

Assessment of the effectiveness of spa treatment – a review of the subject literature

Ocena efektywności klinicznej lecznictwa uzdrowiskowego – przegląd literatury

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Key words

balneotherapy, physical medicine, evidence-based medicine, health technology assessment

Abstract

Objective: Spa treatment arouses a lot of controversy and conflicting opinions. The aim of this study was to evaluate the clinical efficacy and safety profile of spa treatment. Assessment was based on a review of available publications.

Methods: The Cochrane Library, MEDLINE, EMBASE and the Centre for Reviews and Dissemination (CRD) databases were searched for health technology assessment (HTA) reports and systematic reviews. All publications which met the predesigned inclusion criteria were included. The data search was concluded on 27st May 2011. Additionally Acta Balneologica, Rehabilitacja Medyczna and Fizjoterapia Polska were searched for both clinical trials and reviews.

Results: During the search 872 publications were identified of which 41 articles were selected for further analysis, out of which 8 systematic reviews met the inclusion criteria upon the basis of full text analysis. Additionally 11 reports which had been published in Acta Balneologica and 3 in Fizjoterapia Polska were included in the study. Based on the performed review of the available studies, spa treatment appears to be an effective method in the treatment of patients suffering from osteoarthritis, fibromyalgia, chronic low back pain, psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis. Spa treatment is associated with no serious side effects.

Conclusions: Spa treatment is effective in the relief of symptoms of rheumatic diseases and musculoskeletal disorders. However, existing research is not sufficiently strong to draw firm conclusions. Well-designed controlled clinical trials are needed for the assessment of the effects of spa treatment.

Słowa kluczowe

balneoterapia, medycyna fizykalna, medycyna oparta na dowodach naukowych, ocena technologii medycznej

Streszczenie

Założenia: Leczenie uzdrowiskowe budzi wiele kontrowersji oraz skrajnych opinii odnośnie skuteczności i bezpieczeństwa tej formy terapii, a co za tym idzie finansowania leczenia w uzdrowisku ze środków publicznych.

Cele: Celem pracy jest ocena efektywności klinicznej leczenia uzdrowiskowego przeprowadzona na podstawie analizy wyników doniesień naukowych odnalezionych w ramach przeglądu literatury.

Metodyka: Poszukiwano wiarygodnych opracowań wtórnych dostępnych w bazach informacji medycznej: The Cochrane Library, bazie MEDLINE, EMBASE oraz Centre for Reviews and Dissemination (CRD). Włączano wszystkie prace spełniające kryteria włączenia (przeglądy systematyczne oraz niezależne raporty oceny technologii medycznej – raporty HTA), które zostały opublikowane do dnia 27 maja 2011 roku. Dodatkowo przeszukano artykuły opublikowane w polskich czasopismach: „Acta Balneologica”, „Rehabilitacja Medyczna” oraz „Fizjoterapia Polska” (do analizy włączano zarówno pierwotne badania kliniczne, jak również opracowania wtórne).

Wyniki: W wyniku przeszukania elektronicznych baz informacji medycznej odnaleziono 872 pozycje bibliograficzne, z których do dalszej analizy włączono 41 doniesień naukowych. Spośród 41 doniesień naukowych, wstępnie zakwalifikowanych do analizy, na etapie weryfikacji prac na podstawie pełnych tekstów do analizy włączono 8 prac. Dodatkowo do analizy włączono 11 doniesień naukowych opublikowanych w czasopiśmie „Acta Balneologica” oraz 3 prace opublikowane w „Fizjoterapii Polskiej”. Na podstawie wyników odnalezionych doniesień naukowych ocenia się, że lecznictwo uzdrowiskowe istotnie zmniejsza nasilenie bólu oraz poprawia jakość życia pacjentów z chorobą zwyrodnieniową stawów, fibromialgią, przewlekłym bólem odcinka lędźwiowo-krzyżowego kręgosłupa, łuszczykowym zapaleniem stawów, zeszytniającym zapaleniem stawów kręgosłupa oraz reumatoidalnym zapaleniem stawów. Nie raportowano żadnych poważnych działań niepożądanych związanych z leczeniem w uzdrowisku.

Wnioski: Leczenie uzdrowiskowe jest skuteczne w zmniejszaniu nasilenia objawów niektórych chorób układu mięśniowo-szkieletowego. Niezbędne są dalsze, dobrze zaprojektowane, kliniczne badania z grupą kontrolną, oceniające skuteczność leczenia uzdrowiskowego.

INTRODUCTION

Spas and spa treatment, particularly that financed from public funds by the National Health Fund (NFZ) or Social Insurance Institution (ZUS) within the framework of pension prevention, is the source of much controversy and polarises opinion both amongst doctors as well as economists.

Opponents of spa treatment cite first and foremost the lack of reliable scientific evidence for the effectiveness and safety of spa treatment, while adherents of this type of therapy disagree with these views and point to many examples of conscientiously conducted research that point to the effectiveness of treatment within spas¹. So which side is correct? Should we really not fund spa treatment from the public purse and leave the decision as to the choice of treatment as well as its financing to the patients themselves? Or should this form of therapy be treated as an element of public health care, something that should be guaranteed by the state? Is spa treatment as dangerous as some specialists say it is¹? The aim of the present work is an evaluation of the effectiveness and safety profile of spa treatment.

The essence of spa treatment

The essence of spa treatment is comprehensive therapy, rehabilitation or preventative proceedings with particular emphasis placed on the natural healing properties of spa materials such as spa waters used in medicinal baths, drinking treatment programmes, inhalation, and swimming bath exercises), therapeutic gases and peloids – therapeutic peat (used in baths, wraps, compresses, tampons), as well as the specific properties of natural factors such as climate, scenery and the flora of an area considered to be a spa region^{2,3}. It is important that the course of treatment takes place in a closed health care unit with the maintaining of a sanatorium regime. The patient spends his time in a social environment different from the daily norm. Treatment takes place far from the stresses of daily life, current matters and the harmful conditions of the material environment of work

and leisure. Generally the conditions at spas are far more comfortable than those of a normal hospital⁴.

Spa treatment is extremely complex and varied in method, utilising natural treatment methods and physical factors, rehabilitation, preventative approaches, as well as health education⁵. In employing an integrated approach of various forms of treatment, it incorporates at the same time individual abilities for organism regeneration and recuperation to treatment stimuli during the course of the entire treatment period. The complexity of treatment allows for an increased effectiveness in comparison with the application of single forms of treatment, which is characteristic for, for example, medical rehabilitation^{6,7}.

Spa treatment is a way of combining various medical disciplines. The methods employed by spa treatment are treatment stimulating in character. The organism in response to these stimuli experiences a reaction, which is defined according to its character as an adaptive or compensatory reaction. It is important that the treatment applied be in the form of a series of exercises and treatment procedures^{8,9}. The effect of balneological methods is gradual, however the obtained results may be longer lasting in comparison to other treatment methods¹⁰.

Spa treatment most often is a continuation of the hospital or clinic treatment of illnesses, requiring first and foremost rehabilitation and treatment by physical methods^{6,8}. Spa treatment supplements the basic treatment given a patient (i.e. surgical procedures/operations, pharmacotherapy). Spa medicine in many cases also constitutes an alternative to other methods of treatment (e.g. in the preventative treatment of so-called civilization induced diseases)¹¹. Health education is a chance to reduce the rate of illness for many civilization induced diseases and with it reduce mortality rates. An increasing importance in the world is being ascribed to preventative spa treatment and the rectifying of incorrect dietary habits as well as compensating for lack of exercise and movement. This is conducted during vacation periods within the framework of health tourism¹².

Methods

The evaluation of the effectiveness and safety of spa treatment was conducted on the basis of an analysis of the results of scientific reports found within a review of the subject literature.

Reliable secondary studies were sought (systematic reviews as well as independent technology assessment reports – HTA reports) available in: The Cochrane Library, the MEDLINE and EMBASE data bases as well as the Centre for Reviews and Dissemination (CRD) database. During the search in medical data bases there were not applied any automatic filters and no restrictive time division was applied to the search. All studies that fulfilled the inclusion criteria and which had been published by the day the search was conducted (27 May 2011) were included. All reliable systematic reviews were incorporated into the analysis (systematic reviews fulfilling appropriately the Cook criteria¹³ evaluating the effectiveness and/or the safety profile of spa medicine, published in English, Polish, German and French, in accordance with the guidelines for conducting health technology assessment (HTA) developed by AOTM¹⁴. A search strategy of the highest possible degree of sensitivity was developed that was utilised to search the above mentioned electronic data bases. The search criteria were not narrowed down in relation to populations (patients treated at a spa for various illnesses were incorporated). The search also did not limit itself to concrete types of intervention – treatment procedures employed in spa treatment, nor to the clinical trial endpoints (health outcomes). During the search the following key words were used, ones broadly relating to the intervention: *balneotherapy, balneorehabilitation, balneology, thermal, spa, medicine, treatment, procedures, procedure, therapy, rehabilitation*; as well as those relating to the methods of scientific reports: *systematic review, metaanalysis, meta-analysis*, which were appropriately linked by elements of Boolean logics. In the process of verification as to whether a found scientific report was suitable for the analysis, a selection was based

on abstracts, and subsequently based on entire texts of publications.

Additionally all the articles published from 2000 to 2011 in the Polish journal *Acta Balneologica* (previously *Balneologia Polska*) were searched (the search was on the basis of the titles and/or abstracts, and then on the basis of the entire texts of publication)^{15,16}. Equally articles published in the journal *Rehabilitacja Medyczna* (Medical Rehabilitation) (2000 to 2010)¹⁷, and *Fizjoterapia Polska* (2001 to 2011) were searched¹⁸. All original primary clinical studies were included in the analysis, regardless of the work methods (experimental study, observational study with a control group or without one), and also secondary studies (both systematic reviews and meta-analyses based on systematic reviews, as well as all non-systematic reviews) on the effectiveness and safety of spa treatment.

SEARCH RESULTS

The process leading to the final selection of the scientific reports as well as the reason for the exclusion of studies at various stages of the selection process is presented in a diagram form in accordance with QUOROM recommendations (The Quality of Reporting of Meta-analyses)¹⁹ (Figure 1).

As a result of searching electronic medical databases 872 bibliographical positions were found (including titles that repeated themselves) from which 41 were included in further analysis. The main reasons for the exclusion of studies at the selection stage on the basis of abstracts and/or titles were: a lack of agreement between the title and summary and the subject of analysis, and also the evaluation of the individual forms of intervention used in spa treatment (including the massage techniques selected, those of kinesiotherapy, as well as of physical medicine i.e. hydrotherapy and thermotherapy) without the evaluation of a total patient approach utilising many of the forms of intervention simultaneously. From amongst the 41 research papers that initially qualified to be selected, an additional 33 were excluded at the stage of entire text evaluation (chiefly works evaluating

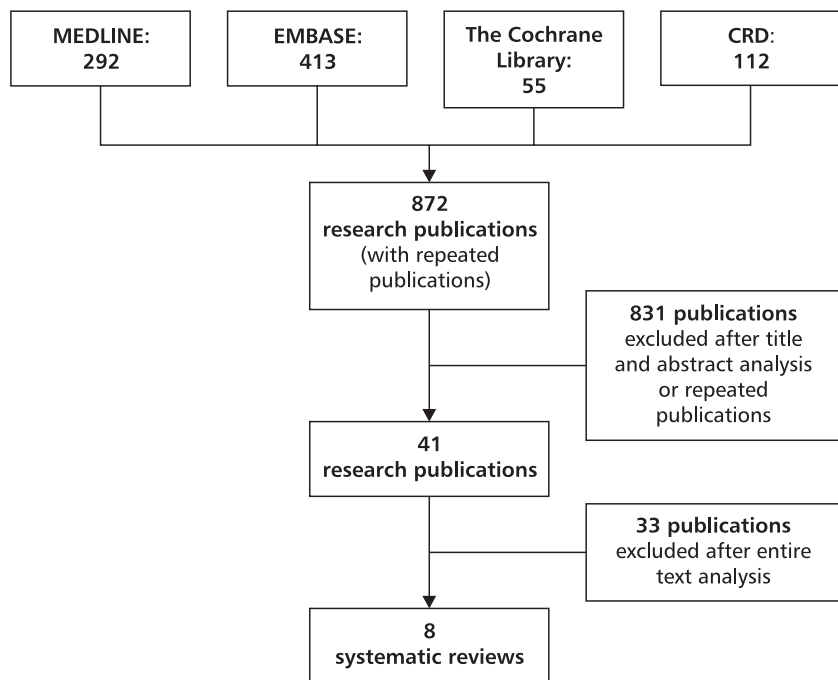


Figure 1
The process of publication selection

selected intervention from the areas of balneotherapy and hydrotherapy, as well as non-systematic reviews). 8 reviews were included in analysis²⁰⁻²⁷. No additional publications were obtained on the basis of the bibliographical references contained in the selected works.

As a result of a search of all the articles published in the journals *Acta Balneologica*, *Rehabilitacja Medyczna* and *Fizjoterapia Polska* 14 works were qualified for analysis. 12 of which were primary clinical studies (most frequently clinical studies without a control group)²⁸⁻³⁹, while two works were non-systematic reviews of the subject literature, of which one concerned an evaluation of the effectiveness of spa medicine in the treatment of women's ailments⁴⁰, and the other an evaluation of the effectiveness of spa medicine in the treatment of rheumatic diseases⁴¹. As a result of the differentiated methodology as well as the heterogeneous nature of the scientific reports found there was not conducted a quantitative synthesis of the results of the individual clinical studies in meta-analyses.

Results on effectiveness

On the basis of the results of the systematic reviews uncovered it was evaluated that spa treatment in comparison with an absence of therapy (the control group was comprised of patients awaiting spa treatment) statistically significantly reduced chronic low back pain²². Spa treatment also reduces the disease symptoms in patients with rheumatoid arthritis^{20,26} and with ankylosing spondylitis²³, although it is inadvisable in the treatment of active forms of rheumatoid arthritis.²⁶ In two of the reports it was claimed that spa treatment has a favourable influence on symptoms of disease and statistically noticeably reduces the intensification of pain in patients with fibromyalgia^{24,27}. In the work by Falagas 2009²⁵ it is shown that balneotherapy (equally as an element of spa treatment) may reduce the intensification of disease symptoms in patients with various rheumatoid diseases, however in relation to other diseases (including: psoriasis, Parkinson's Disease) there is a lack of sufficient evidence to confirm the effectiveness of balneotherapy. Additionally in the systematic review by Bender 2005²¹, the aim of which was, among others, an evaluation of the effectiveness of clinical spa treatment in

the treatment of pain, it was shown that spa therapy not only reduces the intensification of symptoms but eases pain connected with such illnesses as: osteoarthritis, fibromyalgia, chronic low back pain, psoriatic arthritis, ankylosing spondylitis and rheumatoid arthritis, but also improves the quality of life as well as reducing the appearance of depression and anxiety. In one trial, in which spa treatment was evaluated in relation to pharmacological intervention (cyclosporin) in a group of patients with rheumatoid arthritis, patients somewhat favoured balneotherapy cyclosporine therapy²¹.

In none of the systematic reviews found was there an evaluation of the safety profile of spa medicine nor were there reported any serious undesirable effects associated with the treatment^{21,22}.

In the majority of works there was an absence of scientific evidence of a high level of reliability (the scientific reports found within the framework of the systematic reviews were characterised by low methodological quality), consequently the results presented should be treated with some caution.

The results of the foreign systematic reviews that were found are in agreement with the Polish reviews, the aim of which was the evaluation of the effectiveness of spa therapy in the treatment of women's ailments⁴⁰ or rheumatoid diseases⁴¹. In these works it was claimed that in the majority of studies on spa treatment there was shown a significant positive effect for this type of therapy in the treatment of both gynaecological illnesses as equally rheumatic ones, however these works are characterised often by a low methodological quality and therefore there exists the need to conduct clinical study of a higher reliability level.

In 6 of the 12 primary studies the effectiveness of spa treatment in the therapy of degenerative diseases of the spine or joints was evaluated^{29,30,32,36,37,38}. In all the works there was confirmed a positive influence on the part of spa medicine. It was shown that treatment in a spa reduces the intensification of pain and other disease symptoms which are subjectively eval-

uated. Therapy conducted at a spa improves patient fitness and the range of joint movements, resulting in an accelerated return to vocational activity. In patients who have undergone spa treatment there was noted a higher subjective evaluation of the state of health as well as improvement in life quality, something, according to one of the works, that is extremely low, especially amongst older patients³¹. It was equally shown that spa treatment allows for a reduction in the dosage of prescribed medicines.

In one of the study, in which the effects of applied therapies with regard to pain intensity and changes in blood perfusion in the lower limb muscles in patients with spine pain syndromes of a radicular nature in the lumbosacral section 8 weeks after treatment commencement were evaluated, there was observed a statistically significant improvement in the blood flow to the muscles of the lower limbs only in patients who had had physiotherapy treatment, while in those to whom merely pharmacological means had been applied no improvement was noted³⁴.

In one of the works it was also shown that a three-week period of sanatorium treatment utilising broadly understood rehabilitation and physiotherapy is sufficient to obtain improvement in the physical functioning of the upper limbs in patients with rheumatoid arthritis³⁹.

Within the framework of the review there was also found a clinical study, which aim was the evaluation of the effectiveness of spa treatment in obese patients with type 2 diabetes and hyperlipidaemia. The strategy for the treatment of disturbances to the lipid metabolism is complex and involves body mass reduction, changes in nutrition and physical activity, as equally pharmacological treatment. According to the authors of the research it is often difficult to introduce all of the above elements, with the optimal conditions for a realisation of the said being spa treatment. It was shown in the work that after 21 days' treatment patients observe a noticeable reduction in body mass and an improvement in the lipid parameters²⁸. However, the referral of patients to sanatori-

ums contrary to medical recommendations, beside the needless costs, extends the treatment waiting time for other patients at spa establishments³³, meaning that spa treatment referrals should in this sense be controlled.

Clinical study evaluating the influence of the subterranean microclimate of the Salt Mine Resort at Wieliczka on the lipid metabolism and selected hormones conducted in a group of healthy adults was additionally included in the analysis. In this study there was shown, among other things, a significant reduction in the total cholesterol concentration ($p < 0.033$, in 80% of those tested), an insignificant increase in the concentration of HDL cholesterol (in 73.3%) as well as a statistically insignificant reduction in the concentration of triglyceride in 66.6% of those tested³⁵.

The majority of the studies included in the review were experimental trials without a control group, conducted on a numerically small sample, therefore these results should undergo verification within the framework of clinical trials with a control group conducted on a much greater number of patients.

DISCUSSION AND CONCLUSIONS

Spa treatment is an integral part of the health system. It serves as a form of treatment utilising methods unique to itself, using chiefly the effects of natural healing resources. This type of treatment is burdened, however, by the many years of association with the concept of a 'health holiday', where the role of the inherent medical benefits was often marginalised⁴². Too often the methods used in spa treatment were pushed to the distant edges of medical progress. At the same time many of them have a scientific basis. In recent decades clinical studies has resulted in an understanding and explanation of the mechanisms behind their actions. Admittedly they do not bring about results as quickly as in the case of pharmacological methods yet their effect is more physiological while the results obtained are possibly more long lasting. Spa rehabilitation as a result

of the possibility for comprehensive physiotherapeutic treatment as well as a consequence of the changeability in climatic and environment conditions constitutes an excellent supplement to hospital and out-patients' treatment⁴⁰.

The present review has restricted itself to a search of the most important English-language medical sources of information, recommended by the guidelines for conducting health technology assessment (i.e. MEDLINE, EMBASE, The Cochrane Library as well as CRD) as well as the most important Polish journals on medical rehabilitation, which constitutes a significant limitation in the review. Additionally, as a result of the aim and premises of the work, the evaluation was carried out only on the basis of the results of scientific reports into the effectiveness and safety of the complex therapeutic approach that is spa treatment (both physical medicine and equally kinesitherapy, diet and health education) seen as a whole. The results of clinical research evaluating individual methods employed in spa treatment were not incorporated in the research (this type of study is often conducted in accordance with evidence-based medicine (EBM) criteria and is designed as clinical trial with a control group), consequently the analysis conducted was not a complete evaluation of the healing value of spa treatment.

On the basis of the results of the systematic reviews found it is estimated that spa treatment significantly reduces the intensification of pain as well as improving the quality of life for patients with motor system illnesses such as: osteoarthritis, fibromyalgia, chronic low back pain, psoriatic arthritis, ankylosing spondylitis as well as rheumatoid arthritis. The found primary clinical studies also showed the positive influence of spa treatment on the therapy of gynaecological illnesses, and also in the treatment of obesity. There was not reported any undesirable effects of spa treatment. All of the studies related to older patients, over 45 years of age. It is estimated that spa therapy creates conditions for the treatment of patients at an advanced age. It deals with the treatment of

chronic ailments, the appearance of which will constantly rise.

The problem in the assessment of spa treatment lies in its complexity. Patients treated at a spa resort are not simply subjected to therapy involving medicinal waters, they are also subjected to physiotherapy exercises, massages and kinesitherapy. The majority of the reports dealt only with a selected methods of physical medicine (including most often hydrotherapy and balneotherapy) or other forms of intervention employed in spa treatment.

Another problem in the evaluation of spa treatment is the incorrect defining of procedures as well as the fact that concepts such as *spa treatment*, *balneotherapy* or *hydrotherapy* are used interchangeably in various scientific reports. The lack of international unequivocal definitions within this field may partially arise from the fact that balneotherapy and climate therapy are not used in many countries. To date the most frequently employed term in English is *spa treatment*, yet there is a proposal for its change to *thermal treatment*⁴³ or *health resort medicine*⁴⁴.

There is a need within the majority of the secondary studies found for subsequent well-designed controlled clinical trial to be undertaken. However, it follows to remember that the low quality of the clinical study does not merely refer to spa treatment. In researching the methodological differences between clinical study evaluating non-pharmacological technologies (chiefly operational procedures and rehabilitation, and also, among others, spa treatment, education and acupuncture) and clinical studies evaluating pharmacological technologies (first and foremost oral drugs, though also arthroscopic lavage, drugs administered intra-articularly and locally) in patients with degenerative conditions of the hip and knee joints it has been shown that clinical studies of non-pharmacological interventions are noticeably poor in quality (the quality of studies being measured by, among others, the Jadad scale) when compared to works on pharmacological intervention⁴⁵.

It is particularly difficult to design studies within the field of spa medicine, especially if the matter concerns the obtainment of a double blind sample or an appropriately selected control group (placebo). The absence of a double blind sample should not, however, act as a depreciation of the results obtained, for equally in the case of pharmacological therapy (e.g. clinical study evaluating non-steroid anti-inflammatory drugs in the treatment of rheumatoid arthritis) researchers do not always employ the double blind technique in a sample, and here the results are not rejected²¹. The most important thing in newly designed trials is for the test question to be as clearly formulated as possible and that the answer to it be as good as possible. Hitherto clinical studies have incorporated too few patients while the time scope for observations has been too short (most often 6–12 weeks), therefore it is recommended that in subsequent clinical studies more patients participate and that the period of observation be extended (to at least 24 weeks as is the case in the majority of works for pharmacological interventions in rheumatic disease therapy)²².

A problem is also the financing of research works into spa treatment²¹. In the case of other forms of intervention the costs are usually covered by the producer of the given therapy, spa treatment, however, is more complex and often makes use of natural methods of treatment and rehabilitative exercises.

There is an absence of financing, grants, equipment, medicines and other means that could constitute support for article preparation.

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