Clinical studies of Shilajit. Publication 4. Impact on some biochemical parameters of blood for bone fractures

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Clinical research of Mummy (Shilajit)
Publication 4. The influence on biochemical parameters of blood in cases of bone fractures

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SUMMARY

The results of numerous clinical studies on the study of the effect of mummy on some biochemical and clinical parameters of blood in bone fractures have been analyzed. It has been shown that mummy extract has the ability to compensate for the negative changes in the elements and blood formula resulting from trauma, normalizes the blood picture and increases the adaptive physiological abilities of the whole organism.

Key words: mummy, mummy-asil, mummy preparation, bone fracture, leukocytes, erythrocytes, hemoglobin, alkaline phosphatase.

RESUME

The results of numerous clinical studies on the effect on the mumijo some clinical and biochemical parameters of blood in bone fractures are analyzed. It is shown that the extract has the ability to compensate for the mumijo negative changes of blood resulting from an injury, normalizes blood picture and increases the physiological functions of the entire body.

Keywords: mumijo, mumijo-asil, drug mumijo, bones fracture, white blood cells, red blood cells, hemoglobin, alkaline phosphatase.

Previous publication devoted to results informational analytical study of the use of mumiyo preparations in clinical practice for joint-musculoskeletal injuries [3]. This article is a logical continuation of this work and is devoted to the results of studying the effect of mummy on some biochemical parameters of blood in bone fractures.

Most of the currently known studies on the effect of mummy-asil on the consolidation of fractures of long tubular bones in a clinic were carried out by A.Sh. Shakirov (1968–1983) [4, 5] and N.M.Madzhidov et al. (1980) [1]. These authors studied the effect of the mumiyo preparation on the content of leukocytes, erythrocytes, hemoglobin and on the erythrocyte sedimentation rate on more than 1745 patients with fractures of the diaphysis of the thigh, lower leg, shoulder and forearm. In all studies, group I (45 people) consisted of patients

who have not taken the drug mummy. Of these, 34 underwent conservative treatment (reduction of bone fragments followed by application of a plaster cast) and 11 - surgical treatment (osteosynthesis with a pin, Lena's plate). Group II (1700 people) included patients, mainly with fresh fractures, who, along with the main method of treatment, took orally once a day on an empty stomach mumiyo preparation in an amount of 0.2 g for 10 days with 5-10 days break [1, 4, 5]. Mumiyo was washed down with a glass of warm milk or sweet non-hot tea. Patients received 3 courses of treatment for 10 days with intervals of 5–10 days [1]. 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). Shilajit was prescribed to patients in this group two days after the fracture [1]. 825 patients of group II had transverse fractures, 376 - oblique, 243 - 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. 963 patients (56.7%) received conservative treatment (application of traction and reposition of bone fragments followed by immobilization of the limb with a plaster cast), surgical treatment - 737 (43.3%) [1] ...

I. Clinical blood tests

A complete blood count was performed on the day of admission to the clinic and every 5 days for a month [1].

The initial data were taken from the blood test data on the 2nd day after the fracture. These data were compared with the established norm, and the data of the studies carried out on the following days were compared with the baseline [1].

1.1. Influence on the content of leukocytes

In the course of the research, it was noted that in 34% of patients of group II who received mummy, the content of leukocytes continued to increase on the 5th day. An increase was also observed in 66% of patients in the control group. The maximum increase in group II was 60%, in group I - 100%. None of the patients of group II had the leukocyte count exceeding the normal range. In group I, 53% of patients had the character of leukocytosis. In each subsequent five-day period, there was an excess of the initial level of leukocytes in groups II and I, respectively (%): in 33 and 60, 128 and 65, in 32 and 55, in 33 and 51, in 27 and 50. By the end of the study (at 30th day), the leukocyte count returned to normal in 85% of patients in group II (treated with mummy) and in 42% of patients in group I [1].

1.2. Influence on the content of red blood cells

The number of erythrocytes in the blood of patients in group II on the 5th day after the fracture increased relative to the initial one in 89% of patients. In group I, this indicator decreased in comparison with the initial one in 91%. In every next five days, the content of erythrocytes in 73–80% of patients in group II was higher than the initial one, in 75–93% of patients in group I — lower. By the end of the study (on the 30th day), the content of erythrocytes was close to normal (4–5 million). Physiological

fluctuations within 10% were observed in 100% of patients in group II (on the 1st day of fracture - 93%) [1]. The reception of mummy by patients of group II prevented a decrease in the content of erythrocytes for 30 days. For the overwhelming majority, it increased. By the end of the study, the content of erythrocytes returned to normal in all patients of group II. In patients of group I, the content of erythrocytes throughout the entire study period remained below the initial one and by the 30th day it was restored only in 82% [1].

1.3. Influence on the content of hemoglobin

The body's response to injury on the day of admission to the clinic in patients of both groups was expressed in a decrease in the level of blood hemoglobin relative to the norm, by 16.6–16.7%. In some patients, its level dropped to 50%. On the 5th day after the fracture, the hemolobin level in patients of group II increased in comparison with the initial one in 45% of patients, and in two patients it returned to normal. At the same time, in 77% of patients in group I, it decreased by another 20–40%. In each subsequent five-day period, the hemoglobin content in 44–55% of patients in group II was higher than the initial one, and in 53–77% of patients in group I — lower [1].

By the end of the study (on the 30th day), in 4 patients of group II, the hemoglobin content was close to the lower limit of the norm (16.5%); in none of the patients of group I, the hemoglobin content reached this level [1]. Thus, shilajit increased the baseline hemoglobin level in patients with bone fractures throughout the study. In patients who did not take mummy, the opposite phenomenon was observed: the hemoglobin level constantly remained below the initial one [1].

1.4. Effect on erythrocyte sedimentation rate

The erythrocyte sedimentation rate (ESR) on the day of admission to the clinic was accelerated, compared with the norm, in 80% of patients in group II and in 50% - I group. On the 5th day from the start of taking mummy, ESR sharply slowed down compared to the initial one in 92% of patients in group II. In 95% of patients of group I, who did not receive mummy, ESR exceeded the initial one by 2–3 times or more. In the next five days, the accelerated, compared with the initial, ESR continued to slow down in 93–97% of patients in group II and remained accelerated in 87–95% of patients in group I. On the 30th day, ESR was within the normal range in 57% of patients in group II and only in 4.4% of patients in group I [1]. Based on the results of the studies, it was shown that the mummy does not have a negative effect on the state of the most important elements of the blood. In the overwhelming majority of cases, it, on the contrary, compensates for the negative reaction of the organism to trauma, normalizes the blood picture, and enhances the physiological functions of the whole organism [1–6].

II. Biochemical blood tests

Calcium, potassium and inorganic phosphorus play an important role in the formation of the main substrate of bone tissue. In this regard, A.Sh. Shakirov and N.M. Madzhidov studied the effect of mummy on the content of these minerals [1–6].

2.1. Effect on calcium content

The calcium content in the blood serum on the day of admission to the clinic before receiving the mummy in 97% of patients in group II and in 86% of patients in group I was within the normal range (9–12 mg%). On the 5th day after the bone fracture, in 86% of patients of group II, the calcium content in the blood increased to a level higher than the initial one. In 77% of patients in group I, the calcium content decreased in comparison with the initial one. It was higher than the initial one only in 1 out of 35 patients [1]. In group II, on the days following the fracture, the calcium level was higher than the initial one in 91 (day 10), 88 (day 15), 77 (day 20), and 70% (day 25) of patients. On the 30th day, this indicator was higher than the initial only in 28% of patients in this group. On the 25th day, the calcium content within the normal range was observed in 99% of patients in this group, on the 30th day - in 93%; in 6 patients it is below normal. However, the decline, compared with the lower limit of the norm, ranged from 0.1–0.4 mg%, or 1.1–4.4%. Such fluctuation, according to the authors, may be physiological [1].

In group I, the calcium level was lower than the initial one in 91 (on the 10th day), 80 (on the 15th day), 86 (on the 20th day) and 89% (on the 25th day) patients. On the 5th day, the calcium content below the baseline was noted in 77%. And only on the 30th day, the calcium content reached the level of the 5th day after the operation - 77%. On the 25th day after the operation, the calcium content within the normal range was observed in 54% of patients in this group, on the 30th day - in 66%. On the 30th day, the normal level of calcium was in a smaller number of patients (66-68%) than on the 1st day [1]. Thus, in patients with bone fractures, mummy has a pronounced normalizing effect on the calcium content in the blood [1, 4].

2.1. Impact on potassium content

Serum potassium content on the day of admission to the clinic was within normal limits in 87% of patients in group II and in 91% in group I. On the 5th day after the fracture, in group II, the serum potassium content higher than the initial one was observed in 97% of patients; in group I, it was lower than the initial one - in 97% of patients. On the 10th, 15th and 25th days in group II, the level of potassium was higher than the initial one, respectively, in 98, 96 and 87% of the victims, and on the 30th - in 45%. On the 25th day, this indicator was within the normal range in 93% of patients, on the 30th - in 97%. In the rest, it exceeded the norm, however, according to the authors, the excess could be physiological [1].

In group I, on the 10th, 15th and 25th days after the fracture, the level of potassium in the blood serum was lower than the baseline, respectively, in 100, 97 and 97% of patients (on the 5th day, 97% were lower than the baseline). On day 30, potassium levels below baseline were observed in 95% of patients. Within the normal range, the content of this trace element in the blood serum on the 25th day is 95%, below the norm - in 2%, on the 30th day - respectively, in 91 and 7% [1]. Thus, on the day of admission to the clinic, the potassium content in patients of group I did not change predominantly: in 91% of patients it was normal. In the next 30 days, the body's reaction to trauma in almost all patients who did not receive mummy was manifested in a decrease in the initial level of potassium in serum. A different picture was observed in group II:

2.3. Influence on the content of inorganic phosphorus

The content of inorganic phosphorus in the blood serum on the day of the fracture in 66% of patients in group II was within the normal range (3–9 mg%). In the rest, it did not reach the lower limit of the norm (in some cases, up to 47%). In group I, 89% of patients had the phosphorus content within the normal range, in 4 - lower. On the 5th day after the fracture, in 83% of patients of group II, the phosphorus content in the blood serum increased and exceeded the initial one; in 80% of patients in group I, it was lower than the initial one. On the 10th, 15th, 20th, 25th days after the fracture in group II, the phosphorus level higher than the initial level was observed in 86.3% of the victims, on the 30th day - in 35.3%, at the initial level - in 46.4%, below the initial - in 18.0%. On the 25th day, the content of inorganic phosphorus was within the normal range in 90% of patients of group II (on the 1st day of the fracture, only in 66%). On the 30th day, the normal level of inorganic phosphorus was in 80% of patients, below normal in 18%, which did not exceed physiological fluctuations [1]. Thus, in patients of group I, who did not receive mummy, a tendency towards a decrease in the level of inorganic phosphorus in the blood serum was observed throughout the entire period of treatment. As a result, by the end of treatment, the normal content of inorganic phosphorus was observed in fewer patients than on the day of the fracture. In the overwhelming majority of patients of group II, who received mummy, already from the 5th day of taking the drug, the content of inorganic phosphorus increased in comparison with the initial data. By the end of the treatment, the normal level of phosphorus was observed in a significantly larger number of patients than on the day of injury.

2.4. Effect on the content of alkaline phosphatase

The content of alkaline phosphatase on the day of the fracture was within the normal range (2–4 mg%) in 46% of patients in group II. In the rest of the patients in this group, its content did not reach the lower limit of the norm by 0.1–1.4 mg%. In half of the patients of group I, the content of alkaline phosphatase was within the normal range, in the rest it was lower. On the 5th day, in 86% of patients in group II, its content increased, in 2 patients it remained at the same level and in 2 it decreased. In group I, the content of alkaline phosphatase decreased, increased in 1 patient and remained at the same level in 1 patient. On the 10th, 15th, 20th and 30th days after the fracture, the level of alkaline phosphatase in patients of group II increased, compared with the initial one, by 93, 75, 32 and 29%, respectively. In group I, it increased only in 3–4 out of 10 patients, and in 5–7 it fell below the initial value.

Thus, under the influence of mummy, in most patients, the concentration of alkaline phosphatase in the blood increased on the 10th and 15th days after the injury - the most crucial period of bone tissue regeneration. In the following days, when the need for this enzyme disappears, its content significantly decreased and in some cases dropped below the norm [1, 4].

CONCLUSION

The results of clinical studies to study the effect of mummy on some biochemical blood parameters (the content of leukocytes, erythrocytes, hemoglobin, calcium, potassium, inorganic phosphorus, as well as ESR) in bone fractures, indicate its pronounced regenerative activity and ability

- compensate for negative changes in quantitative composition blood elements resulting from trauma,
- normalize the blood picture and increase the physiological adaptive functions of the whole organism.

At the same time, positive shifts in the altered hemodynamics under the influence of mummy are associated not only with a change in the tone of the autonomic nervous system, but also depend on the irritation of the sympathetic receptor zones and an increase in the tone of the sympathetic nervous system [4]. The detected types of biological activity of mummy indicate the prospects and expediency of its use in the complex therapy of bone fractures in adults and children.

Considering the results of this information and analytical study and availability of domestic regulatory documents for standardized Mummy substance (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 expedient to conduct modern clinical trials (in accordance with the requirements GCP) to study the efficacy of standardized mummy preparations for a variety of bone fractures.

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