Clinical studies of Shilajit. Publication 2: Application for diseases of the digestive system L.N. Frolova, T.L. Kiseleva

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Clinical research of Mummy (Shilajit). Publication 2. Application for digestive diseases

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RESUME

The results of a clinical trial of mummy-asil in patients with gastric and duodenal ulcer, chronic gastritis and chronic colitis, conducted in 70-80s of last century a presented. The efficiency of the mummy and the feasibility of its use for prevention and treatment in the therapy of chronic gastro-intestinal diseases are shown.

Keywords: mummy, mummy-asil, gastrointestinal disease, gastric ulcer, duodenal ulcer, gastritis, colitis.

SUMMARY

The results of a clinical study of mumiyo-asil in patients with gastric ulcer and duodenal ulcer, chronic gastritis and chronic colitis, carried out in the 70s and 80s of the last century, are presented. The effectiveness of mummy and the feasibility of its use for prevention and treatment in the complex therapy of chronic gastrointestinal diseases are shown.

Key words: mummy, mummy-asil, gastrointestinal diseases,peptic ulcer, duodenal ulcer, gastritis, colitis.

I. Introduction

The majority of authors associate the steady growth of gastroenterological diseases, among other things, with an unfavorable environmental situation, irrational diet and lifestyle. In Russia, every tenth inhabitant suffers from diseases of this group. The most common are chronic pancreatitis (8–35%), gastric ulcer and duodenal ulcer (8–10%), diseases of the hepatobiliary system, including hepatitis (18–22%) [6]. As a rule, the pathology of the digestive system has a combined and chronic character [6].

In modern gastroenterology, synthetic drugs of different chemical groups are widely used, which, with a pronounced therapeutic effect, have a wide range of side effects, contraindications and restrictions to their use. They usually do not

prevent the development of a relapse of the disease after withdrawal. All this necessitates the development of comprehensive approaches to treatment, including the use of natural medicines, which have a wide range of therapeutic and prophylactic actions, have low toxicity, mild action, are able to eliminate symptoms of exacerbation, prevent relapses and promote recovery. disturbed functions of the gastrointestinal tract [6].

Shilajit is one such remedy that has been used in folk medicine in many countries of the world for many thousands of years. This publication is devoted to the results of an information and analytical study of the use of mummy preparations for diseases of the stomach and intestines.

II. Chronic diseases of the digestive system

W.A. Askarov et al. (1978) studied the effect of mumiyo-asil on chronic gastrointestinal diseases [1]. The studies involved three groups of patients. Group I (60 people) consisted of patients with peptic ulcer disease, of which 8 people - with ulcers localized in the stomach and 52 - in the duodenum. Group II (21 people) consisted of patients with chronic gastritis: 8 people - with increased and preserved gastric secretory activity and 13 - with gastric secretory insufficiency. Group III (69 people) consisted of patients with chronic colitis: 6 - with ulcerative form and 63 - with non-ulcer. The control group consisted of 60 patients: 20 with gastric ulcer and duodenal ulcer, 20 with chronic gastritis, 20 with chronic colitis with appropriate complex treatment without mummy [1].

Mumiyo-asil was initially prescribed orally on an empty stomach once a day - in the morning at a dose of 0.2 g. However, in 3 patients with peptic ulcer disease, the pain syndrome intensified, so the single dose was reduced to 0.1 g, but the frequency of administration was increased to 3 times a day. ... With increased secretion of gastric juice, the mummy was taken 1.5 hours before meals, with reduced secretion - 30 minutes. and with normal - in 45-50 minutes [1].

The results of the dynamic studies carried out indicate a pronounced therapeutic effect of mumie-asil in patients with chronic gastrointestinal diseases. For example, in patients with peptic ulcer disease, the pain syndrome decreased on the 4-6th day of treatment, and the complete disappearance, including local palpation pain, on the 9-12th day, which, on average, 5-6 days earlier than in the control group [1].

The data of X-ray and gastro-fibroscopic studies of the stomach showed a complete reverse development of the ulcer niche in 12 patients (11 with duodenal ulcer and 1 with gastric ulcer). A significant decrease in the ulcer was observed in 28 and a decrease in 20 patients. In all patients with chronic gastritis with secretory insufficiency (13 people), as a result of the treatment, the secretory activity of the stomach was restored. In patients with chronic colitis, as a result of taking mumiyo-asil, the pain syndrome decreased rather quickly (on the 3-4th day of treatment), and the stool returned to normal. In 5 out of 6 patients with chronic ulcerative colitis, by the end of treatment, complete

reverse development of the ulcerative process in the intestine. The best effect was observed in patients with chronic gastritis with secretory insufficiency and in patients with chronic colitis, somewhat less in patients with duodenal ulcer with increased secretion of gastric juice. No contraindications were found during the research [1].

In the course of treatment, the course dose of mummy was specified, depending on the nosological form of the disease, the age and general condition of the patient. So, in case of gastric ulcer, the appointment of mumiyo-asil in a dose of 0.1 g 3 times a day for 25–35 days was effective; in case of duodenal ulcer - in the same dose for 20-25 days; with chronic gastritis - 15–20 days; chronic ulcerative colitis - 30 days; chronic non-ulcer colitis - 20 days. Thus, the course of treatment for patients with chronic gastritis requires 4 to 6 g of mumiyo-asil, peptic ulcer disease - from 6 to 10 g, and chronic colitis - from 6 to 9 g [1].

III. Peptic ulcer and duodenal ulcer

The effectiveness of mummy preparations for gastric ulcer and duodenal ulcer was studied by Yu.N. Nuraliev (1973) in a hospital setting against the background of medical nutrition with the participation of 74 patients: 4 - with gastric ulcer and 70 - with duodenal ulcer [7].

Shilajit was prescribed at a dose of 0.1 g [7] or 100 mg / kg [8] twice a day (morning and evening) for 18-24 [7] - 24-26 [8] days 30 minutes before meals. Before use, the drug was previously dissolved in one tablespoon of tea or boiled water [8]. The therapeutic effect of mummy was pronounced and manifested itself in the disappearance in patients of subjective (decrease or disappearance of the feeling of pain 15–20 minutes after taking the drug) [8] and objective (disappearance of the ulcer or decrease in its size) symptoms by 4–8 (60%)) and 9-12th (92%) days. All dyspeptic symptoms (nausea, vomiting, heartburn, belching, etc.) passed on the 7-10th day of treatment. In patients with a tendency to constipation, stool became regular on the 6-15th day of treatment [8]. In the course of treatment, the mummy niche disappeared in 65 (95.6%) patients, in 3 patients (4, 4%) - sharply decreased in size compared to the baseline. The Gregersen reaction after the course of treatment was negative in all patients (26 people) [8].

The results of the study of gastro-biopsy material showed that on the 8-12th day of treatment, the signs of inflammation disappeared, the trophism of the gastric mucosa was completely normalized. It was shown that the drug has a normalizing effect on the secretory function of the stomach: during hyper- and hypoacid processes, the acidity of gastric juice gradually normalized, the level of pepsinogen increased [7, 8].

Thus, in the course of the studies carried out, it was shown that mummy reduces swelling, inflammation and the phenomenon of hypoxia; enhances the resistance of the stomach wall. The discovered effects can be used to prevent degeneration of the gastric mucosa and accelerate the healing process of ulcers. It was also shown that at a dose of 100 mg (2 times a day, course dose of 3.6-5.0 g) with a duration of treatment of 18-26 days, mummy is good

tolerated by patients [7].

The authors also made an attempt to determine the therapeutic effect of the less mineralized extract of the Trans-Baikal mummy. For this, 6 patients were prescribed the drug at a dose of 200 mg / kg 2 times a day. In the course of research it was found that 5 out of 6 patients disappeared most of the symptoms of the disease on the 9-12th day of treatment. In one case out of 6, the niche did not disappear, but its size sharply decreased after the course of treatment [8].

Three patients with excruciating pains were prescribed mummy together with vikalin. In this case, the pain subsided much earlier than with the prescription of the drugs separately - approximately within 1–3 days [8].

In addition to peptic ulcer disease, 4 patients were diagnosed with chronic cholecystitis, and 5 with chronic spastic colitis. After the course of treatment with mummy, the disappearance of ulcerative symptoms, pain and other symptoms associated with concomitant inflammatory diseases of the biliary system and intestines was observed [8].

Thus, given the presence anti-inflammatory and wound healing effect of mummy, the authors recommended its use in gastroenterological practice for hypo- and hyperacid gastritis, chronic enterocolitis, cholecystitis, in the treatment of ulcerative colitis of various origins [7].

A.S. Vishnevsky et al. (1972) used mummy as a component of the complex spa treatment of patients with gastric ulcer and duodenal ulcer [2].

Shilajit was prescribed daily for 28 days, on an empty stomach, orally at a dose of 0.2–0.3 g in the form of an aqueous solution.

Based on the studies, it was shown that mummy in combination with other resort factors has a beneficial effect on the general condition of the body, improves the functional state of the stomach and duodenum, reduces the vulnerability of the gastric mucosa, improves its trophism, and promotes wound healing [2].

IV. Nonspecific ulcerative colitis

A.S. Vishnevsky and E.V. Vakhlakova (1972) used the Caucasian mummy in patients with ulcerative colitis [3].

Two modes of drug administration have been investigated. The first one - oral before meals 3 times a day (washed down with mineral water). The daily dose was 0.2–0.3 g. The second was direct introduction into the rectum every other day of 1% aqueous solution in an amount of 30 ml (0.3 g) [3].

As a result of the research, positive results were obtained, which allow us to conclude that the use of the Caucasian mummy is promising as a component of the treatment of patients with ulcerative colitis. It was also shown to be effective in patients who were initially treated with sulfa drugs, but were forced to further abandon the use due to individual intolerance [3].

N.R. Rakhimov et al. (1978) studied the effect of mummy on some stimulation processes in chronic ulcerative colitis and

enterocolitis [9]. 122 patients were under observation, of which 86 had ulcerative colitis, 25 had chronic enterocolitis (4 had severe catarrhal-spastic colitis), 11 had catarrhal-erosive proctitis and sphincteritis. Shilajit was prescribed at 0.3 g per day: inside, 10 ml of 1% solution 2 times a day. The third part of the daily dose (0.1 g) was taken in the form of suppositories.

In 35 out of 50 examined patients within 7-10 days there was an increase in daily urine output from a moderate to a pronounced degree (from 1800 to 3000 ml) and, accordingly, a decrease in the weight of patients. From the end of the first or the beginning of the second week, the daily urine output, decreasing, reached the initial level. In 38 patients with ulcerative colitis who received mummy for 25-30 days, there was a good, in 34 - an average therapeutic effect with obvious manifestations of tissue regeneration on the catarrhal-ulcerative surface of the colon mucosa. In 14 patients with severe and moderate forms of ulcerative colitis, when using only one mummy for 12-15 days, there was no improvement in subjective, clinical, sigmoidoscopic, coprological and some other laboratory data, so they underwent complex therapy. In 10 patients with chronic enterocolitis, the therapeutic effect was good, in 12 - average, in 3 - the state did not change. With a good therapeutic effect, the erosivehemorrhagic process disappeared at the end of the 2nd week, the ulcerative process with the appearance of a scar surface - at 4–5 weeks of treatment. In 17 patients with moderate and severe normo- or hypochromic anemia, normalization of the content of erythrocytes and hemoglobin was observed after treatment. In this case, the most pronounced leukopoietic effect of mummy [9]. In 17 patients with moderate and severe normo- or hypochromic anemia, normalization of the content of erythrocytes and hemoglobin was observed after treatment. In this case, the most pronounced leukopoietic effect of mummy [9]. In 17 patients with moderate and severe normo- or hypochromic anemia, normalization of the content of erythrocytes and hemoglobin was observed after treatment. In this case, the most pronounced leukopoietic effect of mummy [9].

In patients with catarrhal-erosive or ulcerative proctitis and sphincteritis, proceeding with symptoms of proctalgia, burning, itching and tingling, a feeling of distention in the anorectal part of the intestine, the mummy was applied topically in the form of suppositories, 0.1 g 3 times a day. A good therapeutic effect was noted in 7 patients, the average - in 3, and in 1 the state did not change. Control sigmoidoscopy showed the disappearance or a sharp decrease in the inflammatory and edematous process, the disappearance of erosions and ulcers or the covering of the ulcerative surface of the colon mucosa with scar tissue, resolution of spastic and painful phenomena [9].

Histomorphological and histochemical studies of biopsy materials from the distal colon, in dynamics during the treatment period, indicate that in 1/3 of patients, inflammatory and destructive changes in the mucous membrane slightly decreased. This indicates some lag in the process of restoration of the morphological structure of the mucous membrane from the clinical effect [9].

The authors also studied the effect of mummy on the intestinal microflora. The patients underwent bacteriological examination of the intestinal contents. It was found that before treatment, the intestinal microbial flora contained a large number of putrefactive and pyogenic microbes (hemolytic Escherichia coli, streptococci, pathogenic staphylococci, etc.), which are absent in a healthy intestine. After a course of treatment, mummy in most patients

nonspecific ulcerative colitis showed a significant decrease in opportunistic microbes, in particular, hemolytic Escherichia coli. Consequently, mummy adversely affects the growth and development of intestinal microflora [9].

S.L. Gokhberg et al. (1978) studied the therapeutic effect of mummy in ulcerative colitis [4]. The study involved 59 patients with chronic ulcerative colitis. Patients received 0.3 g of mummy per day (10 ml of 1% solution 2 times a day by mouth, and the third part of the daily dose in the form of suppositories). Another group of patients was prescribed conventional therapy [4].

During sigmoidoscopy in patients treated with mummy, a decrease in inflammatory processes, the disappearance of erosions and small ulcers, scarring of ulcerative defects in the mucous membrane of the colon were noted. After a 30-36-day course of treatment, despite a decrease in the severity of clinical manifestations of the disease, in 3 out of 59 patients, histological examination revealed a slightly altered mucous membrane of the large intestine. In 16 cases, there was some smoothness of inflammatory-dystrophic changes and the disappearance of lymphoid-plasma cell infiltration. There was a pronounced edema of the interstitial tissue, a wide distance between the crypts, which were lined with a large number of goblet cells. Severe pathological changes in the mucous membrane of the large intestine persisted in 40 patients. Histological examination of biopsy specimens, taken from the distal colon before and after treatment, showed a slight decrease in inflammatory and destructive changes in the mucous membrane in 1/3 of cases. When comparing morphological changes in the mucous membrane of the colon in patients treated with mummy and receiving complex therapy, no difference was found [4].

Thus, in the course of the study it was shown that in the majority of patients with ulcerative colitis and enterocolitis, the disappearance of the phenomena of gastrointestinal dyspepsia was noted, anti-inflammatory,

antispasmodic, local anesthetic, stimulating regeneration and moderate erythroleukopoietic properties of the drug. The data obtained indicate the possibility of using mummy in the complex treatment of ulcerative colitis and enterocolitis [4].

CONCLUSION

The results of a clinical study of mumiyo-asil in patients with gastric ulcer and duodenal ulcer, chronic gastritis and chronic colitis, carried out in the 70s-80s of the last century, indicate its pronounced effectiveness and expediency of its use for prevention and treatment in the complex therapy of chronic gastrointestinal diseases.

Considering the results of this information and analytical study and availability of domestic regulatory documents for the standardized substance of mummy (VFS 42-3084-98 "Dry mummy extract") and tablets from it (VFS 42-3083-98 "Dry mummy extract tablets 0.2") should be

recognize the feasibility of conducting modern clinical studies to study the effectiveness of mumiyo preparations in accordance with the requirements of the GCP.

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