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Predictors of rectovaginal fistula recurrence in patients with Crohn's disease

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ABSTRACT

AIM: to determine the risk factors rectovaginal fistula (RVF) recurrence in patients with CD.

PATIENTS AND METHODS: a retrospective analysis included 60 patients with perianal fistulizing Crohn disease and rectovaginal fistulas (2016–2024). In order to identify the risk factors of RVF recurrence, the clinical and history data of 28 patients who underwent radical treatment for RVF were collected and analyzed.

RESULTS: the follow-up period for the patients after surgery was 3–12 months. According to clinical and instrumental data, recurrence of the disease occurred in 11/28 (39%) females. Multifactorial analysis showed increase the likelihood of RVF recurrence was the avoid of a loose seton at the first stage (odds ratio (OR) = 27.49; 95% confidence interval (CI): 2.02–374.8; $p = 0.013$). Absence of biological therapy to treat Crohn's disease (OR = 15.77; 95% CI: 1.13–220.4; $p = 0.04$) reduces the incidence of RVF recurrence as well.

CONCLUSION: patients with RVF represent the most challenging cohort of patients with perianal fistulizing Crohn disease (PFCD) due the significant recurrence rate, however combined two-step approach and careful assessment of risk factors before surgery improve the results.

KEYWORDS: rectovaginal fistula, Crohn's disease, perianal fistulizing Crohn's disease, PFCD, RVF

CONFLICT OF INTEREST: the authors declare no conflict of interest

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INTRODUCTION

Crohn's disease (CD) is a chronic inflammatory, recurrent disease of the gastrointestinal tract (GIT) of unknown etiology, which in 25% of cases may be followed by perianal fistulas [1]. One of its manifestations is the formation of a rectovaginal fistula (RVF). It is worth noting that Crohn's disease is the second most common cause of RVF after obstetric trauma [2]. The prevalence of RVF is about 10% of all fistulas that occur in patients with CD [3,4]. Clinical manifestations of rectovaginal fistula are symptoms such as the release of gases and intestinal contents from the vagina, as well as dyspareunia, discomfort and pain in the

anus, vagina and perineum, leading to a significant deterioration in the quality of life of female patients [5]. Treatment of rectovaginal fistulas in patients with Crohn's disease is an extremely difficult task and requires a personalized approach. Despite the rapid development of surgery and the improvement of surgical treatment methods, RVF in Crohn's disease still have a high risk of relapse [6,7]. Recently, there is no ideal technique that makes it possible to exclude the recurrence of the disease in postoperative period. Therefore, a study aimed at identifying factors influencing rectovaginal fistula recurrence after surgical treatment in female patients with CD seems relevant.

PATIENTS AND METHODS

The study included 60 women with perianal fistulizing Crohn's disease with rectovaginal fistula, who had undergone surgery in the Center in the period between September 2016 and December 2024. The diagnosis of rectovaginal fistula was proved in the presence of a defect in the rectovaginal septum, confirmed by examination of the perianal area, digital examination of the vagina and rectum, transrectal ultrasound and/or pelvic magnetic resonance imaging (MRI). According to instrumental data, the diameter of the internal fistula opening, the length and diameter of the fistula passage and the presence of purulent tracks and cavities along the fistula were identified. Patients without a confirmed diagnosis of Crohn's disease, as well as without subsequent dynamic follow-up, were excluded.

Prior to the surgery, the patients were consulted by a gastroenterologist and examined in the scope of colonoscopy, gastroscopy, CT-enterography, on the basis of which such data as: history and nature of Crohn's disease; previous operations, associated with complications of the disease; localization of inflammatory sites; availability of anti-recurrence therapy were evaluated.

The following clinical data were retrospectively analyzed: age; body mass index (BMI); duration of history of rectovaginal fistula; number and volume of previous surgeries; number of childbirths; presence of stoma. The study group mainly included young females, whose median age was 35 (28; 45)

years. The clinical characteristics are presented in more detail in Table 1.

Out of the female patients included in the study, 27/60 (45%) ones were those who had not given birth, 18/60 (30%) ones had a history of one childbirth, 13/60 (22%) ones had two childbirths, and 2/60 (3%) ones had three childbirths. 13/60 (21%) females had a previously formed stoma, while the majority of patients did not have a stoma — 47/60 (79%), (Table 2).

The number and volume of previous operations in all 60 female patients were evaluated. The surgical procedures performed on the patients can be divided into three groups: 1) 39/60 (65%) patients underwent fistula tracks incision and latex seton as the first stage of the treatment; 2) 12/60 (20%) patients immediately underwent radical excision of the rectovaginal fistula without seton as the first stage; 3) 9/60 (15%) patients underwent proctocolectomy/intrasphincteric resection without intervention for rectovaginal fistula due to the significant severity of perianal lesions (Fig. 1).

In total, radical surgical treatment was performed in 28 patients (Table 3). This group was analyzed separately to identify factors influencing the recurrence rate after surgery. Recurrence was defined as the persistence of symptoms, such as the release of gases or intestinal contents through the vagina and confirmed by the presence of a defect in the rectovaginal septum during clinical examination, as well as ultrasound and/or MRI of the pelvic organs.

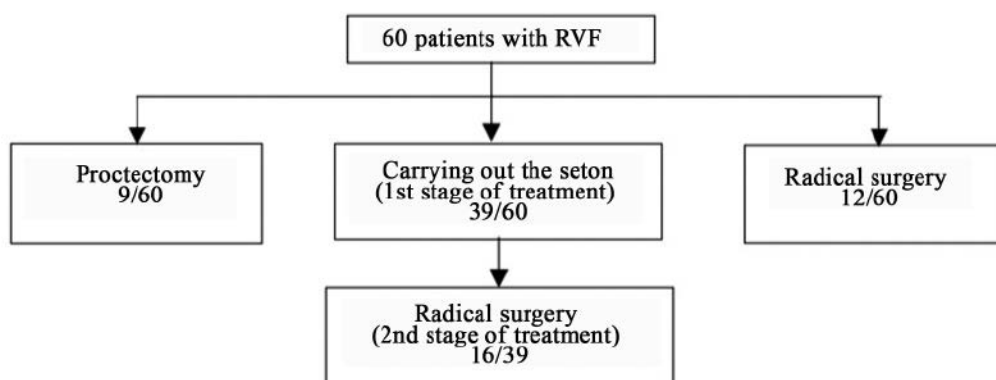


Figure 1. Operations for rectovaginal fistulas

Table 1. Clinical characteristics of patients with rectovaginal fistulas

Parameters	Female patients with RVF, N = 60 Me (Q1; Q3), (min–max)
Age, years	34.5 (27.5; 45), (18–59)
BMI (kg/m ²)	21.5 (18.9; 23.9), (13–37)
CD history (years)	6 (3; 8.5), (0.2–25)
RVF history (years)	2 (0.75; 3), (0.2–10)

Table 2. Clinical and anamnestic data of patients with rectovaginal fistulas

Parameters	Female patients with RVF, N = 60 n (%)
A form of Crohn's disease	
Terminal ileit	3 (6)
Ileocolite	30 (50)
Colitis	27 (44)
A history of childbirths	
0	27 (45)
1	18 (30)
2 and more	15 (25)
The presence of a stoma	13 (21)
Incision of perianal abscess in history	
0	32 (54)
1	20 (34)
2	4 (6)
3	4 (6)
History of operations for RVF	11 (18)
History of intestinal resection for CD	18 (30)

Table 3. Characteristics of radical surgical interventions performed in patients with rectovaginal fistulas

Parameter	Female patients with RVF, who had undergone radical surgeries, N = 28 n (%)
Surgery type	
Advancement rectal flap	13 (46)
Evagination method	10 (36)
Invagination method	3 (11)
Separate suturing	2 (7)

Statistical Analysis

Patient data was entered into Microsoft Excel 2019 for Windows. A statistical data analysis was performed in the Statistica 13.3 program (TIBCO Software Inc., USA). Quantitative data is represented by the median (Me), the lower and upper quartiles (Q1; Q3), as well as the minimum and maximum values (min–max). The significance level of the differences was assumed at $p < 0.05$. To identify risk factors for recurrence, a univariate and multivariate analyses of clinical and anamnestic parameters were performed using logistic regression.

The results obtained are represented by the odds ratio (OR) and the 95% coincidence interval (CI). With a statistically significant influence of factors

in the univariate analysis, these parameters were included in the multivariate model.

RESULTS

Sixteen (57%) of 28 females underwent two-stage surgical treatment with latex seton; 12/28 (43%) patients underwent radical surgery without the first stage of treatment (Fig. 1). The postoperative follow-up period was 3–12 months.

Recurrence developed in 11/28 (39%) patients. It was revealed that factors such as: age, a history of IBD and rectovaginal fistula, number of previous operations (including with the use of bioplastic materials), activity of Crohn's disease; the presence of proctitis or additional cavities in the

Table 4. Risk factors for rectovaginal fistula recurrence

Factors		OR (95% CI)	p
Age (years)		1.05 (0.98–1.14)	0.2
BMI (kg/m ²)		0.89 (0.74–1.07)	0.2
IBD history (years)		1.04 (0.9–1.2)	0.5
RVF history (years)		0.87 (0.61–1.24)	0.4
Opening of perianal abscess in the history (number)		2.03 (0.63–6.6)	0.2
Radical operations (number)		0.22 (0.04–1.25)	0.09
History of intestinal resection	Yes	1	0.3
	No	2 (0.42–9.42)	
The presence of a stoma	Yes	1	0.9
	No	0.9 (0.18–4.5)	
Latex seton (1st stage of treatment)	Yes	1	0.006
	No	13 (2.1–79.6)	
The number of childbirths in the history	0	1	0.6
	1	1.75 (0.22–14.2)	
	2	8.2 (1.03–64.9)	
Crohn's disease activity	Activity	0.73 (0.14–3.94)	0.7
	Remission	1	
A history of proctitis	Yes	1	0.3
	No	0.4 (0.07–2.34)	
Length of the fistula track		0.96 (0.89–1.05)	0.3
Diameter of the fistula		1.15 (0.54–2.43)	0.7
The presence of addition tracks and cavities in the history	Yes	1.44 (0.17–12.2)	0.74
	No	1	
Use of bioplastic materials	Yes	1	0.09
	No	0.13 (0.01–1.4)	
Use of biological therapy	Yes	1	0.038
	No	6.07 (1.1–33.2)	

Table 5. Causes of stoma formation in patients with rectovaginal fistulas

The cause of stoma formation	Female patients with RVF and the presence of a stoma, N = 9, n (%)	Recurrence, n
Intestinal resection with stoma	5 (55)	3/5
Perianal manifestations	4 (45)	1/4

history; length and diameter of the fistula track; presence of stomas did not affect the recurrence rate (Table 4).

According to the results obtained, the absence of latex seton as the first stage of treatment before the excision of the rectovaginal fistula (OR = 13; 95% CI: 2.1–79.6; $p = 0.006$) and the absence of the use of various types of genetically engineered biological drugs (GEBD) as a treatment for Crohn's disease (OR = 6.07; 95% CI: 1.1–33.2; $p = 0.038$) increase the likelihood of rectovaginal fistula recurrence. Also, if there are 2 or more childbirths in the history ($p = 0.047$), the likelihood of a recurrence (Table 4).

The risk factors for diverting stoma were analyzed (Table 5). However, no association between the occurrence of recurrence and the absence of a stoma was found ($p = 0.91$), (Table 4).

A multivariate analysis of risk factors of recurrence revealed that there was no latex seton (OR = 27.49; 95% CI: 2.02–374.8; $p = 0.013$) and avoiding biological therapy (OR = 15.77; 95% CI: 1.13–220.4; $p = 0.04$) were associated with an increased risk of RVF recurrence (Table 6).

Some of the patients were re-operated with a positive outcome (3/11): in 2/11 patients, the rectovaginal fistula was eliminated with the

Table 6. Multivariate analysis of factors affecting rectovaginal fistula recurrence

Factors		Number of recurrences	OR (95% CI)	p
Number of childbirths	0	2/11	1	0.15
	1	3/11	9.2 (0.46-187.14)	
	2 and more	6/11		
Latex seton (1st stage of treatment)	Yes	2/11	1	0.013
	No	9/11	27.49 (2.02-374.8)	
Use of biological therapy	Yes	4/11	1	0.04
	No	7/11	15.77 (1.13-220.4)	

Table 7. Characteristics of retrospective studies on surgical treatment of rectovaginal fistulas in patients with Crohn's disease

Author/ A country	Year	N	Average number of surgeries, N	Healing of RVF	Method	The healing factor	The recurrence factor
El-Gazzaz et al. [8] / USA	2010	65	1	30 (46.2%)	Lowering of the flap (n = 47); Sphincteroplasty (n = 8); Proctectomy (n = 7); Fibrin glue (n = 3)	Immuno- modulators (p = 0.009); Seton (p = 0.08)	Smoking (p = 0.04); Hormones (p = 0.04)
Gaertner et al. [9] / USA	2009	51	1	27 (53%)	Seton (n = 35); The flap (n = 12); Fibrin glue (n = 8); Sphincteroplasty (n = 6); Bioimplant (n = 6)	–	–
Otero- Piñeiro et al. [10] / USA	2022	166	2	55 (33.1%) after the first surgery; 86 (51.8%) after the second surgery; 103 (62.1%) after the third surgery	Fistulectomy, sphincteroplasty, seton, advancement rectal flap, fibrin glue, proctectomy (n = 360)	–	Smoking (p = 0.014); Seton (p = 0.012)
Manne et al. [11] / USA	2016	63	1	47 (75%)	Flap lowering (n = 25); Advancement rectal flap with seton (n = 38)	Seton (p = 0.0012)	Crohn's disease activity
Tracaneli et al. [12] / France	2021	32	3	7 (22%)	Seton (n = 36); Advancement rectal flap (n = 20); Fibrin glue (n = 16); Bioimplant (n = 11); Sphincteroplasty (n = 11)	Biological therapy (p = 0.007)	–
Narang et al. [13] / USA	2016	99	2	63.7 (63%)	Advancement rectal flap (n = 59); Graciloplasty (n = 14) Sphincteroplasty (n = 23); Fibrin glue (n = 3)	Obstetric fistulas (p = 0.002)	–

advancement rectal flap, and 1 more patient (1/11) underwent evagination procedure; 1 patient (1/11) refused surgery due to the absence of a negative effect of the disease on quality of life; 2/11 patients underwent proctectomy for the progression of Crohn's disease; 5/11 patients are scheduled to undergo re-operation.

DISCUSSION

The treatment of rectovaginal fistulas in Crohn's disease is a complex problem that requires a combination of different types of conservative and surgical treatment. Despite the availability of many papers there is currently insufficient data on risk factors affecting the incidence of recurrence. It should be noted that there is no indication in

any foreign publication about the use of evagination treatment method (Table 7).

It was found that age, body mass index, clinical and morphological characteristics of Crohn's disease, duration of the disease, previous surgeries, as well as the presence of a stoma do not significantly affect the recurrence of RVF after surgical treatment. Currently, there is no definitive evidence in favor of stoma formation in the treatment of rectovaginal fistulas [14]. This study confirms the absence of this factors affecting RVF recurrence, which coincides with the results of previously published scientific papers on the treatment of rectovaginal fistulas in the general population [15].

According to the univariate analysis, patients with a history of more than 2 childbirths are at increased risk of recurrence of RVF after surgery. The negative effect of this factor can be explained by the cicatrix deformation of rectovaginal septum that occurs after childbirth, which contributes to both the retraction of the flap and the reverse migration of the 'evaginated' part of the intestine after evagination procedure.

A direct effect of latex seton before surgery with the use of genetically engineered biological drugs on reducing the risk of RVF recurrence was revealed. According to the literature, seton in combination with biological therapy increases the likelihood of successful surgery, reduces the recurrence rate and accelerates the healing of perianal fistulas in patients with CD [16]. Most studies on the perianal fistulizing in Crohn's disease did not include patients with rectovaginal fistulas. This study confirmed the effectiveness of two-stage treatment of rectovaginal fistulas in patients with CD in combination with biological therapy. This approach ensures the suppression of active rectal inflammation and adequate drainage of the fistula. Despite the fact that the use of biological therapy promotes the healing of a fistula, surgery is still the only radical treatment method. In the study, there were no significant differences between one or another surgical method with respect to the recurrence risk.

However, the data may be limited by the small sample size of patients and the retrospective nature of the study. At the same time, the effectiveness of the evagination method is comparable to traditional surgical methods of treating RVF [15]. The choice of the surgical method remains controversial. It should be noted that the characteristic features of perianal fistulas in CD are the presence of a wide internal fistula, as well as significant scarring of the anal canal wall proximal to the opening, which often makes it technically impossible to form a rectal flap [11]. In this regard, the role of the evagination method, which is most effective when the diameter of the fistula is more than 16 mm, increases for the correction of significant defects of the rectovaginal septum [15]. It is impossible to say unequivocally whether the recurrence of rectovaginal fistula is a recurrence or a new manifestation of Crohn's disease due to insufficient therapy aimed at maintaining remission of the disease. The presence of a rectovaginal fistula in Crohn's disease indicates a severe disease and increases the risk of an unfavorable outcome, including proctectomy [17]. Thus, out of the patients included in this study, 11 females underwent proctectomy due to severe perianal fistulizing Crohn's disease, out of whom 2/11 patients had previously undergone unsuccessful surgical treatment of a rectovaginal fistula.

The risk of RVF recurrence in patients with CD remains high regardless of the choice of surgery, which makes it necessary to find new treatment methods. The use of mesenchymal stem cells and auto-transplantation of adipose tissue components demonstrates its effectiveness and safety in the treatment of rectal fistulas in Crohn's disease, and is likely to reduce the incidence of RVF recurrence in this category of patients [18,19].

CONCLUSION

Patients with rectovaginal fistulas represent the most difficult cohort of patients with perianal lesions in Crohn's disease due to the high recurrence rate. However, combined two-stage treatment and

careful assessment of risk factors in the preoperative period can improve the results.

AUTHOR CONTRIBUTIONS

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