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# Early outcomes of chronic anal fissure treatment using the lateral internal sphincterotomy method without excision (randomized trial NCT05117697)

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## ABSTRACT

**AIM:** to estimate efficacy of internal sphincterotomy for chronic anal fissure (CAF).

**PATIENTS AND METHODS:** the study included 70 patients randomized by random number generation into 2 groups: 30 patients underwent lateral internal sphincterotomy only (main group, LIS), and 40 patients underwent LIS in combination with the excision of the fissure (EF) (control group, LIS + EF).

**RESULTS:** the pain intensity after stool and during the daytime in the main group (LIS) has been significantly lower than in the control group (LIS + EF) ( $p < 0.05$ ). The median duration of the patients' temporary disability in the LIS group was 6 (4; 9) days, in the LIS + EF group — 17 (9; 23.5) days ( $p = 0.04$ ). On day 15, the defect has epithelialized in 12/30 (40%) patients of the main group (LIS) and none (0/40) in the control group (LIS + EF) ( $p < 0.0001$ ), on day 30 — in 22/30 (73.3%) and 2/40 (5%) ( $p < 0.0001$ ), on day 45 — in 26/30 (87%) and 20/40 (50%) ( $p = 0.002$ ), and on day 60 — in 28/30 (93.3%) and 38/40 (95%) ( $p = 1.0$ ), respectively. On the day 30 after surgery, 3/30 (10%) patients of the main group and 15/40 (37.5%) of the control group had complaints regarding passing gas ( $p = 0.01$ ), on day 60 — anal incontinence (AI) persisted in 1/30 (3%) patients in the LIS group and in 3/40 (7.5%) patients in the LIS + EF group ( $p = 0.63$ ). Excision of the fissure in 5.4 (1.4–20.9) times increases the chance of developing AI on day 30 after surgery ( $p = 0.015$ ) and 52 (10.2; 268.3) times increases the chance of non-healing of the defect during this period ( $p < 0.0001$ ) and 6.5 (1.9; 22) times on the day 45 ( $p = 0.003$ ), in comparison with the LIS only.

**CONCLUSION:** a refusal to excise the anal fissure and perform the lateral internal sphincterotomy only can reduce postoperative pain, postoperative morbidity and reduce the time of epithelialization of the anoderm defect.

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

**CONFLICT OF INTEREST:** authors declared no conflict of interest

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## INTRODUCTION

Despite the fact that the main pathogenetic mechanism of anal fissure is spasm of the internal anal sphincter, in the country the traditional method of surgical treatment of this disease is excision of the fissure in combination with lateral subcutaneous sphincterotomy [1]. This technique was proposed by Ektov N.N. and Poletov V.N. in

the 1980s of the last century [2,3]. However, the authors do not justify the need for excision of the anal fissure. According to foreign clinical guidelines, the anal fissure is not excised, but is limited exclusively to the elimination of the main point of pathogenesis — spasm of the internal sphincter, while the main method of its elimination is lateral internal sphincterotomy (LIS) [4]. In this regard, a prospective randomized study to compare the results of lateral subcutaneous sphincterotomy with

and without excision of a chronic anal fissure was done.

## AIM

To compare efficacy of lateral internal sphincterotomy with and without fissure excision.

## PATIENTS AND METHODS

### The equivalence hypothesis

The rate of healing of a chronic anal fissure is the same on the 60th day when performing both LIS only and LIS + EF.

Calculation of the sample size with an error of the first kind — 5%, the second kind — 80%, with “success” in the control and experimental groups — 95% and the equivalence limit — 15%.

So, it was required to recruit 37 people in each group.

In October 2021 — October 2022, a prospective randomized single-center study (NCT05117697) was done. Randomization was carried out by generating random numbers in a computer program. The main group included 30 patients who underwent lateral internal sphincterotomy (LIS) only; the control group included 40 patients in whom this technique was combined with fissure excision (LIS + EF) (Fig. 1). At the same time, 6 patients were excluded from the main group, 1 patient — from the control group, due to a violation of the study protocol (they did not appear on the appointed days for control).

The diagnosis of ‘chronic anal fissure’ was established in the presence of at least one of the following parameters: history of the disease for more than 2 months, scar margins of the fissure, fibrous polyp of the anal canal at the proximal margin of the lesion, sentinel pile on distal edge.

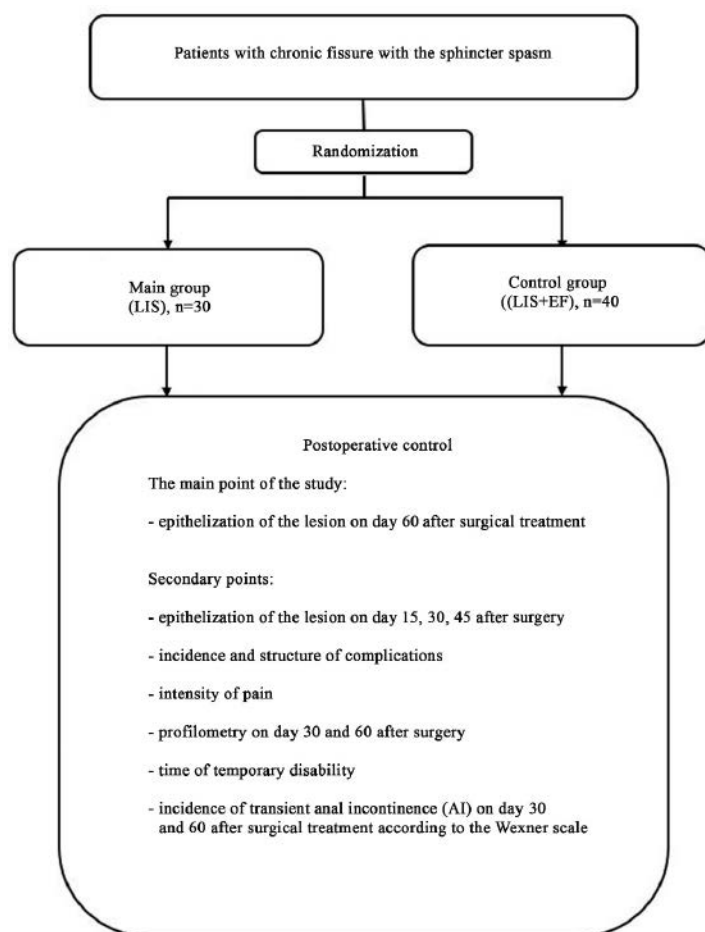


Figure 1. Study design

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

Indicator	Treatment method		p
	Main group, n = 30	Controls, n = 40	
Median age (quartiles)	35.5 (33; 49)	39.5 (31; 50.5)	0.85
Median BMI, kg/m <sup>2</sup> (quartiles)	23.6 (21.8; 27.7)	24.1 (21.1; 27.7)	0.97
Gender			
Male	16 (53.3%)	18 (45%)	0.63
Female	14 (46.7%)	22 (55%)	
History of the disease (months)	7.5 (6; 24)	7.5 (5; 24)	0.88
Anal fissure (N)			
1	25 (83.3%)	26 (65%)	0.1
2	5 (16.7%)	14 (35%)	
Median pain intensity during the daytime (quartiles)	3 (2; 4)	4 (2.5; 5)	0.14
Median pain intensity after stool (quartiles)	6 (4; 7)	6 (4; 7)	1
Fibrous polyp (N)			
1	7 (23%)	5 (12.5%)	0.26
2	0	2 (5%)	
Sentinel pile (N)			
1	17 (56.6%)	21 (52.5%)	0.8
2	2 (7%)	2 (5%)	
External hemorrhoids (N)			
1	1 (3%)	1 (3%)	0.5
2	0 (0%)	1 (3%)	
3	0 (0%)	2 (5%)	
Childbirth (N)	N = 13	N = 22	0.4
0	3 (23%)	6 (27%)	
1	4 (30.5%)	10 (45%)	
2	5 (38.5%)	3 (14%)	
3	1 (8%)	3 (14%)	
4	0	0	
Complicated childbirth in the history	4 (30.7%)	3 (13%)	0.23

**Criteria for inclusion in the study**

- CAF with verified spasm of the internal anal sphincter according to profilometry;
- age of patients over 18 years;
- informed consent of the patient to participate in the study.

**Non-inclusion criteria**

- Patients who have previously undergone surgery on the anal canal and rectum (with exception of minimally invasive techniques);
- the presence of anal incontinence of 1–3 degrees (Wexner score greater than 0 points);
- inflammatory bowel diseases;
- external and internal hemorrhoids of 3–4 stages;
- anal fistula;
- severe comorbidities with decompensation;
- fissure complicated by a fistula.

**Exclusion criteria**

- anal fistulas (detected during intraoperative revision);
- refusal of the patient to be involved the study at any stage;
- non-compliance with the study protocol.

All patients included in the study underwent profilometry before surgery, on days 30 and 60 after surgery on the Solar GI HRAM device (Netherlands). The presence of the internal anal sphincter spasm was proved by increase in at least one of the following profilometry indicators: average pressure in the anal canal at rest (APACR), (normal: 44.0–60.4 mmHg), maximal pressure in the anal canal at rest (MPACR), (normal: 89.4–112.2 mmHg) [5]. Before surgery and daily after it, patients assessed the pain syndrome on a visual analog scale (VAS), answered questions on the Wexner incontinence scale. On days 30 and 60 of

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

Complications	Method of relaxation of the internal anal sphincter		<i>p</i>
	Main Group (LIS) N = 30	Control Group (LIS + EF) N = 40	
Hematoma	14 (46.7%)	15 (37.5%)	0.47
Thrombosis of external hemorrhoids	1 (5%)	2 (5%)	1
Urinary retention	0	0	–
Bleeding in the early postoperative period	0	2 (5%)	0.5
Long-term non-healing wound	2 (6.7%)	2 (5%)	1
Transient AI on day 30 after surgery	3 (10%)	15 (37.5%)	0.01
Transient AI on day 60 after surgery	1 (3.3%)	3 (7.5%)	0.63

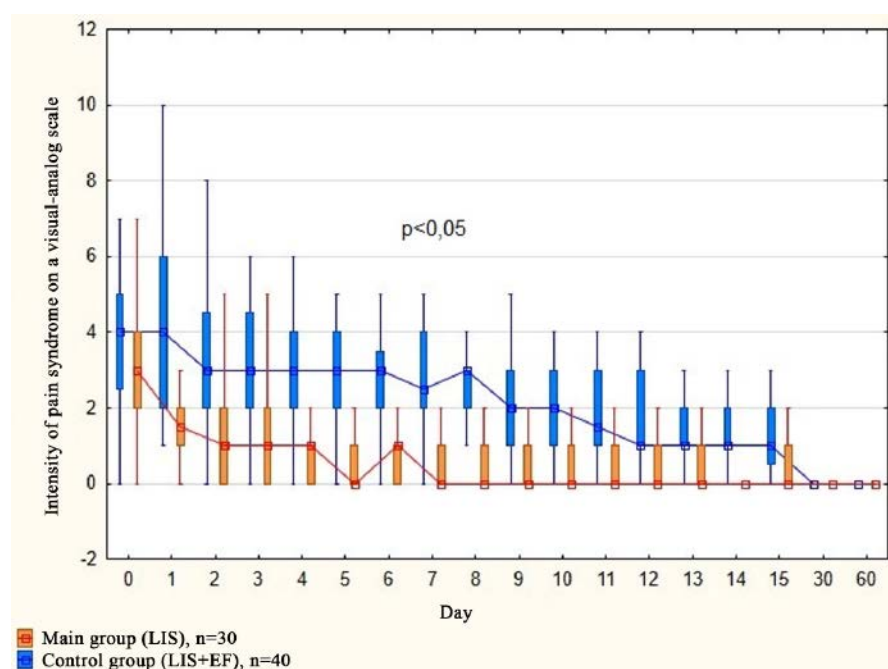
follow-up, clinically, patients underwent a digital rectal examination and anoscopy to assess the effectiveness of treatment. Within 2 months after surgery, the intensity of the pain and their subjective assessment of the possibility of returning to work, the quality of life on the Hemo-Fiss scale, as well as the incidence and time of transient anal incontinence, if present in the postoperative period, were assessed.

Surgery was performed under spinal anesthesia in the position of the patient on his/her back with his/her legs as close to the abdomen as possible. Patients of the main group underwent LIS using a closed technique. In patients of the control group (LIS + EF), the above method was combined with the excision of the fissure in accordance with clinical guidelines [6].

Both groups were homogenous by clinical and morphological criteria: age, body mass index (BMI), gender and changes in the anal canal (Table 1).

### Statistical processing

Due to the non-Gaussian distribution of continuous data (verified by the Shapiro–Wilk criterion), the groups were compared by the Mann–Whitney criterion, the totality was described by Me ( $Q_1; Q_3$ ). For binary data, Fischer’s two-way exact criterion was applied. Comparison of categorical data other than 2x2 was performed by Pearson’s criterion  $\chi^2$ . One-factor analysis was performed using logistic regression. The data were described by OR and 95% CI. For relative values, 95% CI was calculated by the Klopfer–Pearson method. The difference was considered

**Figure 2.** Pain intensity during the day

statistically significant at  $p < 0.05$ . Statistical analysis was performed using the Statistica 13.3 program (TIBCO, USA).

## RESULTS

### Clinical results

The intensity of postoperative pain both after stool and during the daytime in the main group (LIS) was lower than in the control group (LIS + EF) ( $p < 0.0001$ ) (Fig. 2).

When assessing the time of temporary disability, the median indicator in the main group was 6 (4; 9) days, in the controls — 17 (9; 23.5) days ( $p < 0.0001$ ).

For 60 days of follow-up, patients were monitored for postoperative complications (Table 2).

Despite the fact that hematomas of the perianal area in the postoperative period developed in 14/30 (46.7%) patients in the main and 15/40 (37.5%) in the control group, this phenomenon did not require additional administrations and manipulations due to the absence of clinical manifestations, except for changes in the color of the skin. The hematomas was associated with the technique of sphincterotomy, which is quite often accompanied by hemorrhage into the subcutaneous fat of the perianal area [6].

Thrombosis of external hemorrhoids developed in 1/30 (5%) patient in the main group and in 2/40 (5%) patients in the controls ( $p = 1.0$ ). This complication was cured conservatively in accordance with clinical guidelines for hemorrhoids.

In the postoperative period, 2/40 (5%) patients of the control group had episodes of bleeding from the anal canal, which was controlled by suturing. In the main group, no bleeding was detected during 60 days of follow-up ( $p = 0.5$ ). A non-healed lesion in 2 months after surgery was considered a long-term non-healing wound. This complication occurred in 2/30 (6.7%) patients of the main group and 2/40 (5%) patients of the control group ( $p = 1.0$ ). All patients (4/70) with a wound on day 60 after surgery were continued with local dioxomethyltetrahydropyrimidine ointment aimed at wound healing for 2 weeks, which allowed to achieve a positive result in all cases on day 74 of the after surgery. The transient anal incontinence on day 30 after surgery was noted by 3/30 (10%) patients of the main group and 15/40 (37.5%) patients of the control group ( $p = 0.01$ ). At the same time, on day 60 of follow-up, both groups were comparable ( $p = 0.63$ ). AI remained in 1/30 (3%) patient in the main group and in 3/40 (7.5%) patients of the control group. The median scores on the Wexner scale on day 30 were 1 (1; 1) point and 2 (1; 3) points ( $p = 0.18$ ), on day 60 — 1 (1; 1)

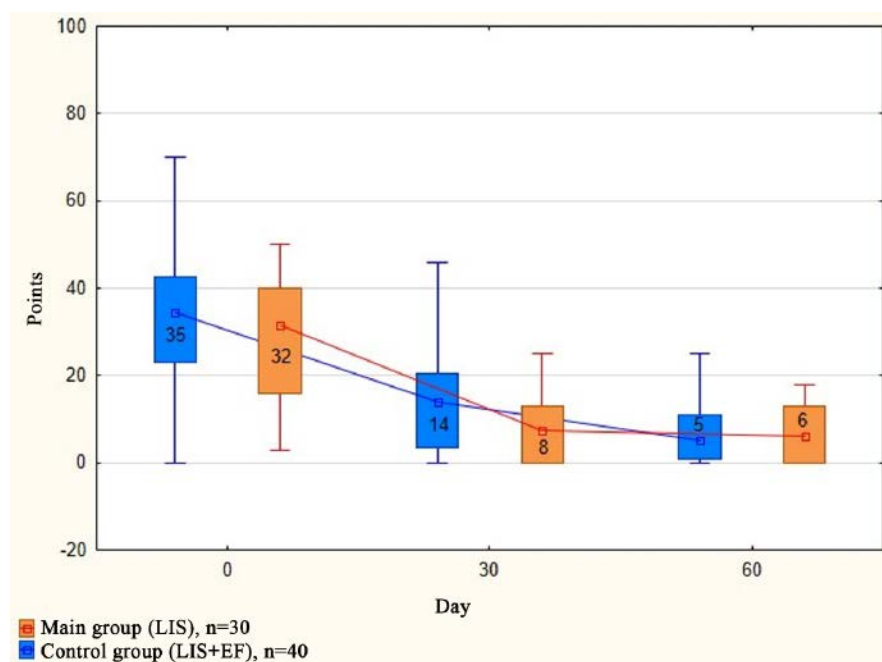


Figure 3. Quality of life according to the Hemo-Fiss scale

**Table 3.** Factors associated with transient anal incontinence on day 30 after surgery

Factor	OR (CI 95%)	p
Treatment method:		
LIS	1	
LIS + EF	5.4 (1.4–20.9)	0.015
Age	1.0 (1–1.09)	0.08
BMI	1.0 (0.9–1.12)	0.91
Gender		
Male	1	
Female	2.3 (0.76–7.16)	0.14
Childbirth (N)		
0	1	
1	9 (0.89–91.2)	0.06
2	3 (0.22–40.1)	0.4
3	9 (0.52–155)	0.13
Complicated childbirth		
No	1	
Yes	1.67 (0.3–9.4)	0.55

**Table 4.** Factors associated with transient anal incontinence on day 60 after surgery

Factor	OR (CI 95%)	p
Method of relaxation of the internal sphincter:		
LIS	1	
LIS + EF	2.3 (0.23–23.8)	0.47
Age	1.06 (0.98–1.15)	0.16
BMI	0.86 (0.66–1.13)	0.3
Gender		
Male	1	
Female	3 (0.3–30.3)	0.35
Childbirth (N)		
0	–	
1	–	–
2	–	–
3 and more	–	–
Complicated childbirth		
No	1	
Yes	11.2 (0.85–148)	0.067

point and 2 (1; 4) points ( $p = 0.76$ ), respectively. The median duration of transient anal incontinence in the main group was 4 (3; 5) days, in the control group — 5 (2; 12) days ( $p = 0.6$ ). It is worth noting that the phenomena of anal incontinence in accordance with the Wexner scale were caused exclusively by gas incontinence in both patients after LIS and after LIS with fissure excision.

A univariate-factor analysis of factors presumably influencing the AI on days 30 and 60 of the post-operative period was carried out (Table 3,4). Thus, the combination of lateral subcutaneous sphincterotomy with fissure excision (LIS + EF) by 5.4 (1.4–20.9) times increases the chance of AI on

day 30 after surgery, compared with its LIS only ( $p = 0.015$ ). On day 60 of follow-up, the influence of this factor is leveled ( $p = 0.47$ ).

When assessing the quality of life on the Hemo-Fiss scale, the groups were homogenous ( $p = 0.1$ ). The median score in the main group (LIS) was 15 (8; 25) points and 17 (7; 35) points — in the control group (LIS + EF) (Fig. 3).

On day 15 after surgery, lesion healing was detected in 12/30 (40%) patients of the main group (LIS), and in the control group, no wound was epithelized in any patient (LIS + EF) ( $p < 0.0001$ ) (Table 5). By day 30, the lesion had healed in 22/30 (73.3%) patients in the LIS group and only in 2/40



**Table 5.** Time of lesion epithelization

Day	Treatment method		<i>p</i>
	Main group (LIS) <i>n</i> = 30	Control group (LIS + EF) <i>n</i> = 40	
15	12 (40.0%)	0 (0%)	0.00001
30	22 (73.3%)	2 (5.0%)	0.00001
45	26 (87.0%)	20 (50.0%)	0.002
60	28 (93.3%)	38 (95.0%)	1

**Table 6.** The level of maximal pressure in the anal canal at rest on days 30 and 60 after surgery

The level of MPACR (mmHg)	Day 30			Day 60		
	LIS + EF, <i>n</i> = 40	LIS, <i>n</i> = 30	<i>p</i>	LIS + EF, <i>n</i> = 40	LIS, <i>n</i> = 30	<i>p</i>
Increased (> 112.2)	2 (5%)	5 (17%)		3 (7%)	5 (17%)	0.5
Norm (89.4–112.2)	18 (45%)	16 (53%)	0.59	15 (38%)	13 (43%)	
Decreased (< 89.4)	20 (50%)	9 (30%)		22 (55%)	12 (40%)	

(5%) patients in the LIS + EF group ( $p < 0.0001$ ). On day 45, epithelialization of the lesion was found in 26/30 (87%) and 20/40 (50%) patients, respectively ( $p = 0.003$ ), by day 60 — in 28/30 (93.3%) and 38/40 (95%) patients, respectively ( $p = 1.0$ ).

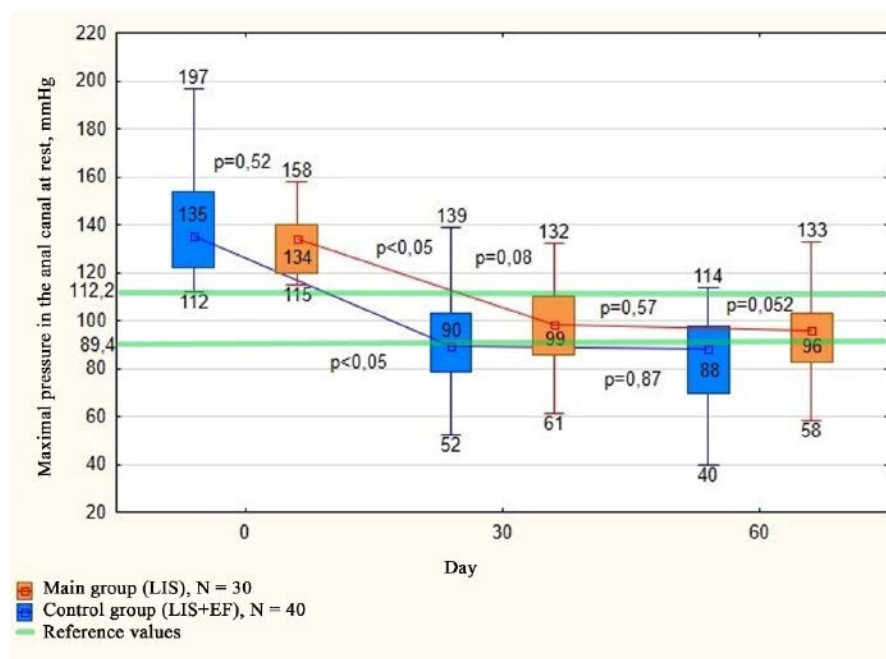
### Functional results

On day 30 after the surgery, a decrease in the maximal pressure in the anal canal at rest (MPACR) was revealed both in the main (LIS) and in the control group (LIS + EF), compared with the indicators obtained before the surgery ( $p < 0.0001$ ) (Fig. 4).

The groups were comparable in MPACR on days 30 and 60 of the postoperative period in accordance with the reference values (Table 6).

The average pressure in the anal canal at rest (APACR) decreased by day 30 of postoperative period in patients in the compared groups ( $p < 0.0001$ ) (Fig. 5). There were no differences between the groups ( $p = 0.57$ ).

According to the studied indicator, the groups were comparable in accordance with the reference values (Table 7).

**Figure 4.** Maximal pressure in the anal canal at rest before and after surgery

**Table 7.** The level of average pressure in the anal canal at rest on days 30 and 60 after surgery

APACR level (mmHg)	Day 30			Day 60		
	LIS + EF, n = 40	LIS, n = 30	p	LIS + EF, n = 40	LIS, n = 30	p
Increased (> 60.4)	2 (5%)	3 (10%)	0.6	4 (10%)	3 (10%)	0.5
Norm (44.0–60.4)	21 (53%)	17 (57%)		16 (40%)	16 (53%)	
Decreased (< 44.0)	17 (42%)	10 (33%)		20 (50%)	11 (37%)	

**Table 8.** Spasm of the internal anal sphincter on days 30 and 60 after surgery

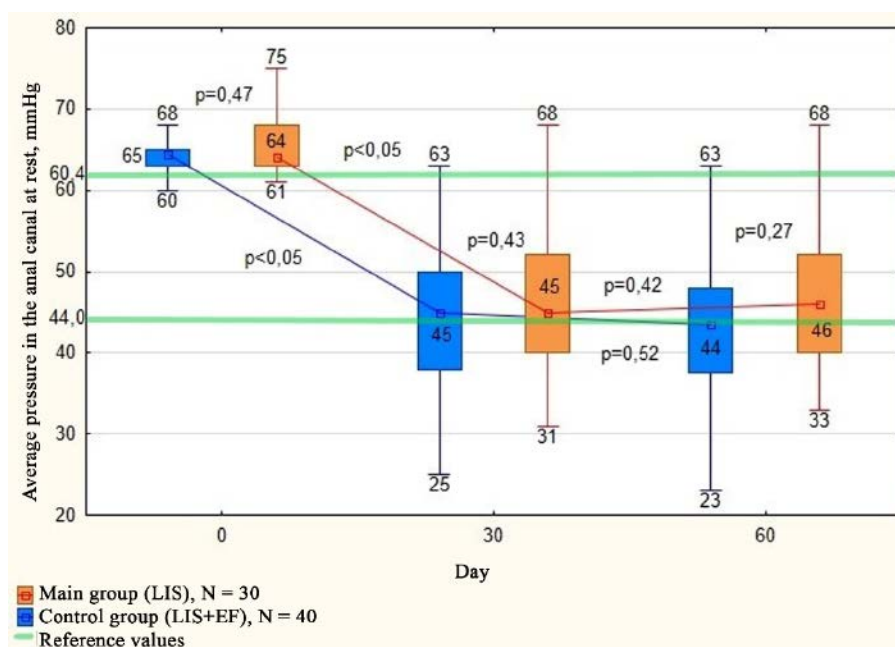
Spasm of the internal anal sphincter	Day 30			Day 60		
	LIS, n = 30	LIS + EF, n = 40	p	LIS, n = 30	LIS + EF, n = 40	p
Yes	6 (20%)	3 (7.5%)	0.15	5 (17%)	4 (10%)	0.48
No	24 (80%)	37 (92.5%)		25 (83%)	36 (90%)	

The spasm of the internal anal sphincter was diagnosed by increase in the level of APACR and/or MPACR relative to the reference values [5]. On day 30 after surgery, spasm persisted in 6/30 (20%) patients of the main group and in 3/40 (7.5%) patients of the control group ( $p = 0.15$ ). By day 60, there was a decrease in the number of patients with increased internal sphincter tone in the main group to 5/30 (17%) patients, and in the control group — an increase to 4/40 (10%) patients ( $p = 0.48$ ) (Table 8).

The groups were homogenous on days 30 and 60 of follow-up in maximal and average pressure with voluntary contraction.

A univariate analysis of factors that presumably influence the timing of lesion epithelialization was carried out (Table 9,10,11,12). It is worth noting that due to the insufficient number of initial indicators, it is not possible to assess the impact of some factors.

To assess the impact of some of the alleged factors affecting epithelialization, it is necessary to continue recruiting patients into the study.

**Figure 5.** Average pressure in the anal canal at rest before surgery and in the postoperative period



**Table 9.** Factors presumably affecting lesion healing on day 15 after surgical treatment

Factor	OR (CI 95%)	p
Treatment method		
LIS	-	
LIS + EF	-	-
Persistent spasm of the internal sphincter:		
No	1	
Yes	1.76 (0.2–15.6)	0.61
History of the disease	0.99 (0.97–1)	0.43
Age	1.04 (0.98–1.11)	0.14
BMI	1.13 (0.97–1.3)	0.11
Gender		
Male	1	
Female	0.7 (0.2–2.5)	0.6
Sentinel pile		
No	1	
Yes	1.5 (0.35–6.3)	0.58
Fibrous polyp		
No	1	
Yes	1.92 (0.3–12)	0.48

**Table 10.** Factors presumably affecting lesion healing on day 30 after surgical treatment

Factor	OR (CI 95%)	p
Treatment method		
LIS	1	
LIS + EF	52 (10.2–268.3)	0.000002
Persistent spasm of the internal sphincter:		
No	1	
Yes	0.36 (0.08–1.5)	0.16
History of the disease	0.99 (0.97–1)	0.4
Age	1 (0.98–1.08)	0.21
BMI	1 (0.9–1.1)	0.87
Gender		
Male	1	
Female	1 (0.4–2.9)	0.86
Sentinel pile		
No	1	
Yes	0.5 (0.1–2.4)	0.4
Fibrous polyp		
No	1	
Yes	0.31 (0.3–3.05)	0.32

LIS with fissure excision reduces the chance of lesion healing by 52 (10.2;268.3) times on day 30 ( $p < 0.0001$ ) and by 6.5 (1.9;22) times — on day 45 ( $p = 0.003$ ) compared with LIS only (Table 12). Any factors affecting fissure epithelialization on days 15 and 60 were not detected (Table 9,12).

## DISCUSSION

According to actual clinical guidelines, the main method of treatment of chronic anal fissure is its excision in combination with lateral internal sphincterotomy [6]. In turn, in foreign clinical practice, the fissure is not excised, but is limited exclusively to the elimination of the main point of pathogenesis — spasm of the internal sphincter [4]. At the same time, questions remain revealed

**Table 11.** Factors presumably influencing lesion healing on day 45 after surgical treatment

Factor	OR (CI 95%)	p
Treatment method		
LIS	1	
LIS + EF	6.5 (1.9–22)	0.003
Persistent spasm of the internal sphincter:		
No	1	
Yes	0.5 (0.1–2.6)	0.42
Anamnesis	1 (0.99–1)	0.46
Age	0.99 (0.99–1.03)	0.82
BMI	1.04 (0.94–1.15)	0.45
Gender		
Male	1	
Female	1.18 (0.44–3.2)	0.74
Sentinel tubercle		
No	1	
Yes	0.2 (0.02–2.35)	0.21
Fibrous polyp		
No	1	
Yes	1.1 (0.01–12.7)	0.9

**Table 12.** Factors presumably influencing lesion healing on day 60 after surgical treatment

Factor	OR (CI 95%)	p
Treatment method		
LIS	1	
LIS + EF	0.73 (0.01–5.6)	0.77
Persistent spasm of the internal sphincter:		
No	1	
Yes	2.4 (0.2–26.1)	0.47
Anamnesis	1 (0.97–1.03)	0.95
Age	0.96 (0.86–1.05)	0.37
BMI	0.98 (0.79–1.2)	0.84
Gender		
Male	1	
Female	0.94 (0.13–7.1)	0.95
Sentinel tubercle		
No	-	
Yes	-	-
Fibrous polyp		
No	1	
Yes	3.66 (0.2–67.6)	0.38

about the effect of fissure excision on the course of both the early and late postoperative period, first of all, this concerns the timing of epithelialization of the wound lesion and the severity of the pain. In the study, the intensity of pain in the early postoperative period was significantly lower in the main group (LIS). It should be noted that, unlike the control group (LIS + EF), it steadily decreased for the entire postoperative period, and did not tend to increase after the first act of defecation. Since the functional results of treatment are

comparable in both groups, most likely such an increase in the intensity of pain in the control group during the first days of the postoperative period is due to the inflammatory process in the area of the postoperative wound on the perianal skin [7]. As noted earlier, the study of the functional results of treatment showed that both types of procedures are comparable in their effect on the anal sphincter, and equally allow for the elimination of the internal sphincter spasm. However, despite this, the incidence of anal incontinence on day 30 of

the postoperative period was significantly higher if the patients underwent excision of the anal fissure — AI developed in 3/30 (10%) patients of the main group and in 15/40 (37.5%) patients of the control group ( $p = 0.01$ ). Since by day 60 of the postoperative period, the differences between the groups disappeared, most likely, the AI is associated with factors that have a temporary effect on the anal sphincter, for example: double-leaf retractor divulsion during the anal fissure excision, temporary anal deformation after the anal fissure excision, severe pain. It will be possible to answer this question more precisely as the material accumulates in further research. According to the literature, the incidence of fissure epithelialization after lateral sphincterotomy varies from 85.8 to 99% [1,8,9,11]. However, despite a significant amount of data from various sources, the general idea of the healing time of a chronic anal fissure is quite abstract, starting from 14 days, and ending with 2 months or more [1,8,9,11]. According to our study, fissure healing was achieved on day 15 in 12/30 (40%) cases only in the LIS group, by day 30 — already in 22/30 (73.3%) cases, while in the LIS + EF group — only in 2 (5%) cases by this time ( $p < 0.0001$ ). And only on day 60, the groups were comparable to each other in terms of the studied indicator, since the lesion healing was noted in 28/30 (93.3%) patients in the main group and in 38/40 (95%) patients in the control group ( $p = 1.0$ ).

Thus, the rejection of fissure excision allowed to accelerate the process of epithelization of the anoderm lesion, and the only factor affecting the rate of epithelization of the anal fissure is the nature of the operation performed, which is confirmed by the data of a univariate analysis. In our opinion, performing LIS without excision makes it possible to achieve fast healing. The recruitment of patients continues, and an assessment of long-term results will be possible a year after surgical treatment.

## CONCLUSION

The refusal to excise the anal fissure and performing lateral subcutaneous internal sphincterotomy only reduces the intensity of postoperative

pain, the incidence of postoperative complications and the time of epithelization of the anoderm lesion.

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