СТАТЬИ НОМЕРА **LEADING ARTICLES** 

https://doi.org/10.33878/2073-7556-2025-24-3-22-34





# Chronic anal fissure treatment using lateral internal sphincterotomy without excision: prospective randomized study (NCT05117697)

Evgeny E. Zharkov<sup>1</sup>, Sergey I. Achkasov<sup>1,2</sup>, Yuri A. Shelygin<sup>1,2</sup>, Ivan V. Kostarev<sup>1,2</sup>, Alexey A. Ponomarenko<sup>1</sup>, Andrey A. Mudrov<sup>1,2</sup>

A.N. Ryzhikh National Medical Research Center of Coloproctology, Ministry of Health of Russia (Salyama Adilya st., 2, Moscow, 123423, Russia)

<sup>2</sup>Russian Medical Academy of Continuous Professional Education, Ministry of Health of Russia (Barrikadnaya st., 2/1, Moscow, 125993, Russia)

ABSTRACT AIM: to assess the outcomes of chronic anal fissure treatment using lateral internal sphincterotomy with and without fissure excision.

> PATIENTS AND METHODS: a prospective, single-center, randomized study included 107 patients with chronic anal fissure (CAF) older than 18 years, without severe comorbidities, rectal fistulas, grade 3-4 hemorrhoids, or clinical manifestations of anal sphincter insufficiency (ASI) from October 2021 to October 2023. Patients were randomized using a random number generator into two groups: 56 patients in the main group underwent lateral internal sphincterotomy (LIS), and 51 patients in the control group underwent LIS combined with fissure excision (LIS + FE). Immediate results were analyzed per protocol in 50 patients per group. Late outcomes were assessed in 44 patients in the main group and 43 patients in the control group. Primary endpoint: epithelialization of the defect on the 60th day after surgery. Secondary endpoints: epithelialization of the defect on the 15th, 30th, and 45th days postoperatively, incidence and structure of complications, pain syndrome (VAS from day 1 to day 60), profilometry indicators on the 30th, 60th, and 365th days postoperatively, time of temporary disability, incidence of ASI on the 30th, 60th, and 365th days postoperatively (Wexner's scale), and recurrence rate.

> RESULTS: by day 60, the anal fissure had epithelialized in 47/50 (94%) patients in the main group, while the postoperative wound had healed in 48/50 (96%) patients in the control group (p = 1). On days 15, 30, and 45, the epithelialization rate of the anal fissure was significantly higher than that of the postoperative wound. Fissure excision increased the likelihood of an unhealed postoperative wound on day 30 (OR 18.7 95% CI: 5.8-60.4; p < 0.0001) and on day 45 (OR 5.23 95% CI: 1.97-13.8; p = 0.0008). In the main group, post-defecation pain intensity was significantly lower than in the control group during the first 30 days (p < 0.0001). On the 30th postoperative day, gas incontinence was reported by 9/50 (18.0%) patients in the main group and 17/50 (34%) in the control group (p = 0.1), while on the 60th day, 2/50 (4.0%) patients in the LIS group and 3/50 (6%) in the LIS + FE group (p = 1.0) reported gas incontinence. The median Wexner score on the 30th postoperative day was 1 (1; 1) in the LIS group and 2 (1; 3) in the LIS + FE group (p = 0.03). Univariate analysis showed that factors increasing the likelihood of anal incontinence on the 30th postoperative day were age (OR = 1.03; 95% CI: 1.0-1.07) and childbirth history (OR = 12.3; 95% CI: 1.3-118.3). Fissure excision had a greater negative impact on patients' quality of life in the early postoperative period. The median Hemo-Fiss score on the 30th postoperative day was 5.5 (0; 13) points in the main group and 11 (5; 20) points in the control group (p = 0.02). The median time of temporary disability was 9 (6; 11) days in the LIS group and 15.5 (12; 23) days in the LIS + FE group (p = 0.0006). In the long-term postoperative period (up to 1 year), the groups were fully comparable in complication rates and nature. Recurrence occurred in 1/44 (2.2%) patients in the main group and 2/43 (4.6%) patients in the control group (p = 1.0). A rectal fistula was identified in 2/44 (4.5%) patients in the main group and 1/43 (2.6%) in the control group. ASI was observed only in the control group in 1/43 (2.3%) patients. Profilometry measurements showed that maximum resting anal canal pressure was 102 (89; 111) mm Hq in the main group and 96 (85; 112) mm Hq in the control group (p = 0.08). The mean resting anal canal pressure was 55 (52; 59) mm Hg in the LIS group and 52 (42; 58) mm Hg in the LIS + FE group (p = 0.1).

> CONCLUSION: performing LIS without fissure excision prevents long-healing wound in the anal canal, reduces pain intensity, decreases the severity of anal incontinence, improves quality of life, and shortens temporary disability. Avoiding fissure excision does not lead to worsening of late outcomes.

KEYWORDS: chronic anal fissure, CAF, internal sphincter spasm, lateral internal sphincterotomy, LIS

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

FOR CITATION: Zharkov E.E., Achkasov S.I., Shelygin Y.A., Kostarev I.V., Ponomarenko A.A., Mudrov A.A. Chronic anal fissure treatment using lateral internal sphincterotomy without excision: prospective randomized study (NCT05117697). Koloproktologia. 2025;24(3):22-34. (in Russ.). https://doi.org/10.33878/2073-7556-2025-24-3-22-34

ADDRESS FOR CORRESPONDENCE: Evgeny E. Zharkov, Ryzhikh National Medical Research Center of Coloproctology, Salyama Adilya st., 2, Moscow, 123423, Russia; e-mail: zee@anck.ru

Received — 10.04.2025

Revised — 23.05.2025

Accepted for publication — 05.08.2025

# INTRODUCTION

Despite the fact that the leading pathogenetic mechanism of anal fissure is a spasm of the internal sphincter, in Russian coloproctology lateral sphincterotomy has never been used as an independent treatment method, since there is a common point of view about the need in all cases to supplement it with excision of the anal fissure. Such vision is based on the fact that cicatricial inflammatory changes that persist in the anal canal have a negative impact on the epithelialization of the anoderma defect and worsen late results [1]. However, we have not found evidence in the literature to support this point of view. Moreover, fissureexcision as an independent method significantly worsens the results of its treatment compared with LIS and leads to an increase in the incidence of complications, including anal sphincter insufficiency (ASI) [1-3]. This is confirmed by preliminary data from a study on the treatment of chronic anal fissure by lateral subcutaneous sphincterotomy without excision (NCT05117697) [4], where, in addition to increasing the intensity of pain and time of epithelialization of the postoperative wound in the group of patients who had an anal fissure excised, the incidence of ASI increased significantly on the 30th day of the postoperative period, and more than 5 times the risk of this complication increased.

However, by the 60th day after surgery, most of these differences had disappeared, and the groups were comparable both in terms of healing incidence and risk of complications. In this regard, the final point on the need for routine excision of the anal fissure when performing LIS can be made only after evaluating the late results, which are given in this study.

# AIM

To assess early and late results of treatment of chronic anal fissure by lateral subcutaneous sphincterotomy with and without excision.

# PATIENTS AND METHODS

An active, prospective, controlled, randomized, blind, single-center trial (NCT05117697) was donein October 2021 — October 2023. Randomization was performed 1:1 in a computer program using the random number generation method. The study included 107 patients: 56 patients in the main group and 51 in the control one. The early results were analyzed per protocol. Thus, due to a violation of the study protocol (refusal of check-up), 6 patients were excluded from the main group, and 1 patient from the control one. Six patients of the main group and 7 patients of the control group refused to undergo check-up in the late postoperative period (Fig. 1).

Patients were diagnosed with 'chronic anal fissure' if one of the following parameters was present: the history of the disease was over 2 months, cicatricial changes in the anal fissure, fibrous polyp of the anal canal or sentinel skin tag.

Inclusion Criteria

Patients over 18 years of age with chronic anal fissure with spasm of the internal anal sphincter according to profilometry, who signed an informed consent to participate in the study.

Non-inclusion Criteria

Previous operations on the rectum and anal canal (with the exception of minimally invasive methods); grade 1–3 ASI (the Wexner's score is greater than 0 point); inflammatory bowel diseases; external and internal hemorrhoids of stages 3–4; anal fistula; severe comorbidities with decompensation; anal fissure complicated by a fistula. The

study also did not include patients whose fibrous polyp or sentinel skin tag caused discomfort, cosmetic problems, or hindered personal hygiene.

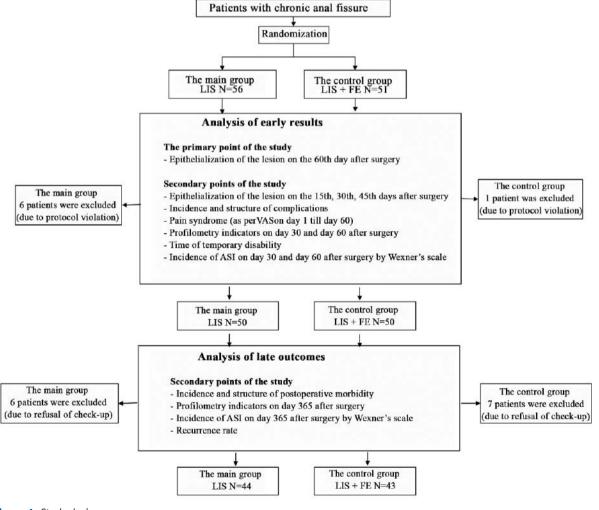
# **Exclusion Criteria**

Anal fistulas revealed during intraoperative revision; patient's refusal to undergo check-up at any stage; violation of the study protocol.

Patients included in the study underwent profilometry before surgery, on days 30, 60, and 365 after surgery using a Solar GI HRAM device (the Netherlands). The presence of spasm of the internal anal sphincter was verified with an increase in at least one of the following profilometry indicators: maximal pressure in the anal canal at rest (MRPAC) (norm: 89.4–112.2 mm Hg); mean pressure in the anal canal at rest (ARPAC) (norm:

44.0–60.4 mm Hg); in the presence of ultraslow wave activity of the internal sphincter.

From the day of surgery to day 60 of the postoperative period, the patients assessed the pain syndrome on a visual analogue scale (VAS), answered questions about the nature of stool as per the Bristol scale and the presence of constipation in accordance with Roman criteria IV. Working patients recorded the date of their employment, while non-working patients gave a subjective assessment of the possibility of returning to work. On days 15, 30, 45, 60, and 365, the patients underwent a digital rectal examination and anoscopy to assess the healing of the lesion in the anal canal. On days 30, 60, and 365, the degree of anal incontinence was assessed as per Wexner's scale and the



**Figure 1.** Study design

**Table 1.** Clinical characteristics of patients with chronic anal fissure

Indicator	LIS + FE n = 50	LIS n = 50	р
Median age (quartiles)	42 (33; 50)	40 (32; 52)	0.9
Median BMI kg/m² (quartiles)	24.3 (21; 27.6)	26.4 (22.5; 30)	0.2
Gender		, , ,	1
Male	24 (48%)	30 (60%)	0.3
Female	26 (52%)	20 (40%)	
Anamnesis (months)	6.5 (5; 22)	6 (4; 18)	0.5
Fissure			
One	38 (76%)	42 (84%)	0.5
Two	12 (24%)	8 (16%)	
Fissure localization			
Posterior	33 (66%)	33 (66%)	0.17
Anterior	4 (8%)	9 (18%)	
Lateral	1 (2%)	_	
Anterior and Posterior	10 (20%)	8 (16%)	
Posterior and Lateral	2 (4%)	_	
Sentinel skin tag			
0ne	27 (42%)	28 (56%)	0.8
Two	2 (4%)	1 (2%)	
Fibrous polyp			
0ne	8 (16%)	13 (26%)	0.2
Two	1 (2%)	0 (0%)	
External hemorrhoidal node			
One One	1 (2%)	1 (2%)	0.2
Two	1 (2%)	0 (0%)	
Three	2 (4%)	0 (0%)	

life quality as per Hemo-Fiss' scale (Appendix 1) [5].

Surgery was performed under spinal anesthesia in the patient's position as for a lithotomy. Patients in the main group (LIS) underwent lateral subcutaneous sphincterotomy using a closed technique. In patients of the control group (LIS + FE), the above method was combined with fissure excision in accordance with Russian clinical guidelines [6]. Both groups were homogeneous in the basic clinical and morphological criteria: age, body mass index (BMI), gender, and clinical manifestations of the disease (Table 1).

### Statistical Processing of the Results

Due to the non-Gaussian distribution of continuous data (verified by Shapiro-Wilk's test), the groups were compared by Mann-Whitney's U-test, and the totality was described by Me (Q1; Q3). For binary data, Fischer's two-way precise test was applied. The comparison of categorical data

other than 2  $\times$  2 was performed using Pearson's  $\gamma^2$  test.

A univariate analysis was performed using logistic regression; its results were presented as a ratio of odds (OR) and 95% coincidence interval (CI). For relative values, 95% CI was calculated using Clopper-Pearson's method. The difference was considered statistically significant at p < 0.05. Statistical analysis was performed using the Statistica 13.3 program (TIBCO, USA).

### **RESULTS**

#### **Immediate Results**

Clinical Characteristics of the Early Treatment Results On day 15 after surgery, anal fissure healing was diagnosed in 15/50 (30%) patients of the main group (LIS), while the postoperative wound had not healed in any patient in the control group (LIS + FE) (p = 0.00002). After 30 days, the fissure was epithelialized in 31/50 (62%) patients in the

LIS group, and the postoperative wound in 4/50 (8%) patients in the LIS + FE group [p < 0.0001]. Epithelialization was detected on day 45 in 43/50 (86%) patients and 27/50 (54%) patients, respectively [p = 0.0008]. On day 60, anal fissure epithelialization was found in 47/50 (94%) patients in the main group, and postoperative wound healing was found in 48/50 (96%) patients in the control group (p = 1.0) (Fig. 2).

For the first 4 weeks of the postoperative period, the intensity of pain after stool in the group of patients who underwent LIS alone was significantly lower (p < 0.0001) than in the group where LIS was performed in combination with fissure excision (Fig. 3).

The intensity of VAS pain for the day was significantly lower for the first 3 weeks of the postoperative period (p < 0.0001) (Fig. 4).

In the early postoperative period, complications were monitored for 60 days (Table 2). 22/50 (44%) patients in the main group and 26/50 (52%) patients in the control group (p=0.6) had hematomas in the area of sphincterotomy, but only in 2 (4%) patients in LIS and 1 (2%) patient in the LIS + FE group (p=1.0), this was accompanied by inflammatory infiltration perianal tissue and the need for antibiotics. In all other cases, the only clinical manifestation was a change in skin colour, which did not require additional prescriptions. Thrombosis of external hemorrhoids was noted in 4/50 (8%) patients in the LIS group and in 4/50 (8%) patients in the LIS + FE group (p=1). Conservative therapy was prescribed for

the complications that occurred in accordance with clinical guidelines for the treatment of hemorrhoids [7].

In the main group, in the postoperative period, 2/50 (4%) patients had bleeding from the postoperative wound, which required revision with control of the bleeding vessel under spinal anesthesia in the operating theatre. In the control group, bleeding from a sphincterotomy wound was found in 1 (2%) patient, which required suturing the wound with a z-shaped suture in the procedure room under local anesthesia (p = 1.0). A lesion/ wound was considered non-healing for a long time if epithelialization did not develop within 60 days after surgery. This complication developed in 3/50 (6%) patients of the main group and in 2/50 (4%) patients of the control group (p = 1). For 2 weeks, those patients continued local ointment therapy with dioxomethyltetrahydropyrimidine, at accelerating wound healing processes, which made it possible to achieve epithelialization in all cases by the 74th day of the postoperative period. The incidence of transient anal incontinence on days 30 and 60 was comparable between the groups (Table 3).

It should be noted that the ASI was manifested exclusively by gas incontinence. The median time of ASI in the main group was 3 (3; 4) days, in the control group — 4.5 (2.5; 9.5) days (p = 0.5).

On the 30th day of the postoperative period, the severity of anal incontinence was significantly greater if the anal fissure was excised. The median Wexner's score in the main group was 1 (1;

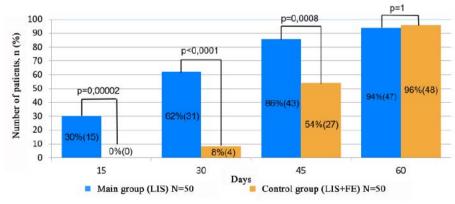


Figure 2. Timing of epithelialization of anal fissure in the main group and postoperative wound in the control group

**Table 2.** Frequency and structure of postoperative complications

	Treatmer	Treatment Method		
Complications	Main Group, (LIS) n = 50	Control Group (LIS + FE), n = 50	р	
Hematoma in the area of sphincterotomy	22 (44%)	26 (52%)	0.6	
Infiltration in the area of sphincterotomy	2 (4%)	1 (2%)	1.0	
Thrombosis of external hemorrhoids	4 (8%)	4 (8%)	1.0	
Bleeding in the early postoperative period	2 (4%)	1 (2%)	1.0	
A long-term non-healing wound	3 (6%)	2 (4%)	1.0	

1), in the control group — 2 (1; 3) (p = 0.03). By day 60, significant differences disappeared, and Wexner's score on day 60 was comparable between the groups: 1 (1; 1) in the main group and 2 (1; 4) in the control group (p = 0.6).

In both groups, a significant decrease in Hemo-Fiss' score was found for 2 months of the postoperative period, which indicated a decrease in the severity of the symptoms of the disease and their impact on the quality of life. Thus, on day 30, the

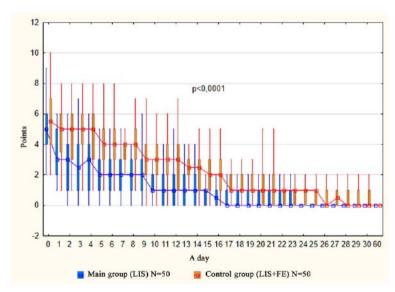


Figure 3. Intensity of pain syndrome after stool according to VAS

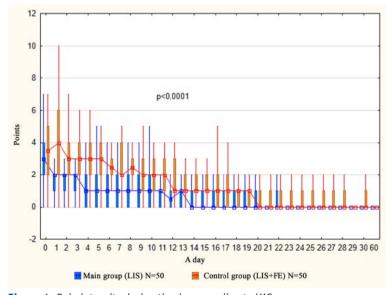


Figure 4. Pain intensity during the day according to VAS

**Table 3.** Frequency of development of NAS in the early postoperative period

Davi	Treatment Method		D
Day	Main Group (LIS), n = 50	Control Group (LIS + FE),n = 50	r
30	9 (18%)	17 (34%)	0.1
60	2 (4%)	3 (6%)	1.0

Table 4. Level of maximum pressure in the anal canal at rest on days 30 and 60 after surgery

Level (MRPAC) mm Hg	Day 30			Day 60		
	LIS, n = 50	LIS + FE, n = 50	р	LIS, n = 50	LIS + FE, n = 50	р
Increased (> 112.2)	8 (16%)	3 (6%)	0.2	6 (12%)	3 (6%)	0.2
Normal (89.4–112.2)	27 (54%)	25 (50%)		27 (54%)	22 (44%)	
Decreased (< 89.4)	15 (30%)	22 (44%)		17 (34%)	25 (50%)	

Table 5. Average pressure level in the anal canal at rest on days 30 and 60 after surgery

Level (ARPAC) mm Hg	Day 30			Day 60		
	LIS, n = 50	LIS + FE, n = 50	р	LIS, n = 50	LIS + FE, n = 50	р
Increased (> 60.4)	6 (12%)	3 (6%)	0.5	5 (10%)	5 (10%)	0.3
Normal (44.0-60.4)	29 (58%)	29 (58%)		31 (62%)	24 (48%)	
Decreased (< 44.0)	15 (30%)	18 (36%)		14 (18%)	21 (42%)	

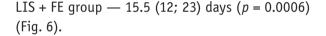
Table 6. Spasm of the internal anal sphincter on days 30 and 60 after surgery

Spasm of the internal anal	Day 30			Day 60		
sphincter	LIS, n = 50	LIS + FE, n = 50	р	LIS, n = 50	LIS + FE, n = 50	р
Yes	10 (20%)	5 (10%)	0.3	7 (14%)	5 (10%)	0.8
No	40 (80%)	45 (90%)		43 (86%)	45 (90%)	

life quality in the main group was significantly better than in the control group: 5.5 (0; 13) points vs 11 (5; 20) (p = 0.02).

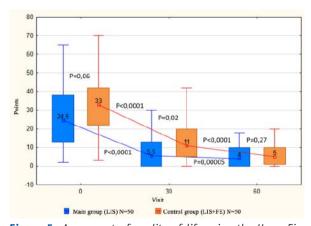
By day 60 of the postoperative period, these differences disappeared. The groups were comparable (p=0.27). The median score in the main group (LIS) was 4 (0; 10), and in the control group (LIS + FE) — 5 (1; 10) points (Fig. 5).

The median indicator of the duration of temporary disability in the LIS group was 9 (6; 11) days, in the

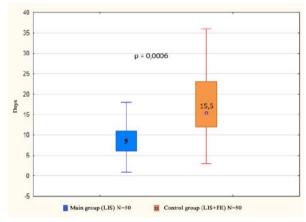


### Functional Treatment Results

The diagnosis of internal spasm of the sphincter was established in patients based on an increase in the indicators of MRPAC and/or ARPAC above the reference values. By the 30th day of the postoperative period, both the main and control groups showed a significant decrease in these indicators (all p < 0.0001). In the both groups, on days 30 and



**Figure 5.** Assessment of quality of life using the Hemo-Fiss scale



**Figure 6.** Duration of temporary disability

**Table 7.** Factors presumably influencing non-healing of the lesion on day 15 after surgery

Factor	OR (95% CI)	р
LIS + FE	_	-
Anamnesis duration	0.99 (0.97–1.0)	0.3
Age	1.05 (0.99–1.1)	0.05
BMI	1.09 (0.96–1.24)	0.1
Female	0.51 (0.16–1.57)	0.2
Sentinel skin tag	1.64 (0.72–3.84)	0.4
Fibrous polyp	0.8 (0.26–2.4)	0.7

Table 8. Factors presumably influencing non-healing of the lesion on day 30 after surgery

Factor	OR (95% CI)	р
LIS + FE	18.7 (5.8-60.4)	< 0.0001
Spasm of the sphincter	1.09 (0.34–3.4)	0.9
Anamnesis duration	0.99 (0.97–1.01)	0.5
Age	1.02 (0.98–1.05)	0.2
BMI	0.98 (0.89–1.06)	0.7
Female	1.01 (0.44–2.32)	1.0
Sentinel skin tag	1.64 (0.72-3.84)	0.3
Fibrous polyp	1.03 (0.42–2.5)	0.9

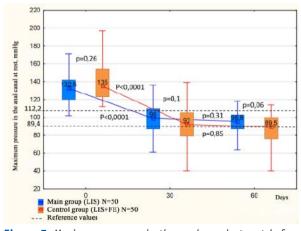
**Table 9.** Factors presumably influencing non-healing of the lesion on day 45 after surgery

Factor	OR (95% CI)	р
LIS + FE	5.23 (1.97-13.8)	0.0008
Anamnesis duration	1.0 (0.99–1.02)	0.3
Age	0.99 (0.96–1.03)	1.0
BMI	0.99 (0.9–1.08)	0.9
Female	1.52 (0.64–3.59)	0.3
Sentinel skin tag	1.59 (0.67-3.77)	0.3
Fibrous polyp	1.34 (0.52-3.48)	0.5

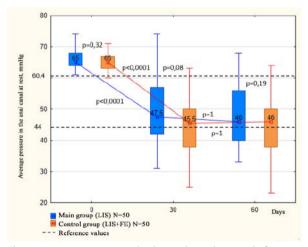
60, the indicators of maximum and average pressure in the anal canal were comparable and were within the reference values (Fig. 7, 8).

Despite a significant decrease in the median values of maximum and average pressure in the anal

canal at rest, sphincter spasm persisted on day 30 in 10/50 (20%) patients in the main group and in 5/50 (10%) patients in the control group (p = 0.26). By day 60, the number of those patients decreased to 7/50 (14%) in the LIS group



**Figure 7.** Maximum pressure in the anal canal at rest before surgery and in the postoperative period



**Figure 8.** Average pressure in the anal canal at rest before surgery and in the postoperative period

**Table 10.** Factors presumably influencing non-healing of the lesion on day 60 after surgery

Factor	OR (95% CI)	р
LIS + FE	0.65 (0.1–4.08)	0.6
Spasm of the sphincter	1.91 (0.19-18.6)	0.6
Anamnesis duration	1.0 (0.96–1.03)	0.9
Age	0.92 (0.83–1.02)	0.1
BMI	0.93 (0.76–1.15)	0.5
Female	0.77 (0.12–4.83)	0.8
Sentinel skin tag	6 (0.6-55.7)	0.1
Fibrous polyp	0.65 (0.1–4.15)	0,7

Table 11. Factors associated with the transient ASI development on day 30 after surgery

Factor	OR (95% CI)	р
LIS + FE	0.42 (0.16–1.07)	0.07
Age	1.03 (1.0–1.07)	0.03
BMI	0.98 (0.89–1.08)	0.8
Female	1.89 (0.76-4.67)	0.2
Childbirth	12.3 (1.3-118.3)	0.02

**Table 12.** Factors associated with the transient ASIdevelopment on day 60 after surgery

Factor	OR (95% CI)	р
LIS + FE	0.65 (0.1–4.08)	0.6
Age	1.02 (0.95–1.1)	0.4
BMI	0.89 (0.72–1.11)	0.3
Female	1.81 (0.28-11.4)	0.5
Childbirth	0.1 (0.007-1.26)	0.07

and 5/50 (10%) in the LIS + FE group (Tables 4–6).

Factors Influencing the Course of the Early Postoperative Period

The only factor influencing the outcome of treatment is the nature of the surgery. Fissure excision significantly increased the chances of non-healing of the postoperative wound on day 30 (OR 18.7; 95% CI: 5.8-60.4; p < 0.0001) and on day 45 (OR 5.23; 95% CI: 1.97-13.8; p = 0.0008) (Tables 7-10).

In a univariate analysis, it was found that age and a history of childbirth are factors that increase the risk of developing ASI on day 30 of the post-operative period. No factors affecting the incidence of ASI on day 60 were identified (Tables 11–12).

#### Late Treatment Results

We considered the recurrence of anal fissure to be the repeated occurrence of an anoderma defect after complete healing, accompanied by spasm of the internal sphincter, which developed in 1/44 (2.2%) patient of the main group and 2/43 (4.7%) patients of the control group (p=1.0). Rectal fistulas developed in 2/44 (4.5%) patients after LIS and 1/43 (2.3%) patient in the group where LIS + FE was performed (p=1.0). It should be noted that no spasm of the internal sphincter was detected in those patients during profilometry. Anal sphincter incontinence was found only in 1/43 (2.3%) patient in the control group (p=1.0) (Table 13).

The medians of maximal and mean pressure in the anal canal at rest by day 365 were comparable in both groups. So, in the main group, the median MRPAC was 102 (89; 111) mm Hg, in the control group — 96 (85; 112) mm Hg (p = 0.08); ARPAC in the LIS group — 55 (52; 59) mm Hg, in the LIS + FE group — 52 (42; 58) mm Hg (p = 0.1).

The groups were comparable in terms of the incidence of MRPAC and ARPAC values (Tables 14–15), and the presence of internal spasm of the sphincter (Tables 14–16).

Table 13. Clinical characteristics of late/long-term treatment results

Laws town two atmospherical to	Treatme	_		
Long-term treatment results	Main Group (LIS), n = 44	Control Group (LIS + FE), n = 43	Р	
Recurrence of the disease	1 (2.2%)	2 (4.6%)	1.0	
ASI	0	1 (2.3%)	1.0	
Anal fistulas	2 (4.5%)	1 (2.3%)	1.0	

**Table 14.** Level of maximal pressure in the anal canal at rest in the late postoperative period

Level (MDDAC) mm He	Day 365				
Level (MRPAC) mm Hg	LIS, n = 44	LIS + FE, n = 43	р		
Increased (> 112.2)	6 (13.6%)	6 (13.9%)	0.052		
Normal (89.4–112.2)	27 (61.4%)	19 (44.2%)			
Decreased (< 89.4)	11 (25%)	18 (41.9%)			

Table 15. Mean pressure level in the anal canal at rest in the late postoperative period

Loyal (ARRAC) mm Ha	Day 365				
Level (ARPAC) mm Hg	LIS, n = 44	LIS + FE, n = 43	р		
Increased (> 60.4)	9 (20.4%)	8 (18.6%)	0.2		
Normal (44.0-60.4)	30 (68.2%)	21 (48.8%)			
Decreased (< 44.0)	5 (11.4%)	14 (32.6%)			

**Table 16.** Spasm of the internal anal sphincter in the late postoperative period after surgery

Spasm of the internal anal	Day 365				
sphincter	LIS, n = 44	LIS + FE, n = 43	р		
Yes	34 (77.3%)	33 (76.7%)	1.0		
No	10 (22.7%)	10 (23.3%)			

# DISCUSSION

The results of the study showed that, contrary to the prevailing point of view, despite the remaining cicatricial changes in the anal canal, the anal fissure heals much faster after performing a lateral sphincterotomy than a postoperative wound.

On the one hand, this once again confirms the leading role of sphincter spasm in the pathogenesis of this disease [6], and on the other hand, data from previous studies indicate that the chances of non-healing wounds increase as the surgery volume increases [8].

A univariate analysis in the study also showed that the chance of non-healing of a postoperative wound on days 15, 30 and 45 is significantly higher than that of an anal fissure. Apart from the surgery nature, no other factors influenced the rate of epithelialization. It is obvious that the absence of a postoperative wound in the anal canal, which significantly exceeds the size of the initial anoderma defect, made it possible to achieve a significant reduction in the intensity of pain in patients in the early

postoperative period. This is consistent with the opinion of a number of authors that the main role in the pathogenesis of pain syndrome in patients undergoing anal canal surgery is played by the inflammatory process in the postoperative wound [9,10]. An important consequence of the reduction in pain intensity and rapid epithelialization of the anoderma defect in the group of patients who did not have an anal fissure excision was an increase in the life quality of patients as per Hemo-Fiss' scale. However, we consider the most significant

result to be a reduction in the period of temporary

disability by more than 40%.

We were unable to confirm the preliminary data that excision of the anal fissure can lead to an increase in the ASI incidence [4], but at the same time, in the group of patients after the anal fissure excision, the severity of symptoms of anal incontinence as per Wexner's scale significantly increased for the first 30 days of the postoperative period. Also, preliminary data on the association of the incidence of this complication with the surgery na-

ture have not been confirmed [4]. The final analysis

of the study results showed that the chance of the ASI development increased with increasing age of patients (OR = 1.03; 95% CI: 1.0-1.07) (p = 0.03) and in women who gave birth (OR = 12.3; 95% CI: 1.3-118.3) (p = 0.02). The main reason for the ASI in this category of patients is the presence of latent functional disorders of the rectal locking apparatus, which is confirmed by other authors [11-14]. These disorders are more common in patients over 60 years of age and women who have given birth [15,16]. Therefore, in this category of patients, most likely, it is necessary to refrain from performing sphincterotomy as the first stage of treatment and to carry out drug relaxation of the internal sphincter.

In the late postoperative period, the recurrence rate and the occurrence of anal fistulas were comparable regardless of whether the anal fissure was excised or not. Thus, contrary to popular belief, the remaining cicatricial change in the anal canal associated with the prolonged existence of an anal fissure has no effect on the course of the late postoperative period. Clinical manifestations of anal sphincter incontinence in the late postoperative period were observed only in 1/44 (2.3%) patient of the control group.

Summarizing the study data, it should be recognized that additional excision of the anal fissure worsens the early results of the treatment with fully comparable late outcomes. In this regard, this surgery should be performed only in cases

where fibrous polyp or sentinel skin tag interfere with personal hygiene, cause discomfort or create cosmetic problems in patients. A similar point of view is shared by our foreign colleagues in their clinical guidelines [17]. Moreover, excision of the anal fissure is considered not as an addition to LIS, but as an independent treatment method, the rate of complications of which, including anal sphincter incontinence, exceeds that after LISonly [1,3]. That is why, in cases where excision of the anal fissure is necessary, some authors suggest limiting the surgery to removing the fibrous polyp or sentinel skin tag without excising the cicatricial edges and bottom of the fissure [18], or after excision of the fissure, closing the lesion with a skin-anal flap [19]. According to Arslanbekova et al., performing anoplasty in this category of patients does not lead to an increase in the rate of complications compared with that after performing LIS [20].

# CONCLUSION

Performing lateral subcutaneous sphincterotomy without excision of the anal fissure avoids extensive, long-term non-healing wound in the anal canal, reduces the intensity of pain, reduces the severity of anal incontinence, improves the quality of life of patients and reduces the period of temporary disability to work. Avoiding the anal fissure excision does not lead to worse late treatment results.

**APPENDIX 1. The HEMO-FISS questionnaire** 

Last week because of my anal symptoms	Al- ways	Quite often	Regu- larly	Sel- dom	Never	Not ap- plicable
B1 I was uncomfortable sitting down						
B2 I had to change my clothes regularly or use a special						
B3 I was uncomfortable standing						
B4 My relationship with my partner has deteriorated						
B5 I was uncomfortable walking.						
B6 I felt ashamed						
B7 I was afraid of defecation/bowel movements						
B8 I was uncomfortable being around people						
B9 I felt discomfort when I was doing sports						
B10 I felt discomfort during bowel movements\defecation						
B11 I felt difficulties when driving a vehicle						
B12 It was difficult for me to take care of my children						
B13 It is difficult for me to ride a bicycle or other two-wheeled vehicles						

Last week because of my anal symptoms	Al- ways	Quite often	Regu- larly	Sel- dom	Never	Not ap- plicable
B14 It is difficult for me to do my job well						
B15 I feel like I am different from others						
B16 I'm doing fewer things than I'd like						
B17 My sexual activity has decreased						
B18 I avoid going out (travelling, vacations, friends)						
B19 My family life is disrupted						
B20 I feel uncomfortable when I do household chores/clean/do manual						
work						
B21 I feel uncomfortable in my own body						
B22 I feel uncomfortable after defecating						
B23 I believe that my illness is incurable						

#### **AUTHOR CONTRIBUTIONS**

Study conception and design: Sergey I. Achkasov, Yuri A. Shelygin, Evgeny E. Zharkov, Alexey A. Ponomarenko

Data collection and processing: Evgeny E. Zharkov Statistical analysis: Evgeny E. Zharkov, Alexey A. Ponomarenko

Writing: Evgeny E. Zharkov

Editing: Yuri A. Shelygin, Ivan V. Kostarev, Alexey A.

Ponomarenko, Andrey A. Mudrov

# **INFORMATION ABOUT THE AUTHORS (ORCID)**

Sergey I. Achkasov — 0000-0001-9294-5447 Yuri A. Shelygin — 0000-0002-8480-9362 Evgeny E. Zharkov — 0000-0003-3403-9731 Ivan V. Kostarev — 0000-0002-1778-0571 Alexey A. Ponomarenko — 0000-0001-7203-1859 Andrey A. Mudrov — 0000-0002-1207-5988

# **REFERENCES**

- 1. Mousavi SR, Sharifi M, Mehdikhah Z. A comparison between the results of fissurectomy and lateral internal sphincterotomy in the surgical management of chronic anal fissure. *J Gastrointest Surg.* 2009;13:1279–1282.
- 2. Tutino R, Nigro C, Paternostro F, et al. Fissurectomy versus lateral internal sphincterotomy in the treatment of chronic anal fissures: no advantages in terms of post-operative incontinence. *Tech Coloproctol*. 2023;27(10):885–889.
- 3. Bara BK, Mohanty SK, Behera SN, et al. Fissurectomy versus lateral internal sphincterotomy in the treatment of chronic anal fissure: a randomized control trial. *Cureus*. 2021;13(9):e18363.
- 4. Goloktionov N.A., Titov A.Yu., Ponomarenko A.A., et al. Immediate results of treatment of chronic anal fissure using lateral subcutaneous sphincterotomy without excision (NCT05117697). *Koloproktologia*. 2023;22(3):50–61. (In Russ.).
- 5. Abramowitz L, Bouchard D, Siproudhis L, et al. Psychometric properties of a questionnaire (HEMO-FISS-QoL) to evaluate the burden associated with haemorrhoidal disease and anal fissures. *Colorectal Dis.* 2019;21(1):48–58.
- 6. Anal fissure. Clinical guidelines. Moscow; 2024. URL: https://cr.minzdrav.gov.ru/preview-cr/172\_3. (In Russ.).

- 7. Hemorrhoids. Clinical guidelines. Moscow; 2024. URL: https://cr.minzdrav.gov.ru/preview-cr/178\_2. (In Russ.).
- 8. Khryukin R.Yu., Zharkov E.E., Goloktionov N.A., et al. Treatment of chronic anal fissure using botulinum toxin type A at a dose of 40 U compared with lateral subcutaneous sphincterotomy (NCT03855046). *Koloproktologia*. 2022;21(1):60–70. (In Russ.).
- 9. Shelygin Y.A., Podmarenkova L.F., Blagodarny L.A., et al. Pathogenesis of pain syndrome after hemorrhoid-ectomy. *Koloproktologia*. 2006;(2):3–12. (In Russ.).
- 10. Khubchandani IT. Internal sphincterotomy with hemorrhoidectomy does not relieve pain: a prospective, randomized study. *Dis Colon Rectum*. 2002;45(11):1452–1457.
- 11. Shelygin Y.A., Zharkov E.E., Orlova L.P., et al. Risk of anal incontinence after excision of anal fissure combined with lateral subcutaneous sphincterotomy. *Koloproktologia*. 2005;(1):10–16. (In Russ.).
- 12. Kement M, Karabulut M, Gezen FC, et al. Mild and severe anal incontinence after lateral internal sphincterotomy: risk factors, postoperative anatomical findings and quality of life. *Eur Surg Res.* 2011;47(1):26–31.
- 13. Ammari FF, Bani-Hani KE. Faecal incontinence in patients with anal fissure: a consequence of internal

sphincterotomy or a feature of the condition? *Surgeon*. 2004;2(4):225–229.

- 14. Elsebae MM. A study of fecal incontinence in patients with chronic anal fissure: prospective, randomized, controlled trial of the extent of internal anal sphincter division during lateral sphincterotomy. *World J Surg.* 2007;31(10):2052–2057.
- 15. Shelygin Y.A., Frolov S.A., Orlova L.P., et al. Anal incontinence in patients who underwent excision of anal fissure in combination with lateral internal-sphincterotomy. *Koloproktologia*. 2008;(3):18–24. (In Russ.).
- 16. Shelygin Y., Tkalich O.V., Ponomarenko A.A., et al. Follow-up results of combination treatment of chronic anal fissure. *International Journal of Pharmaceutical Research*. 2020; 12(Suppl. 2):244–249.
- 17. Stewart DBSr, Gaertner W, Glasgow S, et al. Clinical

- practice guideline for the management of anal fissures. *Dis Colon Rectum*. 2017;60(1):7–14.
- 18. Gupta PJ. Hypertrophied anal papillae and fibrous anal polyps, should they be removed during anal fissure surgery? *World J Gastroenterol*. 2004;10(16):2412–2414.
- 19. Hancke E, Suchan K, Voelke K. Anocutaneous advancement flap provides a quicker cure than fissurectomy in surgical treatment for chronic anal fissure-a retrospective, observational study. *Langenbecks Arch Surg.* 2021;406(8):2861–2867.
- 20. Arslanbekova K.I., Khryukin R.Y., Zharkov E.E. Anoplasty and lateral subcutaneous sphincterotomy in the treatment of chronic anal fissure (systematic review and meta-analysis). *Koloproktologia*. 2020;19(4):115–130. (In Russ.).