

IMPROVING TREATMENT OUTCOMES FOR GASTROESOPHAGEAL REFLUX DISEASE

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<https://doi.org/10.5281/zenodo.10900553>

Abstract. Risk factors for complications of GERD include older age, male gender, white race, abdominal obesity, and tobacco use. The symptoms of GERD and the symptoms of reflux esophagitis, functional dyspepsia and gastroparesis largely overlap, which creates difficulties for the management of patients.

Unfortunately, in the available literature there is little data on the use of laser, and even then, they mainly relate to biopsy under the control of the esophagus with volumetric laser endomicroscopy and laser coagulation. There are studies evaluating possible endoscopic treatment of esophageal tissue with circular laser irradiation. However, the proposed photothermal therapy may be a valid endoscopic treatment method using circumferential irradiation and mechanical dilatation only for Barrett's esophagus (Tran VN, 2018; Sharma P, 2020), while a method to prevent reflux esophagitis or reduce the symptoms of inflammation is needed.

Keywords: laparoscopic fundoplication, reflux esophagitis, percutaneous laser treatment, epigastrium, functional dyspepsia.

Relevance. Gastroesophageal reflux disease (GERD) is the most common gastrointestinal disease worldwide and causes significant morbidity, although associated mortality is rare. The cumulative prevalence of at least weekly GERD symptoms reported in population-based studies worldwide is approximately 13%, but there is significant geographical variation, with rates highest in South Asia and South-East Europe (over 25%) and lowest in South-East Asia, East Asia, Canada and France (below 10%).

Risk factors for complications of GERD include older age, male gender, white race, abdominal obesity, and tobacco use. The symptoms of GERD and the symptoms of reflux esophagitis, functional dyspepsia and gastroparesis largely overlap, which creates difficulties for the management of patients. The clinical management of GERD affects the lives of many people and requires significant expenditure of medical and social resources. It is known that “treatment includes lifestyle modification, PPIs, and laparoscopic fundoplication.” Recently, new endoscopic and less invasive surgical procedures have been developed. PPI use remains the dominant treatment modality, but long-term therapy requires follow-up and reassessment of potential side effects.

Endoscopic treatment of GERD is currently considered suitable for patients with early-stage GERD, as well as for patients with altered anatomy where standard laparoscopic surgical approaches are limited. Currently, the US Food and Drug Administration (FDA) has approved three endoscopic devices that are used to treat GERD: Stretta® for radiofrequency therapy (Restech, Houston, TX), Esophyx-Z® for transoral non-surgical fundoplication (TIF) (EndoGastric Solutions, Redmond, WA) and Overstitch® for endoscopic suturing (Apollo Endosurgery, Austin, TX).

Unfortunately, in the available literature there is little data on the use of laser, and even then, they mainly relate to biopsy under the control of the esophagus with volumetric laser endomicroscopy and laser coagulation (Baibekov I.M., 2008; Suter MJ, 2014; Swager A, 2016; Jain D, 2017; Mosko JD, 2017). There are studies evaluating possible endoscopic treatment of esophageal tissue with circular laser irradiation (Jeong S, 2020). A 532 nm laser was used to continuously deliver 10 W through a diffuser built into the balloon catheter. Ex vivo leporine esophagus was tested to determine thermal responses at different irradiation times. In vivo testing in a porcine model was performed to evaluate the endoscopic feasibility of the integrated device for the treatment of BE. However, the proposed photothermal therapy may be a valid endoscopic treatment method using circumferential irradiation and mechanical dilatation only for Barrett's esophagus (Tran VN, 2018; Sharma P, 2020), while a method to prevent reflux esophagitis or reduce the symptoms of inflammation is needed.

The purpose of the study is to improve the results of treatment of reflux esophagitis by improving the technique of percutaneous laser treatment.

Material and methods.

One of the important areas of healthcare development is the development and implementation of advanced medical technologies for the treatment of widespread diseases that bring not only prolonged suffering to patients, but also cause great economic damage in the form of long periods of disability for the population. For practical surgery in this regard, of particular importance is the introduction of new algorithms for complex treatment of diseases that have already been well studied, but unfortunately still have a large percentage of unsatisfactory results in the early postoperative period and a sufficient number of relapses in the long-term period.

Study of clinical features of GERD in various gastrointestinal pathologies (669 patients);

Determination of the effectiveness of therapy for esophagitis using the SIKHAT-1 laser device in conservative treatment accompanied by GERD (90 patients in the control group and 92 patients in the main group) and in complex surgical treatment of patients with PUD (14 patients in the control group and 17 patients in the main group).

Table 1

Distribution of patients into study groups

Pathology	Control group		Main group		Total	
	abs.	%	abs.	%	abs.	%
Duodenal ulcer	21	23,3%	23	25,0%	44	24,2%
Erosive gastritis or gastroduodenitis	32	35,6%	31	33,7%	63	34,6%
Cardiospasm	14	15,6%	14	15,2%	28	15,4%
Hiatal hernia	11	12,2%	14	15,2%	25	13,7%
Duodenal ulcer and Hiatal hernia	8	8,9%	7	7,6%	15	8,2%
Reflux esophagitis	4	4,4%	3	3,3%	7	3,8%
Total:	90	100,0%	92	100,0%	182	100,0%

In both groups, patients with DU, erosive gastritis or gastroduodenitis predominated: 23.3% and 35.6% in the control group, 25.0% and 33.7% in the main group, respectively. Hernia was detected in 12.2% in the control group and 15.2% in the main group. Reflux esophagitis in isolation, without the presence of other pathology, was diagnosed in the smallest number of patients: 4.4% in the control group and 3.3% in the main group (table. 1).

Table 2

Distribution of patients according to the severity of EC by Savary-Miller

The degree according to Savary-Miller.	Control group		Experimental group		Overall	
	abs.	%	abs.	%	abs.	%
I	56	62,2%	53	57,6%	109	59,9%
II	21	23,3%	23	25,0%	44	24,2%
III	10	11,1%	12	13,0%	22	12,1%
IV	3	3,3%	4	4,3%	7	3,8%
In total:	90	100,0%	92	100,0%	182	100,0%

Table 3

Local (esophageal) manifestations of the disease

Symptom	Control group I		Main group		Total	
	abs.	%	abs.	%	abs.	%
Heartburn	78	86,7%	83	90,2%	161	88,5%
Belching	49	54,4%	52	56,5%	101	55,5%
Epigastric pain	34	37,8%	37	40,2%	71	39,0%
Dysphagia	11	12,2%	13	14,1%	24	13,2%
Odynophagy	15	16,7%	18	19,6%	33	18,1%
Chest pain	28	31,1%	29	31,5%	57	31,3%

It should be noted that not all patients were hospitalized, some were examined and received treatment on an outpatient basis - 53 (58.9%) in the control group and 49 (53.3%) in the main group, the rest were inpatient (Table 4).

Table 4

Distribution of patients by type of treatment

Type of treatment	Control group		Main group		Total	
	abs.	%	abs.	%	abs.	%
Outpatient	53	58,9%	49	53,3%	102	56,0%
Stationary	37	41,1%	43	46,7%	80	44,0%
Total:	90	100,0%	92	100,0%	182	100,0%

Table 5

Methods for studying the esophagus

RESEARCH METHOD	CAPABILITIES OF THE METHOD
Histological, cytological studies	Establish the final diagnosis and nature of esophagitis
X-ray examination of the esophagus	Detects hiatal hernia, erosions, ulcers, esophageal strictures.
Endoscopic examination of the esophagus.	Detects inflammatory changes in the esophagus, erosions, ulcers, esophageal strictures, Barrett's esophagus.
Manometric examination of the esophageal sphincterosb.	Allows you to identify changes in the tone of the esophageal sphincters. Norm according to DeMeester: Basal pressure of the LES 14.3-34.5 mmHg. The total length of the LES is at least 4 cm. The length of the abdominal part of the LES is at least 2 cm.

Considering that this work is a primary scientific study to evaluate the anti-inflammatory effectiveness of the improved laser device SIKHAT-1, based primarily on experimental data, a separate direction for the dissertation was the initial introduction of the proposed medical device into clinical practice. For this purpose, for the period from January 2021 to July 2022, a group of patients was selected who were admitted to the abdominal department of the Republican Research Center for Emergency Medicine and the endoscopic department of the Endomed private clinic in Fergana. A total of 92 patients with gastrointestinal pathology accompanied by GERD were selected for the main group. In all these cases, during preoperative preparation, in order to reduce the inflammatory phenomena of esophagitis, laser therapy was performed with the SIKHAT-1 device. For a comparative assessment, a control group was formed - 90 patients, which was representative in its gender and nosological composition of the main group; the patients were operated on during the same period, they received traditional drug treatment for GERD.

Table 6

Distribution of patients by gender and age

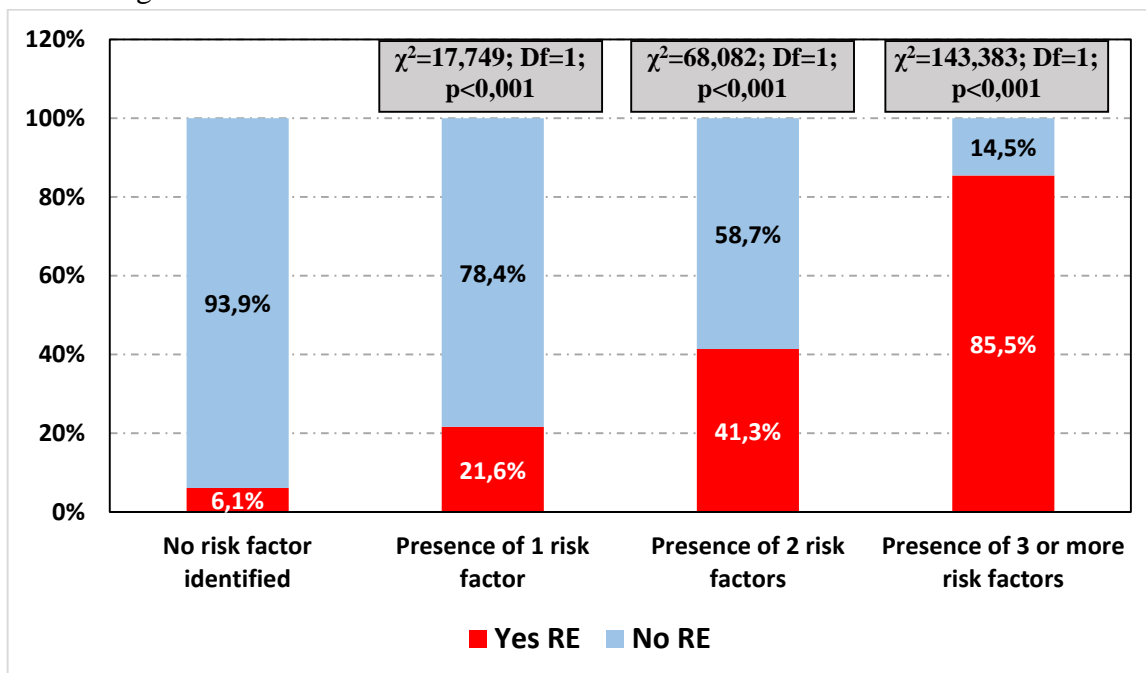
Age	Men		Women		Total	
	abs.	%	abs.	%	abs.	%
Control group						
Under 18 years old	2	2,2%	4	4,4%	6	6,7%
19-44 years	17	18,9%	19	21,1%	36	40,0%
45-59 years old	10	11,1%	15	16,7%	25	27,8%
60-74 years	11	12,2%	12	13,3%	23	25,5%

Total	40	44,4%	50	55,6%	90	100,0%
Main group						
Under 18 years old	3	3,3%	3	3,3%	6	6,5%
19-44 years	16	17,4%	18	19,6%	34	36,9%
45-59 years old	14	15,2%	16	17,4%	30	32,6%
60-74 years	10	10,9%	12	13,1%	22	23,9%
Total	43	46,7%	49	53,3%	92	100,0%

Note: there is no significant difference between the groups ($p > 0,05$)

Results and discussion.

In total, a total of 895 risk factors were identified for 669 patients (Pict. 1). At the same time, no risk factors were identified when collecting anamnesis in 181 (27.1%) patients, among them EC was diagnosed only in 11 (6.1%) cases. One factor was identified in 162 (24.2%) patients, esophagitis was detected in 35 (21.6%), 2 factors were verified in 271 (40.5%) patients (542 factors), ER was detected in 112 (41.3%), 3 or more in 55 (8.2%) (191 factors in 55 patients), EC was diagnosed by endoscopy in 47 (85.5%) patients. Thus, the expected pattern is noted that with an increase in the number of risk factors, the incidence of EC development increases exponentially. This is striking even without statistical calculation.



Note: χ^2 criterion is given in relation to patients without risk factors

Pict. 1. Frequency of development of EC depending on the number of identified risk factors
 Clinical evaluation of the effectiveness of the proposed treatment tactics for EC was carried out in comparison groups, divided into two subgroups. In total, there were 90 patients in the control group, 92 patients in the main group (table 7).

Both groups were divided into a subgroup in which only ER treatment was carried out - 76 patients in the control group and 75 patients in the main group. The second subgroup consisted of patients who had ER as a concomitant disease of the peptic ulcer requiring surgical treatment

(pyloric stenosis, recurrent course complicated by a history of bleeding), that is, before surgical treatment, this subgroup was treated with ER - 14 patients in the control group and 17 patients in the main group.

Table 7

Distribution of patients with EC into subgroups

Subgroup	Control group		Main group	
	abs.	%	abs.	%
Complex treatment of RE as a manifestation of GERD	76	84,4%	75	81,5%
Complex treatment of EC at the stage of preparation for surgical treatment of duodenal ulcer	14	15,6%	17	18,5%
Total	90	100,0%	92	100,0%

Dynamics of the main clinical manifestations and comparative results of complex treatment of RE

It should be noted that before the start of treatment, the groups were comparable both in age and gender composition, and in the frequency of existing symptoms. Thus, in both groups the prevailing complaint was the presence of heartburn 66 (86.8%) / 68 (90.78%), respectively. Belching was slightly less observed in 43 (56.6%) / 44 (58.7%), respectively. Further descending were complaints of pain in the epigastrium and behind the sternum, odynophagia and dysphagia. In any case, there are no significant differences between the groups in terms of symptoms.

An analysis was carried out to determine the period of the average course of therapy with transfer to maintenance treatment. In outpatient treatment, it took 5.2 ± 1.0 weeks in the control group versus 3.7 ± 0.5 weeks in the main group ($t=6.38$; $p<0.05$). Hospital-outpatient treatment required 3.8 ± 1.1 weeks in the control group versus 3.2 ± 0.4 weeks in the main group ($t=3.73$; $p<0.05$). In general, the period of the average course of therapy with transfer to maintenance treatment in the control group was 4.2 ± 1.3 weeks versus 3.4 ± 0.5 weeks in the main group ($t=5.44$; $p<0.05$).

It is natural that when all recommendations were followed, there was a significant difference in the treatment results between the groups ($\chi^2=9.889$; $Df=2$; $p=0.008$): absence of symptoms 60% in the control group and 86% in the main group, rare manifestations 25.5%/ 10.5% and clinical relapse 14.5%/3.5%, respectively.

In case of violation of the diet and supportive treatment, no significant difference in the effectiveness of the treatment was noted

Conclusion.

Thus, the proposed complex of conservative treatment of GERD with the inclusion of laser therapy made it possible to increase the frequency of good results from 60.0% to 86.0%, and reduce the risk of an unsatisfactory treatment outcome from 14.5% to 3.5%. The above approach made it possible to significantly increase the quality of life indicators of patients in all domains, while the value of the overall level of quality of life within a period of up to 1 month of observation was higher in the group with laser therapy, where the increase was from 57.7 ± 2.7 to $72.1 \pm 1, 9$ points, while in the group with traditional treatment the increase was from 59.2 ± 1.7 to 66.9 ± 2.8 points; in turn, the prolonged effect of treatment with a reduced risk of relapse of clinical symptoms allowed for even further improvement by 3 months of observation the level of quality of life in the main group was 74.1 ± 2.0 versus 67.5 ± 2.5 points in the control group. In patients with surgical

complications of DU with concomitant ER, the period of preoperative preparation was reduced from 20.3 ± 10.5 to 10.1 ± 1.8 days, in general, the total duration of the perioperative period was reduced from 29.4 ± 11.4 to 17.4 ± 2.3 days, the risk of developing early local functional-organic complications is reduced from 14.3% to 5.9%.

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