

Department of Orthopedics, Faculty of Medicine, University of Szeged, Hungary

Clinical Medicine Doctoral School

Hydrotherapy and Balneotherapy methods in the treatment of chronic low back pain

PhD Thesis

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INTRODUCTION

The history of healing by water (“sanus per aquam”) treatments dates back thousands of years whilst hydrotherapy and balneotherapy still plays an important role in today’s modern society.

Hydrotherapy is a treatment based on the physical properties of water, treatment with water.

When using balneotherapeutic procedures for various therapeutic purposes in addition to the physical properties of water, absorption of dissolved minerals through the skin play a role in the mechanism of action. Balneotherapy is the discipline investigating the effects of mineral medicinal waters, which means the medical use of natural mineral waters, mud and gases found in nature.

The definition of mineral medicinal waters includes requirement regarding the minimum concentrations of ions and/or gases and that may vary from country to country. In Hungary, mineral water from spontaneous bursting or drilled wells must contain at least 1000 mg/liter of mineral matter, or alternatively a trace element must be present in an increased concentration in the measured water to be called medicinal water.

Low back pain is defined as a pain and muscle tension, or stiffness, that localized below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica), it could be acute when it persists for less than 6 weeks, subacute between 6 weeks and 3 months and chronic when it lasts for longer than 3 months.

Non-specific low back pain is defined as low back pain with no known underlying pathology (e.g., infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder, radicular syndrome, or cauda equina syndrome).

Low back pain symptoms often return over time, most patients with low back pain have a history of previous complaints and may develop later a chronic low back pain syndrome.

Low back pain (LBP) is one of the costliest diseases due to its high prevalence level that continuously increases parallel to the aging of the population in the developed world. Based on a systematic review of 165 studies from 54 countries conducted between 1980 and 2009 its population-based prevalence is estimated to be around 12% on average. These values also depended on age and sociological status, the point prevalences and lifetime prevalences could reach even 79.2%.

The aim of my work is to investigate pain and quality of life changes in patients with low back pain as a result of thermal-mineral water, hydrotherapy, and underwater traction treatments.

AIMS OF THE THESIS

To evaluate the effects of balneo- and hydrotherapy in chronic low back pain through presenting two studies.

- I. The aim of my work was to demonstrate the positive effect of bathing in calcium-magnesium-bicarbonate content thermal mineral water in the clinical parameters of patients with chronic low back pain and whether it leads to the improvement in the quality of life as well.

- II. A number of studies have been done to assess the effectiveness of the different types of traction therapies (e.g., manual, auto-traction, gravitational, aquatic, and mechanical traction) on low back pain. The aim of our study was to examine the effect of underwater traction therapy on chronic low back pain. The primary objective was to analyse the hypothesis that underwater traction therapy has favourable effects on LBP. Our secondary aim was to analyse whether this treatment method could result in an improvement in the quality of life.

ETHICAL ASPECTS

In clinical trials, participants received written information and signed a consent form prior to the studies. The research is in line with the Helsinki Declaration on Ethical Principles in Medical Research.

The studies were approved by the Semmelweis University Regional Scientific and Research Ethics Committee (SE TUKÉB).

METHODS

I. The effects of the calcium-magnesium-bicarbonate content in thermal mineral water on chronic low back pain: a randomized, controlled follow-up study

In this controlled, follow-up study, we evaluated the effects of balneotherapy on chronic low back pain by adding it to regular outpatient care, and by comparing that to outpatient care without it, using two patient groups. The control and study groups were created in accordance with the minimization principles based on VAS scores at rest and during activity, and age and sex.

The number of patients requiring NSAIDs, opioids, muscle relaxants, and paracetamols for low back pain was compared by McNemar's test. Other parameters were processed using the Mann-Whitney and Wilcoxon test. The data was evaluated according to the analysis of intention to treat. Missing outcomes were replaced according to the method "last observation carried forward". The significance level was $p < 0.05$.

Patients with the following conditions were enrolled in the study: outpatients suffering from chronic low back pain (standing for at least 12 weeks of non-specific low back pain); only slightly reduced mobility (able to admit the treatments or visits on his own or without the help of another person); pain intensity of low back pain during activity at least 25 on Visual Analog Scale (0–100 mm VAS); aged 18–75; likely degenerative symptoms. Pain sensitivity due to pressure of the paravertebral muscle and the painful movement of the lumbar spine observed (indicating possible segmental muscle spasms, segmental instability, or other reasons).

Study participants received written information about the methodology and process they would be undergoing, and subsequently signed an informed consent form before the study.

Pain intensity was measured by using the Visual Analog Scale (0–100 mm VAS). VAS scores were expressed in millimeters (zero point—no pain; endpoint—intolerable pain). Patients recorded on the VAS scale the level of low back pain at rest as well as during activity.

Functional disability was assessed by using the Oswestry Disability Index (ODI). This is an easily administered, self-reported questionnaire which examines the patients' perceived level of disability in 10 everyday activities of daily life (e.g., pain intensity, the changing status of pain, personal hygiene, lifting, walking, sitting, standing, sleeping, social activity, and traveling). The patients were asked to read the 10 questions and indicate their score between 0 and 5. The obtained total score between 0 and 50, is expressed in percentage. Furthermore, there was a questionnaire on the quality of life, known as the EuroQol Five Dimensions Questionnaire (EQ-5D). The EQ-5D also included an EQ-VAS scale of 0–100, where respondents evaluated their overall health status (0 being the worst, and 100 being the best possible health status).

Both groups member patients filled out the above questionnaires after enrolment, i.e. directly before the study group started the balneotherapy treatment — (Visit I, week 0); 3 weeks later, directly after the completion of the balneotherapy treatment for the study group (Visit II, week 3) and at the end of the follow-up period (Visit III, week 12). In case any medication therapy (i.e., analgesics, NSAIDs, muscle relaxants, or steroids) was taken during or 1 month prior to the study, it was recorded in a weekly breakdown. In addition, during each of the three visits, a medical examination was carried out, checking the criteria for inclusion / exclusion and recording possible side effects.

II. A multicentre randomized controlled follow-up study of the effects of the underwater traction therapy in chronic low back pain

Patients suffering from low back pain were selected into three groups at random: receiving a combination of the NSAID medication and underwater traction therapy or traction therapy or only NSAID. Enrolment criteria were as follows: outpatients aged 18–85 with non-specific low back pain persisting for at least 12 weeks, showing degenerative symptoms, and suffering from moderately reduced mobility. Additionally, the patient's pain intensity during activity had to be at least of 30 mm on the visual analogue scale (0–100 mm VAS). Written information on the methodology and process to be undertaken was provided to each

participant, and an informed consent form was subsequently signed before the study. A two-way lumbar spinal X-ray taken within a year was required to be presented.

Patients were exposed to indifferent water (33–35°C) for 15 – 20 minutes. At the different clinical centers, different components thermal and mineral waters were used but smooth tap water was not used in any of the pools.

Participants were dipped in the water to the neck while they could not reach the bottom of the pool with their feet. During bilateral armpit support suspension, both sides of the ankles had 3–3kg weights attached. Fifteen weight bath therapy sessions were administered during the 3-week period. The duration of the first session was 15 minutes; this was extended to 20 minutes from the second occasion.

The doctor met patients three times: first, right before the treatment was started; second, straight after the underwater traction therapy treatments; and third, 9 weeks after the treatment was completed (i.e., 12 weeks after the start of the treatment).

The participants were randomly selected and randomly put into three groups: (Group 1) underwater weight bath traction therapy and non-steroidal anti-inflammatory drugs (NSAIDs) medication, (Group 2) only underwater weight bath traction therapy, and (Group 3) only non-steroidal anti-inflammatory drug (NSAID) medication in therapeutic dose and did not receive traction therapy. Throughout the investigation, all participants received their everyday medications. (Participation at physical therapy was allowed for ethical considerations, such as transcutaneous electrical nerve stimulation (TENS) treatments and massage, with these, if any, being documented).

The randomization was done by an independent person based on a pre-set system. Size of the group receiving only traction therapy was intentionally set to be double that of the other two to make statistical analyses more reliable.

To detect the improvement of the patients, we calculated the differences between the later and earlier values of the variables.

Functional disability was assessed by using the Oswestry Disability Index (ODI), on a visual analogue scale (VAS), patients indicated degrees of pain—both at rest and separately during activity—on a scale from 0 to 100 mm for the past week before the visit. The Hungarian form of the specific standardized EuroQol Five Dimensions Questionnaire (EQ-5D-5L) was used to assess the quality of life of the participants.

The surveys (VAS scales of low back pain at rest and during activity and the Oswestry and EuroQol-5D-5L) were self-administered.

To test the statistical differences of the improvement in the three groups, we ran a one-way repeated measures ANOVA model. Normality of the residuals was accepted based on d'Agostino's normality test, and to separate homogeneous groups, Tukey's post hoc test was run.

RESULTS

I. The effects of the calcium-magnesium-bicarbonate content in thermal mineral water on chronic low back pain: a randomized, controlled follow-up study

The parameters of 245 patients were evaluated, of which 16 did not meet the criteria for inclusion, 94 declined to participate, and 30 were excluded for other reasons; 105 patients were enrolled, of which 52 patients were treated with balneotherapy, and 53 were in the control group.

Data from all participants were processed through an intention-to-treat analysis. The two groups of participants were homogeneous by age and gender; furthermore, they were initially comparable for all measured parameters. In the study, 58 males: 30 in balneotherapy and 28 in the control group, and 47 females: 22 in balneotherapy and 25 in the control group, participated. The mean age in the balneotherapy group was 62.94 ± 9.3 years, and in the control group 60.5 ± 11.8 years.

The VAS value of the existing low back pain at rest decreased significantly in the group treated with balneotherapy by the end of the treatment compared to the baseline ($p < 0.001$); this improvement was observed as well at the end of the follow-up in Visit III. Conversely, there was no significant change in this value in the control group. The differences between

the two groups were significant in Visit II and Visit III as well ($p = 0.002$ and $p = 0.006$, respectively).

The VAS value for lumbar pain during activity also significantly decreased in the balneotherapy group by the end of the treatment compared to the initial stage ($p < 0.001$) and this improvement was also observed in Visit III. At the same time, there were no significant changes in the VAS values of the control group. The differences between the two groups were significant at Visit II and Visit III as well ($p = 0.001$ and $p < 0.001$, respectively).

Oswestry index specific for low back pain significantly improved in the balneotherapy group by the end of the treatment, compared to the initial stage ($p < 0.001$), and this was also observable during Visit III. Simultaneously, there was no significant change in the control group by either Visit II or Visit III. The differences between the two groups thus were significant at Visit II and Visit III as well ($p = 0.016$ and $p = 0.006$, respectively).

The EuroQol-5D index on quality of life also exhibited significant improvement in the balneotherapy group at the end of the treatment compared to the initial stage ($p < 0.001$), which was also observed during Visit III. There was no significant change in the control group. The differences between the two groups were significant during Visit II and Visit III as well ($p = 0.0019$ and $p = 0.003$, respectively).

EuroQol-VAS showed that the current general health status also improved in the balneotherapy group ($p < 0.001$), while there were no changes in the control group. The differences between the groups were significant both during Visit II and Visit III ($p = 0.002$ and $p = 0.001$, respectively). In parallel, the number of patients requiring NSAIDs, opioids, muscle relaxants, and paracetamols for low back pain decreased in the group treated with balneotherapy, while there was no change in the control group. The differences between the two groups were significant both during Visit II and Visit III ($p = 0.003$ and $p = 0.001$, respectively).

II. A multicentre randomized controlled follow-up study of the effects of the underwater traction therapy in chronic low back pain

A total of 226 patients with chronic low back pain were recruited for the study, and 176 were included in the data analysis. Due to the randomization process, the distribution of patients per study arm was imbalanced, which resulted in the following group allocations: Group 1 = 43, Group 2 = 90, Group 3 = 43 patients enrolled.

The mean age in Group 1 was 58.65 years, in Group 2 was 61.28 years, and in Group 3 was 55.14 years.

The VAS values at rest decreased significantly in both groups which were treated with underwater traction therapy by the end of the treatment period compared to the baseline ($p < 0.05$); this improvement was observed as well at the follow-up in Visit III. There was no significant change in this value in the control group (Group 3) where patients received only NSAID medication for chronic low back pain.

While there were no significant differences in the VAS values between the three groups at the time of the first Visit, by Visit II and Visit III, the differences in the VAS values between Group 1 and Group 3 as well as between Group 2 and Group 3 became significant.

The VAS values for lumbar pain during activity also significantly decreased in the groups treated with underwater traction therapy by the end of the treatment compared with the initial stage ($p < 0.001$), and these improvements were also observed in Visit III. There were no significant changes in the VAS values in Group 3. The differences between the two groups (the underwater traction therapy groups) and the only NSAID medication group were found to be significant during Visit II as well as Visit III.

Neither the Oswestry functional disability index nor EuroQol-5D-5L quality of life index showed any significant change between the visits in any of the three groups. At the same time the EuroQol-VAS values showed that the current general health status improved in the underwater traction therapy groups ($p < 0.01$) while there was no change in Group 3. The differences between the groups were significant during Visit II and Visit III.

Only patients in Group 3 did require extra NSAIDs, opioids, muscle relaxants, or paracetamols for low back pain during the study period.

CONCLUSIONS AND NEW RESULTS

Nowadays, more and more protocols and recommendations appear regarding the treatment of chronic non-specific low back pain. The lumbar spine is the most stressed segment of the spine, where lesions and pain develop most often. Non-specific low back pain is also a major public health issue in the world.

The short- and long-term favorable effects of the calcium-magnesium-bicarbonate content thermal water on chronic low back pain were shown compared to the control group not receiving balneotherapy. The clinical parameters set for the pain movement functions and the improvement in the quality of life through the balneotherapy treatment were significant and permanent compared to the baseline. After the treatment, the observed parameters showed a significantly better level compared to the control group based on VAS scores, the Oswestry, and the EuroQol-5D indexes, and this difference remained significant throughout the follow-up period.

The worsening trend of the status of the control group, with respect to certain parameters, is explained by the fact that the vast majority did not receive substantial treatment. The significant improvement of the balneotherapy treatment group is explained by the favorable effects of thermal mineral water. The physical composition of water, and its exertion of mechanical and thermal effects, combined with the absorption of mineral solutes and potential anti-inflammatory effects, might have a role in the mechanism of action of mineral water. During balneotherapy, mechanical and thermal effects might also occur similarly to those at hydrotherapy. The pain control theory, the circulatory centralization resulting from hydrostatic pressure, the increase in the circulation of deep muscle structures, and the modified neuromuscular function during immersion may possibly result in a beneficial effect. According to the results of our study it can be concluded that bathing in thermal bath has favorable effects on the clinical parameters and quality of life of patients with chronic low back pain in the short and long term as well if compared to patients with only routine outpatient care. It can be further stated that bathing in thermal mineral water with calcium

magnesium and sodium bicarbonate content serves as a therapeutic option for the treatment of patients with chronic low back pain.

While we were conducting our studies using modern and standardized methods and data, we also searched for a treatment option that has not yet been analysed in a large number of randomized trials, which led us to investigate the impact of underwater traction therapy on LBP.

In our multicenter randomized study, we proved that underwater traction therapy has its place in the physio-, balneotherapy palette. It has been shown that traction treatment results in long term healing effects with minimal risk and low cost.

In our findings, the decline in the level of pain in rest or during activity of LBP patients measured on VAS and the change in the EQ-5D-5L VAS values were both significant in case of those patient groups that underwent traction therapy, proving the improvement in pain sensitivity. However, the Oswestry and the long-term EQ-5D-5L index values remained unchanged. That might be explained by the fact these indexes have lower sensitivity to change in patients' perceived pain level.

Furthermore, analysis showed that NSAID medication was not efficient in improving chronic low back pain that confirmed the results of several earlier investigations.

Nevertheless, it should also be noted that a report that as age progresses, the extensibility of spinal segments decreases.

Underwater weight bath therapy, a therapy that is a long used, low cost, easily accessible therapeutic option with local traditions, might serve as a useful alternative therapeutic treatment in non-specific low back pain to replace NSAID therapy that has common side effects.

LIST OF PUBLICATIONS INCLUDED IN THE DISSERTATION

- I. Gáti T, Czímer É, Cserháti G, Fehér J, Oláh M, Kulisch Á, Mándó Z, Bender T. A multicentre randomized controlled follow-up study of the effects of the underwater traction therapy in chronic low back pain. Int J Biometeorol. 2020 Aug; 64(8):1393-1400. doi: 10.1007/s00484-020-01919-8. Epub 2020 May 2. PMID: 32361959; PMCID: PMC7374437. **IF: 2,377**

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Cumulative impact factor: – 32,922

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Gáti T, Czímer É, Cserhádi G, Fehér J, Oláh M, Kulisch Á, Mándó Z, Bender T. A Multicentre randomised controlled follow-up study of effects of the underwater traction therapy in chronic low back pain – 13. Jun.2019. EULAR/ MADRID poster ID: THU0493,

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Bender T, Gáti T: Underwater traction therapy in chronic low back pain, a multicentric randomized controlled follow up study (presentation) 44th World Congress of International Society of Medical Hydrology

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