Low-variation methods of diagnosis and therapy of the patient and their application in information medicine

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SUMMARY

The paper substantiates the possibility of conducting a correct, from the point of view of evidence-based medicine, clinical research within the framework of an informational approach to diagnosis and therapy. For this purpose, the concepts of low-variability and closed algorithms for diagnostics and therapy have been introduced. It is shown that, within the framework of the informational approach, the use of closed low-variability algorithms for diagnostics and therapy is a strict methodological analogue of taking certain allopathic drugs within the framework of an orthodox academic research. Examples of clinically effective closed low-variance algorithms for diagnostics and therapy are given.

Key words: informational approach, diagnostics and therapy,evidence-based medicine, patient-centered approach, constitutional therapy, bioresonance therapy, autonomic resonance test.

RESUME

The publication justifies the possibility of correct clinical research in frame of informational approach to diagnostics and therapy from point of view of evidence based medicine. Terms lowvariability and closed algorithms of diagnostics and therapy were introduced. We demonstrate that use of closed lowvariability algorithms of diagnostics and therapy in frame of informational approach is a strong methodological analogue of medicament therapy protocol in orthodox academic research. Examples of clinically effective closed lowvariability algorithms of diagnostics and therapy are provided.

Keywords: informational approach to diagnostics and therapy, evidence based medicine, patientoriented approach, constitutional therapy, algorithm, bioresonance therapy, vegetative resonance test.

INTRODUCTION

One of the fundamental problems of the interaction of the informational approach in medicine with modern evidence-based medicine is the conduct of a clinical trial within the framework of the first approach, the results of which could be unambiguously assessed - accepted or rejected - within the framework of the second [1]. The main problem is taking into account the constitutional component of the patient (the tendency of a patient-centered approach in medicine) - in this case, it is as follows.

On the one hand, an undoubted fact is the presence of an individual physiological constitution (individual phenotype) in each of the patients participating in a clinical study, which affects both the diagnosis and therapy of the disease studied in this study. After the discovery of genetically and epigenetically determined diseases [2], as well as correlations between most chronic diseases and genetic / epigenetic predisposition to them [3], this fact is a consequence, in particular, of the existence of an individual genotype in a patient. Taking into account the patient's constitution is an integral part of the informational approach to diagnosis and therapy. The result of an informational examination of a patient is his informational diagnosis, as well as the therapy signal selected or made on the basis of this diagnosis - information preparation (IP) - significantly depend on the individual constitution of the patient. As a result, they tend to be significantly different for two patients with the same nosology.

With another parties, addiction information diagnosis and informational prescription from the patient's constitution prevents the statistical processing of the results of a clinical trial in the informational approach and, consequently, its interaction with evidence-based medicine, the conclusions of which are usually considered based on the statistical processing of the results of prescribing the same therapy drug to a sufficiently large group of patients. Thus, the illusion arises of the impossibility of using evidence-based medicine methods to substantiate the effectiveness of the information approach.

Problems of this nature in Soviet science were called “dialectical contradictions”, that is, they were qualified as fundamentally unresolvable if we fix a certain “level” (of knowledge, technology, resources, etc.) at which the problem arose, and easily solvable ("Removable"), if you go to a higher "level" of their consideration. It is these "dialectical contradictions" that were considered by Soviet philosophers as genuine scientific problems. The development in the 70s and 80s of the last century of the theory of invention and rationalization led to the understanding that the basis of most technical inventions also lies precisely in the “removal of the“ dialectical contradiction ”arising from the formulation of a particular technical problem [4].

There is also a number of "secondary" problems that can, relatively speaking, be considered undeveloped "technical" problems of interaction between the indicated branches of medicine:

1. Selection of suitable criteria for determining a particular nosology in the patient.

The criteria can differ significantly in the paradigms of informational and traditional medicine, which makes it extremely difficult to compare the survey results. For example, within the framework of the R. Voll method and the ART method, the presence or absence of a particular virus in the patient's body is determined based on the change in the indicators of electropuncture testing upon presentation

the body of the corresponding test indicator [5–8]. Modern PCR methods and analysis for the presence of antibodies also make it possible to establish its presence or absence, based on changes in the biochemical reactions of the blood. However, electropuncture test results may not match PCR and antibody test results. Questions arise: how, in this case, to interpret one diagnosis of a patient relative to another, that is, a biochemical diagnosis relative to an informational one, and vice versa? And what kind of diagnosis - informational or biochemical - is it necessary to rely on when treating a patient?

2. Selection of suitable criteria for improvement or worsening of the condition the patient.

Often, outside of the narrow paradigm of clinical research, it is, in principle, difficult to understand whether the patient has not only been cured or not cured, but even whether his condition has worsened or improved? For example, in the case of treatment of hepatitis C with the methods of constitutional homeopathy, the attending physician does not set the task of eliminating the hepatitis virus in principle. Instead, the goal is to ensure maximum quality and maximum life expectancy of the patient. At the same time, we can observe a patient who was treated for hepatitis with the methods of constitutional homeopathy for 40 years, reached the age of 80, retained vigor and clarity of mind, and plays sports at the stadium closest to his home. At the same time, the hepatitis C virus remained in his blood, but he does not care much. On the other hand, the orthodox approach sets the task of eliminating the virus, even in the case when this elimination itself is frankly harmful to the body. The orthodox approach treats a range of diseases using methods that can result in poor quality and shorten the patient's life, but are assumed to be “lesser evil” compared to the underlying disease.

3. Selection of a suitable mathematical apparatus.

It is necessary to select a suitable mathematical apparatus within which it would be possible to compare the statistical results of clinical trials within the framework of the informational and orthodox approaches. There is also a garden of pitfalls here, since the result of a clinical examination, as a rule, does not represent just a certain number of fully recovered patients and a certain other number of patients who have not recovered. In reality, the resulting picture can be quite complicated. And if we take into account the above-described multi-criteria for determining the initial state of the patient and assessing the improvement in his health, then the situation becomes simply very difficult for a mathematical description.

OBJECTIVES OF THE STUDY

1. Give an answer to the question whether it is possible within the framework of the information approach clinical trials that meet all the requirements for evidence-based medicine clinical trials.

2. Formulate, if necessary, a list of meaningful differences between clinical trials within the framework of the informational approach from

clinical research in the framework of the pharmacological paradigm.

3. To identify the most promising, in terms of assessing clinical efficiency, directions of informational diagnostics and therapy.

4. Give specific examples of promising areas informational diagnostics and therapy and assessment of their effectiveness.

The problem of taking into account the individual constitution of the patient and low variability therapy algorithms

The nature of the contradiction between the constitutional and pharmacological approaches to therapy is quite simple:

1. In the vast majority of In clinical trials on evidence-based medicine, patients from the main group were treated with the same pharmacological drug.

2. In a clinical trial, within the framework of an informational approach, therapy patients are initially carried out by various information drugs - control signals of therapy, since it is obliged to take into account the patient's constitution.

Therefore, if we understand the informational drug in the same way as the pharmacological drug, then it is impossible to conduct an evidence-based study within the framework of the informational approach.

The way out of the contradiction is to analyze what is actually being studied in clinical trials carried out according to the schemes of evidence-based medicine. It turns out that they are not at all about assessing the effectiveness of a particular pharmacological preparation. In fact, the effectiveness of some elementary (irreducible into simpler) therapy method is assessed. Since academic medicine does not take into account the patient's constitution, an elementary method of therapy is usually (but not always!) Identified with the patient taking a single pharmacological drug, sometimes with a standard physiological procedure. To understand that evidence-based medicine is not studying a drug, but an elementary method of therapy, two examples are enough:

1. First, within the framework of a well-conducted clinical trial the pharmacological drug prescribed to the patient of the main group is dosed in proportion to his weight. Therefore, at least its dose depends on the individuality of the patient to whom it is prescribed. In addition, the randomization used in the formation of the main and control groups of patients in large enough groups leads to the fact that some patients (from both groups) also suffer from other diseases besides the studied one. This circumstance precisely reflects the presence of an individual constitution in the patient within the framework of the orthodox approach. In the course of evidence-based research, patients from both groups suffering from additional diseases naturally also take pharmacological drugs for these diseases. Thus, as in the main one,

a pharmacological drug is very difficult. It is more correct to speak about the effectiveness of an elementary method of therapy, consisting in the appointment of appropriate doses of the studied drug against the background of the usual therapy compensating for the patient's constitution. As a study of an elementary method of therapy, such a clinical study is quite correct.

2. Secondly, in modern pharmacology, a situation often arises in which the study drug is impossible or impractical to prescribe without covering up another drug or a complex of such drugs. For example, in the treatment of hepatitis C, alpha-interferon preparations are usually combined with ribaverin. In the framework of evidence-based medicine, clinical research is carried out specifically for the alpha-interferon-ribaverin complex, and not for each of these drugs separately. And this does not bother anyone.

Thus, within the framework of evidence-based medicine, the result of a clinical study is an assessment of the effectiveness of an elementary therapy algorithm, which consists in prescribing a separate pharmacological drug to a patient. At the same time, in a clinical study within the framework of evidence-based medicine, the patient's constitution can also be implicitly taken into account by prescribing pharmacological drugs to him that stop his other diseases.

A correct analogue of the elementary method of therapy in academic medicine is the use of a single elementary ("indecomposable into its constituent parts") algorithm for the selection or production of an information preparation, which is the same for all patients of the main group.

Such an algorithm, being applied to different patients, due to the difference in their constitutions, gives “at the output” various informational preparations. At the same time, it does not change from patient to patient and does not depend on the doctor conducting it.

Let us call a sequence of diagnostic and treatment steps that does not change from patient to patient and does not depend on the doctor who implements them as low-variance algorithms.

Transition from a separate informational preparation to a low-variance algorithm:

1. First, more precisely than the reception of a single information of the drug, follows the scheme of a clinical trial in evidence-based medicine.

2. Secondly, it allows conducting clinical trials within the framework of informational approach, using a number of tested algorithms for informational diagnostics and therapy, which have shown high efficiency in the treatment of various nosologies.

The criterion for the "elementary" algorithm of diagnostics and therapy in information medicine, closed algorithms

Within the framework of the study of an individual pharmacological drug using the methods of academic evidence-based medicine, it is completely clear what an elementary therapy algorithm is. It is taking one single pharmacological drug. It would seem that the reception of a single information drug - a single control signal, should be considered an informational analogue of an elementary algorithm of pharmacological therapy,

compensating unit test. This definition is often accepted as the only criterion for the elementary nature of an algorithm even in methodological manuals on information medicine [5–8]. However, this class of elementary therapy algorithms does not solve the problem of taking into account the patient's constitution.

In the general case, after the introduction of a certain PI into the testing circuit, which compensates for a single test, the patient experiences two types of reactions:

1. First, compensation for a single test, in particular a test for which IP was selected.

2. Secondly, the emergence of new decompensated tests is possible, detected only when filtering through this IP.

We will call an IP optimal if, when filtering through it, no tests are detected, that is, a virtual state of the patient's health is observed [9].

We will call an IP constitutionally oriented if, when filtering through it, new decompensated tests are not revealed.

It is natural to interpret the phenomenon of the emergence of new single tests when filtering through some IP as a representation of the price paid by the body for the adaptation reaction caused by it [10]. That is, in the literal sense, when treating one disease, in the event of an unsuccessful selection of PI, we cause another (the price for adaptation to the first disease), and it is not a fact that the caused disease will be lighter than the initial one. To remove the “price disease”, it is necessary to “correct” the initially selected therapy with an additional drug, for example, PI_{one}... However, the new drug PI + PI_{one} will cause, in general, a new "price disease". In case of an unsuccessful selection of information drugs, the process of optimizing therapy:

$IP \rightarrow IP + IP_{one} \rightarrow IP + IP_{one} + IP_2 \rightarrow ... IP + IP_{one} + IP_2 + ... + IP_n \rightarrow ...$

can last indefinitely. It is clear that, starting from a certain step, we will only worsen the patient's condition, since it will begin to overload him with conflicting control signals.

In view of the foregoing, the elementary therapy algorithm, consisting in the appointment of a PI that compensates for a single test from the patient's information diagnosis, in the general case, cannot be considered either optimal or constitutionally oriented.

Effective therapy requires a class of elementary algorithms that is qualitatively different from the compensation algorithms for single tests. Algorithms from this new class should automatically take into account the patient's constitution.

An algorithm for choosing the optimal therapy will be called closed if it is a finite sequence of steps, at each of which a constitutionally oriented informational preparation is selected or manufactured, and after a finite number of steps, the total informational preparation S = PI + PI_{one} + IP_2 + ... + IP_n becomes optimal - it does not cause decompensation, and no other tests are detected through it.

Closed algorithms are elementary in the sense that any

the subalgorithm of a closed algorithm (except for itself) is no longer closed, since it does not allow obtaining an optimal information product "at the output".

In other words, the closed algorithm cannot be decomposed into its component parts, which are themselves closed algorithms.

Closed algorithms can be considered as a new class of elementary algorithms, qualitatively different from elementary algorithms based on compensation for single tests. Low-variance closed algorithms can be used to conduct clinical research in the framework of evidence-based medicine.

As always in medicine, one should speak not about the “ideal closure” of the low-variance algorithm or its “ideal constitutional orientation”, but about the statistical analogs of these properties. This requires an appropriate mathematical apparatus.

The prerequisites for the development of closed algorithms for diagnostics and therapy are described in [12].

The first example of a low-variability algorithm is the method for creating a general and particular bioresonance drug proposed by Yu.V. Gotovsky at the end of the twentieth century [11].

Examples of closed low-variance algorithms for diagnostics and therapy are:

1. Algorithm of constitutional diagnostics and therapy, developed by T.V. Akayeva and K.N. Mkhitaryan, based on the selection of a constitutional homeopathic element that compensates for the KMX marker ↓ + NANCr ↑, where KMX is a complex marker of chronosemantics, NANCr is the compensating potency of the patient's blood autonosode [13–15].

2. A modular algorithm for diagnostics and therapy, developed by O.V. Vasilkovskaya and K.N. Mkhitaryan, based on the alternation of its three constituent modules, depending on the test results: algorithms for the elimination of pathogenic agents, restoration of tissues, organs and systems of the patient, and compensation for constitutional errors [16–18].

3. Algorithm of "opening a hook", developed by K.N. Mkhitaryan and approved by T.V. Akaeva on the example of diagnostics and therapy using mantic BAP [19].

Clinical studies in a volume sufficient to assess the effectiveness were carried out only for the first two of the listed algorithms.

Let's summarize:

1. At least from a formal point of view, there are classes elementary (indecomposable) low-variance algorithms, qualitatively different from the compensation algorithms for individual tests.

2. One of such classes is the class of closed low-variance algorithms.

3. Closed low-variance algorithms are a natural class algorithms for conducting evidence-based clinical trials.

Selection of suitable criteria for the diagnosis (assessment of the condition patient)

So, in evidence-based clinical studies on information medicine, it should be about comparing the effectiveness of low-variance algorithms and algorithms for pharmacological therapy. Therefore, as a system of nosological units in which the patient's condition is assessed, the generally accepted system of nosologies is used, which today is ICD10. In other words, the criterion for a patient's participation in an evidence-based clinical trial is the presence of a generally accepted nosology from ICD10, confirmed by a set of generally accepted medical research and test results.

On the contrary, the patient's constitution is assumed to be completely randomized - no criteria for selecting patients for any constitutional criteria are used. It is assumed that the patient's constitutional features are taken into account in the low-variability diagnostic and therapeutic algorithm used in the clinical trial. Moreover, a clinical study of the effectiveness of the low-variance algorithm within the framework of the informational approach is carried out against the background of the gradual withdrawal of all other drugs, both pharmacological and informational. Thus, the “constitutional component” of the patient is considered fully compensated by the information drug obtained as a result of the application of the studied low-variability therapy algorithm.

The given scheme for choosing a criterion for making a diagnosis is the only correct scheme for comparing the effectiveness of information and pharmacological low-variability algorithms in a clinical trial [13–20].

Selection of suitable criteria for the success of therapy

Based on the same reasoning that was used in the previous section, criteria for the success of therapy should be selected in accordance with the standards used in the modern academic paradigm. That is, the disease should be considered cured (compensated, partially compensated, etc.) if it is considered as such in accordance with the results of generally accepted clinical studies and analyzes used in academic medicine to assess the patient's condition.

Within the framework of a clinical study, however, an additional criterion is needed that specifies the fact of complete or partial recovery of the patient, indicating when we can consider a change in his state against the background of therapy to be its success, and when not. A list of such specifying criteria is usually provided by academic medicine itself. For example, viral hepatitis B and C or viral encephalitis are considered cured if in the patient's blood, after several repeated samples, antibody tests and PCR tests for the corresponding virus give negative reactions. The presence of symptoms of hepatitis or other diseases that arose after a patient was infected with a virus, and possibly, and sometimes reliably associated with it, is considered in this case a consequence of the disease, and not its manifestations. Despite the seeming paradoxicality of this approach, with

from the point of view of an intuitive understanding of the "health" of the patient, it is absolutely necessary in cases when it is required to obtain a scientific assessment of the effectiveness of a particular method.

If the "entry point" to a clinical trial requires academicconfirmation (attributed to ICD10) the patient's nosology, then the “exit” from it requires a result that is unambiguous relative to the selected criterion: has the therapy been “successful”, “yes” or “no” [13–20]?

Statistical criteria, used to evaluate informative clinical research

The choice of a statistical criterion for evaluating the results of an informative clinical trial is due to three of its features:

1. First, in the framework of the study, as a rule, nothing is known about constitutions of patients receiving information therapy. In particular, the peculiarities of their immunity, the ability to regenerate, and other factors that allow predicting the success or failure of therapy are not known. Therefore, the statistical test used should be non-parametric; it should not include distributions of any patient characteristics, since these distributions are usually unknown.

2. Second, the result of a clinical trial, in accordance with said above, it is convenient to represent in the form of a certain number of "successes" and "failures" of therapy, for example, in the main and control groups. Consequently, the statistical method used should work with a binary system of treatment outcomes: "success" - "failure" and, which seems to be the most natural, with the percentage of "successes" and "failures" in each of the clinical groups.

3. Thirdly, in a clinical trial, not only the effectiveness of any method of therapy in the absence of such, but also the effectiveness of several different methods of informational and conventional therapy. This is almost inevitable, for example, if there is a sufficiently effective method of treating the nosology in question in academic medicine. In this case, it turns out to be necessary not only to establish the fact that the method of therapy used has led to a reliably high percentage of "success", but also to statistically significant differentiation of the effectiveness of several such methods.

The most famous statistical criterion that satisfies all three of these criteria is the criterion- *Fisher [21]. In addition to of the above qualities required for use in informational clinical research, this criterion also satisfies a number of "bonus" conditions:

1. It is extremely simple from a computational point of view and allows you to do without when calculating a statistically reliable assessment of the effectiveness of the study method of therapy without special software.

2. After a slight modification [22], the result of applying the criterion - * the percentage interval [X%, Y%] becomes, such that if the inequalities X1 <X2, Y1 <Y2 are true for any two therapy methods M1 and M2, then the M2 method is statistically more effective than the M1 method

(of course, at the same level of significance p). A consequence of the described modification is the possibility, in some cases, to do without a control group altogether when conducting a clinical trial. Indeed, for a number of nosologies, the percentage prognosis of the development of the disease is reliably known. This prognosis can be taken as an assessment of the effectiveness of the "therapy" M1 (or lack thereof) in the control group. At the same time, in the main group receiving M2 therapy, this estimate is calculated directly from the results of the clinical study. Since both estimates are percentage intervals of the form [Xi%, Yi%], where i = 1, 2, it remains only to check the conditions X1 <X2, Y1 <Y2. In this case, we will say that a clinical study uses a virtual control group method, or simply a virtual control group.

Building the correct methodological model (design) of the study

Based on the foregoing, a correctly conducted evidence-based clinical study within the framework of the informational approach must satisfy the following conditions:

1. It is assumed that all participants in the study using methods orthodox medicine revealed the same nosology. The subject of the research is the effectiveness of its treatment using the specified algorithm of information diagnostics and therapy.

2. After clinical confirmation of the selected nosology and obtaining informed consent of patients by randomization, divided into several groups (if possible, equal in number). The minimum number of groups is two - this is the main group and the control group.

3. The main group receives treatment with the help of the selected for evaluation. the effectiveness of the algorithm for information diagnostics and therapy.

4. The control group (possibly virtual) is not receiving treatment, or receives it on the basis of other methods of diagnosis and therapy.

5. After the expiry of the agreed period or upon reaching the agreed the patient's health status, his therapy ends. A study is considered clinically completed when all patients in the study group have completed therapy.

6.Using a nonparametric statistical test, for example, criterion - * Fisher, the results of treatment in the main and control groups are compared. If the study contains, in addition, other groups, the number of successes and failures of therapy in each of them is compared.

7. Based on the comparison, a conclusion is made (usually this numerical estimate) on the effectiveness of therapy of the studied low-variability method of diagnosis and therapy.

Provisions are accepted that:

- the studied nosology is detected exclusively by the methods of academic medicine and corresponds to one of the nosological units of ICD10;
- the results of therapy are assessed based on the criteria of cure (recovery, improvement, no changes, etc.), adopted in the academic

medicine;

- the algorithm of diagnostics and therapy, with the help of which information drugs are selected or manufactured for the treatment of patients from the main group, is a closed, low-variability algorithm for diagnostics and therapy.

CONCLUSIONS

1. Within the framework of the information approach, clinical trials are possible, satisfying all the requirements for clinical research by evidence-based medicine.

2. The only meaningful difference between clinical trials is
The informational approach from clinical trials within the pharmacological paradigm is the use of low-variability diagnostic and therapeutic algorithms instead of the algorithms for taking a fixed drug.

3. The most promising, in terms of assessing the effectiveness of clinical experiment, are closed low-variability algorithms for diagnosis and therapy, taking into account the patient's constitution.

4. Clinical studies carried out to date
confirm the high efficiency of at least two investigated closed low-variance diagnostic and therapeutic algorithms.

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