The use of the homeopathic drug Gastropan EDAS-954 in complex treatment stomach ulcer

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Application homeopathic products Gastropan Edas-954 in complex treatment of gastric ulcer

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SUMMARY

The aim of the work is to summarize the results of the use of homeopathic preparations "EDAS" in the complex treatment of gastric ulcer and duodenal ulcer associated with Helicobacter pylori (Hp) infection. The results of the study show the effectiveness of their use and their good compatibility with traditionally used pharmacotherapy.

Key words: Stomach ulcer and Duodenal ulcer, homeopathy, multicomponent preparation Gastropan-EDAS-954, mutual compatibility.

RESUME

The aim is to generalize the results of the use in treatment of peptic ulcer and 12 duodenal ulcers associated with Helicobacter pylori (Hp) infection, homeopathic medicines “EDAS”. The results show the effectiveness of their application and their good compatibility with the traditionally used pharmacotherapy.

Keywords: Peptic ulcer and 12 duodenal ulcer, homeopathy, multi-drug Gastropan EDAS-954, interoperable.

INTRODUCTION

The results of recent large-scale studies in different countries of the world have shown that the share of peptic ulcer disease associated with infection Helicobacter pylori (Hp), accounts for 70-80% of duodenal ulcers and more than 50-60% of stomach ulcers. This allows us to speak about the multifactorial nature of the pathogenetic mechanisms of damage to the gastrointestinal tract, and to consider complex therapy as the basis for the treatment of these injuries. When choosing one or another drug for the treatment of ulcerative lesions, it is necessary to take into account not only the intensity of acid production, but also the stage of the course of the ulcer [1]. A variety of antibacterial agents are also available to eradicate Hp. In some cases, an ulcer can heal only from a drug that effectively suppresses gastric acid production, in other cases, the use of the entire arsenal of antiulcer drugs is ineffective, and there is a need for surgical intervention. It is known about the effectiveness of homeopathic treatment with the correct selection of funds, which is the most difficult moment for doctors. One of the directions in homeopathy, which greatly facilitates the choice of a drug for treatment, is the production of multicomponent homeopathic preparations. Thus, the formulation of EDAS preparations is based on the many years of experience of well-known homeopaths who worked in different eras and the results of scientific research aimed at studying the mutual compatibility of the components of the preparations, which was determined using the methodology we developed [2, 3]. Our research shows that EDAS drugs and, in particular, Gastropan EDAS-954 are compatible with most pharmacological agents, which are most often used for the same indications [3]. One of the directions in homeopathy, which greatly facilitates the choice of a drug for treatment, is the production of multicomponent homeopathic preparations. Thus, the formulation of EDAS preparations is based on the many years of experience of well-known homeopaths who worked in different eras and the results of scientific research aimed at studying the mutual compatibility of the components of the preparations, which was determined using the methodology we developed [2, 3]. Our research shows that EDAS drugs and, in particular, Gastropan EDAS-954 are compatible with most pharmacological agents, which are most often used for the same indications [3]. One of the directions in homeopathy, which greatly facilitates the choice of a drug for treatment, is the production of multicomponent homeopathic preparations. Thus, the formulation of EDAS preparations is based on the many years of experience of well-known homeopaths who worked in different eras and the results of scientific research aimed at studying the mutual compatibility of the components of the preparations, which was determined using the methodology we developed [2, 3]. Our research shows that EDAS drugs and, in particular, Gastropan EDAS-954 are compatible with most pharmacological agents, which are most often used for the same indications [3]. The formulation of EDAS preparations is based on the many years of experience of well-known homeopaths who worked in different eras and the results of scientific research aimed at studying the mutual compatibility of the components of the preparations, which was determined using the methodology we developed [2, 3]. Our research shows that EDAS drugs and, in particular, Gastropan EDAS-954 are compatible with most pharmacological agents, which are most often used for the same indications [3]. The formulation of EDAS preparations is based on the many years of experience of well-known homeopaths who worked in different eras and the results of scientific research aimed at studying the mutual compatibility of the components of the preparations, which was determined using the methodology we developed [2, 3]. Our research shows that EDAS drugs and, in particular, Gastropan EDAS-954 are compatible with most pharmacological agents, which are most often used for the same indications [3].

Target

To study the efficacy, tolerability, safety, as well as undesirable and side effects of the homeopathic medicinal product Gastropan EDAS-954 in the treatment of patients with exacerbation of gastric ulcer and duodenal ulcer (12-p.c.).

Materials and methods

The selection of patients was carried out taking into account the criteria for inclusion in the study according to the provided Protocol of the clinical trial: exacerbation of gastric ulcer and 12-p.c.; the duration of the disease - no more than 3 years, the frequency of exacerbations - no more than 1 time per year, or newly diagnosed; ulcerative process of the stomach or 12-p.k. can be characterized by deep damage to the mucous membrane, but does not affect the muscle layer and blood vessels; age of patients
- from 18 years old; informed consent of the patient to participate in a clinical trial.

Exclusion criteria were stomach cancer; multiple ulcers; old, deep ulcers with pitted edges and an inflammatory shaft; penetration of the ulcer; perforation of the ulcer; bleeding ulcer; individual intolerance to the drug; severe concomitant diseases requiring systemic therapy; During pregnancy and breastfeeding. Each group included 30 patients, 80% of them were male patients and 20% were female patients (Table 1). 28 patients (46.7%) were 29–40 years old, 21 patients (35%) were 41–50 years old, and 11 patients (18.3%) were 51–60 years old. There was no significant difference in age and gender between the groups. Thus, under our supervision there were 60 patients of both sexes with exacerbation of ulcer of the stomach and duodenum at the age from 29 to 60 years (mean age 44.8 ± 0.9 years), the duration of the disease - up to 3 years.

Table 1

Distribution of patients by sex and age

Основная группа						Контрольная группа					
возраст (лет)						возраст (лет)					
мужчины			женщины			женщины			мужчины		
29–40	41–50	51–60	29–40	41–50	51–60	29–40	41–50	51–60	29–40	41–50	51–60
11	8	4	3	3	1	2	2	1	12	8	5
23			7			5			25		
30						30					

Symptoms - epigastric pain, nausea, heartburn, gastroduodenoscopic characteristics of the mucosal defect (hereinafter referred to as gastroduodenoscopy) were assessed using a verification 3-point scale.

Epigastric pain: 0 points - no symptom; 1 point - episodic pain, provoked by a violation of the diet, quickly goes away on its own; 2 points - the duration of the pain attack is no more than half an hour, it is stopped by eating, using heat, drug therapy (anticholinergics); 3 points - an attack of pain lasting more than half an hour, difficult to correct.

Nausea: 0 points - no symptom; 1 point - episodic nausea, provoked by a violation of the diet and / or the intake of abundant food; 2 points - nausea that occurs more than 2 times a day, corrected by drug therapy; 3 points - long-term nausea, with episodes of vomiting, difficult to drug correction.

Heartburn: 0 points - no symptom; 1 point - episodic heartburn, provoked by a violation of the diet and / or the intake of abundant food; 2 points - heartburn appears when dieting, but is easily relieved by local alkalinization; 3 points - heartburn is difficult to relieve by local alkalinization;

Gastroduodenoscopy: 0 points - no mucosal defect; 1 point - mucosal defect

with clear edges, bottom without overlaps; 2 points - a defect of the mucous membrane with edematous edges, the bottom is covered with dirty gray overlays; 3 points - an inflammatory reaction in the tissues surrounding the ulcer defect, necrosis of granulation tissue is noted.

The initial examination included examination, collection of general data, complaints and anamnesis of the disease. Assessment of the duration of the disease, the frequency and duration of exacerbations. A general blood test (with the determination of blood sugar, the number of red blood cells and the level of hemoglobin) and urine. Conducting gastroduodenoscopy. Assessment of symptoms of the disease and examination results, taking into account the criteria for inclusion in the study and exclusion from the study. Identification of the pathology concomitant with the underlying disease for the appointment, if necessary, of additional drug therapy.

After 7 days of treatment: assessment of the clinical manifestations of the disease; blood test for leukocytes and ESR; assessment of the tolerance and effectiveness of the drug, a description of the nature of side effects, if any. After 14 days of treatment: assessment of the clinical manifestations of the disease; blood test for leukocytes, erythrocytes, hemoglobin, ESR; gastroduodenoscopy. Evaluation of the tolerance and effectiveness of the drug, a description of the nature of side effects, if any. After 28 days of treatment: assessment of the clinical manifestations of the disease. Blood test for leukocytes, erythrocytes, hemoglobin, ESR; gastroduodenoscopy. Evaluation of the tolerance and effectiveness of the drug, a description of the nature of side effects, if any. Representative post-registration open,

Control group. Patients receive phosphalugel according to1 sachet (16 g) - 3 times a day for 4 weeks, diet, treatment regimen.

Main group. Patients, in addition to therapy in the control group, receivehomeopathic granules Gastropan EDAS-954 5 granules under the tongue until completely dissolved 3 times a day outside meals for 4 weeks. The effectiveness of treatment of patients was assessed by the degree of reduction of symptoms - epigastric pain, nausea, heartburn, gastroduodenoscopy and the normalization of leukocytes, erythrocytes, hemoglobin, ESR.

Results and discussion

Before treatment in patients of both groups, symptoms of exacerbation of gastric ulcer and 12 - p.to. epigastric pain, nausea and heartburn were moderate and severe. The severity of symptoms ranged from 1.8 ± 0.18 to 2.1 ± 0.21 points in the main group and from 1.8 ± 0.19 to 2.0 ± 0.21 points in the control group (Table 2).

table 2

The dynamics of symptoms of exacerbation of gastric ulcer and 12-sc. in patients (n = 30)

Симптомы / Группа	до лечения	7 дней лечения		14 дней лечения		28 дней лечения	
	M ± m	M ± m	p <	M ± m	p <	M ± m	p <
Боль в эпигастрии:							
основная	1,9 ± 0,20	1,3 ± 0,14	0,02	0***	0,001	0	
контрольная	1,8 ± 0,19	1,4 ± 0,14		0,3 ± 0,07			
Тошнота:							
основная	1,8 ± 0,18	1,3 ± 0,13	0,05	0			
контрольная	1,9 ± 0,20	1,5 ± 0,12		0			
Изжога:							
основная	2,1 ± 0,21	1,5 ± 0,16	0,05	0			
контрольная	2,0 ± 0,21	1,6 ± 0,17		0			
Гастродуоденоскопия:							
основная	2,2 ± 0,23	1,8 ± 0,17		0,9 ± 0,11*	0,001	0,4 ± 0,06**	0,001
контрольная	2,1 ± 0,21	1,8 ± 0,18		1,3 ± 0,14	0,01	0,7 ± 0,09	0,001
Лейкоциты (4–9 тыс. = N):							
основная	11,9 ± 0,6	10,4 ± 0,4	0,05	8,5 ± 0,3*	0,001	7,8 ± 0,2*	0,001
контрольная	11,7 ± 0,5	10,6 ± 0,4		9,6 ± 0,4	0,001	8,6 ± 0,3	0,001
СОЭ (10 мм/ч = N):							
основная	23,9 ± 2,1	18,4 ± 1,7	0,05	8,2 ± 1,0*	0,001	7,4 ± 0,6*	0,001
контрольная	24,2 ± 2,3	20,1 ± 1,9		11,5 ± 1,3	0,001	9,6 ± 0,9	0,001
Эритроциты (3,9–5 x 10^{12}/л = N):							
основная	3,2 ± 0,05	3,4 ± 0,08	0,01	3,9 ± 0,10*	0,001	4,1 ± 0,11*	0,001
конрольная	3,3 ± 0,05	3,4 ± 0,07		3,6 ± 0,09	0,01	3,8 ± 0,10	0,001
Гемоглобин (120–160 г/л = N):							
основная	105 ± 1,9	111 ± 2,2	0,05	118 ± 2,4	0,001	124 ± 2,5*	0,001
контрольная	107 ± 2,0	110 ± 2,2		115 ± 2,3	0,01	117 ± 2,2	0,001

Примечание. Межгрупповая достоверность различия (* p < 0,05; **p < 0,01; ***p < 0,001).

Dynamic observation of patients of the main group who received Gastropan EDAS-954 as part of complex therapy showed a significant decrease in the severity of these symptoms after 7 days of treatment (p <0.05–0.02) and their complete reduction after 14 days. In the control group, where patients received basic therapy, there was an insignificant tendency towards a decrease in the severity of symptoms and their reduction after 14 days of treatment, except for the symptom of epigastric pain. The severity of this symptom after 14 days of therapy was 16.7% of the outcome and was significantly higher than in the main group (p <0.001; Tables 2 and 3).

At the end of the gastroduodenoscopic picture of pathological changes in the gastric mucosa or 12-p.c. in patients of both groups it was pronounced and was estimated at 2.2 ± 0.23 points in the main group and 2.1 ± 0.21 points in the control group. These changes were characterized by the presence of a mucosal defect with edematous edges, dirty gray overlays, an inflammatory reaction in the tissues surrounding the ulcer defect. In the course of treatment, there was a clear positive dynamics in the regression of a mucosal ulcer in patients of both groups. At the end of treatment, the severity of the ulcerative process in the main group of patients who received Gastropan EDAS-954 in combination therapy was reduced by 81.8% (p <0.001). In the control group, where patients received basic therapy, the reduction in the severity of the ulcerative process was 66.7% (p <0.001), i.e. 15.1% less

Table 3

The dynamics of symptoms of exacerbation of gastric ulcer and 12-sc. in patients,%

Симптомы / Группа	%			
	до лечения	длительность лечения		
		7 дней	14 дней	28 дней
Боль в эпигастрии:				
основная	100	-31,6 (9,4)*	-100 (16,7)	-100
контрольная	100	-22,2	-83,3	
Тошнота:				
основная	100	-27,8 (6,8)	-100	
контрольная	100	-21,0	-100	
Изжога:				
основная	100	-28,6 (8,6)	-100	
контрольная	100	-20,0	-100	
Гастродуоденоскопия:				
основная	100	-18,2 (3,9)	-59,1 (21,0)	-81,8 (15,1)
контрольная	100	-14,3	-38,1	-66,7
Лейкоциты:				
основная	100	-51,7 (11,0)	-100 (22,2)	-100
контрольная	100	-40,7	-77,8	
СОЭ:				
основная	100	-39,6 (10,7)	-100 (10,6)	-100
контрольная	100	-28,9	-89,4	
Эритроциты:				
основная	100	+28,6 (11,9)	+100 (50,0)	+100 (16,7)
контрольная	100	+16,7	+50,0	+83,3
Гемоглобин:				
основная	100	+40,0 (16,9)	+86,7 (25,2)	+100 (23,1)
контрольная	100	+23,1	+61,5	+76,9
Σ M ± m:				
основная	100	-33,3 (9,9)	-93,2 (18,2)	-97,7 (6,8)
контрольная	100	-23,4	-75,0	-90,9

Примечание. * – Межгрупповая разница редукции симптомов в %.

Before treatment, patients in both groups had moderate leukocytosis and increased ESR, which were 11.9 ± 0.6 thousand in 1 μl and 23.9 ± 2.1 mm / hour and 11.7 ± 0.5 thousand in 1 μl and 24.2 ± 2.3 mm / hour, respectively, in the main and control groups (Table 2). Dynamic observation of patients of the main group who received Gastropan EDAS-954 as part of complex therapy showed a significant decrease in the number of leukocytes in the blood and increased ESR after 7 days of treatment, respectively, by 51.7% and 39.6% (p <0, 05; Table 3) and their complete reduction after 14 days of observation (p <0.001; Table 2). In the control group, where patients received the basic preparation fosfalugel, a significant decrease in the number of leukocytes in the blood and increased ESR were noted after 14 days of treatment (p <0.001), and the normalization of their levels was achieved only at the end of the study. It should also be noted that the indicators of leukocytosis and ESR after 14 and 28 days of treatment were significantly lower in the main group than in the control group (p <0.05; Table 2), and their average reduction rate was 13.6% higher in the main group (Table 3).

Before starting treatment, the patients had moderate anemia, which was expressed in a decrease in the number of erythrocytes and the level of hemoglobin in the blood to 3.2 x 10^{12} ± 0.05 / l and 105 ± 1.9 g / l, respectively, in the main group and 3, 3 x 10^{12} ± 0.05 / L and 107 ± 2.0 g / L - in the control group of patients (Table 2). In dynamics, both indicators significantly increased, starting from the 7th day of treatment (p <0.05–0.01), in patients of the main group who received

Gastropan EDAS954, and reached normal values by the end of the course of treatment ($p < 0.001$; Table 2). In the control group, where patients received the basic preparation phosphalugel, there was a tendency to an increase in the number of erythrocytes and the level of hemoglobin in the blood at all stages of the study compared with the outcome. However, even by the end of treatment, they did not reach normal values, amounting to $3.8 \times 10^{12} \pm 0.10$ / L and 117 ± 2.2 g / L, respectively ($p < 0.001$; Table 2). It should also be noted that the indicators of the number of erythrocytes and the level of hemoglobin in the blood of patients in the main and control groups significantly differed between themselves after 14 and 28 days of treatment ($p < 0.05$), and the average rate of normalization of these indicators in the main group was 22.8 % more than in the control group (Table 3).

The average total rate of reduction of symptoms of gastric ulcer and 12-sc. in patients of the main group exceeded by 11.6% the same indicator in the control group. And at the end of treatment, the average total reduction in the severity of symptoms in the main group was 97.7% versus 90.9% in the control group, i.e. 6.8% more in the main group than in the control (Table 3). Evaluating the effectiveness of treatment of patients with exacerbation of gastric ulcer and 12-p.c., it should be noted that in the main group of patients who received Gastropan EDAS-954 as part of complex therapy, good results were obtained in 29 patients (96.7%) and unsatisfactory - in 1 patient (3.3%). In the control group, where patients received basic therapy, good results were achieved in 25 patients (83.3%), satisfactory in 3 patients (10%) and unsatisfactory in 2 patients (6.7%). A clinical study has shown the safety of use, good compatibility with the allopathic preparation fosfalugel and good tolerance of homeopathic granules Gastropan EDAS-954 by patients. In no case were there any side and / or undesirable effects.

Output

Clinical study results convincing enough demonstrate the efficacy of the homeopathic drug Gastropan EDAS-954 in the complex treatment of patients with exacerbation of gastric ulcer and 12-p.c. in comparison with basic therapy.

Thus, the homeopathic drug Gastropan-EDAS-954 as part of the complex therapy of patients with exacerbation of gastric ulcer and 12-sc. increases the effectiveness of treatment of patients in comparison with basic therapy by 13.4%. It is safe to use, combines well with the allopathic drug phosphalugel and is well tolerated by patients, does not cause side and / or unwanted effects. The proposed scheme of complex treatment is the most optimal and convenient for use. All this taken together makes it possible to recommend Gastropan EDAS-954 for introduction into wide medical practice for the complex treatment of patients with ulcer of the stomach and duodenum.

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