Balneotherapy in Elderly Patients: Effect on Pain from Degenerative Knee and Spine Conditions and on Quality of Life

János Gaál MD PhD[1], József Varga PhD[2], Zoltán Szekanecz MD PhD DSci[3], Julia Kurkó MD[3], Andrea Ficzere MD PhD[4], Edit Bodolay MD PhD DSci[5] and Tamás Bender MD PhD[6,7]

[1]Department of Rheumatology, Kenézy Gyula County Hospital, Debrecen, Hungary
[2]Department of Nuclear Medicine, University of Debrecen, Medical and Health Science Center, Debrecen, Hungary
[3]3rd Department of Internal Medicine, Rheumatology Division, University of Debrecen, Medical and Health Science Center, Debrecen, Hungary
[4]Aquaticum Ltd., Balneotherapy Unit, Debrecen, Hungary
[5]3rd Department of Internal Medicine, Division of Immunology, University of Debrecen, Medical and Health Science Center, Debrecen, Hungary
[6]Polyclinic of the Hospitaller Brothers of St. John of God in Budapest, and [7]University of Szeged, Department of Orthopedic Surgery, Szeged, Hungary

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Abstract

Background: Balneotherapy is an established treatment modality for musculoskeletal disease, but few studies have examined the efficacy of spa therapy in elderly patients with degenerative spine and joint diseases.

Objectives: To assess the effects of balneotherapy on chronic musculoskeletal pain, functional capacity, and quality of life in elderly patients with osteoarthritis of the knee or with chronic low back pain.

Methods: The 81 patients in the study group underwent a 1 day course of 30 minute daily baths in mineral water. Changes were evaluated in the following parameters: pain intensity, functional capacity, quality of life, use of non-steroidal anti-inflammatory or analgesic drugs, subjective disease severity perceived by the patients, investigator-rated disease severity, and severity of pain perceived by the patients. We analyzed the results of 76 subjects as 5 did not complete the study.

Results: Compared to baseline, all monitored parameters were significantly improved by balneotherapy in both investigated groups. Moreover, the favorable effect was prolonged for 3 months after treatment.

Conclusions: This study showed that balneotherapy is an effective treatment modality in elderly patients with osteoarthritis of the knee or with chronic low back pain, and its benefits last for at least 3 months after treatment.

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Balneotherapy is a medical specialty utilizing the effects of medicinal waters (Latin *balneum* = bath). This treatment modality evolved primarily in countries rich in thermal water, such as France, Hungary, Italy, Germany, Japan, Israel and New Zealand [1]. Components of its mode of action include the physical properties of mineral water, the transcutaneous absorption of mineral solutes, and the inhalation of vapors or gases released in the water. Hydrotherapy – used almost throughout the world – is a treatment based on the physical properties of water [2]. Spa therapy is a complex modality that uses mineral or tap water as treatment under specific circumstances, and its effects are augmented by other methods of physical therapy (e.g., remedial gymnastics, massage, mudpacks, electrotherapy, psychotherapy) – as well as by the influence of environmental and climatic changes [3]. Various forms of osteoarthritis, including osteoarthritis of the knee and spine, predominantly afflict the elderly. The prevalence of osteoarthritis increases with advancing age: almost 70% of the population aged 55–74 suffer from osteoarthritis of the hands, and the proportion of individuals with osteoarthritis of the knee exceeds 10%. In the United States for example, this corresponds to 20 million afflicted patients and an annual treatment cost of US$ 65 billion [4]. In France, direct medical costs of the management of osteoarthritis totaled € 1.6 billion in 2002 [5]. Chronic low back pain afflicts 80% of the population during a lifetime, and in 85% of cases the initial episode is followed by recurrences. Low back pain and its relapses occur more frequently in the elderly [6].

The purpose of the present study was twofold: to ascertain whether the external use of mineral water could accomplish a substantial symptomatic improvement in our patients, and to detect potential changes in their quality of life and in their consumption of analgesics during treatment with mineral water.

Patients and Methods

Eighty-one patients were enrolled: 41 with osteoarthritis of the knee and 40 with chronic degenerative low back pain. Seventy-six patients completed the study (38 in each group). The mean age was 63.92 years (SD 10.06) and the female-to-male ratio was 24/14 in the group with knee osteoarthritis, and 60.92 years (SD 11.42) and 27/11 in the group with chronic low back pain.

The study protocol

The inclusion criteria were age over 50, primary or secondary osteoarthritis of the knee joint diagnosed according to American College of Rheumatology criteria (clinical and ra-

diological or clinical and laboratory) [7], low back pain of at least 3 months duration if potential underlying causes (tumor, inflammation, congenital abnormality, metabolic disorder) could be ruled out, and endorsement of the informed consent form after the subject read and understood the patient information leaflet. In the case of patients with osteoarthritis of the knee, inclusion was assured if the patient had knee pain, stiffness for less than 30 minutes, crepitation, tenderness/enlargement of the bone without heat, erythrocyte sedimentation rate less than 40 mm/h, and negativity for serum rheumatoid factor. If the patient refused to undergo laboratory tests, anteroposterior knee radiographs were obtained in the fully extended standing position. We were compelled to take knee X-rays in 15 of the 41 osteoarthritic patients. If X-rays revealed osteophytes in symptomatic patients (pain, crepitation, less than 30 minutes morning stiffness) they were also included in the study. In patients with chronic low back pain, anteroposterior and lateral lumbar spine radiographs and laboratory tests were performed. If radiography did not demonstrate elevated erythrocyte sedimentation rate, C-reactive protein with normal blood count or degenerative changes, the patient was included in the study. In patients with osteoarthritis of the knee, radiography had detected central and/or marginal osteophytes (15 patients), joint space narrowing (15 patients), subchondral sclerosis (14 patients), subchondral cysts (9 patients) and soft tissue calcification (2 patients). In the 40 patients with chronic low back pain, degenerative changes on spine radiography were found, including loss of disk height in one disk at least (40 patients), reactive sclerosis of the adjacent vertebral bodies (38 patients), vaccuum phenomenon (12 patients), osteophyte formation (40 patients), and ligament ossification (8 patients).

The exclusion criteria comprised the inflammatory arthropathies, collagen gene mutations, metabolic disorders, sarcoidosis, underlying malignancy, uncontrolled liver disease, decompensated heart disease, uncontrolled mental disorder, uncontrolled hypertension, incontinence, and concomitant use of other forms of physical therapy for target joints.

All patients gave informed consent; spa therapy was administered and the whole study was implemented in conformity with the principles of good clinical practice. The study was conducted between 1 May and 30 September 2006. The mineral water used was drawn from the thermal spring at Bánk, a settlement in the environs of Debrecen, Hungary. The water contains sodium bicarbonate, fluoride and metaboric acid; its total mineral solute content is 2613 mg/L with original temperature of 57.1°C. Water quality testing by the National Public Health and Medical Officer Service did not reveal microbiological or chemical contaminants. For balneotherapy the water was cooled to neutral temperature (33–36°C).

Except for weekends, 15 balneotherapy sessions lasting 30 minutes were administered daily, at the same time of day, in a provisional pool equipped with a filtering and water recirculation system. The patients traveled to the spa from their home every day. There were four visits during the course of the study – visit 0 (screening), visit 1 before the start of spa therapy and at least 4 weeks after visit 0, visit 2 within 2 weeks after the end of spa therapy, and visit 3 (the final visit) between 10 and 14 weeks after the end of spa therapy. An experienced rheumatologist performed a detailed physical examination in all the patients. Improvement was indicated by an increase in knee and spine motion and a decrease in pain during the physical examination. Patient compliance was considered adequate if the patient completed 80% of the prescribed 15 balneotherapy sessions.

The patients were allowed to take the non-steroidal anti-inflammatory or analgesic drug of their choice; these were fully recorded in each patient at the start and end of the study. The study protocol was approved by the Ethical Committee of the University of Debrecen, Medical and Health Science Centre (document # 2364-2005).

The study endpoints

The primary endpoints were: a) changes in the functional capacity of patients using WOMAC (patients with osteoarthritis of the knee) and Oswestry Low Back Pain Disability Index (subjects with chronic low back pain) questionnaires, and b) changes in the patient's quality of life, using the SF-36 Health Survey. The secondary endpoints were: a) changes in NSAID/analgesic usage, b) changes in subjective disease severity perceived by the patients, c) changes in investigator-rated disease severity, and d) changes in the severity of pain perceived by the patients

Statistical analysis

Since the variances of the changes between visits were significantly different in several indices (by Mauchly's test of sphericity), the non-parametric Friedman test was applied to evaluate the effect of treatment on the evolution of study parameters during the period between visits 1 and 2. Data from the next period (i.e., interval between visits 3 and 4) were used to ascertain whether the effects of balneotherapy persist in the long term.

Results

Seventy-six of the 81 enrolled patients completed the study. Five patients dropped out: one revoked informed consent before starting balneotherapy, two patients were excluded owing to poor compliance, and two failed to attend the control visits. No adverse reactions related to balneotherapy were observed. The number of subjects completing the study was identical (38 and 38) in the two groups.

Patients with osteoarthritis of the knee

The proportion of patients taking NSAIDs/analgesic agents was 60.5% (n=23) at visit 1. Seven of them took paracetamol, six took diclofenac, five took meloxicam, two took nimesulide, two took metamizole and one took naproxen. The proportion of patients taking any of these drugs was 10.5% (n=4) at visit 2 ($P < 0.001$ for the period between visits 1 and 2). A significant decrease in mean disease severity rated by the patients on a visual analogue scale was observed during the period between the initial two

NSAID = non-steroidal anti-inflammatory drug

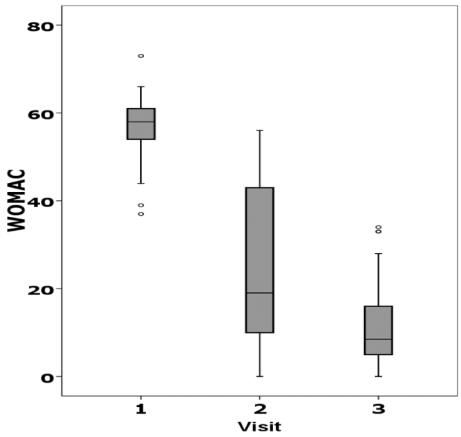

Figure 1. Changes in WOMAC scores during the periods between control visits

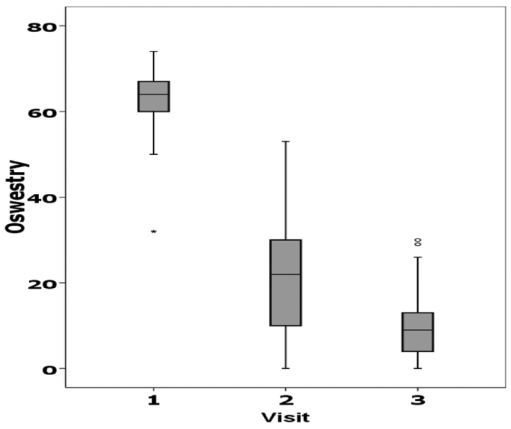

Figure 2. Changes in the Oswestry Index during the periods between control visits

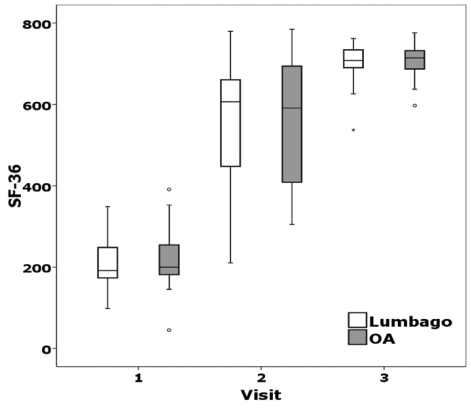

Figure 3. Changes in SF-36 total scores during the periods between control visits. OA = osteoarthritis.

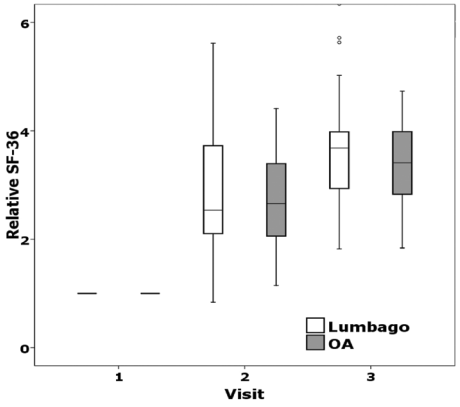

Figure 4. Relative changes in SF-36 total scores compared to values recorded at visit 1

visits ($P < 0.001$). VAS score was 68.53 mm (SD 10.6 mm) at visit 1, 15.63 mm (SD 7.98 mm) at visit 2, and 12.58 mm (SD 7.12 mm) at visit 3. Within-group means of investigator-rated VAS scores were 80.47 mm (SD 8.43 mm) at visit 1, 19.71 mm (SD 10.41 mm) at visit 2 ($P < 0.001$), and 19.82 mm (SD 9.7 mm) at visit 3. Within-group means of the VAS scores of subjective pain intensity were 83.18 mm at visit 1 (SD 7.81 mm), 17.82 mm (SD 11.52 mm) at visit 2 ($P < 0.001$), and 21.82 mm (SD 10.7 mm) at visit 3. Within-group means of total WOMAC scores reflecting changes in the functional capacity of patients were 57.42 (SD 6.9) at visit 1, 23.42 (SD 17.77) at visit 2 ($P < 0.001$), and 10.84 (SD 9.22) at visit 3. The changes in WOMAC scores are illustrated in Figure 1.

Patients with chronic low back pain

At the time of visit 1, 16 patients (42.11%) used NSAIDs or other analgesics (6 of them took paracetamol, 5 took diclofenac, 4 took ibuprofen, 1 took nimesulide); this number decreased to 4 patients (10.5%) by visit 2, and to zero by visit 3. The reduction in analgesic requirements was significant ($P < 0.001$) during the period between visit 1 and visit 2. Within-group VAS scores of perceived disease severity were 68.03 mm (SD 9.48 mm) at visit 1, 13.08 mm (SD 5.49 mm) at visit 2, and 13.21 mm (SD 7.29 mm) at visit 3. The reduction observed during the interval between visits 1 and 2 was statistically significant ($P < 0.001$). Within-group means of investigator-rated VAS scores were 80.76 mm (SD 8.73 mm) at visit 1, 18.89 mm (SD 6.93 mm) at visit 2 ($P < 0.001$), and 22.21 mm (SD 9.05 mm) at visit 3.

Within-group means of the VAS scores of subjective pain intensity were 81.84 mm (SD 9.1 mm) at visit 1, 19.82 mm (SD 9.08 mm) at visit 2 ($P < 0.001$), and 22.58 mm (SD 9.59 mm) at visit 3. Within-group means of total Oswestry scores indicating changes in the functional capacity of patients were 61.55% (SD 8.96%) at visit 1, 20.63% (SD 14.88%) at visit 2 ($P < 0.001$), and 10.03% (SD 8.32%) at visit 3. The changes of Oswestry scores are shown in Figure 2.

Changes in quality of life in the two groups

In the group with osteoarthritis of the knee, mean cumulative SF-36 scores (index measuring quality of life) were 216.93 (SD 61.17) at visit 1, 558.78 (SD 150.25) at visit 2 ($P < 0.001$), and 708.66 (SD 42.29) at visit 3. Mean scores of patients with chronic low back pain were 206.48 (SD 56.89), 553.85 (SD 144.32) ($P < 0.001$), and 700.39 (SD 45.69) respectively. Absolute and relative changes of cumulative SF-36 scores are depicted in Figures 3 and 4, respectively.

Discussion

Balneotherapy is a well-established treatment for musculoskeletal disease. Evidence-based knowledge has been available for decades and its volume has multiplied during recent years. Szücs and co-authors [8] from Püspökladány (Hungary) were the first in the world to conduct a double-blind study investigating the effects of thermal water in patients with osteoarthritis of the knee. Yilmaz et al. [9] and Guillemin et al. [10] demonstrated marked improvement in life quality (using the SF-36 and AIMS2 scales, and the Duke Health Profile, respectively) in patients undergoing short-term balneotherapy for osteoarthritis of the knee. Forestier

VAS = visual analogue scale

[11] reported favorable outcomes in an open follow-up study [11], and Tishler and team [12] found a clinical improvement in patients undergoing a 6 week course of weekly balneotherapy sessions for osteoarthritis of the knee.

Similar to balneotherapy, mudpacks also exert a beneficial effect in patients with gonarthrosis. Prolonged mud-packing suppresses the synthesis of prostaglandin E2 and leukotriene B4-I [13]. Mud has a favorable effect on cartilage-destroying cytokines and binds tumor necrosis factor [14]. The Naiad Project investigated the magnitude of cost-savings afforded by balneotherapy. Patients with osteoarthritis were followed for 2 consecutive years. The study was conducted in a population of 11,437 patients with primary or secondary osteoarthritis, but only 6111 (53.4%) remained in the study during the second year. All patients underwent a course of balneotherapy and mudpacks once a year. Subjects were free to receive treatment in any of the 98 collaborating Italian spas, which use a variety of medicinal waters (containing sulphur, sodium chloride, bromine, iodine, sulphate, or bicarbonate). The results confirmed the clinical efficacy of balneotherapy for osteoarthritis; the treatment was highly effective in mitigating the symptoms caused by osteoarthritis of the cervical or lumbar spine. As shown by the analysis of relevant socioeconomic indices, balneotherapy assures lasting treatment benefits. According to the results of the Naiade Project, this modality significantly reduces the need for other types of treatment (hospitalization, physical therapy, pharmacotherapy), and, furthermore, reduces absenteeism [15].

In addition to the above, the efficacy of balneotherapy might be related to other mechanisms. A hot bath elevates beta-endorphin and stress hormone levels, thereby exerting a direct analgesic action [16]. Kubota and co-workers [17] observed a significant rise in beta-endorphin levels in healthy individuals (from 16.2 to 49.5 pg/ml) 2 minutes after completing a 3 minute bath in 47ºC hot-spring water, with no change in methionine enkephalin levels. Kuczera and Kokot [18,19] showed a rise in plasma concentration of ACTH, cortisol, growth hormone, prolactin and erythropoietin after 20 days of spa therapy. Chemical effects are much less known than physical modes of action. Mineral elements in various layers of the skin accumulated during bathing are assumed to form deposits that slowly release mineral substances into the blood circulation and exert systemic actions. The skin – which is the largest element of the immune system – is the first line of contact between mineral water and the organism. Studies in psoriatic patients showed that bathing in Dead Sea water (in southern Israel) with its high salt content increases the cutaneous uptake of manganese, bromine and lithium [20,21].

Successful management of osteoarthritis might improve the quality of life of elderly patients [22]. Among other treatment modalities, balneotherapy might assume an important role in accomplishing this goal [23]. The analgesic effect of spa therapy is a potentially useful factor in the management of the elderly [24]. Often, patients with degenerative joint and spine disorders – including those with osteoarthritis – are inclined to prefer treatments involving less risk. Balneotherapy is known to be free of the side effects of systemic anti-inflammatory and analgesic drugs [25]. Although this treatment is not a substitute, it may prove to be an invaluable add-on to traditional pharmacotherapy.

Study limitations

The main limitation of this study was the lack of a control population. It is very difficult to maintain the blindness factor, because the physicochemical properties (color, odor, feel by touch) of the mineral water significantly differ from tap (control) water and can easily be discerned by patients.

Conclusions

Our study showed that a 15 day course of balneotherapy with mineral water from thermal spring # I at Bánk (Debrecen, Hungary) improves functional capacity, leads to an improvement in quality of life, substantially reduces analgesic consumption, diminishes the intensity of perceived pain, mitigates subjective disease severity assessed by patients with osteoarthritis of the knee or chronic low back pain, and reduces investigator-rated disease activity in patients with advanced age. Furthermore, these effects persisted for 3 months after the study. The results of our study confirm the clinical efficacy of balneotherapy in the management of knee osteoarthritis and chronic low back pain in elderly patients, and it is our belief that treatment with thermal mineral water could substantially improve the quality of life in this age group.

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Correspondence: Dr. J. Gaál, Dept. of Rheumatology, Kenézy Gyula Hospital 2-26 Bartók Béla str., Debrecen, Hungary.
Phone: (36-52) 511-777
Fax: (36-52) 511-833
email: gaalja@freemail.hu