https://doi.org/10.33878/2073-7556-2026-25-1-71-80

Displaced lateral rectal flap for anal fistulas

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ABSTRACT *AIM: evaluating effectiveness and safety of the method of fistula repair using a lateral rectal flap in patients with anal fistulas involving more than 1/3 of the external sphincter (complex anal fistulas).*
PATIENTS AND METHODS: a single-centre, prospective, single-group study included 60 patients who underwent anal fistula repair using a lateral rectal flap (LRF). The check-up before and after the surgery was carried out using instrumental methods — transrectal ultrasound (TRUS) and sphincterometry. The majority of patients had an extrasphincteric fistula (41/60 (68.3%)), pararectal cavities were detected in 39/60 (65%) patients, including multiple cavities in 23/39 (38.3%). The late results were studied after 3–12 months. The median follow-up was 7 (4; 8) months. The primary endpoint was the rate of non-recurrence cases (treatment effectiveness), the secondary ones were the assessment of continence, pain syndrome, risk factors for unsatisfactory results (recurrence).
RESULTS: the effectiveness of the LRF method was 48/60 (80%; 95% CI 67.7; 89.2) cases. Sphincterometry and Wexner's incontinence scale showed no worsening of continence after surgical treatment (1 (0; 3) point before the surgery and 2 (0; 3) points after 3–6 months (p = 0.68)). The assessment of risk factors for unsatisfactory results of LRF application revealed such factors as excess body weight (body mass index ⩾ 30.7 kg/m²) (body mass index ⩾ 30.7 kg/m²) (odds ratio (OR) = 1.14 (95% coincidence interval (CI) 1.02; 1.29), p = 0.02); purulent intersphincteric leaks (OR = 5.50 (95% CI 1.14; 26.6), p = 0.03); purulent ischioanal leaks(OR = 16.8 (95% CI 3.20; 7.55), p = 0.0009) and purulent pelviorectal leaks(OR = 7.86 (95% CI 1.69; 36.6), p = 0.008), as well as multiple purulent cavities (OR = 4.40 (95% CI 1.14; 16.9), p = 0.03).At the same time, the LRF method allows to achieve recovery in 28/39 (71.8%) patients with solitary cavities, and in 15/23 (65.2%) cases of multiple cavities.
CONCLUSION: the LRF method allows for the one-stage elimination of "complex" anal fistulas in 80% of cases, without worsening of anal continence. According to the Visual Analogue Scale, the median score did not exceed 3 for the entire follow-up period, what corresponds to a low level of pain; at the same time, the maximum intensity was noted on the 2–4 days after surgery, whereas by the 10 day almost all patients did not experience pain.

KEYWORDS: *anal fistula, RF, lateral rectal flap, LRF, anal incontinence, AI*

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

FOR CITATION: Nikishin T.V., Kostarev I.V., Titov A.Yu., Ignatenko M.A., Zharkov E.E., Dadashev I.I., Biryukov O.M., Pershina A.E., Mudrov A.A. Displaced lateral rectal flap for anal fistulas. *Koloproktologia.* 2026;25(1):71–80. (in Russ.). https://doi.org/10.33878/2073-7556-2026-25-1-71-80

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Received — 05.12.2025 *Revised — 19.12.2025* *Accepted for publication — 17.02.2026*

INTRODUCTION

Recently, all surgical methods for "complex" anal fistulas can be roughly divided into two groups. A conceptual feature of modern, so-called sphincter-sparing methods is the predominance of preserving sphincter function over radicality (Table 1).

Thus, it can be seen from Table 1 that modern sphincter-sparing methods are safe and non-traumatic, but effectiveness leaves much to be desired. In addition, additional fistula tracks remain a significant limitation to their use, in the vast majority of cases multi-stage treatment (seton) is required, and it is still necessary to carry out a separate transanal stage of the surgery — the

Table 1. *Effectiveness and safety of sphincter-sparing techniques for anal fistulas*

Method	Effectiveness (Min–Max, %)	Postoperative AI (Min–Max, %)	Purulent cavities (Min–Max, %)	Preventive seton (Min–Max, %)
LIFT [1,2,3]	28–94	1–23	6	43
VAAFT [4,5]	22–87	0–1	2	39
Fibrin glue [6,7]	42–79	0	0	68
Stem cells [8,9]	27–100	0	0	59
Collagen mesh[10,11]	20–88	0	0	73
OTSC [12,13]	38–65	0	0	98
FiLaC [14,15]	30–82	0–10	0	81

Table 2. *Effectiveness and safety of traditional methods in the treatment of anal fistulas*

Method	Effectiveness (Min–Max, %)	Postoperative AI (Min–Max, %)	Additional fistula tracks (Min–Max, %)	Preventive seton (Min–Max, %)
"Cutting" ligature [16,17]	70–93	8–22	0	0
Fistulectomy with sphincteroplasty [18–21]	84–96	7–27	–	48
Rectal advancement flap(proximal) [22,23]	55–99	0–25	35	65

Table 3. *Clinical characteristics of patients included in the study*

Indicators	All patients included in the study N = 60
Gender, n(%) Female Male	 32 (53.3%) 28 (46.7%)
Age, years, Me (Q1; Q3) Min–Max	46.5 (39.0; 55.5) 32–66
BMI, kg/m^2, Me (Q1; Q3) Min–Max	27.3 (24.9; 31.1) 18.9–40.6
Disease duration, months, Me (Q1; Q3) Min–Max	7 (4; 13) 1–112
The recurrent nature of the fistula, *n* (%)	10 (16.7%)
Preventive ligature, *n* (%)	13 (22.0%)

elimination of the internal fistula by various methods, including "traditional" ones. The effectiveness of "traditional" methods is higher (Table 2).

However, the risk of sphincter damage when using these methods reaches 26%. It should be noted that additional purulent tracks can also be a relative obstacle to the use of "traditional" methods, and therefore seton as the first stage is performed in 48–65%.

In 2022, a method for anal fistulas by moving the lateral rectal flap was developed and implemented at the Center [24].

AIM

To evaluate the effectiveness and safety of the surgical method for the removal of anal fistulas with a lateral rectal flap for "complex" rectal fistulas.

PATIENTS AND METHODS

To assess the effectiveness and safety of the surgical removal of "complex" rectal fistulas by moving the lateral rectal flap, a single-center, single-group prospective study included 60 patients with

Table 4. *Main sonographic characteristics of anal fistula as per TRUS*

Indicators	All patients included in the study N = 60
The position of the fistula relative to the external sphincter, *n* (%)	
Transsphincteric (surface portion)	8 (13.3%)
Transsphincteric (deep portion)	11 (18.3%)
Extrasphincteric	41 (68.3%)
Localization of the internal fistula opening, *n* (%)	
Anterior	36 (60.0%)
Lateral	6 (10.0%)
Posterior	18 (30.0%)

Table 5. *Localization and features of purulent extensions (according to TRUS)*

The nature and localization of purulent leaks	All patients included in the study N = 60, *n* (%)
Multiple tracks(> 1)	23 (38.3)
Subcutaneous track	16 (26.7)
Ishio-anal track	21 (35.0)
Retrorectal track	11 (18.3)
Pelviorectal track	9 (15.0)
Intersphincteric track	8 (13.3)
Submucosal track	2 (3.33)
In the rectovaginal septum	5 (8.3)
Intramural track	3 (5.0)

complex anal fistulas between November 2022 and January 2025.

The study group was slightly dominated by 32 (53.3%) women, 28 (46.7%) men. The age ranged from 32 to 66 years with a median of 46.5 (39.0; 55.5) years, and the disease history ranged from 1 to 112 months with a median of 7 (4.0; 13.0). Drainage (seton) were performed in 13/60 (22.0%) patients (Table 3).

Diagnostics

All patients underwent transrectal ultrasound, sphincterometry and Wexner's scale before and after (within 3 to 6 months) surgery by LRF method. As part of the follow-up protocol, patients underwent daily pain syndrome assessment on a visual analog scale (VAS) after surgery.

Transrectal Ultrasound

Extrasphincteric fistulas were detected in 41 (68.3%) patients. Additional purulent cavities in the ischioanal space and/or the rectal wall was also visualized in most cases (39/60 (65.0%)). Moreover, 23/39 (38.3%) patients had multiple cavities and tracks (Tables 4, 5).

Assessment of Continence

According to the sphincterometry data, 49/60 (81.7%) patients included in the study showed a decrease in pressure in the anal canal at the preoperative stage, corresponding to grade 1 anal incontinence. It should be noted that in none of the cases in that group of patients were there clinical manifestations of anal sphincter incontinence. In 3/60 (5.0%) cases, anal sphincter incontinence of the 2nd grade was revealed, with clinical manifestations in the form of incontinence of gases and liquid stools (Table 6).

When assessing the continence using Wexner's anal incontinence scale in the preoperative period, the scores ranged from 0 to 11, and the median was 1 (0; 3) point.

Table 6. *Sphincterometry parameters before surgery*

Anal pressure readings		Norm (min–max)	The study group, N = 60	
			Me (Q1; Q3)	Min–Max
Average anal resting pressure, mmHg	Females	41–63	38 (37; 40)	29–50
	Males	43–61		
Maximum absolute anal squeeze pressure, mmHg	Females	110–178	148.5 (127; 169)	93–236
	Males	121–227		

Surgical Technique and Management of Patients in the Postoperative Period

The surgery is performed under spinal anesthesia in a supine position, as for a lithotomy. After revision of the perianal region, anal canal, probing, staining with dye of the fistula track and purulent cavities, the first stage of the surgery is performed — fistulectomy up to the intestinal wall, as well as opening and drainage of purulent-inflammatory foci.

The second stage is the plastic closure of the internal fistula using a lateral rectal flap. After water injection the submucosal layer of the anal canal wall and the distal part of the low rectum in the projection of the internal fistula, an arcuate incision of the anoderm is performed to mobilize the lateral mucosal-submucosal flap. Then, by transanal access, from the fistula opening in the anal canal laterally, the mucosal-submucosal flap of the wall of the low rectum with cavernous tissue (the internal hemorrhoid node closest to the surgery site) is mobilized, if present. Extremely economical excision of pathologically altered tissues in the area of the "skeletonized" internal fistula opening is performed, or its curettage, followed by its suturing.

Next, the formed flap is shifted towards the fistula opening, closing it. Then the edge of the displaced flap is fixed to the edge of the wound.

No bed rest was prescribed to the patients on the first day after the surgery. In the postoperative period, patients underwent daily wound control the fixed flap, sutures and postoperative complications.

A digital rectal examination was not performed for 1 month after the surgery, in order to reduce the risk of reverse displacement of the fixed flap.

To evaluate the results of using the LRF method, primary and secondary endpoints were identified: the primary endpoint is the incidence of non–recurrence of the disease (treatment effectiveness), the secondary one is the assessment of the rectal closure apparatus function, severity of pain syndrome, risk factors for recurrence.

Statistical Analysis

Statistical data processing was performed in RStudio (R v. 4.4.1 (R Core Team, Vienna, Austria)) using the libraries base, gtsummary, ggplot2, pROC, ROCR and GenBinomApps. The values of qualitative nominal features were given in the form of absolute and relative frequencies (*n* (%) or *n*/N (%)). Continuous and qualitative ordinal values (with a number of values ⩾ 5) were described by the median, lower and upper quartiles (Me (Q1; Q3)), as well as the span (Min-Max). In order to assess the changes in quantitative values, Wilcoxon's criterion was applied for related groups. The search for factors that could be associated with the occurrence of relapse was carried out using a univariate logistic regression analysis indicating the value of the odds ratio (OR) and its 95% CI according to Wald's method. To assess the effect of a quantitative variable on outcome, a ROC analysis was performed, the area under the ROC curve (AUC), its standard deviation, 95% CI, and significance level were calculated. The cut-off point was determined by Yoden's criterion; sensitivity, specificity, predictive value of a positive result (PPV) and predictive value of a negative result (NPV) were calculated for it; for these indicators, as well as for the primary point of the study, 95% CI was calculated using Clopper-Pearson's method.

Table 7. *Assessment of anal sphincter function before and after lateral rectal flap repair*

Values	Before surgery N = 60	After surgery N = 46	*p*
Wexner's scale score, points, Me (Q1; Q3) Min–Max	1 (0; 3) 0–11	2 (0; 3) 0–12	0.68
Average anal resting pressure, mm Hg, Me (Q1; Q3) Min–Max	38 (37; 40) 29–50	38 (36; 40) 27–46	0.86
Maximum absolute anal squeeze pressure, mm Hg, Me (Q1; Q3) Min–Max	148.5 (127; 169) 93–236	150.5 (130; 164) 98–224	0.46

The differences were considered statistically significant at $p < 0.05$.

RESULTS

The operation time ranged from 15 to 95 minutes with a median of 40 (30; 50) minutes, and no intraoperative complications occurred. In the postoperative period, patients got nonsteroidal anti-inflammatory drugs, there was no need to prescribe narcotic analgesics. The median pain level did not exceed 3 points for the entire follow-up period in all patients. The maximum intensity of pain was noted on the 2–4 days after the surgery, which is most likely due to the first act of defecation in the postoperative period. After 4 days, the intensity of pain begins to decrease actively, and by the 10th day there is practically no pain (Fig. 1).

In the postoperative period, on day 14, 1/60 (1.7%) patient produced a lateral flap retraction, and the patient underwent seton outpatient.

The median number of days spent by patients in hospital was 7 (6.0;8.5).

All the patients were examined within 3–6 months. According to the clinical and instrumental examination, recurrence of the disease was diagnosed in 12/60 (20.0%; 95% CI: 10.8 — 32.3) patients. Thus, the effectiveness of the method was 48/60 (80%; 95% CI 67.7; 89.2) cases.

An assessment of the continence, using sphincterometry and Wexner's scale and performed in 46 patients after the surgery, showed the absence of

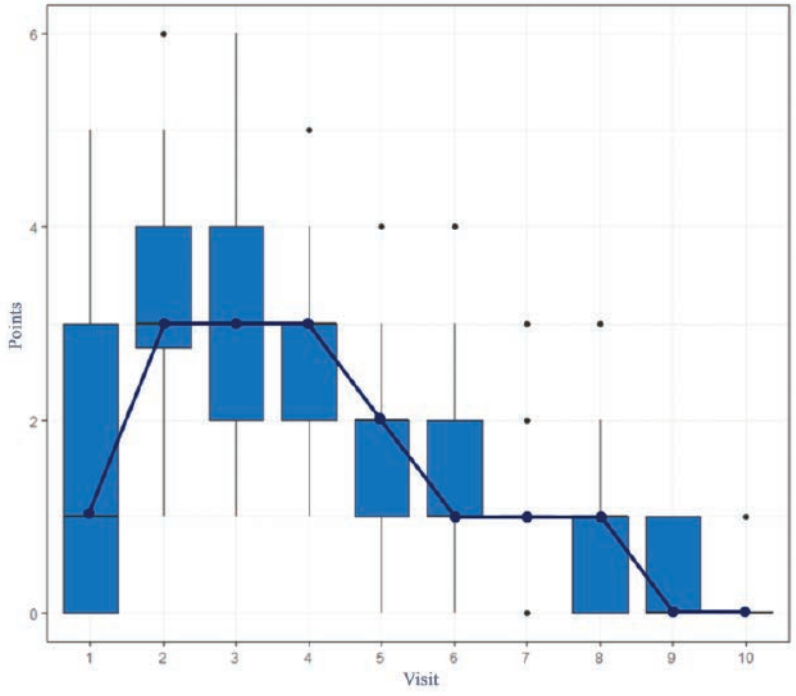

Figure 1. *Pain scores (according to the Visual Analogue Scale, VAS) for 10 days in postoperative period*

Table 8. *Univariate analysis of factors potentially influencing AF recurrence*

Factors		OR (95% CI)	*p*
BMI, kg/m²		1.14 (1.01; 1.29)	**0.02**
Age, years		1.01 (0.95; 1.07)	0.82
Duration of the disease, months		1.01 (0.98; 1.04)	0.55
Radical surgery for a history of fistula		1.00 (0.18; 5.46)	1.00
Seton before LRF		0.27 (0.03; 2.34)	0.23
History of anal surgery		0.15 (0.02; 1.27)	0.08
The nature of resolving acute paraproctitis	Spontaneous opening of acute abscess	1.29 (0.36; 4.57)	0.69
	Operative incision of acute abscess	0.78 (0.22; 2.76)	0.69
The position of the fistula relative to the muscles of the external sphincter	Transsphincteric	0.53 (0.06; 4.80)	0.57
	Extrasphincteric	6.60 (0.79; 55.5)	0.08
Diameter of the internal fistula opening, mm		0.96 (0.59; 1.57)	0.88
The presence of purulent-inflammatory foci (leaks)	Multiple tracks(> 1)	4.40 (1.14; 16.9)	**0.03**
	Subcutaneous track	0.90 (0.21; 3.84)	0.88
	Ishio-anal track	16.8 (3.20; 88.5)	**0.0009**
	Retrorectal track	1.67 (0.37; 7.55)	0.50
	Pelviorectal track	7.86 (1.69; 36.6)	**0.008**
	Intersphincteric track	5.50 (1.14; 26.6)	**0.03**
	Submucosal track	4.27 (0.25; 73.8)	0.31
	Intramural track	9.40 (0.77; 144)	0.07

Table 9. *Impact of purulent tracks and their location on the success of LRF in complex anal fistulas*

The presence, nature and localization of purulent leaks	Number of cured patients (*n*/N (%))
Purulent tracks	28/39 (71.8%)
Multiplepurulent tracks	15/23 (65.2%)
Intersphincteric track	4/8 (50.0%)
Ishio-anal track	11/21 (52.4%)
Pelviorectal track	4/9 (44.4%)
Retrorectal track	8/11 (72.7%)
Submucosal track	½(50.0%)
Intramural track	1/3 (33.3%)
Subcutaneous track	13/16 (81.3%)
Track in the rectovaginal septum	5/5 (100%)

damaging effects of the LRF method on the anal sphincter (Table 7).

To assess possible predictors of rectal fistula recurrence after the use of a displaced lateral flap, a univariate analysis of potential risk factors was performed (Table 8).

One of the identified factors that increased the risk of anal fistula recurrence was an increased body mass index. When constructing the ROC curve, it was found that with a body mass index ⩾ 30.7 kg/m², the probability of disease recurrence increases (OR = 1.14; 95% CI 1.02; 1.29; $p = 0.02$) (Fig. 2).

In addition, significant risk factors for fistula recurrence were purulent tracks in the intersphincteric (OR = 5.50 (95% CI 1.14; 26.6), $p = 0.03$), ischio-anal (OR = 16.8 (95% CI 3.20; 7.55), $p = 0.0009$) and pelviorectal spaces (OR = 7.86 (95% CI 1.69; 36.6), $p = 0.008$), as well as their combination (multiple

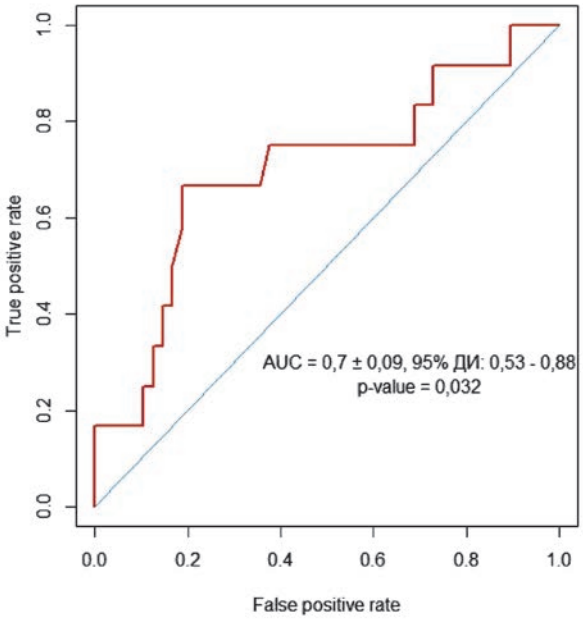

Figure 2. *ROC is the curve of AF recurrence versus body mass index. AUC = 0.7 ± 0.09 (95% CI 0.53; 0.88), p = 0.032, cut-off point corresponds to kg/m2. TPR = 66.7% (95% CI 34.9; 90.1%). FPR = 81.3% (95% CI 67.4; 91.1%). PPV (positive predictive value) = 47.1% (95% CI 23.0; 72.2%). NPV (negative predictive value) = 90.7% (95% CI 77.9; 97.4%)*

tracks) (OR = 4.40 (95% CI 1.14; 16.9), $p = 0.03$). At the same time, purulent-inflammatory foci located retrorectally, submucosally, and intramurally did not worsen the prognosis of LRF use. It is worth noting that 39/60 (65.0%) patients included in the study had purulent-inflammatory foci (tracks), of whom in 28/39 (71.8%) patients, recovery was achieved. In 23/39 (59.0%) cases, the leaks were multiple; after applying the proposed method, the fistula was eliminated in 15/23 (65.2%) patients. Thus, even in the presence of leaks, which statistically significantly affects the outcome of the use of LRF, healing was achieved in more than 60% of those patients (Table 9).

Recurrence was detected in 12/60 (20.0%) cases. Of those, 2/12 (16.7%) patients refused re-operation. 10/60 (16.7%) patients underwent re-operation in 4–9 months. In 8/10 (80.0%) cases, seton was performed. Further, taking into account the distal migration of the fistula after the application of the lateral flap and the subsequent migration of the seton, the fistulectomy into the intestinal lumen was performed in all 8 cases. In 1/10 (10.0%) case, the fistula was successfully eliminated by seton in the intersphincteric space. In 1/10 (10.0%) cases, the LRF displacement method was reused with a positive result (Fig. 3).

DISCUSSION

The prototype for the LRF method is the currently most popular method of surgical treatment of

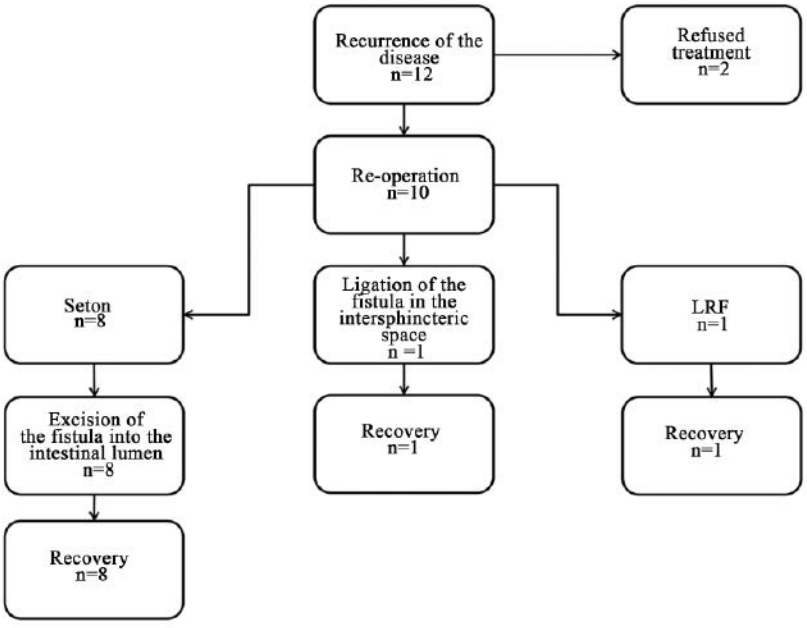

Figure 3. *Management strategy for patients with recurrent anorectal fistula after lateral flap procedure*

"complex" anal fistulas — the rectal (proximal) flap, compared to which, in our opinion, the lateral rectal flap has a number of advantages in certain clinical situations:

- The method is technically simpler, since the "angle of attack by the surgeon" during lateral flap mobilization is located significantly more distally than with the proximal flap;
- The possibility to choose the most optimal tissue for the flap.

So, if with a proximal flap there is no alternative to the rectum located above the internal fistula opening, then with a lateral flap, it is possible to evaluate two options for the formation of a flap, to the right and to the left of the internal fistula opening;

- Sufficient vascularization of the displaced flap: flap mobilization is performed with incorporation into the layers of cavernous tissue;
- Lack of connection between the anatomical area of flap extraction and the cellular spaces, where the presence of purulent leaks is possible;

In our opinion, the method of eliminating the internal fistula with a displaced lateral flap can be considered as one of the full-fledged methods of surgical treatment of "complex" rectal fistulas with any localization of the purulent process, despite the fact that its effectiveness is statistically significantly worse in the presence of purulent-inflammatory leaks in the intersphincteric, ischioanal, pelviorectal spaces. The currently accepted concept of surgery for "complex" rectal fistulas in the presence of a purulent process in the cellular spaces involves a multi-stage treatment, where the first stage is the opening and drainage of purulent tracks, and then the choice of a method of radical treatment of rectal fistula is necessary. That is, in most cases, patients are "doomed" to at least two operations.

The proposed method, with minimal trauma to the anal canal (in fact, the transanal stage is comparable in terms of surgical trauma to "hemorrhoidectomy of one node (without its removal)" or the formation of a site in the anal canal during ligation), even in the presence of the most unfavorable factors, makes it possible to achieve recovery after the first surgery in almost half of patients with "complex" rectal fistulas (50% of patients with leaks in intersphincteric space; in 52.4% of cases — with ischioanal localization of the purulent process; in 44.4% of cases — with pelviorectal tracks). If a recurrence of the disease is suspected, a drainage ligature is performed, that is, the "other" half receives treatment within the framework of the "classical" concept of surgery for complex rectal fistulas.

CONCLUSION

The method of eliminating the internal fistula with a displaced lateral flap allows for the single-stage elimination of "complex" rectal fistulas in 80% of cases. Two-stage surgical treatment, including repeated use of the LRF method, makes it possible to achieve a cure in 96.7% of patients. Taking into account the minimal risk of postoperative complications, the low intensity of pain syndrome, and the absence of a negative effect on the functional state of the anal sphincter, the LRF method is safe and low-traumatic.

AUTHORS CONTRIBUTION

Concept and design of the study: *Andrey A. Mudrov, Timur V. Nikishin*

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