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Posted Date: 14 July 2025

doi: 10.20944/preprints2025071088.v1

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Article

Nano-Organotherapy: Precision Medicine with Organ Specific Nano-Peptides

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Abstract

Organotherapy is a field of medical practice that uses animal-origin organ extracts to treat the same organs in human. This therapeutic modality has gone through a long history from the empirical use of organ-specific extracts in antiquity to the use of nano-sized peptides today. The main features of organotherapy are the use of a mixture of the active ingredients; all active ingredients are derived from a natural source; the used concentration and combination of the active ingredients correspond to the natural concentration and combination of these substances in a healthy organ. Since the effectiveness of any treatment depends on the competence of the physician, so, the more knowledgeable and experienced the doctor who practices organotherapy, the higher the expected therapeutic effect, and the greater the likelihood that the treatment can be attributed to "Precision Medicine."

Keywords: nano-organotherapy; organ specific extract; nano-peptides; precision medicine

1. Introduction

As the name implies, "Precision Medicine" means effective treatment that uses an individualized protocol for delivering pharmaceutical or non-pharmaceutical treatments tailored to each patient according to his condition [1]. The main criteria of this approach must be the high efficacy of the therapy.

As we know, the formalization of the laws of nature has gone through a certain history. The basic discoveries in mathematics and physics were done in ancient times. Archimedes' law, ideas of inertia and atomic structure, or multiplication tables appeared thousands of years ago and they have not lost their value in the 21st century.

Ancient medical science had its canons too. The most important recommendations were: "to strengthen that which is deficient, and sedate that which is excessive" [2]. The derived rule was "to warm what is cold and cool what is hot" [3]. Organotherapy as well as other methods of treatment was used to strengthen the function of the organ which was weakened by a chronic disease, and the choice of the animal provided a warming or cooling effect in relation to the diseased organ.

Based on the common laws, as well as on the knowledge of the affinity of certain remedies for certain organs, ancient doctors could conduct effective individualized therapy, which we could call "Precision Medicine".

Further discoveries have been added to the main canon which was still in use. Thus, process of the development in medicine was the same as in mathematics and physics but until the 16th–17th centuries only.

Since the time of the scientific and technological "revolution", everything that turned out to be incomprehensible (due to lack of knowledge) or not repeatable (due to lack of experience) was discarded as a non-scientific heritage. So, commonly professional incompetence was presented as an achievement of modern scientific thought.

A vivid example of ignoring the world's medical heritage was the story of the Swiss doctor Paracelsus (*Philippus ... von Hohenheim*), who, at his first lecture at the University, publicly burned medical canons written by the famous doctors as Hippocrates, Galen, Avicenna, etc. [4].

Further development of medicine did not follow the basic canon, and treatment was not addressed to a primary cause of disease. Nowadays despite the fact that deficiency patterns are the causes of the majority of chronic diseases, especially among elderly people, antagonists, blockers, or inhibitors are used for therapy. Before prescribing sedative therapy, patients are not tested whether the corresponding target is in an excited state or not.

Typical examples of ignoring the pathogenesis of a disease is the prescription of inhibitors of the precursors of the enzyme glucose-6-phosphatase in patients with type 2 diabetes mellitus or the prescription of calcium channel blockers in patients with arterial hypertension. So, a rational medical sense is ignored, and patients have to take medication for all their life.

2. Organotherapy Has Been an Important Field of Medicine Throughout Human History

Since the known history of mankind, doctors have used various minerals, plants, and animal organs for the prevention and treatment of diseases. The prescription of those therapeutics was based on the results obtained in the course of clinical trials that lasted for many centuries. One of the important medical laws stated that in case of a disease of a certain organ, medicine should be prepared from the same organ taken from a young animal [5,6].

In the 16th century, German doctor Heinrich Cornelius Agrippa expressed the widespread opinion: *"As it is well known amongst physicians that the brain helps the brain, and lungs the lungs"* [7]. The majority of books on *Materia Medica* published in Europe included large sections where the preparation of animal-origin therapeutics was described [8–10]. Application of animals derived drugs continued to be a common practice until the end of the 18th century [11].

After a short break therapeutic application of animal-origin drugs was revived late 19th century. In 1889, French physician C.-É. Brown-Séquard experienced the effect of an extract derived from animal testicles on himself and reported his results at the session of the French Medical Academy of Science [12].

Some years later application of the extracts prepared from animal organs and tissue got the name "Organotherapy". Dr. Max Kahane of Germany wrote in 1893: *"Organotherapy is the use of organic tissues and of their extracts, as well as of organic juices for therapeutic purpose. It is based upon the rational physiological and experimental pathological foundation which warrants further research"* [13]. By the early 20th century organotherapy was already widely used in Europe and the United States [14].

3. Scientific Discoveries in the Field of Organotherapy

After the revival of organotherapy research began to isolate the active ingredients from organ-specific extracts. As a result of those studies hormones and hormone-like substances were discovered [15]. Gradually a new field of medicine called *Endocrinology* branched from Organotherapy, and hormone replacement therapy became a part of the common practice among modern physicians [16].

However, research continued in the field of classic organotherapy too. Among the important results of that study was the confirmation of the affinity of organ-specific extracts to certain organs, which was proved by using special dyes and isotopes [17,18].

In 2018, two reports were presented that described the effects of extremely low-concentrated organ-specific peptides of nano-size. In one study nano-peptides isolated from the testicles tissue of cattle (MW = 1000-10,000 and 65,712 Da) increased motility of human spermatozoa in vitro by 50-70% and this effect persisted for several hours [19]. In the second study nano-peptides isolated from the bovine ovarian tissue (MW = 800-6000 and 66,690 Da), improved the viability and maturation of follicles in ovarian tissue in vitro [20]. In both studies the concentration of the peptides did not exceed 0.01-0.001 ng/ml.

In 2019, samples of rabbit-derived organ-specific extracts were tested at Monash University Malaysia. The average content of protein/peptide was around 110 µg/1 mL and varied from 89.42 to 130.93 µg/1 mL [21]. Identification of proteins from a sample, derived from rabbit placenta ('APR') was performed by using Liquid chromatography-mass spectrometry (LCMS-MS). The test revealed various proteins and peptides, including well-known as Profilin (10,607 Da), Acyl-CoA-binding protein (9,915 Da), Small Muscle Protein X-linked Protein (9,397 Da), Ubiquitin (9,397 Da), and Thymosin beta-4 (5,037 Da), etc. [22].

Discovered peptides helped to explain the most common subjective effects among the male and female users of 'APR'. Presumably, "better sleep" could refer to the effect of Acyl-CoA-binding protein, and "increased activity during the day" could refer to the effect of Thymosin beta-4.

4. Classic and Modern Alternative Approaches to Treatment

Currently there are two main approaches used to prescribe medications or therapeutic methods. Due to the long history of the first approach to treatment, it can be called the classic option. The second approach has appeared relatively recently, so it can be called an alternative option.

4.1. Classic Approach to Treatment

Since ancient times, treatment was carried out according to the classical scheme. It is assumed that at the medical school student receives the necessary medical knowledge, including the technique to collect symptoms, complaints and medical history; making a diagnosis, including definition of the etiology and pathogenesis of the disease; as well as pharmacology, including the specific and nonspecific effects of medicines, and selecting an individual treatment protocol. With the accumulation of knowledge and practical experience, the effectiveness of treatment, carried out by a doctor, gradually increased. Therefore, patients admired a knowledgeable and experienced doctor, not an effective medicine.

Thus, at first the doctor identified the similarity of the existing symptoms with the standard description of the diseases and made a diagnosis, and then the doctor identified the difference between the patient's condition and the standard description of the disease and prescribed individual therapy.

This classical scheme of treatment means the use of a protocol that is tailored to one particular patient, therefore such treatment belongs to the category of "Precision Medicine". Sometimes it is referred to as "off-label therapy."

Despite the high efficiency of the individualized therapy, its results will fall into the category of anecdotal cases and will not be considered a scientific study. When conducting a meta-analysis, these results will be rejected due to the "bad statistic."

4.2. Modern Alternative Approach to Treatment

With the modern alternative approach, a large group of patients with the same nosological diagnosis is formed. All patients in this group are treated with the study drug according to the standard protocol. In addition to the main group of patients, there is a control group of similar patients who undergo sham treatment. After completion of the study, the results in both groups are compared. The differences between the two groups are identified and then a conclusion is made about the effectiveness or non-effectiveness of the study drug. Based on the results obtained, the tested drug is added to the list of the drugs recommended for the treatment of a particular disease or it is removed from this list. This alternative approach was borrowed from homeopathic physicians who studied their new remedies [23]. Nowadays this type of study became a platform for "Evidence-Based Medicine". It is recommended for doctors who do not have sufficient knowledge and experience, and it helps to reduce the likelihood of adverse reactions in patients during therapy.

The main challenge of such a study is to choose a doctor who has sufficient knowledge and experience in the study field to prepare the trial protocol. Actually clinical trial helps to reveal whether the doctor knows how to form a group of patients that is homogeneous in the sense of

pathogenesis (or etiology) of the disease, and whether the used drug corresponds to the pathogenesis of the disease in the study group patients. Therefore, this type of research reveals the knowledge and experience of the doctor, but not the efficacy of the studied therapeutic remedy.

If a doctor carries out a new study and obtains “negative results,” his background should be checked to know if he has already positive results in the study field. If he had only negative results it means he just proved his incompetence again and his negative results and conclusion should be ignored.

If a doctor has enough knowledge and experience to recognize the pathogenesis of the disease, gather the homogeneous group, and choose the best medicine for this particular pathogenesis, in his study efficiency of the tested medicine should be close to 100%. If a doctor has not enough experience results of his study can lead to an erroneous conclusion about the low effectiveness of the drug tested.

5. Practical Application of Organotherapy

Until now, organotherapy has been used based on the classical approach. A doctor who already has a medical education undergoes additional training in organotherapy. He studies how to use organ-specific extracts to treat the corresponding organ in a patient. Such treatment is focused not on the nosological diagnosis, but on the localization of the primary and secondary pathological processes. For this, all the necessary modern methods of examining the patient are used.

It has been proven by the previous generations of doctors, that “the brain helps the brain, and lungs the lungs”, [7] so there is a relatively good understanding of what extract should be prescribed for chronic disease of the certain organ, for example, extract of the liver is used to support the function of the liver, kidney—for kidney, brain—for brain, skin—for skin, etc. However, there are more questions while prescribing extracts that affect the entire body, for example, extracts of the placenta and thymus.

5.1. Application of Placenta Extract

A review published in 2012 listed the main indications when placenta extract was used. In particular, they used it for stimulating immunity, wound healing, reduction of the skin pigmentation, and treatment of various patients suffering from gynecological disorders, etc. [24].

According to the research conducted by Dr. Emanuel Revici, the beneficial effect of the placenta extract in a group of terminal patients suffering from advanced cancer was observed only if the patient's urine pH was acid, but not alkaline [25]. Therefore, measurement of urinary pH may be an important sign for patient selection while prescribing placenta extract.

If a doctor is familiar with the theory of traditional Chinese medicine (TCM) he can use an additional algorithm for using organotherapy. In TCM Materia Medica all therapeutics (herbs, minerals or parts of animals) have specific effects, so they are divided into the groups of antipyretics, diuretics, hypnotics, etc. In addition, each therapeutic affects heat production, and has affinity to a specific organ [26].

For example, human placenta extract has a warming effect and has an affinity to the liver, lungs, and kidneys [27]. Therefore, it is used for toning and warming, in case of symptoms of “cold” (lack of heat production) and “lack of energy” (lack of ATP production).

Besides it was noticed that if the concentration of the blood uric acid increases the patient has signs of “heat,” i.e., increasing heat production [28]. So, a blood test on uric acid may be an additional criterion for selecting patients who can be prescribed placenta extract. If uric acid is higher than the middle of the normal range, placenta extract is not recommended, if uric acid is lower than the middle of the normal range, placenta extract can be used for its specific or general beneficial effects.

As research into organotherapy continues, more data will be available to the physician who uses biological types of therapeutics. The isolation of nano-peptides from the rabbit placenta extract, including Profilin, Acyl-CoA-binding protein, Ubiquitin, Thymosin beta-4, etc., [22] starts a new era of organotherapy and helps the doctor to use the placenta extract based on the already known effects described for the isolated peptides.

5.2. Application of Thymus Extract

The thymus is an important organ of the immune system: it is the source of thymus-dependent T-cell immunity, which in turn has a regulatory effect on all other components of the immune system. Due to the degeneration process taking place in the thymus while aging, its activity gradually declines [29].

The Immunomodulatory effect of thymus extract was revealed by Dr. Leonard C. Wooldridge in 1888 [30]. So, the history of the therapeutic and prophylactic use of thymus extract has been more than 130 years [31]. The main indication of thymus extract is T-cell immune deficiency, caused by infectious and non-infectious pathogens, and by aging. Before the application of thymus extract blood test on immunity is recommended to define initial immune status and to follow up results of treatment. If there is a combination of immunodeficiency with a chronic disease of a particular organ, then a combination of thymus extract and an extract of a sick organ is used [32].

6. Discussion

Although hormone replacement therapy is a part of organotherapy, nevertheless, there are some differences between these two fields of medicine, which can be demonstrated in the following study.

In 2002, Cussons et al., attempted to repeat the experiment reported by Dr. C.-É. Brown-Séquard in 1889. They prepared extracts from the testicles of young dogs according to the technique described by Dr. Brown-Séquard. They have not injected the testicle extract either to elderly volunteers or patients nor to the old dogs. Assuming that testosterone was the main active ingredient of the extracts, they tested its concentration. Then they calculated, that the dose of the testosterone that Dr. Brown-Séquard injected himself did not exceed 200 ng per day. Since the standard therapeutic dose of the testosterone used nowadays varied from 5 to 10 mg per day, it was concluded that all the described therapeutic effects could be explained by the placebo mechanism [33].

This study demonstrated a common error which is the reason for the impossibility of repeating the trial which was done by our famous predecessors. When testing old therapeutic modalities, it is necessary to adhere to the described protocol, and not to stop halfway. To understand the cause of the error one should recall that the natural testosterone is highly active, compared with the non-active epitestosterone. The difference between them lies only in the angle of rotation of the OH group relative to the axis of rotation in the C-17 position. All artificial drugs used for testosterone replacement therapy have differences in the chemical formula and molecular mass compared with the natural testosterone [34]. Moreover, it has been already proven that artificial testosterone has no advantages over natural testosterone [35]. Thus, it is logical to suggest that an effective dose of artificial testosterone will always be higher than a therapeutic dose of the natural one.

Probably most functions of the human body are regulated on the basis of the analog principle, not the digital one. The only exceptions are some physiological processes, such as reading information encoded in nucleic acids or in the formation of specific antibodies.

One may assume that a variety of active ingredients must follow the natural distribution law. There must be substances with average activity (60-70%), and substances with high activity (15-20%) and low activity (15-20%) compared with the average activity. Logically it suggests that the sensitivity of the specific receptors follows a law of natural distribution too. So sensitivity of the receptors can vary from the average sensitivity to the high and low sensitivity. All these parameters are changeable and flexible within wide limits, and the final effect of the interaction can be determined by many variables.

Therefore, a complex study requires in order to draw reliable conclusions about the effectiveness of the particular therapeutic. In a case of simplification of the study protocol, unique and important effects can be lost.

7. Conclusions

Throughout human history, medicine has always been scientific, effective, and “modern” for that time. The proof of this statement is the fact that humanity has survived to this day, despite repeated epidemics of infectious diseases, as well as natural disasters [36].

Organotherapy as a field of medicine has also gone through a long history from the empirical use of organ-specific extracts in antiquity to the use of nano-sized peptides today.

The main features of organotherapy are the use of a mixture of the active ingredients, i.e., “biochemical noise”; all active ingredients are derived from a natural source; the used concentration and combination of the active ingredients correspond to the natural concentration and combination of these substances in a healthy organ.

Since the effectiveness of any treatment depends on the competence of the physician, so, the more knowledgeable and experienced the doctor who practices organotherapy, and the more diagnostic methods he uses to determine the primary localization and the pathogenesis of the disease, the higher the expected therapeutic effect, and the greater the likelihood that the treatment can be attributed to the “Precision Medicine.”

Funding: None.

Acknowledgments: A report titled “Nano-Organotherapy: Precision Medicine with Organ Specific Nano-Peptides” was presented at the 2nd International Conference on Precision Health in the Industrial Revolution. At the Hospital AlSultan Abdullah, UiTM, iPROMISE, Kuala Lumpur, 27 Aug 2023. An abstract was published at the J of Clinical Health Sciences, 2024, 9(1), S6; Supplementary—[https://doi.org/10.24191/jchs.v9i1\(S\).25791](https://doi.org/10.24191/jchs.v9i1(S).25791)

Conflicts of Interest: The authors declare that they have no conflicts of interest.

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