On the question of the effectiveness of homeopathy M.S. Tomkevich (National Association of Traditional and Complementary Medicine, Moscow)

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SUMMARY

This work shows the presence of biological activity of homeopathic medicines, their difference from placebo, the analysis of the largest clinical trials on homeopathic medicines is carried out.

Key words: homeopathy, clinical research, biologicalactivity.

RESUME

Biological activity of homeopathic preparations and their difference from placebo are presented. Largest clinical studies of homeopathic remedies are analyzed. Keywords: homeopathy, clinical research, biological activity.

INTRODUCTION

Homeopathy as a method of treatment for various pathologies has been used in the world for over 200 years. Formulated by the German physician and researcher F.H.S. Hahnemann in 1796, the method of homeopathy spread widely around the world, especially after the results of treatment, which were demonstrated by homeopaths during the European cholera epidemics in Europe in the 19th century. In 1833, by the Imperial Decree, homeopathy was allowed for use in Russia. The Russian contribution to homeopathy is known all over the world thanks to S.N. Korsakov, who, being in correspondence with Hahnemann, proposed his own method for obtaining homeopathic medicines, which was included in all pharmacopoeias.

Currently, homeopathy is used in 80 countries of the world [55]. In some countries (for example, Brazil, Mexico, India, Great Britain) it is recognized at the state level, in others it is included in compulsory (for example, Switzerland) or voluntary (for example, Germany) insurance [55].

The World Health Organization calls for the use of all the best for treatment and calls unconventional, complementary medicine (which includes homeopathy) "a health resource". The World Congress of Integrative Medicine held in Germany in the summer of 2016 approved the arguments of doctors and researchers regarding the future of medicine, which is clearly seen in the integration of the achievements of modern medicine and the experience of many generations of doctors. Homeopathy is certainly part of this integrative medicine [1, 2, 3].

Reception with a homeopath takes quite a long time. This is due to the fact that most often the doctor not only tries to choose a medicine to relieve a certain syndrome, but must assess the patient's condition, including his inherent individual characteristics, i.e. to treat not only the disease, but also sick. There is a widespread belief that it is with such a long and attentive conversation that the effectiveness of the treatment is associated. It is assumed that in the operation of homeopathic treatment there is a contribution of the psychological aspect of the consultation itself. Indeed, it has long been known that after consulting a good doctor, the patient feels better, and the psychological attitude is extremely important for successful treatment.

Research in homeopathy is more often aimed at examining the effective effect of homeopathic dilutions of various drugs in comparison with placebo. Trevor et al. [4, 5] carried out work aimed at defining and evaluating the role of "active participants" in homeopathic treatment. Without denying the psychological significance of a well-conducted consultation, the authors note a statistically significant difference in effect between placebo and homeopathic medicine.

By 2016, 1120 clinical trials on homeopathy were conducted, of which 483 were randomized controlled ones, 127 of them were based on individualized (personalized) prescriptions, 323 - on non-individualized (associated with the syndrome).

DOES THE MEDICINE HAVE BIOLOGICAL ACTIVITY?

The experiment has repeatedly shown the biological activity of small doses of substances used in homeopathy [6]. In a clinical study [5], against the background of the appointment of an individually selected (personalized) homeopathic medicine to eighteen patients, half of them showed deterioration, one had proving symptoms, and several responded not to the first dose, but to subsequent ones. All this indicates that a homeopathic medicine cannot be considered as a placebo, especially since its biological activity has been shown by different authors in various studies. The authors of the article believe that it is more correct in the studies conducted to compare the effect of a homeopathic medicine not with a placebo, but with a standard of treatment or with the action of another as detailed consultation as a homeopathic one. A number of articles suggest that that the design of homeopathic research should be improved in order to bring it closer to the accepted concept of medical clinical trials, but not lose the features inherent in homeopathy, i.e. also take into account the general condition of the patient and the quality of his life [7]. However, most of the clinical research in homeopathy is done in comparison with placebo.

PLACEBO OR MEDICINE

Milgrom LR in 2007 [8] compared the placebo effect in 25 paired, doubleblind, placebo-controlled clinical trials of classic homeopathic medicines and pharmacological drugs. The criteria for comparison were the severity of the condition, the duration of treatment, and the final results. This study also confirms that the effect of a homeopathic remedy is positively different from that of a placebo. The difference between the action of a homeopathic medicine and a placebo is confirmed in other works in the same way, as well as the inappropriateness of blind studies in these cases [9, 10].

Other articles [11, 12] criticize contemporary homeopathic research as being conducted by a diverse group of researchers - either university researchers or homeopathic practitioners. The first focus on blind and randomized trials, the second on case description, selection of an individual means, i.e. researchers speak different languages. Therefore, the authors propose to include in the study on a mandatory basis specialists in both homeopathy and clinical trials.

In 1989, a study was conducted in the UK on the possibilities of a homeopathic treatment for primary fibromyalgia. In one study, Rhus toxicodendron 6C was used in comparison with placebo, in the other, homeopathic remedies were selected individually in the observed group. The results obtained in these studies allow us to conclude that homeopathic treatment with both approaches was effective in terms of reducing pain zones and improving the quality of life and general condition of patients [13, 14].

Reilly D. et al. [15, 16] showed the importance of isopathy in the treatment of various allergic conditions. 144 patients, divided into two groups, received a preparation prepared from pollen from different trees, Pollen 30C, or a placebo. Studies have shown that when using the homeopathic drug Pollen 30C reliably relative to placebo, the manifestations of hay fever and the need for antihistamines are reduced.

Given the prevalence of tuberculosis and information in recent years about severe microbial antibiotic resistance, a study was carried out in India on the possibilities of mixed treatment of tuberculosis (standard treatment + homeopathic / placebo). It was shown that both subjective condition and X-ray control data were significantly better in the group of patients receiving additional homeopathic treatment [17]. Chakraborty D. et al. [18] after many years of research showed the effectiveness of the use of homeopathic medicines Sulfur 200C and Mercurius sol. 200C for various forms of leprosy to restore the sensitivity and structure of the skin. These findings were presented at the 2016 International Leprosy Congress and are included in the leprosy treatment protocols.

Studies carried out in the field of obstetrics and gynecology are of interest. A placebo-controlled study was conducted in women who needed to stop lactation after childbirth. For 10 days, in one group of patients, homeopathic medicines Apis mellifica 9C and Bryonia 9C were added to anti-inflammatory treatment (naproxen, 1 tablet 2 times a day), 5 granules 2 times a day; in the other group, the patients additionally received placebo. By the second day in women included in the "homeopathic" group, the state of health improved, chest pain decreased significantly, chest tension and milk flow significantly decreased by the 4th day [19], which, according to these indicators, significantly exceeded the results obtained in the other group. The positive dynamics of these manifestations in the placebo group was more

slow, these changes did not come to normal within 10 days of observation. The authors believe that the treatment combined with homeopathic medicines can be an important tool in the doctor's arsenal. In 2012, data were published on the efficacy of the homeopathic drug Acteane (Cimicifuga 4CH + Arnica 4CH + Glonoinum 4 CH + Lachesis 5CH + Sanguinaria 4CH) compared with placebo for 12 weeks in menopausal women. There was a significant positive difference in the number and severity of hot flashes in the "homeopathic" group relative to placebo. However, other manifestations of menopause (insomnia, irritability, asthenia, quality of life, etc.) remained at the same level in both groups [20].

Studies of the effectiveness of Oscillococcinum relative to placebo in the treatment and prevention of influenza-like syndromes were carried out in France, Germany, Italy, and Russia. In these studies, 1200 patients took part in two groups. The observation was carried out for 7-10 days, but after 48 hours a statistically significant positive dynamics was recorded in the group receiving the study drug in terms of the rate of disappearance of fever and other catarrhal symptoms, restoration of subjective well-being, as well as a decrease in the consumption of other drugs (antipyretic, etc. .) commonly used in such cases. Patients returned to work faster, and there were no side effects. In addition, the possibility of preventing the development of respiratory infections with the help of oscillococcinum has been shown. Convincing epidemiological data are presented [21–26]. Beigghi GM, MorselliLabate AM [27] from 2002 to 2011 conducted an observational study on the preventive effect of oscillococcinum on acute respiratory infections. The study consisted of two groups: 248 patients received oscillococcinum and 211 received placebo. A statistically significant effect of the drug was shown relative to placebo.

J. Jacobs et al. [28] (USA) conducted a meta-analysis of three controlled clinical trials in Nepal and Nicaragua on the use of homeopathic treatment for acute diarrhea in 242 children. An individually matched (personalized) homeopathic remedy or placebo was administered once every five days until a positive result (stool less than three times a day for two consecutive days). Homeopathic treatment performed significantly better than placebo.

Many systematic reviews and meta-analyzes have been written on the effectiveness of homeopathic treatment, but there has been no previous analysis of the effectiveness of individually prescribed (personalized) homeopathic treatment versus placebo. Mathie et al. [29] showed that in such studies, the effect of homeopathic medicines is 1.5–2 times better than the placebo effect. It can be concluded that the opinion that homeopathic medicines are placebos does not correspond to the results of the studies carried out. In addition to clinical studies, one should talk about the results of experimental studies (on cells, animals and plants), as well as the treatment of animals, for example, the treatment of diarrhea caused by E. coli in piglets [30] or the treatment of animals in the Great Moscow Circus [31].

The British Homeopathic Association Memorandum provides data from complete systematic reviews of randomized trials in homeopathy, which provide a qualified conclusion that homeopathy is different from placebo [32, 33]. When discussing the problems of homeopathy in the British Parliament, Mr. Wilson [34] reported data from a study conducted at the Charite Hospital in Berlin. This study involved 3700 patients, and showed great advantages of using the homeopathic preparation Arnica compared to standard tactics in patients with long-term chronic situations, including those with a tendency to bleeding in the postoperative period. There are similar data in other articles [35, 36].

COHORT STUDIES

Cohort studies carried out in a comparative analysis of the treatment of diseases of the musculoskeletal system in three groups - using standard methods, in combination with homeopathic treatment and only homeopathically, showed preferential effects in the latter group. It was in this group with fibromyalgia that the consumption of analgesic drugs sharply decreased. After a year of observation of these patients in the homeopathic group, efficacy was shown comparable to the other two groups, with a decrease in NSAID consumption and no side effects [37-40]. We also compared patients with depression and sleep disturbances who received homeopathic or standard treatment. A significant decrease in the need for psychotropic and hypnotic drugs has been shown with equal effectiveness in the homeopathic group and the group receiving standard treatment [41]. Similar data were obtained in the study of respiratory diseases. Follow-up for a year for patients with acute respiratory infections who received homeopathic or standard treatment, included in a large study of the French Ministry of Health (EPI3), included an assessment of the course of the initial disease, the need for antibiotics and antipyretics, the presence of complications (otitis media, sinusitis, etc.), analysis of incidence throughout the year. It was noted that with equal efficacy in the comparison groups, patients in the homeopathic group decreased the need for symptomatic pharmaceuticals, there were no complications, and they did not have acute respiratory diseases during the year [42]. who received homeopathic or standard treatment, included in a large study of the French Ministry of Health (EPI3), included an assessment of the course of the initial disease, the need to take antibiotics and antipyretics, the presence of complications (otitis media, sinusitis, etc.), analysis of the incidence during the year. It was noted that with equal efficacy in the comparison groups, patients in the homeopathic group decreased the need for symptomatic pharmaceuticals, there were no complications, and they did not have acute respiratory diseases during the year [42]. who received homeopathic or standard treatment, included in a large study of the French Ministry of Health (EPI3), included an assessment of the course of the initial disease, the need to take antibiotics and antipyretics, the presence of complications (otitis media, sinusitis, etc.), analysis of the incidence during the year. It was noted that with equal efficacy in the comparison groups, patients in the homeopathic group decreased the need for symptomatic pharmaceuticals, there were no complications, and they did not have acute respiratory diseases during the year [42].

In France, a study was conducted on the effectiveness of homeopathic therapy in relation to antibiotics. This was a non-randomized, pharmacoeconomic study that included children aged 13 to 18 years with more than 5 episodes of the disease per year. The study involved 529 children, of which 231 children were followed up by general practitioners who do not use homeopathic medicines, 268 - by general practitioners who use homeopathy. These children were assessed for episodes of acute respiratory illness, side effects, quality of life, direct and indirect costs of treatment, and the time of parents released from work to care for the child. The homeopathic strategy turned out to be more effective in influencing the course of the disease (p <0.001), in the absence of complications (p <0.001),

the number of medical consultations (p <0.001), quality of life (p <0.001), parental time spent (p <0.001), the direct costs of treatment required [43].

In Germany and Switzerland, a large study was carried out with an assessment of the quality of life using the SF36 questionnaire, supplemented with information about age, gender, educational level, and duration of the disease. The study involved 3981 patients and 103 homeopaths. Patients in this study rated homeopathic treatment as having better outcomes than conventional treatment and also in terms of cost of treatment [44]. Clinically significant improvements were observed in groups with the following diagnoses: migraine and headache, chronic rhinitis, back pain, elderly patients, menstrual pain and psoriasis. Statistical analysis of data on the quality of life in a long-term study revealed positive differences from the values typical for these diseases [45]. These data were rechecked and confirmed after two and eight years [46, 47].

The multinational study IPCOI [48] involved 4 countries, 30 doctors and 456 patients with acute respiratory diseases. 281 patients received homeopathic treatment and 175 received standard treatment. The results were evaluated on the 14th day. Positive results were observed in 82.6% of homeopathic patients and in 68% with standard treatment. Adverse effects were observed in 7.8% of homeopathic patients and in 22.3% of those receiving standard treatment.

A similar study was carried out by other authors [48]. This study enrolled 1,577 patients, 57 primary care rooms from eight countries. 86.9% of patients - children and adults, who received homeopathic treatment, on the 14th day demonstrated a complete and reliable cure for acute respiratory infections. Significant improvement with homeopathic treatment occurred on the 7th day, i.e. faster than those who received conventional treatment. Adverse reactions were more common in adults who received standard treatment. Swiss researchers, after analyzing 29 clinical studies of homeopathic treatment of upper respiratory tract infections, conclude that homeopathic treatment is very effective [49]. French researchers have determined

Interesting data is presented by the analysis of the effectiveness of treatment in homeopathic hospitals in the UK [51]. The Liverpool Homeopathic Ward analyzed 1,100 patients treated during 1999–2000. 76.6% noted a significant improvement in their condition immediately after the start of homeopathic treatment, of which 60.3% believe that the main improvement is associated precisely with homeopathic treatment. 814 out of the total number of patients received mixed treatment, of which 52% stated that they could refuse standard treatment at any time. In 2003, a similar study was conducted by the Royal London Homeopathic Hospital. 72% of patients with skin diseases reported improvement and refused previously received treatment. Also, many patients stated that they choose homeopathic treatment, because they are concerned about the safety of the treatment. An observational study conducted at Bristol Homeopathic Hospital in 2005 covered 6,500 patients and 23,000 visits over six years. 70% of patients noted a significant improvement in health. A sample of 200 patients from a previous study in 2016 showed statistical continuing improvements in health and quality of life. Analysis of the work of six homeopathic hospitals during the month covered 1602 patients, of which 34% noted a significant improvement already at the second visit, at the sixth visit, 59% said about a significant improvement in well-being. We are talking about the treatment of diseases such as eczema, chronic fatigue syndrome, menopausal disorders, osteoarthritis, depression, etc.

ANALYSIS AND META-ANALYSIS OF THE RESEARCH PERFORMEDIN 2016, members of the German Society for Scientific Homeopathy published a brochure on the current state of research in homeopathy [45].

A review of meta-analyzes in the field of homeopathy concludes that the results with the highest statistical significance compared with placebo indicate a particular efficacy of potentized drugs.

The first meta-analysis by Kleijnen, Knipschild and ter Riet (1991) dates back to what might be called the childhood of evidence-based medicine. The authors begin by saying that homeopathy is on the one hand implausible and, on the other hand, impossible to research with modern methods (controlled research). They included 105 homeopathic studies in their analysis. Of these, 14 were associated with classical homeopathy and individual selection of the drug, 58 with the prescription of one drug in accordance with the clinical diagnosis, 26 studies were associated with the use of complex homeopathic medicines and 16 with the use of isopathy. As a result, the authors conclude that "the evidence presented in clinical trials is positive, but this conclusion is not conclusive, since the studies carried out were of low quality. Research into homeopathy should be continued and high quality research conducted. "

Two other meta-analyzes were carried out by Linde et al. (1997), and these analyzes only considered articles published in The Lancet. Of the 119 studies, the authors considered 89 eligible for inclusion in the meta-analysis. They considered these works to be methodologically good, using their own assessment methodologies. Of the 89 papers, 52 were of the highest possible quality when evaluated on the Jadad scale. The authors conclude that the results of this study indicate that the effect of homeopathy is not a placebo. But the results obtained are not enough to conclude that homeopathy is absolutely effective for any clinical condition. Good quality assured research is required. This was the first conclusion. But remember that the authors selected studies for analysis according to their own criteria, It turned out that high-level studies on this scale show a large difference from placebo. A fourth meta-analysis (Cucherat et al., 2000) was reviewed in a European Parliament report. This analysis looked at studies using homeopathic medicines at dilutions above C3. Of the 118 clinical studies, 16 were selected and analyzed in this meta-analysis. It turned out that 65%; The selected papers demonstrated the benefits of homeopathy and the difference between homeopathy and placebo. The authors conclude that although the homeopathic effects are far from placebo, this kind of research should continue.

The fifth meta-analysis (Shang et al., 2005), published in the updated journal The Lancet, received the largest response in the press and in the scientific literature. The Lancet accompanied this study with an article with the biased title "The End of Homeopathy." The authors used for their analysis almost all of the same papers that were included in the second analysis, papers that were given a fairly high rating for the methodological approach. The studies were compared with similar studies in academic medicine from the Cochran database. All comparative data obtained were reliable. However, the authors concluded: "Presented are placebo-controlled studies in homeopathy and conventional medicine. A weak specific effect of homeopathic remedies and pronounced for conventional ones is noted. This allows us to conclude that homeopathic effects are comparable to placebo. " This study received a very strong negative response due to the lack of transparency in all stages of the study. Many authors have conducted a second meta-analysis of the same studies and believe that Shang et al. (2005) made the wrong conclusions, explained by methodological inconsistency and bias.

The sixth meta-analysis (Mathie et al., 2014) includes work with individualized assignments. The authors understood that the prescription of potentized drugs could not be interpreted as a measure of coherence. Clinical homeopathy, complex homeopathy, isopathy, etc. differ from the classical one in that the latter is more time-consuming than other prescription practices. The selection of 32 individualized homeopathy works for meta-analysis is not the only limitation of this study. Qualitative research on individualized appointments was reviewed using the Cochrane database. Of the 32 papers selected, at least 22 present sufficient data to be guaranteed to be correctly included in the study. These works represent very positive results regarding homeopathy. According to these authors, homeopathic treatment is 1.5–2 times more effective than placebo.

DISCUSSION

Professional expert analysis, being specialists Evidence-based medicine and homeopathy at the same time, has shown that certain theoretical biases play an essential role. This phenomenon, according to experts [45], is the cause of systematic errors in a number of

works.

For several reasons [52] critics of homeopathy in the United States are alarmed - even well-organized research does not provide a technological outlet for practice. the main direction of treatment is individualized, which means it should be applied by specialists. Critics believe that such differentiated (individualized) treatment is inappropriate in research. Maybe it is worth changing the rules of research, rather than adjusting age-old methods to the newly emerging rules? Homeopaths, in turn, criticize clinical trials and their analysis for the wrong choice of homeopathic medicine or dilution or conditions of use, and also object to the meta-analysis of clinical trials in homeopathy according to the general rules.

Speaking about research in homeopathy, one should take into account the fact that homeopathy is built on a different principle - here the basis of the medical approach is the methodology of a personalized approach to the patient as a person, and not a formalized technology adopted to assess the effectiveness in evidence-based medicine. This is the very "bottleneck", which is not always correctly assessed by experts in evidence-based medicine. To evaluate homeopathic research, meta-analysis is often used retrospectively to aggregate available data into large statistically significant groups. At the same time, errors are inevitable, which the formalization of data that is not intended for this, related to individualized treatment, is inevitable, figuratively speaking: "to summarize apples with oranges, and sometimes with lemons".

Kienle GS et al. [53] believe that it is time to start a methodological dialogue. Without denying the merits of evidence-based medicine (transparency in clinical decision-making, liberation from the oppression of opinion leaders, critical analysis of the treatment routine, and much more), the authors talk about the limitations of this technology and offer options for resolving the issue. For example, they say that, having a doctor at the heart of medicine, clinical trials do not take into account his role at all, do not take into account the patient's characteristics, when doing tests in clinics, do not take into account that at the initial appointment with a general practitioner, most patients have nonspecific complaints, often do not have a diagnosis, and sometimes the diagnosis is combined with other serious diseases, which are criteria for exclusion in randomized clinical trials. The question is

Data from a study of the flow of cases among the population living in the United States indicates that out of a thousand people, only one falls into conditions appropriate for conducting clinical trials. Thus, in academic medicine, the transition of recommendations from clinical trials to practice is not so great.

It should be remembered that an important limiting point of randomized clinical trials is the fact that positive results are of clinical relevance and negative ones are not significant evidence of ineffectiveness [53, 54]. This important position within evidence-based medicine is usually ignored in methodological discussions.

CONCLUSIONS

1. The analyzed clinical studies have shown that homeopathic medicine has biological activity and in clinical trials significantly differs from placebo.

2. Cohort studies have reliably shown in a number of conditions the effectiveness of the homeopathic treatment carried out.

3. Analysis of meta-analyzes on homeopathic research shows that this technology, applicable to homeopathy, inevitably makes mistakes associated with the formalization of data that is not intended for this. Evidence-based research in homeopathy requires technology that takes into account a personalized approach to treatment.

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