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Are routine intraoperative and postoperative leakage tests needed in bariatric surgery?

Bariatrik cerrahide rutin intraoperatif ve postoperatif kaçak testlerine ihtiyaç var mı?

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Abstract

Aim: We aimed to evaluate the efficacy of the results of intraoperative methylene blue test and postoperative upper gastrointestinal contrast graphies for detecting leakage in both primary and revisional bariatric surgery. Methods: Two-hundred-eighty-seven patients, who underwent primary and revision bariatric surgery and routine intraoperative methylene blue test and upper gastrointestinal contrast studies postoperatively for leakage were included in the study. Patients' demographic characteristics, comorbidities, length of hospital stay, operation time, intraoperative, and postoperative complications were analyzed retrospectively.

Results: In our study, 256 of 287 (89.1%) patients underwent primary surgery, 221 (75.7%) patients were female, the mean patient age was 38.4 ± 11.9 years, and the mean body mass index was 44.3 ± 7.6 kg/m². The number of patients who had previous abdominal surgery and comorbidity was 108 (37.6%) and 149 (51.9%), respectively. Leakage was detected by a methylene blue test in one (0.3%) patient who underwent one-anastomosis gastric bypass surgery. In one (3.2%) patient who underwent revisional surgery with negative results of methylene blue test, leakage was detected on the first postoperative day due to the clinical findings. There was no leakage detected in any patient with postoperative swallow graphies. There was no statistical difference in leakage between primary and revisional surgery groups (p = 0.23). There was no mortality.

Conclusion: It could be unnecessary to use postoperative gastrointestinal contrast studies in both primary and revisional bariatric surgery, but the routine use of the intraoperative methylene blue test could be considered useful due to its positive results for the detection of leakage.

Keywords: Bariatric surgery, leakage, methylene blue, radio contrast imaging

Öz

Amaç: Primer ve revizyonel bariatrik cerrahide kaçak tanısı için uygulanan intraoperatif metilen mavisi testi ile postoperatif üst gastrointestinal sistem kontrastlı grafilerin etkinliklerini ve sonuçlarını değerlendirmeyi amaçladık.

Yöntemler: Primer ve revizyonel cerrahi uygulanan, kaçak tespiti için rutin olarak intraoperatif metilen mavisi testi ile postoperatif üst gastrointestinal kontrastlı grafi yapılan 287 hasta çalışmaya dahil edildi. Hastaların demografik özellikleri, komorbid hastalıkları, hastanede yatış süresi, ameliyat süresi, intraoperatif ve postoperatif komplikasyonlar retrospektif olarak incelendi.

Bulgular: Çalışmamızdaki 287 hastanın 256'sına (%89,1) primer cerrahi uygulandı ve hastaların 221'i (%75,7) kadın, ortalama yaş 38.4 ± 11.9 yıl ve ortalama beden kitle indeksi 44.3 ± 7.6 kg /m2 idi. Daha önce abdominal cerrahi geçiren ve komorbid hastalığı olan hasta sayıları sırasıyla 108 (%37,6) ve 149 (%51,9) idi. Bir (% 0,3) tek-anastomozlu gastrik bypass olgusunda metilen mavisi testinde kaçak tespit edildi. Revizyon cerrahisi uygulanan 1 (%3,2) olguda, metilen mavisi testinde kaçak tespit edilmeyip, postoperatif 1. gün klinik bulgulara göre kaçak tespit edildi. Postoperatif kontrastlı grafi sonuçlarında hiçbir hastada kaçak tespit edilmedi. Primer ve revizyonel cerrahi uygulanan olgular arasında görülen kaçaklarda istatistiksel olarak anlamlı fark tespit edilmedi (p=0,230). Mortalite yok idi.

Sonuç: Primer ve revizyonel bariatrik cerrahide postoperatif gastrointestinal kontrast çalışmalarının kullanılmasına gerek olmayabilir, ancak kaçak tespitindeki pozitif sonuçları nedeniyle intraoperatif metilen mavisi testinin rutin olarak uygulanması düşünülebilir.

Anahtar Kelimeler: Bariatrik cerrahi, kaçak, metilen mavisi, radyo kontrastlı görüntüleme

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Introduction

The most effective treatment for morbid obesity and obesity-related comorbid conditions is bariatric and metabolic surgery [1]. These surgeries provide long-term weight loss and an increase in life expectancy. The most feared complication after these operations is leakage, and the incidence of leakage has been reported to be between 0.1% and 5.6%, depending on the type of surgery [2]. Various techniques have been described, including larger bougie size in sleeve gastrectomy (SG), reinforcement of staple line with Fibrin Glue, use of absorbable buttressing material, and oversewing staple lines to prevent the leakage [3]. Early diagnosis and treatment of leaks are important to prevent problems such as hemodynamic shock, respiratory distress, and multiorgan failure that might cause mortality [4, 5]. The risk factors that increase the risk of leakage in bariatric and metabolic surgery are: gender (male), age > 50 years, body mass index (BMI) > 50 kg/m², lack of surgical experience, Type 2 diabetes, hypertension, sleep apnea syndrome, and revisional surgery [6-8].

Various methods can be used for intraoperative testing for leaks, including air leak test, methylene blue dye, and endoscopy. The positive results of these tests for leakage are important for early diagnosis, but negative results do not eliminate the possibility of leakage. For these reasons, performing routine intraoperative leak tests is controversial [9, 10]. Postoperative swallow studies are used for the diagnosis of a leak in many centers, but its routine use is controversial as an intraoperative leakage test [11]. In the literature, there is little data for the necessity of routine use of both intraoperative and postoperative leakage tests in bariatric surgery.

This paper aims to evaluate our practice of routine use of both the intraoperative methylene blue test and postoperative gastrointestinal contrast study in our center.

Material and methods

We retrospectively analyzed the records of the 287 patients who underwent primary and revisional bariatric surgery, which routinely performed intraoperative methylene blue test (IMBT) and postoperative swallow graphy, from January 2018 to November 2019 at Bezmialem Vakif University School of Medicine. The Local Ethics Committee approved the study (2019-18890). The study was conducted according to the principles described in the Declaration of Helsinki. Written informed consent was not obtained from patients due to the retrospective nature of the study. Primary bariatric surgeries included sleeve gastrectomy (SG) and one anastomosis gastric bypass (OAGB); the revisional surgeries were included adjustable gastric band (AGB) to SG/OAGB, SG to OAGB/ Roux-en-Y gastric bypass (RYGB), and OAGB to distal RYGB. Patient details were identified from a prospectively maintained database. The inclusion criteria of the patients who underwent primary bariatric and metabolic surgery were: morbidly obese $(BMI > 40 \text{ kg/m}^2)$ patients and patients with a BMI of 35 kg/m² and had at least one obesity-related comorbidity, such as type 2 diabetes, hypertension, hyperlipidemia, sleep apnea syndrome. The inclusion criteria of the patients who underwent revisional (RS) were: complications (leakage, stenosis, surgery gastroesophageal reflux, twist) that occurred after the primary surgery, the rate of excess weight loss (EWL%) within 2 years postoperatively was less than 50% or weight regain was at least 25% of the total weight loss, and inadequate and/or recurrence of comorbid conditions resolution. Extralumination of methylene blue or contrast agent from the stapler line or gastroenterostomy anastomosis area was evaluated as leakage. For anastomotic or staple line leaks, procedural complications such as esophageal

perforation, massive bleeding due to the insertion of an orogastric tube, and adverse reactions for both methylene blue and contrast agent were evaluated. Visualization of emerging from the staple line would indicate a staple line defect, which can then be immediately repaired or reinforced. Also, operative time, hospital length of stay, re-admission, and overall 30-day complications were examined.

Techniques of the leakage tests

The orogastric tube routinely inserted was intraoperatively to all patients at the end of the operation by the anesthesiologists. In the SG, the pylor was occluded using a stapler. The jejunum distal to the gastrojejunostomy was occluded with a laparoscopic bowel grasper in OAGB or RYGB by the surgeon. Between 50 and 70 ml of saline solution, which is stained with 3 ml methylene blue, was introduced via the orogastric tube to control the leakage from the staple line or anastomosis (Figure 1). On the second postoperative day, all patients drunk 100 ml water, which included 50 ml Iohexol 350 mg I/ml (GE Healthcare, Ireland), and the presence of the contrast extravasation was evaluated in the swallow grafies (Figure 2).



Figure 1: Intraoperative methylene blue test in SG (a) and OAGB (b).



Figure 2: Postoperative swallow grafies in SG (a) and revision of SG to OAGB (b).

Statistical Analysis

SPSS 23.0 (SPSS Inc., Chicago, IL, USA) software was used for all statistical analyses. Continuous variables were expressed as mean \pm standard deviation and as the median value, if necessary. Categorical variables were expressed as frequencies with percentages. The sensitivity and specificity of tests were calculated. An appropriate Chi-square test was used to determine the significance between nominal variables.

Results

Two-hundred-fifty-six (89.1%) primary bariatric procedures (SG n=236 patients and OAGB n=20 patients) and 31 (10.8%) revisional surgeries (SG to RYGB n=8 patients, SG to distal OAGB n=18 patients, AGB to SG n=3 patients, AGB to OAGB n=1 patient, OAGB to distal RYGB n=1 patient) were done consecutively in the study period at the single institution. The patients' demographic characteristics are shown in Table 1. Synchronous laparoscopic cholecystectomy and hiatal henia

repair were done in 12 (4.1%) and three (1%) patients, respectively. Two of 31 (6.5%) revisional laparoscopic procedures were converted to laparotomy because of the adhesions resulting from previous abdominal surgery. Three revisional operations were done by open surgery. Overall, the methylene blue test was positive in only 0.3% and demonstrated a sensitivity of only 50%. In this patient, who underwent primary OAGB, leakage was detected by intraoperative methylene blue test at the gastrojejunostomy and the leaking area immediately repaired, and a subsequent confirmatory intraoperative methylene blue test was done. This patient was discharged without any complication on the third postoperative day. In one patient (3.2%), who underwent RS from SG to OAGB, a leak was diagnosed on the postoperative first day by seen bile in an abdominal drain and underwent the second operation without any diagnostic radiological test. Laparoscopy was performed, and the leakage was detected in gastrojejunostomy. The leaking area was oversewn by 2/0 prolen suture and the patient discharged on the fifth postoperative day without any complication. No leakage was diagnosed in the results of the swallow studies, so sensitivity could not be calculated for this test. The sensitivity of the methylene blue test was calculated as 50%. The specificity of both tests was 100%. Subgroup analysis of primary and RS shows no differences in leakage (Fisher exact test, p = 0.23). There was no mortality in the postoperative period. There were no intraoperative and/or postoperative complications during the use of leakage tests, such as esophageal perforation and allergic reactions, in our study group.

Table 1: Demographic and clinical characteristics of the study sample.

Characteristic	Primary surgery group	Revisional surgery group
Gender ^β		
Female	193 (75.4)	26 (83.8)
Male	63 (24.6)	5 (16.2)
Age (years) $^{\text{¥}}$	37.6 ± 11.9	44.6 ± 10.3
BMI $(kg/m^2)^{\text{¥}}$	45.4 ± 7.1	35.5 ± 6.3
Previous abdominal surgery β	80 (31.2)	31 (100)
Comorbidities β		
Type2 DM*	98 (38.2)	10 (32.2)
Hypertension	66 (25.7)	9 (29)
Hyperlipidemia	26 (10.1)	2 (6.4)
Sleep apnea	22 (8.5)	1 (3.2)
Duration of surgery (minute) [¥]	76 ± 23	185 ± 36
Hospital stay $(day)^{4}$	3.1 ± 0.6	3.4 ± 1.1
30-day morbidity β		
Hemorrhage	2 (0.7)	1 (0.3)
Deep vein thrombosis	-	1 (0.3)
Readmission β	-	3 (9.7)
^{β} : n(%), [‡] : Mean±SD		

*Diabetes Mellitus

Shaberes Miellitus

Discussion

Bariatric surgery remains the only proven modality for sustained weight loss with improvement in obesity-related comorbidities in the morbidly obese patient population worldwide. With the increase of the primary bariatric and metabolic surgery numbers, surgeons aim to prevent complications, which can result in prolonged hospital stay and mortality. Parallel to the increase in the rate of primary surgery, the rates of revisional surgeries are increasing. The risk of complications might increase in revision surgery due both to the state of the tissue and the complexity of the procedure itself [4, 12]. Postoperative leakage is the most feared complication after bariatric surgery and the clinical signs of a leak require emergency treatment, such as exploration, endoscopic procedures, and percutaneous drainage. Surgeons use a variety of techniques (such as staple line reinforcements, methylene blue test, or air insufflation under saline or endoscopic examination of the anastomosis and staple line) to reduce complication rates, especially on leakage, and improve patients' safety. However, a standard technique has not yet been accepted.

The international consensus group on sleeve gastrectomy has not reached a definitive conclusion on whether there is a benefit in the use of routine intraoperative leak tests [10]. On the other hand, some studies found the limited benefit of intraoperative leak tests, but the results of these tests could not predict or prevent leakage in all bariatric procedures [13, 14]. Intraoperative leak tests can only detect the rare leaks due to technical failures, such as stapler misfire or surgeon inexperience [13,15]. In a large multicenter study with 4284 SG patients, 37 (0.9%) postoperative leakages were found. Two of 37 (0.08%) leaks were diagnosed by intraoperative leak test and 21 of 37 patients (0.49%) who had negative intraoperative test findings developed leakage. Leakage occurred in the postoperative period in 14 of 37 patients (32%) who had no intraoperative test. When comparing cases with and without intraoperative leak tests performed, there was no significant difference in leak rates among patients who underwent intraoperative leak tests compared to those that did not (1.0% vs. 0.7%, p = 0.41) [16]. In our study, we detected only one positive intraoperative leak test and one postoperative leak had a normal intraoperative methylene blue test. We had a low number of leaks, which might have diminished the value of the leak test. We presume this is due to the experience of the surgeons who perform these operations, as this is known to have a positive impact on outcomes [17]. In our experience, leaks can be avoided by including some important technical points: avoidance of distal stenosis and/or twist, especially in SG; adequate compression time during stapling; gentle tissue handling; avoiding thermal damage at anastomosis and staple line; and staying away from the gastroesophageal junction. We did not identify any major benefit in the routine use of a methylene blue leak test in primary and revisional bariatric surgery.

Many surgeons perform postoperative radiological upper gastrointestinal (UGI) series routinely as screening tests for leakage. However, the role of routine postoperative use of these contrast studies in detecting leaks after bariatric surgery is controversial [18]. The early leaks, which are likely due to technical error or staple line failure, might be detected by routine postoperative UGI contrast studies.

In a study by Sethi et al. [18], routine postoperative UGI contrast studies identified only two of 20 leaks. The patients with both early and delayed leaks demonstrated significant clinical abnormalities, such as fever, abdominal pain, and tachycardia at the time of leak presentation, before the confirmatory radiographic study. The vast majority of leaks returned normal results in the UGI series and presented 2-3 weeks after discharge. These authors concluded that the clinical indicators are the most useful factors to raise concern for leaks and UGI studies and may be preferred in selective patients. Mbadiwe et al. [11] performed a meta-analysis of 10,139 UGI series after bariatric surgery and found the sensitivity and specificity of these tests in detecting leak were 54% and 100%, respectively. Some studies in the literature have reported false negative radiological UGI results [5,19]. Mizrahi et al. [20] reported their large series, and none of the five leaks were detected by routine radiological UGI on the first postoperative day. These authors concluded that routine UGI is not an efficient screening test for the leak after bariatric surgery, and recommended abandoning this practice. We identified only one leak at the first postoperative day without any radiological test, and the results of all UGI studies were

negative. In our study, the specificity of swallow graphy in detecting leak was 100%.

Our study has some limitations: this is a retrospective study, and it includes a small patient group. The occurrence of the leak is low in both primer and revisional surgeries; large numbers are required to detect a significant difference in leak rates.

In conclusion, a negative intraoperative leak test result does not preclude the possibility of a staple line or anastomotic leakage. It is likely unnecessary to use postoperative gastrointestinal contrast studies in both primary and revisional bariatric surgery, but the routine use of the intraoperative methylene blue test could be considered due to its positive results for the detection of leakage.

References

- 1. Nguyen NT, Varela JE. Bariatric surgery for obesity and metabolic disorders: state of the art. Nat Rev Gastroenterol Hepatol. 2017;14:160-9.
- Schulman AR, Thompson CC. Complications of Bariatric Surgery: What You Can Expect to See in Your GI Practice. Am J Gastroenterol. 2017;112:1640-55.
- 3. Aurora AR, Khaitan L, Saber AA. Sleeve gastrectomy and the risk of leak: a systematic analysis of 4,888 patients. Surg Endosc. 2012;26:1509–15.
- Arteaga-González I, Martín-Malagón A, Martín-Pérez J, Carrillo-Pallarés A. Usefulness of Clinical Signs and Diagnostic Tests for Suspected Leaks in Bariatric Surgery. Obes Surg. 2015;25:1680-4.
- Sakran N, Goitein D, Raziel A, Keidar A, Beglaibter N, Grinbaum R, et al. Gastric leaks after sleeve gastrectomy: a multicenter experience with 2,834 patients. Surg Endosc 2013;27:240–5.
- DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. Surg Obes Relat Dis. 2007;3:134–40.
- Schauer P, Ikramuddin S, Hamad G, Gourash W. The learning curve for laparoscopic Roux-en-Y gastric bypass is 100 cases. Surg Endosc. 2003;17:212–5.
- Oliak D, Ballantyne GH, Weber P, Wasielewski A, Davies RJ, Schmidt HJ. Laparoscopic Roux-en-Y gastric bypass: defining the learning curve. Surg Endosc. 2003;17:405–8.
- Aggarwal S, Bhattacharjee H, Chander Misra M. Practice of routine intraoperative leak test during laparoscopic sleeve gastrectomy should not be discarded. Surg Obes Relat Dis. 2011;7:e24-5.
- Rosenthal RJ, International Sleeve Gastrectomy Expert Panel, Diaz AA, Arvidsson D, Baker RS, Basso N, et al. International sleeve gastrectomy expert panel consensus statement: best practice guidelines based on experience of >12,000 cases. Surg Obes Relat Dis. 2012;8:8-19.
- Mbadiwe T, Prevatt E, Duerinckx A, Cornwell E 3rd, Fullum T, Davis B. Assessing the Value of Routine Upper Gastrointestinal Contrast Studies Following Bariatric Surgery: A Systematic Review and Meta-Analysis. Am J Surg. 2015;209:616-22.
- 12. Shin RB. Intraoperative endoscopic test resulting in no postoperative leaks from the gastric pouch and gastrojejunal anastomosis in 366 laparoscopic Roux-en-Y gastric bypasses. Obes Surg. 2004;14:1067-9.
- Sethi M, Zagzag J, Patel K, Magrath M, Somoza E, Parikh MS, et al. Intraoperative leak testing has no correlation with leak after laparoscopic sleeve gastrectomy, Surg Endosc. 2016;30:883-91.
- Bingham J, Lallemand M, Barron M, Kuckelman J, Carter P, Blair K, et al. Routine intraoperative leak testing for sleeve gastrectomy: is the leak test full of hot air? Am J Surg. 2016;211:943-7.
- Sakran N, Goitein D, Raziel A, Keidar A, Beglaibter N, Grinbaum R, et al. Gastric leaks after sleeve gastrectomy: a multicenter experience with 2,834 patients. Surg Endosc 2013;27:240–5.
- 16. Bingham J, Kaufman J, Hata K, Dickerson J, Beekley A, Wisbach G, et al. A multicenter study of routine versus selective

intraoperative leak testing for sleeve gastrectomy. Surg Obes Relat Dis. 2017;13:1469-75.

- 17. Celio AC, Kasten KR, Brinkley J, Chung AY, Burruss MB, Pories WJ, et al. Effect of surgeon volume on sleeve gastrectomy outcomes. Obes. Surg. 2016;26: 2700–4.
- Sethi M, Magrath M, Somoza E, Parikh M, Saunders J, Ude-Welcome A, et al. The utility of radiological upper gastrointestinal series and clinical indicators in detecting leaks after laparoscopic sleeve gastrectomy: a case-controlled study. Surg Endosc. 2016;30:2266-75.
- Wahby M, Salama AF, Elezaby AF, Belgrami F, Abd Ellatif ME, El-Kaffas HF, et al. Is routine postoperative gastrografin study needed after laparoscopic sleeve gastrectomy? Experience of 712 cases. Obes Surg. 2013;23:1711–7.
- Mizrahi I, Tabak A, Grinbaum R, Beglaibter N, Eid A, Simanovsky N, et al. The utility of routine postoperative upper gastrointestinal swallow studies following laparoscopic sleeve gastrectomy. Obes Surg 2014;24:1415–9.