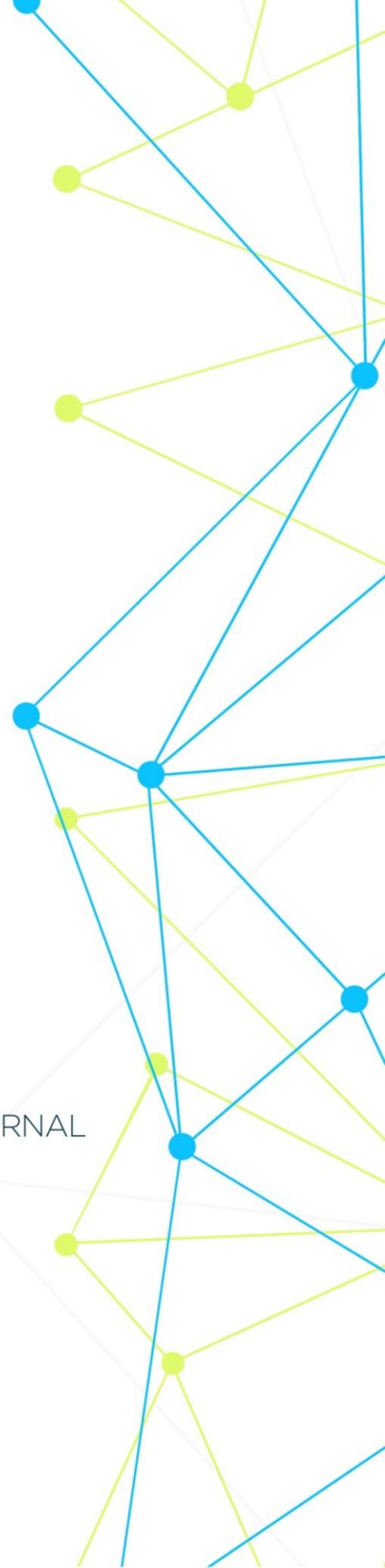


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## CLINICAL ASSESSMENT OF THE EFFECTIVENESS OF THE NEW METHOD OF SURGICAL TREATMENT OF PARARECTAL FISTULAS

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**Abstract.** The article presents the results of operations in 217 patients with pararectal fistulas. The authors applied laser mucosectomy with photosensitization effect, which provided an improvement in the course of early postoperative rehabilitation due to a significant reduction in the intensity of pain symptoms, the frequency of complications, due to which good immediate results were improved from 67% to 91.1%.

**Keywords:** pararectal fistula, mucosectomy, FarGALS, low-intensity laser, photosensitization.

### Introduction

Chronic paraproctitis is the third most frequent proctological disease requiring surgical treatment. The disease is more common in the age group of 30-50 years, mainly in men, which determines its socio-economic significance. The development of minimally invasive surgical technologies in the treatment of chronic paraproctitis is a promising young direction in coloproctology [2]. More and more often, in clinical practice, coloproctologists use laser technologies for outpatient treatment of extract and transfinter pararectal fistulas, in particular, laser technology FiLaC.

Elfeki H, et al. (2020) conducted a systematic review and meta -analysis of safety and effectiveness of laser closure of the fistula [3]. Fistula laser closure (FiLaC) is a new sphincter-preserving technique for treating anal fistulas. It is concluded that FiLaC can be considered an effective and safe sphincter -preserving method of treating anal fistulas with an acceptable low level of complications.

Kotenko K.V. (2022) considers the FiLaC laser technology based on the use of a radial flexible laser light guide, which does not cause damage to the mucous membrane of the anal canal, the development of pain in the postoperative period, rectal postoperative bleeding and strictures, to be a fairly promising method for minimally invasive surgery of anal fistulas. anal canal [1]. The use of the modified FiLaC technology in the treatment of trans- and extrasphincteric fistulas of the rectum made it possible to minimize postoperative complications, fully preserve the function of anal retention, and achieve healing of fistulas in 82.5% of cases with a median follow-up of 31 months.

The ideal surgical treatment of anal fistula should be aimed at eradicating sepsis and accelerating tract healing while preserving sphincters and urinary continence. For simple and most distal fistulas, traditional surgical options such as opening the fistula tract appear to be relatively safe and therefore well accepted in clinical practice. However, for more complex fistulas, in which a significant portion

of the anal sphincter is involved, there remains a great deal of concern about sphincter injury and subsequent poor functional outcome, which is entirely inevitable after conventional surgical treatment. For this reason, over the past two decades, many sphincter-sparing procedures for the treatment of anal fistula have been introduced with the common goal of minimizing damage to the anal sphincters and maintaining optimal function. Among these, the intersphincter fistula ligation procedure appears to be safe and effective and can be routinely considered for complex anal fistulas. Another method, an anal fistula plug derived from porcine small intestine submucosa, is safe but moderately effective on long-term follow-up, with success rates ranging from 24% to 88%. The failure rate may be related to its extrusion from the fistulous tract.

To avoid this, a newly developed cork (GORE BioA<sup>®</sup>) was introduced, but long-term data on its effectiveness are scarce. Fibrin glue showed a poor and variable healing rate (14%-74%). FiLaC and video assisted anal fistula treatments, respectively using laser and electrode energy, are costly and have yet to be carefully evaluated in clinical practice [5]. A therapy using autologous stem cells derived from adipose tissue has recently been described. Their properties to regenerate tissues and suppress the inflammatory response should be better studied in anal fistulas, so research is ongoing [4].

### **Materials and methods**

The work is based on the analysis of the results of operations in 217 patients with pararectal fistulas of various types. All patients were treated on the basis of a multidisciplinary clinic of the Center for the development of professional qualification of medical workers and the “Soglom umr” clinic. Considering that the proposed method will be tested in clinical practice for the first time, only transsphincteric fistulas covering more than 30% of the external anal sphincter portion and various extrasphincteric fistulas were included in the study. All patients, according to the designated tasks, were divided into two study groups. The main group included 56 patients operated on in 2022 according to the proposed method of laser mucosectomy combined with photosensitization. The comparison group consisted of 161 patients who were operated on in 2020-2021. This group according to the method of operations was divided into two subgroups. The first subgroup - the traditional elimination of pararectal fistulas - 109 patients who underwent excision of the fistula into the lumen of the rectum with opening and drainage of streaks or excision of the fistula with suturing of the sphincter in the traditional way. The second subgroup - laser mucosectomy - 52 patients who underwent laser mucosectomy.

Table 1 shows the distribution of all patients depending on the group and type of treatment used. Criteria for inclusion in the study: age of patients 18+, without severe concomitant diseases, transsphincteric and extrasphincteric fistulas of the rectum, primary (that is, not previously operated on for rectal fistula), fistula length of at least 2.0 cm.

**Table 1**

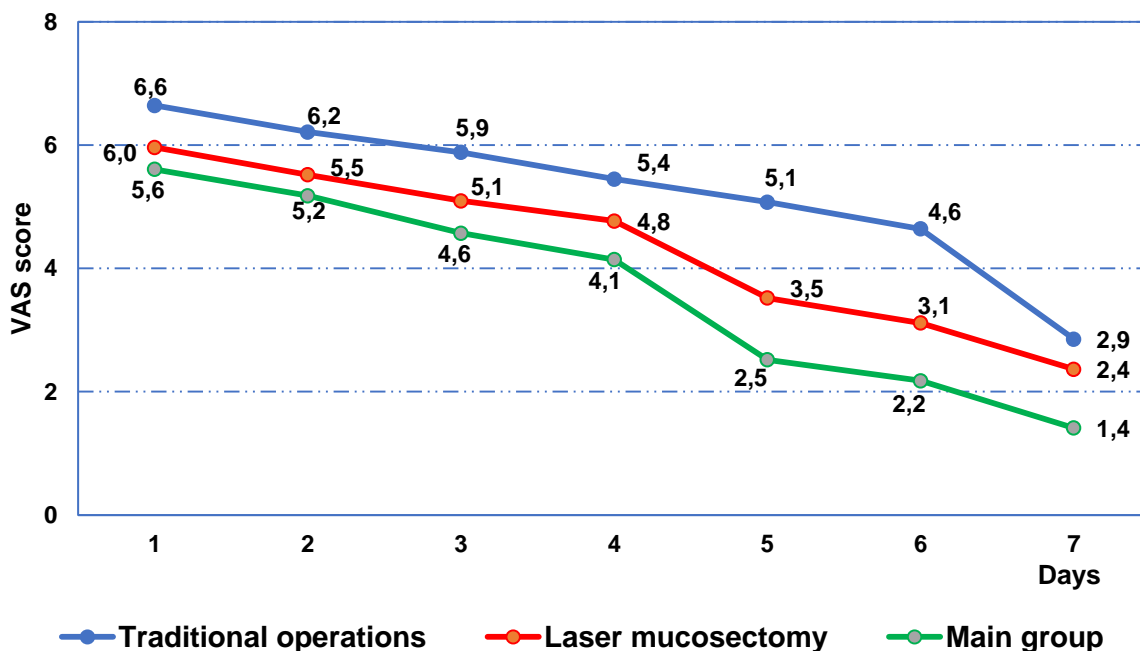
### **Distribution of patients by type of surgery for pararectal fistulas**

Operations	Comparison group		Main group		Total	
	abs	%	abs	%	abs	%
<b>Multidisciplinary clinic of the Center for the development of professional qualification of medical workers</b>	109	67,7%	0	0,0%	109	50,2%
Dissection and excision of the fistula in the intestinal lumen	71	44,1%	0	0,0%	71	32,7%
Fistula excision with sphincter closure	23	14,3%	0	0,0%	23	10,6%
Two-stage operations: conducting a cutting ligature followed by excision of the fistula	15	9,3%	0	0,0%	15	6,9%
<b>“Soglom umr” Clinic</b>	52	32,3%	56	100,0%	108	49,8%
Laser mucosectomy	39	24,2%	37	66,1%	76	35,0%
Two-stage operations: cutting ligature with laser mucosectomy	13	8,1%	19	33,9%	32	14,7%
<b>Total</b>	161	100,0%	56	100,0%	217	100,0%

## Results

Most patients refrain from surgery for a long time due to fear of upcoming pain, so one of the main factors affecting the physical and mental state of the patient after surgery is the intensity of the pain syndrome. When assessing pain on the VA scale (Visual Analog Scale) on the first day of the postoperative period, it turned out that in the group of traditional operations 60.6% of patients noted severe pain - 7-8 points, while in the group of laser mucosectomy this figure was 32.7%, and in the main group 26.8%. That is, the use of new technologies significantly reduced the intensity of the pain syndrome ( $\chi^2=28,657$ ;  $df=2$ ;  $p<0,001$ ). A similar picture was observed on the 3rd day of the postoperative period, 21.1% of patients in the group of traditional operations complained of severe pain, 11.5% in the group of laser mucosectomy and only 3.6% in the main group ( $\chi^2=25,904$ ;  $df=2$ ;  $p<0,001$ ). On the 5th day of the postoperative period, the difference between the groups is more pronounced. So, in the main group, no one complained of severe pain, most of the patients noted slight soreness, which corresponded to 1-4 points. In the laser mucosectomy group, severe pain was noted by 3.8% of patients, the majority corresponded to 4-5 points on the VA scale ( $\chi^2=9,856$ ;  $df=4$ ;  $p=0,043$ ). Unfortunately, in the group of traditional interventions, 8.3% still complained of severe pain, the vast majority - 66.1%, noted pain corresponding to 5-6 points on the VA scale ( $\chi^2=79,364$ ;  $df=4$ ;  $p<0,001$ ). A week later, the difference between all groups in comparison with the main one is distinct. If in the main group 21 (37.5%) patients had no complaints of pain, then in the group of traditional operations this figure was only 2 (1.8%), on the contrary, 3 (2.8%) suffered from severe pain, while in the main group they no longer bothered anyone ( $\chi^2=42,885$ ;  $df=4$ ;  $p<0,001$ ). The following diagram clearly demonstrates the dynamics of pain intensity after surgery. This became possible to evaluate due to the calculation of the average score in the group. As a result, we see that in the group of traditional interventions, the severity of the pain syndrome is maximum and the

dynamics of pain intensity reduction is slow; by 6-7 days after the operation, most patients still complain of significant pain in the area of interest. In the main group, the intensity of pain is initially low already on the first day of the postoperative period, there is a rapid decrease in the intensity of pain, by the 6th-7th day, pain is practically absent in most patients, some have slight soreness. In the laser mucosectomy group, the curve is closer to the main group, although the performance is somewhat worse (Fig. 1).



Days	1	2	3	4	5	6	7
T-criterion: traditional operations to the main group	-5,63	-4,98	-6,98	-6,17	-9,65	-9,16	-5,60
T-criterion: laser mucosectomy to the main group	-1,61	-1,38	-2,18	-2,35	-2,84	-2,65	-2,89

**Fig. 1. Dynamics of pain syndrome intensity after surgery (mean VAS score;  $M \pm \delta$ )**

It is natural that the severity and duration of the pain syndrome affects the need for medications, namely NSAIDs. Therefore, it is not surprising that no one in the main group needed to take NSAIDs after 3 days. In the laser mucosectomy group, after 3 days, no one took NSAIDs either, but most patients took these drugs for 2-3 days - 53.8%, while in the main group 69.6% of patients used NSAIDs for 1 day ( $\chi^2=7,191$ ;  $df=2$ ;  $p=0,028$ ). In the group of traditional operations, more than a third of patients took NSAIDs for 5-7 or more days ( $\chi^2=81,907$ ;  $df=4$ ;  $p<0,001$ ). The results of operations are usually assessed by the presence or absence of complications in the early postoperative period (Table 2).

**Table 2  
The frequency of complications in the immediate postoperative period**

Complication	Traditional operations		Laser mucosectomy		Main group	
	abs	%	abs	%	abs	%
Bleeding	5	4,6%	0	0,0%	0	0,0%
Anal sphincter insufficiency (grade 2-3)	20	18,3%	0	0,0%	0	0,0%
Acute paraproctitis	2	1,8%	1	1,9%	1	1,8%
Total complications	27	24,8%	1	1,9%	1	1,8%
Without complications	82	75,2%	51	98,1%	55	98,2%
Reliability to the main group	$\chi^2=15,198$ ; df=2; p=0,002		$\chi^2=0,003$ ; df=1; p=0,958		-	

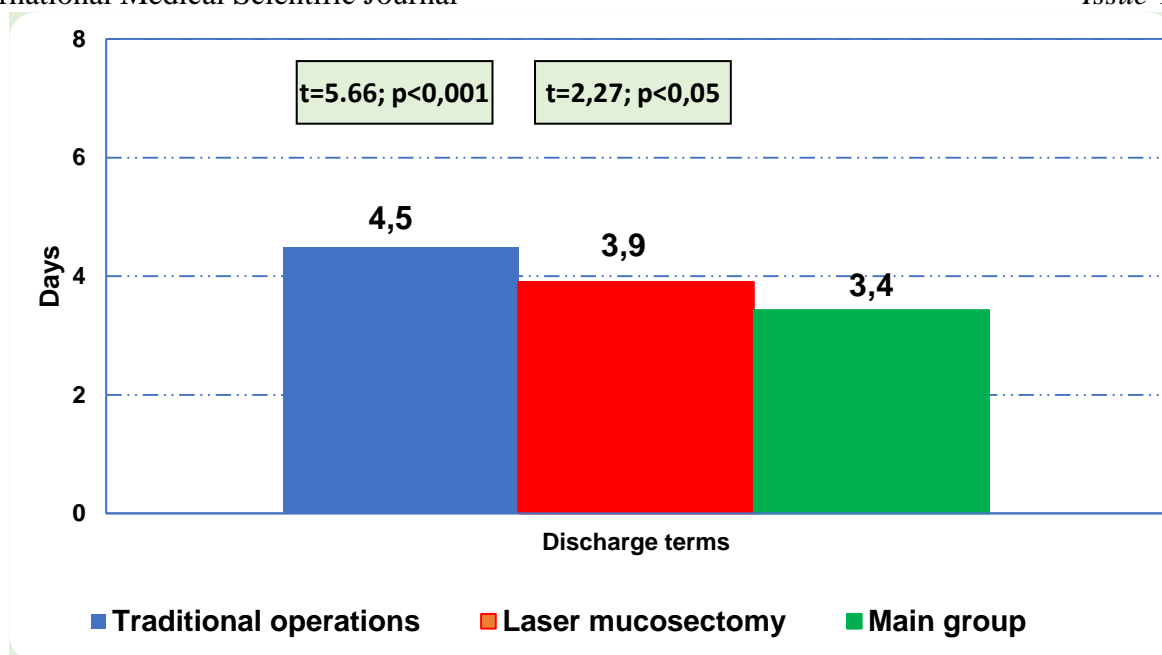
In the main group and with isolated laser mucosectomy, 1 complication was noted in the form of acute paraproctitis ( $\chi^2=0,003$ ; df=1; p=0,958). What cannot be said about the group of patients who underwent traditional operations, there were only 27 (24.8%) complications, bleeding in 5 (4.6%) cases, insufficiency of the anal sphincter of 2-3 degrees in 20 (18.3%) cases, 2( 1.8%) case of paraproctitis ( $\chi^2=15,198$ ; df=2; p=0,002).

With laser mucosectomy, muscle fibers are not excised during the operation, and the radial emission of laser light obliterates the blood vessels around the wound, thereby preventing complications such as bleeding and anal sphincter insufficiency. Bleeding from the postoperative wound on the 2nd day after the act of defecation was observed in 5 patients (3 extra-, 2 transsphincteric fistulas) in the group of traditional operations. In 3 cases, bleeding was stopped conservatively (sodium etamsylate intramuscularly 2 times a day during the day). In the other 2 cases, a bleeding muscle vessel (catgut 1) was sutured under local anesthesia, followed by coagulation.

Anal sphincter insufficiency (ASI) of 2-3 degrees developed in 20 patients (in 5 patients with transsphincteric fistulas with damage to deep muscles and 15 patients with extrasphincteric fistulas), which was due to the intersection of a part of the external and internal anal sphincter. At the same time, the average score was  $8.9 \pm 4.6$  on the Wexner scale. Within 1 to 6 months this symptom regressed with sprouting of muscle fibers in 16 patients. 4 patients with extrasphincteric fistula were subsequently offered the operation "Sphincteroplasty".

Acute paraproctitis developed on the 7-14th day after the operation. In all 4 patients, the purulent cavity was opened under local anesthesia. The wounds healed by secondary intention.

The course of the postoperative period directly affected the terms of discharge of patients (Fig. 2). In the main group, 41 (73.2%) patients were discharged after 3 days, while half of the patients ( $\chi^2=6,505$ ; df=4; p=0,165), were discharged within the same period after laser mucosectomy, and less than a third in the group of traditional operations. And if by the 5th day in the main group only 9% of patients remained in the hospital, then in the group of laser mucosectomy 21.1%, and in the group of traditional operations - 43.1% ( $\chi^2=28,129$ ; df=4; p<0,001).

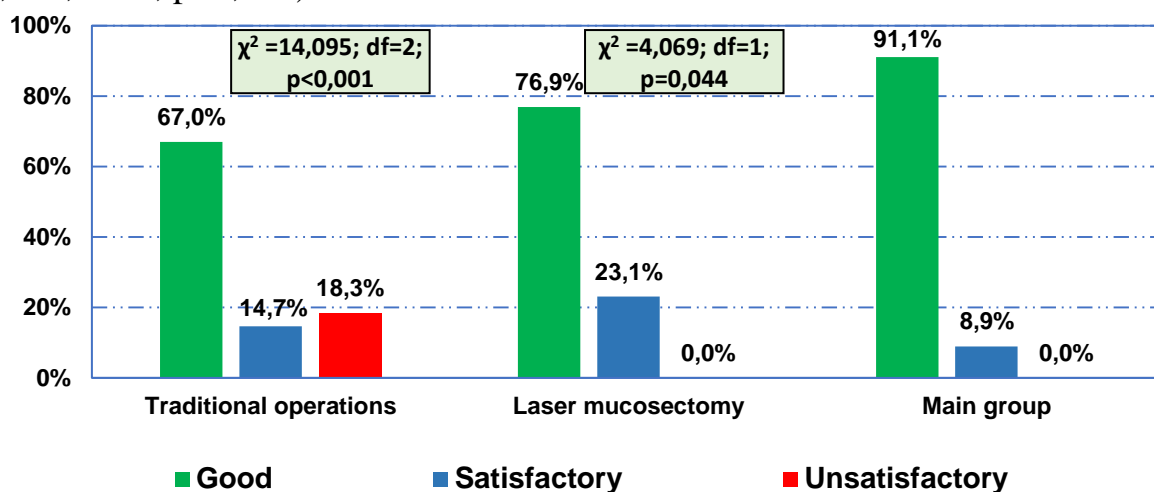


**Fig. 2. Average discharge time after surgery (days; M±δ)**

Average hospital discharges were significantly lower in the main group -  $3.4 \pm 0.9$ , in the group of laser mucosectomy  $3.9 \pm 1.3$  ( $t=2.27$ ;  $p<0.05$ ), in the group of traditional operations -  $4.5 \pm 1.5$  ( $t=5.66$ ;  $p<0.001$ ).

The results of the immediate period were interpreted according to the following criteria: good - regression of hyperemia, disappearance of perifocal edema, no signs of ASI; satisfactorily - reduction of edema, regression of the process of exudation, suppuration of the wound, the appearance of acute subcutaneous paraproctitis; unsatisfactory - the presence of ASI.

In the main group, good results were noted in 91.1%, satisfactory in 8.9%, which is significantly higher than in the laser mucosectomy group, where good results were noted in 76.9%, satisfactory in 23.1% ( $\chi^2 = 4,069$ ;  $df=1$ ;  $p=0,044$ ). The difference with the group of patients where traditional operations were applied is even greater: good results were noted in 67%, satisfactory in 14.7%, unsatisfactory in 18.3% ( $\chi^2 = 14,095$ ;  $df=2$ ;  $p<0,001$ ).



Note:  $\chi^2$  is indicated to the main group.



**Fig. 3. Summary immediate postoperative results in the comparison groups (up to 15 days of observation)**

**Discussion**

Thus, the addition of laser mucosectomy with the effect of photosensitization made it possible to improve the course of early postoperative rehabilitation due to a significant decrease in the intensity of pain symptoms starting from the first day of observation in relation to traditional operations ( $p < 0.05$  on days 1-7) and from the third day compared to with laser destruction ( $5.1 \pm 1.3$  versus  $4.6 \pm 1.2$  points on the VA scale;  $t = 2.18$ ;  $p < 0.05$ ). With both methods of laser mucosectomy (in the comparison group and in the main group), due to the absence of excision of muscle fibers during the operation, the development of ASI was leveled (20 patients - 18.3% in the group of traditional operations), and the radial radiation of laser light led to obliteration of blood vessels in the wound, which prevented the development of postoperative bleeding (5 patients - 4.6% in the group of traditional operations). In total, the frequency of complications in the comparison group with traditional operations was 24.8% (27 patients; in the main group -  $\chi^2 = 15.198$ ;  $df = 2$ ;  $p = 0.002$ ), in the comparison group with laser operations - 1.9% and in the main group - 1.8% (1 patient each). Improving the course of the rehabilitation period made it possible to achieve a reduction in the duration of the postoperative hospital stage in the main group from  $4.5 \pm 1.5$  days in the comparison group with traditional operations ( $t = 5.66$ ;  $p < 0.001$ ) and from  $3.9 \pm 1.3$  days in the comparison group with laser surgery ( $t = 2.27$ ;  $p < 0.05$ ) up to  $3.4 \pm 0.9$  days in the main group.

Taking into account the quality of the course of the early postoperative period and the frequency of complications, good immediate results in the main group were improved with 67% (73 out of 109 patients in the comparison group with traditional operations) and with 76.9% (40 out of 52 patients in the comparison group with laser operations) to 91.1% (in 51 of 56 patients) ( $\chi^2 = 14.095$ ;  $df = 2$ ;  $p < 0.001$  and  $\chi^2 = 4.069$ ;  $df = 1$ ;  $p = 0.044$ , respectively).

**Conclusions**

The conducted studies made it possible to substantiate that the addition of laser mucosectomy with the effect of photosensitization improves the course of early postoperative rehabilitation due to a significant decrease in the intensity of pain symptoms starting from the first day of observation in relation to traditional operations ( $p < 0.05$  on days 1-7) and from the third days compared with laser destruction ( $5.1 \pm 1.3$  versus  $4.6 \pm 1.2$  points on the VA scale;  $t = 2.18$ ;  $p < 0.05$ ).

The frequency of complications in the comparison group with traditional operations was 24.8% ( $\chi^2 = 15.198$ ;  $df = 2$ ;  $p = 0.002$ ), in the comparison group with laser operations - 1.9% and in the main group - 1.8%. Good immediate results in the main group were improved from 67% (in the comparison group with traditional operations) and from 76.9% (in the comparison group with laser operations) to 91.1% ( $\chi^2 = 14.095$ ;  $df = 2$ ;  $p < 0.001$  and  $\chi^2 = 4.069$ ;  $df = 1$ ;  $p = 0.044$  respectively).

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