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Balneotherapy for Osteoarthritis. A Cochrane Review

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ABSTRACT. Objective. Balneotherapy (or spa therapy, mineral baths) for patients with arthritis is one of the oldest forms of therapy. We assessed effectiveness of balneotherapy for patients with osteoarthritis (OA).

Methods. We performed a broad search strategy to retrieve eligible studies, selecting randomized controlled trials comparing balneotherapy with any intervention or with no intervention. Two authors independently assessed quality and extracted data. Disagreements were solved by consensus. In the event of clinical heterogeneity or lack of data we refrained from statistical pooling.

Results. Seven trials (498 patients) were included in this review: one performed an intention-to-treat analysis, 2 provided data for our own analysis, and one reported a “quality of life” outcome. We found silver-level evidence of mineral baths compared to no treatment (effect sizes 0.34–1.82). Adverse events were not measured or found in included trials.

Conclusion. We found silver-level evidence concerning the beneficial effects of mineral baths compared to no treatment. Of all other balneological treatments, no clear effects were found. However, the scientific evidence is weak because of the poor methodological quality and the absence of an adequate statistical analysis and data presentation. (J Rheumatol First Release May 1 2008)

Key Indexing Terms:

OSTEOARTHRITIS METAANALYSIS BALNEOTHERAPY SYSTEMATIC REVIEW

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Osteoarthritis (OA) is a degenerative joint disease marked by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane¹. OA is one of the most common forms of arthritis and affects men and women equally. For many adults OA is one of the most important causes of longterm disability^{1,2}. While it can involve any joint, OA usually affects the hips, knees, hands, and spine. The knee appears to be the joint most prone to the development of OA³. This may be

because it is a major weight-bearing joint, and prone to effects of obesity, trauma, as well as metabolic diseases⁴. Movement or weight-bearing exacerbates pain in the knee. Stiffness, edema and deformity, and reduced function such as in walking are common complaints in patients with OA of the knee.

There is no cure for OA at present, so treatment often focuses on management of symptoms such as pain, stiffness, and mobility. Treatment options include pharmacological interventions, physiotherapy treatments, or balneotherapy.

The term balneotherapy, from the Latin *balneum* (bath) and classically used to mean bathing in thermal or mineral waters, has been distinguished from hydrotherapy; since the beginning of this century, however, both terms were accepted for all forms of treatment with water⁵. We use the term balneotherapy since bathing for therapeutic use very often happens in spas. The water (thermal, sea, or tap water) is generally used at a temperature of around 34°C⁶. The hydrostatic force (Archimedes' principle) brings about relative pain relief by reducing loading⁶; the water reduces gravity on painful and rheumatic joints.

Bathing in water (balneotherapy or spa therapy) was frequently used in classical medicine as a cure for diseases. Water from mineral and thermal springs was particularly valued⁷. In Homeric times baths were applied primarily to cleanse and refresh. At the time of Hippocrates, bathing was regarded as more than a simple hygienic measure. It was considered beneficial to cure most illnesses⁸. The Romans used water for therapeutic treatment of orthopedic conditions, but after the Roman era spa therapy fell into disuse.

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Since the 16th century, when baths were rediscovered, spa therapy has been practiced continuously in the management of musculoskeletal conditions^{3,8}.

Spa therapy is a popular treatment for all forms of arthritis in many European countries and in Israel^{9,10}. In Western Europe spa therapy is mostly offered at centers with thermal baths or seawater baths¹¹. In Israel, the main health resort area is located along the western shore of the Dead Sea. The unique environmental conditions in this area are considered beneficial to patients with rheumatic diseases¹². The aim of balneotherapy is to improve range of joint motion, strengthen muscle, relieve muscle spasm, maintain or improve functional mobility, and soothe pain and thus relieve patients' suffering and let them feel well^{9,12,13}. Balneotherapy is most often prescribed for patients with any form of arthritis. In 1994 the Italian Ministry of Health supported a project (the Naiade Italian project) to evaluate the role of spa medicine in various diseases, including the evaluation of spa therapy in OA¹⁴. The project involved a large cohort study evaluating over 11,000 patients for 2 years. All patients were treated in Italian spas. The study found a reduction of additional treatments and sick leave, especially in patients with OA of the spine.

Despite its popularity, reported scientific evidence for the effectiveness of balneotherapy is sparse. Our review evaluates the effects of balneotherapy in patients with OA. As a primary objective we performed a systematic review of the effects of balneotherapy in patients with OA.

MATERIALS AND METHODS

Search strategy. Using the Cochrane search strategy, studies were found by screening EMBASE and PubMed database from onset up to October 2006, the database from the Cochrane "Rehabilitation and Related Therapies" Field up to October 2006, Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 3, 2006), Pedro database up to October 2006, and by checking references and personal communications with authors to retrieve eligible studies. In PubMed the following subject-specific search strategy was combined with all 3 levels of the optimal trial search strategy as defined by the Cochrane Handbook¹⁵: (arthritis OR arthritis) and (balneotherapy OR balneology OR spa therapy OR water therapy OR hydrotherapy OR thalassotherapy). No language restrictions were applied, but studies not reported in English, Dutch, Danish, Swedish, Norwegian, German, or French are awaiting assessment. First titles and abstracts of identified published articles were reviewed in order to determine the relevance of the articles. Two reviewers (APV and JL) performed the search independently.

Study selection. Studies were eligible if they were randomized controlled trials (RCT); at least 90% of trial participants had OA; and balneotherapy had to be the intervention under study and had to be compared with another intervention or with no intervention.

Balneotherapy was defined as bathing in water. Water could contain minerals (added or natural). Main endpoints found relevant were: pain, physical function, patient global assessment, and quality of life, measured using the Western Ontario McMaster University Osteoarthritis Index, the Indices of Clinical Severity, AUSCAN index, Algofunctional Index, Health Assessment Questionnaire, and Arthritis Impact Measurement Scale-II (AIMS-II). At least one of these endpoints had to be among the main outcome measures. Studies were excluded when only laboratory variables were reported as outcome measures.

Methodological quality. The effectiveness of balneotherapy is presented and discussed based upon methodological quality. Methodological quality is assessed by means of the "Delphi list" for quality assessment of RCT¹⁶. All criteria have a "yes," "no," or "don't know" answer format. In this review the quality components of the studies were determined independently by 2 of 3 authors (HCWdV, RAdB, APV), followed by a consensus meeting. If disagreements persisted the third author made a final decision.

Data extraction and analysis. Two authors (JC, APV) independently extracted data regarding the interventions, type of outcome measures, followup, loss to followup, and outcomes, using a standardized form.

High quality is defined as: presenting a concealed randomization procedure and blinding of the outcome assessor. We calculated reproducibility of the overall quality assessment using intraclass correlation coefficients (ICC). ICC > 0.7 are considered as good agreement, between 0.5 and 0.7 moderate, and < 0.5 as poor agreement.

Dichotomous data results are expressed, when possible, as relative risks (RR) with corresponding 95% confidence intervals (CI), and as weighted mean differences with 95% CI for continuous data¹⁷. In case of clinical heterogeneity, or if data were lacking, we analyzed the results using the system of the Cochrane Musculoskeletal Group¹⁸.

Our pre-planned analyses were trials comparing: (a) balneotherapy versus no treatment, or waiting list controls; (b) different types of balneotherapy; or (c) balneotherapy with other treatment(s) (e.g., exercise, oral medication).

RESULTS

Study selection. In total, 70 references were selected based on title and abstract. Of these, 63 studies were excluded because: (a) study was awaiting assessment based on language (n = 22); (b) design not an RCT (n = 18); (c) did not concern patients with OA (n = 11); (d) no balneotherapy given (n = 8); and (e) lack of relevant outcome measure (n = 4). Seven trials were found to meet eligibility criteria¹⁹⁻²⁵.

Patients. A total of 498 patients were enrolled, and the number of patients in the intervention groups varied from 10 to 97 (Table 1). When mentioned, the percentage of males was between 0% and 26%; mean age varied between 54.6 and 68 years.

Interventions. In all but one study²⁰ the intervention included mineral baths, and in one study the intervention was in combination with mudpacks²⁵. Four studies included a control group receiving no treatment^{19,22-24}, and in 2 studies a control group received tap water^{21,25}. In one study, bathing was evaluated as an add-on treatment to home exercise²⁰. In that study, no information was provided about the water, no instructions about the bathing procedure (called hydrotherapy, but with no information provided about exercise in water), and no data on pain and function. In all trials patients continued their medication during balneotherapy. In one study several mineral baths (sulfur baths and Dead Sea baths) were compared²³.

Outcome measures. All studies used a number of outcome measures including pain and function; in one study²² a "quality of life" instrument (AIMS) was used. Three studies^{20,22,25} mentioned a followup period of 18, 20, or 24 weeks; all other studies measured at start and end of treatment.

Methodological quality. The results of the assessment of methodological quality are shown in Table 2. Concerning

Table 1. Characteristics of included studies. From Verhagen, et al. Cochrane Database Sys Review 2007; CD006864; with permission.

Study	Methods	Participants	Interventions	Outcomes	Results	Notes
Allard 1998 ¹⁹	Unclear allocation concealment; overall quality score: 1	Northern France spa, rheumatic disease, 4% patients with RA, n = 148	I: Spa therapy, n = 74 C: No treatment, n = 74 Also nonrandomized spa therapy group (n = 72)	Medication, costs	No data	14 dropouts in I, 6 in C; study designed to evaluate costs
Green 1993 ²⁰	Unclear allocation concealment; blinded outcome assessment; overall quality score: 3	St. James Hospital, Leeds, UK; radiographic hip OA; n = 63	I: Deep pool baths twice weekly + home exercise twice daily, n = 24; 25% male, mean age 65.7 yrs C: Home exercise twice daily, n = 23; 26% male, mean age 68 yrs; treatment for 6 wks; followup at 9, 12, 18 wks	Pain (VAS), function, range of motion, muscle strength	Stiffness: WMD = 19.2 (95% CI -4.4; 42.7)	16 dropouts
Kovacs 2002 ²¹	Unclear allocation concealment; blinded patients and outcome assessment; overall quality score: 4	Cserkeszőlő health resort, Hungary; clinically and radiologically established knee OA; n = 70	I: Deep bathing in thermal water for 30 min for 15 days, n = 31 C: Daily bathing in tap water (placebo) for 30 min for 15 days, n = 27	Pain (VAS), range of motion (goniometer), function (stair climbing, 4-pt Likert), perceived recovery	Pain: Abs ben: 0.0006%	12 dropouts; only pre-post analysis
Nguyen 1997 ²²	Unclear allocation concealment; observer clearly aware of treatment allocation; overall quality score: 4	France; knee, hip or lumbar spine OA; n = 233	I: Spa treatment for 21 days, n = 91; 22% male, mean age 64 yrs; mean DOC 11 yrs C: No treatment, routine maintained, n = 97; 16% male, mean age 63, mean DOC 12 yrs; followup at 24 wks	Pain (VAS), function (WDI, AIMS), mobility, medication	Pain: Abs ben: 0.09%; Rel ben: 18.5% (WMD = -0.3; 95%CI -0.6; -0.1); AIMS: WMD = -0.4; (95% CI -0.7; -0.1)	45 dropouts directly after randomization, 4 extra dropouts
Sukenik 1999 ²³	Unclear allocation concealment; blinded outcome assessment; overall quality score: 4	Outpatient clinic, Soroka Medical Centre, Israel; moderate or severe radiographic knee OA, n = 40	II: Sulfur baths, n = 10; 20% male, mean age 63.2 yrs, mean DOC 11.6 yrs; 12: Dead Sea baths, n = 10; 10% male, mean age 65.4 yrs, mean DOC 9.2 yrs; 13: II + 12; n = 10; 0% male, mean age 57.6 yrs; mean DOC 9.3 yrs C: No treatment, n = 10; 11% male; mean age 65.9 yrs, mean DOC 8.4 yrs. All treatments 20 min twice daily for 2 wks I: Mineral baths once weekly for 6 weeks, n = 48; 21% male, mean age 65.2 yrs, mean DOC 8.6 yrs C: No treatment, n = 24; 21% male, mean age 63.1 yrs, mean DOC 7.5 yrs; followup at 10 wks	Pain (patient assessment of severity), function (Lequesne Index), range of motion	Pain: Abs ben II vs C: 0.004%; 12 vs C: 0.009%; 13 vs C: 0.014%; Rel ben II vs C: 6.6% (WMD = -0.4; 95% CI -1.8; 1.0); 12 vs C: 14.8% (WMD = -0.5; 95% CI -1.7; 0.7); 13 vs C: 23% (WMD = -0.9; 95% CI -2.5; 0.7)	3 dropouts in 13, 1 in C; only pre-post analysis
Tishler 2004 ²⁴	Unclear allocation concealment; overall quality score: 4	Israel, patients with knee OA, n = 72	I: Mineral baths once weekly for 6 weeks, n = 48; 21% male, mean age 65.2 yrs, mean DOC 8.6 yrs C: No treatment, n = 24; 21% male, mean age 63.1 yrs, mean DOC 7.5 yrs; followup at 10 wks	Pain (VAS), pain (WOMAC), analgesic intake	Pain: Abs ben: 0.376%; Rel ben: 56.6% (WMD = -1.6; 95%CI -2.2; -1.1); analgesic intake: RR = 0.05 (95% CI 0.01; 0.2)	4 dropouts in I; pre-post analysis
Wigler 1995 ²⁵	Unclear allocation concealment; blinded patients and outcome assessment; overall quality score: 6	Tiberias spa hotel, Israel; moderate or severe radiographic knee OA, n = 33	I: Mineral baths daily + mud packs on alternate days for 20 min, n = 12; 16% male, mean age 65 yrs, mean DOC 7 yrs; treatment period of 2 wks; followup: 20 wks C2: tap water baths daily + rinsed mud packs on alternate days for 20 min, n = 12; 16% male, mean age 65 yrs, mean DOC 7 yrs; treatment period of 2 wks; followup: 20 wks	Pain (VAS), function (ISK)	No data	2 dropouts

OA: osteoarthritis, DOC: duration of complaints; I: intervention; C: control; VAS: visual analog scale; WDI: Waddell Disability Index; HAQ: Health Assessment Questionnaire; WMD: weighted mean difference; ISK: index of severity knee osteoarthritis; WOMAC: Western Ontario and McMaster Universities OA Index; Abs ben: absolute benefit; Rel ben: relative benefit; sign: statistical significant difference. RR: relative risk; CI: confidence interval.

the quality assessment the ICC between reviewers appeared to be high: 0.76 (95% CI 0.40–0.95).

No studies mentioned a concealed randomization procedure; therefore no study was considered of high quality. In most studies much information concerning study design was lacking or unclear. Blinding of the outcome assessor (observer) is mentioned in 4 studies^{20,21,23,25}, and blinding of the patient, twice^{20,24}, but success of blinding was never evaluated. In one study²⁴, randomization was said to be blinded to the patient, but when patients had to sign informed consent, 14 withdrew on reading the protocol and 2 after being randomized to the control group. Therefore we did not consider this study blinded for the patient²⁴.

In all studies the proportion of patients with OA was over 90%. Included participants had radiographic hip OA in 1 study; radiographic knee OA in 2 studies; clinical and radiographic knee OA in 1 study; clinical knee OA in 1 study; and knee, hip or lumbar OA in 1 study. Five studies had 2 treatment groups; 1 study compared 3 treatment groups²⁵, and one study compared 4 treatment groups²³. Four studies provided enough data to permit a between-group analysis in the present review^{21–24}. All studies used different interventions or comparison treatments and a wide variety of outcome measures; therefore study populations, interventions, and outcome measures were considered very heterogeneous. Only one study assessed side effects but none were found²⁵.

Trials comparing balneotherapy with placebo or no treatment/waiting list controls. Four studies included a control group receiving no treatment^{20,22–24}. In all studies the patients were not (or could not be) blinded for treatment. Three studies provided data showing beneficial effects of balneotherapy on pain, quality of life, and analgesic intake^{22–24}, with difference between groups varying from 7.2% to 56.6%. At the end of treatment, data showed no evidence of statistically significant differences between Dead Sea baths and no treatment²³. Also, sulfur baths alone showed no evidence of statistically significant differences when compared to no treatment, but the overall power of the study was low²³. When Dead Sea baths were combined with sulfur baths, beneficial effects were shown on pain and function only at end of treatment or 1-month followup, but not at 3 months²³. The results of 2 studies^{22,24} on pain (18.5% and 56.6%, respectively) reached statistical significance, which was more profound in the short term (end of treatment).

One study evaluated additional effectiveness of balneotherapy on home exercise²⁰. No information on the intervention procedure was provided, nor data on outcome measures such as pain or function, so no conclusion about its effectiveness can be drawn. The authors mention no additional value of bathing.

Trials comparing different types of balneotherapy. In 2 studies mineral baths (combined with 2 different mud packs in one) were compared to tap water baths lacking the special

element of the specific intervention of each study^{21,25}. Both studies did not provide data; in one study only graphs were presented showing rather similar results on pain and function in all 3 groups²⁵, and in one study the authors mentioned more improvement in the mineral bath groups when compared to tap water on pain, range of motion, function, and perceived recovery²¹. In one study Dead Sea salt baths were compared with sulfur baths²³. No significant differences in favor of one treatment were found between Dead Sea salt baths and sulfur baths. The study was of low quality and had low power.

Trials comparing balneotherapy with other treatments (e.g., exercises, oral medication). No studies were found that compared balneotherapy with another form of treatment.

DISCUSSION

We conclude that mineral baths seem more beneficial, when compared to no treatment, regarding pain, quality of life, and analgesic intake. Dead Sea baths alone and sulfur baths alone showed no evidence of effect. We further conclude that one type of mineral bath is probably no more effective than another. We found only silver-level evidence concerning the positive effect of balneotherapy (mineral baths) when compared to no treatment on pain, quality of life, and analgesic intake. Our conclusions confirm those of Brosseau, *et al*³, although they more clearly focus on clinically relevant differences. They are also comparable with the results of another Cochrane review on balneotherapy in patients with rheumatoid arthritis²⁶.

Strengths and limitations

This review evaluated the effectiveness of balneotherapy in patients with osteoarthritis (OA). Unfortunately, most studies were of low power and had methodological flaws. When information concerning trial design (especially strategies to avoid bias) is lacking, possible bias in the trial cannot be excluded. Therefore, a robust analysis of the effectiveness of balneotherapy cannot be presented.

A limitation of our review is possible selection bias based on language. Several studies were found presented in Hebrew, Japanese, or in an Eastern European language. Often the English abstract lacked information about the design of the study. These studies await assessment.

We used the “Delphi list” for quality assessment¹⁶. Overall, this criteria list can be regarded as a reliable and valid instrument²⁷. Nevertheless misclassification is always possible. The quality assessment in our review appeared to be reliable. Based on the quality components “concealed randomisation” and “blinding the outcome assessor,” no study appeared to be of high quality.

OA is a chronic and disabling disease and has great impact on quality of life. When evaluating balneotherapy, the outcome measures used and the followup period chosen should be adequate. The main aim of balneotherapy is to

maintain or improve functional mobility, soothe pain, and let patients feel well. "Quality of life" was used as an outcome measure in only 1 of 7 studies. This is surprising, because one of the aims of balneotherapy, or therapy for chronic patients in general, is to improve health related quality of life. In daily life patients use coping strategies to deal with pain. Pain was reported as an outcome measure in the Methods sections of most of the studies, but data concerning the pain were only reported in 3 studies concerning 345 participants²²⁻²⁴. Also, the followup period seems short, and was lacking in 3 studies (outcomes were only measured at the end of treatment).

We noted heterogeneity of the intervention "balneotherapy." In one study, mineral baths (38°C, daily for 20 min) plus mud packs (for 20 min) were evaluated; in another, Dead Sea baths (daily for 20-30 min), sulfur baths (daily for 20 min), or a combination of Dead Sea and sulfur baths; and in 3 studies "spa therapy" was evaluated (Table 1). This makes it difficult to determine which form of balneotherapy is most effective. The "spa environment" is an important factor in treatment results^{12,28}. Many factors may contribute positively to reported effects⁹, such as change of environment, the "spa scenery," the absence of (house) work duties, physical and mental relaxation, the noncompetitive atmosphere with similarly suffering companions, physical therapy, etc. As such, spa benefits could perhaps be attributed also to the effects of factors unrelated to the "water" therapy per se. These spa benefits are especially important in studies evaluating the effects of balneotherapy compared to no treatment or another treatment.

CONCLUSION

Implications for practice

Most studies presented positive findings, but we found silver-level evidence concerning the beneficial effects of mineral baths compared to no treatment. In most studies the scientific evidence was insufficient because of poor methodological quality, absence of an adequate statistical analysis, and absence of, for the patient, essential outcome measures (pain, quality of life). Because of these methodological flaws a firm answer about the effectiveness of balneotherapy cannot be provided based on the included studies.

Implications for research

1. Large, high-quality research studies are needed, focusing on appropriate allocation concealment, blinding, and adequate data presentation and analysis. The design and reporting of future trials should conform to the CONSORT statement²⁹.
2. New research should use outcome measures that are relevant to patients, adequate, and responsive to the treatment under study. Followup should be of sufficient length to assess longterm effects, all according to the OARSI guidelines^{30,31}.

3. New research should provide full data on outcome measures, including mean and standard deviation or 95% confidence interval, and making comparisons between intervention groups.

4. Future research should examine the effect of balneotherapy not only in pragmatic trials comparing various interventions with each other, but also in more explanatory trials comparing the intervention with a no-treatment control group. When possible, the beneficial effect of the spa environment should be accounted for in the design of the trial.

We conclude that performing randomized studies with high methodological quality concerning the effectiveness of balneotherapy is both possible and necessary in order to obtain strong evidence on the effects of balneotherapy. Flaws found in the reviewed studies could and should be avoided in future trials.

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