Risk factors for anastomotic complications after elective intestinal resection in Crohn's disease

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ABSTRACT

Objective: Anastomotic leaks are the most feared complications after surgery in patients with Crohn's disease. Identifying associated risk factors is crucial for prevention. We aimed to evaluate possible risk factors for anastomotic complications in our case series.

Material and Methods: This was a single-center, retrospective, observational study. Eighty-six patients who underwent intestinal resection due to Crohn's disease at the Department of General Surgery, Marmara University, Faculty of Medicine, from 2015 to 2023 were enrolled. Adult patients of either sex who are over 18 years old were included. Cases, where the anastomosis was defunctioned with a proximal diverting ileostomy or colostomy were excluded from the study.

Results: The mean (StD) age was 34.8 (14.4) years, and 50 patients (58.1%) were male. Twenty-five patients had post-operative complications (29.1%), and 10 of them (11.6%) were above grade three according to the Clavien-Dindo classification. Anastomotic leakage was observed in two, intra-abdominal collection in two, sepsis in two, enterocutaneous fistula in three, and ileus in the remaining one. While the albumin value <3 gr/dL (OR 5.15, p< 0.03) and pre-operative medical treatment (OR= 4.79; p= 0.05) were associated with higher odds of post-operative overall complications, only hypoalbuminemia 3 g/dL (OR= 14.3; p= 0.04) was associated with a higher probability of post-operative anastomotic/septic complications.

Conclusion: In patients with pre-operative hypoalbuminemia, temporary stoma creation should be considered due to the potential increased risk of high anastomotic complications. The medical treatments should be discontinued in the pre-operative period due to the increased risk of complications.

Keywords: Crohn's disease, post-operative complications, anastomotic leakage

INTRODUCTION

Crohn's patients require surgical treatment involving intestinal resection at some point in their lives. The probability of intestinal resection increases over the years from the initial diagnosis, with respective probabilities of 61% for the first year, 77% for five years, and 83% for ten years (1). Although the majority of Crohn's patients are young and do not have significant comorbidities, the rate of post-operative complications after intestinal resection is higher compared to other benign conditions (2). Mainly, intrabdominal septic events such as anastomotic leakage, enterocutaneous fistula, and intra-abdominal abscess are the most troublesome post-operative issues, with occurrence rates ranging from 5% to 20%. While the failure of anastomotic healing may manifest as leakage at the anastomotic site, leading to septic complications, chronic anastomotic healing failure may lead to the formation of enterocutaneous fistulas at incision sites or drainage canals, sometimes occurring within weeks after hospital discharge (3). In addition, the realization that these complications also contribute to another serious problem, namely disease recurrence, clearly reveals the magnitude of the problem (2,4).

Several different risk factors have been suggested for post-operative septic complications following intestinal resection in Crohn's disease, which include preoperative albumin levels, poor nutritional status, duration of symptoms, preoperative steroid, immunomodulatory or biological agents use, presence of abscess during laparotomy, positive histological margins, colo-colonic anastomoses, and repeated resections (2,5-10). However, other studies have reported that some of these factors are not associated with septic events, leading to ongoing debates. Better knowledge and valid evidence identifying perioperative risk factors for anastomosis safety would enable surgeons to decide in the perioperative period which patients are suitable for stoma formation or which patients provide optimal conditions for primary anastomosis.

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Therefore, this study aimed to identify independent risk factors associated with anastomotic leakage or intra-abdominal sepsis in patients undergoing bowel resection and primary anastomosis without stoma formation in Crohn's disease.

MATERIAL and METHODS

Study Design

This study was a single-center, retrospective, observational study. One hundred and two patients underwent intestinal resection due to Crohn's disease at the Department of General Surgery, Marmara University Faculty of Medicine, from 2015 to 2023, and 86 patients who met the inclusion criteria were enrolled. Patients' clinical, operative, pathologic, and short-term outcomes were recorded prospectively and analyzed retrospectively. The study protocol was approved by the Ethics Committee of Faculty of Medicine, Marmara University, and was conducted by the principles of the Declaration of Helsinki (Protocol no: 09.2023.890). The study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies (11).

Study Population and Data Collection

Adult patients of either sex who were over 18 years of age and underwent intestinal resection with primary anastomosis for active Crohn's disease were included. Patients under the age of 18, cases where the anastomosis was defunctioned with a proximal diverting ileostomy or colostomy, emergency or urgent surgical procedures, underwent stricturoplasty and instances where data were missing or invalid, preventing analysis were excluded from the study (Table 1). Patients' data, including age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, nutritional risk score (NRS), smoking, pre-operative blood tests, if any pre-operative medical treatments or interventions, characteristic of the disease, localization, anastomotic technique, operative and postoperative parameters, early post-operative complications, length of hospital stay, reoperations, readmissions, and mortality rates were recorded and analyzed as possible risk factors for anastomotic leak.

Table 1. Study population				
n= 102				
Intestinal resection plus anastomosis				
	Two loop ileostomy			
	Two loop colostomy			
	Two end colostomy			
	Ten end ileostomy			
n= 86				
Intestinal resection plus anastomosis				
Without stoma				

Outcomes

This retrospective study aimed to examine patient- and surgery-related risk factors that could impact the safety of anastomosis in patients with Crohn's disease undergoing intestinal resection. Secondary outcomes included the overall complication rate, length of hospital stay (LOS), reoperations, and mortality rate within 30 days.

Surgical Approach

The decision for surgical resection was made during multidisciplinary meetings of the inflammatory bowel disease (IBD), which included gastroenterologists, general and gastrointestinal surgeons, and radiologists. All surgeries were performed with a conservative approach (open technique). By adhering to the basic principles of bowel resection for Crohn's disease, all visible disease was eliminated with limited and clear surgical margins-all patients who had intestinal anastomosis, conducted with either stapled or hand-sewn methods. Hand-sewn anastomoses were performed by either end-to-side or side-toside anastomoses. Stapled anastomoses were performed by two methods: Functional side-to-side anastomosis with the use of a linear stapler and side-to-end anastomosis with the use of a circular stapler. The choice between hand-sewn anastomosis and stapled anastomosis was left to the surgeon's discretion.

Outcome Measures

Anastomotic leak was defined based on the 1991 UK Surgical Infection Study Group, and it was confirmed if there was fecal discharge from the drain, peritonitis, post-operative cutaneous fistulas from the anastomotic site, or by imaging methods such as computed tomography (12). The Clavien-Dindo (C-D) classifications defined post-operative complications, categorizing surgical complications from grade I to grade V (13). Surgical site infection within 30 days is defined according to the Centers for Disease Control criteria (14).

Statistical Analysis

All statistical analysis was performed using the SPPS software program version 26.0 (SPSS, Inc., Chicago, IL, United States of America). Descriptive statistics were presented as either mean standard deviation (StD) or median for continuous variables according to their normality of distribution. Categorical data were expressed as numbers and proportions. Univariate analysis was used to identify the factors significantly associated with overall and anastomotic/septic complications. Then, variables with p< 0.25 in the univariate analysis were entered into a multivariate binary logistic regression analysis to determine the independent predictors of these overall and anastomotic complications. The area under the model's curve was calculated to evaluate the discriminatory ability of the model utilized. P< 0.05 indicated significant results.

RESULTS

Demographic Characteristics

Clinical characteristics and pre-operative parameters of all patients (n= 86, 100%) who met the inclusion criteria and those who underwent intestinal resection due to Crohn's disease from 2015 to 2023 were analyzed. Mean (StD) age was 34.8 (14.4) years, and 50 patients (58.1%) were males. Mean (StD) BMI of the patients was 21.4 (3.8) kg/m². According to the ASA score, the study population had no severe comorbidities (ASA I/II, 93%). A small number of patients were active smokers (25.6%). In most patients, albumin value was over 3 gr/dL (69.8%). However, hemoglobulin value was below 12 gr/dL in 61.6% of patients. Demographic data are shown in Table 2.

Most (68.6%) patients used medical treatment before surgery, including corticosteroid, immunomodulator, biological, or combination. Median disease duration before intestinal resection was 61.7 months (range, 0-204), and 44.2% of the patients required surgery within the first five years after initial diagnosis. Forty patients (46.5%) had a previous abdominal surgery. Ten patients (11.6%) had an intra-abdominal abscess before surgery and were drained preoperatively. Indication for surgery was non-stenotic, non-perforating disease in 45 patients (52.3%), 18 (20.9%) stenotic and 22 (25.6%) perforating. Most patients had no perianal involvement (82.6%). The disease was located in the small bowel only in 32 patients (37.2%), small and large bowel in 41 patients (47.7%), and large bowel only in 13 patients (15.1%). Baseline patient characteristics are shown in Table 3.

Operative and Post-operative Results

While 69 patients (80.2%) underwent ileocecal resection, 13 patients (15.1%) underwent colon, and only four (4.6%) underwent ileum resection. Gastrointestinal continuity was achieved with a stapler in 55 patients (64%), and the handsewn anastomosis was performed in 30 patients (34.9%). Anastomosis configuration was end-to-side in 43%, side-toside in 45.3%, and end-to-end in 9.3%. In the post-operative pathological examination, 75% of the patients were perforating type, and 55% had positive surgical margins. Within the study population, 25 patients had post-operative complications (29.1%), and 10 (11.6%) were above grade three according to the Clavien-Dindo classification. Of these ten patients with serious complications, anastomotic leakage was observed in two, intra-abdominal collection in two, sepsis in two, enterocutaneous fistula in three, and ileus in the remaining one. Incisional surgical site infection was observed in eleven patients, and wound dehiscence occurred in four. Three patients were re-operated, two due to anastomotic leakage and one patient due to ileus and wound dehiscence. No

	All Cases		
	n= 86 (%)		
Age, mean ± StD	34.8 ± 14.4		
Age, montreal, years			
<16	3 (3.5)		
17-40	55 (64)		
40<	27 (31.4)		
ex			
Female	36 (41.9)		
Male	50 (58.1)		
BMI, mean ± StD, kg/m ²	21.4 ± 3.8		
BMI, kg/m ²			
19<	26 (30.2)		
<19	9 (10.5)		
ASA			
1	35 (40.7)		
2	45 (52.3)		
3	5 (5.8)		
Nutritional risk score			
Normal	29 (33.7)		
Low	30 (34.9)		
Smoking			
No	63 (73.3)		
Yes	22 (25.6)		
Hb, g/dL			
12<	28 (32.6)		
<12	53 (61.6)		
Albumin, g/dL			
3<	60 (69.8)		
<3	14 (16.3)		
Leukocyte, mm³			
<10000	55 (56.7)		
10000<	42 (43.3)		
CRP, mg/L			
<5	9 (10.5)		
5<	41 (47.7)		

patient died during the 30-day post-operative period. Median length of hospital stay was six days (range 3-28). Operative and post-operative data are shown in Table 4.

Table 3. Patient characteristics	
	All Cases
	n= 86(%)
Medical treatment	
No	23 (26.7)
Yes (corticosteroid or anti-TNF)	59 (68.6)
Time from first diagnosis to surgery, months (min-max)	61.7 (0-204)
Time from first diagnosis to surgery, years	
<5	38 (44.2)
5<	35 (40.7)
Previous abdominal surgery	
No	37 (43)
Yes	40 (46.5)
Pre-operative abdominal drainage	
No	75 (87.2)
Yes	10 (11.6)
Pre-operative clinic behaviour	
Non stenotic non penetrating	45 (52.3)
Stenotic	18 (20.9)
Penetrating (fistulizing)	22 (25.6)
Perianal disease	
No	71 (82.6)
Yes	14 (16.3)
Location	
Small intestine	32 (37.2)
lleocecal	41 (47.7)
Colonic	13 (15.1)
Pre-operative medical treatment	
Not interrupted	27 (31.4)
Interrupted	20 (23.3)

Factors Associated with Post-operative Overall Complications

In the univariate analysis, post-operative overall complications were associated with the low albumin level, below 3 g/dL (OR= 2.7; p= 0.089), perianal disease (OR= 2.0; p= 0.22), pre-operative medical treatment (OR= 3.6; p= 0.04), surgical technique (OR= 1.9; p= 0.21), and histopathology (OR= 2.3; p= 0.089). According to multivariate regression analysis, albumin value <3 gr/dL (OR= 5.15, p< 0.03) and pre-operative medical treatment (OR= 4.79; p= 0.05) were associated with higher odds of postoperative overall complications. Factors associated with overall complications in both univariate and multivariate analyses are presented in Table 5.

	All Cases
	n= 86 (%)
Surgery	
Small intestine resection	4 (4.6)
lleocecal resection	69 (80.2)
Colectomy	13 (15.1)
Anastomosis	
End to side	37 (43)
Side to side	39 (45.3)
End to end	8 (9.3)
Surgical technique	
Hand-sewn	30 (34.9)
Stapler	55 (64)
Surgical margin	
Positive	14 (16.3)
Negative	70 (81.4)
Histopathology	
Perforan	27 (31.4)
Non-perforan	57 (66.3)
Post-operative complications	
No	61 (70.9)
Yes	25 (29.1)
Anastomotic leak	2/25 (8)
Intra-abdominal collection	2/25 (8)
Sepsis	2/25 (8)
Enterocutaneous fistula	3/25 (12)
lleus	1/25 (4)
Surgical site infection (incisional)	11/25 (48)
Wound dehiscence	4/25 (16)
Dindo-Clavien classification	
Dindo-Clavien grade 1-2	76 (88.3)
Dindo-Clavien grade 3a ≤	10 (11.6)
Hospital stay, days, median (min-max)	6 (3-28)
Re-operation*	3 (3)
Mortality (first 30 days)	0

Factors Associated with Post-operative Anastomotic/ **Septic Complications**

In the univariate analysis, post-operative anastomotic/septic complications were associated with the low albumin level,

	No Complications	Complications	Univariate	р	Multivariate	р
	n= 61	n= 25	OR (95% CI)		OR (95% CI)	
Albumin, g/dL			2.7 (0.8-9.0)	0.089	5.15 (1.16-22.85)	0.03
3<	44	16				
<3	7	7				
Perianal disease			2.0 (0.6-6.6)	0.22		
No	52	19				
Yes	8	6				
Medical treatment			3.6 (0.9-13.8)	0.04	4.79 (0.99-23.11)	0.05
No	20	3				
Yes (corticosteroid or anti-TNF)	38	21				
Surgical technique			1.9 (0.6-5.6)	0.21		
Hand-sewn	24	6				
Stapler	37	18				
Histopathology			2.3 (0.86-6.2)	0.089		
Perforan	44	13				
Non-perforan	16	11				

below 3 g/dL (OR= 5.6; p= 0.017), low nutritional risk score (OR= 7.0; p= 0.049), and smoking (OR= 4.4; p= 0.049). According to multivariate regression analysis, only albumin value below 3 g/ dL (OR= 14.3; p= 0.04) was associated with a higher probability of post-operative anastomotic/septic complications. Factors associated with anastomotic leak in univariate and multivariate analyses are presented in Table 6.

	All Cases	Anastomotic Leakage	Univariate	р	Multivariate	р
	n= 86	n= 9	OR (95% CI)		OR (95% CI)	
Sex			1.2 (0.27-5.47)	0.79		
Female	33	3				
Male	45	5				
Smoking			4.4 (0.9-21.7)	0.049		
No	60	3				
Yes	18	4				
Nutritional risk score			7 (0.78-62.3)	0.049		
Normal	28	1				
Low	24	6				
Albumin, g/dL			5.6 (1.2-26.1)	0.017	14.3 (1.0-195.2)	0.04
3<	56	4				
<3	10	4				
Surgical technique			1.4 (0.25-7.69)	0.69		
Hand-sewn	28	2				
Stapler	50	5				

DISCUSSION

Anastomotic leaks and intrabdominal sepsis are the most feared complications after intestinal resection in patients with Crohn's disease. Identifying associated risk factors is crucial for deciding whether intestinal anastomosis can be performed during surgery. Therefore, numerous and heterogeneous risk factors have been identified that adversely affect early postoperative morbidity and mortality. These factors range from pre-operative laboratory values, medications used preoperatively, duration and clinical characteristics of the disease to perioperative features and even pathological characteristics. However, the results of subsequent studies have led to the guestioning of these risk factors. Additionally, most previous studies were retrospective, the study populations were heterogeneous, and limitations ensured that the subject always remained current and active.

These are the initial results of an observational study designed by our clinic, as a tertiary referral center for inflammatory bowel disease, to evaluate risk factors for anastomotic/septic complications in patients with Crohn's disease. In this retrospective analysis, anastomotic/septic and overall complication rates were 10.4% and 29.1%, respectively. The analysis of factors related to anastomotic/septic complications revealed that only serum albumin levels independently influence the anastomotic leakage. Interestingly, previously identified risk factors for anastomotic complications, including steroids, biologicals, the presence of percutaneous drainage of intra-abdominal abscess before surgery, and a hand-sewn anastomosis were not related to the development of anastomotic leaks in this study, which might be attributed to the exclusion of all diverted patients, unlike in previous studies. Excluding diverted patients would eliminate those considered high-risk. In terms of general complications, low albumin levels and pre-operative medical treatment were found to be associated. As we cannot fully characterize pre-operative medical treatment, it is impossible to say which agent is effective in this. Considering that the most common problem among the overall post-operative complications of our case series is wound dehiscence and superficial surgical site infection, we can predict that the most likely agent is steroids, which negatively affect wound healing. Therefore, stopping steroid treatment in the pre-operative period is essential in terms of superficial surgical site complications.

On the other hand, there are controversial results in the literature regarding pre-operative medical treatments with immunosuppressive and biological agents. It is known that immunosuppressive and biological agents have opposing dual effects, including reducing inflammatory activity and worsening immunomodulatory activity (10). In a meta-analysis, pre-operative biologic therapy has been found to be associated

with a modest increase in the risk of infectious complications. with a trend toward mostly non-infectious complication rates. In contrast, a recent study has found a significant association between pre-operative infliximab therapy and infectious and non-infectious post-operative complications, respectively (15,16). In contrast, two meta-analyses and one retrospective international multicenter study have reported no significant association between pre-operative biological therapy and the incidence of post-operative complications (10,17,18). Most of the studies included in these meta-analyses are retrospective or case-control studies and, therefore, do not allow control for critical confounding factors such as concomitant steroid therapy, as in our study.

Albumin, a negative acute phase reactant, can reflect the severity of systemic inflammation, malnutrition, or concomitant liver dysfunction, as well as serve as an essential element for collagen synthesis and fibroblast proliferation during the proliferative and remodeling phases of the wound healing process (19,20). In the current study, pre-operative hypoalbuminemia (<3 gr/dL) was an independent risk factor for anastomotic leakage, which is consistent with previous reports (7,20-22). Although hypoalbuminemia is not a direct indicator of pre-operative nutritional status, pre-operative feeding by enteral or parenteral may be considered if malnutrition exists and has been shown to improve outcomes (23).

Patients who necessitate pre-operative percutaneous drainage of intra-abdominal abscesses face heightened risks of anastomotic leakage and post-operative morbidity subsequent to intestinal resection and primary anastomosis (24). A recent multicenter study, involving 335 Crohn's disease patients undergoing percutaneous drainage followed by surgery, has reported a complication rate of 32.2% (25). It is known that this high rate is generally due to the fact that patients have the perforating type, which has a more aggressive course with excessive inflammation and high recurrence rates (24). In our current study, we did not observe a relationship indicating that pre-operative percutaneous abscess drainage increases the rate of anastomotic leakage or overall complication rates. We attribute this to the small number of total patients, the limited number of patients who underwent percutaneous abscess drainage, and the low number of patients with perforating type. Therefore, our study cannot provide guidance for patients who underwent pre-operative abdominal abscess drainage.

Current smoking habits also showed a significant correlation with anastomotic complications in the univariate but not multivariate analysis. Tobacco use is a risk factor for both anastomotic leak and disease recurrence due to various nicotine-related mechanisms, as shown in previous studies (26). Microthrombosis caused by increased platelet adhesion, decreased perfusion, reduced tissue oxygenation, and

vasoconstriction are among the mechanisms implicated, which suggests that patients with active or recent smoking habits should be informed about the increased risk of anastomotic leakage and disease recurrence (27).

Similar to many studies on this topic, the design of the current study is limited, notably by its retrospective observational analysis without a pre-operative protocol that can cause the presence of selection bias. Second, we were unable to fully characterize the severity of a patient's illness before surgery due to some data not being available, including weight loss, body mass index, and pre-operative medical treatment regimes. However, we believe that the level of albumin could provide an idea approximately in this regard. Third, we did not include emergency cases. Although this may seem like a limitation, it perhaps increases the value of our results. Because patients operated on in acute settings are likely those with septic conditions or intestinal obstruction, potentially increasing their risk of post-operative complications, it would lead to heterogeneity in our results. Although this study reported the results of the tertiary reference center for inflammatory bowel disease, large-scale prospective randomized controlled studies are needed to determine definitively the risk factors for an astomotic/septic complications in Crohn's disease.

Finally, well-timed, well-optimized elective surgery can only be achieved in a setting of close cooperation and multidisciplinary approach between inflammatory bowel disease surgeons and gastroenterologists (24,28). This collaboration will also help us better understand the course and characteristics of the disease and reduce post-operative complications and disease recurrences.

CONCLUSION

Understanding these risk factors could assist in the preoperative management of patients with Crohn's disease. First, it could signify the need for pre-operative nutritional support in instances of inadequate nutritional status. Second, the medical treatments should be discontinued in the pre-operative period due to the increased risk of overall complications. Finally, in patients with pre-operative hypoalbuminemia, temporary stoma creation should be considered due to the potential increased risk of high anastomotic complications.

Ethics Committee Approval: This study was obtained from Marmara University Faculty of Medicine Clinical Research Ethics Committee (Decision no: 09.2023.890, Date: 14.07.2023).

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ORİJİNAL ÇALIŞMA-ÖZET

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Crohn hastalığında elektif intestinal rezeksiyon sonrası anastomoz komplikasyonları için risk faktörleri

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ÖZET

Giriş ve Amaç: Cerrahi tedavi gerektiren Crohn hastalarında, anastomoz kaçakları morbiditenin en önemli sebeplerinden biridir. Bu komplikasyonu önlemek açısından ilişkili risk faktörlerinin belirlenmesi çok önemlidir. Olgu serimizde, anastomoz komplikasyonları açısından olası risk faktörlerini değerlendirmeyi amaçladık.

Gereç ve Yöntem: 2015-2023 yılları arasında Marmara Üniversitesi Tıp Fakültesi Genel Cerrahi Kliniğinde Crohn hastalığı nedeniyle bağırsak rezeksiyonu ve anastomoz yapılan, 18 yaş üzeri 86 hasta retrospektif, gözlemsel ve tek merkezli olarak planlanan bu çalışmaya dahil edildi. Proksimal saptırıcı ileostomi veya kolostomi ile anastomoz yapılmayan olgular çalışma dışı bırakıldı.

Bulgular: Hastaların ortalama yaşı 34,8 (±14,4) yıl olup, 50 (%58,1)'si erkektir. Yirmi beş hastada ameliyat sonrası komplikasyon (%29,1) görüldü ve bunların 10 (%11,6)'u Clavien-Dindo sınıflamasına göre derece üç ve üzerindeydi. İki hastada anastomoz kaçağı, iki hastada intra-abdominal koleksiyon, iki hastada sepsis, üç hastada enterokütanöz fistül ve bir hastada ileus görüldü. Albümin değeri <3 g/dL (OR= 5,15, p< 0,03) ve ameliyat öncesi medikal tedavi (OR= 4,79; p= 0,05) postoperatif genel komplikasyonlarla ilişkili bulunurken, yalnızca hipoalbüminemi <3 g/dL (OR= 14,3; p= 0,04) postoperatif anastomoz/septik komplikasyonlarla ilişkili bulundu.

Sonuç: Crohn hastalarında postoperatif anastomoz kaçağı ile ilişkili tek risk faktörü olarak albümin düşüklüğü saptanmıştır. Hipoalbüminemili hastalarda koruyucu stoma düşünülmelidir. Pre-operatif dönemde kullanılan Crohn'a özgü medikal tedavilerin genel komplikasyonları arttırabilmesi nedeniyle, bu tedavilerin pre-operatif dönemde kesilmesi önerilir.

Anahtar Kelimeler: Crohn hastalığı, postoperatif komplikasyonlar, anastomoz kaçağı

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