo GIA™ 60 mm purple tri-staplers. Suture reinforcement wasn't performed on the stapler line. An intraoperative methylene blue stress leak test was routinely performed. A 10 mm Jackson- Pratt drain was routinely inserted along the suture line in all patients. All of the patients were started on liquid nutrition at the post-operative hour 24.

Statistical Analysis

The current study was planned from the outset to increase validity and reliability. For descriptive statistics, the mean and SD values were used if the variables were continuous, while the median and percentage values were used for discrete variables. The normality of the variables was analyzed using the Kolmogorov–Smirnov test. Statistical comparisons between groups were performed using the "Repeated ANOVA Test" followed by the Post-Hoc Bonferroni Test. Two-sided p values were considered statistically significant at $p \leq 0.05$. All statistical analyses were carried out by using the R software/programming [version 3.6.2 (2019-12-12) – CRAN].

Results

In total, 138 patients were operated on 104 (75.36%) patients were female. All surgeries were performed laparoscopically. The average age was 37.41±12.33, the average BMI 56.36±7.661 and the average EW 82.95±21.15. There were 44(31,88%) patients with BMI≥60. Ninety (65.21%) patients underwent SG, 23 (16.66%) patients underwent SG + cholecystectomy, 21 (15.21%) patients underwent SG+HHR and 4 (2.89%) patients underwent SG + HHR + Cholecystectomy. The baseline characteristics, obesity-related comorbidities, surgery types, and laboratory parameters in this study are shown in Table 2.

Weight Loss

The average BMI, EWL% and TWL% values in months 0, 3, 6, 9, 12, 18, 24 are provided in Table 3. In months 12, 18 and 24, the average EWL% was found to be 67.58%, 72.45% and 74.14%, the average BMI 35.48, 33.96 and 33.41 and the average TWL% was found to be 36.93%, 39.62% and 40.65% (Table 3, Figure 1). The mean values of all mounts were found significantly different for EWL%, TWL% and BMI (p<0.001). According to the Bonferroni multiple comparison test result, all possible binary comparison results for the reference months (0, 3rd, 6th, 12th, 18th, 24th) were significantly different for EWL%, TWL% and BMI variables (p<0.001), but EWL% (p = 0.527), TWL (p = 0.396) and BMI (p=0.657) were not found significantly different between the 18th and 24th months. With the success rate for EWL being considered as ≥50%, it was found to be 93.55 in year 1 and 92% in year 2. With the success rate for BMI being considered as ≤35, it was found to be 59.13 in year 1 and 60% in year 2. With the success rate for BMI being considered as 40, it was found to be 84.94% in year 1 and 88% in year 2(Table 4, Figure 2).

No mortality or major morbidity such as stapler line leaks, gastrointestinal bleeding or intraabdominal bleeding was seen within the first 30 days. One patient developed tetany due to hypocalcemia, which improved with intravenous calcium and vitamin D treatment. One patient had fever and gastroenteritis, which improved with treatment. No deep vein thrombosis or pulmonary embolism were seen.

Resolution of Comorbidities

While complete remission of Type 2 diabetes was seen in 42 (89.36%) patients, it was observed that 5 patients had improved. In diabetic patients, the average pre-operative HbA1c was 7.41±1.885 g/dL while the average post-operative HbA1c was 5.482±0.687 g/dL (p=0,00). Complete remission developed in 13 patients with obstructive sleep apne (OSA) syndrome, they stopped using continious positive airway pressure equipment. Recovery was seen in only 5 of 11 patients with hyperlipidemia, no remissions were seen. Full remission of hypertension was seen in 41 patients and 3 patients had improvement. The reflux symptoms of 25 patients, who had reflux complaints and received hiatal hernia repair, completely disappeared (Table 5).

Discussion

Today, Sleeve Gastrectomy is the most frequently performed restrictive bariatric surgical procedure in the patient group with BMI≥50 since it is technically easier than other bariatric procedures and due to patient preference(18,19). SG was developed as the first stage of a 2-stage bariatric surgical procedure especially for the super obese patient group with BMI≥50(20,21). The consequent studies proved that SG on its own was also an effective bariatric surgical procedure (8,22,23). Some studies performed showed that SG provided more weight loss and caused less development of insulin sensitivity as compared to RYGB(24,25). On the other hand, recent randomized clinical studies showed that SG and RYGB were equally effective in weight loss and treatment of comorbidities(26,27). One of the most important methods used to assess the success of surgery is EWL%. In our study, we identified that the average EWL% was 67.58±13.37 in month 12 and 74.14± 10.03 in month 24. The mean values of all months were found significantly different (p<0.001). According to the Bonferroni multiple comparison test, in all possible binary comparisons (3rd, 6th, 12th, 18th, 24th), EWL% were significantly different (p<0.001), except for the 18th – 24th months. It was seen in the study performed that the process of

weight loss continued until month 24, but there were no statistically significant difference between months 18 and 24. accepting the success rate as EWL%≥50 according to the Modified Reinhold criteria, it was found to be 93.55%, 96.8% and 92% in months 12, 18 and 24, respectively. When assessed according to the Biron criteria (BMI≥40), it was found to be 84.92%, 92.4% and 88% in months 12, 18 and 24.

As far as current studies are concerned, Bhandari et al performed a study with 514 super obese patients. In years 2 and 3 of this study, the EWL% was found to be 74.24% and 62.38% in the SG group and 71.4% and 69.55% in the RYBG group. Again, in the same study, this rate was identified as 87.88% and 85.11% in the Banded SG group (27). Rendo A et al. performed a study on 134 patients who received SG and their EWL% in years 1 and 2 were 61.3%, 62.6%, respectively (28). In a study conducted by Silva R et al. with 213 SO patients, the group that received SG had EWL% of 58.74 and 59.90 in years 1 and 2, respectively. In the RYGB group, these were 67.58 and 72.19, respectively (29). In a study performed by Arapis K et al. which included 210 SSO patients, the EWL% was 48.81 and 54.17 in the SG group in years 1 and 2, respectively. In the RYGB group, these were 53.96 and 60.64, respectively (10). Celio AC et al. conducted a study with 50987 SO patients, EWL% was 49% and %58 in the SG and RYBG group, respectively (30). In a study conducted by Uno K et al. consisting of 48 SO patients, the EWL% was reported as 57.7% and 65.1% in the SG group in years 1 and 2, respectively; in the RYGB group, it was reported as 73.4% and 73.7%, respectively (31). Wang Y et al. conducted a meta-analysis study comprising 12 studies, where they reported that RYGB was found superior in terms of EWL% in the first 12 months while the situation was equalized between SG and RYGB in month 24(32). Similarly, Bhandari et al. performed a study where they reported similar average EWL% values for RYGB and SG in year 3(27). Arapis K et al. also recommended SG as the primary surgical procedure in a study on a group of SSO patients. Once again, in the same study, it was reported that SG and RYGB produced similar results in terms of changes in EWL% and BMI in year 4(10). (Table 6)

More recently, a randomized Swiss Multicenter Bypass or Sleeve Study (SM-BOSS) which compared bariatric surgery patients that received SG and RYBG reported that no significant differences were seen between the SG and RYGB groups. The excessive Body Mass Index loss was found to be similar between LSG and LRYGB at each time point (1 year: 72.3±21.9% vs. 76.6±20.9%, P =0.139; 2 years: 74.7±29.8% vs. 77.7±30%, P = 0.513; 3 years:70.9±23.8% vs. 73.8±23.3%, P =0.316)(26).

The patients that were operated on were observed to have a significant improvement in comorbid diseases, as well. While full remission or improvements were noted in comorbidities such as DM, HT, Hyperlipidemia, OSA and GERD, full remission was not observed in patients with hyperlipidemia. It was observed that only 45.45% of patients with hyperlipidemia had improvement. There are studies which state that better results are obtained with RYGB in the improvement of comorbid diseases, especially Type 2 DM(32). A recent meta-analysis comparing SG and RYGB, which included 18455 patients and 62 studies to assess obesity-related comorbidities, found that RYGB had a statistically significant superiority in the remission of Hyperlipidemia and GERD. However, no statistically significant differences were seen in the DM and OSA remission(33). Singla V et al. conducted a study with 75 SO patients and found that the remission rate for Type 2 DM was 85.7% in the SG group and 77.7% in the RYGB group (p=0.59)(34). Silva et al. found that there were no differences in terms of the remission of diabetes in years 1 and 2 among RYGB, SG and AGB (p=0.91-p=0.13)(29). Different pathophysiological mechanisms other than weight loss also play a role in the correction of comorbidities following LSG. These include mechanisms such as increased gastric emptying and intestinal transit, increased GLP-1 hormone level and decreased ghrelin levels(35,36). Also in our study, Type 2 DM patients demonstrated a remission rate of 89.36% (n=42). The average HbA1c level of patients in the pre-operative period was 7.41±1.885 g/dL while it was identified as 5.482±0.687 g/dL in the post-operative period. As for the OSA patients, remission was observed in all of them. GERD following SG is an important problem. All patients that had reflux symptom and hiatal failure before surgery also received concomitant hiatal hernia repair. In all of these patients, the reflux symptoms disappeared in the post-operative period.

Especially in the SO patient group, SG can be performed more easily and safely than other surgical procedures given the large liver volume, limited intraabdominal operating space, increased abdominal wall thickness and increased abdominal fat tissue(37). Since the accompanying comorbidities are higher in number in super obese patients, their complications and mortality rates are also higher(28,30,38,39). As the risk of mortal progress is high when super obese patients develop complications, surgeries need to be performed with minimal complications especially in this patient group. Intervening on complications that develop in such patients is more difficult as compared to other patients. This is another factor that affects mortality. As per some studies performed, the rate of complications such as stapler line leaks, stricture, intraabdominal hemorrhage, abscess, PE, DVT, pneumonia, myocardial infarction and wound infection is in the range of 3.8-15.7%. The duration of surgery and hospital stay are also relatively long(5,28,30,40,41). According to the studies conducted, the mortality rate was in the range of 0.008-0.18% in the non-super obese patient group while the super obese patient group had mortality rates ranging up to 3.7%(28,30,39,40,42,43,44). No mortality and major complications were observed in our study. The concomitantly performed surgeries such as cholecystectomy and hiatal hernia repair did not have an effect on mortality and morbidity. One of the major complications that may be observed during SG surgery is stapler line leaks. The possibility of having a leak as a result of a technical error was checked via methylene blue leak test conducted during surgeries. It was ensured during surgery that the stapler line was straight and there were no twists in the stomach. The patients were recommended to avoid drinking liquids in one ago and to drink them slowly, in small sips so to prevent a leak secondary to increased intraluminal pressure in the post-operative period, as well.

Conclusion

Our study has shown that SG is a rather effective method on its own for weight loss and resolution of comorbidities in patient with a BMI ≥ 50 kg/m² groups. It can be performed at experienced centers with minimal morbidity and no mortality. Considering the large liver volume, limited intraabdominal operating space and increased abdominal wall thickness in super obese patients, SG should be considered as the first option. Long-term prospective randomized studies are needed in order to confirm these findings.

Abbreviations

SG: Sleeve Gastrectomy; BMI: Body Mass Index; HHR: Hiatal Hernia Repair; EWL%: The percentage of excess weight loss; TWL%: The percentage of total weight loss; DM: Diabetes mellitus; HT: Hypertension; SO: Super obese (BMI≥50 kg/m²);

SSO: Super-super obese (BMI≥60 kg/m²); RYGB: Roux and Y Gastric Bypass; EW: Excess weight; GERD: Gastroesophageal reflux disease; OSA: Obstructive sleep apne.

Declarations

Ethics approval and consent to participate

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional review board of ethics committee and national research committee with the 1964 Helsinki declaration and its later amendments. The institutional review board of our institution approved the study (Biruni University Ethics committee, number 2021/47-46) The informed consent requirement was waived.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Study conception: AO; Study design: AO; Data acquisition: AO, YC ; Quality control of data and algorithms: AO, YC ; Data analysis and interpretation: AO, YC; Statistical analysis: YC; Manuscript preparation: AO, YC; Manuscript editing: AO; Manuscript review: AO; Final approval of the article: all authors. All authors read and approved the final manuscript.

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Tables

Table 1: Modified Reinhold Classification

Result	BMI (kg/m²)	Excessive Weight Loss %
Excellent	≥30	≥75
Good	30-35	50-75
Failure	≤35	≤50

Table 2:Patient Characteristic

-	n(%)	
Total Number of Patients	138 (100)	
Female	104 (75.36)	
Age	37.41±12.33	
Height	162.7± 8.783	
Weight	149.3±24.16	
BMI	56.36±7.661	
Excess Weight	82.95±21.15	
Surgery Type		
-Sleeve Gastrectomy	90 (65.21)	
-SG + Cholecystectomy	23 (16.66)	
-SG + HHR	21 (15.21)	
-SG + HHR + Cholecystectomy	4 (2.89)	
Hospital Stay (median)	3 (3-6)	
Hypertension	44 (31.88)	
Type 2 DM	47 (34.05)	
Cardiac Disease	7 (5.07)	
OSA	13 (9.42)	
Respiratory Disease	25 (18.11)	
GERD	25 (18.11)	
Psychological Disorders	8 (5.79)	
	Before Surgery	After Surgery
HbA1c	6.10±1.498	5.20±0.505
-HbA1c (Diabetic Patients)	7.41±1.885	5.482±0.687
Glucose	114.4±36.27	88.80±11.08
Total Cholesterol	190.9±41.68	191.2±41.98
LDL	123.2±30.66	122.5±36.22

Table 3. Distribution of the mean BMI (kg/m^2), EWL% and TWL% for patients in different months and the results of "Repeated ANOVA Test" followed by Post-Hoc Bonferroni Test

Time (month)	n	BMI	±SD	P	EWL%	±SD	p	TWL%	±SD	p
0	138	56.36	7.660							
3rd	125	45.10	7.128		36.70	8.294	<0.001*	20.17	4.049	
6th	116	39.76	6.165	<0.001*	54.34	10.62		29.59	5.706	<0.001*
12th	93	35.48	6.285		67.58	13.37		36.93	6.657	
18th	79	33.96	5.305		72.45	13.42		39.62	7.130	
24th	50	33.41	6.198		74.14	10.03		40.65	8.696	

Table 4. Postoperative success rate according to the excess weight loss percentage (EWL%), Body Mass Index (BMI) and Reinhold criteria during follow-up

	EWL%				**BMI**				
Follow-up	**EWL< 50[a] n (%)**	**EWL50–74[b] n (%)**	**EWL≥75[c] n (%)**	**Good and Excellent[b,c] %**	**<30[a] n (%)**	**30-35[b] n (%)**	**>35[c] n (%)**	**Good and Excellent[a,b] %**	**BMI≥40 n (%)**
3rd Month	117/125 (93.60)	8/125 (6.4)	-	6.4	-	1/125 (0.008)	124/125 (0.992)	0.008	20/125 (16)
6th Month	33/116 (28.45)	78/116 (67.24)	5/116 (4.310)	71.55	3/116 (2.586)	20/116 (17.24)	93/116 (80.17)	19.83	80/116 (68.96)
12th Month	6/93 (6.452)	51/93 (54.84)	36/93 (38.71)	93.55	17/93 (18.27)	38/93 (40.86)	38/93 (40.86)	59.13	79/93 (84.94)
18th Month	3/79 (3.797)	38/79 (48.10)	38/79 (48.10)	96.8	25/79 (31.65)	31/79 (39.24)	23/79 (29.11)	70.89	73/79 (92.4)
24th Month	4/50 (8.0)	20/50 (40.0)	26/50 (52.0)	92.0	16/50 (32.00)	14/50 (28.00)	20/50 (40.00)	60.00	44/50 (88)

Table 5. Resolution of Comorbidities

	Patients (n)	Resolved	Improved
Diabetes	47	42 (89.36%)	5
Hypertension	44	41 (93.18%)	3
Hyperlipidemia	11	-	5 (45.45%)
OSA	13	13 (100%)	-
GERD	25	25 (100%)	-

Table 6: Studies of Patients with a BMI ≥ 50 kg/m²

Study Name and Year	Number of Patients	BMI	EWL% YEAR 1	EWL% YEAR 2	Mortality - Major Complications
Silva R	SG (67)	54.73±4.89	58.74±17.78	59.90±18.15	0% -6.6%
(2018)	RYGB (127)	54.32±4.28	67.58±14.26	72.19±14.62	
Rendo A	SG (134)	55.9±6.7	61.3±18	62.6±22.7	3.7% - 15.7%
(2019)					
Uno K	SG (28)	57.1±5.1	57.7±21.4	65.1±23.4	0-10.7%
(2017)	RYGB (20)	55.7±4.2	73.4±16.1	73.7±22	0-20%
Heredia R	SG (77)	64.9±4.2	43.6±13.8	45.8±19.2	0-2.2%
(2015)	RYGB (12)	64.2±2.5	61.4±18.4	68.5±16.8	0-0
Singla W	SG(50)	54.18±4.06	56.2±18.92		0 / %4
(2019)	OAGB(25)	53.76±3.28	74.57±13.24		0 / 0
Celio A C	SG(8868)	57.8	49±15.7		0.2% - 11.1%
(2016)	RYGB(42119)	57.3	58±14.5		0.3% - 11.5%
Arapis K	SG(91)	68.2±7.1	48.81±5	54.17±5	1.09%-16.1%
(2018)	RYGB(119)	65.1±4.3	53.96±5	60.64±5	0.84%-26%

Figures

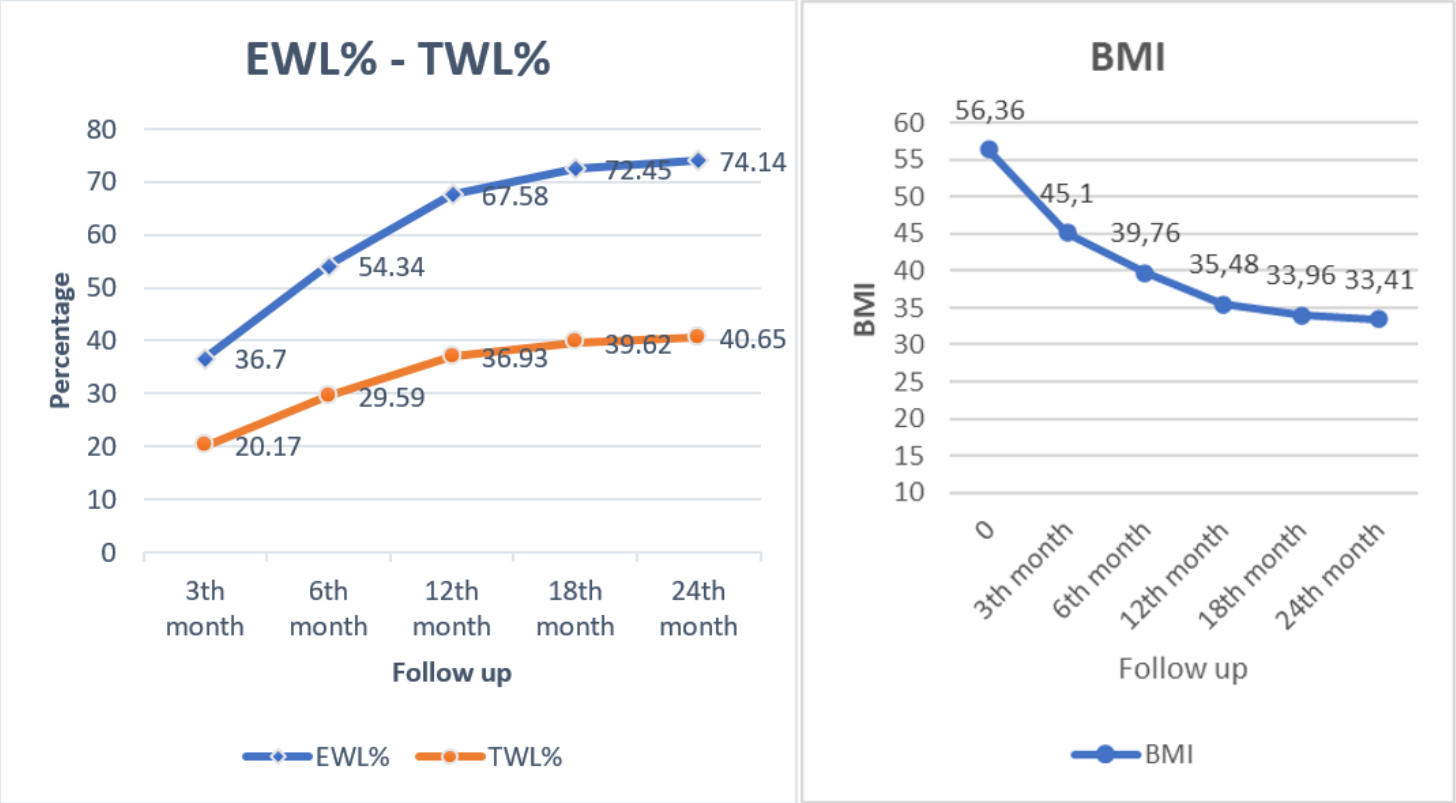

Figure 1

Distribution of the mean BMI (kg/m2), EWL% and TWL% for patients in different months and the results of "Repeated ANOVA Test" followed by Post-Hoc Bonferroni Test. Months (0, 3rd, 6th, 12th, 18th, 24th) were significantly different for EWL%, TWL% and BMI variables ($p<0.001$), but EWL% ($p = 0.527$), TWL ($p = 0.396$) and BMI ($p=0.657$) were not found significantly different between the 18th and 24th months.

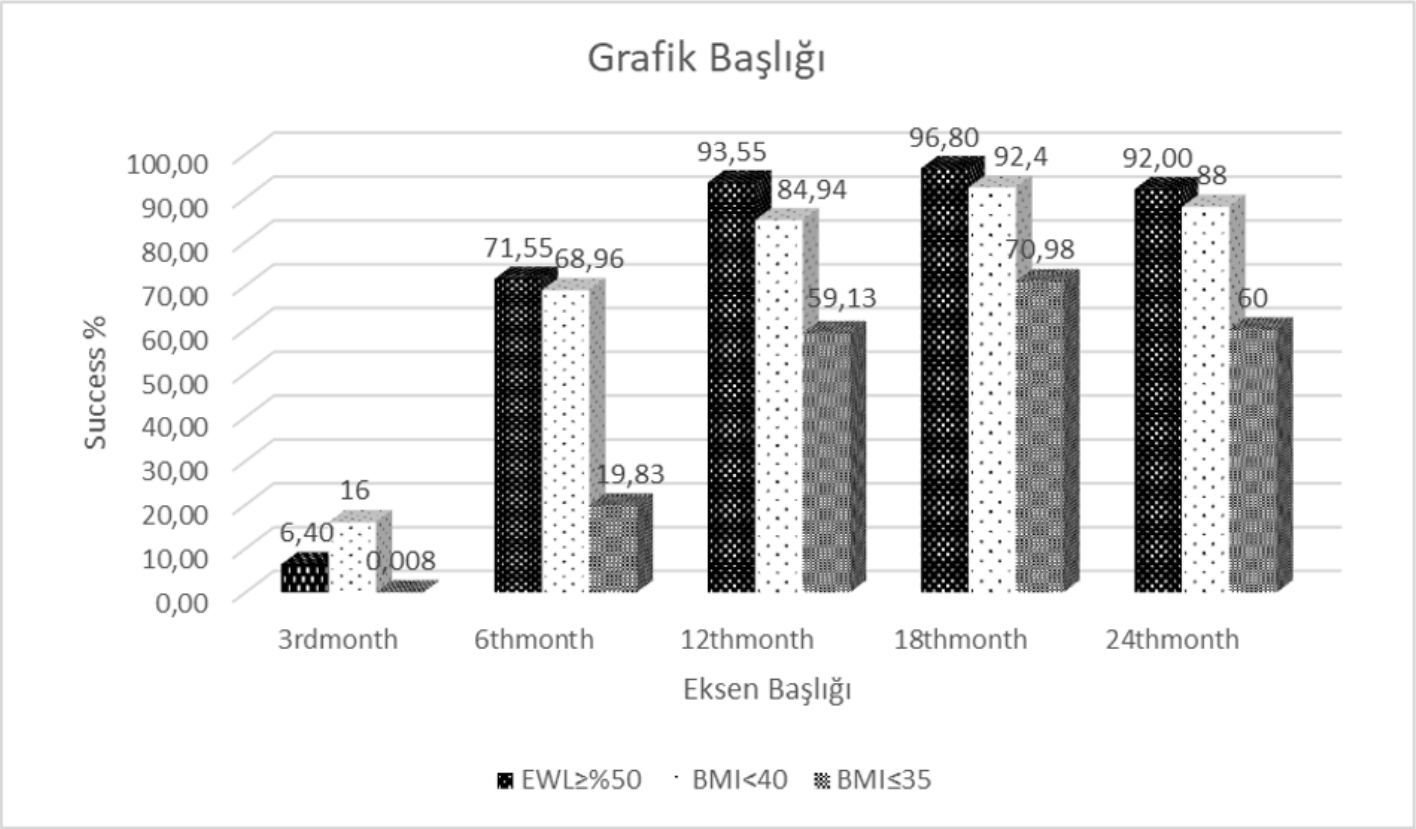

Figure 2

Success rate