OUTCOMES OF SURGERY FOR HIGH TRANSSPHINCTERIC ANAL FISTULAS: PROSPECTIVE RANDOMIZED TRIAL

Churina Yu.A.,
Shlyk D.D.,
Rzayev R.T.,
Balaban V.V.,
Tsarkov P.V.

I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University) (Trubetskaya str. 8/2, Moscow 119991, Russian Federation)

Corresponding author:
Yuliya A. Churina,
e-mail: churina.1238@mail.ru

ABSTRACT

Background. *Reliable data on the efficacy and safety of fistulectomy with primary sphincter repair for the treatment of high transsphincteric anal fistulas are deficient.*
The aim. *To compare the efficacy and safety of fistulectomy with advancement muco-muscular flap (F) and fistulectomy with primary sphincter reconstruction (SR) for the treatment of high anorectal fistulas.*
Methods. *A cohort of 92 consecutive patients with transsphincteric anal fistula involving 1/3 to 2/3 of the sphincteric complex were included in prospective randomized study. The primary endpoint was the recurrence rate. The duration of surgery, blood loss, pain intensity, postoperative complications, the duration of wound healing, incontinence, quality of life were registered.*
Results. *Forty-six patients were randomized in each group. A statistically significant difference was obtained for operative time (Group "F" – 45 (20–160) min, Group "SR" – 33 (10–55) min). The blood loss was 3 (1–20) and 2 (1–10) ml in Groups "F" and "SR", respectively ($p = 0.482$). The return to work in Groups "SR" and "F" occurred after 7 (2–14) and 8 (4–20) days, respectively ($p = 0.005$). The pain syndrome was significantly greater in Group "F" ($p < 0.05$) on days 1 and 7. Recurrence rate was in 23.9 % (11 cases) in Group "F" and in 6.5 % (3 cases) in Group "SR" ($p = 0.042$). Incontinence was in 7 (15.2 %) people in Group "F", in 10 patients (21.7 %) – in Group "SR" ($p = 0.591$). There was no statistically significant difference in postoperative complications.*
Conclusion. *Findings can expand the indications for the treatment of high transsphincteric anorectal fistulas involving from 1/3 to 2/3 of the sphincter complex without statistically significant risk for functional results.*

Key words: *fecal incontinence, fistula, surgical flaps, recurrence, magnetic resonance imaging*

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РЕЗУЛЬТАТЫ ЛЕЧЕНИЯ ПАЦИЕНТОВ С ВЫСОКИМИ ТРАНССФИНКТЕРНЫМИ АНОРЕКТАЛЬНЫМИ СВИЩАМИ: ПРОСПЕКТИВНОЕ РАНДОМИЗИРОВАННОЕ ИССЛЕДОВАНИЕ

Чурина Ю.А.,
Шлык Д.Д.,
Рзаев Р.Т.,
Балабан В.В.,
Царьков П.В.

ФГАОУ ВО Первый Московский государственный медицинский университет имени И.М. Сеченова Минздрава России (Сеченовский Университет) (119991, г. Москва, ул. Трубецкая, 8, стр. 2, Россия)

Автор, ответственный за переписку:
Чурина Юлия Александровна,
e-mail: churina.1238@mail.ru

РЕЗЮМЕ

Обоснование. *Существует недостаток убедительных данных об эффективности и безопасности иссечения свища в просвет с ушиванием сфинктера для лечения высоких транссфинктерных аноректальных свищей.*

Цель исследования. *Сравнение эффективности двух методик – иссечение свища с пластикой слизисто-мышечным лоскутом (Л) и иссечение свища в просвет с ушиванием дефекта сфинктерного комплекса (УС) – для лечения высоких аноректальных свищей.*

Методы. *В проспективное рандомизированное исследование последовательно были включены 92 пациента с транссфинктерным свищом при вовлечении от 1/3 до 2/3 запирательного аппарата. Первичной конечной точкой являлась частота рецидивов заболевания. В ходе исследования проанализированы длительность операции, объём кровопотери, болевой синдром, частота и характер послеоперационных осложнений, длительность заживления раны, инконтиненция, качество жизни.*

Результаты. *Количество пациентов в каждой группе составило 46 человек. Статистически значимая разница получена для длительности операции (группа «Л» – 45 (20–160) мин; группа «УС» – 33 (10–55) мин), при этом объём кровопотери оценивался в 3 (1–20) и 2 (1–10) мл в группах «Л» и «УС» соответственно (p = 0,482). Возвращение к труду в группах «УС» и «Л» наступило через 7 (2–14) и 8 (4–20) дней соответственно (p = 0,005). Болевой синдром был статистически значимо больше в группе «Л» (p < 0,05) на 1-е и 7-е сутки. В группе «Л» рецидивы выявлены в 11 (23,9 %), в группе «УС» – в 3 (6,5 %) случаях (p = 0,042). Инконтиненция в группе «Л» наблюдалась у 7 (15,2 %) человек, в группе «УС» – у 10 (21,7 %) пациентов (p = 0,591). Не получено статистически значимой разницы в отношении послеоперационных осложнений.*

Заключение. *Полученные результаты могут расширить показания для лечения высоких аноректальных свищей при вовлечении от 1/3 до 2/3 сфинктерного комплекса без значимого риска для функциональных результатов.*

Ключевые слова: *анальная инконтиненция, свищ, перемещённый лоскут, рецидив, магнитно-резонансная томография*

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OBJECTIVES

The goal of surgical treatment of anorectal fistulas of any complexity is to prevent recurrence of the disease while preserving fecal continence [1]. Excision of the fistulous passage through the sphincter complex (transsphincteric fistula), its external and internal opening and restoration of sphincter integrity are characterized by the lowest recurrence rates [2, 3]. The higher the level of the location of the internal opening of the fistula, the larger the part of the sphincter that must be crossed and repaired. There is a direct correlation between the volume of the transected part of the rectal closing apparatus and the probability and severity of subsequent incontinence. In this case, the lower third of the anal canal is the boundary beyond which the risk of developing incontinence becomes real.

For higher fistulas, various sphincter-preserving procedures are currently performed. They can be divided into excisional and obliterative procedures. Excisional procedure is aimed at excision of the fistulous passage and its branches with closure of the internal opening using various flaps. Obliteration procedure is aimed at suturing the internal opening of the fistula, which is accompanied by physical, chemical and biological methods aimed at its healing and closure without excision [4–7]. The advantage of the sphincter-preserving surgery is a low rate of incontinence (0–10 %) [8]; the disadvantage is a high rate of recurrence, which varies depending on the procedure, frequency, duration of follow-up and can range from 25 to 100 % [4].

This prospective trial compared two excisional treatments of high transsphincteric anorectal fistulas.

HYPOTHESIS OF THE TRIAL

The hypothesis of the trial was the assumption that fistulectomy with sphincter reconstruction (SR), when 1/3 to 2/3 of the closing apparatus is involved, is accompanied by a lower number of recurrences and does not increase the incontinence rate compared to fistulectomy without sphincter transection and repair of the internal opening using a muco-muscular flap (F).

MATERIALS AND METHODS

The trial was conducted at the I.M. Sechenov First Moscow State Medical University (Sechenov University) and was approved by the local ethics committee (Record No. 18-01 dated 30.09.2017).

Inclusion criteria:

1) transsphincteric rectal fistula, involving 1/3 to 2/3 of the rectal closing apparatus according to magnetic resonance imaging (MRI) of the pelvic organs (Fig. 1);

2) the age of the trial participant is older than 18 years of age;

3) signed informed voluntary consent to participate in the trial.

Exclusion criteria:

1) transsphincteric, involving less than 1/3 and more than 2/3 of the sphincter complex; intersphincteric; extrasphincteric rectal fistula;

2) recurrent fistula (recurrence of the disease after previous surgical treatment for a rectal fistula with an internal opening of the same localization);

3) incontinence 1–20 points (according to the CCFFIS (Cleveland Clinic Florida Fecal Incontinence Score) scale) [9];

4) inflammatory bowel diseases confirmed by endoscopic and morphological methods (ulcerative colitis, Crohn's disease);

5) anterior anorectal fistula in women;

6) acute purulent paraproctitis;

7) inability to perform MRI of the pelvic organs (presence of metal implants, claustrophobia, etc.);

8) patient's refusal to participate in the trial.

Placement of drainage ligature was not an obligatory stage of treatment, but its presence did not serve as a contraindication to the inclusion of patients in the trial. In case of ligature placement, surgery was performed 8 weeks after that.

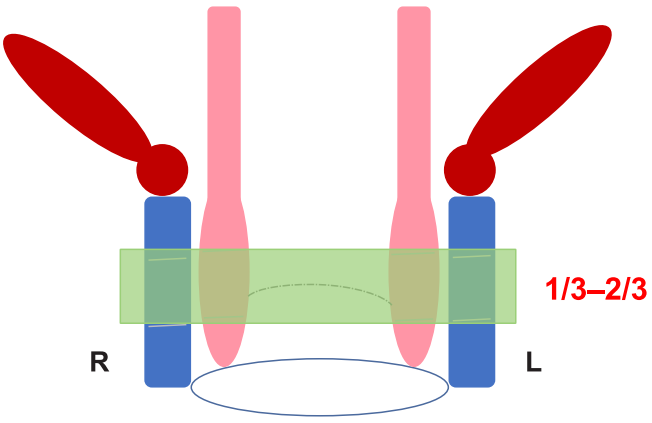


FIG. 1.
Schematic drawing of rectal obturator in patients included in the trial

The primary endpoint of the trial was the recurrence rate of the disease.

One condition or a combination of several conditions was considered recurrence:

1) recurrence of clinical picture not earlier than 2 months after surgical intervention in the form of development of acute inflammation and/or discharge from the wound after its complete healing;

2) chronic non-healing wound (absence of complete epithelialization for more than 3 months);

3) fistulous passage and/or residual cavities according to control MRI of the pelvic organs with intravenous contrast.

The secondary endpoints chosen were:

1) duration of the surgery;
2) volume of blood loss;
3) pain syndrome;
4) frequency and nature of postoperative complications;
5) duration of wound healing;
6) Incontinence from 1 to 20 points (CCFFIS scale);
7) quality of life (SF-36 (Short Form 36) scale) [10].

The following postoperative complications were evaluated: bleeding, flap retraction, postoperative wound pyogenesis, and suture failure on the muscle complex.

The design of the randomized single-center trial is shown in Figure 2.

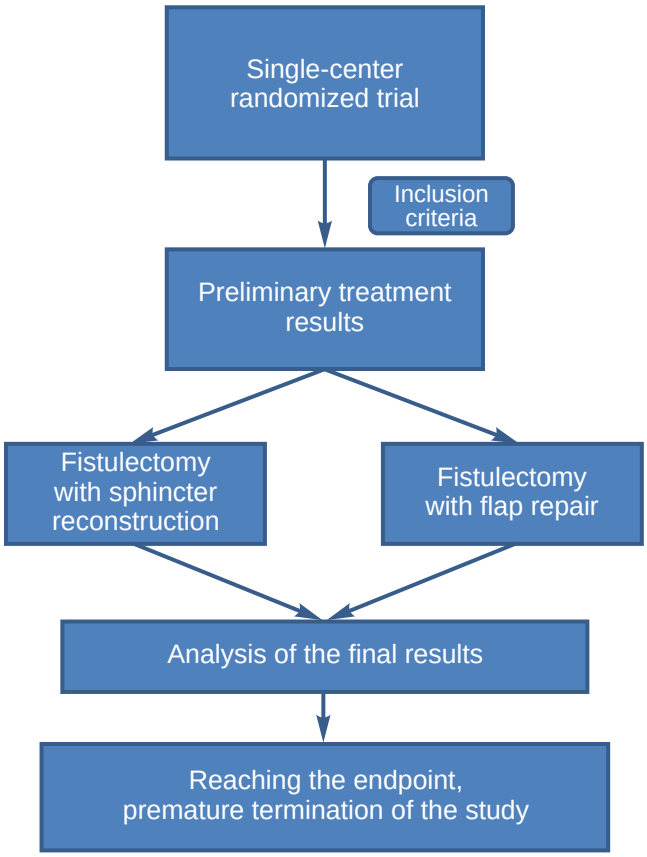


FIG. 2.
Design of a single-center prospective randomized trial

Sample size calculation

The number of patients required to compare the results of fistulectomy with primary sphincter suturing and the use of a mobilized muco-muscle flap was determined using Lehr's formula. The value of a minimum clinically significant difference in recurrence rate of 15 % is based on available data from the literature and our own retrospective experience. Therefore, considering a given power of the trial of 80 % and a type 1 error of 5 %, and to achieve the expected difference, the minimum sample size was 158 patients (79 patients in each group). Interim data analyses were performed when 50 % of the planned number of subjects were enrolled.

Randomization

After meeting the inclusion/non-inclusion criteria, patients were randomly allocated to groups by cluster randomization using Random Allocation Software. Therefore, a sample of 158 units including 2 groups of patients was formed. Patients of Group 1 underwent fistulectomy with sphincter reconstruction, and Group 2 underwent fistulectomy with repair of the internal opening using a muco-muscular flap of the rectal wall. The probability of a patient being placed in one group or another was 50 %.

Given the hypothesis testing nature of the trial, an interim analysis of the results was conducted when 50 % of the planned sample was reached.

In an interim analysis of 92 patients, a statistically significant difference in the number of disease recurrences was obtained, reaching the expected primary endpoint of the trial prematurely and stopping the trial for ethical reasons.

Statistical data processing

The data were analyzed using the SPSS Statistics software package version 22.0 (IBM Corp., USA) after testing for normality of distribution using the Kolmogorov–Smirnov test. The following parameters were used in the analysis: Student's t-test, Mann – Whitney U test, Pearson's chi-squared test, Fisher's exact test. A p value < 0.05 was considered statistically significant.

Preoperative examination

Visual inspection of the perianal area and digital rectal examination were performed. All patients underwent full colonoscopy.

It was also mandatory to perform pelvic MRI with IV contrast on a tomograph with a 3 Tesla magnetic field.

All studies included the following sequence: T1-weighted image (WI), T2-WI with short- and long-axis to the anal canal, T2-WI with suppression of signal from adipose tissue to anal canal, T1-WI with suppression of signal from adipose tissue with intravenous injection of contrast agent into the cubital vein. The record included the following characteristics: localization of the internal and external fistula openings, extent, topographic-anatomical characteristics (direction of the passage, location of the passage in relation to the external sphincter, leakage), assessment of inflammatory changes (infiltrate, abscesses, sphincter involvement).

Continence function was also assessed using the CCFFIS scale and patient's quality of life using

the SF-36 Questionnaire (MH (Mental Health) – mental health assessment; PH (Physical Health) – physical health assessment).

Postoperative patient management

During the postoperative period, antibacterial therapy with broad-spectrum drugs (ciprofloxacin, metronidazole) was performed.

Pain syndrome correction was carried out depending on its severity according to the Visual Analogue Scale (VAS). Monotherapy with non-steroidal anti-inflammatory drugs or combination with narcotic analgesics was used in case of pain intensity more than 6 points. The intensity of pain syndrome was recorded 1, 7 and 28 days after surgery.

There was no stool retention, and the first defecation was performed after the urge to defecate using microclysis. Wound care consisted of daily dressings with treatment with aqueous antiseptic solution, followed by application of hydrophilic ointments.

Quality of life was assessed 14, 28 days and 12 months after surgery using the SF-36 Questionnaire. The level of incontinence was assessed using the CCFFIS scale 28 days and then 12 months after surgery.

Surgical technique

Preoperative preparation

The surgical intervention was performed in a modified lithotomy position using subarachnoid anesthesia.

During intraoperative revision, the fistulous passage was stained through the external fistulous opening with a dye solution in order to identify the internal fistulous opening. A bulbous-end probe was inserted into the fistulous passage to further assess the nature of the passage, the degree of involvement of the sphincter complex, and secondary leakage. If inclusion criteria were met, the patient was randomized to one of the groups.

Fistulectomy with repair of the internal opening using a muco-muscular flap (F)

The external fistulous opening was grasped with an Allis clamp and an electrocoagulator was used to make a skin incision in its projection. The fistulous passage was then sequentially isolated in a single block without dissecting the tissues overlying the fistula.

The next step was mobilization of a lip-shaped muco-muscular flap of the rectal wall (the ratio of the flap width to its length was at least 2:1). The flap was formed according to the size of the sphincter defect after previously performed fistulectomy.

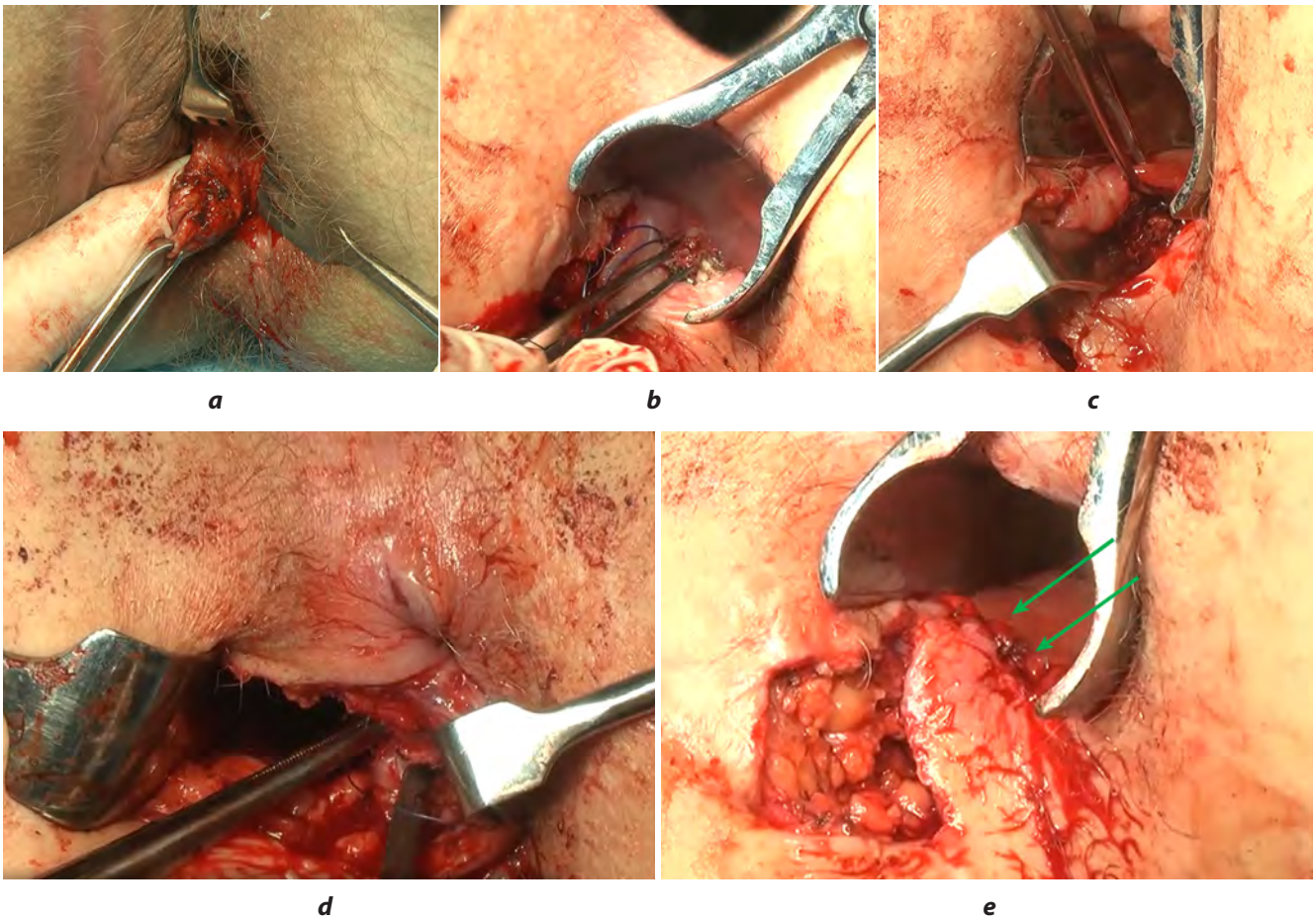


FIG. 3.

*Steps of surgery in Group "F": **a** – fistulectomy; **b** – excision of the internal opening; **c** – mobilization of the muco-muscular flap; **d** – suturing of the sphincteric defect; **e** – fixation of the flap to the anoderm*

The flap was fixed to the distal edge of the defect without tension with separate knotted sutures using Vicryl/Polysorb 3/0. The muscle skeleton defect was sutured with separate knotted sutures on the wound side (Vicryl/Polysorb 2/0). The external perianal wound was not sutured (Fig. 3).

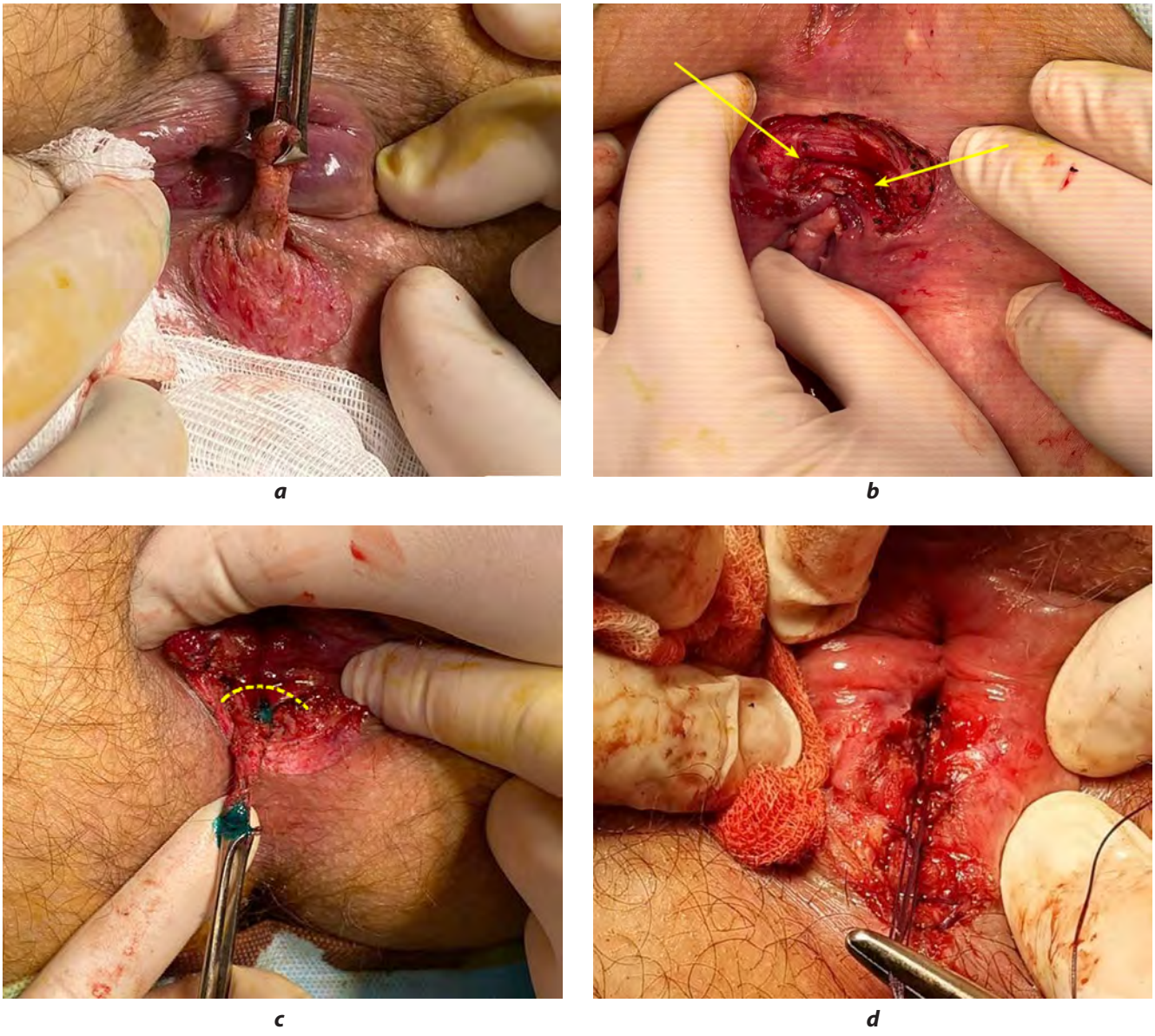
Technique of fistulectomy with sphincter reconstruction (SR)

The external fistulous opening was grasped with an Allis clamp and an electrocoagulator was used to make a skin incision in its projection. The incision was then continued along the course of the main fistulous tract towards the anal canal lumen. The passage was isolated from the surrounding tissues while preserving the integrity of its lumen to remove it en bloc and prevent fragmentation.

After complete removal of the passage, the intersphincteric space, the bed of the affected gland, becomes accessible for visual inspection.

In the projection of the anal canal mucosa, excision was performed with grasping the internal opening.

Sequential suturing of the sphincter defect was performed using individual knotted sutures (Vicryl/Polysorb 2/0). The edges of the sphincter and subcutaneous adipose tissue were aligned with each other to form a flat wound surface without recesses. Suturing of the anal canal mucosa, anoderm and skin over the wound was not performed (Fig. 4).



a ***b*** ***c*** ***d***

FIG. 4.

*Steps of surgery in Group "SR": **a** – visualization of the posterior wall of the fistula during excision with en-block; **b** – intersphincter space after fistulectomy (indicated by arrows); **c** – the border of internal opening excision (highlighted with a dotted line), the internal opening is painted; **d** – final appearance (separate sutures on the muscle complex)*

RESULTS

The clinical characteristics of the patients are summarized in Table 1.

The groups were comparable in terms of sex, age and duration of ligature placement. In Group "F", drainage ligature was placed statistically significantly more frequently than in Group "SR" ($p = 0.036$). This difference was probably a result of the small sample size.

According to the MRI data, the number and nature of leakage in Groups "F" and "SR" are not statistically significantly different.

When patients' quality of life was assessed using the SF-36 preoperative questionnaire, no statistically significant differences were found in both groups, neither in PH (SF-36) nor in MH values (SF-36).

The duration of surgical intervention in Groups "F" and "SR" was 45 (20–160) and 33 (10–55) min, respective-

TABLE 1
CHARACTERISTICS OF PATIENTS

Characteristics	Group "F" (*n* = 46)	Group "SR" (*n* = 46)	*p*
Age, years	40 ± 10	40 ± 11	0.884
Male, *n* (%)	32 (69.6 %)	34 (73.9 %)	0.817
Female, *n* (%)	14 (30.4 %)	12 (26.1 %)	
Presence of ligature, *n* (%)	26 (56.2 %)	15 (32.6 %)	0.036
Duration of ligature placement before surgery, days	62 (24–397)	81 (18–545)	0.117
Localization of the internal fistulous opening:			
posterior, *n* (%)	27 (58.7 %)	25 (54.4 %)	0.785
anterior, *n* (%)	16 (34.8 %)	17 (37 %)	
lateral, *n* (%)	3 (6.5 %)	4 (8.6 %)	
Presence of leakage			
yes, *n* (%)	11 (23.9 %)	5 (10.9 %)	0.170
no, *n* (%)	35 (76.1 %)	41 (89.1 %)	
Leakage localization			
ischiorectal	3 (6.5 %)	4 (8.7 %)	0.209
intersphincteric	3 (6.5 %)	2 (4.3 %)	
subleavatory	4 (8.7 %)	0	
SF-36 (MH)	53.1 (53.1–54.0)	53.1 (46.2–54.0)	0.151
SF-36 (PH)	54.2 (53.5–57.6)	54.8 (535.–57.6)	0.914

ly, and statistically significant differences between groups were obtained ($p = 0.004$).

The volume of blood loss was 3 (1–20) and 2 (1–10) ml in the "F" and "SR" groups, respectively ($p = 0.482$).

At statistical analysis of VAS 1 and 7 days after the operation there is a statistically significantly greater pain syndrome in the group with repair of the rectal wall using a mucous-muscular flap in comparison with primary fistulectomy with sphincter reconstruction ($p < 0,05$), but after 28 days this difference ceases to be significantly statistically significant ($p = 0,733$).

The following complications were recorded in the early postoperative period: bleeding from the wound, which required re-hospitalization of one patient in the group. One patient in this group was found to have wound infection, which required additional drainage and debridement with antiseptic solutions. In addition, there were two cases of flap retraction that did not require repeated surgical intervention, and conservative treatment consisted of transanal irrigation of the failure area with antiseptic solutions. Two cases of partial suture line disruption on the muscle complex with subsequent wound healing by secondary tension were noted in Group "SR".

The groups were comparable in terms of the number and nature of complications.

The healing time of the external perianal wound in Group "F" was 30.10 ± 1.99 days and in Group "SR" was 26.73 ± 2.55 days and had no statistically significant differences ($p = 0.311$).

During the postoperative period, impaired continence function was noted among 7 (15.2 %) patients in Group "F" and in 10 (21.7 %) patients in Group "SR" ($p = 0.591$) (Fig. 5).

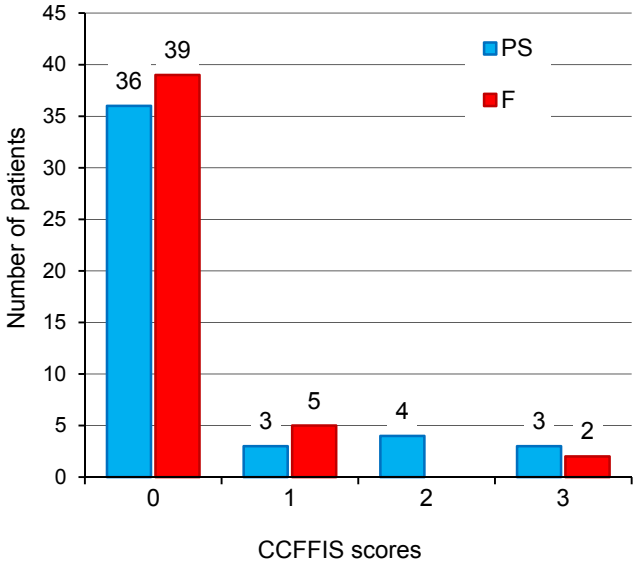


FIG. 5.
Assessment of postoperative incontinence with CCFFI scores

No statistically significant differences were obtained when patients' quality of life was assessed 14, 28 days and 12 months after surgery. A statistically significant difference was obtained only for the physical health assessment (SF-36 (PH)) at day 14 ($p = 0.009$), as shown in Figure 6.

The number of disease recurrences in Group "F" was 11 (23.9 %) cases, in Group "SR" – 3 (65 %), and statistically significant difference in the studied groups is determined ($p = 0.042$).

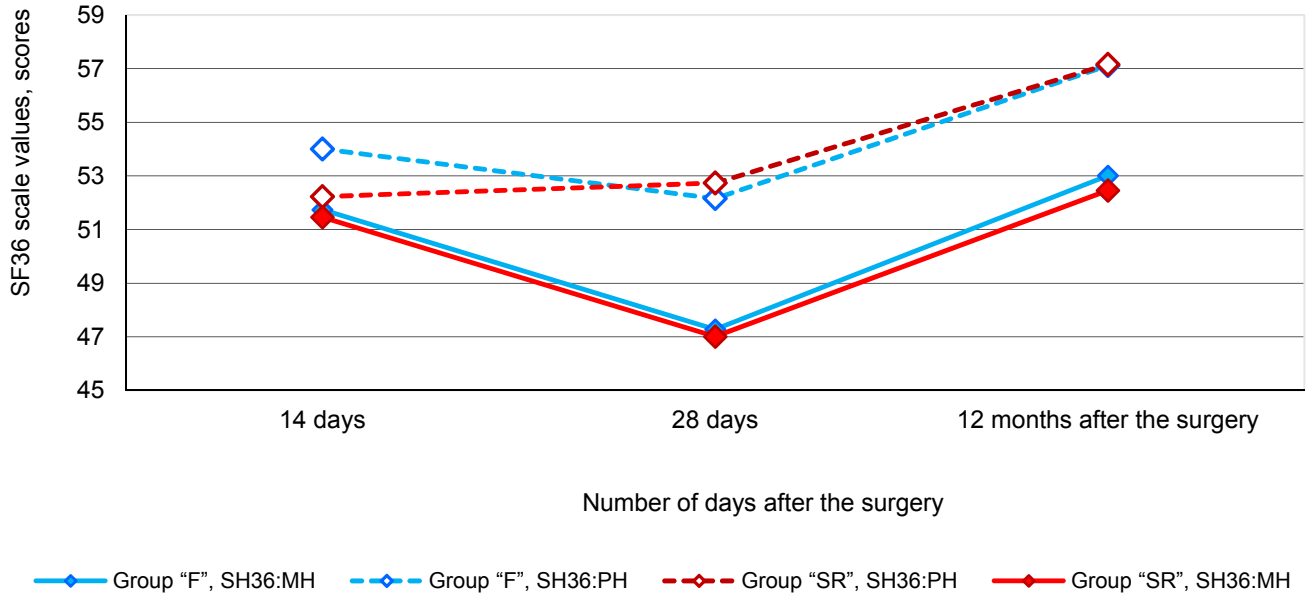


FIG. 6.
Postoperative quality of life. SF-36 (MH) – mental status, SF-36 (PH) – physical status. Patients in Group "SR" recovered faster than those in Group "F" (7 (2–14) and 8 (4–20) days, respectively ($p = 0.005$)).

RESULTS DISCUSSION

Finding the optimal treatment for transsphincteric rectal fistula is a challenge for colorectal surgeons due to a number of aspects, the main ones being preservation of the continence function and prevention of recurrence in the postoperative period.

The position regarding rectal fistulas occupying up to 1/3 of the sphincter complex is now well established, in which fistula dissection or fistulectomy into the intestinal lumen is recommended. The incidence of impaired continence function after such interventions is 0–45 % [11] with a high success rate of 92 % to 97 %.

Various sphincter-preserving techniques have been recommended for transsphincteric fistulas occupying more than 1/3 of the sphincter complex [12, 13]. The advantage of this approach is the low rate of incontinence, the disadvantage is the high recurrence rate even with a highly skilled reference center surgeon [7, 13]. However, the efficacy of the procedure in relation to healing ranges from 65.6 % to 83.7 % [14] for cryptoglandular fistulas.

The absence of a clear position for such a difficult category of patients, when we are talking about the involvement in the pathological process of the area of the sphincter complex (1/3–2/3) provides conditions for further search for an appropriate method of treatment.

In practice, digital and probe examinations were more often used to determine the involvement of the closing apparatus, which was rather subjective. The emergence of more accurate methods for determining the height of the fistula location (transrectal ultrasound (TRUS), MRI of the pelvic organs) has raised the question of the possibility of a continence-safe change in the scope of the use of fistulectomy with sphincter reconstruction.

The experience of the clinic and reports in the literature indicated that the formation of a «safe» scope of fistulectomy with subsequent reconstruction of the closing apparatus took place in an era when it was impossible to confidently determine the height of the passage location and the volume of the sphincter part below this level.

Nevertheless, fistulectomy with primary sphincter reconstruction is now routinely used by surgeons to treat simple low-grade anorectal fistulas with a high recovery rate and without significant compromotation of sphincter function [2, 15, 16]. Fistulectomy in different modifications for high-level fistulas is used only by a number of authors with satisfactory functional results and a relatively low recurrence rate of 12 % [17].

In order to improve functional results, it was proposed in the middle of the 20th century to combine the excision stage with subsequent suturing of the sphincter or suturing of the wound edges to the fundus. However, a number of authors have argued against any kind of plastic surgery in fistulectomy because of the risk of wound infection, sphincter edge dehiscence and subsequent incontinence.

Our trial compared two excisional treatments for high transsphincteric anorectal fistulas.

During the course of the work, a statistically significant difference in disease recurrence between Group “F” and Group “SR” was obtained when assessing the intermediate outcomes, thus confirming the hypothesis and stopping the trial prematurely for ethical reasons. It was possible to prove the safety of fistulectomy with sphincter reconstruction from the point of view of functional results, which expands the indications for use in patients with involvement of the closing apparatus more than 1/3 (less than 2/3).

When analyzing the results, it was found that the duration of surgery was statistically significantly longer in patients with muco-muscular flap formation. This fact is probably due to the fact that fistulectomy without separation of the sphincter fibers is technically more difficult. In addition, the duration of the intervention is also increased by shaping the flap according to certain requirements (sufficient mobility, adequate blood supply).

There are also statistically significant differences in the intensity of pain syndrome: patients in Group “F” have statistically significantly higher VAS scores on day 1 and day 7.

The determined difference in quality of life in patients on day 14 is noted only when analyzing physical health. Statistically significant differences in the form of lower SF-36 (PH) indicators in patients in Group “F” may be due to pain syndrome, size of the wound defect and reduced ability to work.

Incontinence was diagnosed in patients of both groups, but without statistically significant difference ($p = 0.59$). The degree of incontinence, according to the CCFFIS scale, did not exceed 3 points in all patients, which corresponds to minimally severe manifestations of incontinence. According to the meta-analysis by I. Balciscueta et al., the incidence of incontinence increases with increasing flap thickness [16].

However, we did not obtain a statistically significant difference in functional results in the compared groups, but the rate of disease recurrence was statistically significantly higher in the group with flap repair surgery.

The main limitation of this trial is its single-center nature. The surgeries were performed in a reference center with participation of highly qualified surgeons. The presented methods performed by coloproctologists at other clinics may lead to worse results due to their position on a learning curve. Further multicenter studies involving surgeons specializing in treating fistulas are essential.

Also, the trial did not include patients with recurrent fistulas and incontinence, so for this category of patients, fistulectomy with sphincter reconstruction should be recommended with caution.

Another limitation is the fact that after preliminary analyses of patient data, due to a statistically significant difference in recurrence rates, the trial was stopped for ethical reasons.

CONCLUSIONS

Fistulectomy with primary reconstruction of the sphincter complex for the treatment of high transsphincteric fistulas is safe from the point of view of the development of incontinence, accompanied by a lower number of recurrences in comparison with flap repair surgery. The findings may expand the indications for the treatment of high anorectal fistulas when 1/3 to 2/3 of the sphincter complex is involved without significant risk to functional outcomes. Preoperative diagnostics of high accuracy, in particular pelvic MRI with IV contrast, is required to plan surgical treatment from the point of view of the involvement of closing apparatus in the pathological process and the presence of secondary retractions.

Conflict of interest

The authors declare the absence of a conflict of interest regarding this work.

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Information about the authors

Yuliya A. Churina – Teaching Assistant at the Department of Surgery, N.V. Sklifosovsky Institute of Clinical Medicine, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University), e-mail: churina@kkmx.ru, https://orcid.org/0000-0001-9642-8260

Darya D. Shlyk – Cand. Sc. (Med.), Assistant Professor at the Department of Surgery, N.V. Sklifosovsky Institute of Clinical Medicine, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University), e-mail: shlykdarya@gmail.ru, https://orcid.org/0000-0002-9232-6520

Ramin T. Rzayev – Cand. Sc. (Med.), Radiologist at the Department of Radiology, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University), e-mail: ramin-rz@mail.ru, https://orcid.org/0000-0002-6005-6247

Vladimir V. Balaban – Cand. Sc. (Med.), Associate Professor at the Department of Surgery, N.V. Sklifosovsky Institute of Clinical Medicine, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University), e-mail: balaban@kkmx.ru, https://orcid.org/0000-0002-7226-4641

Petr V. Tsarkov – Dr. Sc. (Med.), Professor at the Department of Surgery, N.V. Sklifosovsky Institute of Clinical Medicine, I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University), e-mail: tsarkov@kkmx.ru, https://orcid.org/0000-0002-7134-6821