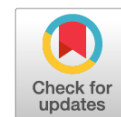


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# Application of pantohepatogen dry for treatment of discirculatory disorders in chronic prostatitis (experimental and clinical study)

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**PURPOSE:** To study in experiment and in clinical conditions the effectiveness of the preparation pantogematogen dry, obtained from the blood of a maral, for the correction of discirculatory disorders in the prostate gland.

**MATERIALS AND METHODS:** The experimental and morphological part of the work was performed on 90 male Wistar rats with local venous congestion in the small pelvis due to ligation of the internal iliac veins. Animals of the main group ( $n = 30$ ) underwent enteral correction with dry pantohepatogen (in a daily dose of 10 mg per 100 g of animal weight) starting from the 7<sup>th</sup> day after modeling the disease, the course was 14 days. The rats of the 2<sup>nd</sup> group ( $n = 30$ ) after modeling of venous stasis were not treated. Group 3 consisted of intact animals. During the clinical phase of the study, 61 patients with chronic congestive prostatitis were treated. All patients received standard therapy, and patients in the treatment group ( $n = 30$ ) additionally received highly dispersed aerosol transrectal irrigation with an aqueous solution of pantohepatogen, daily, for a course of 10 procedures.

**RESULTS AND DISCUSSION:** Morphological examination of the prostate gland of laboratory animals with experimental discirculatory prostatitis and its subsequent enteral correction with pantohepatogen dry indicated significant differences compared with animals of the 2<sup>nd</sup> group. A tendency towards restoration of the normal structure of the prostate, its metabolism, regional and organ blood and lymph outflow, improvement of the drainage-detoxification and transport activity of its regional lymph nodes was noted. In the clinical part of the study, the effectiveness of the use of pantogematogen in patients with chronic congestive prostatitis was shown. At the end of the course of treatment in patients of the 1<sup>st</sup> group, the disappearance of pain (in 72.4% of cases) and dysuric (in 86.2% of cases) syndromes was observed, and in the rest – a decrease in their intensity. According to the TRUS of the prostate in patients of the 1<sup>st</sup> group, after treatment in 52% of cases, a decrease in the volume of the prostate was noted.

**CONCLUSIONS:** The results of an experimental clinical study indicate the prospects for the inclusion of pantogematogen in the complex therapy of patients with chronic congestive prostatitis.

**Keywords:** dry pantohepatogen; venous congestion in the small pelvis; experimental model; discirculatory prostatitis; chronic congestive prostatitis.

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## Применение пантогематогена сухого для лечения пациентов с дисциркуляторными расстройствами при хроническом простатите (экспериментально-клиническое исследование)

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**Цель.** Изучить в эксперименте и клинических условиях эффективность препарата пантогематоген сухой, полученного из крови марала, для коррекции дисциркуляторных расстройств в предстательной железе.

**Материалы и методы.** Экспериментально-морфологическая часть работы выполнена на 90 крысах-самцах Вистар с локальным венозным застоем в малом тазу вследствие лигирования внутренних подвздошных вен. Животным основной группы ( $n = 30$ ) проводили энтеральную коррекцию пантогематогеном сухим (в суточной дозе 10 мг на 100 г массы животного) начиная с 7-х суток после моделирования заболевания, курс 14 сут. Крысам 2-й группы ( $n = 30$ ) после моделирования венозного застоя лечение не проводили. Третью группу составили интактные животные. Во время клинического этапа исследования проводили лечение 61 больного хроническим конгестивным простатитом. Все пациенты получали стандартную терапию, а пациентам группы лечения ( $n = 30$ ) дополнительно проводили высокодисперсные аэрозольные трансректальные орошения водным раствором пантогематогена, ежедневно, на курс 10 процедур.

**Результаты и обсуждение.** Морфологическое исследование предстательной железы лабораторных животных с экспериментальным дисциркуляторным простатитом и последующей его энтеральной коррекцией пантогематогеном сухим свидетельствовало о значимых различиях по сравнению с животными 2-й группы. Отмечена тенденция к восстановлению нормальной структуры простаты, ее метаболизма, регионарного и органного крово- и лимфооттока, улучшению дренажно-детоксикационной и транспортной активности ее регионарных лимфатических узлов. В клинической части исследования показана эффективность применения пантогематогена у больных хроническим конгестивным простатитом. По окончании курса лечения у пациентов 1-й группы наблюдали исчезновение болевого (в 72,4 % случаев) и дизурического (в 86,2 % случаев) синдромов, а у остальных — уменьшение их интенсивности. По данным трансректального ультразвукового исследования предстательной железы у пациентов 1-й группы после лечения в 52 % случаев было отмечено уменьшение объема предстательной железы.

**Выводы.** Результаты экспериментально-клинического исследования указывают на перспективность включения пантогематогена в комплексную терапию больных хроническим конгестивным простатитом.

**Ключевые слова:** пантогематоген сухой; венозный застой в малом тазу; экспериментальная модель; дисциркуляторный простатит; хронический конгестивный простатит.

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## INTRODUCTION

Chronic prostatitis (CP) is the most common infectious and inflammatory disease of the genitalia of men of reproductive age and the third most frequent diagnosis in men over 50 years of age [1–4]. According to statistics, every second, man experience symptoms of prostatitis throughout his life [5–7]. The CP prevalence ranges from 2.2% to 9.7% among all men [7]; in the USA, about 8% of visits to the urologist are due to CP [8]. In recent years, there has been a progressive increase in the incidence of this disease [9].

Currently, the UPOINT CP classification principle has become widespread; it is performed according to six clinically defined areas (domains): urinary, psychosocial, organ-specific, infectious, neurological, and pain. UPOINT phenotyping for the choice of effective treatment methods is recommended to be used as a guideline for the therapy performed [10].

CP is characterized by a prolonged recurrent course. Even with the use of the most modern methods of treatment, the process exacerbation during the first 2 years becomes frequent in 40% of cases [11, 12]. There are certain standards for treating CP patients using first-line drugs (antibiotics, alpha-blockers, non-steroidal anti-inflammatory drugs, etc.); however, their efficacy is often insufficient. Therefore, the search for alternative methods of treatment for CP is crucial.

Antler maral breeding products are widely used as a preventive measure. The raw material base is extremely diverse; it includes antler cooking waters, alcoholic tinctures of maral antlers, and a number of biological products and cosmetic medicine, including lyophilized pantohepatogen. The most technologically advanced method for obtaining dry pantohepatogen is its cryoextraction from the maral blood plasma in a vacuum [12]. This technology for obtaining pantohepatogen provides the maximum preservation of biologically active components (including protein complexes), which have protective properties in relation to the male sex glands. The resulting active product is a dark powder (TU9158-036-74701043-15) which is easily absorbed through the mucous membrane of the stomach or colon, depending on the administration route.

The therapeutic effect of pantohepatogen is assumed to be based on the most complete restoration of its active components in contact with the mucous membrane of the rectal ampulla. The close proximity to the point of application of the test product suggests a positive organ-specific effect on prostate tissue, considering the clinically proven prostatoprotective effect of the agent [12–14].

It seems relevant to evaluate the efficiency of the use of aerosol highly dispersed transrectal irrigation with an aqueous solution of pantohepatogen in the treatment of

chronic congestive prostatitis patients and to compare the data obtained with the results of morphological studies using an original model of experimental dyscirculatory prostatitis (EDP) in small laboratory animals [15]. According to the authors, this approach is most justified from the viewpoint of the principle of evidence-based clinical medicine.

*This study aimed* to analyze the effect of the drug dry pantohepatogen in experimental and clinical conditions for the correction of dyscirculatory disorders in the small pelvis in CP.

## MATERIALS AND METHODS

The present study consisted of two parts, experimental and clinical.

The experimental part of the study was conducted in the Research Institute of Clinical and Experimental Lymphology, a branch of the Federal Research Center Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences (Novosibirsk) within the framework of a joint research project. At this stage, EDP was simulated in 90 male Wistar rats weighing 220–260 g according to the original method [15] by creating local venous stasis in the small pelvis. The animals were divided into groups 1 and 2, each including 30 animals; venous congestion in the small pelvis was created by ligating the internal iliac veins on both sides, and the procedure was performed under nembutal anesthesia.

The group 1 animals, starting from day 7 after the EDP initiation, underwent enteral correction by addition of dry pantohepatogen (10 mg/day per 100 g of animal weight) and plant fiber (as part of the dietary supplement for food Panfiten-M; sanitary epidemiological conclusion no. 77.99.20.919.V.000446.04.04, dated February 4, 2004). The comparison group consisted of the group 2 animals with EDP; morphological examination was performed on day 21 of the experiment. The control group, group 3, consisted of 30 intact male rats. Histological examination of the prostate tissue and its regional lymph nodes (iliac) of all the animals was performed using the morphometry method [15–17]; laser peak fluorometry was the standard method used to assess the state of tissue perfusion, and atomic emission spectrometry was used to assess the macro- and microelement composition of the prostate with arc excitation of spectra (after preliminary mineralization of samples by the method of dry ashing at  $t = 450^{\circ}\text{C}$  for 2.5 h) [15, 16].

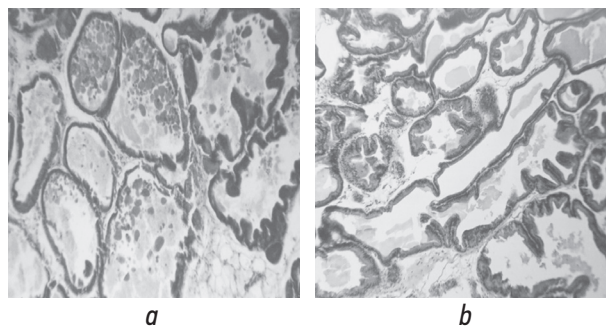
In contrast, the clinical part of the study was conducted in the sanatorium-preventorium “Stankostroitel” (Barnaul). The study included 61 patients with chronic congestive prostatitis aged 22–37 years, who were undergoing sanatorium rehabilitation. All studies were performed with the informed consent of the subjects and in accordance with the ethical standards of the Declaration

of Helsinki, considering the explanatory note of the cl. 29, approved by the General Assembly of the World Medical Association (Washington, 2002). The patients underwent general urological examination according to the generally accepted scheme. The patients were distributed into two groups. In both groups, climatotherapy, nonspecific hydrotherapy, balneotherapy, mechanotherapy, and aeronotherapy were prescribed as basic treatments. The group 1 patients (treatment group,  $n = 30$ ) additionally received highly dispersed aerosol transrectal irrigation with an aqueous solution of pantohepatogen (active substance dose, 500 mg; aerosol particle density upon spraying, 1.0 g/cm<sup>2</sup>; size, 0.5–50.0 microns; compressed air pressure for spraying microparticles, 1 atm), with the total volume of the injected solution at 50.0 ml and the duration of the procedure of 10 minutes, and the procedure was performed daily (in the morning) with 10 procedures per course.

The treatment efficiency was monitored according to the changes in the patients' complaints and the results of laboratory tests (including microscopy of prostate secretions) and transrectal ultrasound (TRUS) of the prostate using the duplex scanning mode.

## RESULTS AND DISCUSSION

In the group 1 animals with EDP, which underwent enteral correction with dry pantohepatogen, the morphological study of the prostate tissue on day 21 of the experiment, a significant increase in the area of the prostate parenchyma (19.5%;  $p < 0.05$ ) and a decrease in stroma (32.6%;  $p < 0.05$ ) were noted compared with animals of groups 2 and 3 (Fig. 1). Moreover, a significant decrease in the area of venules by 58% ( $p < 0.05$ ) was observed, which indicated an increase in the tone and elasticity of the venous wall and an improvement in venous



**Fig. 1.** The prostate gland of male Wistar rats with experimental discirculatory prostatitis (a) and after its enteral correction with pantohepatogenous dry (b: there is a decrease in the severity of congestion). Stained with hematoxylin-eosin,  $\times 150$

**Рис. 1.** Предстательная железа крыс-самцов линии Вистар при экспериментальном дисциркуляторном простатите (a) и после его энтеральной коррекции пантогематогеном сухим (b: отмечается уменьшение выраженности конгестии). Окраска гематоксилином и эозином. Ув.  $\times 150$

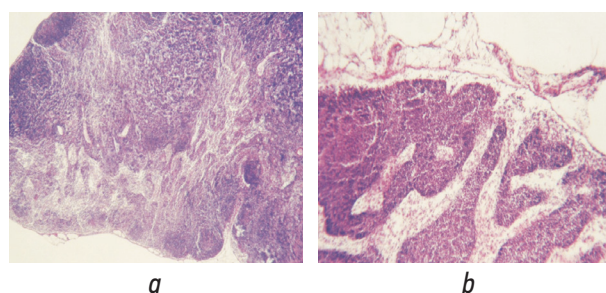
outflow. The study of the content of microelements in the prostate tissue revealed that in the group 1 animals, compared with the group 2 animals, the iron (50.8%) and zinc levels (65.6%) were significantly higher, and the manganese level (33.5%) was lower. In the group 1 animals, the restoration of the parenchymal-stromal relationship in the iliac lymph nodes was registered, which did not differ from that in the intact animals of group 3. Furthermore, the cortical-cerebral index, equal to 0.31, corresponded to the fragmented type (according to the classification of Academician Yu. I. Borodin, 1969) [17]. Improvement of venous outflow was accompanied by a significant increase in lymph outflow, apparently due to the predominance of its transit path through the marginal sinus of the regional lymph nodes (e.g., the iliac ones; Fig. 2). The area of cerebral sinuses of the group 1 animals was larger by 16.7%, and their area of the marginal sinus was 4.3 times ( $p < 0.001$ ) larger than those of the group 2 animals. In the structural and functional areas of the iliac lymph nodes of the group 1 animals, signs of activation of proliferative processes were registered.

Moreover, the clinical part of the study revealed the efficiency of pantohepatogen in patients with chronic congestive prostatitis. The main complaints of our patients before the start of treatment were discomfort in the perineum, urinary disorders, and decreased sexual function. In the prostate secretion, an increase in leukocyte count and a decrease in lecithin granules were noted. At the end of the clinical stage of the study, the group 1 patients noted the arrest of pain (72.4% of cases) and dysuric syndromes (86.2% of cases) ( $p < 0.05$ ), and the rest of the patients noted a decrease in their intensity. The leukocyte count in the secretion of the prostate gland in patients of this group decreased 2.8 times ( $p < 0.01$ ) and the amount of lecithin granules increased by 1.9 times ( $p < 0.05$ ) compared with those of the initial data.

According to the TRUS of the prostate (Fig. 3), in the group 1 patients after treatment, a decrease in the volume of the prostate was noted in 52% of cases, on average by 28%.

In assessing the state of microcirculation in the prostate gland, a tendency to an increase in both linear peak and diastolic blood flow velocity in the central and peripheral regions was noted. The resistance index of the group 1 patients decreased on average by 24.2% in the central and by 15.3% in the peripheral zones ( $p < 0.05$ ). Increased libido, stabilization of morning erection, and the erection component of sexual intercourse were noted in 58.6% of the group 1 patients ( $p < 0.05$ ). In group 2 (comparison group), all the studied indicators tended to improve; however, the changes were not significant.

The morphological study of the prostate gland of laboratory animals (male Wistar rats) with EDP and its subsequent enteral correction with dry pantohepatogen

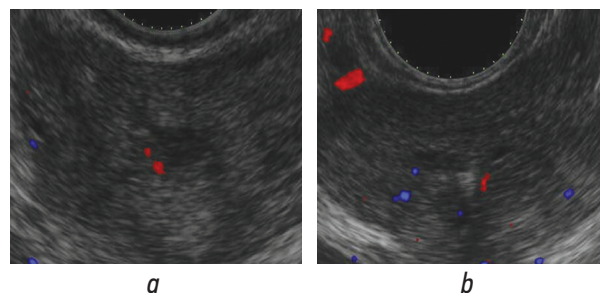


**Fig. 2.** The iliac lymph node of a male Wistar rat with experimental discirculatory prostatitis after enteral correction with dry pantohematogen. There is an increase in cerebral and marginal sinuses. Stained with hematoxylin-eosin.  $\times 150$  (a),  $\times 500$  (b)

**Рис. 2.** Подвздошный лимфатический узел крысы-самца линии Вистар с экспериментальным дисциркуляторным простатитом после энтеральной коррекции пантогематогеном сухим. Отмечается увеличение мозговых и краевых синусов. Окраска гематоксилином и эозином. Ув.  $\times 150$  (a),  $\times 500$  (b)

showed significant differences in comparison with animals of group 2. A tendency toward restoration of the normal structure of the prostate (Fig. 1, b) and its metabolism and regional and organ blood and lymph efflux, improvement of the drainage-detoxification and transport activity of its regional lymph nodes (e.g., the iliac ones), and an increase in proliferation processes was observed.

The results of the clinical part of the study demonstrated the efficiency of transrectal highly dispersed aerosol irrigation with dry pantohematogen in the traditional therapy of congestive CP. More significant improvement in the clinical symptoms of the disease compared with the control group was registered, including



**Fig. 3.** Results of TRUS of the prostate of a patient with severe congestion (a) and after correction with pantohematogenous highly dispersed aerosol irrigation (b: decrease in the severity of congestion)

**Рис. 3.** Результаты трансректального ультразвукового исследования простаты пациента с выраженной конгестией (a) и после коррекции пантогематогеновыми высокодисперсными аэрозольными орошениями (b: уменьшение выраженности конгестии)

improvement in dysuria, pain, and sexual function. Subjective improvement was accompanied by beneficial changes in laboratory parameters (a decrease in the leukocyte count and an increase in the amount of lecithin granules in the prostate gland secretion), TRUS data, and duplex scanning of the prostate (Fig. 3, b). The decrease in prostate volume was due to the anti-inflammatory effect of the treatment.

## CONCLUSIONS

The results of an experimental clinical study suggest the inclusion of pantohematogen in the complex therapy of patients with chronic congestive prostatitis.

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