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Impact of the method of internal opening closure of anal fistula on outcomes after laser fistula coagulation. Preliminary results of randomized clinical trial

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ABSTRACT *AIM: to estimate the outcomes after fistula laser coagulation for transsphincteric anal fistulas. PATIENTS AND METHODS: a prospective randomized single-center study included 42 patients with transsphincteric anal fistulas, 36 (85.7%) of them had a follow-up > 3 months. Nineteen patients were randomized to the group of laser thermocoagulation of the fistula track (diode laser 1560 nm) combined with ligation of intersphincteric fistula track (LC + LIFT). Seventeen patients were randomized to the group of laser thermocoagulation of the fistula combined with closure of internal fistula opening by advancement flap (LC + AF). Mean follow-up period was 6.5 months. Perioperatively (before surgery, 1 and 2 months after surgery), patients underwent ultrasound to assess fistula healing and early detection of recurrence. RESULTS: no intraoperative and early postoperative complications occurred. In the LC + LIFT group, healing rate was 89.5% (17/19 patients), in the LC + AF group — 64.7% (11/17 patients). Endorectal ultrasound confirmed healing or early recurrence. No significant factors affecting recurrence rate were identified in both groups. CONCLUSION: treatment of transsphincteric anal fistulas by LC + LIFT showed better results compared with LC + AF technique. However, further recruitment of patients into study groups is required with evaluation of late results.*

KEYWORDS: anal fistula, laser, FiLaC, LIFT, advancement flap

CONFLICT OF INTEREST: The authors declare no conflict of interest

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Over the past 30 years, there have been significant changes in the paradigm of treatment of anal fistulas.

A lot of techniques and technological solutions have appeared, aimed primarily at eliminating the fistula with maximum preservation of the function of the anal sphincter. This group of operations was called “sphincter-preserving”. Nevertheless, there is currently no optimal method that allows to reliably eliminate the fistula with minimal risk of disease recurrence and preservation of the structures of the sphincter in an intact state. Among all

sphincter-preserving procedures, two methods have gained the greatest popularity and widely spread in clinical practice: ligation of the fistula in the intersphincteric space (LIFT) and laser thermocoagulation of the anal fistula (FiLaC™). According to a systematic review of the literature performed at the Center, after using the laser coagulation technique, the healing rate averaged 69.9% [1]. However, it should be noted that when analyzing publications, the method of completing the surgery after performing the stage of laser coagulation of the fistula track varies greatly. And the method

of closing the internal fistula opening is perhaps the key point of any procedure for anal fistulas, especially in their complicated forms [3,5,6,7,8,11]. Thus, the authors from Turkey, after applying the FiLaC™ technique, do not perform suturing of the internal fistula opening [5], other authors perform its suturing with separate sutures and closure with a mucosal-muscular or skin-anal flap [6,7,8,10]. However, there are no clear advantages of the option of completing procedures (with or without suturing the internal fistula opening, advancement flap / suturing with separate sutures) to date, which indicates the relevance of research aimed at identifying the optimal way to close the internal fistula opening. According to the work performed by Kostarev I.V. et al., the best results were obtained with laser coagulation of fistulas with closure of the internal fistula opening using a mucomuscular flap (healing in 73.7%) [2,3]. Among the recent works summarizing the literature data concerning the LIFT technique, the meta-analysis conducted by Sameh H.E. et al. in 2020 is of the greatest interest, which included the results of treatment of 1,378 patients mainly with transsphincteric fistulas, the average healing rate of anal fistulas was 76.5% [9].

Considering that in some studies, in order to improve the results of surgery, combined sphincter-preserving techniques such as BioLIFT (a combination of the LIFT technique with the installation of a bioimplant), video-assisted treatment of fistulas (VAAFT) in combination with the introduction of fibrin glue, etc., our attention was attracted by the combination of the FiLaC™ technique with ligation of the fistula in the intersphincteric space. This combination was used in the work by Vasiliev S.V. et al. [12].

The study included 28 patients, the fistula healing rate was 75%. However, after the mobilization of the fistula track in the intersphincteric space, the authors performed its laser coagulation throughout, which may increase the risk of early eruption of sutures isolating the lumen of the rectum from the wound due to necrotic changes in the fistula wall and, accordingly, affect the recurrence rate.

Thus, one of the unexplored issues when using the FiLaC™ technique remains the choice of the optimal method for closing the internal fistula opening, which could increase the incidence of healing of fistulas to a level competing with radical procedures.

AIM

The aim of this study is to improve the results of surgery for patients with transsphincteric anal fistulas by using sphincter-preserving technologies.

PATIENTS AND METHODS

A single-center randomized prospective comparative study has been launched since November 2020, which is planned to recruit 120 patients with transsphincteric anal fistulas.

As part of the study design, patients are randomized, depending on the method of closing the internal fistula opening, into 2 groups: laser thermocoagulation of the fistula track, supplemented by its ligation in the intersphincteric space (LC + LIFT); laser thermocoagulation of the fistula track with closure of the internal fistula opening by the advancement flap (LC + AF).

The criteria for inclusion of patients in the study are as follows: patient's consent, transsphincteric anal fistula, the absence of deep additional tracks of the fistula, as well as the absence of radical procedures for anal fistula in the history.

The criteria for non-inclusion in the study are as follows: fistulas on the background of inflammatory bowel diseases (ulcerative colitis, Crohn's disease), oncology, specific etiology of fistulas (tuberculosis, actinomycosis).

For laser thermocoagulation, a medical laser — "IRE-Pole" (Russia) was used. The radiation power is 12 W, the wavelength is 1560 nm, the operating mode is continuous. Optical fibers with radial energy emission (Biolitec®, Germany) were used as the functional end.

The procedure was performed in the patient's position on the table as for lithotomy. After the revision of the anal canal and the perianal region, a dye sample was performed and the fistula was probed, the location of the fistula in relation to the anal sphincter was evaluated, the presence or absence of additional tracks along the fistula. Depending on the option of closing the internal fistula opening, the further type of the procedure differed.

With the method of elimination of the fistula by laser coagulation with ligation of the fistula track in the intersphincteric space, a semilunar incision of the skin up to 2 cm in the projection

of the intersphincteric furrow was performed. The space between the external and internal sphincters was dissected, a part of the fistula track in the intersphincteric space was identified. Ligation of the fistula track was performed directly at the internal sphincter with 2 ligatures (polyglycolide-based thread, 3-0) with invagination of the fistula stump with a Z-shaped suture. A probe was inserted into the fistula track through the external fistula opening, its end was removed through the wound in the intersphincteric space. Then a hollow latex seton was put on the probe, the latter is carried through the fistula track through the

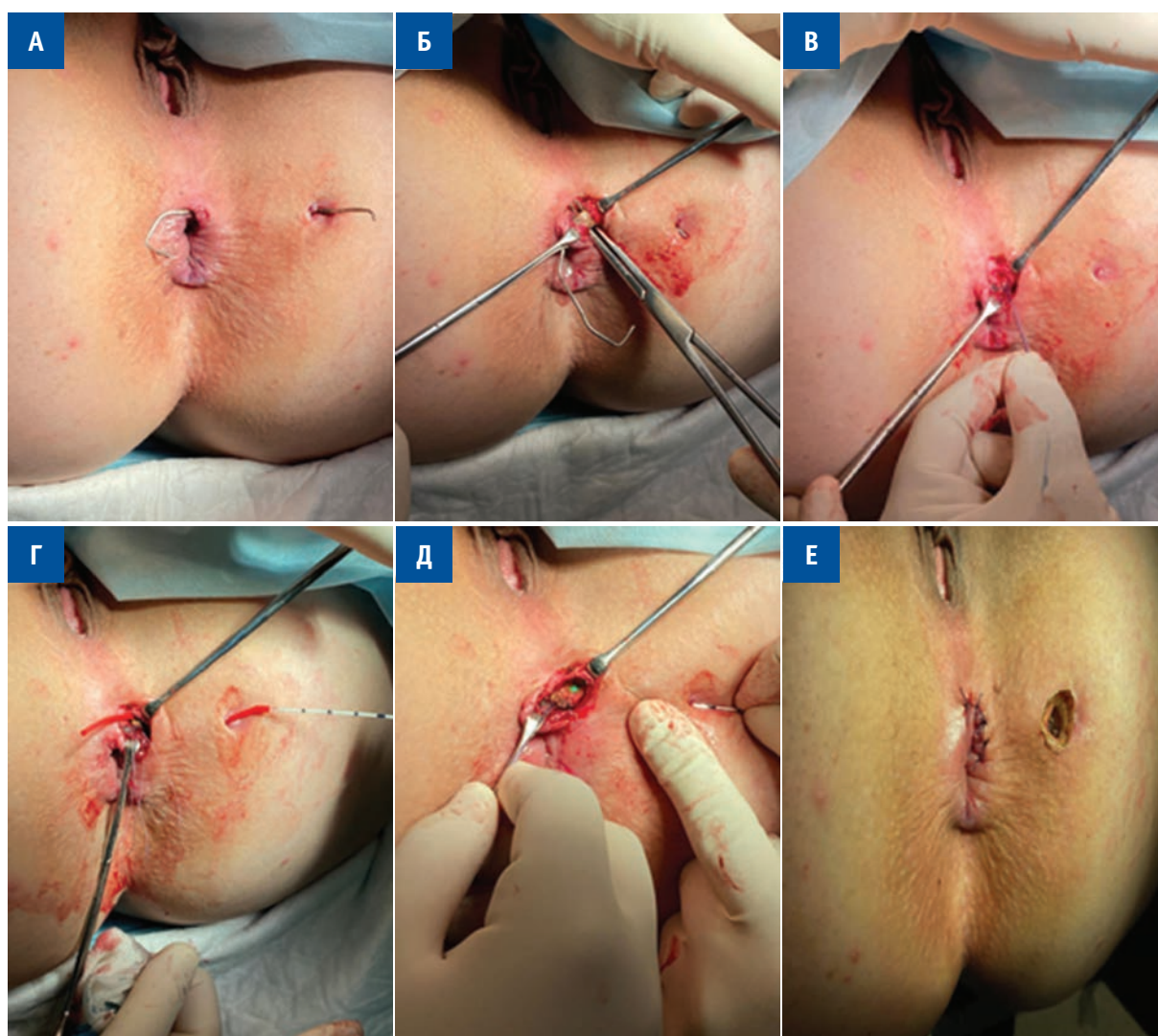


Figure 1. Laser thermocoagulation of the anal fistula combined with ligation of intersphincteric fistula track. A — anterior trans-sphincteric anal fistula; Б — mobilization of the part of anal fistula in the intersphincteric space; В — ligation of fistula track in the intersphincteric space; Г — introduction of laser fibre in fistula channel through latex seton; Д — laser coagulation of fistula track; Е — excision of part of the fistula in the area of the external fistula opening, suturing of wound in the intersphincteric sulcus.

probe. With the help of a latex seton used as a conductor, the laser light guide was carried through the fistula track and then removed through the wound in the intersphincteric space. Gradually, at a speed of 1 mm per second, the light guide was brought out, while

the diode laser radiation has been applied to the inner lining of the fistula throughout its entire length. Thus, in order to prevent an increase in the diameter of the internal fistula opening due to coagulation necrosis, the area of the fistula track running in the thickness of

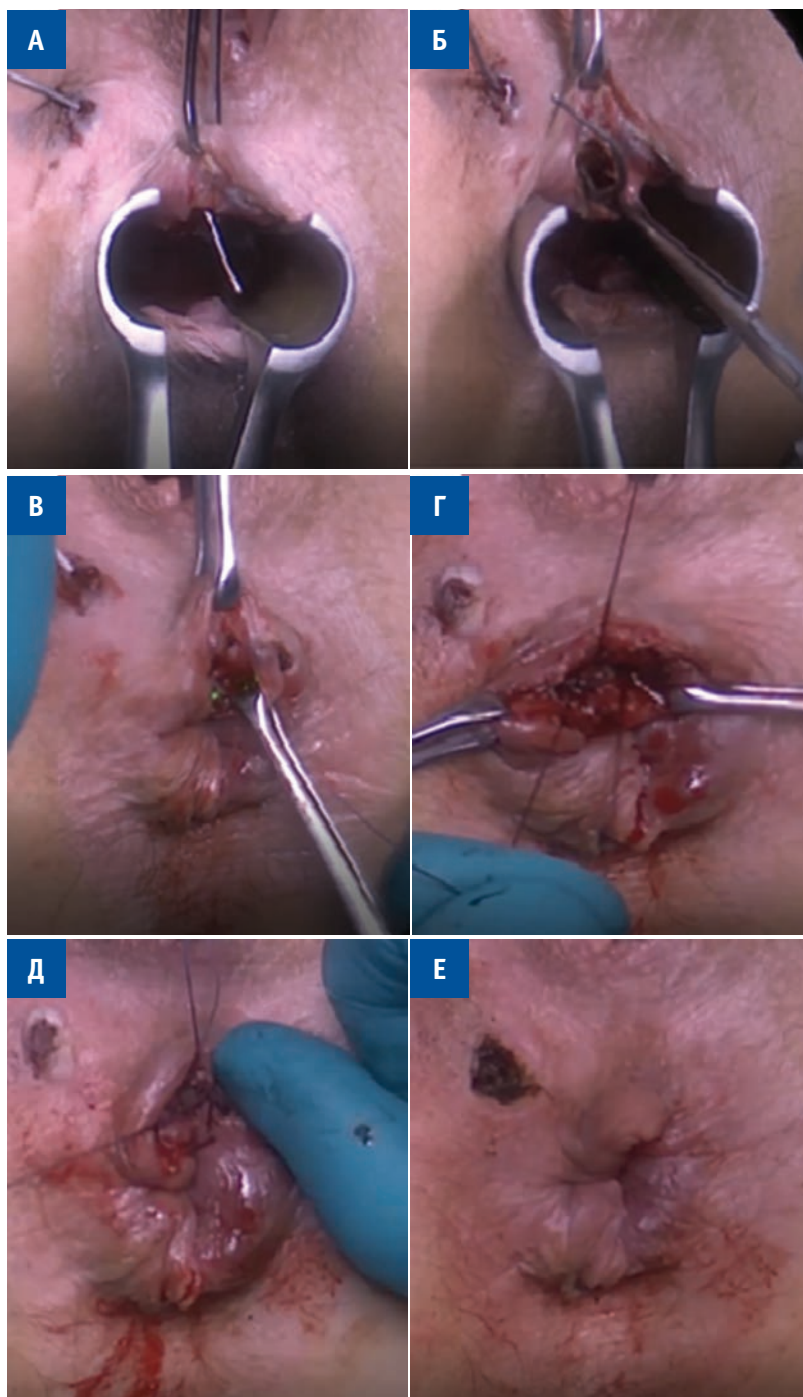


Figure 2. Laser thermocoagulation of the fistula combined with closing of internal fistula opening by advancement flap. A — anterior transsphincteric anal fistula; Б — mobilization of the flap above the internal fistula opening; В — laser thermocoagulation of the anal fistula; Г — fixation of the base of the flap to the bottom of the wound; Д — fixation of the distal edge of the flap to the perianal skin; Е — excision of part of the fistula in the area of the external fistula opening.

Table 1. Characteristics of the study groups ($n = 36$)

| Estimated parameter | LC + LIFT ($n = 19$) | LC + AF ($n = 17$) | <i>P</i> |
|---|---------------------------|-------------------------|----------|
| Males, n | 14 | 12 | 1.0** |
| Females, n | 5 | 5 | |
| Age, years | 37 (26–70) | 38 (27–62) | > 0.05* |
| History of the disease, months | 8 (1–120) | 9 (2–60) | > 0.05* |
| Transsphincteric fistula, n : | 3 | 3 | 0.823** |
| Subcutaneous part | 11 | 11 | |
| Superficial part | 5 | 3 | |
| Deep part | | | |
| Location of internal fistula opening, n : | 8 | 3 | 0.122** |
| Posterior | 11 | 12 | |
| Anterior | 0 | 2 | |
| Lateral | | | |
| Presence of additional tracks, n : | 11 | 9 | 0.843** |
| No | 4 | 5 | |
| Subcutaneous | 4 | 3 | |
| Ileoanal | | | |
| Previous seton | 1 | 1 | 1.0** |

* The calculation was performed using the Mann-Whitney test

** The calculation is performed using the Fisher criterion

the internal sphincter and directly at the internal fistula opening was not treated with the laser. As a result, laser thermocoagulation of the fistula was performed in the body of the external sphincter, as well as in the area of the fistula running in soft tissues. The wound in the area of the intersphincteric space is sutured with separate nodular sutures. In order to adequately drain the laser thermocoagulation zone, a circular incision of the skin around the external fistula opening was performed, the distal part of the fistula was excised to a depth of 1.0 cm (Fig. 1).

With the method of laser thermocoagulation of the fistula track with closure of the internal fistula opening by advancement flap, a semi-lunar incision of the mucous membrane was made from the side of the anal lumen, retreating 0.5–1.0 cm distal to the internal fistula opening. Next, the site of the rectal wall was mobilized, including the mucous membrane, the submucosal layer and the circular muscle

layer. The selected segment was mobilized to a height of up to 2 cm above the internal fistula opening. The flap width was 2–3 cm. Further, according to the method described above, a laser light guide was carried out along a latex conductor into the anal lumen, when the light guide is removed, laser coagulation of the walls of the fistula was carried out. The radiation power, wavelength, as well as the speed of the light guide along the fistula track were similar to those described above. The base of the flap was fixed with 2–3 single sutures to the bottom of the wound. The edge of the flap was fixed by sutures with a polyglycolide-based thread to the perianal skin. At the end of the procedure, tissue excision in the area of the external fistula opening was performed with a circular incision in order to adequately drain the coagulated fistula track (Fig.2).

The use of new imaging techniques is one of the important components of diagnostics in the treatment of anal fistulas. In this study,

patients underwent 3D endoanal ultrasound preoperatively with routine monitoring 1 and 2 months after surgery. Also, five patients underwent surgery using a diode laser under the ultrasound navigation (Fig.3). The purpose of ultrasound navigation during the surgery is additional monitoring of the presence/ absence of the additional tracks along the fistula, assessment of the correctness of the laser light guide through the fistula, as well as direct visualization of the perifistular area throughout the laser exposure zone during coagulation. The pain syndrome was assessed by 10-point visual analog scale (VAS) from the 2nd day after surgery. Patients independently noted the mean level of pain before taking analgesics and out of connection with the stool. Pain assessment was performed for 10 days.

RESULTS

For the period from January 2021 to January 2022, forty-two patients were included in the study. The results were assessed in 36 (85.7%) patients in cases when the follow-up period exceeded 3 months (Me = 9, interval 3–12). Nineteen patients were randomized to the group of laser thermocoagulation of the fistula in combination with its ligation in the intersphincteric space (LC + LIFT), 17 — to the group of laser thermocoagulation of the fistula with closure of the internal fistula opening with an advancement flap (LC + AF). The

average follow-up period for patients was 6.5 months.

By gender, age, location of the internal fistula opening, location of the fistula track in relation to the external anal sphincter (through subcutaneous, superficial, deep parts), presence/absence of additional tracks, the groups were statistically comparable (Table 1).

In the LC + LIFT group, fistula healing was detected in 17 (89.5%) of 19 patients. In 2 cases, a recurrence of the disease developed, while in 1 patient there was a preservation of part of the fistula track between the wound in the intersphincteric space and the external fistula opening, in 1 case the fistula track was preserved throughout between the internal and external fistula openings. According to 3D endoanal US, probing of the fistula track, as well as by dye test, in a patient with the preservation of part of the fistula, its connection with the anal canal was not detected. After 2 months of follow-up, the patient underwent excision of the remaining fistula track under local anesthesia. The second patient with the disease recurrence underwent excision of the fistula with sphincteroplasty.

In the group of laser thermocoagulation in combination with the advancement flap, healing occurred in 11 (64.7%) of 17 observations. At the same time, in one of the 6 patients with the disease recurrence, there were no clinical manifestations of the fistula, and the data for the presence of a residual fistula track were obtained only with a control three-dimensional

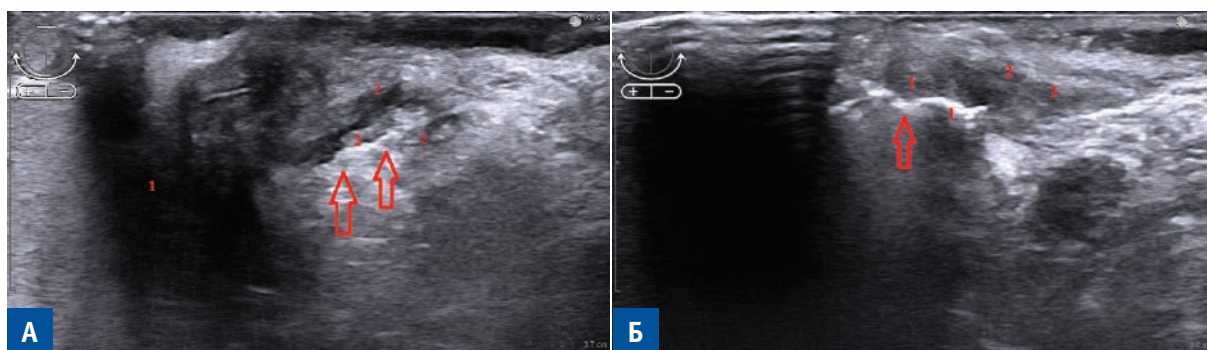


Figure 3. Intraoperative ultrasound navigation. A — ultrasound image of posterior transsphincteric anal fistula with subcutaneous abscess. 1. Subcutaneous abscess. 2. Transsphincteric anal fistula. B — ultrasound image of the fistula area immediately after its laser coagulation with ligation of the proximal part of the anal fistula track in the intersphincteric space, opening and drainage of subcutaneous abscess. 1. Hyperechogenic structure at the site of anal fistula after its laser coagulation. 2. Ligation area of the anal fistula in the intersphincteric space.

Table 2. Comparative analysis of treatment results in the studied groups depending on various factors ($n = 36$)

| Estimated parameter | LC + LIFT | | LC + AF | | P^* |
|--|------------|------------|------------|------------|-------|
| | Healing | Recurrence | Healing | Recurrence | |
| Treatment results in study groups, n (%) | 17 (89.5%) | 2 (10.5%) | 11 (64.7%) | 6 (35.3%) | 0.113 |
| Gender | | | | | |
| Males | 13 | 1 | 9 | 3 | 0.306 |
| Females | 4 | 1 | 2 | 3 | 0.285 |
| Fistula location: | | | | | |
| Subcutaneous + superficial part | 12 | 2 | 9 | 5 | 0.230 |
| Deep part | 5 | 0 | 2 | 1 | 0.375 |
| Presence/absence of leaks: | | | | | |
| No | 9 | 2 | 6 | 3 | 0.616 |
| Yes | 8 | 0 | 5 | 3 | 0.1 |

* The calculation is performed using the Fisher criterion

ultrasound examination 2 months after surgery. According to the ultrasound, the patient showed signs of a residual, partially obliterated fistula-like cavity in the distal part of the anal canal; dynamic monitoring is currently continuing. In 2 out of 6 cases, the fistula track in relation to the external sphincter shifted somewhat distally, while, in fact, there was a transformation of the fistula from transsphincteric to intrasphincteric, which subsequently required surgery in the volume of the fistula excision into the anal lumen.

Preservation of the fistula track was noted in 3 patients — the fistulectomy with sphincteroplasty was performed in all cases, which led to recovery, according to 3D ultrasound monitoring after 1 and 2 months, no residual and additional fistula tracks were detected, tissues in the operation area had mixed echogenicity and visually represented scar tissue.

Thus, ultrasound monitoring made it possible to objectively prove the healing or early recurrence of the fistula during routine examinations of patients in the postoperative period. The intraoperative ultrasound navigation contributed to the implementation of additional control of the correctness of the installation of the laser light guide and the assessment of the uniformity of tissue changes during laser thermocoagulation.

Nevertheless, considering that ultrasound navigation was carried out only in 5 cases, it is not possible to evaluate its advantages. It is necessary to increase the number of patients who will undergo ultrasound control intraoperatively to study the effectiveness of this diagnostic procedure during surgeries using laser coagulation.

Complications during the surgery and the immediate postoperative period were not noted in any case.

The average postoperative hospital stay after LC + LIFT ranged from 1 to 7 days ($Me = 4.5$), after LC + AF — from 3 to 7 days ($Me = 3.0$). There were no significant differences between the groups for this indicator ($p > 0.05$).

When conducting the comparative analysis of the results, taking into account factors such as gender, the location of the fistula in relation to the anal sphincter, the presence/absence of additional tracks within each of the groups, no significant differences were found ($p > 0.05$) (Table 2).

The pain syndrome in the postoperative period demonstrated that on the first day, the intensity of pain, on average, was 2.0 (1–7) points according to VAS. By the 5th day after surgery, the pain syndrome averaged 1.0 point (0–5), and by the 7–9th days it was at the level of 0 to 2 points ($Me = 0.5$).

Patients were also surveyed using the Wexner anal incontinence scale (0 points — normal retention function, 20 points — incontinence of all components of intestinal contents with impaired quality of life and the need for regular wearing of pads). There was no statistically significant increase in the level of points compared with the values before the surgery, which, along with the sphincterometry data, indicates the absence of a pronounced effect of surgeries on the functional state of the anal sphincter, regardless of the option of closing the internal fistula.

DISCUSSION

The study with an assessment of the results after 3 months or more demonstrated that with laser thermocoagulation with the closure of the internal fistula opening from the intersphincteric space, the healing rate was 89.5%. The results obtained by us are close to the indicators published in 2007 by Rojanasakul, A. et al. — the healing rate is 94.4% [13] and in 2013 Tsunoda A. et al. — the healing rate is 95% [14]. However, in most studies, the healing rate after using the LIFT technique varies between 40% and 80%. So, according to the meta-analysis by Sameh H.E. and co-authors, which includes 26 publications from 2007 to 2019, the average healing rate with the LIFT technique is at the level of 76.5% [9].

With the method of laser thermocoagulation with the closure of the internal fistula opening by advancement flap of the rectal wall, the healing rate in patients included in the study was 64.7%. The results obtained, in general, correspond to the data of the world literature [6,8], as well as the indicators published based on the results of previous studies [2,3].

The healing rate when using the original method approaches the traditional surgical methods. The method is accompanied by a low intensity and a short duration of pain syndrome, and is associated with the absence of long-term restrictions on physical activity.

CONCLUSION

Thus, when evaluating the preliminary results of the study, the combination of laser thermocoagulation of the fistula track with the closure of the internal fistula opening by ligating it in the intersphincteric space demonstrates a tendency to improve treatment results compared to the laser thermocoagulation technique in combination with the closure of the internal fistula opening with an advancement flap. Nevertheless, taking into account the sample size of 36 patients, there were no statistically significant differences in healing rates between the groups. To obtain clearer statistical data, further recruitment of patients into study groups and evaluation of treatment results in a more distant period is required.

AUTHORS CONTRIBUTION

Concept and design of the study: *Ivan V. Kostarev, Alexander V. Zakharyan*

Collection and processing of the material: *Alexander V. Zakharyan, Ivan V. Kostarev*

Statistical processing: *Alexander V. Zakharyan, Ivan V. Kostarev*

Writing of the text: *Alexander V. Zakharyan, Ivan V. Kostarev*

Editing: *Alexander Yu. Titov, Andrey A. Mudrov, Leonid A. Blagodarny, Dmitry O. Kiselev, Sabina B. Kozyreva*

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