

SON 5 YILDA MORBİD OBEZİTE SEBEPLİ SLEEVE GASTREKTOMİ YAPILAN HASTALARIN POST OPERATİF ERKEN DÖNEM SONUÇLARININ DEĞERLENDİRİLMESİ

EVALUATION OF EARLY POSTOPERATIVE OUTCOMES IN PATIENTS WHO UNDERWENT SLEEVE GASTRECTOMY FOR MORBID OBESITY OVER THE PAST FIVE YEARS

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ÖZET

AMAÇ: Obezite, Dünya Sağlık Örgütü (DSÖ) tarafından 'Vücuttaki yağ birikiminin sağlığı bozacak boyuta ulaşması' olarak tanımlanmaktadır. Günümüzde laparoskopik sleeve gastrektomi obezite tedavisinde kullanılan en sık cerrahi yöntemdir ve doğru yönetilmediği zaman beraberinde birçok komplikasyon getirmektedir. Stapler hattından kaçak gelişmesi, kanama ve pulmoner tromboemboli en ciddi erken dönem komplikasyonlar olarak görülmektedir. Biz bu çalışmamızda ameliyat sonrası erken dönemde ortaya çıkan komplikasyon oranlarımızı literatür eşliğinde tartışarak araştırdık.

GEREÇ VE YÖNTEM: Genel Cerrahi Kliniği'nde 1 Ocak 2017 ile 1 Mart 2022 tarihleri arasında laparoskopik sleeve gastrektomi yapılan 335 hasta retrospektif olarak çalışmamıza dahil edilmiştir. Standart laparoskopik sleeve gastrektomi tekniği yapılan tüm hastaların 311 (%92,8)'inde fibrin yapıştırıcı kullanılmıştır. 317 (%94,6) hastaya 5 tane stapler, 18 (%5,4) hastaya 6 tane stapler kullanılmıştır. Postoperatif dönemde 1. aya kadar oluşan komplikasyonlar kayıt altına alınmıştır.

BULGULAR: Araştırmaya yaşları 18 ile 72 arasında değişen, 67'si erkek 268'i kadın hasta olmak üzere 335 hasta dahil edildi. Cerrahi sonrası %2,4 oranında kaçak, %0,6 oranında kanama, %0,6 oranında pulmoner tromboemboli görüldü. Hastalarda kullanılan fibrin yapıştırıcı ve stapler sayısı kaçak açısından istatistiksel olarak anlamlı değildi. Fibrin yapıştırıcı kullanılmayan hastalarda fibrin yapıştırıcı kullanılan hastalara göre istatistiksel olarak anlamlı bir şekilde kanama daha yüksekti ($p=0,018$).

SONUÇ: Cerrahi sonrası kaçak, kanama ve pulmoner tromboemboli komplikasyon oranlarımızın literatür çalışmalarıyla uyumlu olduğu görüldü. Kullandığımız fibrin yapıştırıcının kaçak önleme konusundaki etkinliği tartışılmalı olmakla birlikte kanama üzerine etkisi yüksek görülmüştür. Cerrahi tedavi yapılan hastalarda fibrin yapıştırıcının stapler hattından kanamayı etkili bir şekilde önlemesi açısından kullanılabileceği düşüncesindeyiz.

ANAHTAR KELİMELEER: Fibrin yapıştırıcı, Kaçak, Kanama.

ABSTRACT

OBJECTIVE: According to the World Health Organization (WHO), obesity is defined as 'the accumulation of excess fat in the body to a degree that may impair health.' Currently, laparoscopic sleeve gastrectomy is the most commonly performed surgical procedure for obesity treatment and, if not managed properly, may result in various complications. The most serious early postoperative complications include staple line leakage, bleeding, and pulmonary thromboembolism. This study examines the incidence of early postoperative complications in sleeve gastrectomy patients, with a discussion of relevant literature.

MATERIAL AND METHODS: This retrospective study included 335 patients who underwent laparoscopic sleeve gastrectomy at the General Surgery Clinic between January 1, 2017, and March 1, 2022. Fibrin sealant was applied in 311 patients (92.8%) who underwent the standard laparoscopic sleeve gastrectomy technique. Five staplers were used in 317 patients (94.6%), while six staplers were used in 18 patients (5.4%). Postoperative complications occurring within the first month were recorded.

RESULTS: This study included 335 patients (67 males, 268 females), aged between 18 and 72 years. Postoperatively, the leak rate was 2.4%, while both the bleeding and pulmonary thromboembolism rates were 0.6%. Neither the use of fibrin sealant nor the number of staplers had a statistically significant effect on leak rates. However, bleeding was significantly higher in patients who did not receive fibrin sealant compared to those who did ($p = 0.018$).

CONCLUSIONS: Our rates of post-surgical leaks, bleeding, and pulmonary thromboembolism were found to be consistent with the existing literature. While the effectiveness of fibrin sealant in preventing leaks remains debatable, its impact on bleeding has been observed to be significant. Fibrin sealant appears to be an effective measure in preventing bleeding from the staple line in patients undergoing surgical treatment.

KEYWORDS: Fibrin sealant, Leak, Bleeding.

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INTRODUCTION

Obesity is defined by the World Health Organization (WHO) as "an accumulation of fat in the body to the extent that it may impair health" (1). To diagnose, treat, and monitor obesity, WHO approved the Body Mass Index (BMI) as the criterion for obesity in 1997. Accordingly, obesity classification by BMI is calculated using the formula $\text{Weight (kg)}/\text{Height(m}^2\text{)}$ (2). Based on BMI, individuals are categorized as overweight between 25-29.9 kg/m², class 1 obese (pre-obese) between 30-34.9 kg/m², class 2 obese between 35-39.9 kg/m², class 3 (morbid) obese between 40-49.9 kg/m², class 4 (super) obese between 50-59.9 kg/m², and class 5 super-super obese (SSO) at 60 kg/m² and above (2). Patients suitable for surgery are those with a BMI of 40 kg/m² and above or those with a BMI above 35 kg/m² along with comorbid health conditions. According to the BMI analysis by the Turkish Statistical Institute (TUIK), the rate of obese individuals aged 15 and above was 19.6% in 2016, which increased to 21.1% in 2019. Gender differentiation shows that in 2019, 24.8% of women were obese and 30.4% were pre-obese, whereas 17.3% of men were obese and 39.7% were pre-obese (3).

Laparoscopic Sleeve Gastrectomy (LSG) has become the most frequently used method among all bariatric procedures due to the preservation of the pylorus avoiding dumping syndrome, reduction in ghrelin levels, no risk of internal herniation, short operation time, ease of learning and performing by the surgeon, and being easily revisable to other surgical procedures. According to the American Society for Metabolic and Bariatric Surgery (ASMBS), the usage rate of LSG among all bariatric procedures increased from 17.8% in 2011 to 61.4% in 2018 (4).

The high frequency of use has also increased the significance of associated complications. Leak from the staple line, bleeding, and pulmonary thromboembolism (PTE) are seen as the most serious early postoperative complications (5).

In this study, we investigated the rates of complications occurring in the early postoperative period alongside literature discussions.

MATERIALS AND METHODS

The study included a retrospective analysis of 335 patients aged between 18 and 70 who underwent LSG from January 2017 to March 2022 at the Afyonkarahisar Health Sciences University Faculty of Medicine, General Surgery Clinic. The patients were included in the study by reviewing the hospital information system and patient files. Preoperative tests, comorbid diseases, age, sex, BMI, and demographic characteristics of the patients, as well as complications developed during their stay at our general surgery clinic after LSG and within the first month after discharge when they came for control or to the emergency department, were recorded.

Patients whose files could not be found during the screening of electronic and archive files, or those without demographic data, anesthesia, and ward follow-up forms were not included in the study. Patients routinely underwent preoperative upper GI endoscopy at our clinic. At 24:00 on the pre-operative night, 0.4 IU of low molecular weight heparin (LMWH) (Oksapar 4000 anti-Xa IU/0.4 ml) was administered. On the day of surgery, patients were fitted with anti-embolism stockings.

Under general anesthesia, access was gained through a 12 mm trocar inserted above the umbilicus to establish vision. The patient was then placed in the reverse Trendelenburg position. A Nathanson liver retractor (ANKA LABS, REF NO:108) was used from the subxiphoid for retraction of the left lobe of the liver. A total of two 12 mm ports were placed along both mid-clavicular lines. Subsequently, a 5 mm port was placed supero-laterally to the port on the patient's left side. The intraabdominal pressure was set to an average of 15 mmHg.

Starting approximately 4 cm proximal to the pylorus, the greater curvature of the stomach and the omentum, including the fundus, were separated from the spleen using an energy-based vessel-sealing and cutting device (Covidien Ligasure Atlas 10 mm- 20 cm, REF: LS 1020) up to the angle of His. An anesthesiologist inserted a 34 Fr bougie orally, advancing it up to proximal to the pylorus. Then, 5 or 6 60 mm laparos-

copic linear green cartridge thick tissue staples (Echelon, EthiconEndosurgery or EndoGIA, Covidien green 60 mm, 2.5 mm, USA) were used to cut the stomach from the antrum to the angle of sensation under spark plug guidance without tension. Subsequently, fibrin sealant (Tisseel Kit Fibrin Sealant, Baxter®) was applied along the staple line. The resected stomach tissue was removed through the trocar site. A Jackson Pratt drain was placed to view the staple line in the left subdiaphragmatic area, concluding the procedure. Each operation lasted an average of 1 hour. All patients were mobilized at the 8th hour post-surgery. On the 1st postoperative day, all patients drank a diluted contrast solution (Biemexol 350 mg solution) for leak testing under fluoroscopy. Likewise, a dietician determined the nutrition program on the 1st postoperative day. Post-surgery, 0.4-0.6 IU LMWH was continued subcutaneously every 12 hours until discharge. After discharge, patients were prescribed a proton pump inhibitor once daily, ciprofloxacin twice daily, painkillers, and 0.4 IU LMWH every 12 hours for 10 days. Patients were called for a follow-up after 10 days.

Ethical Committee

This study was approved by the Afyonkarahisar health Sciences University Clinical Research Ethics Committee on 15.04.2022/224 with the ethics committee code 2011-KAEK-2.

Statistical Analysis

For categorical variable comparisons between groups, the chi-square test was used. The suitability of continuous variables for normal distribution was checked using visual histograms and analytical methods (Kolmogorov-Smirnov and Shapiro-Wilk tests). The comparison of continuous variables between groups, depending on the presence of a normal distribution, was conducted using either the independent samples t-test or the Mann-Whitney U test. Statistical analyses were performed with SPSS 26.0 (IBM Statistics, New York). Presented p-values are two-tailed, with $p < 0.05$ considered statistically significant.

RESULTS

Of the 335 patients included in the study, 67 (20%) were male and 268 (80%) were female. The median age of the patients was 35 years. (IQR = 20 years). 87.2% of the patients were classified as morbidly obese, while 12.8% were classified as super obese. Hypertension was present in 46 (13.6%) patients, Diabetes Mellitus in 73 (21.8%), and hypothyroidism in 22 (6.6%). Five staplers were used in 317 (94.6%) patients, and six staplers in 18 (5.4%) patients. All patients underwent laparoscopic surgery, with fibrin sealant applied to 92.8% of them. Leakage was the most common complication in 8 patients (2.4%) (**Table 1**).

Table 1: General Characteristics of the Patients

	(n)	(%)
Gender		
Male	67	20%
Female	268	80%
Body mass index		
Morbidly obese	292	87,2%
Super Obese	43	12,8%
Comorbidities		
Hypertension	46	13,6%
Diabetes Mellitus	73	21,8%
<i>Chronic obstructive pulmonary disease</i>	14	4,2%
Coronary Artery Disease	4	1,2%
Hypothyroidism	22	6,6%
Smoking	68	20,3%
Number of Staplers		
5 staplers	317	94,6%
6 staplers	18	5,4%
Use of Tisseel	311	92,8%
Complications		
Leak	8	2,4%
Bleeding	2	0,6%
Pulmonary thromboembolism	2	0,6%

A 0.6% incidence rate of PTE was observed post-LSG. The median age of patients with PTE was 51.5 years. There was no statistically significant difference in the development of PTE concerning age, gender, and smoking status. When grouped according to BMI, the risk of PTE development was higher in super obese patients compared to morbidly obese patients, although not statistically significant (**Table 2**).

A leakage rate of 2.4% was observed in our study. The median age of patients with leakage was 32 years (19). There was no statistically significant difference in leakage development concerning age, gender, and smoking status. Although there was no statistically significant difference in the development of leakage between patients

with 5 or 6 staplers used, leakage was observed in 11.1% of patients using 6 staplers (**Table 3**).

Table 2: General Characteristics of Patients with Pulmonary Thromboembolism.

	Pulmonary Embolism Present (n= 2)	Pulmonary Embolism Absent (n= 333)	P-value
Age (years), median (IQR) (min-max)	51,5 (0) (51-52)	35 (20) (16-71)	0,094
Gender, n (%)			0,478
Male	0	67(100%)	
Female	2 (0,7%)	266 (99,3%)	
BMI Group			0,115
Morbidly obese	1(0,3%)	291(99,7%)	
Super obese	1(2,3%)	42(97,7%)	
Smoking, n (%)			0,474
Yes	0	68(100%)	
No	2 (0,7%)	265(99,3%)	
History of Hypertension			0,135
Yes	1(2,2%)	45(97,8%)	
No	1(0,3%)	288(99,7%)	
History of Diabetes Mellitus			0,332
Yes	1 (1,4%)	72 (98,6%)	
No	1(0,4%)	261(99,6%)	
History of Chronic obstructive lung disease (COPD)			0,767
Yes	0	14 (100%)	
No	2 (0,6%)	319(99,4%)	
History of Coronary artery disease (CAD)			0,876
Yes	0	4 (100%)	
No	2 (0,6%)	329 (99,4%)	
History of Hypothyroidism			0,707
Present	0	22(100%)	
Absent	2 (0,6)	311(99,4%)	
Use of Tisseel			0,694
Yes	2 (0,6%)	309 (99,4)	
No	0	24(100%)	

IQR: InterquartileRange.

Table 3: Characteristics of Patients According to Leak Complications.

	Leak present (n= 8)	Leak absent (n= 327)	P-value
Age (years), median (IQR) (min-max)	32 (19) (19-55)	35 (20) (16-71)	0,647
Gender, n (%)			0,055
Male	4(6%)	63 (94%)	
Female	4 (1,5%)	264 (98,5%)	
Group by Body Mass Index			0,726
Morbidly obese	7 (2,4%)	285 (97,6%)	
Super obese	1(2,3%)	42 (97,7%)	
Smoking, n (%)			0,208
Yes	3 (4,4%)	65 (95,6%)	
No	5 (1,9%)	262 (98,1%)	
History of Hypertension			0,302
Yes	2 (4,3%)	44 (95,7%)	
No	6 (2,1%)	283 (97,9%)	
History of Diabetes Mellitus			0,379
Yes	3 (4,1%)	70 (95,9%)	
No	5 (1,9%)	257 (98,1%)	
History of Chronic obstructive lung disease (COPD)			0,708
Yes	0	14 (100%)	
No	8 (2,5%)	313 (97,5%)	
History of Coronary artery disease (CAD)			0,753
Yes	0	4 (100%)	
No	8 (2,4%)	323 (97,6%)	
History of Hypothyroidism			0,577
Present	0	22(100%)	
Absent	8 (2,6%)	305(97,4%)	
Use of Tisseel			0,548
Yes	8 (2,6%)	303 (97,4%)	
No	0	24(100%)	
Number of Staplers			0,063
5 pcs	6 (1,9%)	311 (98,1%)	
6 pcs	2 (11,1%)	16 (88,9%)	

IQR: InterquartileRange.

A 0.6% incidence rate of bleeding was observed in our study. The median age of patients who experienced bleeding was 45.5 years. There was no statistically significant difference in bleeding development concerning age, gender, and smoking status. Bleeding was observed in 25% of patients with coronary artery disease (p=0.024). No statistical difference was found among other comorbidities. Patients who did not receive Tisseel experienced significantly higher rates of bleeding compared to those who did (p=0.018) (**Table 4**).

Table 4: General Characteristics of Patients with Bleeding

	Bleeding Present (n= 2)	Bleeding Absent (n= 333)	P-value
Age (years), median (IQR) (min-max)	45,5 (0) (44-47)	35 (20) (16-71)	0,241
Gender, n (%)			0,478
Male	0	67 (100%)	
Female	2 (0,7%)	266 (99,3%)	
By body mass index			0,586
Morbidly obese	2 (0,7%)	290 (99,3%)	
Super obese	0	43 (100%)	
Smoking, n (%)			0,208
Yes	0 (4,4%)	68 (100%)	
No	2 (0,7%)	265 (99,3%)	
History of Hypertension			0,135
Yes	1 (2,2%)	45 (97,8%)	
No	1 (0,3%)	288 (99,7%)	
History of Diabetes Mellitus			0,454
Yes	0	73 (100%)	
No	2 (0,8%)	260 (99,2%)	
History of Chronic obstructive lung disease (COPD)			0,767
Yes	0	14 (100%)	
No	2 (0,6%)	319 (99,4%)	
History of Coronary artery disease (CAD)			0,024*
Yes	1 (25%)	3 (75%)	
No	1 (0,3%)	330 (99,7%)	
History of Hypothyroidism			0,707
Present	0	22 (100%)	
Absent	2 (0,6%)	311 (99,4%)	
Use of Tisseel			0,018**
Yes	1 (0,3%)	310 (99,7%)	
No	1 (4,2%)	23 (95,8%)	
Number of Staplers			0,735
5 pcs	2 (0,6%)	315 (99,4%)	
6 pcs	0	18 (100%)	

IQR: Interquartile Range.

*Fisher's Exact Test. ** Pearson Chi-Square

DISCUSSION

According to a report published by the WHO in 2016, Türkiye had the highest obesity prevalence in Europe at a rate of 29.5%. A meta-analysis conducted by the Turkish Cardiology Association in 2018 indicated that the prevalence of obesity was 30% among women and 17% among men (6). Although the distribution of 20% male and 80% female participants in our study was not calculated according to population numbers, it supports the observation that obesity prevalence is higher in women compared to men.

Leaks arising from mechanical reasons associated with the stapler firing device or the stapler itself in LSG operations occur within the first 3 postoperative days, while leaks due to ischemic reasons occur between the 5th and 7th days. Despite various methods being tried to prevent bleeding and leakage from the staple line, the results are confusing, and a standard method has yet to be established (7).

Fibrin sealant functions by mimicking the blood clotting cascade and is produced from human plasma. In addition to its hemostatic property, studies have shown it to be effective in wound healing by facilitating fibroblast migration (7). In a study by Gentileschi et al. (8), the application of fibrin sealant was shown to

be effective in reducing bleeding and leakage. However, a study by Aydın et al. (9) reported that the use of fibrin sealant did not reduce the rate of leakage, increased costs due to its high price, and extended the operation time.

Matteo et al. (10) reported that reinforcing the staple line with fibrin sealant reduced complications of leakage and bleeding. Mario et al.'s (11) study found that while the incidence of bleeding was significantly higher in patients without fibrin sealant (group A vs. group B, $p = 0.03$), there was no statistical significance regarding leakage. In a prospective study by Akıcı et al. (12), where four different staple line reinforcement techniques were applied to the resected stomach patterns of 48 patients undergoing LSG, it was suggested that fibrin sealant might be more effective in preventing leakage compared to other staple line reinforcement methods. The incidence of staple line leakage and bleeding in LSG has been reported as 0.5–3% and 2%, respectively, in the literature (13).

In our study, leakage was observed in 8 patients (2.4%), which is consistent with the literature. Although there was no statistically significant difference in the development of leakage among patients who received fibrin sealant, the occurrence of leaks only in patients who used fibrin sealant suggests that its properties of fibroblast migration and adhesion may not withstand increases in intragastric pressure adequately.

In a study by Piotr et al. (14) investigating the effect of the number of staplers on the incidence of leakage in LSG, the number of staplers used for stomach transection was reported to be an average of 4 (min. 3–max 8). It was suggested that using more staplers could lead to technical errors and potentially increase complications due to the prolonged duration of the surgery. Although there was no statistically significant difference in the incidence of leakage between patients who had 5 staplers used and those who had 6 ($p = 0.063$), leakage was observed in 1.9% of patients with 5 staplers used, while 11.1% of patients with 6 staplers experienced leakage. This suggests that an increased number of staplers might elevate the

risk of leakage, aligning with our observations. In the 8 patients with leakage complications we observed, endoscopic examination revealed that all leaks originated from the staple line in the proximal stomach. Intra-luminal stents were placed and removed within a 6–8-week interval. Consequently, closure of the fistula was observed in all patients. Musella et al. (15) argued that the use of fibrin sealant in patients resulted in less bleeding. In our study, bleeding occurred at a rate of 0.6%, which is consistent with the literature. Bleeding was statistically significantly higher in patients who did not use fibrin sealant compared to those who did ($p = 0.018$). The two patients who bled were identified within the first 24 hours post-operation due to hemorrhagic output from the drain. The hemoglobin value of the patients at 24 hours postoperatively decreased by more than 3 units. Hemostasis was achieved with conservative treatment without the need for diagnostic laparoscopy. Although the effect of fibrin sealant on leaks remains confusing, we believe it to be effective in terms of bleeding. The American Society of Cardiology in the Circulation journal recommends that prophylactic treatment for pulmonary thromboembolism (PTE) in general surgery patients should start with subcutaneous LMWH at 40 mg/day (0.4 IU) 12 hours preoperatively, and continue 12 hours postoperatively to prevent the significant complications of PTE, including pulmonary embolism (16). Stein and colleagues (17) showed that prophylaxis applications in hospitalized surgical patients reduced the incidence of PTE by 30%. Chan et al. (18), in their study of 500 LSG cases, stated that operation duration alone was an independent risk factor for PTE, separate from patients' comorbidities. Sakon et al. (19) considered the operation area, female gender, and age as independent risk factors. In all patients included in our study, prophylactic LMWH was used preoperatively, and its continuation postoperatively was ensured. In our LSG patients, age, gender, comorbid disease, and smoking were not seen as risk factors for the development of PTE. Although not statistically significant, the risk of developing PTE in super obese patients categorized by BMI was proportionally higher (2.3%) compared to morbidly obese patients.

In conclusion, we believe that proper perioperative assessment of patients scheduled for LSG and approaches during the operation can significantly reduce the complications encountered in the postoperative period.

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