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RISK FACTORS FOR THE DEVELOPMENT OF COMPLICATIONS OF ILEAL POUCH IN PATIENTS WITH ULCERATIVE COLITIS

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AIM: to reveal risk factors of complications after ileal pouch-anal anastomosis (IPAA) in ulcerative colitis (UC).
PATIENTS AND METHODS: from September 2011 by July 2018, 144 patients, who underwent IPAA surgery for UC were included in the study. Univariate and multivariate analyses were performed to reveal the risk factors for complication of IPAA, such as pouchitis, cuffitis, pouch fistulas, anastomotic stricture, pouch leakage, bleeding from IPAA, incontinence and small bowel obstruction (SBO).
RESULTS: multivariate regression analysis showed that left-sided UC (OR=12,5, 95% CI 1,7-92; p=0,01), patient's age ⩽33 years (OR=5,7, 95% CI 1,54-21,3; p=0,009) and hormone-free period before the IPAA ⩽10 months (OR=6,86, 95% CI 1,49-31,56; p=0,01) were associated with cuffitis. The fibrotic changes/wound infection in the anal canal (OR=5,02, 95% CI 1,02-24,69; p=0,04) and albumin <35 g/l (OR=8,11, 95% CI 2,12-30,99; p=0,002) were associated with fistulas. Time between IPAA formation and preventive ileostomy closure >5,6 months was associated with SBO (OR=2,82, 95% CI 1,01-8,31; p=0,0495). Steroid therapy at the time of IPAA surgery was associated with pouch leakage (OR=15,62, 95% CI 2,09-116,64; p=0,007). Hand-sewn IPAA (OR=42,54, 95% CI 3,51-516,43; p=0,003) were associated with incontinence. Ulcerative defects in the distal part of the rectum according to transrectal ultrasound were associated with anastomotic stricture (OR=10,46, 95% CI 1,52-71,75; p=0,017). There were no statistically significant risk factors for pouchitis and IPAA bleeding.
CONCLUSION: determination of the risk factors for complications of IPAA is a crucial clinical issue for patients with UC. We identified several factors associated with increased risk of complications after pouch surgery. Nevertheless, it seems promising to continue the study in order to create the mathematical model that predicts the development of a specific pouch-related complications and determines a group of patients with UC in whom the formation of IPAA is not recommended due to high risk of complications and impaired quality of life.

[Key words: ulcerative colitis; ileal pouch; complications; risk factors]

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INTRODUCTION

Removal of the large intestine with the ileal pouch-anal anastomosis (IPAA) was first performed in 1978 by Parks and Nichols [1], and in recent years has become the «gold standard» in the surgical treatment of patients with ulcerative colitis (UC) [2]. To date, the J-pouch is the most common, because it combines simplicity of design and satisfactory treatment results [3,4]. However, despite the improvement in the quality of life of patients, expressed in the possibility of maintaining anal defecation, there are many IPAA-associated complications, the incidence of which remains high and ranges from 30 to 60% [5-7]. In this regard, the definition of risk factors for such complications is extremely relevant.

PATIENTS AND METHODS

The retrospective single-center study included 144 patients who had IPAA operated between September 2011 and July 2018. The median follow-up for patients with IPAA was 32 (20; 43) months. The aim of this study was to improve the results of treatment of patients with UC who underwent removal of the large intestine and IPAA formation.

A regression analysis of the influence of various factors on the development of the most common complications was done: pouchitis, cuffitis, pouch fistulas, anastomotic stricture, pouch leakage, bleeding from IPAA, incontinence, small bowel obstruction (SBO) [7-9]. The following factors were used for the analysis: gender, age of patients,

Table 1. *Characteristics of patients who underwent IPAA formation (n=144)*

Factor	Value	Min–Max
Gender (M/W)	83 (58%) /61 (42%)	–
Age (years old), Me (quartiles)	31 (26; 41)	18-57
Height (cm), Average ±σ	172.4±10.2	149-199
Weight (kg), Me (quartiles)	68 (56; 79)	42-97
BMI (kg/m^2), Average ±σ	22.8±3.5	15.4-32.1

Table 2. *Anamnestic data of patients who underwent IPAA formation (n=144)*

Factor	Value	Min–Max
The UC history before IPAA formation (months.), Me (quartiles)	32.5 (14; 58)	1-240
HT in the anamnesis (YES/NO)	122 (85%)/22 (15%)	–
Over all HT duration(months)), Me (quartiles)	3 (1; 6)	0,1-40
Maximum dose of prednisone (mg), Me (quartiles)	100 (70; 125)	25-625
Hormone-free period before IPAA formation (months.), Me (quartiles)	7.5 (5; 12,5)	0-132
HT in IPAA formation (YES/NO)	5 (3.5%)/139 (96.5%)	–
Biological therapy (BT) in the anamnesis (YES/NO)	31 (21.5%)/113 (78.5%)	–
Number of BT courses, Me (quartiles)	3 (2; 5)	1-26
Use of oral 5-aminosalicylic acid (5-ASA) in the anamnesis (YES/NO)	121 (84%)/23 (16%)	–
The treatment duration with oral forms of 5-ASA (months.), Me (quartiles)	7 (3; 13)	1-108

Table 3. *Data of instrumental methods of study of patients before IPAA formation*

Factor	Value
Presence of cicatricial/purulent-septic changes in the anal canal YES/NO, *n*=144	11 (7.5%) /133 (92.5%)
The degree of inflammatory process activity in the rectum according to colonoscopy (Schroeder classification), *n*=144	
– is absent	16 (11.1%)
– light	72 (50%)
– moderate	46 (31.9%)
– severe	10 (7%)
The degree of inflammatory process activity in the large intestine according to colonoscopy (Schroeder classification), *n*=143	
– is absent	0
– light	4 (2.8%)
– moderate	16 (11.2%)
– severe	123 (86%)
Length of bowel lesion according to colonoscopy (Montreal classification), *n*=143	
– proctitis	0
– left-sided colitis	8 (5.6%)
– total colitis	135 (94.4%)
The presence of ulcerative defects in the distal part of the rectum according to TRUZI IS/is NOT, *n*=129	21 (16.3%) /108 (83.7%)
Pathological vascularization in the distal part of the rectum according to) – transrectal ultrasound (TRUS), *n*=129	
– is absent	36 (27.9%)
– light	23 (17.8%)
– moderate	33 (25.6%)
– severe	37 (28.7%)
The wall thickness of the rectal distal part according to TRUS (mm), Me (quartile) (min-max)	4.2 (3.5; 5) (2.1-8)
Evaluation of the anal incontinence (AI) according to sphincterometry, *n*=137	
– norm	81 (59.1%)
– AI of the 1 degree	52 (38%)
– AI 2 degree	3 (2.2%)
– AI 3 degree	1 (0.7%)

anthropometric data (Table 1), the patient's history before IPAA formation (Table 2), instrumental data (Table 3) and laboratory (Table 4) research methods, as well as intraoperative data (Table 5) and morphological data of the removed large intestine (Table 6).

Taking into account the retrospective nature of the study and the lack of information necessary for analysis in a number of patients, some regression analyses studied the influence of risk factors for complications in groups smaller than 144 patients. Most of the patients were young. Thus, the median of this indicator

Table 4. *Data of laboratory methods of study of patients before IPAA formation*

Factor	Value	Min–Max
Average hemoglobin level (g/l) ±σ, *n*=141	129.4±17.5	80-179
The average level of erythrocytes (10^{12}/l) ±σ, *n*=140	4.9±0.6	2.8-6.7
Leukocytes(10^9/l), Me (quartiles), *n*=141	6.7 (5.5; 8.4)	2,9-19
Platelets (10^9/l), Me (quartiles), *n*=140	295.5 (244; 354)	140-715
Erythrocyte sedimentation rate by Westergren (mm/h), Me (quartiles), *n*=128	14.5 (6; 21)	2-43
Total protein (g/l), Me (quartiles), *n*=135	73.7 (69; 77)	53-95
Albumin (g/l), Me (quartiles), *n*=130	44 (40; 47)	24-54
Glucose (mmol/l), Me (quartiles), *n*=138	4.9 (4.5; 5.4)	2.7-11.1
C-reactive protein (mg/l), Me (quartiles), *n*=106	2.2 (1.2; 8.7)	0.2-188.9

Table 5. *Intraoperative data in IPAA formation (n=144)*

Factor	Value	Min–Max
The period from colectomy/coloproctectomy to IPAA formation (months), Me (quartiles)	6.6 (4.5; 10,3)	0-84.3
Number of surgical steps in the anal defecation recovery: (2/3)	25 (17.4%) /119 (82.6%)	–
Operation duration (min.), Me (quartiles)	220 (180; 262.5)	115-540
Volume of intraoperative blood loss (ml), Me (quartiles)	80 (50; 100)	5-1300
Pouch length (cm), Me (quartiles)	17 (16; 18)	12-25
Length of the rectal stump (cm), Me (quartiles)	1 (1; 1.5)	0-3
Type of anastomosis: pouch ileal rectal/anal anastomosis (PIRA/PIAA)	127 (88.2%) /17 (11.8%)	–
The pouch anastomosis tension in IPAA formation YES/NO	18 (14.3%) /126 (85.7%)	–

Table 6. *Morphological data of the removed bowel*

Factor	Value
The degree of inflammatory process activity in the removed rectum according to morphological study, *n*=142	
– is absent	5 (3.5%)
– minimum	32 (22.5%)
– moderate	65 (45.8%)
– severe	40 (28.2%)
The degree of inflammatory process activity in the removed bowel according to morphological study, *n*=138	
– is absent	1 (0.7%)
– minimum	0
– moderate	15 (10.9%)
– severe	122 (88.4%)
Presence of severe dysplasia/colorectal cancer YES/NO, *n*=133	3 (2.3%) /130 (97.7%)

was 31 (26; 41) years old. There were 83 (58%) men and 61 (42%) women. The average height of the patient was 172±10.15 (149-199) cm, median weight – 68 (56; 79) (42-97) the Average body mass index corresponded to normal values – 22.8±3.5 (15.43-32.05) kg/m^2.

To determine the risk factors for IPAA-associated complications, a univariate and multivariate Cox regression analysis was performed in Statistica 13.3.

In the future, continuous data series were reduced to binary values using ROC analysis in the MedCalc program.

Among the studied continuous signs subjected to binary transformation were: age, height, weight of the patient, the level of hemoglobin, albumin, the hormone-free period before the IPAA formation, the rectal stump length, the period from the IPAA formation to the closure of the ileostomy.

RESULTS

Of the 144 patients who underwent the IPAA formation, 89 (61,8%) during the entire follow-up period from September 2011 to May 2019 and at various times revealed 140 IPAA-associated complications (Table 7).

At the same time, 4 complications were registered in 2 patients, 3 complications in 6 patients, and 2 complications in 33 patients. 48 patients developed one complication each. The median complication number per patient was 1.0 (0; 2).

Forty-two (29,2%) of the 144 patients who had undergone the IPAA formation developed pouchitis. However, when we conducted a univariate analysis, none of the studied risk factors showed statistical significance for the incidence of this complication. Proctitis in the postoperative period was detected 24 (16,7%) patients. In a univariate analysis, the risk

Table 7. *The nature and incidence of IPAA-associated complications in patients who have undergone the IPAA formation*

Complication*	Number of patients (*n*=144)
Pouchitis	42 (29.2%)
Proctitis	24 (16.7%)
Fistula	18 (12.5%)
Small bowel obstruction	16 (11.1%)
Pouch leakage	14 (9.7%)
Anal incontinence (AI)	13 (9%)
Stricture	11 (7.6%)
Bleeding	2 (1.4%)
** The total amount of complications is not equal to 100% because patients had a combination of two or more complications.*	

Table 8. *Cox-regression analysis of risk factors for proctitis*

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
Age of patient (⩽33 years old)	4.38	1.41-13.57	0.011	5.7	1.54-21.3	0.009
Hormone-free period before the IPAA formation (⩽10 months)	6.54	1.45-29.49	0.015	6.86	1.49-31.56	0.01
Extent of lesion (left-sided colitis)	5.78	1.33-24.88	0.019	12.5	1.7-92	0.01

Table 9. *Cox-regression analysis of risk factors for the development of fistulas*

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
The level of albumin (<35 g/l)	7.72	2.09-28.4	0.002	8.11	2.12-30.99	0.002
Cicatricial/purulent-septic changes in the anal canal (Yes)	7.69	2.06-28.73	0.002	5.02	1.02-24.69	0.04

Table 10. *Cox-regression analysis of risk factors for pouch leakage*

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
The length of the rectal stump (⩽0.5 cm)	5.84	1.84-18.55	0.003	4.28	0.61-30.01	0.144
Anastomosis type (PIAA)	5.46	1.57-18.96	0.007	0.64	0.07-5.90	0.693
HT in IPAA formation (YES)	7.06	1.07-46.45	0.042	15.62	2.09-116.64	0.007
The pouch anastomosis tension in IPAA formation (YES)	7.38	2.19-24.82	0.001	4.67	0.68-32.09	0.117

factors leading to the development of this complication were: the extent of the bowel lesion according to colonoscopy (total colitis/left-sided colitis) – (OR=5.75, 95% CI 1.33-24.88; *p*=0.019), the patient's age less than or equal to 33 years old – (OR=4.38, 95% CI 1.41-13.57; *p*=0.011), the hormone-free period before the IPAA formation is less than or equal to 10 months – (OR=6.52, 95% CI 1.45-29.49; *p*=0.015). When multivariate analysis of independent risk factors for proctitis were recognized all of the above factors: the presence of left-sided lesions according to colonoscopy – (OR=12.5, 95% CI 1.7-92; *p*=0.01), the patient's age is less than or equal to 33 years old- (OR=5.7, 95% CI 1.54-21.3; *p*=0.009), and the hormone-free period before the IPAA formation is less than or equal to 10 months – (OR=6.86, 95% CI 1.49-31.56; *p*=0.01) (Table 8).

IPAA fistulas were detected in 18 (12.5%) cases. As a result of univariate analysis, risk factors were determined: the presence of cicatricial/purulent-septic changes in the anal canal – (OR=7.69, 95% CI 2.06-28.73; *p*=0.002); the level of albumin less than 35 g/l – (OR=7.72, 95% CI 2.09-28.4; *p*=0.002).

When conducting a multivariate analysis, both of these factors demonstrated independent prognostic value as increasing the probability of fistula development – (OR=5.02, 95% CI 1.02-24.69; *p*=0.04) and (OR=8.11, 95% CI 2.12-30.99; *p*=0.002) (Table 9).

In 16 (11.1%) patients during the follow-up in a hospital small bowel obstruction developed.

Among all the analyzed risk factors, the only significant factor leading to this complication was only the period from the IPAA formation till the closure of the ileostomy more than 5.6 months – (OR=2.82, 95% CI 1.01-8.31; *p*=0.0495).

Pouch leakage was detected in 14 (9,7%) patients.

Predictors of pouch leakage in univariate analysis were: type of anastomosis (IRAA) – (OR=5.46, 95% CI 1.57-18.96; *p*=0.007), the HT in the IPAA formation – (OR=7.06, 95% CI 1.07-46.45; *p*=0.042), the tension of the pouch anastomosis in the IPAA formation – (OR=7.38, 95% CI 2.19-24.82; *p*=0.001), the length of the rectal stump is less than or equal to 0.5 cm – (OR=5.84, 95% CI 1.84-18.55; *p*=0.003).

When conducting a multivariate analysis, the only independent risk factor for the development of pouch leakage was the HT in the IPAA formation – (OR=15.62, 95% CI 2.09-116.64; *p*=0.007) (Table 10).

Table 11. *Cox-regression analysis of risk factors for AI*

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
Number of surgical steps in the anal defecation recovery (3)	0.29	0.09-0.97	0.045	0.3	0.07-1.36	0.117
The pouch anastomosis tension in IPAA formation (YES)	3.71	1.01-13.65	0.048	0.28	0.02-4.09	0.349
Age of the patient (>31 years old)	6.51	1.39-30.52	0.0175	4.24	0.75-24.11	0.103
Anastomosis type (PIAA)	14.12	3.98-50.11	0.00004	42.54	3.51-516.43	0.003

Table 12. *Cox-regression analysis of risk factors for anastomosis strictures*

Factor	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
Patient's gender (M)	0.14	0.03-0.69	0.015	0.16	0.01-2.73	0.206
Anastomosis type (PIAA)	13.31	3.49-50.71	0.0001	10.38	0.72-148.68	0.085
The presence of ulcerative defects in the distal part of the rectum according to TRUS (YES)	8.13	1,97-33,49	0.004	10.46	1.52-71.75	0.017
The height of the patient (⩽167 cm)	10.38	2.11-51.16	0.004	1.29	0.12-13.57	0.831
The weight of the patient (⩽44.7 kg)	10.38	2.11-51.16	0.004	5.14	0.47-56.88	0.182
The anastomosis tension (YES)	7.69	2.06-28.73	0.002	0.64	0.038-11.04	0.761

Anal incontinence (AI) in the postoperative period revealed in 13 (9%) patients.

In a univariate analysis, the factors that increase the risk of AI were: anastomosis type (PIAA) – (OR=14.12, 95% CI 3.98-50.11; *p*=0.00004), the number of surgical stages in the anal defecation recovery equal to three – (OR=0.29, 95% CI 0.09-0.97; *p*=0.045), the pouch anastomosis tension in the IPAA formation – (OR=3.71, 95% CI 1.01-13.65; *p*=0.048), patient's age over 31 years old – (OR=6.51, 95% CI 1.39-30.52; *p*=0.0175).

When conducting a multivariate analysis, only the type of formed anastomosis (OR=42.54, 95% CI 3.51-516.43; *p*=0.003) was a significant factor that increased the risk of AI in patients (Table 11).

In 11 (7.6%) patients anastomotic pouch stricture was diagnosed. Among the studied risk factors in a univariate analysis, significant were: male gender of the patient – (OR=0.14, 95% CI 0.03-0.69; *p*=0.015), pouch – anal anastomosis type – (OR=13.31, 95% CI 3.49-50.71; *p*=0.0001), the presence of ulcerative defects in the distal part of the rectum according to TRUS – (OR=8.13, 95% CI 1.97-33.49; *p*=0.004), the pouch anastomosis tension in the IPAA formation – (OR=7.69, 95% CI 2.06-28.73; *p*=0.002), the patient's height is less than or equal to 167 cm – (OR=10.38, 95% CI 2.11-51.16; *p*=0.004), the patient's weight is less than or equal to 44.7 kg – (OR=10.38, 95% CI 2.11-51.16; *p*=0.004).

When carrying out a multivariate analysis, a significant independent risk factor for the anastomosis stricture was only the presence of ulcerative defects in the distal part of the rectum according to TRUS – (OR=10.46, 95% CI 1.52-71.75; *p*=0.017) (Table 12).

Two (1,4%) patients developed bleeding from IPAA sutures. However, in a univariate analysis, none of the factors demonstrated its significance in relation to the influence on the development of bleeding.

DISCUSSION

Our study is devoted to the analysis of risk factors for pouch-associated complications. The analysis was carried out separately for each type of complication. Comparing the results of the study with similar ones may be of interest, due to the possibility of predicting the risk of complications. Wu B. et al. (2013) revealed that evaluated risk factors for distal proctitis in 931 patients. As a result of the study, toxic megacolon or fulminant colitis (*p*=0.001), preoperative biological therapy (*p*=0.0001), and stapler pouch anastomosis formation without mucosectomy (*p*=0.02) were recognized as independent risk factors [10]. In this study, the above risk factors did not show significance.

Independent risk factors for the development of proctitis were the patient's age less than or equal to 33 years old, which in our opinion may be due to greater inflammation activity in young patients, and the hormone-free period before the IPAA formation less than 10 months, which may cause the occurrence of a relapse of inflammation in the distal rectum on the background of the cancellation of hormone therapy. IPAA fistulas are a rather difficult to eliminate complication, often leading to the pouch inefficiency. According to Tekkis P. et al. (2005), risk factors for their development after the IPAA formation are male gender – (OR=0.74, 95% CI 0.58-0.95; *p*=0.018), the presence of anal fistulas – (OR=4.02, 95% CI 1.27-12.77; *p*=0.018), perianal abscesses – (OR=3.43, 95% CI 2.43-4.84; *p*=0.001), and Crohn's disease – (OR=1.73, 95% CI 1.07-3.48; *p*=0.033) [11]. In the study, the gender of the patient did not demonstrate itself as a significant factor for fistulas, but were obtained the data similar to the results of Tekkis regarding the effect of wound infection in the anal canal on the development of this complication. At the same time,

the significance was demonstrated by the presence of hypoalbuminemia (albumin level <35 g/l); this factor was associated with an increased risk of IPAA fistula.
Many authors associate the development of small bowel obstruction after IPAA formation with the number of surgery stages and with the surgical access type. So Kameyama H. et al. (2018) in their study revealed that two-stage surgical treatment is an independent risk factor for SBO in comparison with three-stage surgery – (OR=2.85, 95% CI 1.01-8.04; *p*=0.048) [12]. A group of researchers from France, Italy, the Netherlands, and Belgium (2018) identified as independent risk factors for small bowel obstruction the cumulative complications associated with stoma – (OR=3.95% CI 1-6; *p*=0.03) and longterm postoperative hernia – (OR=6.95% CI 2-18; *p*=0.003). While subtotal colectomy as the first stage and laparoscopic access during the 2nd stage of surgical treatment were independent and reducing the risk of SBO factors – (OR=0.4, 95% CI 0.2-0.8; *p*=0.002) and (OR=0.2, 95% CI 0.07-0.8; *p*=0.02), respectively [13].
In this study, an independent factor in the development of small bowel obstruction was determined only the period from the IPAA formation till the closure of the ileostomy lasting more than 5.6 months. In 2002, Heuschen U. established that independent risk factors for pouch leakage was the hormone therapy at a dose higher than 40 mg/day and the age of patients older than 50 years old [14]. However, when analyzing our data, the only independent risk factor for the PL development was the HT in the IPAA formation. This fact, apparently, can be explained by the suppression of regeneration of the tissues of the anastomosed parts by steroids, which most likely impairs the healing of the anastomosis.
When conducting a multivariate analysis, only the type of anastomosis (RIAA) became a significant risk factor for the AI development in patients, which is most likely due to trauma to the anal sphincter during intersphincteric resection of the rectum and the pouch anal anastomosis. Many authors consider the risk factors for the strictures to include the imposition of a diverse loop ileostomy, tension of the mesentery of the small intestine, purulent-septic processes in the pelvis, an increased body mass index and a hand-sewed pouch anastomosis [15-17]. However, in the study, these factors were insignificant in multivariate analysis, but the significance was demonstrated by the presence of ulcerative defects in the distal part of the rectum according to TRUS.
In this study, none of the assessed risk factors demonstrated their influence on the development of pouchitis. According to Angriman I. (2014), total inflammation of the colorectal mucosa, retrograde ileitis, extraintestinal manifestations of UC, the presence of primary sclerosing cholangitis are among the risk factors for the pouchitis development. Also, the risk group includes non-smokers and regularly taking non-steroidal anti-inflammatory drugs (NSAIDs) patients [18].
Given the retrospective nature of our study, factors such as smoking and the frequency of NSAIDs use were not evaluated. However, all other risk factors have not shown their influence on the pouchitis development.

CONCLUSION

Summing up the results of the study, it should be noted that the independent risk factors for the development of proctitis were the presence of left-sided colitis according to colonoscopy, the patient's age less than or equal to 33 years old and the hormone-free period before the IPAA formation less than or equal to 10 months. For the fistulas, the presence of cicatricial/purulent-septic changes in the anal canal and hypoalbuminemia were the factors that significantly increased the probability of their development. The risk factor for the small bowel obstruction was the period from the IPAA formation till the closure of the preventive ileostomy lasting more than 5.6 months. HT in IPAA formation increases probability of the pouch leakage. The risk factor for the AI after the IPAA formation was the type of anastomosis. And the development of the pouch anastomosis stricture was influenced by the presence of ulcerative defects in the distal part of the rectum according to TRUS.
The analysis did not reveal significant risk factors for the pouchitis and bleeding from the IPAA. Thus, the problem of determining the risk factors for the development of the ileal-pouch complications remains relevant today. It is quite interesting to continue this study to create a mathematical model that predicts a particular complication in each patient, and to determine the group of patients with UC, in whom the IPAA formation is associated with an increased risk of complications.

THE PARTICIPATION OF THE AUTHORS:
Concept and design of the study: *Kulikov A.E., Achkasov S.I., Sushkov O.I.*
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The authors declare no conflict of interest.

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