

Preclinical Trials of Anti-Inflammatory Activity
homeopathic gels based on witch hazel

M.V. Korokin², O.A. Korvyakova³, E.I. Underdevelopment³, A.E. Oleinik³, M.V. Pokrovsky¹,
A.E. Korolev¹

(¹Department of Pharmacology, Kursk State Medical University, Kursk, ²Research Institute of Ecological Medicine of the Kursk State Medical University, Kursk, ³LLC "Krasnodar Regional Center for Homeopathy" Krasnodar)

SUMMARY

The aim of the work was to study the anti-inflammatory activity of the drugs "Hamamelis 10%" and "Hamamelis C1" in comparison with the currently produced drugs "Ginkor-gel" manufactured by Balkanpharma (Bulgaria) and "Indomethacin" gel manufactured by Beaufour Ipsen. The experiments were carried out on sexually mature male albino rabbits weighing 1800–2400 g. To study the anti-inflammatory effect of drugs, a method was used to study the effect of drugs on vascular permeability in modeling an aseptic inflammatory response. The study of the anti-inflammatory activity of the drugs was carried out according to the method of I.A. Oyvin [3]. The obtained experimental data allow us to conclude that the homeopathic gel "Witch hazel C1" has a pronounced antiphlogistic effect,

Keywords: witch hazel, anti-inflammatory research actions, antiphlogistic action, Indomethacin, Ginkor-gel, homeopathy, Hamamelis.

Introduction

Homeopathic medicines have long been successfully used in medical practice. An example of effective use in homeopathy can be preparations prepared on the basis of homeopathic witch hazel tincture. Hamamelis was introduced to homeopathy in 1851 by Dr. Preston. Preston found the remedy to cause congestion to the head and nosebleeds. He studied Hamamelis well and found it to be one of the best remedies for varicose veins, thrombophlebitis and bleeding hemorrhoids. The value of the therapeutic effect of this agent on the venous system was also confirmed by Goering and Gale. Like Arnica, this remedy is widely used for various injuries with crushing of tissues, with sharp soreness; what is the indication for the appointment of Hamamelis in trauma [1]. Hamamelis is a good hemostatic agent for bleeding from a wide variety of organs, especially when the patient complains of pain and weakness, which often do not correspond to bleeding. Hamamelis is successfully used in obstetric, gynecological and surgical practice [2]. Today, one of the main tasks of modern homeopathic pharmacy is the creation and

introduction of new effective homeopathic medicinal funds. It is also important to refine the components already known for their properties into dosage forms adapted to modern life. Considering these tendencies, the Krasnodar Regional Center for Homeopathy has proposed a new dosage form - a gel with witch hazel tincture (Witch hazel 10%) and a gel with trituration of witch hazel tincture (Witch hazel C1). Among the expected effects of the proposed gels, it is necessary to note the venotonic, wound healing and anti-inflammatory effects.

In this regard, at the first stage of studying the pharmacological activity of new dosage forms of witch hazel, the purpose of this work was to study the anti-inflammatory activity of the preparations "Witch hazel 10%" and "Witch hazel C1" in comparison with the currently produced preparations "Ginkor-gel" produced by Beaufour Ipsen (France) and "Indomethacin" gel manufactured by Balkanpharma (Bulgaria).

Materials and methods

The experiments were carried out on sexually mature male albino rabbits weighing 1800–2400 g. The animals were randomized by weight. To study the anti-inflammatory effect of drugs with venotonic properties, the optimal method is to study the effect of drugs on vascular permeability in modeling an aseptic inflammatory response. The study of the anti-inflammatory activity of the drugs was carried out according to the method of I.A. Oyvin [3]. The rabbits were fixed, the hair on the skin of the abdomen was preliminarily clipped (section 13 cm). During the study, albino rabbits were given the preparations "Hamamelis 10%", "Hamamelis C1", "Indomethacin" gel and "Ginkor-gel" 45 minutes before the introduction of a permeability indicator, the role of which was played by a solution of trypan blue. In the control group of animals, physiological saline was applied to the epilated area of the skin. Trypan blue was injected into the marginal vein of the ear in the form of a 1% solution in 0.9% sodium chloride solution at the rate of 2 ml per 1 kg of animal weight. Then, 12 drops of o-xylene were applied to the abdominal skin area. The time of appearance of blue-colored spots on the skin and their diameter served as an indicator of capillary permeability. The difference in the time of the appearance of spots and their diameter before and after the application of the drugs was judged on their anti-inflammatory effect.

Statistical processing of the results of the study of the pharmacodynamics of the drugs "Hamamelis 10%" and "Hamamelis C1" was carried out according to methods generally accepted in pharmacology, calculating the average values of indicators (M) and the arithmetic mean error ($\pm m$). The significance of differences between the means was determined by the Student's test. The probability of the results obtained was assessed at a significance level of at least 95% ($p \leq 0.05$).

Research results

The results of a study of the anti-inflammatory activity of drugs by the method of I.A. Oyvin are presented in table. 1.

Table 1

Anti-inflammatory activity of homeopathic gels "Witch hazel 10%"

and "Hamamelis C1" in comparison with the preparations "Ginkor-gel" and "Indomethacin" gel ($M \pm m$)

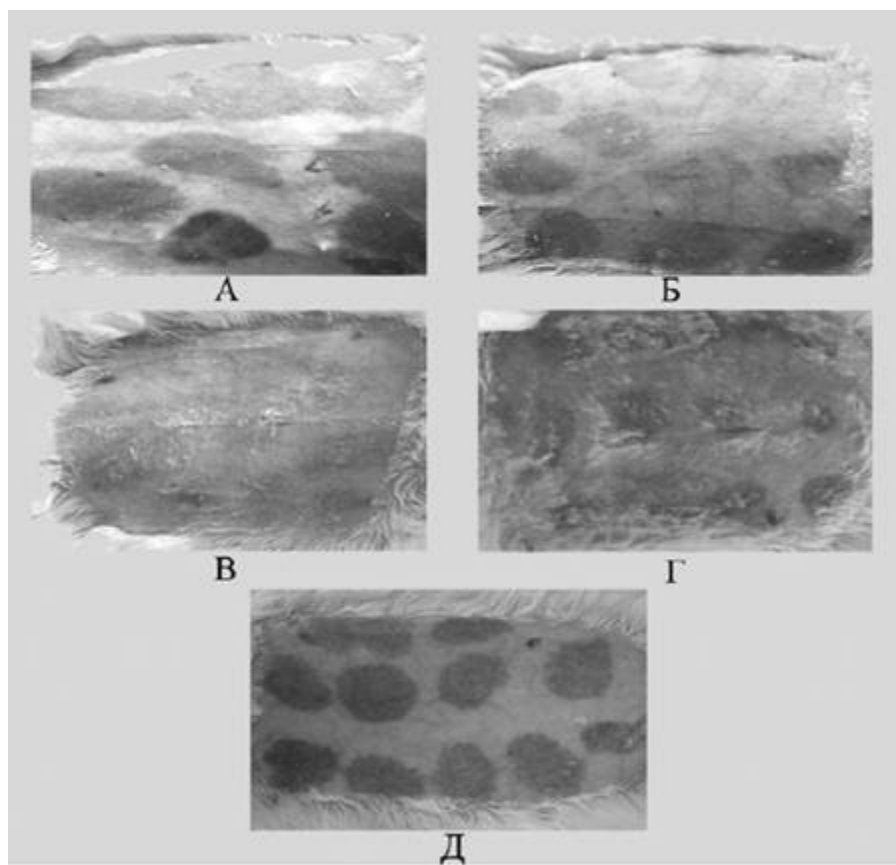
| Препараты | Кол-во пятен | Общая площадь пятен, см ² | Средняя площадь пятен, см ² | Время появления пятен, сек. |
|--------------------|--------------|--------------------------------------|--|-----------------------------|
| Интактные | 12 | 65,03 | 5,42 ± 0,38 | 236,7 ± 7,0 |
| «Гамамелис 10%» | 12 | 34,98 | 3,18 ± 0,3* | 365,4 ± 18,6* |
| «Гамамелис С1» | 12 | 26,44 | 1,03 ± 0,09*у | 570,4 ± 19,3*у |
| «Индометацин» гель | 12 | 37,60 | 3,42 ± 0,47* | 337,1 ± 21,8* |
| «Гинкор-гель» | 12 | 47,80 | 3,98 ± 0,45* | 299,6 ± 12,9* |

Примечание:

1) * – при $p < 0,05$ по отношению к интактной группе;

2) у – при $p < 0,05$ по отношению к экспериментальным группам.

In fig. 1 shows photographs of the site of application of the studied gels 8 minutes after modeling the inflammation with xylene. Attention is drawn to the fact that in the control group of animals, blue-colored spots tend to merge and are clearly visible already 8 minutes after the application of xylene (Fig. 1A). The use of the studied drugs to varying degrees led to an increase in the time to the appearance of spots and a decrease in their area.



Rice. 1. Study of the anti-inflammatory activity of drugs by the method of I.A. Oyvin. Note: A - Control; B - Witch hazel 10%; B - Witch hazel C1; G -

Indomethacin gel; D - Ginkor-gel.

The data presented in table. 1, as well as in Fig. 1 show that a single application of the studied drugs causes a statistically significant antiphlogistic effect, which is expressed in a decrease in the diameter of blue-colored spots and an increase in the time of their occurrence.

Conclusion

Chronic venous insufficiency (CVI) and varicose veins of the lower extremities are currently the most common pathology of the human vascular system. CVI of the lower extremities is a complex syndromic complex characterized by impaired blood outflow from the venous basin, which entails a cascade of pathological changes at the molecular, cellular and tissue levels [4]. We owe the appearance of this pathology in the spectrum of diseases of the human body to the transition of our distant ancestors to movement in an upright position. Man is the only representative of the animal world of the planet suffering from CVI. According to the generalized data of epidemiological studies, 35-60% of the working-age population suffer from this disease in different countries. According to V. Savelyev (1999), 35-38 million people in Russia suffer from varicose veins and the consequences of the postponed thrombophlebitis of superficial and deep veins, and 15% of them have trophic skin changes, open or recurrent trophic ulcers [6]. CVI occurs with a frequency of 10-15% in men and 20-25% in women [7].

CVI syndrome is primarily based on varicose veins, which occurs in 40% of the population [9] and is characterized by a predominant lesion of the superficial veins with their tortuosity and the formation of nodes. It is believed that the disease is based on congenital weakness of the wall of the venous vessels, which is a consequence of insufficient synthesis of type III collagen. In addition, a large contribution to the development of varicose veins is made by increased hydrostatic pressure in the legs in persons whose work is associated with a long stay in an upright position and lifting weights. In women, in addition, the strength of the venous wall largely depends on the level and mutual ratio of estrogens and gestagens. Thus, almost every person can identify certain factors

Prevention and conservative therapy of CVI and varicose veins play a decisive role, since surgical treatment is applicable no more than 10-15% of patients and does not provide a complete guarantee of recurrence of CVI symptoms [4].

Conservative treatment was, is and will be, obviously, the main method of treating varicose veins for many years to come. It can be an independent type of treatment or supplement surgical interventions in preparing a patient for surgery, as well as serve as a method for preventing the recurrence of the disease in the postoperative period.

Before the drug treatment of CVI there are many tasks that are solved primarily based on the severity of clinical symptoms, but the main drug in the treatment of any form of CVI should be a drug that has phlebotonizing and anti-inflammatory effects. As the degree of CVI increases, an additional effect on the lymphatic system is required, the fight against edema, the improvement of microcirculation and the correction of blood rheology.

Pharmacotherapy of CVI is based on the use of phleboprotectors (phlebotonics), which can be defined as drugs that normalize the structure and function of the venous wall. Phleboprotectors are the basis of CVI drug therapy, regardless of its origin (varicose veins, the consequences of deep vein thrombosis, congenital anomalies, phlebopathies, etc.).

More than 20 different venotonic drugs are registered in Russia. The frequency of their use is determined by many factors (the severity of CVI; the prevailing syndrome is edematous, painful, trophic disorders; tolerance; concomitant treatment; patient's material capabilities) and is 1–2% for most drugs, 26% for aescuzans, and 30 for diosmin. %, for Troxevasin - 31%.

Witch hazel is known in the form of various homeopathic dosage forms, but given its venotonic, wound healing, analgesic, anti-inflammatory properties, external forms for its use are most in demand. Taking into account the fact that the therapeutic effect of the external dosage form is determined not only by the medicinal substance, but also depends on the ointment base, which allows to slow down or accelerate the release of medicinal substances in the tissues of the body, we have carried out the selection of ointment bases corresponding to the appointment of the future dosage form.

The experimental data obtained allow us to conclude that the homeopathic gel "Witch hazel C1" has a pronounced antiphlogistic effect on the selected model of the study of antiphlogistic activity, in terms of the severity of which it reliably surpasses both the gel "Witch hazel 10%" and the comparison drugs - "Ginkorgel" and "Indomethacin" gel.

It can be assumed that the decrease in the permeability of the vascular wall, which underlies the inflammatory reaction and the manifestation of symptoms of chronic venous insufficiency, is an important component of the phleboprotective effect of the studied homeopathic gels based on witch hazel. However, this hypothesis needs further development and confirmation in experimental and clinical studies of the venotonic and wound healing effects of the homeopathic gels "Witch hazel 10%" and "Witch hazel C1".

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Author's address

Ph.D. Korvyakova O.A.

Gene. Director of Krasnodar Regional Center for Homeopathy LLC

krasnhom@mail.kubtelecom.ru

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