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# Pouch failure in patients with ulcerative colitis

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**ABSTRACT** *AIM: to assess results of pouch surgery for ulcerative colitis (UC).*

*PATIENTS AND METHODS: the retrospective single-center study included 144 patients who underwent J-pouch surgery in 2011-2018 (4 patients refused ileostomy closure due to nonmedical reasons and were excluded from analysis). Median follow-up was 32 (20; 43) months. The definition of «pouch failure» (PF) was clarified as a condition, when J-pouch associated complications do not permit ileostomy closure ⩾ 12 months or more after pouch surgery.*

*RESULTS: PF was detected in 30/140 (21.4%) cases and only in 8/140 (5.7%) patients pouch was removed. The most common complication identified by PF was pouch fistula, which was detected in 16/30 (53.3%) patients. Of the 30 patients with PF, 22 (73.3%) managed to "save" the pouch, of which — in 11/30 (36.7%) cases, anal defecation was restored, and in other cases — 11 (36.7%) the ileostomy was not closed, but the pouch was preserved and is being treated conservatively. In 9/30 (30%) patients, the identified complications were performed by transanal removal of the remaining part of the rectum with the formation of a pouch-anal anastomosis, followed by closure of the ileostomy. In 8/30 (26.6%) cases pouch was removed. The multivariant analysis revealed hypoalbuminemia at the time of pouch surgery (OR = 5.74; 95% CI = 1.83-18.01; p = 0.003) as independent risk factors for PF.*

*CONCLUSION: the only independent risk factor for complications which lead to PF was hypoalbuminemia. Multi-stage surgical treatment of complications associated with the pouch made it possible to "save" the ileal pouch in 22/30 (73.3%) cases, and completely overcome PF and restore anal defecation in 11/30 (36.7%) cases. In 8/140 (5.7%) patients, the pouch had to be removed and a permanent ileostomy was done.*

***KEYWORDS:*** *ulcerative colitis, ileal pouch, complications, pouch failure, risk factors*

***CONFLICT OF INTEREST:*** *the authors declare no conflict of interest*

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## INTRODUCTION

Total proctocolectomy with J-pouch was first performed in 1978 [1], and since then has become the "gold standard" in the surgery for ulcerative colitis (UC) [2]. The J-pouch is the most attractive, because it combines simplicity of design and satisfactory results [3,4].

However, despite the possibility of preserving anal defecation, there are many pouch-associated complications, the incidence of which reaches 62% [5–7]. In a number of patients, the developed complications are the reason for the inability to use J-pouch, which may even require its removal [8–13]. Such a condition in the English-language literature is designated by the term "pouch failure" (PF) [14]. According to large-scale studies, the incidence of PF varies in the range from 5% to 18.2% [12,14,15]. To date, there is a discrepancy in the interpretation of this condition, which consists in the lack of a clear understanding of the timing of the onset of PF.

At the same time, most researchers define PF as the impossibility of its use and the need to

preserve a preventive ileostomy for a period of 6 to 24 months [12,13,16].

## AIM

To improve the results of treatment of ulcerative colitis who have undergone the pouch procedure.

## PATIENTS AND METHODS

A retrospective single-center cohort study included 144 patients with UC who underwent pouch surgery in 2011–2018. Median follow-up was 32 (20; 43) months. The following factors were used for the analysis: gender, age, anthropometric data, history of the disease, instrumental and laboratory tests, as well as intraoperative data (Table 1). Taking into account the retrospective nature of the study and the lack of information necessary for the analysis in a number of patients, the value of some of the analyzed signs was less than 144.

The median age of the patients who had J-pouch was 31 (26; 41) years. There were 83 (58.0%) men among them. The average height of the patients is 172 ± 10.15 cm, the median weight is 68 (56; 79) kg. The average body mass index corresponded to normal values — 22.8 ± 3.5 kg/m$^2$.

The median UC history was 32.5 (14; 58) months. One hundred twenty-two (85.0%) patients received steroids. At the same time, the formation of J-pouch against the background of steroid therapy was performed only in 5 (3.5%) cases.

Only 36 (27.9%) patients had no pathological vascularization in the distal part of the rectum before the formation of J-pouch, according to ultrasound data, while 37 (28.7%) of the patients had pronounced pathological vascularization.

The level of hemoglobin ⩾ 120 g/l before the J-pouch formation was found in 104 (72.4%) cases. Normal values of the leukocytes level were noted in 116 (80.9%) cases, and the level of blood albumin ⩾ 35 g/l was determined in 133 (92.3%) patients. The level of C-reactive protein ⩽ 5 mg/l was in 97 (67.7%) patients.

The median period from colorectal resection to J-pouch formation was 6.6 (4.5; 10.3) months.

A two-stage approach to restoring anal defecation was used in 16.7%, and a three-stage approach was used in 83.3% of patients. The median time of the pouch surgery was 220 (180; 262.5) minutes.

At the same time, in 122 (88.2%) cases, the formation of a stapler pouch-rectal anastomosis (PRA) was performed, and in 17 (11.8%) — hand sewn pouch-anal anastomosis (PAA).

Tension of the pouch anastomosis after the J-pouch formation noted by the surgeon during the surgery occurred in 18 (14.3%) patients.

## STATISTICAL ANALYSIS

To determine the risk factors for the pouch failure, a univariate and multivariate Cox-regression analysis was performed in Statistica program 13.3. In the future, continuous data series were reduced to binary values using ROC-analysis in the MedCalc program. The period of onset of pouch failure was also calculated using ROC-analysis in the MedCalc program.

## RESULTS

**Determination of Ileal Pouch Failure**

Out of 144 patients with J-pouch, 4 (2.8%) were excluded from the analysis due to the fact that they refused to close the preventive ileostomy and restore anal defecation for reasons unrelated to the complications. Thus, the analysis of the incidence, timing and risk factors for the development of pouch failure was carried out in 140 (97.2%) of 144 patients. At the same time, at the end of the study, the ileostomy was not closed in 23 (16.4%) of these 140 patients.

To determine the timing of the onset of PF, the period of ileostomy was evaluated. The median follow-up of the patients was 32 (20; 43) months.

To determine the correlation between the period of ileostomy after the J-pouch formation and the probability of its closure, a ROC-analysis was performed. The best sensitivity and specificity indicators predicting the impossibility of closing the ileostomy were recorded for a period > 11.9 months. The area under the curve was 0.983, which characterizes the quality of the model as

**Table 1.** *Characteristics of patients who underwent the J-pouch formation*

| Factor | Value | Min–Max |
|---|---|---|
| Gender M/F | 83 (58%) /61 (42%) | – |
| Age (years), 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/m2), Average ± σ | 22.8 ± 3.5 | 15.4–32.1 |
| Duration of UC anamnesis before J-pouch formation (months), Me (quartiles) | 32,5 (14; 58)<br>32.5 (14; 58) | 1–240 |
| Steroids in the history YES / NO | 122 (85%) /22 (15%) | – |
| Total duration of steroid therapy (months), Me (quartiles) | 3 (1; 6) | 0.1–40 |
| Steroids during J-pouchformation YES / NO | 5 (3.5%) /139 (96.5%) | – |
| Presence of cicatricial or inflammatory changes in the anal canal YES/NO, n = 144 | 11 (7.5%) /133 (92.5%) | |
| Presence of ulcerative defects in the distal part of the rectum according to TRUSYES/NO, n = 129 | 21 (16.3%)/108 (83.7%) | |
| Pathological vascularization in the distal part of the rectum according to TRUS, n = 129 | | |
| – Absent | 36 (27.9%) | |
| – Weak | 23 (17.8%) | |
| – Moderate | 33 (25.6%) | |
| – Pronounced | 37 (28.7%) | |
| Hemoglobin (g/l) ± σ, *n* = 141 | 129.4 ± 17.5 | 80–179 |
| Leukocytes (109/l), Me (quartiles), *n* = 141 | 6.7 (5.5; 8.4) | 2.9–19 |
| Albumin (g/l), Me (quartiles), *n* = 130 | 44 (40; 47) | 24–54 |
| C-reactive protein (mg/l),<br>Me (quartiles), *n* = 106 | 2.2 (1.2; 8.7) | 0.2–188.9 |
| Period from colectomy/proctocolectomy to J-pouch (months), Me (quartiles) | 6.6 (4.5; 10.3) | 0–84.3 |
| Number of surgical stages in the restoration of anal defecation: (2/3) | 25 (17.4%) /119 (82.6%) | - |
| Operative time (min.), Me (quartiles) | 220 (180; 262.5) | 115–540 |
| Intraoperative blood loss (ml), Me (quartiles) | 80 (50; 100) | 5–1300 |
| Pouch length (cm), Me (quartiles) | 17 (16; 18) | 12–25 |
| Rectal stump length (cm), Me (quartiles) | 1 (1; 1.5) | 0–3 |
| Type of anastomosis: pouch-rectal/anal anastomosis (PRA/PAA) | 127 (88.2%) /17 (11.8%) | - |
| Tension of pouch anastomosis during J-pouch formation YES/NO | 18 (14.3%) /126 (85.7%) | - |

**Table 2.** *The frequency of complications in 30 patients with inefficiency of the reservoir*

| Complication | *N* (%) |
|---|---|
| Fistula | 16 (53.3%) |
| Proctitis | 7 (23.3%) |
| Pouch leakage | 5 (16.7%) |
| Small bowel ileus | 5 (16.7%) |
| Pouchitis | 4 (13.3%) |
| Anastomosis stricture | 4 (13.3%) |
| Anal incontinence | 4 (13.3%) |
| Infectious spondylodis citis | 1 (3.3%) |

**Table 3.** *Cox-regression analysis of risk factors for complications that led to pouch failure*

| Sign | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | *p* | OR | 95% CI | *p* |
| Perianal lesions (YES/NO) | 5.2 | 1.46–18.46 | 0.011 | 4.06 | 0.94–17.6 | 0.061 |
| Duration of steroid therapy (> 4 months / ⩽ 4 months) | 2,55 | 1.05–6.2 | 0.038 | 2.36 | 0.84–6.62 | 0.1 |
| Albumin level (< 35 g/l / ⩾ 35 g/l) | 5.74 | 1.83–18.01 | 0.003 | 7.24 | 1.81–28.88 | 0.005 |

excellent, while the sensitivity was 100%, and the specificity was 92% (Fig.1).

Thus, 12 months after the J-pouch formation, the probability of the ileostomy closure is minimal, and makes it possible to regard this period as the moment of the onset of the pouch failure.

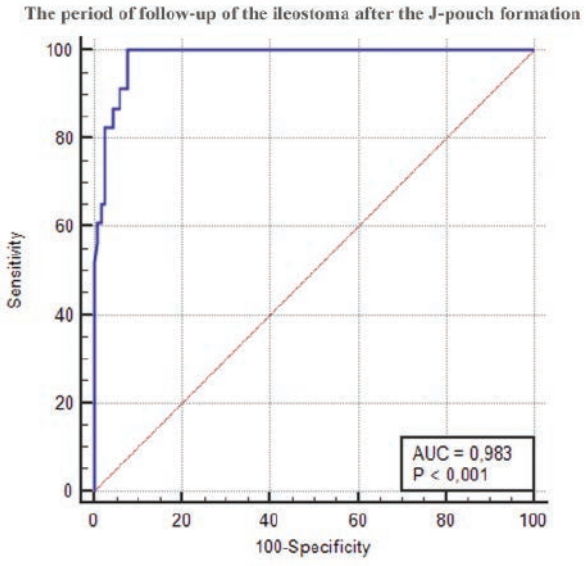


**Figure 1.** *ROC-curve of the correlation between the period of ileostomy after the J-pouch formation and the onset of the pouch failure. The area under the curve is 0.983 (95% CI: 0.95–0.99, p < 0.001). Cut-off point > 11.9 months*

Taking into account the literature data and the results obtained here, the term "pouch failure" should be understood as a pathological condition that occurs as a result of pouch-associated complications, and requires diversion of the J-pouch re-ileostomy or pouch removal, or does not allow closing the ileostomy after 12 months or more.

Thirty (21.4%) of 140 patients met the PF criteria we formed.

**Risk Factors for Pouch Failure in Patients with Ulcerative Colitis**

Out of 140 patients with J-pouch, 46 complications leading to the development of PF were registered in 30 patients. Of these, in 16 cases it was caused by one, in 12 cases — 2, and in 2 cases — 3 complications. The most common of these was pouch fistula, which was detected in 16 (53.3%) patients with pouch failure (Table 2).

To determine risk factors for complications leading to PF, preoperative and intraoperative data were analyzed.

Among the categorical indicators were: the gender of the patient; the number of stages of J-pouch formation; the type of operative access; the type of pouch anastomosis; the presence of steroid therapy in the history; the use

**Table 4.** *Cox-regression analysis of the impact of complications on the chance of developing pouch failure*

| Sign | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | *p* | OR | 95% CI | *P* |
| Pouchitis | 0.64 | 0.25–1.64 | 0.36 | | | |
| Proctitis | 2.28 | 0.86–6.04 | 0.1 | | | |
| Fistula | 61.14 | 12.7–294.47 | < 0.001 | 127.93 | 19.86–824.07 | < 0.001 |
| Anastomosis stricture | 2.64 | 0.69–10.05 | 0.15 | | | |
| Pouch leakage | 4.43 | 1.42–13.88 | 0.011 | 5.55 | 1.06–29.14 | 0.043 |
| Bleeding | 3.72 | 0.23–61.36 | 0.36 | | | |
| Anal incontinence | 2.53 | 0.76–8.38 | 0.13 | | | |
| Small bowel ileus | 3.38 | 1.14–10.03 | 0.028 | 13.72 | 2.86–65.87 | 0.001 |

of steroid therapy at the time of J-pouch formation; the presence of biological therapy in the history; the presence of perianal lesions; the activity of the inflammatory process in the rectum — according to colonoscopy; the activity of the inflammatory process in colon — according to colonoscopy; extent of colorectal lesion — according to colonoscopy; the presence of pathological vascularization in the distal part of the rectum — according to ultrasound; the presence of ulcerative defects in the distal part of the rectum — according to ultrasound; tension of the pouch anastomosis during the J-pouch formation; the degree of activity of the inflammatory process in the removed rectum — according to morphological research; the degree of activity of the inflammatory process in the removed colon — according to morphology.

Among the continuous indicators: the patient's age; height; weight; BMI; the period from colectomy to the J-pouch formation; the period from the J-pouch formation to the closure of ileostomy; the duration of the UC history; the maximum dose of steroids (in terms of prednisone); the duration of steroid therapy; the duration of the steroid-free period before the J-pouch formation; the number of courses of biological therapy; the duration of 5-ASAtherapy; wall thickness of the distal part of the rectum according to ultrasound; hemoglobin level; erythrocyte level; leukocyte level; platelet level; ESR; total protein level; albumin level; CRP level; glucose level; operative time; intraoperative blood loss; length of the pouch; length of the remaining part of the rectum.

As a result of the univariate analysis, the following factors were identified that increased the risk of complications leading to PF: the presence of perianal lesions (OR = 5.2, 95% CI 1.46–18.46, $p$ = 0.011), the duration of steroid therapy for more than 4 months. (OR = 2.55, 95% CI 1.05–6.2, $p$ = 0.038) and hypoalbuminemia (albumin level < 35 g/l) (OR = 5.74, 95% CI 1.83–18.01, $p$ = 0.003).

In the multivariate analysis, the only factor increasing the risk of complications that caused the development of PF was hypoalbuminemia (OR = 6.06, 95% CI 1.5–24.42, $p$ = 0.011) (Table 3).

Since PF is a condition caused by the development of pouch-associated complications, we evaluated the impact of each of them on the likelihood of failure. In the univariate analysis, the significance was demonstrated by the development of a pouch fistula, the pouch leakage and small bowel ileus (Table 4).

In the multivariate analysis, all of them became independent factors that increased the likelihood of PF: pouch fistula (OR = 127.93, 95% CI 19.86 -824.07, $p$ < 0.001), pouch leakage

(OR = 5.55, 95% CI 1.06 -29.14, $p$ = 0.043) and small bowel ileus (OR = 13.72, 95% CI 2.86 -65.87, $p$ = 0.001) (Table 4).

**Results of Treatment of Pouch-associated Complications That Led to the Development of Ileal Pouch Failure in Patients with Ulcerative Colitis**

Out of 30 patients with pouch failure, in 18 (60.0%) cases PF was detected after ileostomy closure, and in 12 (40.0%) — after J-pouch formation before preventive ileostomy closure.

In the group of 18 patients with PF diagnosed after the closure of the ileostomy, in order to eliminate the developed complications, J-pouch was diverted by re-ileostomy in 15 (83.3%) cases, and in 3 (16.7%) cases, its removal was performed due to the refusal of the patients from multi-stage surgical treatment. In 7 out of 15 cases, after re-ileostomy, transanal removal of the remaining part of the rectum was performed with the formation of a pouch-anal anastomosis. As a result of the treatment of these 15 patients, 9 of them had their ileostomy closed, 4 — did not have it closed, but J-pouch was preserved, and 2 patients required J-pouch removal.

In the group of 12 patients in whom PF developed before ileostomy closure, conservative treatment was performed in 10 (83.3%) cases, and the transanal removal of the remaining part of the rectum with the pouch-anal anastomosis formation was performed in 2 (16.7%) cases. As a result, out of the 12 patients, only 2 had an ileostomy closed, 7 patients did not have ileostomy closed, but they retained J-pouch, and 3 had J-pouch removal, of whom 2 patients refused multi–stage surgical treatment.

Thus, out of 30 patients with PF, in 11 (36.7%) cases the preventive ileostomy was closed, in 11 (36.7%) cases the ileostomy was not closed, but J-pouch was preserved, and in 8 (26.6%) cases J-pouch was removed. At the same time, in the group with removed J-pouch in 5 (16.7%) cases, this surgery was performed due to the refusal of patients from multi-stage surgical treatment.

## DISCUSSION

As a result of the study, we have defined the term “pouch failure” and analyzed the timing of its onset, identified risk factors for PF, and evaluated the results of treatment of complications that led to PF in patients with ulcerative colitis. To date, there are various interpretations of the term “pouch failure”. Many authors understand PF as a condition requiring removal of J-pouch or its disconnection from the passage of intestinal contents by re-forming an ileostomy, or the need to remove the remaining part of the rectum with resection of the distal sections of the J-pouch from the perineal access with the PIAA formation, or the formation of a new pouch [9–11]. At the same time, analyzing the time intervals of the onset of PF, it is indicated that it is impossible to use J-pouch and the need to remove ileostomy for a period of 6 to 24 months, while most authors indicate a period of 12 months [12,13,16]. As a result of the study, we have defined the term “pouch failure” as a pathological condition that occurs as a result of pouch-associated complications and requires diversion of the J-pouch from the passage of intestinal contents by removing it or re-ileostomy, and also does not allow closing the ileostomy after 12 months or more. This interpretation of the term, including the timing of the onset of PF, coincides with the opinions of most authors with extensive experience in “pouch surgery”.

According to Leowardi, C. and co-authors (2010), in 294 patients with a median follow-up of 11.5 years, the overall incidence of PF was 12.6%. At the same time, 5, 10 and 15 years after the J-pouch formation, it developed in 7.7%, 11.3% and 15.5% of patients, respectively [13]. In a later study by Mark-Christensen, A. and co-authors (2018) out of 1,991 patients with J-pouch with a median follow-up of 11.4 years, pouch failure occurred in 14.8% of cases. While after 5, 10 and 20 years, its rate was 9.1%, 12.1% and 18.2%, respectively [12]. The best results of J-pouch formation were demonstrated by Fazio, V.W. et al. in his paper in 2013.Out of 3,707 patients, only 197 (5.3%) had pouch failure. Among them, in 3.2% of cases pouch removal was required, in 0.9% — its prolonged switching off, and in 1.2% — it

was possible to re-form the J-pouch [17]. In our study, the incidence of pouch failure was higher than in the above studies, and amounted to 21.4%. Analyzing the results obtained, we assume that this may be due to two reasons. Firstly, with less experience in the J-pouch formation, only 140 patients were included in the study, while the median follow-up was 32 (20; 43) months. Secondly, with the frequent refusal of patients themselves from multi-stage surgical treatment of complications, the incidence of which was 16.7%. It is worth emphasizing that in 11 (36.7%) of 30 patients with PF, multi-stage treatment eventually allowed anal defecation to be restored.

In the study, 30 (21.4%) of 140 patients met the PF criteria before the treatment of complications. It seems to us that to designate this group of patients, it is advisable to introduce the term "primary" pouch failure, since after the treatment in 11 (36.7%) out of 30 patients, we managed to eliminate PF and, accordingly, to close the preventive ileostomy. At the same time, in 19 (13.6%) patients, the treatment did not bring a positive result, and in this group of the patients, the pouch failure can be called "secondary".

The analysis of predictors of its development is quite important from the point of view of predicting the pouch failure. So, in the previously mentioned study by Mark-Christensen, A. and co-authors (2018), a direct correlation was demonstrated between the risk of PF onset and the female sex (OR = 1.39, 95% CI 1.10–1.75), refusal to form a preventive ileostomy (OR = 1.63, 95% CI 1.11–2.41), as well as little experience in the pouch formation in a medical institution (⩽ 5 per 1 year versus ⩾ 20 per 1 year) (OR = 2.30, 95% CI 1.26–4.20) [12]. According to the study by Forbes, S.S. et al. (2009), in 1,554 observations of patients with J-pouch, the incidence of PF was 6.8%, and the factors significantly increasing the risk of PF were Crohn's disease (OR = 7.5, 95% CI 4.7–12.0) and purulent-septic complications in the pelvic region (OR = 6.6, 95% CI 4.4–9.8) [18]. In our study, the female gender did not demonstrate its influence on the PF development, which may be due to a relatively small sample of patients. Factors such as the refusal of preventive ileostomy and little experience in the J-pouch formation in a medical institution were not analyzed, since all pouch procedures in the institution ended with the removal of preventive ileostomy, and the number of such procedures was over 20 per year. In turn, in the multivariate analysis, hypoalbuminemia turned out to be an independent risk factor for PF, which is most likely due to a decrease in the reparative capabilities with a low level of albumin, and, accordingly, a higher risk of complications leading to PF. Also, the multivariate analysis showed independent factors that increase the likelihood of PF– complications associated with the J-pouch: pouch fistula, pouch leakage, which corresponds to the literature data, and small bowel ileus which is associated with a high incidence of re-ileostomy.

Thus, the problem of determining the risk factors for the pouch failurerecently remains quite relevant. It seems quite interesting to continue this study to determine a group of UC patients in whom the pouch is associated with a high risk of developing PF, which may cause rejection of its formation, as well as to increase the follow-up period for this group of patients and to analyze the effectiveness of their treatment in the long term.

## CONCLUSION

Results of the study showed that the only independent risk factor for the development of complications that led to PF was hypoalbuminemia. Pouch fistula, pouch leakage and small bowel ileus statistically significantly increased the likelihood of PF.

Multi-stage surgical treatment of complications associated with J-pouch allowed 11 (36.7%) of 30 patients to overcome PF and restore anal defecation. In 8 (5.7%) of 140 patients, complications developed in the J-pouch area led to its removal and the formation of permanent ileostomy.

**AUTHORS CONTRIBUTION**

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