

# In Memory of Jana Zvárová: a Project for a Comprehensive Assessment of the Clinical Effect of Specifically Selected Natural Remedies on the Treatment of Knee Osteoarthritis

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## Abstract

Jana Zvárová had a lion's share in the founding of the Balneology Research Institute, a public research institute, in 2011. She played an important role in promoting the approach of Evidence Based Medicine and Information Based Medicine in the Czech balneology research. The aim was to establish a successor of the former state Balneological Research Institute, which was discontinued in 1992 without being replaced by another institution. Her scientific erudition has brought the elements of preclinical analysis and clinical evaluation into the scientific work of the Balneology Research Institute. The result was a scientific study not only of the extent of the positive effects but also of how natural remedies will improve the health

state of the patient. In this contribution the project "The objective evaluation of the clinical effect of specifically selected natural remedies used for the treatment of knee osteoarthritis of the 2nd and 3rd degree" will be discussed as a tribute to Jana's influence. The used methodology was a fundamental innovation in balneology science and research. Unfortunately this project wasn't approved by The Ministry of Education, Youth and Sports support programs. We will follow Jana Zvárová's approach in the future and will continue to try raising funds for the project.

## Keywords

Evidence based; Balneology; Electronic health record; Clinical Study

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## 1 Introduction

We started working with Jana Zvárová in 2005. At that time, our colleague Petr Hanzlíček brought us to the EuroMISE Center of the Institute of Information Technology of the Czech Academy of Sciences. We were looking for partners to support us with the biostatistical evaluation of the project Objectification of the choice of the spa curative plan for hip arthrosis. Statistical analysis makes it possible to determine the strength of the correlation between the type of curative plan and the therapeutic outcome. At the Euromise Center we met Jana Zvárová. She first expressed an unusual question: Why Evidence Based Medicine is not applied to spa treatment? Why does there not exist a successor institution of the state Balneological Research Institute, which was discontinued in 1992? Czech spas moved step by step out of the health services system, managed by the Ministry of Health of the Czech Republic. As a result balneology traditional healing is used nowadays only. Health insurance companies pay spa treatments without interest in the effectiveness of

such treatment. The Czech Baths provided and provide actual healing rather than medical care based on Evidence Based Medicine (EBM). Jana agreed to cooperate and she had a lion's share in the founding of the Balneology Research Institute, a public research institute, in 2011.

To provide some insight in the project mentioned above and in what kind of curative plans are used in balneotherapy I give a short description. It concerned a study among 51 patients with 3rd degree coxarthrosis that underwent a comprehensive three-week lasting spa therapy. The basic version of the curative plan included: 6 times 30 min. - therapeutic gymnastics in the pool, 8 times 30 min. - individual curative gymnastics, 8 times 30 min. - hip joints magnetotherapy, 8 x peat wrap, 15 min, 42°C (every patient for 3 weeks, 2 to 3 times a week), further therapy (hydrotherapy, etc.). Another version of the treatment plan was also investigated. It was identical to the above curative plan with the exception of having carbonated baths instead of peat wraps. It was investigated whether the effects of

selected therapeutic procedures in the curative plan correlated with changes in the patient's state of health such as the difference between walking without support before and after the spa treatment. The analysis showed that there was a significant improvement in the curative plan group of 8 peat wraps. This was apparent from the strengthening of the majority of the attenuated muscle groups monitored and improvements in the magnitude of momentum. In the group without peat wrap, there was only minor improvement.

Our gratitude to Jana for her inspiration for the application of EBM in balneology will last. After the foundation of Balneology Research Institute in 2011, Jana was the Vice President of the Council for the entire period. She was the main architect of scientific work and helped us to obtain financial support for all our scientific research work. I worked closely with her on several important (and laborious) requests for subsidy. The last time (2016) it concerned financial support to put together an excellent team for the project "The objective evaluation of the clinical effect of selected natural remedies used for the treatment of knee osteoarthritis of the 2nd and 3rd degree."

## 2 Problem Description

Several EMA members participated in the preparation of this project. Main research manager L. Mankovecky of the Balneology Research Institute formulated the methodology of the clinical research on the basis of a systematic review. Osteoarthritis (OA) of the knee joint is one of the most common diseases. OA treatment involves several different approaches. In clinical practice, chronic pain is suppressed in the case of knee OA by analgesics and non-steroidal anti-inflammatory drugs (NSAIDs), while drugs that modify OA disease as well like intra-articular administration of both viscolubricants and corticosteroids are also used. The disadvantages of using these treatment modalities are, among other things, undesirable side effects and moreover it concerns treatment of symptoms only, not the disease itself. At the same time, potential stem cell applications or the use of biologic therapy are still very expensive and their effectiveness for the treatment of knee OA is still under investigation. As a last resort for severe 4<sup>th</sup> degree gonarthrosis, the possibilities of radical surgery, partial osteotomy or complete replacement of the joints, are available. In addition to pharmacotherapy and the therapeutic approaches already mentioned, rehabilitation methods and spa treatments are also used.

Empirical experience shows that the application of spa treatment is also suitable for use in case of developing and / or progressive degenerative changes, i.e., the 2nd and 3rd degree of knee OA. In spite of the positive effect of natural remedies to relieve pain and improve the functionality and mobility of patients who are suffering from OA, the mechanisms of action of natural remedies have not yet been clearly elucidated. Therefore, in recent years, OA research has focused on determining the effect of biomarkers, including immunomarkers. At present, there is a lack of studies exploring the effects of natural remedies for the knee

joint of OA patients. Very important is the monitoring of changes in the dynamics of the biomarkers already identified, with regard to their interaction with natural remedies.

Unfortunately the Ministry of Education, Youth and Sports rejected the request for support. We will try to continue with a simplified version of this project. In the next sections I will describe the initial project.

## 3 What is the Goal of the Project?

The aim of this project is to determine:

- Whether or not the selected natural remedies that are utilized for the therapy for gonarthrosis of the 2nd and/or the 3rd degree will influence the metabolism of the subchondral bone whether selected natural remedies will affect the joint and/or the process of cartilage regeneration or, on the other hand, inhibit the process of the degeneration of the cartilage or
- Whether they will influence immunological processes that could trigger the degeneration of the cartilage and/or cause damage to the joint synovium.

An assessment of these processes will be carried out through monitoring of any quantitative changes that occur in the complex of selected biomarkers and that are also related to changes in the functional capacity and mobility of the affected joint(s), to pain symptoms and to the quality of the life of the person with knee OA. It is a comprehensive and, in terms of its approach, also a unique type of assessment, given the projected interdisciplinary project team.

## 4 Methods

This project offers a comprehensive interdisciplinary (physiotherapy, rehabilitation, balneology, physiology, anthropometrics, biomedicine, bioinformatics) perspective with the purpose of objectifying the clinical effect(s) of natural remedies of the spa treatment of osteoarthritis. The scope of this project is exclusively research to verify, define and also refine scientific theories. This research project focuses on the clinical evaluation of 6 peloids (peat or peat soil) and 6 healing natural mineral waters. The effect assessment will be done at two levels. First, the assessment of quantitative changes in a broader set of 20 selected biomarkers. Secondly the functional capacity and mobility of the affected joint, as well as the pain and quality of life of the proband will be assessed. The systematic search for clinical research articles that focused on the effects of natural remedies via the world's leading search sites Medline (PubMed), Scopus, Web of Science, Cochrane Library, and Google Scholar confirmed a number of similar global scale approaches with different levels of quality. So we had the benefit of knowing the latest results in this area. The choice of biomarkers and the way they were monitored will allow not only to ascertain the effects of

natural remedies but also to focus on the issue of how natural remedies work. Every natural remedy will be tested through a double-blind randomized study.

## 5 What Changes are Expected Due to the Project?

A comprehensive and multidisciplinary view to solve the examined problems, including support through international cooperation has a high potential to generate results that are comparable with the research outputs of prestigious foreign institutions. Additionally, this project opens a door for the creation of a unique international and interdisciplinary communication network for scientific fields in which there is a high priority for the creation of new jobs that are intended to support excellent young researchers.

## 6 In What Aspect is the Proposed Solution Actually Innovative?

Previous studies that focused on the treatment of gonarthrosis by means of natural remedies always assessed individual criteria that correlated the treatment outcomes with either X-ray, CT, MRI or ultrasonography imaging but mostly, however, with the assessment of the subjective perception of pain and of the quality of life. None of the studies addressed the assessment of biochemical, immunological and functional criteria and the criterion of pain in quantitative terms. Previous research assessed the role of individual anti-inflammatory biomarkers of immunopathological processes taking place in the knee joint, in the synovium and/or in the cartilage that characterize either bone metabolism, anabolism or catabolism. These were mainly descriptive studies, however, without any illumination of the principles that determine how the values of these markers vary in relation to the natural remedies that have been applied. Therefore, compared with previous studies our research is designed to enable, in accordance with the application of selected natural remedies, the monitoring of any changes within the entire complex of the defined biomarkers (biochemical and immunological) and their interaction in relation

to changes in the functional parameters of mobility and in regard to pain perception. An objective evaluation of specific functional changes of mobility and agility, together with an emphasis on changes in stability, was only rarely utilized as a research topic. Also exceptional is the monitoring of changes within the complex of the selected biomarkers and of aspects of the quality of life 4 and 12 months subsequent to the experimental intervention. Such a detailed and comprehensive solution of the objectification process in relation to the effects of natural remedies is therefore unique in this area of scientific research.

## 7 Conclusion

Within the EU Evidence Based Medicine (EBM) is increasingly promoted. At the 21st Annual Conference of the European Spa Association (ESPA), held on 26 May 2016, President Thierry Dubois introduced the pillars of his program. He said there was a need to support research with evidence-based approaches to the spa treatment.

In the Czech Republic, access to spa treatment, based on the recognition of traditional healing practices based on experience, gained over many decades, is still prevalent in the spa community. The ambition of the joint workforce of the Faculty Physical Education and Sport and the Balneology Research Institute is to promote the application of EBM in Czech and international spa practice and to give the Czech balneological research back a leading position in Europe. In practice, the only way is to introduce a clinical research methodology into the evaluation of the effects of natural remedies and to objectivize the evaluation of the effects of spa treatment.

As mentioned above, we intend to proceed with our project in a simplified scope and at considerably lower costs. In doing so, we want to preserve the main idea of this research, to promote Evidence Based Medicine in the Spa branch of medical services. We want to continue the journey that we have started with Prof. Jana Zvárová.