

Evidence-based medicine: perspectives for homeopathy
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SUMMARY

The article outlines approaches to planning and conducting clinical trials to form an acceptable evidence base for homeopathic therapy. According to the author, the stumbling block for the acceptance of the results of modern randomized clinical trials (RCTs) of homeopathic medicines is the erroneous application of Avogadro's law for ideal gases to potentiated solutions and the requirement for randomization when forming the study sample. Variants of clinical trial design are proposed, which will improve the methodological quality of studies without violating the requirements for the organization of RCTs, which are pleasant in evidence-based medicine.

Keywords: homeopathy, evidence base for homeopathy, randomized clinical trials in homeopathy.

RESUME

The article outlines approaches to planning and conducting clinical trials to form an acceptable evidence base of homeopathic therapy. According to the author, the stumbling block for accepting the results of modern randomized clinical trials (RCTs) of homeopathic medicines is the erroneous application of Avogadro's law for ideal gases to potentiated solutions and the requirement of randomization in the formation of the sample under study. Variants of clinical research design are proposed that will improve the methodological quality of research without violating the requirements for the organization of RCTs that are used in evidence-based medicine.

Keywords: homeopathy, evidence base of homeopathy, randomized clinical trials in homeopathy.

The history of medicine knows a huge number of methods for treating human diseases, which were positioned as "new" and "very effective", but did not stand the test of time and very soon disappeared into oblivion. However, the same cannot be said for homeopathy, which has held out for over 200 years and is not going to give up its position. And this despite the lack of government funding (with rare exceptions) and powerful, often aggressive criticism using the entire arsenal of means: from the lecture hall department to the air of popular health programs in the media. Now homeopaths have had to overcome the "veto" of the commission on pseudoscience of the Russian Academy of Sciences. This openly hostile attitude towards the treatment approach is not surprising when one considers the losses of pharmaceutical corporations and others associated with them.

medical institutions when patients decide to go to a homeopathic clinic. At the same time, the main argument against the use of homeopathy among modern critics is the lack of a proven effect. Indeed, opening, for example, the Russian-language Wikipedia page on homeopathy on the Internet, one can see a considerable number of references to negative results of controlled studies, including meta-analyses with the highest (A) level of evidence [12, 13]. It's hard not to believe it!

Obviously, practicing homeopaths, who observe the effects of high dilutions of drugs in their daily routine practice, will disagree with such negative results of clinical trials of homeopathic medicines. The paradox of the situation lies in the fact that during the more than 200-year history of homeopathy, doctors and their patients observe the effect, but researchers who try to evaluate the same effect do not find it. And if they do, they attribute it to the "placebo" effect. This, in my opinion, is due to two important contradictions that remain a stumbling block in the proof of the effectiveness of the homeopathic method.

The first contradiction is due to the fact that, according to fairly simple calculations, in accordance with the physical law of Avogadro, there is not a single molecule of the active substance in the high-dilution dosage form. At the same time, it is silent that Avogadro's law is a law in relation to ideal gases, and not to solutions, and the devastating arguments in the above-mentioned article of the Russian-language Wikipedia, based on mathematical calculations based on the specified law, are deeply erroneous, and for this reason they should not be accepted in payment. Obviously, in the aquatic environment during the preparation of homeopathic preparations, processes occur (some authors call them "water memory") that cannot be detected by the methods of modern analytical chemistry. Perhaps this is a matter of the near future, and the answers will be obtained using the methods of quantum physics, which is just beginning to be introduced into medical research. Another Nobel laureate, theoretical physicist R. Feynman, one of the developers of quantum electrodynamics, who came up with the idea of creating new materials based on atomic assembly technology, which was later called nanotechnology, pointed out in 1956 that overcoming the barrier of 10^{-9} (nano-level) leads to the emergence of new, unusual properties of substances [6]. It is possible that it is this phenomenon that we observe during the potentiation of solutions, and the mystery of the phenomenon of dynamization of solutions by shaking them after each dilution lies in the field of atomic friction physics, which is still largely a mystery [24]. Therefore, the rejection of homeopathy can partly be reduced to the expression "I don't know, therefore I am against".

The second contradiction not allowing reproduce effects homeopathic drugs, like the effects of pharmacological ones, is a contradiction between the methodology of clinical trials and the specificity of the homeopathic approach, the main condition of which is the individual choice of the drug in accordance with the principle of "similarity". Here are the typical conclusions of one of the many publications devoted to the assessment

the effectiveness of homeopathy based on the principles of modern evidence-based medicine: "according to the findings of a high-quality meta-analysis, an individualthe choice of homeopathic medicine may have a small, specific effect, "and also:" Despite the significant growth in research since 1994, doubts about the quality of the research limit the interpretation of the available RCT data. The question of whether the homeopathic intervention differs from the "placebo" awaits a decisive answer "[eighteen].

This is a contradiction of D.R. Lawrence and P.N. Benitt, the authors of the famous manual on clinical pharmacology, formulated back in the 80s of the last century, as follows: "there is only one fundamentalThe disagreement between orthodox scientific and traditional and complementary medicine (although often obscured by detailed disputes over certain types of treatment) is the question of what kind of acceptable evidence (i.e. its nature, quality, interpretation of the data) should be in order to allow everyone to accept proposed treatment methods and perceived hypotheses "[5].

As you know, any clinical trial of high methodological quality should be randomized, controlled, with "blinding", and the latter can be simple, double, triple and even complete. In contrast to the unconditional requirement of control and "blinding", the condition of the need to ensure randomization, in my opinion, is the main obstacle to the formation of an acceptable evidence base for homeopathy. This is due to the specificity of homeopathy, or, to be more precise, its law of "similarity", deviation from which inevitably leads to failures in therapy and loss of reproducibility of the results described by other authors. It is called a law precisely in order to emphasize the need for its unconditional observance.

As you know, the main task of randomization is to ensure the homogeneity of groups of patients in all signs that affect the outcome of the disease. It is generally accepted that it is possible to achieve the possibility of comparability of observation groups to the fullest extent possible only with a random distribution of patients into groups, when the researcher conducting the recruitment of patients does not need to know which groups (control or test) they (patients) fall into ("blind selection ") [3].

In connection with these circumstances, for a correct study of the effectiveness of homeopathic drugs in accordance with the requirements of modern evidence-based medicine, it is necessary to develop a protocol (design) of a clinical trial that would allow, without violating the basic methodological requirements for the organization and conduct of randomized clinical trials (RCTs), to overcome contradiction between the requirement of randomization and the need for unconditional adherence to an individual approach based on the law of "similarity". This is the purpose of this article. After all, it is the law of "similarity" is at the heart of homeopathy, not the use of high dilutions, which has been repeatedly emphasized by the authors of practical guidelines on homeopathy.

As you know, the development of the design of a clinical trial is preceded by the formulation of clinical questions, the goals of the study. Of such

In my opinion, there can be several questions-goals.

1. Does the homeopathic medicine have a high dilution, specific activity?

The need to get an answer to this question is due to the statements that, in accordance with the physical law of Avogadro, there is not a single molecule of the initial substance in a homeopathic drug in a dilution above C12, and therefore there can be no specific activity.

This does not mean the healing effect, but the effect in general. There are a number of experimental works published, including in academic journals, which prove the retention of activity in solutions at a high degree of dilution [2, 4, 7, 10], but these works, with their undoubted scientific value, have nothing to do with homeopathy. Homeopathy, as already emphasized [1], is not the use of small doses, but the observance of the principle of "similarity" when choosing a drug for the treatment of a particular patient. If this principle is observed, a substance (xenobiotic) is selected for the patient, to which a paradoxical high sensitivity is found in the patient, which is nothing more than idiosyncrasy. If the same genetic mutations underlie the patient's idiosyncrasy and illness, then, on the one hand, we observe a high selective sensitivity to the selected agent (but not to all impurities in the solution!), and on the other hand, a decrease as a result of treatment of sensitivity to the drug and to etiological factors ("triggers") underlying the pathology. This is possible as a result of the formation of an adaptive response (with an adaptive response, the body becomes less sensitive to high, toxic, doses of substances), which, in my opinion, is the essence of the mechanism of action of homeopathy.

In clinical studies, in order to correctly answer the question posed above, the reproducibility of symptoms should be assessed when taking dilutions above C12, when in the initial solution, in accordance with Avogadro's law (the above the legitimacy of applying this law in relation to solutions was questioned), the substance cannot be. Here, as evidence of the effect, one should refer to the practice of homeopathic trials (provings), which are essentially similar to the 1st phase of clinical trials of pharmacological agents. In this case, clinically healthy subjects are encouraged to take the drug and a "placebo". In our case, if the effects of high potencies (for example, C30) are evaluated, after taking several doses, for example three, the subjects should describe all the sensations they experienced. If in a group where patients receive a homeopathic remedy, patients begin to experience painful sensations (and in the control group receiving placebo, they are not), and they coincide with the effects of toxic doses, the result can be considered positive. Naturally, in this case, the "null hypothesis" must be rejected by statistical analysis.

Another evidence of the activity of high dilutions is drug exacerbations in the treatment of homeopathic medicines. Exacerbations develop most often with the use of high dilutions, in which, if

judged by the same Avogadro law, there is no substance.

Several treatments of Ipecacuana C30 can be offered to vehement critics of homeopathy, and the nausea-vomiting-diarrhea triad will be a convincing case for the method.

2. Is the effect of a homeopathic medicine the effect of a "placebo"? One of the arguments that the effect of homeopathic drugs is not a "placebo" effect is the effectiveness of these drugs in children, especially in younger age groups, and in the treatment of animals in veterinary medicine. There are many such RCTs published, but their acceptance is hindered by requirements for the methodological quality of research, which cannot always be met in homeopathic treatment.

In practice, following the requirements for the methodological quality of the study, it is as difficult to collect the required sample size for the individual choice of a homeopathic medicine (when the monotherapy option is chosen for assessment), which is usually called classical homeopathy, as is the formation of a sample for the treatment of orphan (rare) diseases. It takes a lot of time, and the quality of execution of the law of "similarity" depends very much on the experience and qualifications of a homeopathic physician. This is due to the fact that when choosing a drug for the treatment of a chronic disease, one should take into account not only the symptoms of the disease (for example, symptoms of allergic rhinitis), but also the constitutional characteristics of the patient (his "miasm", that is, the type of reaction and the nature of the source for preparation medicines (mineral, plant, animal, nosode) and, which is also important, dilution of homeopathic medicine. These complexities in RCT planning are reflected in the ambiguous findings of systematic reviews and meta-analyses of RCTs. Thus, an analysis of 36 systematic reviews of RCTs carried out over 20 years (from 1994 to 2015) [17, 18] showed that 16 of them came to the conclusion about positive or approximately positive conclusions about the clinical efficacy of homeopathy, and the conclusions of the remaining 20 were negative or inconclusive. Reviews have tended to be limited in their conclusions by the low quality of the original evidence in RCTs. Three comprehensive systematic reviews cautiously concluded that homeopathy may differ from placebo; the fourth such review yielded negative findings. At the same time, according to the findings of a high-quality meta-analysis, individual selection of a homeopathic remedy may have a small, specific effect. The conclusion of the author who analyzed the publications is characteristic: "Despite the significant growth of scientific research since 1994, doubts about the quality of the studies limit the interpretation of the available RCT data. The question of whether homeopathic intervention differs from "placebo" remains a decisive answer "[18].

A fairly simple way out of this situation is, in my opinion, the following research design. Healthy volunteers without obvious clinical signs of the disease can be prescribed a homeopathic drug, for example, Pulsatilla C30, which will provoke the appearance of a number of symptoms that the patient did not have before, for example, rhinitis with a characteristic worsening indoors.

After randomization, the sample of subjects is divided into two subgroups: one receives a "placebo" in the form of homeopathic grains that do not contain the potentiated drug, and the other receives a homeopathic antidote in the same form. This can be a universal antidote for herbal homeopathic preparations Camphor C6. A more rapid resolution of rhinitis symptoms in patients who received the antidote would indicate that the effect was not related to the placebo effect. In my practice, I widely use this antidote in the treatment of homeopathic exacerbations in adults and children. It is equally effective at both ages, the symptoms of exacerbation (even severe) when using the specified antidote are eliminated much faster.

3. How effective is the homeopathic remedy at relieving symptoms? diseases?

To get the correct answer to this question, you need to carefully follow the rules or, more precisely, the laws of homeopathy. It will not be superfluous to recall that the most important is the law of "similarity", according to which the symptoms of a disease and the symptoms of a drug (pathogenesis) obtained in "provings" (studies of drugs on healthy volunteers) must coincide. The higher the match, the more effective the therapy.

If, in the treatment of acute diseases, a "simple similarity" is sufficient without taking into account the "miasm" and the nature of the source of the drug, in the treatment of chronic diseases, as already mentioned above, the correspondence between the "miasm" and the nature of the source (plant, mineral, animal drug and nosode) is required ... In addition, as I indicated above, another condition for the successful choice of a remedy is the difficulty of forming a homogeneous sample of patients with chronic disease in order to comply with the condition of randomization.

If you turn to the Complete Dynamics homeopathic repertory, you can see that the incomplete list of drugs for the treatment of seasonal hay fever (heading "hay fever") is more than 200 drugs (the difference in fonts indicates the severity of the symptom in 4 degrees):

Nose; hay fever, hay rhinitis, allergies every year:acon adren agar agath-a AIL alco ALL-C alum ALUM-CHR am-c AMBRO aml-n ANT-T antho antipyrin apoc ARAL arg-n arist-cl ARS ARS-I arum-d ARUM-T ARUND ASC-C ASC-T aspin aur-mn bac BAD bamb-a bani-c bar-ar BELL benz-ac beryl bomb-pr BOV BROMbros-g bry CALAD CALC calc-chln calc-f calc-ln calc-sil camph cand-a canth carb-ac CARB-V CARC card-m caust cer-o cer-p CHIN chin-ar chlol CHLOR CIST cocain con cordys-s cortiso CUMIN cupr- acet cupr-ar CYCL diox DULC DYS-CO echi-a electr ephev erb eucal EUPH euph-pi EUPHR excr-can ferr-m foll fuc gado-n gall gall-ac GALPH GELS gink glech glon glyc-g GRAPH grin guano haliae-lc hed HEP her-s HIST hochholm-o hydr-ac ichth ICTOD ign imp IOD IP JUST KALI-BI KALI-C kali-fcy KALI-I KALI-P kali-s kali-s-chr LACH larre-t laur linu-c linu-u LOB lob-p lob-s lyc lycpr mag-m mag-p malar mang mang-acet MED meph MERC merc-if merc-ki MOSCH myos-a NAJA NAPHT NAPHTIN NAT-AR nat-c nat-i NAT-M nat-p NAT-S neod-c nuph nux-m NUX-V OL-AN olea OP oxyg parac-h paraph parth pect per ph-ac phase phel phenob PHLE PHOS plb plut-n poll PSOR PULS pyrog queb rad-br RAN-B rhus-t ros-ca-a ROS-

D ros-g SABAD sal-ac SANG SANGUIN-N SANIC saroth scorp senec seneg SEP SILsilphu sin-a SIN-N SKOOK solid SQUIL STICT stry succ SUCC-AC sul-ac sul-i SULPHsupren syc-
co ter teucr ther thuj thul-p tour-w trif-p TUB uran uro-h visc WYE.

If you strictly follow the principle of "similarity", they are not interchangeable! If you allocate funds from the specified list in accordance with the season of exacerbation of the disease, you can see that the list of drugs is significantly reduced:

Nose; hay fever, hay rhinitis, allergies every year; Spring:ALL-C bamb-a dulc GELS lach naja plut-n psor pyrog sabad sang tub.

Nose; hay fever, hay rhinitis, allergies every year; summer:all-c ambro DULC GELS kali-s-chr mag-p naja naphtin nat-m phle sanguin-n sin-n stict.

Nose; hay fever, hay rhinitis, allergies every year; summer; August:ALL-C ambro dulc gels kali-s-chr naja nat-m sanguin-n sin-n stict.

Nose; hay fever, hay rhinitis, allergies every year; autumn:ambro dulc kali-s-chr MERC phle PSOR solid wye.

It follows from this that the correct, from the point of view of homeopathy, the choice of the remedy dictates the need to assess the effectiveness of a large number of drugs in one group of subjects. And vice versa, the drug chosen for the study, when comparing its pathogenesis with the symptoms of the patients of the group, may not be shown to any of them! That is why, based on the lack of effect when assessing, for example, the results of osteoarthritis treatment with Rhus toxicodendron, it is concluded that homeopathic therapy for this disease is ineffective [21].

In this case, which J. Vithoukas also refers to in his article [23], not only was the principle of "similarity" not observed, the drug turned out to be incorrect for the treatment of osteoarthritis. Homeopaths are well aware that Rhus tox, unlike Causticum, potassium salts, calcium salts or sodium salts is almost never indicated in cases of osteoarthritis, but it is effective in some cases of fibrositis (muscle rheumatism) and in some rheumatic diseases.

According to J. Vithoukas: "The negative conclusion obtained in the result of this test is similar to the result of testing to determine the effect, for example, of antibiotics in the treatment of anxiety neurosis, which shows no result from the use of the latter in this pathology; and further, on the basis of this negative conclusion, it is concluded that conventional medicine is useless!" [23].

Similar examples can be cited in relation to many other diseases.

At all recently were published results comparative a randomized, placebo-controlled veterinary study [15] that evaluated the efficacy of individualized homeopathy and antibiotics in the treatment of mastitis in cows. The authors concluded that "The results of this study suggest that the effectiveness of individualized homeopathy does not go beyond the placebo effect." However, they do not categorically reject the homeopathic approach, but recommend

its use in the treatment of mastitis in cows "only under certain conditions, in particular: treatment of mastitis caused by specific pathogens of mastitis, in combination with antibiotics (complementary therapy), timely and regular observation, sufficient time for homeopathic clinical research, knowledge of homeopathic principles (!) and the use of homeopathic remedies as an initial treatment until the results of culture do not involve other methods of treatment. "

According to the authors, the result of the study could be due to methodological problems: "the detection and assessment of individual homeopathic symptoms (such as modalities or specific symptoms) can be challenging in practical terms and can be a cause of uncertainty even for a veterinary expert in homeopathy. Despite the veterinarian's experience and the use of a computerized repertory, it is possible that an inappropriate homeopathic remedy was chosen, resulting in a negative impact on the rate of treatment. "

Another reason for the negative result of the study, the authors consider "A unified dosage of the chosen homeopathic remedy, when all cows received the drug in a dose (potency) of C30, which was done to standardize the treatment procedure and could have an impact on the final results of treatment" [15]. We must pay tribute to the authors for their honesty and impartiality in assessing the research results.

In connection with the inevitable methodological problems with the choice of a drug in RCT, as a model for studying the clinical efficacy of homeopathy, in my opinion, the choice as a model of an acute epidemic disease is more appropriate. As a rule, it has stereotyped manifestations, and therefore often one single remedy is required for treatment [8, 9, 14, 16].

As an example, let us discuss the evidence base of the well-studied homeopathic remedy Oscilloccinum C200, the level of evidence for which, according to a systematic review by the Cochrane Center, is categorized as B1 (with proven overall efficacy) [22]. It was not only effective in the treatment of influenza and influenza-like SARS, but also had a preventive effect. According to the data of a retrospective observational study evaluating the effectiveness of the drug Oscilloccinum® for the prevention of respiratory tract infections (we used the observation results for the period from January 1, 2002 to December 31, 2011 in 459 patients with respiratory tract infections, 248 patients received Oscilloccinum® according to 1 dose per week for 8 months a year, control: 211 patients who did not receive the drug), in the Oscilloccinum® group,

The use of the drug Otsilokoktsinum was not only an effective prophylactic agent, but also cost-effective, since it led to a decrease in the number of visits to medical institutions in connection with the development of infections of the upper

respiratory tract [11].

Despite the high methodological quality research and the persuasiveness of the results, the stubborn rejection of such results is quite characteristic and can be illustrated by an article in the Russian-language Wikipedia devoted to the drug Oscillococcinum: it does not contain references to publications where the effectiveness was shown in RCTs and confirmed in a meta-analysis of RCTs, and an unambiguous conclusion about the absence of proven The effect is based on the findings of systematic reviews and meta-analyzes of RCTs, which are not so categorical in their conclusions about the effectiveness of the drug. Here are some of them: "There is not enough conclusive evidence to draw valid conclusions about Oscillococcinum (®) for the prevention or treatment of influenza and influenza-like illnesses. Our results do not rule out the possibility that Oscillococcin (®) may have a clinically beneficial therapeutic effect, but given the low quality of the relevant studies, the data are not conclusive. There was no evidence of clinically important harm due to Oscillococcinum "[twenty].

Other conclusions from the later publications of the same authors (I have already quoted them above, but in fairness I will repeat myself): "according to conclusions high-quality meta-analysis, individual choice of homeopathic medicine may have a small, specific impact, "and also: " Despite the significant growth in research since 1994, doubts about research quality limit the interpretation of available RCT data. The question of whether the homeopathic intervention differs from the "placebo" awaits a decisive answer "[eighteen].

D.R. Lawrence and P.N. Benitt (1991) comment on this long-standing situation as follows: "the dogmas of homeopathy have brought self-ridicule, it outrages its adherents, insisting that they are misunderstood, and sourly watching critics fail to study homeopathy. However, all of this is true for all treatments. Pharmacologists generally feel that in the absence of conclusive evidence from empirical therapeutic research conducted according to current standards, there is no basis for discussing the homeopathic hypothesis until some evidence is obtained that satisfies the usual criteria of scientific research method. However, it should be borne in mind that useful discoveries can be made by following unconfirmed hypotheses, and that empirical research can be carried out without any theory "[5].

Then why is homeopathy a "pseudoscience"?

CONCLUSIONS

1. Proof of the effectiveness of homeopathy by methods of modern Evidence-based medicine critically depends on the correct organization of RCTs.
2. Proof of the specific activity of homeopathic drugs in high dilutions can be carried out by provings.
3. Research on the clinical efficacy of homeopathy is preferable on

models of acute epidemic diseases rather than chronic pathology.

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