

Clinical studies of Shilajit. Publication 3. Application for fractures

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Clinical research of Mummy (Shilajit). Publication 3. Application for bone fractures

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RESUME

Presents the results of clinical studies on the effectiveness of mumijo-asil for recovery of bone fractures, spent to 70–80th years of the last century.

The efficiency of the mumijo and the feasibility of its use for prevention and treatment in the treatment of bone fractures in adults and children.

Keywords: mumijo, mumijo-asil, mumijo-bragshun, drug mumijo, bones fracture.

SUMMARY

The article presents the results of a clinical study to study the effectiveness of mumijo-asil in bone fractures, carried out in the 70s-80s of the last century. The efficacy of mummy and the expediency of its use for prevention and treatment in the complex therapy of bone fractures in adults and children have been shown.

Keywords: mummy, mummy-asil, mummy-bragshun, mummy preparation, broken bones.

The XX century brought to mankind enormous achievements in social and public life, successes in medical science, discovering the mechanisms of development of the most common human diseases, which made it possible to increase the life expectancy of people in developed countries almost twice. However, the legacy of this century is considered to be diseases of bones, joints, and musculoskeletal injuries, causing concern to the medical community and health authorities in connection with the constantly growing costs of treating patients, a high level of temporary disability and early disability [4].

Injuries resulting from road traffic accidents, drowning, poisoning, falls or burns, etc. account for 9% of all deaths in the world and threaten the health of people in every country. A significant proportion of people who survived injuries suffer from temporary or permanent disability [4].

The present publication devoted to results informational analytical study of the use of mummy preparations in clinical

practice for joint-musculoskeletal injuries.

Most of the studies related to the study of the effectiveness of shilajit in various fractures of tubular and flat bones were carried out by A.Sh.Shakirov for the period 1966-1969. The author studied the effect of the mumiyo preparation on the regenerative processes in fractures of the bones of the forearm, shoulder, thigh and lower leg on more than 2500 patients. In all studies, the first group consisted of patients who did not take the mumiyo drug. The second group consisted of patients who, along with the main method of treatment, took orally once a day on an empty stomach, mumiyo in an amount of 0.2 g for 10 days with a 10-day break [11–15].

Fracture consolidation was monitored by clinical observation and X-ray every 10 days. At the same time, clinical blood tests and its biochemical study were performed for the content of trace elements - calcium, potassium phosphorus and alkaline phosphatase [11–15].

During the study and analysis of X-ray images of injured limbs, the dependence of the rate of callus formation and the intensity of its consolidation on the location and nature of the fracture, the type of displacement of the fragments was established [11–15].

Analysis results clinical and radiological and biochemical studies of patients in the second group showed that under the influence of the drug mumiyaasil, the process of callus formation and the period of fracture consolidation accelerated by 13–17 days in comparison with the control group. The drug improved the altered blood picture after surgery and normalized it. Positive shifts in altered hemodynamics, according to the author, are associated not only with a change in the tone of the autonomic nervous system, but also depend on irritation of the sympathetic receptor zones and an increase in the tone of the parasympathetic nervous system [15].

Under the influence of mummy, the formation of bone regenerate was accelerated and the quality of the latter increased. The patients showed a marked improvement in the general condition and rapid restoration of the function of the injured limb, a reduction in the duration of pathological mobility, edema disappeared more quickly, and hematomas resolved [11–15].

The beneficial effect of mummy on mineral metabolism, according to A. Sh. Shakirov, is associated with the biostimulating effect of incoming macro- and microelements. Shilajit is not only their source, but also promotes the migration of bioavailable minerals from the mineral depot into the blood and to the fracture area, having a general nonspecific stimulating effect on the entire human body. Therefore, the drug can be used in the complex treatment of fractures of long bones along with modern conservative and surgical methods of treatment [11–15].

At the Department of Traumatology and Orthopedics of the Tashkent State Medical Institute and in the orthopedic and traumatology department of the Clinical Emergency Hospital, on the basis of the decision of the Pharmacological Committee of the USSR Ministry of Health dated April 15, 1966, a clinical study of mummy-asil was carried out in the treatment of fractures of long tubular bones in children in age

from 2 to 16 years old [7]. Mumiyo-Asil treatment was carried out in 82 children. Melificin was used as a comparison drug, with which 94 children were treated [7].

Shilajit was prescribed in the form of pills or 1-2% aqueous solution orally in 2-3 doses. Children under the age of 5 years - in the amount of 0.1-0.2 g; up to 10 years - 0.2-0.4 g; up to 15 years old - 0.4-0.6 g per day. The course of treatment was 2-3 weeks [5-7].

As a result of the studies, it was found that the drug significantly improves the general condition, normalizes body temperature, reduces tissue edema, accelerates the restoration of the anatomical shape and function of the injured limb [5-7].

Clinical and radiological observations have shown that the inclusion of mumiyasil in the complex of treatment of fresh fractures of long bones in children contributes to the recovery of 80% of patients (in the control group - only 67%). When observed from 3 months to 4 years after the trauma, the complete restoration of the anatomical shape, bone structure and function of the injured limb occurred in 92.5%, in the control group - in 84% [5-7].

Thus, on the basis of the studies carried out, the effectiveness and rationality of the use of mumiyo-asil in the complex therapy of bone fractures in a growing organism has been shown [5-7].

On the basis of the clinic of traumatology and orthopedics of the Leningrad Sanitary and Hygienic Institute K.F. Blinova et al. (1971) studied the regenerative capacity of the Transbaikal mummy-bragshun. 72 people took part in the research, of which 37 - with fractures of the shins, 14 - hips, 1 - elbow, 1 - shoulder, 4 - multiple fractures. It was found that oral administration of finely ground mummy powder promotes the formation of good calluses in a shorter time than in patients with similar injuries, but treated with other means (specific data are not given). The authors suggest that good regeneration ability is due to the presence of urea and steroid compounds in the chemical composition [2, 3].

A large number of studies on the effect of mummy-asil on the consolidation of fractures of long tubular bones in a clinic was studied by N.M.Madzhidov et al. (1980) [8]. The study included 1745 patients with fractures of the diaphysis of the thigh, lower leg, shoulder and forearm. Patients of group I (45 people) did not receive mummy. Of these, 34 underwent conservative treatment (reduction of bone fragments followed by application of a plaster cast), 11 - surgical treatment (osteosynthesis with a pin, Lena's plate). In all patients who were treated promptly, the wounds healed by primary intention. Group II consisted of 1700 patients who received mummy in the general complex of treatment. 825 of them had transverse fractures, 376 had oblique fractures, 243 had screw-shaped fractures of the leg, 256 - comminuted. Fractures with displacement of fragments were observed in 1542 people, without displacement - in 158; there were 1275 patients with diaphyseal fractures, 425 with epiphyseal fractures. Treatment of patients of group II was carried out in a complex, conservative (in combination with mummy) and surgical methods. Conservative treatment (application of traction and reduction of bone fragments with subsequent immobilization of the limb with a plaster cast) were subjected to

963 patients (56.7%), operative - 737 (43.3%). Group II consisted mainly of patients with fresh fractures; a small percentage were cases of slowly healing or non-healing fractures and pseudoarthrosis. 2 days after the fracture, patients in this group took orally mummy on an empty stomach in a single dose of 0.2 g once a day with a glass of warm milk or sweet tea. Patients received 3 courses of treatment for 10 days with intervals of 5–10 days [8].

For fractures of the forearm, shoulder, or large tubular bones with exact matching of bone fragments, the use of mummy was limited to 1–2 courses (2.0–4.0 g) [8].

In order to control the course of reparative regeneration of bone tissue in the area of the fracture, the author carried out clinical and radiological studies. When assessing the clinical picture, the presence and absence of pain at the fracture site, the degree of soft tissue atrophy, the color of the skin and the range of motion in adjacent joints were taken into account [8]. When evaluating the data of X-ray studies, the severity and nature of the periosteal callus, the duration of the preservation of the fracture line and the process of attachment of the callus were taken into account [8].

In the course of a study of 1,700 people with fractures of tubular bones, it was found that on the 10-15th day after the fracture of the forearm around the bone fragments, a noticeable shadow was found - the initial signs of a periosteal reaction and an unclear fracture line. A clear callus appeared on the 20-30th day [8].

With diaphyseal fractures of the brachial bone, on radiographs, periosteal callus appeared first of all, which was located mainly around the bone fragments. In most patients, on the 10th day after the fracture, an initial cloud-like shadow of the periosteal reaction was visible around the bone fragments. Weak calluses became more distinct by 20-30 days after the fracture. A clear callus was identified by the 15th day; massive callus around bone fragments - by the 30th [8].

Fractures of the femur were observed in 539 (31.7%) patients. Conservative treatment (traction, reduction, plaster cast) was performed in 241 patients. Surgical treatment was received by 298 people. In 100% of cases, the postoperative period was uneventful. The wounds were healed by primary intention. The timing of callus formation and the size of the callus depended on the level and juxtaposition of the thigh bone fragments. With conservative treatment, the formation of calluses occurred due to the endosteum and periosteum. During osteosynthesis, the periosteal callus was initially formed [8].

In all cases, regardless of the nature and method of treatment, an earlier formation of callus was found in patients who received mummy. The initial signs of callus formation in the form of a slight shadow in hip fractures appeared on the 10th, 15th, 20th and 30th days. A weak callus was formed by the 45th day. The rates of fracture union on radiographs were consistent with clinical data. Crepitus and mobility of bone fragments in most patients disappeared by 8–12 days after the fracture. General condition, sleep, appetite improved significantly after 7-10 days of taking mummy. With fractures of the lower leg, the initial signs of calluses in the form of a shadow appeared by the 15–20th day, weak callus -

by 20–30, clear - by 30, massive - by 45 [8].

Thus, taking mumiyo-asil in doses of 0.2 g once a day does not cause any complications in patients. At the same time, the general condition, mood, appetite improve, sleep normalizes, the intensity of pain at the fracture site decreases. After one course of taking mummy, patients gain weight. Analysis of the dynamics of initial and massive callus formation in the most severe types of fractures - hip and tibia - indicates the stimulating effect of mummy on the process of callus formation [8].

A number of researchers have studied autoimmune changes in the body of patients with fractures of tubular bones.

Z. Abdukhaliyov, A. Sh. Shakirov (1973), it was found that mummy in the complex treatment of open and complicated fractures significantly accelerates the resorption of destructive tissues, which leads to a decrease in the titer and the frequency of detection of autoantibodies in the blood. Under the influence of mummy, the general reactivity of the body increases, characterized by the rapid disappearance of autoantigens and the pathological focus. The entry into the blood of autoantigens and the production of autoantibodies are reduced [1, 12]. Studies of the transaminase activity of blood in open fractures have shown that mummy provides an earlier normalization of the enzymatic activity of the blood [1, 12].

N.M. Majidov et al. (1980) studied autoimmune changes in patients with open uncomplicated and complicated bone fractures. Studies were carried out on 1925 nonspecific serological reactions with and without biostimulants at different stages and with various clinical forms of open fractures at 10, 20, 30, 40, 50 and 60 days after injury [8].

In patients of group I (who did not receive mummy) with open fractures on the 10th day after injury, autoantibodies to antigens of the skin ($42.9 \pm 8.71\%$; 8.0%), muscles ($36.8 \pm 5, 7\%$; 4.8%) and cartilage ($39.2 \pm 5.0\%$; 4.8%). According to the authors, this indicates the presence of a pathological focus formed as a result of a necrobiotic process. Autoantibodies to liver and kidney antigens were detected during the entire study period, respectively, in 33 and 15.1% of patients, which indicates degenerative processes in these organs with complications of septic conditions, long-term destructive changes, as well as old age [8].

In the first 20–40 days, autoimmune reactions increased. By the 50th day, with an uncomplicated course of open fractures, they moderately decreased. The wounds were healed by primary intention. Increase in the frequency of autoantibody detection by the 50th day (to skin antigens $50.6 \pm 30\%$; 23%, muscles - $40 \pm 21.4\%$; 17.6% and cartilage - $68.5 \pm 14.1\%$; 12.3%) is associated, according to the authors, with complications of the fracture. With complicated open fractures, autoimmune reactions in most of the examined patients increased within 60 days. At times, undulations appeared in the antigenic structure and detectability of antibodies in the blood. These fluctuations reflected the severity, course and duration of destruction. In severe complications of open fractures, the autoimmune reaction did not correspond to the clinical course [8].

With open fractures of a simple type in half of the patients under the influence

mummy wounds healed by primary intention and fractures healed in the early stages [8].

After the first course of shilajit, the content of autoantibodies in the serum to skin antigens and the frequency of their detection decreased ($28.3 \pm 54.7\%$; 35.4%). After 2-3 courses, autoantibodies were not detected in the blood (except for complicated open fractures). If, before the start of the first course of treatment, mummy autoantibodies to skin antigens in a titer of 1:80 were found in 7.0% of patients, then after the end of its high titer was not detected. In group I, a positive serological reaction by this time was in 7.7% of patients [8].

After the first course of shilajit, the frequency of detection of autoantibodies to muscle antigens significantly decreased (from $53.9 \pm 7.2\%$; 6.7% to $25.5 \pm 5.01\%$; 4.8%). This was especially noticeable at a dilution of 1:80. By the end of treatment, autoantibodies to muscle antigens were detected in 5.2% of patients ($31.3 \pm 14.1\%$; 12.3%). A decrease in the frequency of detection of autoantibodies to cartilage antigens persisted even after the 3rd course of taking mummy; medium and low titers were detected at the end of treatment ($20.7 \pm 18.1\%$; 15.3%) [8].

Thus, in open uncomplicated fractures, the first course of mummy reduced the titer of autoantibodies to antigens of the skin, muscles, and cartilage. After the 2nd and 3rd courses, the titers of autoantibodies dropped sharply to the point of disappearance. This is due to the fact that the mummy promoted the resorption of destroyed tissues (autoantigens) in the focus of injury and stimulated the body's defenses. In the body with open fractures of the long bones, autoantibodies were formed. These changes in the blood indicate aseptic or purulent destruction of tissues in the area of open fractures, which leads to delayed consolidation, ununited fracture, pseudarthrosis, osteomyelitis [8].

Autoantibodies in blood serum have cytotoxic properties, reducing oxygen uptake by the liver tissue by an average of $0.61 \pm 0.08\%$ ($p < 0.1\%$). In control donors, these indicators were $0.88 \pm 0.01\%$. Thus, under the action of the mummy, an increase in the general reactivity of the body occurred, which was accompanied by the early elimination of autoantigens (pathological focus): there was a rapid cleansing of wounds, the blood picture normalized, purulent discharge decreased, and early granulation was observed.

CONCLUSION

The results of a clinical study on the efficacy of mumiyaasil in bone fractures, carried out in the 70s-80s of the last century, indicate its pronounced regenerative activity and the feasibility of using it for treatment in the complex therapy of bone fractures in adults and children.

Considering results the present information and analytical research and Availability domestic regulatory documents on 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"), it should be recognized that it is advisable to conduct modern clinical studies to study the effectiveness of mummy preparations in accordance with the requirements of the GCP.

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